# STATE OF MICHIGAN IN THE COURT OF CLAIMS

VIRIDIS LABORATORIES, LLC,
a Michigan limited liability company, and
VIRIDIS NORTH, LLC,
a Michigan limited liability company,

Case No. 21- -MB

Plaintiffs,

v.

MICHIGAN MARIJUANA REGULATORY AGENCY, a Michigan state agency, ANDREW BRISBO, Individually, JULIE KLUYTMAN, Individually, DESMOND MITCHELL, Individually, and CLAIRE PATTERSON, Individually.

Defendants.

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# **VERIFIED COMPLAINT**

There is no other pending or resolved civil action between these parties arising out of the same transaction or occurrence as alleged in this Complaint.

Plaintiffs Viridis Laboratories, LLC and Viridis North, LLC (collectively "Plaintiffs"), by and through their attorneys, Foster, Swift, Collins & Smith, P.C. and Honigman, LLP, for their Verified Complaint against Defendants Michigan Marijuana Regulatory Agency, Andrew Brisbo, Desmond Mitchell, Julie Kluytman, and Claire Patterson state as follows:

#### INTRODUCTION

- 1. Michigan courts have "carefully limited the powers of administrative agencies to ensure they do not abuse or make baseless expansions of the limited powers delegated to them by the Legislature. Therefore, being creations of the Legislature, they are only allowed the powers that the Legislature chooses to delegate to them through statute." Herrick Dist Library v Library of Michigan, 293 Mich App 571, 582; 810 NW2d 110 (2011); McKibbin v Mich Corp & SEC Comm, 369 Mich 69, 82; 119 NW2d 557 (1963).
- 2. This case illustrates the extraordinary dangers created when a state administrative agency is allowed to regulate from the shadows without proper oversight by a neutral, detached decision maker and, worst of all, motivated at least in part by what appears to be the whims and political objectives of its director and employees.
- 3. On November 17, 2021, the Marijuana Regulatory Agency commenced the largest recall of cannabis products in Michigan's history. The recall covers between 60 to 70% of the cannabis industry's existing on-the-shelf legal products or products that were on their way to shelves for consumer use. This equates to approximately \$229 million in commerce disturbed because of the Marijuana Regulatory Agency's recall decision. All of the cannabis products covered and included in the Marijuana Regulatory Agency's recall were tested for microbial contamination by Plaintiffs, marijuana safety compliance facilities, in accordance with Michigan

law. The Marijuana Regulatory Agency couched its justification for the recall on the basis of public health and safety. However, this is inaccurate; there is no public health or safety risk justifying the recall at all. Further, as detailed below, the MRA instituted the recall in violation of its numerous rules and flaunted the proper processes for addressing health and safety issues. Among other things, for example, the MRA has still not provided any written notice articulating its rationale for the recall.

- 4. Prior to the Marijuana Regulatory Agency's recall, Plaintiffs controlled the "lion's share" of the cannabis testing industry, testing for between 60 to 70% of the state's growers and producers. It provided high quality and accurate tests to its customers, which the market responded to by flocking to Plaintiffs for its testing needs. While Plaintiffs do not know the MRA or its director or employees' exact motivations, the record evidence set forth below strongly suggests that the Marijuana Regulatory Agency wrongfully targeted Plaintiffs for improper purposes such as, among other things, and upon information and belief, a desire to "level the playing field" so that all marijuana safety compliance facilities would get an equal share of the cannabis testing market. The recall is the Marijuana Regulatory Agency's disguised means of reaching its desired political result that it could not achieve through the powers delegated to it under Michigan law.
- 5. By instituting the recall, the Marijuana Regulatory Agency achieved its desired goal. Among other things, the recall cast Plaintiffs in a false, negative light with its customers, put significant financial strain on Plaintiffs due to the enormous fiscal size of the recall, and, ultimately, placed Plaintiffs in the precarious position of potentially having to shutter their doors depending upon what occurs within the upcoming *days*, not even weeks or months. To make matters worse, the Marijuana Regulatory Agency has continued its improper vendetta against

Plaintiffs' business operations by summarily restricting and effectively suspending their licenses to test cannabis products for microbial contamination, meaning Plaintiffs *cannot* even retest the samples that are subject to the recall to mitigate the devastating economic effects the recall will have on its customers. In effect, the MRA has orchestrated a coordinated campaign to, among other things and as described below, upon information and belief, destroy Plaintiffs' credibility and standing within the cannabis industry, drastically dilute its market share within the industry, and intentionally structured its campaign to prevent Plaintiffs from seeking any form of review or oversight that may hinder its overall objectives. Plaintiffs have explicitly told the MRA numerous times that its orchestrated campaign of product holds and ignoring recall rules appears to be a deliberate choice to effectively shut down Viridis without following the established procedures to do so via summary suspension (which would involve some oversight and require the MRA to articulate its rationale to an ALJ). This has left Plaintiffs no choice but to bring this action against the Marijuana Regulatory Agency.

6. Plaintiffs seeks to shed light on the activities that the Marijuana Regulatory Agency had hoped to keep behind closed doors and to obtain legal and equitable relief for the wrongs committed against it by the Marijuana Regulatory Agency and the responsible employees.

### PARTIES, JURISDICTION, VENUE

7. Plaintiff Viridis Laboratories, LLC ("Viridis Lansing") is a Michigan limited liability company formed under the laws of the State of Michigan and conducts business through a laboratory established in the City of Lansing, Ingham County, Michigan.

- 8. Plaintiff Viridis North, LLC ("Viridis Bay City") is a Michigan limited liability company formed under the laws of the State of Michigan and conducts business through a laboratory established in Bay City, Bay County, Michigan.
- 9. Although Plaintiffs share "Viridis" in their name, and have common principals, they are separate and distinct business entities with entirely different ownership structures.
- 10. Defendant Michigan Marijuana Regulatory Agency ("MRA") is a type I Michigan state agency established within the Michigan Department of Licensing and Regulatory Affairs ("LARA") and is charged with implementing, enforcing, licensing, and overseeing compliance with Michigan laws relating to marijuana.
- 11. Andrew Brisbo is the Executive Director of the MRA and a state officer or employee. Mr. Brisbo is sued in his individual capacity.
- 12. Desmond Mitchell is the Operations Director of the MRA and a state officer or employee. Mr. Mitchell is sued in his individual capacity.
- 13. Julie Kluytman is the Enforcement Division Director of the MRA and a state officer or employee. Ms. Kluytman is sued in her individual capacity.
- 14. Claire Patterson is a Manager of the Scientific & Legal Section Enforcement Division of the MRA and a state officer or employee. Ms. Patterson is sued in her individual capacity.
- 15. The Court of Claims has "exclusive" jurisdiction to "hear and determine any claim or demand, statutory or constitutional," or any claim or demand for "an extraordinary writ against the state or any of its departments or officers." MCL 600.6419(1)(a).
- 16. Because the MRA is a state agency and the individual named defendants are state officers or employees, this Court has jurisdiction over this matter.

- 17. Because the MRA, a state agency and the individual named defendants are state officers or employees, venue is appropriately before this Court.
- 18. Consistent with the rules of notice pleading in Michigan, the purpose of this Verified Complaint is to put the MRA on notice of claims consistent with the allegations contained herein and is not meant to be an exhaustive identification of each and every actionable act or omission committed by the MRA.

### **GENERAL ALLEGATIONS**

- 19. Plaintiffs are marijuana safety compliance facilities licensed by the MRA under the Medical Marihuana Facilities Licensing Act ("MMFLA") (MCL 333.27101, et seq.) and the Michigan Regulation and Taxation of Marihuana Act ("MRTMA") (MCL 333.27951, et seq.) to sample and test adult-use and medical cannabis products.
- 20. The MRA regulates marijuana laboratories like Viridis through the MMFLA and MRTMA.
- 21. Viridis was founded by former Michigan State Police laboratory scientists with greater than 75 years combined experience working within a strictly regulated and nationally accredited forensic science industry, which included high volumes of marijuana testing.
- 22. Viridis Lansing received its license from the MRA to test medical marijuana on June 5, 2019, and its adult-use license on December 7, 2020.
- 23. Viridis Bay City received its license from the MRA to test medical marijuana on April 6, 2020, and its adult-use license on June 10, 2020.
  - 24. The MRA requires marijuana safety compliance facilities to be accredited.
- 25. Plaintiffs use A2LA ISO 17025:2017 accredited methods. The A2LA is the leading accrediting body in the nation for cannabis testing laboratories.

- 26. Viridis Lansing received accreditation on July 23, 2020.
- 27. Viridis Bay City received accreditation on February 4, 2021.
- 28. Plaintiffs' research and development is led by Michele Glinn, Ph.D, F-ABFT, the former program coordinator for the Michigan State Police crime labs.
- 29. Dr. Glinn is a well-respected toxicologist around the country and testifies as an expert witness for prosecutors in 40 to 50 cases a year.
- 30. The A2LA performed a full review of the validation and Standard Operating Procedures (SOP) of Plaintiffs' testing methods prior to its accreditation.
- 31. Licensed marijuana safety compliance facilities like Plaintiffs are required to not only follow the requirements of the MMFLA and MRTMA, but also the rules promulgated by the MRA.
- 32. Under the MRA's Sampling and Testing Rules (the "Testing Rules"), a laboratory, which is defined to include marijuana safety compliance facilities like Plaintiffs, must perform various tests on batches of marijuana products. MAC R.420.301(m) and 305(3)(a).
- 33. The Testing Rules require that Plaintiffs "use analytical testing methodologies for the required safety tests in subrule (3) of this rule that are validated by an independent third party and may be monitored on an ongoing basis by the agency or a third party. In the absence of reference to compendia or published methods, Appendix K of Official Methods of Analysis authored by the Association of Official Analytical Chemists [("AOAC")] must be published in full. The agency shall approve the validated methodology used by the laboratory and confirm that it produces scientifically accurate results for each safety test it conducts." MAC R.420.305(2).

- 34. It is necessary for the MRA to rely on accrediting bodies such as the A2LA and scientific organizations like the AOAC for accreditation and approvals because the MRA scientists lack requisite scientific knowledge to govern the testing labs themselves, a fact that the MRA has previously acknowledged.
- 35. The MRA, through scientist Allyson Chirio, has historically and openly admitted that its scientists and employees have little-to-no experience or idea of what they are doing when it comes to regulatory oversight of marijuana facilities or testing methodologies. In fact, most recently, Ms. Chirio compared the MRA and its employees to infants and toddlers. Ms. Chirio stated that when the MRA took over the reins of regulating the cannabis industry in 2019 that it was like an infant (i.e., could barely function on its own and could not do anything for itself). Fast forward three years, Ms.Chirio compared the MRA to a toddler (i.e., can still barely function on its own but has learned some lessons from the past).
- 36. Plaintiffs implement and are known for employing state-of-the-art lab equipment and conducting accurate, correct, and reliable tests on cannabis products. Indeed, Plaintiffs consistently finds ways to innovate its and other methodologies to create more accurate testing results. This has resulted in Plaintiffs developing a patent-pending method for cannabis potency analysis (the "Viridis Method"). The Viridis Method is not set forth here because of its protected status as proprietary and trade secret information.
- 37. As Plaintiffs' regulatory body, the MRA has continuously monitored their testing methods, both in-person and via video, since Viridis Lansing and Viridis Bay City began operations. Over the course of years, the MRA has time and time again *observed* and *approved* Plaintiffs' testing methodologies after conducting audits and monitoring its methods.
  - 38. Plaintiffs have also consistently passed proficiency tests instituted by the MRA.

- 39. A proficiency test is a quarterly inter-laboratory comparison between competing marijuana safety compliance facilities. The purpose of the test is to verify that the labs are able to reach similar results when testing sample marijuana provided by the MRA.
- 40. Although the MRA requires marijuana safety compliance facilities to undergo proficiency testing, it does not publish the results of its testing. However, during a group question and answer session during one of the MRA's workshops in 2021, Executive Director Andrew Brisbo indicated that the MRA did "not see anything" out of the ordinary from a proficiency testing standpoint.
- 41. Viridis Lansing and Viridis Bay City have also successfully completed and passed external proficiency tests the previous two years as required annually by the MRA and the A2LA for accreditation purposes. These external proficiency tests are provided through Absolute Standards Inc., an approved, accredited third-party test provider recognized by the MRA.
- 42. Recently, in June 2021, Viridis Lansing successfully passed their annual accreditation surveillance assessment by the A2LA. This assessment included review of all of Plaintiffs' SOPs. (Exhibit A, A2LA Assessment).
- 43. Because Plaintiffs provide accurate and reliable test results using the most up-to-date methods and equipment, the cannabis market, specifically growers and producers, have flocked to Plaintiffs to test their products. By 2021, Plaintiffs tested for between 60 to 70% of the cannabis market, meaning that 60 to 70% of all legal products on retail shelves have been tested by Plaintiffs.
- 44. The MRA took notice of Viridis' large percentage of market share in the cannabis industry.

- 45. Upon information and belief, there are only nineteen medical and seventeen adult-use marijuana safety compliance facility licensees in Michigan. Viridis Lansing and Viridis Bay City hold two of the licenses, which means there are seventeen medical and fifteen adult-use non-Viridis related facilities that perform cannabis testing (the "competitors"). The competitors split the remaining 30 to 40% of the cannabis flower testing market.
- 46. Some of the competitors have taken issue with Plaintiffs' organic market share of the cannabis testing industry. Rather than out-competing Plaintiffs, some of the other facilities have indicated that they want to remove Plaintiffs from the market and industry entirely.
- 47. Several competitors have openly indicated to Plaintiffs and the MRA during open, public calls that they wanted to see Plaintiffs shut down and put out of business to open more market opportunities for themselves.
- 48. The MRA's own internal political objective for the cannabis testing market is to ensure that all marijuana safety compliance facilities have a "fair share" of the testing market. In fact, during a recent webinar, Ms. Patterson indicated that the MRA's political objective is to ensure that there is not too much of a market concentration in one particular lab. Ms. Patterson put on a slide, which was part of the webinar, that the MRA is asking marijuana safety compliance facilities to "work together," that the MRA is seeking a "level playing field" between facilities, and takes issue with the fact that facilities are "not wanting to share proprietary methods." (Exhibit B, Slide). Simply put, the MRA does not want marijuana safety compliance facilities to compete in an open market where the most efficient, up-to-date, and reliable lab wins. Instead, the MRA wants a homogenized group of mediocre labs where innovation will be stifled because of the MRA's desire for labs to share proprietary information. While the MRA

may want the cannabis testing industry to engage in a race to the bottom, that is not how open markets work.

- 49. Upon information and belief, based on its own stated policy goals and the vocal concerns of Plaintiffs' competing marijuana safety compliance facilities, the MRA took issue with Plaintiffs having a 60 to 70% market share of the cannabis testing industry.
- 50. The MRA has no inherent authority to regulate or cap a marijuana safety compliance facility's share of the cannabis testing market. However, as explained below, upon information and belief, there are strong, well-documented patterns that show that the MRA has weaponized its own administrative rules and processes to reach its desired goal. The MRA and its employees have engaged in a concerted effort and campaign to artificially dilute Plaintiffs' market share in the industry or to remove Plaintiff from the cannabis testing industry altogether. In either scenario, the result will be the same: the competitors will obtain a larger piece of the cannabis testing pie.
- 51. The MRA started its campaign against Plaintiffs by taking issue with the Viridis Method for potency analysis.
- 52. Around November 2020, the MRA inquired about the Viridis Method despite having seen it performed by Plaintiffs several times in the past.
- 53. On October 1, 2021, during a phone call between Julie Kluytman, MRA enforcement division director, and Greg Michaud (Viridis' CEO), Ms. Kluytman told Mr. Michaud that the MRA had received at least 15 complaints that the MRA was required to investigate.
- 54. Since November 2020, the MRA has attempted to prevent Plaintiffs from using the Viridis Method for potency analysis and has systematically attempted to retroactively

disapprove its use. The MRA and Plaintiffs' dispute over this issue eventually resulted in the MRA filing several administrative complaints against Viridis that are currently the subject of contested case hearings.

- 55. On October 29, 2021, Assistant Attorney General, Risa Hunt-Scully, sent counsel for Plaintiffs an investigation report related to the administrative complaints that had been filed by the MRA. The report was dated September 27, 2021, by Investigator Allyson Chirio and was approved by Claire Patterson on October 13, 2021.
- 56. The administrative complaints were dated August 25, 2021, and the "investigation report" was over a month later. The investigation report includes reference to an anonymous alleged licensed grower that claimed that Plaintiffs were inflating potency levels and guaranteeing growers that retests would pass. Plaintiffs engaged in no such conduct.
- 57. The MRA has improperly used these unreliable complaints from anonymous competitors to justify their continued attacks against Viridis.
- 58. In response, due to the MRA's continued unnecessary disruption to Plaintiffs' business, on October 25, 2021, Plaintiffs used the formal and appropriate administrative process found in the MMFLA to file a complaint against the MRA ("Unnecessary Business Disruption Complaint"). MCL 333.27302(i); MAC R. 420.706(1). A copy of the complaint, absent exhibits, is attached as **Exhibit C**.
- 59. The MRA sat on responding to Plaintiffs' Unnecessary Business Disruption Complaint for three weeks. Plaintiffs were ultimately required to inform the Assistant Attorney General that if the Unnecessary Business Disruption Complaint was not properly processed that a Complaint for Mandamus would be filed in this Court. The Complaint was submitted to the Michigan Office of Administrative Hearings and Rules the following day. A hearing on

Plaintiffs' Complaint is set for December 22, 2021 at 9:00 a.m., but the administrative law judge does not have jurisdiction to address the numerous issues alleged in this Complaint.

- 60. Consistent with the MRA's attempts to prevent Plaintiffs from using the Viridis Method for potency analysis, on October 12, 2021, during the pendency of the administrative complaints that the MRA had filed against Viridis, Claire Patterson sent an e-mail to Viridis with investigation requests for outstanding and "current, on-going investigations."
- 61. The investigation requests from Ms. Patterson included 18 requests, consisting in part, of the following:

# **Currently Outstanding Investigation Requests**

- A. Video footage of Viridis Bay City;
- B. Potency prep sheets for 6 specific samples;
- C. Follow up request for calculation sheet for mold, pests and powdery mildew along with specific questions related to those calculations;
- D. Request for Method analysis added to Certificate of Analysis;

# **Currently Outstanding Method /Validation Requests**

- E. The request states that in order to approve any updates made to the potency method (SOP LOM-7.1a Cannabinoid Analysis by HPLC-DAD), that is any updates that alter the method form the reference method, we require a complete validation to AOAC Appendix K. This also includes updates to the prep method that was approved by the MRA in January 2020.
  - i. Submit a validation report, with an appropriate experimentation, statistical power, statistical design (e.g. RCBD or CRBD) and statistical analyses (e.g. ANOVA, Turkey HSD or Fisher LSD) to enable acceptance of the null hypothesis (Ha).
  - ii. Alternatively, the laboratory may opt to run the reference method. If the laboratory opts to return to the reference method, they must also adhere to the appropriate SMPR's for the Potency.
- F. Microbial Testing approval request for SOP matrix expansion;
- G. Requirement for additional information about Terpenoid Analysis;
- H. Request for information related to a requested Chemical Residue SOP matrix expansion;

# **New Investigation Requests**

- I. Request for Initial Demonstration of Capability (IDOC) for all technicians performing foreign matter analysis;
  - i. The documents(s) used to train staff about identifying foreign matter as well as how to calculate foreign matter for the entire sample;

- J. Request for photos of samples which contain foreign matter detected in flower samples for the last 6 months;
- K. Request for all calculations performed for foreign matter for that past 30 days that determine whether a sample is pass or fail;
- L. Request for information about two specific METRC samples asking for amount left in storage;
- M. Request for the SOP currently used by staff to complete foreign matter analysis;
- N. Request for an instrument read-out of all tests performed on both the gene-up and aria platforms within the past 3 months;
- O. Request for Incubation logs for all Aspergillus tests performed in the month of September;
- P. A complete list of all currently employed methods, the date of the last update, and the date that the method was approved by the MRA, as well a copy of <u>all</u> current SOPs currently in use;
- Q. A copy of all internal audits performed in 2020-2021;
- R. A daily schedule of when analyses are typically performed, or if ongoing throughout the day, please let us know;
  - 1. In addition, a request for several dates and time during the next two weeks for both Viridis locations when all technicians/analysts can be available for interview.

A copy of the above requests is attached as **Exhibit D**.

- 62. METRC is Michigan's statewide seed-to-sale marijuana tracking system that serialized tags attached to every plant and labels attached to wholesale packages to track marijuana inventory. <a href="https://www.michigan.gov/mra/0,9306,7-386-100002-510865--,00.html">https://www.michigan.gov/mra/0,9306,7-386-100002-510865--,00.html</a>
  - 63. METRC is a third party that is contracted by the state.
- 64. On October 19, 2021, Plaintiffs received a returned ticket from METRC stating, "per the MRA, 'Please ask for the equipment maintenance log of all incubators along with least temperature verification performed by an outside company." The MRA has *never* requested this information in the past and arbitrarily requested Plaintiffs perform additional tests by outside vendors without explanation as to why the test was being performed.

- 65. The MRA has effectively weaponized METRC by requiring METRC to now act as an enforcement arm seeking information on behalf of the MRA that is outside of its intended purpose.
- 66. Subsequent to receiving the above requests from the MRA, on October 21, 2021, the MRA indicated in an email to Plaintiffs that it intended to conduct full-day audits at both Viridis Lansing and Viridis Bay City. The MRA intended to "perform audits of the methods and procedures in real time" and to ask "questions related to the method and SOP." A copy of the MRA's email exchange and proposed schedules is attached as **Exhibit E**.
- 67. Viridis Lansing followed up on the MRA's email request and inquired if the audits were for "quality assurance" or "post-complaint" investigation. The MRA responded that it would be "quality assurance audits, post-complaint audits, and investigatory audits." (Exhibit E).
- 68. On October 25, 2021, the MRA escalated its campaign against Plaintiffs by revealing to Viridis' competitors that it was under investigation via e-mail. In that e-mail, the MRA directed that 10 of Viridis Lansing's previously tested samples were to be retested as part of the audit by other marijuana safety compliance facilities for microbial testing, including aspergillus, total yeast and mold, foreign matter, and pesticides. The MRA "randomly" selected several of the competitors for the audit testing. Copies of the sample audit notices from METRC are attached as **Exhibit F**. The MRA did not require any sample from Viridis Bay City to be retested as part of this audit request.
- 69. The MRA does not have its own safety compliance facility, so it selected "random" testing facilities to re-test Viridis' previously tested cannabis products.

- 70. Several of the marijuana safety compliance facilities that the MRA "randomly" selected to perform audits of Viridis Lansing's samples are the same competitors that have consistently complained about Plaintiffs, as a whole, having a large portion of the market for cannabis testing and have publically stated that they want to see Plaintiffs put out of business.
- 71. Unsurprisingly, 6 out of 10 of Viridis Lansing's previously tested samples that were sent to its competing labs as part of the October Audit were ultimately "failed."
- 72. On October 26 and 27, 2021, the MRA, through its employees Noah Rosenzweig, Patrice Fields, Allyson Chirio, and Claire Patterson, conducted its on-site "audits" at Viridis Lansing and Viridis Bay City's respective facilities (the "October Audits"). At the time of the October Audits, the MRA knew and had received a copy of the complaint attached as **Exhibit C**.
- 73. During the October Audits, the MRA observed Plaintiffs perform numerous tests on cannabis samples, including microbial analysis for aspergillus, total yeast and mold, foreign matter, and pesticides.
- 74. On November 15, 2021, almost three weeks *after* the MRA completed the October Audits, it released and forwarded to Plaintiffs its Onsite Audit Findings (collectively the "October Audit Findings"). (Exhibit H, Viridis Lansing's Onsite Audit Findings; Exhibit I, Viridis Bay City's Onsite Audit Findings).
- 75. Unlike the MRA's prior practice, the October Audit Findings did not provide Plaintiffs any opportunity to respond to the alleged deficiencies in its practices or testing procedures. Instead, on the same day, the MRA during a Teams phone call notified Plaintiffs that it was going to notice a recall of <u>all</u> of Plaintiffs' previously tested cannabis products that were tested between August 10, 2021 and November 16, 2021.

- 76. Ever since the MRA first mentioned the possibility of a recall, the MRA has articulated (via phone and/or Teams or Zoom, but still not in writing as required under the rules) only two bases for the recall. First, the MRA asserted that Plaintiffs had failed to keep a log book showing that they had kept the samples tested for aspergillus and other microbials in its bioMerieux incubator (a machine required for the test) at a certain temperature for 24 to 48 hours. After Plaintiffs explained, and the MRA acknowledged, that such logs are not required by statute, rule, any informal MRA guidance, or Plaintiffs' SOPs, at that point the MRA shifted and said the recall was warranted because it asserted that Viridis Lansing's 6 out of 10 retested and "failed" samples evidenced issues with the accuracy of Viridis Lansing's prior microbial analysis tests, specifically for aspergillus.
- 77. Neither of two grounds the MRA provided to Plaintiffs for the recall are not supported by any applicable law or rule. In fact, Plaintiffs never deviated from the method accredited by A2LA and the SOP approved by the MRA and which it observed Viridis perform numerous times over the course of two years Not once did the MRA comment on the lack of an incubator log.
- 78. The MRA proposed to issue the recall for between August 10, 2021 and November 16, 2021, which is completely arbitrary. This was pointed out first in a phone call with the MRA, on November 16, 2021. Plaintiffs explained that it had never kept log books since its inception, and, if that was the basis for a recall, then the proposed recall would necessarily include all microbial tests ever completed by every marijuana safety compliance facility within the industry. During that conversation, Desmond Mitchell told Plaintiffs that he was "doing them a solid" by not making the recall much broader in scope.

- 79. The fact that the MRA knew and approved Plaintiffs' procedure for microbial testing, including aspergillus, which has never included keeping logs for the incubator shows that this recall has nothing to do with public health and safety.
- 80. The fact that the MRA sat on this information for three weeks and did nothing shows that this recall has nothing to do with public health and safety.
- 81. Rather, upon information and belief, the timing of the recall was intended to impose maximum damage, as it came just before the busy Thanksgiving holiday and so-called "Green Wednesday," which is among the busiest sales days of the year for cannabis retail locations.<sup>1</sup>
- 82. As stated above, the MRA continuously monitors Plaintiffs and has been fully aware of its SOP, which does not include keeping log books.
- 83. The MRA has approved this method and the A2LA has done an accreditation of the method, which is pending approval.
- November 17, 2021, Mr. Mitchell stated "[t]he investigation is still ongoing. As part of that investigation, we'll determine if the recall should be expanded as you've indicated [this was in response to Viridis counsel pointing out that Viridis has never kept log books and the MRA has known that since it first started testing]. If it does, we expand the recall. However, as Kevin [Blair] has pointed out before this is a public health and safety issue and we need to act on this as soon as possible." (Exhibit I, Email Correspondence between MRA and Viridis' Counsel).

 $<sup>^{\</sup>rm 1}$  https://www.forbes.com/sites/lindseybartlett/2020/11/30/cannabis-sales-in-the-us-soar-on-green-wednesday/?sh=10f8aa27625d

- 85. Upon information and belief, many—if not all—marijuana safety compliance facilities have not or do not keep log books for their incubators for microbial analysis, which the MRA has knowledge of but has never issued any recall related to this failure.
- 86. The MRA's position is not supported by the evidence before it, and was specifically designed to set Plaintiffs up to fail.
- 87. Over the course of several days, the MRA, through its various representatives, and Plaintiffs, through their counsel, corresponded about the proposed recall and the grounds for said recall. Copies of those correspondences are attached as **Exhibit I**. The most egregious parts of the MRA's communications with Plaintiffs are highlighted in the body of this Verified Complaint, but the Court should read **Exhibit I**, in its entirety, to understand the full context of the situation.
- 88. In addition to the written communications attached as **Exhibit I**, the MRA also had numerous telephone conversations with Plaintiffs' counsel. The MRA, through Mr.Mitchell indicated that a lack of log book, on its own, would not warrant a recall. He indicated that the MRA was making the recall because of the alleged deficiencies in Viridis Lansing's 10 samples that were rested by the competitors.
- 89. Plaintiffs challenged the MRA's reliance and means of retesting Viridis Lansing's 10 samples as part of the October Audits. By using the competitors, especially those who have publically indicated they desire to see Plaintiffs shutter their doors, the MRA placed Plaintiffs on the path to failure. (Exhibit I).
- 90. Plaintiffs also challenged the MRA's reliance on the absence of log books. A marijuana safety compliance facility is *not* required by statute, administrative rule, or even the MRA's own technical guidance to keep a log book of hours in an incubator or temperature. Nor

does the AOAC (the organization referenced and relied upon by the MRA for scientific guidance) or the incubator's manufacturer, bioMerieux.

- 91. The MRA observed Plaintiffs perform microbial analysis testing, including for aspergillus, for over two years and has *never* raised concerns of Plaintiffs not having a log book for its incubation process. It curiously now takes issue with this fact. In July 2021, the MRA conducted a proficiency test of Viridis Lansing and approved all 60 aspergillus samples tested by Viridis Lansing using the exact procedure that the MRA now claims is unreliable. (Exhibit M, Method Approval).
- 92. Viridis Bay City also challenged the breadth of the MRA's proposed recall because the MRA did *not* request that it send *any* samples for audit. Put simply, the only grounds the MRA had for recalling Viridis Bay City's tested products was the lack of log books, which the MRA consistently indicated was not sufficient, on its own, to warrant a recall. Yet, the MRA issued the recall for Viridis Bay City anyway, merely because it has the word "Viridis" in its name.
- 93. Plaintiffs also challenged the MRA's proposed recall on the grounds that it was overbroad because it included samples (around 10% of the cannabis products covered by the recall) that were *not* tested for microbials and would have nothing to do with the alleged deficiencies identified in the October Audits.
- 94. When the MRA would not change its position on the recall based on Plaintiffs' own correspondence, Viridis contacted representatives from the AOAC and bioMerieux the vendor of the aspergillus testing platform known as GeneUp, to learn their positions on the matter, especially as to the MRA's use of several of the competitors to perform the sample audits.

- 95. Patrick Bird, a widely respected consultant from the AOAC<sup>2</sup>, that the MRA routinely relies on for expertise, concluded that the MRA's methodology was scientifically flawed and would not be sufficient to support a recall. In his e-mail to the MRA, on November 17, 2021 trying to educate the MRA on why a recall would be inappropriate stating the following:
  - 1. AOAC INTERNATIONAL's role in the cannabis industry is to develop standards and guidance to allow alternative methods to be certified through one of its conformity assessment programs. The certification of the method demonstrates its fit for purpose for use in that industry if the method is performed as written in the validation guidelines. AOAC is not involved in laboratory assessment and/or accreditation.
  - 2. Determining if a laboratory is performing a method correctly falls on the accreditation organization that issues the ISO 17025 certificate. If a method is certified during the accreditation it demonstrates that the laboratory is competent to run that method. The MRA's decision to recall these products due to the lack of traceability of the incubation logs indicates an issue with the accreditation process and not AOAC's certification. In this instance, the lab has demonstrated they can competently perform the method through their accreditation, although we all acknowledge there is a gap in the data collection process that fully supports this.
  - 3. The additional testing of materials at other labs is not something that I believe supports a recall as there are many factors in play that may have lead to the different results (same batch but different test portions analyzed, time gaps in analysis from one lab to another, etc).

(Exhibit I).

96. Maria McIntyre, from bioMerieux,<sup>3</sup> mirrored the consultant from the AOAC's position as well. She indicated that the methodology used by the MRA was not able to produce

<sup>&</sup>lt;sup>2</sup> The MRA relies on the AOAC as part of its Testing Rules, which require licensees to follow Appendix K of the AOAC. MAC R. 420.305(3).

<sup>&</sup>lt;sup>3</sup> bioMerieux's incubator is the same platform used by all of the labs that the MRA sent the samples to that tested Viridis' samples. bioMerieux has more expertise on their platform and the reliability of these tests than anyone else.

scientifically accurate or reliable results and that, in essence, the only thing that the MRA was basing its recall on was the absence of log books. In an email to MRA, on November 17, 2021, she also tried to educate the MRA on why a recall based on its reasoning was flawed:

- 1. Methods utilized have AOAC approval. This data collection usually includes robustness data that may or may not be a change in temperature. Please know, we are working to confirm if this data is available from the work for AOAC. This may take time to capture as I am collaborating with John Mills- Scientific Affairs Manager and Dr. Ron Johnson- former AOAC President.
- 2. ISO 17025 accreditation impacts the discussion as ISO sets the benchmark for the quality standards within accredited laboratories. If a recall is generated under these circumstances it's a reflection of a gap in ISO accreditation and does not relate to AOAC or the method itself. The lab has completed training on the method reflected in the training certificates and demonstrated via the ISO 17025 accreditation process.
- 3. When there is uncertainty in results either retesting or confirmation testing generally holds greater value than a multi-lab study. In such a study, there are many variable in the equation leading to variability.
- 4. The iso files have been reviewed and the assay appears to be running properly. The files have been transferred to the R&D team who created this assay for a 2<sup>nd</sup> opinion and to determine if other areas require addressing.

# (Exhibit I).

- 97. Plaintiffs tried to reason and educate with the MRA up until the very last minute. Not only did the two most reliable subject matter experts opine that the recall was inappropriate based on these flawed tests, Plaintiffs offered for the MRA to review the video evidence that it already had in its possession and to supplement that with further video so that the MRA could confirm that Plaintiffs had properly tested for microbial contamination, including aspergillus, for the required time. The MRA refused to look at the video evidence.
- 98. Notwithstanding irrefutable evidence that the MRA's rationale for a recall was not based in science, the MRA refused to budge and issued the recall bulletin on November 17, 2021. (Exhibit J, Recall Bulletin). Interestingly, the MRA used a bulletin to recall the Viridis'

previously sampled products even though said action does *not* have the force of law. MCL 24.232(5).

- 99. Because Viridis tested for 60 to 70% of the cannabis industry that means the recall covers 60 to 70% of all cannabis products in the market. The MRA's recall has created chaos and panic within the cannabis industry. Growers, producers, and retailers are scrambling trying to get their products back on the market. Smaller growers and retailers have voiced their concerns over the lack of product and indicated to the MRA, Plaintiffs, and others in the cannabis industry that they will not be able to survive because of the product and cash flow interruptions caused by the recall.
- 100. As previously stated, the recall is overbroad. It covers not only <u>all</u> of Plaintiffs' previously tested products, including products that were tested for items unrelated to microbials analysis and were thus unrelated to the MRA's concerns, but also products from Viridis Bay City, which, again, did not provide *any* samples for audit because they were not requested by the MRA.
- 101. Upon information and belief, as of the date of filing this Verified Complaint, no consumer has reported adverse side effects from any cannabis products tested by Plaintiffs.
- 102. The MRA's recall included over 64,000 lbs. of flower totaling over \$229 million using the average retail price per lbs. between August 10, 2021 and November 16, 2021.
- 103. Over 10% of the recalled cannabis products were not testified for microbial analysis.
  - 104. The MRA's recall is improper in both scope and substance.
- 105. Upon information and belief and reasonable inference, the MRA issued the recall, at least in part, as retaliation for Viridis filing the complaint attached as **Exhibit C**.

- 106. Many of Viridis' customers learned about details of the recall prior to it being issued on November 17, 2021, which upon information and belief was leaked from within the MRA.
- 107. Upon information and belief, the competitors were celebrating the recall prior to November 17, 2021.
- 108. To add insult to injury, after the MRA issued the recall notice, it indicated to Plaintiffs in an email that because it had "corrected" the log book issue by implementing said process into its microbial testing process, that it was approved to begin re-commence microbial analysis testing. An email evidencing this fact is attached as **Exhibit K**.
- 109. The MRA then changed its position in less than 24 hours and indicated that Plaintiffs could only test for aspergillus. (Exhibit K). The MRA then changed its position again by informing Plaintiffs' customers, without informing Plaintiffs, that Plaintiffs cannot perfom any microbial testing as a result of the recall.
- 110. The MRA's recall notice has put growers, producers, retailers, and others connected to Plaintiffs in chaos because of its breadth and unexpectedness. The recall, by its terms, allows those affected by it to have the product retested for microbial analysis.
- 111. Several of Plaintiffs' existing customers called the MRA to verify that Plaintiffs can perform the retest. In response, the MRA responded that Plaintiffs are prohibited from performing *any* analysis related to microbials. Plaintiffs' customers have informed Plaintiffs of the MRA's position and statements on its ability to perform microbial analysis.
- 112. The MRA told Plaintiffs' customers one thing and Plaintiffs another. They both cannot be right, and the MRA has taken contrary positions.

- 113. The MRA's actions related to microbial testing is contrary to the promulgated rules, which do not allow the MRA to unilaterally suspend or restrict a previous approval of a testing methodology or a marijuana safety compliance facility's license.
- 114. The MRA has refused to provide Plaintiffs with adequate, written, or clear guidance on what it may do moving forward and has actively sought to hinder their ability to address the recall with their customers.
- 115. The recall, by its very terms, allows cannabis products to be retested for microbial analysis. (Exhibit J). Because the MRA has restricted and prevented Plaintiffs from conducting microbial analysis, Plaintiffs have sought guidance form the MRA on what is needed to get reauthorization to test for microbials such that it can assist its customers.
- 116. In subsequent conversations with the MRA, it sent Plaintiffs a "check list" of items that needed to be completed prior to it re-authroizing Plaintiffs to complete microbial analysis. During a zoom call, the MRA revealed that the check list was even longer than originally anticipated, but represented that only the items listed in bold needed to be completed for Plaintiffs to get up and running. In a follow up email, Plaintiffs sought to verify what needed to be completed on the checklist (not the entire list but only bolded items). However, Julie Kluytman changed the MRA's position yet again, moved the goal posts back, and indicated that *everything* on the checklist needed to be approved before Plaintiffs could re-commence microbial testing. (Exhibit I).
- 117. Plaintiffs managed to complete or substantially comply with every item listed on the checklist and sought the MRA's approval the following day. The MRA nevertheless rejected Plaintiffs' efforts and demanded that it start its efforts over from scratch.

- 118. As of November 22, 2021, and subsequent to the unlawful recall, the MRA is now allowing growers to have samples that Plaintiffs had originally tested submit new samples to other safety compliance facilities to be retested, and treating the Plaintiffs' test results as failed tests.
- 119. The MRA is requiring these retests to have two consecutive passes and then allowing the growers to take the products to market.
- 120. These retests include samples that Plaintiffs have tested that have been homogenized, cross-contaminated with unground foreign matter, had spatulas and had tweezers poked in the sample during the initial testing, and overall have been adulterated during the testing process.
- 121. The MRA is diverting from each marijuana safety compliance testing facility's approved SOPs and the MRA's own ruless. *See, e.g.*, MAC R.420.306 ("A failed marijuana product must pass 2 separate tests *with new samples* consecutively to be eligible to proceed to sale or transfer.") (emphasis added); *Sampling and Testing Technical Guidance for Marijuana Products*, MRA, July 1, 2021, p 25, https://www.michigan.gov/documents/mra/Sampling\_and\_Testing-

\_Technical\_Guidance\_for\_Marijuana\_Products\_694124\_7.pdf, ("A failed marijuana product must pass 2 separate tests with *new samples* consecutively to be eligible to proceed to sale or resale.").

122. These retests, which are using adulterated as opposed to new samples, have no scientific value or reliability. Upon information and belief, the MRA will use these faulty results to again punish Plaintiffs by questioning their testing of the original, not new, samples.

- 123. The MRA's conduct cannot be reviewed in a vacuum. It had stated publically that it did not want a concentrated cannabis testing industry, and over the course of about one year, has specifically targeted Plaintiffs for various "violations" that it cannot support with any substantial or reliable evidence.
- 124. Upon information and belief, the MRA's conduct was carried out by and amongst its employees to target Plaintiffs because of their market share in the cannabis testing industry.
- 125. Upon information and belief, the MRA's conduct was carried out in retaliation for Plaintiffs using the proper and appropriate administrative channels for addressing its grievances with the MRA.
- 126. The MRA has significantly deviated from prior practice when dealing with violations of this nature, as explained below, opting to institute the largest cannabis product recall in the state's history. By doing so, it has discredited Plaintiffs, their methods, and their principals.
- 127. A substantial number of Plaintiffs' customers have already jumped ship to other marijuana safety compliance facilities to get their products on the market. Plaintiffs are losing market share by the hour.
  - 128. The MRA's wrongful conduct is the direct cause of all of this.
- 129. The MRA's above conduct has effectively suspended or restricted Plaintiffs' licenses under Michigan law because it prohibits them from continuing to operate their business.
- 130. The MRA has consistently taken the position that its recall is warranted because, among other things, the public health and safety was at risk and, by extension, allowing Plaintiffs to do *any* microbial testing puts the public's health and safety at risk. In these circumstances, the

MRA was required to follow the procedures and processes set forth by statute and administrative rule to summarily suspend Plaintiffs' licenses. MCL 24.292; MAC R. 420.705(1)

- 131. The MRA did not follow the correct procedures to suspend Plaintiffs' licenses, which was required because the MRA constructively suspended and actually restricted Plaintiffs' licenses.
- 132. Upon information and belief, the MRA has orchestrated its above described efforts in a manner to prevent Plaintiffs from obtaining any form of relief from an administrative proceeding *or* judicial review. If the correct procedures would have been followed by the MRA, then Plaintiffs would have been afforded notice of their license suspensions and an opportunity to contest said suspensions. As it currently stands, it has neither.
- 133. Plaintiffs do not have an adequate remedy at law. Plaintiffs cannot, themselves, compel the MRA to follow the necessary procedures to suspend their licenses or unilaterally obtain an expedited hearing of the suspensions in front of an administrative law judge. The MRA controls those remedies entirely.
- 134. Without any viable alternatives, Plaintiffs are forced to turn to this Court for assistance.
- 135. Prior to the MRA's recall, Plaintiffs tested almost 70% of flower samples in the state. Plaintiffs have been irreparably harmed by the MRA because it is losing market share and customers by the hour as a direct and proximate result of the recall.
- 136. The MRA's conduct is excess, unnecessary regulatory overreach and abuse that has significantly disrupted Plaintiffs' business operations and their operations as a marijuana safety compliance facility, and has placed it at significant risk of having to shutter their doors.

- 137. The above allegations, taken together and under the totality of the circumstances, evidence the MRA has continued to take step after step to interfere with Plaintiffs' business and effectively suspend and actually restrict their licenses without following the proper procedures required by law, thereby depriving Plaintiffs of a clear right to relief from a neutral, detached, and fair fact finder.
  - 138. The MRA's actions interfere with or impair Plaintiffs' legal rights and privileges.
  - 139. The MRA's conduct is contrary to its own regulations and Michigan law.
- 140. Plaintiffs have a right under MCL 600.631 to seek judicial review of any "order, decision, or opinion of any state . . . agency" that adversely affects it.
  - 141. Plaintiffs are entitled to the relief sought in this Verified Complaint.

# COUNT I PRELIMINARY AND PERMANENT INJUNCTION (MRA AND ANDREW BRISBO)

- 142. Plaintiffs reassert and reallege the preceding paragraphs as if fully set forth herein.
- 143. As explained and alleged above, the MRA has wrongfully targeted Plaintiffs for improper purposes that have nothing to do with public health and safety. Plaintiffs do not know precisely what the improper motives were, but there is a well-documented and inferential pattern that strong suggests that the MRA was very likely motivated by one or more of the following:
  - A. The MRA wanted to further its political objective of equalizing market share of the cannabis testing industry between Plaintiffs and the competitors. Upon information and belief, this was done to either artificially dilute and cap Plaintiffs' market share within the cannabis testing industry or to effectively destroy

- Plaintiffs' business operations thereby compelling Plaintiffs' customers to seek to do business with the competitors;
- B. The MRA instituted the recall in retaliation for Plaintiffs using the process outlined in the MMFLA and the MRA's administrative rules for filing an administrative complaint against the MRA for unnecessarily disrupting their business operations and their operations as marijuana safety compliance facilities; and
- C. The MRA engaged in a personal vendetta for the numerous times that Plaintiffs challenged their arbitrary, wrongful, and unlawful proclamations (collectively with the above are referred to as the "ulterior motives").
- 144. As explained and alleged above, the MRA has wrongfully treated Plaintiffs as a collective entity instead of different business entities. Viridis Lansing is a separate and distinct entity with an entirely different ownership structure than Viridis Bay City. Contrary to the MRA's position, none of the samples that were retested as part of the October Audit were associated with Viridis Bay City. Each and every one of them were associated with Viridis Lansing. This means that the MRA instituted a recall of cannabis products tested by Viridis Bay City without a failed audit test and based on the absence of incubator logs alone, which the MRA, itself, has acknowledged is insufficient to sustain a recall of this magnitude.
- 145. As explained and alleged above, the MRA has wrongfully and arbitrarily included all cannabis products tested by Plaintiffs as part of its recall, including around 10% of those cannabis products that were *not* analyzed for aspergillus or other microbials. This means that the MRA has recalled every cannabis product tested by Plaintiffs from August 10, 2021, through

November 16, 2021, even if it had no relation to the alleged deficiencies that formed the basis of the recall.

- 146. Viridis does not have an adequate remedy at law to address the MRA's wrongful conduct. The MRA has acted unilaterally to implement a scientific and factually unjustified, overbroad, and detrimental recall of all cannabis products tested by Plaintiffs that has wreaked havoc upon greater than \$229 million of commerce within the state. Its high ranking officials ignored evidence from a highly respected consultant associated with the AOAC, the organization whose standards are directly incorporated into the MRA's administrative rules for marijuana safety compliance facilities, *see*, *e.g.*, MAC R.420.705(3), and the manufacturer of Plaintiffs' microbial analysis incubators, indicating that no recall, let alone a recall of this nature, was justified. In essence, the MRA has based the recall entirely upon the lack of incubator logs which the MRA, itself, has acknowledged is insufficient to compel a recall of this nature.
- 147. As detailed by the factual allegations above and as explained in Plaintiffs' motion for temporary restraining order and preliminary injunction, Viridis has a substantial likelihood of succeeding on the merits of this Verified Complaint.
- 148. Plaintiffs (and the entire cannabis industry) will suffer great, severe, and irreparable harm if the MRA's recall is allowed to remain in effect. Viridis tests for between 60 to 70% of the cannabis testing industry, meaning that 60 to 70% of all cannabis products in the *entire state* are subject to the MRA's recall. This disruption is exacerbated by the fact that it

comes directly before one of the busiest days of the year for retail cannabis businesses, so-called "Green Wednesday."

- 149. Plaintiffs and their customers will experience significant revenue, cash flow, reputational, and economic harm as a direct and proximate result of the recall. There is a significant likelihood, if the recall is allowed to take effect, that Plaintiffs and a sizable number of its customers will have to shutter their doors.
- 150. The only relief that will prevent Plaintiffs, its customers, and the cannabis industry as a whole from suffering the great, severe, and irreparable harm described above is injunctive relief of a preliminary and permanent nature enjoining the MRA from enforcing the recall.
- 151. The MRA will suffer *no harm* if this Court enters a preliminary and permanent injunction. The MRA is a governmental agency and, itself, cannot consume cannabis products.
- 152. As explained above and throughout this Verified Complaint, Plaintiffs, their customers, and the entire cannabis industry will suffer great, severe, and irreparable harm if the MRA's recall is allowed to remain in effect or be enforced on an ongoing basis.
- by this Court entering a temporary restraining order or preliminary and permanent injunction enjoining the MRA from enforcing the recall. There was no scientific or factual basis for the MRA to institute the recall, its actions of waiting greater than 3 weeks after completing its audits to issue the recall, and its acknowledgment that relying on incubator logs standing alone will not support a recall of this magnitude all evidence that the public will not be put in harm's way.

https://www.forbes.com/sites/lindseybartlett/2020/11/30/cannabis-sales-in-the-us-soar-on-green-wednesday/?sh=505b536a625d

Indeed, upon information and belief, as of the date of filing this Verified Complaint, the MRA has received *no* complaints from consumers of any adverse effects or experiences with any cannabis product tested by Plaintiffs.

- 154. In the absence of an injunction of a preliminary and permanent nature, the balance of harms weighs strongly in favor of Plaintiffs and not the MRA.
- 155. The Court should grant a preliminary and ultimately a permanent injunction enjoining the MRA from enforcing or carrying out the recall.
- 156. In addition to the MRA, Andrew Brisbo is sued in his individual capacity under Ex Parte Young, 209 US 123 (1908) to enjoin him from carrying out the recall based on the numerous violations of federal law set forth in this Verified Complaint.

WHEREFORE, Plaintiffs respectfully requests this Court enter a judgment in its favor and against the MRA and Andrew Brisbo permanently enjoining them from enforcing and carrying out the recall; granting Plaintiffs their costs and attorney fees for having to bring this action; and awarding Plaintiffs any other relief this Court deems just and proper.

# COUNT II WRIT OF MANDAMUS AND MOTION FOR EX PARTE RELIEF (MRA)

- 157. Plaintiffs reassert and realleges the preceding paragraphs as if fully set forth herein.
- 158. A writ of mandamus is appropriate if (1) Plaintiffs has a clear legal right to the performance of the duty sought to be compelled; (2) the MRA has a clear legal duty to perform the requested act; (3) the act is ministerial; and (4) no other remedy exists that might achieve the same result. Coalition for a Safer Detroit v Detroit City Clerk, 295 Mich App 363, 367; 820 NW2d 208 (2012).

- 159. As explained above and alleged throughout this Verified Complaint, the MRA has represented to Plaintiffs that they are prohibited from performing *any* microbial analysis, with the exception of aspergillus, for cannabis products.
- 160. As explained above and alleged throughout this Verified Complaint, Plaintiffs have made significant efforts to resolve this issue with the MRA without administrative or judicial intervention. However, such discussions have been unproductive and two-faced on the part of the MRA.
- 161. As explained above and alleged throughout this Verified Complaint, throughout numerous phone or zoom calls, the MRA would continually represent to Plaintiffs that it needed to complete certain items in order to be re-approved for microbial analysis. But once off the phone or zoom cal, the MRA would take an entirely different position, move the goal posts, and misrepresent the substance of the prior phone or zoom call that occurred less than 10 minutes before Plaintiffs' email to the MRA.
- 162. As explained above and alleged throughout this Verified Complaint, after prohibiting Plaintiffs from performing microbial analysis, the MRA sent Plaintiffs a list of "checklist" items that asserted and represented that Plaintiffs needed to complete in order for the MRA to re-approve Plaintiffs for microbial analysis testing. Plaintiffs completed the MRA's "checklist" in less than a day and sent proof of compliance to the MRA. The MRA rejected Plaintiffs' proof on suspect grounds and continually moved the goal post on what Plaintiffs would need to do in order for the MRA to re-approve Plaintiffs for microbial analysis.
- 163. As explained above and alleged throughout this Verified Complaint, the MRA's position that Plaintiffs are prohibited from performing microbial analysis on cannabis products is effectively a partial suspension of Plaintiffs' licenses.

- 164. As explained above and alleged throughout this Verified Complaint, the MRA has failed to follow the necessary and required procedures set forth by statute and administrative rule for suspending Plaintiffs' licenses.
- 165. As explained above and alleged throughout this Verified Complaint, the MRA has chosen to not formally suspend Plaintiffs' licenses because that would allow for administrative or judicial review of its actions. The MRA has orchestrated the recall in such a manner as to avoid any form of oversight from an administrative law judge or the Court.
- 166. As explained above and alleged throughout this Complaint, for all intents and purposes, the MRA has partially summarily suspended Plaintiffs' licenses but has not followed the proper processes or procedures.
- 167. The MRA has a clear legal duty under MCL 24.292 to provide Plaintiffs of notice of its intent to suspend its licenses, an opportunity for Plaintiffs to show that suspension is not warranted, and, where its license is summarily suspended, the immediate commencement of proceedings before an administrative law judge to adjudicate the propriety and appropriateness of the suspension. The MRA has not provided Plaintiffs with the required notice, an opportunity to contest the suspension, or instituted immediate proceedings before an administrative law judge.
- 168. The MRA has a clear legal duty under MAC R.420.705 to follow the necessary processes for summarily suspending Plaintiffs' licenses, including the legal duty to institute immediate proceedings before an administrative law judge to adjudicate the propriety and appropriateness of the suspension.
- 169. Plaintiffs have a clear legal right under MCL 24.292 and MAC R.420.705 to receive notice of the MRA's intent to suspend their license, an opportunity to contest the

suspension, and, where summary suspension of their licenses is involved, a right to an immediate proceeding before an administrative law judge.

- 170. As explained above and alleged throughout this Verified Complaint, the MRA has effectively and for all practical purposes partially summarily suspended Plaintiffs' licenses for microbial testing, yet did not provide Plaintiffs with notice of its intent to suspend its license, and has not instituted immediate proceedings before an administrative law judge to adjudicate the propriety or appropriateness of the suspension.
- 171. It is too late for Plaintiffs to receive notice of the MRA's intent to suspend its license or to present evidence against such suspension. However, it is *not* too late for Plaintiffs to receive an immediate hearing in front of an administrative law judge because of the MRA's effective summary suspension.
- 172. The MRA's duty of instituting immediate proceedings in front of an administrative law judge relating to its effective summary suspension of Plaintiffs' license is ministerial in nature. The MRA merely needs to send a form to the Michigan Office of Administrative Hearings and Rules (an agency located under the *same* broader department as the MRA) to institute the proceedings. There is no exercise of discretion at all to carry out this duty.
- 173. Plaintiffs have no adequate remedy at law other than mandamus that will achieve the correct legal result of requiring the MRA to commence immediate proceedings before an administrative law judge relating to the propriety and appropriateness of its effective, partial summary suspension of Plaintiffs' licenses.
- 174. Based on the forgoing, as provided in MCR 3.305(C), Plaintiffs move the Court for an *ex parte* order ordering the MRA to show cause why the requested writ of mandamus should not be issued. A proposed order to this effect is attached as **Exhibit L**.

WHEREFORE, Plaintiffs respectfully requests this Court grant Plaintiffs' ex parte motion pursuant to MCR 3.305(C) and issue an order to show cause why writ of mandamus should not be entered against the MRA; issue a writ of mandamus directing the MRA to immediately commence proceedings before an administrative law judge relating to the propriety and appropriateness of the MRA's effective, partial suspension of Plaintiffs' licenses regarding microbial analysis; grant Plaintiffs their costs and attorney fees for having to bring this action; and award Plaintiffs any other relief this Court deems just and proper.

#### **COUNT III**

### DECLARATORY JUDGMENT THAT THE MICROBIAL RULE AND LOG RULE ARE PROCEDURALLY AND SUBSTANTIVELY INVALID

- 175. Plaintiffs reassert and reallege the preceding paragraphs as if fully set forth herein.
- 176. MCR 2.605(A)(1) states that "[i]n a case of actual controversy within its jurisdiction, a Michigan court of record may declare the rights and other legal relations of an interested party seeking a declaratory judgment."
- 177. An "actual controversy" exists where a declaratory judgment or decree is necessary to guide a party's future conduct in order to preserve his legal rights. *Kircher v City of Ypsilanti*, 269 Mich App 224, 227; 712 NW2d 738 (2005).
- 178. The crux of Plaintiffs' APA rule claim against the MRA is that it has improperly and arbitrarily promulgated new rules by creating standards by which it can recall cannabis products tested by marijuana safety compliance facilities.
- 179. The only relevant MRA administrative rule relating to recalls is found at MAC R.420.505(2), which provides "[t]o ensure access to safe sources of marihuana products, the agency, if alerted in the statewide monitoring system, may place an administrative hold on

marihuana products, recall marihuana products, issue safety warnings, and require a marihuana business to provide information material or notifications to a marihuana customer at the point of sale." This rule, by its plain language, does *not* provide any standards by which the MRA can institute a recall.

- 180. The MRA's above alleged conduct shows that it improperly and arbitrarily created new rules relating to when a recall may be instituted without following the mandatory "notice-and-participation" requirements of the Michigan Administrative Procedures Act ("APA") (MCL 24.201, et seq.); Mich AFL-CIO v Sec of State, 230 Mich App 1, 6; 583 NW2d 701 (1998) ("Ordinarily, agencies must follow the notice-and-participation rule-making procedures contained in the APA.").
- 181. The MRA's new, improper rules are: (1) where an original marijuana safety compliance facility conducts a microbial analysis on a cannabis product and a *different* lab tests the same sample under an audit that the MRA may institute a recall of the cannabis products tested by the original marijuana safety compliance facility (the "Microbial Rule"); and (2) where a marijuana safety compliance facility fails to keep a log book for an incubator used for microbial analysis showing temperature and length of incubation of the sample that the MRA may institute a recall of the cannabis products tested by the marijuana safety compliance facility (the "Log Rule"). The MRA enforced the Microbial Rule and Log Rule against Plaintiffs when it instituted a recall of <u>all</u> cannabis products tested by Plaintiffs.
- 182. The APA defines a "rule" as "an agency regulation, statement, standard, policy, ruling, or instruction of general applicability that implements or applies law enforced or administered by the agency, or that prescribes the organization, procedure, or practice of the

agency, including the amendment, suspension, or rescission of the law enforced or administered by the agency." MCL 24.207.

- 183. The MRA did not collect public comments, data, or arguments about the new standards set forth in the Microbial Rule or Log Rule.
  - 184. The Microbial Rule and Log Rule have the full force and effect of law.
- 185. The Microbial Rule and Log Rule do not interpret, guide, or explain the MRA's positions on existing rules and instead provides *new standards* that Plaintiffs must follow to stay in compliance with MRA regulations. As explained above, the Microbial Rule and Log Rule invert the status quo entirely.
- 186. For all intents and purposes the Microbial Rule and Log Rule are a "rule" as defined by the APA.
- 187. The MRA failed to comply with the requirements of the APA when promulgating the Microbial Rule and Log Rule, including, but not limited to, MCL 24.239, 24.241, or 24.242. Furthermore, the MRA has failed to show a finding that the Microbial Rule or Log Rule are necessary for the preservation of the public health, safety, and welfare, and failed to include a statement that the governor concurs in the finding of an emergency as required for the issuance of emergency rules by MCL 24.248.
- 188. The MRA's foregoing failures render the Microbial Rule and Log Rule null and void under the APA. MCL 24.243.
- 189. Plaintiffs and the MRA sharply disagree over whether the Microbial Rule and the Log Rule are rules under the APA. Plaintiffs maintain and the evidence will show that the Microbial Rule and the Log Rule are rules promulgated in violation of the procedures required by the APA.

- 190. A declaratory judgment is necessary to guide Plaintiffs and the MRA's future conduct and preserve the parties' legal rights.
- 191. "Ordinarily, agencies must follow the notice-and-participation rule-making procedures contained in the APA." *Mich State AFL-CIO*, 230 Mich App at 6.
- 192. Where an agency fails to promulgate an emergency rule in compliance with the APA, the rule is "invalid and may be stricken by a court. . . ." *Mich State AFL-CIO*, 230 Mich App at 24.
- 193. The Microbial Rule and Log Rule are procedurally invalid because, among other things:
  - A. The MRA did not follow any of the very important, usual procedural safeguards required by the APA;
  - B. The MRA did not follow any of the procedures necessary to create an emergency rule under the APA or even take steps to show that a true emergency exists; and
  - C. Even if the circumstances constitute a true emergency, the alleged threat only affects a small subgroup of the general public, which is insufficient, as a matter of law, to justify deviating from the usual APA procedural safeguards.
  - 194. The MRA failed to follow any of the procedural safeguards required by the APA.
- 195. The Microbial Rule and Log Rule have already caused substantial disruption to the cannabis industry. Between 60 to 70% of the state's lawful cannabis products have been recalled, the equivalent of around \$229 million in commerce. This disruption is exacerbated by the timing of the recall, which occurred just before the busy Thanksgiving holiday, which, upon information and belief, is one of the busiest sales days of the year for retail marijuana businesses. The true, lasting effects of the Microbial Rule and Log Rule are unknown, but the most immediate effect is Plaintiffs are likely to go out of business. This is especially arbitrary and capricious because other marijuana businesses are also likely to go out of business due to cash

flow issues and lack of product availability caused by the recall, even though they had *nothing* to do with microbial analysis or logs.

- 196. Interestingly, microbial analysis *is not* required for patient caregivers to provide cannabis products.
- 197. A declaratory judgment is also necessary because the Microbial Rule and Log Rule are substantively invalid.
- 198. Under the APA, this Court must "set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 USC 706(2)(A); see also MCL 24.306(e).
- 199. Courts defer to an agency's findings of fact only if they are supported by "substantial evidence." 49 USC 46110(c); see also MCL 24.306(d).
- 200. "[A] fundamental requirement of administrative law is that an agency set forth its reasons for decision; an agency's failure to do so constitutes arbitrary and capricious agency action." *Amerijet Int'l, Inc v Pistole*, 753 F3d 1343, 1350 (DC Cir 2014) (internal citation and quotation omitted).
- 201. A statute that grants power to an administrative agency must be strictly construed and the administrative authority drawn from such statute must be granted plainly, because doubtful power does not exist. *Lake Isabella Dev, Inc v Vill of Lake Isabella*, 259 Mich App 393, 675 NW2d 40 (2003).
- 202. The Microbial Rule and Log Rule are also substantively invalid because they are arbitrary and capricious and, among other things:
  - A. The MRA ignored substantial evidence contradicting its overall conclusions about the Microbial Rule and Log Rule; and

- B. The MRA has crafted an overly broad and sweeping recall that covers products from Plaintiffs Bay City that did *not* fail the alleged Microbial Rule but also products that were *not* subject to Plaintiffs' microbial analysis, which means they would *not* have fallen within the Microbial Rule or Log Rule, even if such rules were properly promulgated or issued.
- 203. Therefore, Plaintiffs requests a declaratory judgment under MCR 2.605.

WHEREFORE, Plaintiffs respectfully requests this Court enter a judgment in its favor and against the MRA declaring the Microbial Rule and Log Rule were adopted contrary to and in violation of the APA; determining that the Microbial Rule and Log Rule are procedurally and substantively invalid; issue a permanent injunction enjoining the MRA from enforcing the Microbial Rule or Log Rule and carrying out the recall; granting Plaintiffs their costs and attorney fees for having to bring this action; and awarding Plaintiffs any other relief this Court deems just and proper.

### COUNT IV DECLARATORY JUDGMENT THAT THE MRA LACKS AUTHORITY TO SUMMARILY RESTRICT MARIJUANA BUSINESS LICENSES

- 204. Plaintiffs reassert and reallege the preceding paragraphs as if fully set forth herein.
- 205. MCR 2.605(A)(1) states that "[i]n a case of actual controversy within its jurisdiction, a Michigan court of record may declare the rights and other legal relations of an interested party seeking a declaratory judgment."
- 206. An "actual controversy" exists where a declaratory judgment or decree is necessary to guide a party's future conduct in order to preserve his legal rights. *Kircher*, 269 Mich App at 227.

- 207. Even if the Court finds that the MRA's actions do not amount to a summary suspension of Viridis' licenses as averred in Count II, those actions are a restriction on Viridis' licenses, and the imposition of such a restriction must follow proper administrative procedures.
- 208. Plaintiffs and the MRA sharply disagree over the MRA's ability to summarily restrict a marijuana business's license without following proper procedures under statute or administrative rule. Plaintiffs maintain that the MRA lacks such authority.
- 209. A declaratory judgment is necessary to guide Plaintiffs and the MRA's future conduct and preserve the parties' legal rights.
- 210. Under MAC R.420.806(1), the MRA may impose sanctions on a 'licensee found in violation of the acts or the [] rules," including, but not limited to "[m]arihuana license denial[,]" "[1]imitations on a marihuana license[,]" and "[r]evocation, suspension, nonrenewal of a license, or an administrative hold on a marihuana license."
- 211. The MRA may sanction a licensee after it has conducted an investigation and found that a licensee has violated the MMFLA, MRTMA, or the other rules promulgated thereunder, in which case it must "serve the formal complaint on the licensee by certified mail, return receipt requested, or in person by a representative of the agency." MAC R.420.808(1).
- 212. Once the licensee receives the formal complaint, it has three options: (1) to request a compliance conference; (2) to request a contested case hearing; or (3) to request both a compliance conference and a contested case hearing. MAC R.420.808(2), (3).
- 213. Under MAC R.420.704(1), "[a] licensee who has been notified of a marihuana license violation, or of the agency's intent to suspend, revoke, restrict, or refuse to renew a marihuana license or impose a fine, may be given an opportunity to show compliance with the requirements before the agency taking action as prescribed by these rules." This is consistent

with MCL 24.292(1), which states, in relevant part, that "[b]efore beginning proceedings for the suspension, revocation, annulment, withdrawal, recall, cancellation or amendment of a license, an agency shall give notice, personally or by mail, to the licensee of facts or conduct that warrants the intended action. The licensee shall be given an opportunity to show compliance with all lawful requirements for retention of the license..."

- 214. Under MAC R.420.704(2), "[a] licensee aggrieved by an action of the agency to suspend, revoke, restrict, or refuse to renew a marihuana license, or impose a fine, may request a contested case hearing in writing within 21 days after service of the notice of *the intended action*." At that contested case hearing, the MRA "has the burden of proving, by a preponderance of the evidence, that sufficient grounds exist for *the intended action* to suspend, revoke, restrict, or refuse to renew a state license, or to impose a fine, or summarily suspend a license." Once the contested case hearing is complete, the administrative law judge issues a proposal for decision, MAC R.420.707, and the MRA makes a decision in writing, which is its final decision for purposes of judicial review. MAC R.420.708.
- 215. Implicit in the above provisions is the idea that a licensee must receive notice of a suspension, revocation, restriction, or nonrenewal prior to that action being taken by the MRA. That comports with basic notions of due process and the APA, which is applicable to licensing actions taken by the MRA. *See, e.g.*, MCL 333.27407(2) ("The [MRA] shall comply with the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328, when denying, revoking, suspending, or restricting a license or imposing a fine.").
- 216. The MRA may act summarily and not offend notions of due process, but only in certain, limited circumstances. As courts have recognized, "[a]gencies may, consistent with the principles of due process, summarily suspend a license without hearing if necessary to protect

the public interest." M & S, Inc v Attorney General, 165 Mich App 301, 305; 418 NW2d 441 (1987) (citing Rogers v Bd of Ed, Trenton Public Schools, 61 Mich App 682; 233 N.W.2d 141 (1975).

- 217. While the MRA's own rules allow it to deny, revoke, suspend, restrict, or not renew a license, the same rules only allow it to summarily suspend a license. Specifically, MAC R.420.705(1) allows the MRA to "summarily suspend[] a marihuana license without notice or hearing upon a determination that the safety or health of patrons or employees is jeopardized by continuing the marihuana business's operation..." Similarly, the APA allows a license to be summarily suspended "[i]f the agency finds that the public health, safety or welfare requires emergency action..." MCL 24.292(2). In such circumstances, both the APA and the MRA's rules build in procedural safeguards, namely that a hearing before an administrative law judge be "promptly commenced and determined." *Id.*; *see also* MAC R.420.705. See, also, Mich Admin Code, R 420.705(1).
- 218. A marijuana business's license cannot be summarily restricted in the same manner that it can be summarily suspended. The policy rationale underpinning this is clear: summary suspensions should only be issued in the gravest of circumstances, where public health and safety are jeopardized by continuing operations of a licensee. If the public health and safety can be protected by merely restricting a licensee's activities, then health and safety are not truly such an egregious issue as to warrant suspension without even a modicum of due process.
- 219. Nothing in the MRA's own rules, the APA, or principles of due process allow the MRA to summarily restrict, as opposed to suspend, a license.
- 220. As explained above and alleged throughout this Verified Complaint, the MRA has summarily restricted Plaintiffs' licenses to conduct microbial analysis without notice of its

intended action and has specifically orchestrated its conduct to avoid oversight from an administrative law judge or this Court.

- 221. In short, by summarily restricting Plaintiffs' licenses instead of summarily suspending them, the MRA has contrived a mechanism that, it apparently believes, allows it to simply ignore the procedural requirements necessary to restrict a license without notice and opportunity for a hearing, while also circumventing the procedural safeguards required of summary suspensions.
- 222. The MRA's improper and wrongful conduct affects not only Plaintiffs, but also every other marijuana business licensee in the state. If the MRA can blatantly ignore its own rules, the APA, and well-established principles of due process relating to Plaintiffs, then it can do so with every other licensee as well.
- 223. Plaintiffs seek a declaratory judgment declaring that the MRA lacks authority to summarily restrict all or part of any marijuana business's license without following its administrative rules, the APA, or fundamental notions and principles of due process.

WHEREFORE, Plaintiffs respectfully request this Court enter a judgment in their favor and against the MRA declaring that the MRA lacks authority to summarily restrict a marijuana business's license and instead must follow the procedures set forth in its own rules, the APA, and fundamental principles of due process; issuing a permanent injunction enjoining the MRA from summarily restricting any license and deviating from the appropriate process or ignoring fundamental procedural safeguards; granting Plaintiffs their costs and attorney fees for having to bring this action; and awarding Plaintiffs any other relief this Court deems just and proper.

#### **COUNT V**

### VIOLATION OF PLAINTIFFS' PROCEDURAL DUE PROCESS RIGHTS UNDER ARTICLE 1, SECTION 17 OF THE MICHIGAN CONSTITUTION AND THE FOURTEENTH AMENDMENT OF THE UNITED STATES CONSTITUTION (ALL DEFENDANTS)

- 224. Plaintiffs reasserts and realleges the preceding paragraphs as if fully set forth herein.
- 225. Article I, Section 17 of the 1963 Michigan Constitution provides that no person shall be "deprived of life, liberty or property, without due process of law." 1963 Const, Art I, § 17.
- 226. The Fourteenth Amendment to the United States Constitution similarly provides in Section 1 that no state shall "deprive any person of life, liberty, or property, without due process of law." US Const, Amend XIV, § 1.
- 227. The due process guarantees of the Michigan Constitution are coextensive with its federal counterpart. *Mays v Snyder*, 323 Mich App 1, 58; 916 NW2d 227 (2018).
- 228. The fundamental tenets of the procedural protections afforded by the Michigan and United States Constitutions are notice and an opportunity to be heard before an impartial decision maker at a meaningful time and a meaningful manner. *Reed v Reed*, 265 Mich App 131, 159; 693 NW2d 825 (2005).
- 229. Plaintiffs have a vested property interest in their licenses as a marijuana safety compliance facility to test cannabis products and a liberty interest to engage in their chosen profession and line of work.
- 230. In addition to violating the APA, the MRA violated Plaintiffs' procedural due process rights.

- 231. As explained above and alleged throughout this Verified Complaint, Plaintiffs were denied every procedural protection afforded by the due process clauses of the Michigan and United States Constitutions.
- 232. Plaintiffs were not provided with notice of the MRA's intent to restrict or, as explained above, effectively suspend their licenses relating to microbial analysis.
- 233. Plaintiffs were not provided notice or the opportunity to participate in the MRA's arbitrary and improper promulgation of the Microbial Rule or Log Rule. If Plaintiffs had notice of the proposed Microbial Rule or Log Rule they would have participated and provided commentary in the manner provided by law, including the APA.
- 234. Plaintiffs were not afforded an opportunity to be heard to challenge the Microbial Rule or Log Rule.
- 235. Plaintiffs were not afforded an opportunity to be heard to challenge the appropriateness of the MRA's recall of their tested marijuana products. This is especially true for Plaintiff Bay City. As explained above, Plaintiff Bay City's tested cannabis products were *not* tested by other facilities, which means its products were recalled based solely on the Log Rule, an action the MRA, itself, acknowledged was insufficient for the recall.
- 236. The most egregious violation of Plaintiffs' due process rights, however, was that they were denied the opportunity to contest the MRA's actions in front of a neutral decision maker. So far, the MRA has played the role of prosecutor, judge, jury, and, if its actions are left in place, the executioner of Plaintiffs' business. As explained above and alleged throughout this Verified Complaint, the MRA has specifically orchestrated its actions to avoid oversight from an administrative law judge or this Court. The MRA was far from neutral in making its decisions regarding Plaintiffs, as is evidenced by the exhibits and verified allegations of this Complaint.

- 237. As direct and proximate result of the MRA's wrongful conduct, Plaintiffs were deprived of vested property and liberty interests without due process of law. Plaintiffs will continue to suffer substantial, irreparable harm if the MRA is not enjoined from enforcing the Microbial Rule or Log Rule or continuing its current orchestrated campaign against Plaintiffs.
  - 238. Ms. Patterson, Ms. Kluytman, and Mr. Mitchell are state actors.
  - 239. Ms. Patterson, Ms. Kluytman, and Mr. Mitchell all acted under color of state law.
- 240. Ms. Patterson, Ms. Kluytman, and Mr. Mitchell's actions alleged throughout this Verified Complaint violated the due process clause of the Fourteenth Amendment of the United States Constitution.
- 241. Ms. Patterson, Ms. Kluytman, and Mr. Mitchell subjected or caused Plaintiffs to be deprived of their rights guaranteed under the due process clause of the Fourteenth Amendment to the United States Constitution.
- 242. As a direct and proximate result of Ms. Patterson, Ms. Kluytman, and Mr. Mitchell's wrongful conduct, Plaintiffs have suffered actual and nominal damages.
- 243. Plaintiffs are authorized by 42 USC 1983 to bring this suit against Ms. Patterson, Ms. Kluytman, and Mr. Mitchell for their wrongful conduct in violation of federal law.
- 244. Plaintiffs are authorized to recover their damages, along with its costs and attorney fees, under 42 USC 1988.
- 245. Andrew Brisbo is sued in his individual capacity under *Ex Parte Young*, 209 US 123 (1908) to enjoin him from carrying out the recall based on the numerous violations of Plaintiffs' procedural due process rights secured by the United States Constitution.

WHEREFORE, Plaintiffs respectfully request this Court enter a judgment in their favor and against Ms. Patterson, Ms. Kluytman, and Mr. Mitchell for damages; enjoining the MRA

and Mr. Brisbo from carrying out the recall and enjoining Ms. Patterson, Ms. Kluytman, and Mr. Mitchell from further depriving Plaintiffs of their due process rights under the Michigan and United States Constitutions; granting Plaintiffs their costs and attorney fees for having to bring this action; and awarding Plaintiffs any other relief this Court deems just and proper.

#### **COUNT VI**

### VIOLATION OF PLAINTIFFS' SUBSTANTIVE DUE PROCESS RIGHTS UNDER ARTICLE 1, SECTION 17 OF THE MICHIGAN CONSTITUTION AND THE FOURTEENTH AMENDMENT OF THE UNITED STATES CONSTITUTION AS TO ALL DEFENDANTS

- 246. Plaintiffs reassert and reallege the preceding paragraphs as if fully set forth herein.
- 247. Article I, Section 17 of the 1963 Michigan Constitution provides that no person shall be "deprived of life, liberty or property, without due process of law." 1963 Const, Art I, § 17.
- 248. The Fourteenth Amendment to the United States Constitution similarly provides in Section 1 that no state shall "deprive any person of life, liberty, or property, without due process of law." US Const, Amend XIV, § 1.
- 249. The due process guarantees of the Michigan Constitution are coextensive with its federal counterpart. *Mays*, 323 Mich App at 58.
- 250. The due process clause of the Michigan and United States Constitutions protect a substantive right to due process, in addition to the above described procedural rights. The substantive component "protects against the arbitrary exercise of governmental power." *Bonner v City of Brighton*, 495 Mich 209, 224; 848 NW2d 380 (2014).

- 251. Plaintiffs have a vested property interest in their licenses as a marijuana safety compliance facility to test cannabis products and a liberty interest to engage in their chosen profession and line of work.
- 252. In addition to violating Plaintiffs' procedural due process rights, the MRA has violated their substantive due process rights.
- 253. The MRA has wrongfully targeted Plaintiffs to further its political objective of equalizing market share of the cannabis testing industry between Plaintiffs and the competitors throughout the state. Upon information and belief, this was done to either artificially dilute and cap Plaintiffs' market share within the cannabis testing industry or effectively destroy Plaintiffs' business operations thereby compelling Plaintiffs' customers to seek to do business with its competitors.
- 254. As explained and alleged above, the MRA has wrongfully targeted Plaintiffs in retaliation for using the process outlined in the MMFLA and its administrative rules for filing an administrative complaint against the MRA for unnecessarily disrupting their business operations and their operations as a marijuana safety compliance facility.
- 255. As explained and alleged above, the MRA has wrongfully treated Viridis as a collective entity instead of different business entities. Viridis Lansing is a separate and distinct entity with an entirely different ownership structure than Viridis Bay City. Contrary to the MRA's position, none of the samples of the October Audit were associated with Plaintiff Bay City. Each and every one of them was associated with Plaintiffs Lansing. This means that the MRA instituted a recall of cannabis products tested by Plaintiffs Bay City without a failed audit test and based on the absence of incubator logs alone, which, the MRA, itself, has acknowledged, is insufficient to sustain a recall of this magnitude.

- 256. As explained and alleged above, the MRA has wrongfully and arbitrarily included all cannabis products tested by Plaintiffs as part of its recall, including around 10% of those cannabis products that were *not* analyzed for aspergillus or other microbials by Plaintiffs. This means that the MRA has recalled every cannabis product tested by Plaintiffs during a three-month period even if it had no relation to the alleged deficiencies that formed the basis of the recall.
  - 257. The MRA's improper and wrongful conduct is arbitrary in the strictest sense.
- 258. The MRA's improper, arbitrary, and wrongful conduct shocks the conscience and has no place in ordered liberty.
- 259. As direct and proximate result of the MRA's wrongful conduct, Plaintiffs were deprived of vested property and liberty interests without due process of law. Plaintiffs will continue to suffer substantial, irreparable harm if the MRA is not enjoined from enforcing the Microbial Rule or Log Rule or continuing its current orchestrated campaign against Plaintiffs.
  - 260. Ms. Patterson, Ms. Kluytman, and Mr. Mitchell are state actors.
  - 261. Ms. Patterson, Ms. Kluytman, and Mr. Mitchell all acted under color of state law.
- 262. Ms. Patterson, Ms. Kluytman, and Mr. Mitchell's actions alleged throughout this Verified Complaint violated the due process clause of the Fourteenth Amendment of the United States Constitution.
- 263. Ms. Patterson, Ms. Kluytman, and Mr. Mitchell subjected or caused Plaintiffs to be deprived of their rights guaranteed under the due process clause of the Fourteenth Amendment to the United States Constitution.
- 264. As a direct and proximate result of Ms. Patterson, Ms. Kluytman, and Mr. Mitchell's wrongful conduct, Plaintiffs have suffered actual and nominal damages.

- 265. Plaintiffs are authorized by 42 USC 1983 to bring this suit against Ms. Patterson, Ms. Kluytman, and Mr. Mitchell for their wrongful conduct in violation of federal law.
- 266. Plaintiffs are authorized to recover their damages, along with their costs and attorney fees, under 42 USC 1988.
- 267. Andrew Brisbo is sued in his individual capacity under *Ex Parte Young*, 209 US 123 (1908) to enjoin him from carrying out the recall based on the numerous violations of Plaintiffs' substantive due process rights secured by the United States Constitution.

WHEREFORE, Plaintiffs respectfully request this Court enter a judgment in their favor and against Ms. Patterson, Ms. Kluytman, and Mr. Mitchell for damages; enjoining the MRA and Mr. Brisbo from carrying out the recall and enjoining Ms. Patterson, Ms. Kluytman, and Mr. Mitchell from further depriving Plaintiffs of their due process rights under the Michigan and United States Constitutions; granting Plaintiffs their costs and attorney fees for having to bring this action; and awarding Plaintiffs any other relief this Court deems just and proper.

#### **COUNT VII**

### VIOLATION OF PLAINTIFFS' EQUAL PROTECTION RIGHTS UNDER ARTICLE 1, SECTION 2 OF THE MICHIGAN CONSTITUTION AND THE FOURTEENTH AMENDMENT OF THE UNITED STATES CONSTITUTION (AS TO ALL DEFENDANTS)

- 268. Plaintiffs reassert and reallege the preceding paragraphs as if fully set forth herein.
- 269. Article 1, Section 2 of the 1963 Michigan Constitution provides that "no person shall be denied the equal protection of the laws."
- 270. The Fourteenth Amendment to the United States Constitution similarly provides in Section 1 that no state shall "deny to any person within its jurisdiction the equal protection of the laws." US Const, Amend XIV, § 1.

- 271. The equal protection guarantees of the Michigan Constitution are coextensive with its federal counterpart. *Crego v Coleman*, 463 Mich 248, 258; 615 NW2d 218 (2000) ("This Court has found Michigan's equal protection provisions coextensive with the Equal Protection Clause of the federal constitution.").
- 272. Plaintiffs have been treated disparately from other similarly situated marijuana safety compliance facilities.
  - 273. The MRA commenced a recall of all of Plaintiffs' tested cannabis products.
- 274. The MRA's purported reason for doing so was that it identified "inaccurate and/or unreliable results" related to Plaintiffs' testing. (Exhibit J).
- 275. As explained above and alleged throughout this Verified Complaint, Plaintiffs did not deviate from their standard practice for microbial analysis and has accurately reported results relating to the cannabis products they tested.
- 276. Upon information and belief, no consumer has experienced any adverse effects associated with Plaintiffs' tested cannabis products.
- 277. Even if the MRA's position were to be taken at face value, its actions are excessive, overbroad, and not in line with its prior practice. In a prior case relating to Iron Laboratories, LLC, a marijuana safety compliance facility, the MRA discovered that Iron Laboratories was *actually* falsifying records in a way that directly affected safety. The MRA and Iron Laboratories entered a consent order that, among other things, temporarily suspended Iron Laboratories' license and fined it \$100,000. Despite Iron Laboratories *actually* falsifying its records, the MRA *did not* immediately issue a recall of its tested cannabis products but instead waited two weeks later on August 30, 2019. Likewise, the MRA did not issue a recall related to

the Spott where the MRA found that it had incuarrately reported potency results from May 3, 2019, to July 11, 2019. No recall as issued as a result.

- 278. Most glaringly, the MRA has not recalled cannabis products from *any* marijuana safety compliance facility that failed to keep logs for its incubators to perform microbial analysis.
- 279. Plaintiffs have not falsified their records and have accurately reported their test findings, but the MRA commenced the recall of all of its tested cannabis products.
- 280. There is no rational basis for the MRA's disparate treatment of Plaintiffs and from Iron Laboratories.
  - 281. The MRA's conduct was intentional, arbitrary, and capricious.
- 282. As a direct and proximate result of the MRA's wrongful conduct, Plaintiffs' equal protection rights were violated. Plaintiffs will continue to suffer substantial, irreparable harm if the MRA is not enjoined from continuing its current orchestrated campaign against Plaintiffs or carrying out the recall.
  - 283. Ms. Patterson, Ms. Kluytman, and Mr. Mitchell are state actors.
  - 284. Ms. Patterson, Ms. Kluytman, and Mr. Mitchell all acted under color of state law.
- 285. Ms. Patterson, Ms. Kluytman, and Mr. Mitchell's actions alleged throughout this Verified Complaint violated the equal protection clause of the Fourteenth Amendment of the United States Constitution.
- 286. Ms. Patterson, Ms. Kluytman, and Mr. Mitchell subjected or caused Plaintiffs to be deprived of their rights guaranteed under the equal protection clause of the Fourteenth Amendment to the United States Constitution.

- 287. As a direct and proximate result of Ms. Patterson, Ms. Kluytman, and Mr. Mitchell's wrongful conduct, Plaintiffs have suffered actual and nominal damages.
- 288. Plaintiffs are authorized by 42 USC 1983 to bring this suit against Ms. Patterson, Ms. Kluytman, and Mr. Mitchell for their wrongful conduct in violation of federal law.
- 289. Plaintiffs are authorized to recover their damages, along with their costs and attorney fees, under 42 USC 1988.
- 290. Andrew Brisbo is sued in his individual capacity under *Ex Parte Young*, 209 US 123 (1908) to enjoin him from carrying out the recall based on the numerous violations of Plaintiffs' equal protection rights secured by the United States Constitution.

WHEREFORE, Plaintiffs respectfully request this Court enter a judgment in their favor and against Ms. Patterson, Ms. Kluytman, and Mr. Mitchell for damages; enjoining the MRA and Mr. Brisbo from carrying out the recall and enjoining Ms. Patterson, Ms. Kluytman, and Mr. Mitchell from further depriving Plaintiffs of their due process rights under the Michigan and United States Constitutions; granting Plaintiffs their costs and attorney fees for having to bring this action; and awarding Plaintiffs any other relief this Court deems just and proper.

# COUNT VIII TORTIOUS INTERFERENCE WITH BUSINESS RELATIONSHIPS, EXPECTANCIES, AND CONTRACTS (AS TO MS. PATTERSON, MS. KLUYTMAN, AND MR. MITCHELL)

- 291. Plaintiffs reassert and reallege the preceding paragraphs as if fully set forth herein.
- 292. Plaintiffs had business relationships, expectancies, and contracts with growers, producers, and retail facilities who produced and sold cannabis products tested by Plaintiffs.

- 293. Ms. Patterson, Ms. Kluytman, and Mr. Mitchell knew of Plaintiffs' business relationships, expectancies, and contracts with the above identified entities and persons. Indeed, the MRA has acknowledged that Viridis Lansing and Viridis Bay City are the first and third largest aspergillus testing facilities in the state, respectively.
- 294. As explained above and alleged in this Verified Complaint, Ms. Patterson, Ms. Kluytman, and Mr. Mitchell intentionally and improperly undertook efforts to interfere with Plaintiffs' business relationships, expectations, and contracts by improperly instituting the Microbial Rule, the Log Rule, and the recall.
- 295. Ms. Patterson, Ms. Kluytman, and Mr. Mitchell's actions caused or induced disruption, termination, and potential breach of Plaintiffs' business relationships, expectancies, and contracts.
- 296. Ms. Patterson, Ms. Kluytman, and Mr. Mitchell's actions were wrongful, intentional, and improper.
- 297. As a direct and proximate result of Ms. Patterson, Ms. Kluytman, and Mr. Mitchell's wrongful conduct, Plaintiffs have suffered significant damages.

WHEREFORE, Plaintiffs respectfully request this Court enter a judgment in their favor and against Ms. Patterson, Ms. Kluytman, and Mr. Mitchell for damages in an amount exceeding \$25,000, including Plaintiffs' costs and attorney fees for having to bring this action; and award Plaintiffs any other relief this Court deems just and proper.

# COUNT X ABUSE OF PROCESS (AS TO MS. PATTERSON, MS. KLUYTMAN, AND MR. MITCHELL)

298. Plaintiffs reassert and reallege the preceding paragraphs as if fully set forth herein.

- 299. Ms. Patterson, Ms. Kluytman, and Mr. Mitchell had ulterior motives and purposes for instituting the Microbial Rule, Log Rule, and commencing the recall. Their ulterior motives and purposes are described above.
- 300. Ms. Patterson, Ms. Kluytman, and Mr. Mitchell used process in a manner that is improper in the regular prosecution of proceedings.
- 301. As explained and alleged above, the MRA has wrongfully targeted Plaintiffs to further its political objective of equalizing market share of the cannabis testing industry between Plaintiffs and the competitors. Upon information and belief, this was done to either artificially dilute and cap Plaintiffs' market share within the cannabis testing industry or effectively destroy Plaintiffs' business operations thereby compelling Plaintiffs' customers to seek to do business with its competitors.
- 302. As explained and alleged above, the MRA has wrongfully targeted Plaintiffs in retaliation for using the process outlined in the MMFLA and its administrative rules for filing an administrative complaint against the MRA for unnecessarily disrupting their business operations and their operations as a marijuana safety compliance facility.
- 303. As explained and alleged above, the MRA has wrongfully treated Plaintiffs as a collective entity instead of different business entities. Viridis Lansing is a separate and distinct entity with an entirely different ownership structure than Viridis Bay City. Contrary to the MRA's position, none of the samples of the October Audit were associated with Viridis Bay City. Each and every one of them were associated with Viridis Lansing. This means that the MRA instituted a recall of cannabis products tested by Viridis Bay City without a failed audit test and based on the absence of incubator logs alone, which, the MRA, itself, has acknowledged, is insufficient to sustain a recall of this magnitude.

- 304. As explained and alleged above, the MRA has wrongfully and arbitrarily included all cannabis products tested by Viridis as part of its recall, including around 10% of those cannabis products that were *not* analyzed for aspergillus or other microbials. This means that the MRA has recalled every cannabis products even if it had no relation to the alleged deficiencies that formed the basis of the recall.
- 305. As a direct and proximate result of Ms. Patterson, Ms. Kluytman, and Mr. Mitchell's wrongful conduct, Plaintiffs have suffered significant damages.

WHEREFORE, Plaintiffs respectfully request this Court enter a judgment in their favor and against Ms. Patterson, Ms. Kluytman, and Mr. Mitchell for damages in an amount exceeding \$25,000, including Plaintiffs' costs and attorney fees for having to bring this action; and award Plaintiffs any other relief this Court deems just and proper.

### COUNT XI CIVIL CONSPIRACY

- 306. Plaintiffs reassert and reallege the preceding paragraphs as if fully set forth herein.
- 307. Ms. Patterson, Ms. Kluytman, and Mr. Mitchell took concerted actions with each other.
  - 308. Ms. Patterson, Ms. Kluytman, and Mr. Mitchell are two or more persons.
- 309. Ms. Patterson, Ms. Kluytman, and Mr. Mitchell engaged in several underlying torts with each other, including violating Plaintiffs' procedural and substantive due process and equal protection rights under the Michigan and United States Constitutions, abusing process, and tortuously interfering with Plaintiffs' business relationships, expectancies, and contracts.

310. As a direct and proximate result of Ms. Patterson, Ms. Kluytman, and Mr. Mitchell's wrongful conduct, Plaintiffs have suffered significant damages.

WHEREFORE, Plaintiffs respectfully request this Court enter a judgment in their favor and against Ms. Patterson, Ms. Kluytman, and Mr. Mitchell for damages in an amount exceeding \$25,000, including Plaintiffs' costs and attorney fees for having to bring this action; and award Plaintiffs any other relief this Court deems just and proper.

Respectfully submitted,

FOSTER, SWIFT, COLLINS & SMITH, P.C. Counsel for Plaintiffs

Dated: November 22, 2021 By:

/s/ David R. Russell
David R. Russell (P68568)
Brandon M. H. Schumacher (P82930)

HONIGMAN, LLP Co-Counsel for Plaintiffs

By: /s/ Kevin M. Blair w/permission
Kevin M. Blair (P76927)

### VERIFICATION

The undersigned signs and verifies this Complaint pursuant to MCL 600.6431(1), and declares under penalty of perjury that this Complaint has been examined by me and that its contents are true to the best of my information, knowledge, and belief.

Viridia Laboratories, LLC and Viridis North, LLC

Greg Michaud

Chief Executive Officer Viridis Laboratories, LLC

Subscribed to and sworn to me this 22nd day of November, 2021.

Marissa A Loughrige
Notary Public of Michigan
Cathoun County
Expires 10/31/2027/1000/
Acting in the County of

Marissa A. Loughrige Notary Public Ingham County, Michigan

Acting in Calhoun County, V

My Commission Expires: 10/31/202

### **EXHIBIT A**



October 1, 2021

Gregoire Michaud Viridis Laboratories Lansing, MI

Dear Mr. Michaud,

We have received the assessor report and assessor deficiency report for the first year surveillance assessment of your organization that occurred on June 30, 2021.

Your corrective action response has been reviewed by A2LA staff and appears to be complete. Based upon the contents of the surveillance report and your corrective action response, your organization's management system, SOPs and technical capabilities appear to be in compliance with the accreditation requirements spelled out in ISO/IEC 17025:2017

This completes the information necessary to reaffirm your accreditation. Your accreditation is reaffirmed until August 31, 2022.

At this time, we would like to invite your attention to the next part of the accreditation cycle. Six months prior to your anniversary date, we will initiate the renewal accreditation process, which will require completing and uploading the required renewal forms, supporting documentation, and submitting payment. This step will initiate the complete renewal process, which includes an onsite assessment, submission of corrective action responses (if necessary), and the review and approval of the assessment records.

To learn more about the renewal of accreditation process or accreditation cycle, please contact your Accreditation Officer.

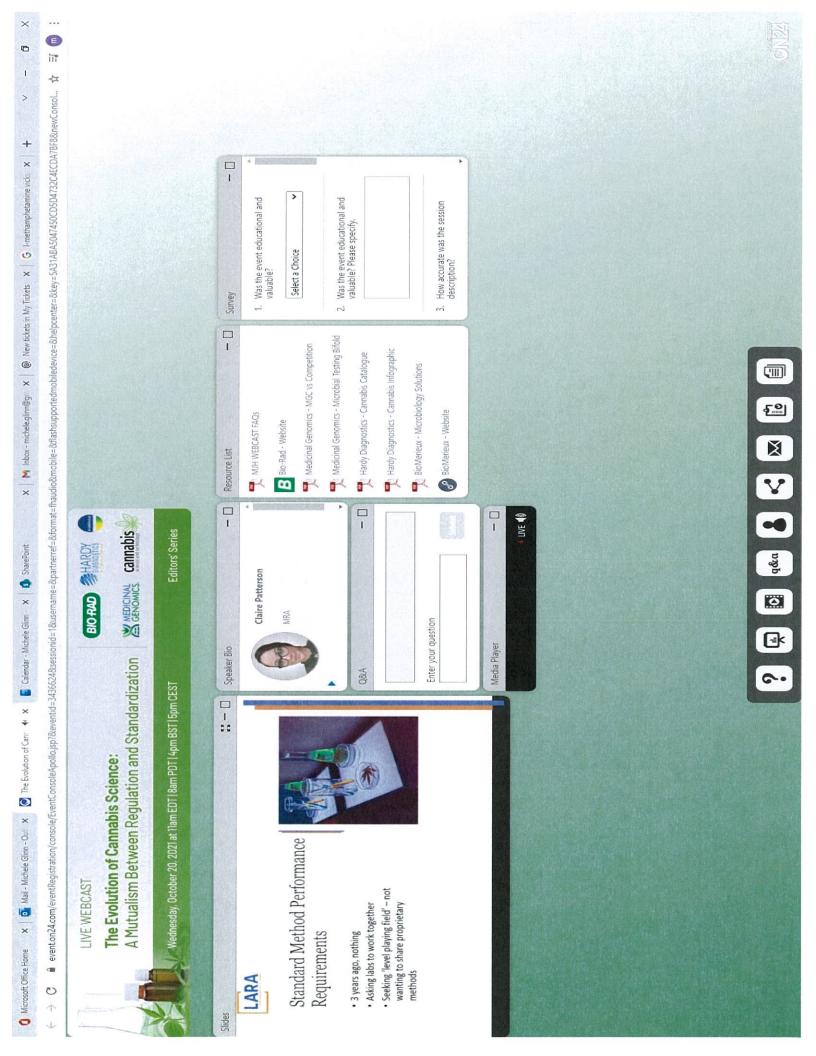
We would like to take this opportunity to say that we appreciate your participation in the leading national accreditation program and we welcome your feedback at any time. As always, if you have any questions regarding your accreditation, feel free to contact us.

Sincerely,

Renee Delauter

Accreditation Officer, A2LA

### **EXHIBIT B**



### **EXHIBIT C**

## STATE OF MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS MARIJUANA REGULATORY AGENCY

VIRIDIS LABORATORIES, LLC, a Michigan limited liability company, and VIRIDIS NORTH, LLC, a Michigan limited liability company, Plaintiffs,	CMS No.
v.	
MICHIGAN MARIJUANA REGULATORY AGENCY, a Michigan state agency,	
Defendant.	

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### COMPLAINT FOR UNNECESSARY DISRUPTION OF FACILITY OPERATIONS

Plaintiffs Viridis Laboratories, LLC and Viridis North, LLC (collectively "Viridis"), by and through their attorneys, Foster, Swift, Collins & Smith, P.C. and Honigman, LLP, for their Complaint against Defendant Michigan Marijuana Regulatory Agency, state as follows:

#### PARTIES, JURISDICTION, VENUE

- 1. Plaintiff Viridis Laboratories, LLC ("Viridis Lansing") is a Michigan limited liability company formed under the laws of the State of Michigan and conducts business through a laboratory established in the City of Lansing, Ingham County, Michigan.
- 2. Plaintiff Viridis North, LLC ("Viridis Bay City") is a Michigan limited liability company formed under the laws of the State of Michigan and conducts business through a laboratory established in Bay City, Bay County, Michigan.
- 3. Defendant Michigan Marijuana Regulatory Agency ("MRA") is a type I Michigan state agency established within LARA and is also charged with implementing, enforcing, licensing, and overseeing compliance with Michigan laws relating to marijuana.
- 4. The MRA (identified as the "Board" in the applicable statute and administrative rules) has jurisdiction under the Michigan Medical Marihuana Facilities Licensing Act (MMFLA) (MCL 333.27101, et seq.) for "[r]eviewing and ruling on any complaint by a licensee regarding any investigative procedures of this state that are believed to be unnecessarily disruptive of marijuana facility operations." MCL 333.27302(i).
- 5. Under the MRA's administrative rules "a licensee may file a written complaint with the agency regarding any investigative procedures of this state he or she believes to be unnecessarily disruptive of the marijuana facility operations." MAC R. 420.706(1).
- 6. The MRA may either (a) "delegate to a subcommittee of the agency to hear, review, or rule on" this Complaint or (b) "delegate authority to an administrative law judge" to have the merits adjudicated as a contested case. MAC R. 420.706(2) and (3).
- 7. Consistent with the rules of notice pleading in Michigan, the purpose of this Complaint is to put Defendant on notice of claims consistent with the allegations contained

herein and is not meant to be an exhaustive identification of each and every actionable act or omission committed by Defendants.

8. It is unclear at this point whether the MRA has any established policies and procedures for addressing these types of complaints, or any guidance or rules on the parameters of that process. There are certain aspects of this Complaint and certain details that Viridis is deliberately not addressing in detail because they are confidential and any public dissemination of such information would cause even further unnecessary disruption of its business operations and operations as a marijuana safety compliance facility. Viridis respectfully submits that the existence of this Complaint should remain confidential (at least pending a determination on the merits), and that Viridis should have an opportunity to submit materials and/or witness testimony under seal, as appropriate.

#### **GENERAL ALLEGATIONS**

- 9. Viridis is a marijuana safety compliance facility licensed by the MRA under the MMFLA and the Michigan Regulation and Taxation of Marihuana Act ("MRTMA") (MCL 333.27951, et seq.) to sample and test adult-use and medical cannabis products.
- 10. MRA regulates marijuana laboratories like Viridis through the MMFLA and MRTMA.
- 11. Viridis was founded by former Michigan State Police laboratory scientists with greater than 75 years combined experience working within a strictly regulated and nationally accredited forensic science industry, which included high volumes of marijuana testing.
- 12. Viridis Lansing received its license from the MRA to test medical marijuana on June 5, 2019, and its adult-use license on December 7, 2020.
- 13. Viridis Bay City received its license from the MRA to test medical marijuana on April 6, 2020, and its adult-use license on June 10, 2020.

- 14. The MRA requires marijuana safety compliance facilities to be accredited.
- 15. Viridis has accreditation ISO 17025:2017 by A2LA.
- 16. Viridis Lansing received accreditation on July 23, 2020.
- 17. Viridis Bay City received accreditation on February 4, 2021.
- 18. Licensed marijuana safety compliance facilities like Viridis are required to not only follow the requirements of the MMFLA and MRTMA, but also the rules promulgated by the MRA.
- 19. Under the MRA's Sampling and Testing Rules (the "Testing Rules"), a laboratory, which is defined to include marijuana safety compliance facilities like Viridis, must perform various tests on batches of marijuana products, including potency analysis. MAC R 420.301(m) and 305(3)(a).
- 20. The Testing Rules require that Viridis "use analytical testing methodologies for the required safety tests in subrule (3) of this rule that are validated by an independent third party and may be monitored on an ongoing basis by the agency or a third party. In the absence of reference to compendia or published methods, Appendix K of Official Methods of Analysis authored by the Association of Official Analytical Chemists must be published in full. The agency shall approve the validated methodology used by the laboratory and confirm that it produces scientifically accurate results for each safety test it conducts." MAC R. 402.305(2).
- 21. Part of the required testing, set forth in the Testing Rules, includes: "[p]otency analysis performed just as the marijuana product is without any corrective factor taken for moisture content that includes concentrations of the following: Tetrahydrocannabinol (THC)." MAC R. 402.305(3)(a).
- 22. The purpose of potency analysis is to test, identify, and measure the levels of certain compounds within marijuana products for health and safety concerns, especially the

concentrations of the psychoactive constituent tetrahydrocannabinol (THC) that gives marijuana its well-known effects.

- 23. The results of all potency tests completed by testing laboratories must be reported to the MRA's record keeping and tracking system-METRC. The MRA's record keeping and tracking system allows the MRA to review potency testing data at its discretion.
- 24. Viridis' methodology for completing marijuana product potency analysis combines well-known and widely available laboratory equipment with Viridis' in-house developed, innovative, and market competitive method of extraction, which has been developed by extensive in-house research and development as part of its validation.
- 25. Viridis' research and development is led by Michele Glinn, Ph.D, F-ABFT, the former program coordinator for the Michigan State Police crime labs.
- 26. Dr. Glinn is a well-respected toxicologist around the country and testifies as an expert witness for prosecutors in 40 to 50 cases a year.
- 27. Viridis uses A2LA ISO 17025:2017 accredited methods. The A2LA is the leading accrediting body in the nation for cannabis testing laboratories.
- 28. The A2LA performed a full review of the validation and Standard Operating Procedures (SOP) of Viridis' testing method prior to its accreditation.
- 29. In January 2020, Viridis' first potency method via UHPLC-DAD was validated and approved.
- 30. Viridis continued to improve its UHPLC-DAD potency method by optimizing only the sample collection portion of the method after it was validated. An updated SOP was sent to the MRA on November 24, 2020 (the "November SOP") for continued monitoring. See Exhibit A.

- 31. The November SOP allows Viridis to more accurately report the true, maximum total THC potency in marijuana plant material as compared to Viridis' prior SOP. The November SOP results in enhanced accuracy in THC potency testing that protects consumers from being misinformed about the potency of their selected products.
- 32. It is not unusual for Viridis' potency method, outlined in the November SOP, to show that a sample's total THC potency can reach levels exceeding 30%. Viridis' method reaches those results because of the increased accuracy from its innovative, developed, and researched methods as compared to more antiquated methods.
- 33. Viridis' average total THC potency results are around 21%, which is aligned with existing peer reviewed studies.
- 34. Around December 3, 2020, Viridis, the MRA, and representative members of the Michigan Coalition of Independent Cannabis Testing Laboratories ("MICIL") attended a conference call where high potency results were discussed, along with the MRA's continual requests for audits for any laboratory that posted potency testing results exceeding 29% (the "December 3 phone call").
- 35. During the December 3 phone call, some competing laboratories voiced concerns to the MRA about "certain labs" reporting potency analyses exceeding 30% THC levels and the need to "audit" such results.
- 36. Since the December 3 phone call, the MRA has audited Viridis numerous times for potency test results.
- 37. Viridis has voiced its concerns to the MRA, especially relating to the fact that it may be the only lab being continually audited for high potency results.
- 38. The MRA represented that its requests for Viridis to audit its potency test results has nothing to do with complaints of other laboratories, and that its standard operating procedure

"is and always has been to request re-analysis of potency samples exceeding ~27%." The MRA then recommended that if Viridis has concerns about "the direction of conversations made by members of the association," that Viridis contact them directly.

- 39. Since the December 3 phone call, the MRA has continued to request that Viridis audit its potency test results any time they exceed 27% THC levels. To date, the MRA has requested Viridis retest greater than 500 marijuana samples for potency results. This has resulted in lost revenue exceeding \$30,000, and an average of one day of lost productively on a weekly basis, further and continually decreasing Viridis' revenues.
- 40. On December 22, 2020, Viridis' Lansing and Bay City laboratories were subject to virtual inspections by the MRA. During the inspections, the MRA observed Viridis testing under the November SOP in real time. The MRA's inspection reports for the laboratories indicated that Viridis had passed the inspections. See Exhibit B.
- 41. In December 2020, Viridis sent the MRA all monthly and quarterly potency results for the November SOP showing remarkable consistency and reproducibility. In addition to the potency results, Viridis also submitted to the MRA peer reviewed literature on potency studies across the nation that closely aligned with Viridis' data. See Exhibit C.
- 42. On February 5, 2021, Viridis Lansing was subject to an MRA review for a new microbial analytical method. The MRA's method review reports included an updated approval for the Viridis Method's potency analysis. See Exhibit D.
- 43. On March 19, 2021, Viridis Bay City received a method approval form from the MRA without any notation set forth in the potency section. See Exhibit E.
- 44. Viridis has since learned that following the MRA's inspection of its Lansing and Bay City facilities that its inspectors completed reports up to three months *after* the inspection had concluded. The MRA did not take immediate action to prevent Viridis from using the

November SOP, or inform Viridis that it was taking the position that the November SOP was not approved.

- 45. On June 4, 2021, in preparation for annual accreditation assessments, the MRA sent Viridis Lansing copies of Viridis' December 2020 passing inspection reports.
- 46. On June 7, 2021, the MRA conducted a semi-annual inspection of Viridis Lansing, and on June 9, 2021, agents Noah Rosenzwig and Claire Patterson performed an on-site inspection that included a potency demonstration consistent with the November SOP. The MRA provided Viridis Lansing with a passing report and indicated that "[n]o deficiencies were found." See Exhibit F.
- 47. On June 8, 2021, the MRA also conducted a semi-annual inspection of Viridis Bay City via video that included a potency demonstration consistent with the November SOP. The MRA provided Viridis Bay City with a passing report, noting that "[n]o deficiencies were found." See Exhibit G.
- 48. On July 9, 2021, Viridis Lansing received another method approval report without any updates to the potency section. See Exhibit H.
- 49. On July 15, 2020, Viridis Bay City also received its second post-November-SOP method approval report that did not include any new notations to the potency section. See Exhibit I.
- 50. On August 2, 2021, MRA scientists, P. Fields and A. Chirio, performed a surprise visit to Viridis Lansing to observe its potency analysis method. Viridis Lansing performed the potency test as requested, again in conformance with the November SOP.
- 51. On August 10, 2021, Viridis Lansing received a third post-November-SOP method approval report, which again had no notations in the potency section. See Exhibit J.

- 52. Viridis Bay City received the same on August 25, 2021, receiving its third post-November-SOP method validation summary that also had no new notations regarding potency.

  See Exhibit K.
- 53. Since December 22, 2020, the MRA has observed, witnessed, and monitored Viridis perform the November SOP potency analysis four times (twice via video and twice in person).
- 54. The MRA has known since late 2020 that Viridis was using the November SOP, and the MRA has been monitoring Viridis perform the November SOP for almost one full year.
- 55. On 13 separate occasions since the November SOP was implemented, the MRA has reviewed and approved Viridis' potency methodology.
- 56. Notwithstanding the fact that the November SOP has been validated and approved by the A2LA as required by MAC R. 420.305 ("Rule 305") and has been continuously monitored by the MRA, the MRA now contends that Viridis' latest approved potency SOP is the one that the MRA approved on July 8, 2020. See Exhibit L.
- 57. On August 25, 2021, the MRA filed three complaints against Viridis Lansing and three complaints against Viridis Bay City (collectively the "Complaints").
- 58. The Complaints will not be detailed here because of their recklessly inaccurate and salacious accusations that would only further the unnecessary disruption of Viridis' facility operations.
- 59. The Complaints will also not be detailed here because they contained confidential and proprietary information that is not subject to disclosure pursuant to MCL 333.27302(m)(i), 27401(3), and 27959(7).
- 60. The Complaints rely on the MRA's inaccurate allegations that it never received, monitored, and approved the November SOP.

- 61. It is impossibly arbitrary and capricious, and unnecessarily disruptive of Viridis' facility operations, for the MRA to disavow the November SOP after monitoring and approving it 13 times in less than one year.
  - 62. The MRA's actions are not based on scientific justifications or fact.
- 63. The MRA's actions have directly interfered with and disrupted Viridis' business operations and its operations as a marijuana safety compliance facility.
- 64. On September 7, 2021, in response to the Complaints, Viridis, through counsel, requested a compliance conference as provided by MAC R. 420.740(1) and a contested case hearing as provided by MCL 333.27407(4), 27947(1)(c), and MAC R. 420.704(2).
- 65. Viridis also requested a copy of the MRA's file related to the Complaints as contemplated by MCL 24.274(2).
- 66. On September 7, 2021, for the first time, Claire Patterson from the MRA sent an e-mail to Viridis seeking a verification of the SOP that Viridis is currently using. In Ms. Patterson's email, she stated "we have two dates on record for method updates, one in 2020 and one 2021. The one dated for 2021 was denied for use, so I want to make sure that the appropriate method is being used until the appropriate validations are provided to the agency for approval."
- 67. The MRA had observed the November SOP four times and approved it 13 times by the time Claire Patterson sent the September 7, 2021, e-mail.
- 68. On September 7, 2021, one of Viridis' members, Greg Michaud, responded asking for clarification as to the 2020 and 2021 SOP's that Ms. Patterson was referencing.
- 69. Around the same time, on September 7, 2021, the Marijuana Enforcement Tracking Reporting & Compliance (i.e., METRC) indicated to Viridis via email that the MRA had flagged several of its analyzed samples as needing re-tests because of high potency results.

Among other things, METRC personnel requested that Viridis indicate the SOP used to prepare the potency reports and the date of the last update to the method.

- 70. Viridis responded to METRC by indicating that the November SOP was used and that it received approval from the MRA in December 2020.
- 71. The MRA responded that the November SOP was not approved and that the latest approved SOP it has on record relates to a SOP submitted in July 2020.
- 72. Viridis' samples cannot be retested, and more important retested accurately, until the MRA gives METRC approval to accept re-tests based on the November SOP. Until METRC receives the MRA's approval, Viridis' customers' products cannot be released into the market and are effectively left indefinitely in queue.
- 73. The MRA's attempt to retroactively disapprove the November SOP through METRC has unnecessarily and unreasonably disrupted Viridis' business as it has effectively stopped it from doing business through the METRC system for samples showing high potency results.
- 74. On September 8, 2021, Ms. Patterson responded back to Greg Michaud attaching SOP's that did not include the November SOP.
- 75. As a result of the MRA's attempt to disavow its approval of the November SOP, counsel for Viridis immediately attempted to facilitate discussions with the MRA related to the November SOP and why Ms. Patterson was representing that the MRA did not have the November SOP.
- 76. On Monday, September 13, 2021, counsel for Viridis had a phone call with Jessica Fox from the MRA to discuss the Complaints. Viridis again voiced its concerns about the Complaints' inaccurate accusations, again requested an expedited compliance conference, and again requested a copy of the MRA's file.

- 77. Ms. Fox represented that the MRA would turn over its file and asked counsel to follow up with an e-mail again seeking the file.
- 78. On September 13, 2021, Viridis, through counsel, again asked for a copy of the file via an e-mail to the MRA.
- 79. On September 14, 2021, Viridis' counsel received notice that the compliance conference was scheduled for November 30, 2021.
- 80. On September 14, 2021, the MRA sent Viridis a Request for Video for Viridis Lansing and Viridis Bay City's previous 30 days of operation. The MRA gave Viridis two days in order to turn over hundreds of hours of requested video from a significant number of video cameras. The MRA later agreed to provide more manageable parameters for the request, but at an additional cost of \$5,000 to Viridis.
- 81. On September 23, 2021, counsel for Viridis had a follow-up phone call with Jessica Fox seeking to further clarify the issues about the November SOP.
- 82. On September 28, 2021, the MRA sent Viridis a Request for Information, seeking foreign matter work logs for Viridis Lansing and Viridis Bay City's previous six months of operations and any error logs for "the Tempo," specifically relating to error code "c19." The MRA gave Viridis Lansing a deadline of close of business October 1, 2021, a total of three days to comply.
- 83. Viridis Lansing responded to the MRA's Request for Information by indicating that a request of that magnitude would "negatively impact our daily operations for approximately 7-8 working days" in light of the fact that Viridis would have to go through greater than 1,800 document bundles manually to recover the requested documents.
- 84. On October, 1, 2021, without ever providing a copy of the MRA's file or any of Viridis' requested information, Jessica Fox sent an e-mail to Viridis' counsel that the file had

been turned over to the Attorney General's office and the MRA refused to have any further communication with Viridis' counsel.

- 85. There is no reason for the MRA to continue requesting Viridis reanalyze its potency results using the November SOP. This is supported by the MRA's own random proficiency testing.
- 86. A proficiency test is a quarterly inter-laboratory comparison between competing marijuana safety compliance facilities. The purpose of the test is to verify that the labs are able to reach similar results when testing sample marijuana provided by the MRA. The primary goal is to look for outliers who may be inflating potency values or whose method is creating bad data.
- 87. Although the MRA requires marijuana safety compliance facilities to undergo proficiency testing, it does not publish the results of its testing. However, during a group question and answer session during one of the MRA's workshops, Executive Director Andrew Brisbo indicated that the MRA did "not see anything" out of the ordinary from proficiency testing.
- 88. Viridis used the November SOP to complete one or all of the MRA's proficiency tests.
- 89. To date, Viridis has participated in three proficiency tests required by the MRA. The MRA has not raised any issues with its submitted potency proficiency results. This means that the November SOP is an appropriate method of potency analysis based on the MRA's own testing and data.
- 90. Viridis Lansing and Viridis Bay City have also successfully completed and passed external proficiency tests for potency the previous two years as required annually by the MRA and the A2LA for accreditation purposes. These external proficiency tests are provided through

Absolute Standards Inc., an approved, accredited third-party test provider recognized by the MRA.

- 91. The MRA's decision to retroactively disapprove the November SOP is not meant to protect the public. The MRA is, in essence, requiring Viridis to complete potency testing through antiquated and less-accurate methods of analysis. In other words, the true levels of THC in the marijuana products being tested *will not* be as accurate as if the November SOP was used.
- 92. The MRA mandates that all laboratories use "analytical testing methodologies . . . that are validated by an independent third party and may be monitored on an ongoing basis by the agency or a third party" to complete the testing required by the Testing Rules. MAC R. 420.305(2). Rule 305 further provides that the MRA "shall approve the validated methodology used by the laboratory and confirm that it produces scientifically accurate results for each safety test it conducts." *Id.* In the absence of reference to compendia or published methods, Rule 305 defaults to Appendix K of Official Methods of Analysis authored by the Association of Official Analytical Chemists. *Id.*
- 93. Neither Rule 305 nor any other administrative rule promulgated by the MRA provides what criteria it will use to determine whether a testing method is "validated."
- 94. The MRA admits that there is no criteria for determining what methods are "validated" in a guidance memo where it states "a standard method for the quantitative analysis of cannabinoids [(i.e., THC)] has not yet been published." In other words, even though there is

<sup>&</sup>lt;sup>1</sup> Sampling and Testing Technical Guidance for Marijuana Products (Revised July 1, 2021), Michigan Marijuana Regulatory Agency, p. 15, <a href="https://www.michigan.gov/documents/mra/Sampling\_and\_Testing-">https://www.michigan.gov/documents/mra/Sampling\_and\_Testing-</a>
Technical Guidance for Marijuana Products 694124 7.pdf.

no standard method for the quantitative analysis of THC (i.e., potency testing), the MRA has attempted to retroactively disapprove the November SOP.

- 95. In June 2021, Viridis Lansing successfully passed their annual accreditation surveillance assessment by the A2LA. This assessment included the review of all SOPs, including the November SOP potency method. See Exhibit M.
- 96. The MRA cannot arbitrarily withdraw or refuse to approve a potency analysis method.
- 97. The MRA has since continued to escalate and complicate these issues by unnecessarily and directly interfering with Viridis' day-to-day operations through overreaching investigatory requests, some of which are contrary to its own regulations.
- 98. On October 12, 2021, MRA agent Claire Patterson sent an e-mail to Viridis with investigation requests for outstanding and "current, on-going investigations."
- 99. The investigation requests from Ms. Patterson included 18 requests, consisting in part, of the following:

### **Currently Outstanding Investigation Requests**

- a. Video footage of Viridis Bay City;
- b. Potency prep sheets for 6 specific samples;
- c. Follow up request for calculation sheet for mold, pests and powdery mildew along with specific questions related to those calculations;
- d. Request for Method analysis added to Certificate of Analysis;

### Currently Outstanding Method /Validation Requests

e. The request states that in order to approve any updates made to the potency method (SOP LOM-7.1a Cannabinoid Analysis by HPLC-DAD), that is any updates that alter the method form the reference method, we require a complete

validation to AOAC Appendix K. This also includes updates to the prep method that was approved by the MRA in January 2020.<sup>2</sup>

- Submit a validation report, with an appropriate experimentation, statistical power, statistical design (e.g. RCBD or CRBD) and statistical analyses (e.g. ANOVA, Turkey HSD or Fisher LSD) to enable acceptance of the null hypothesis (Ha).
- ii. Alternatively, the laboratory may opt to run the reference method. If the laboratory opts to return to the reference method, they must also adhere to the appropriate SMPR's for the Potency.
- f. Microbial Testing approval request for SOP matrix expansion;
- g. Requirement for additional information about Terpenoid Analysis;
- h. Request for information related to a requested Chemical Residue SOP matrix expansion;

### **New Investigation Requests**

- Request for Initial Demonstration of Capability (IDOC) for all technicians performing foreign matter analysis;
  - The documents(s) used to train staff about identifying foreign matter as well as how to calculate foreign matter for the entire sample;
- j. Request for photos of samples which contain foreign matter detected in flower samples for the last 6 months;

<sup>&</sup>lt;sup>2</sup> This request is directly related to the 6 complaints filed by the MRA on August 25, 2021, set forth in paragraph 54 above.

- k. Request for all calculations performed for foreign matter for that past 30 days that determine whether a sample is pass or fail;
- Request for information about two specific METRC samples asking for amount left in storage;
- m. Request for the SOP currently used by staff to complete foreign matter analysis;
- n. Request for an instrument read-out of all tests performed on both the gene-up and aria platforms within the past 3 months;
- Request for Incubation logs for all Aspergillus tests performed in the month of September;
- p. A complete list of all currently employed methods, the date of the last update, and the date that the method was approved by the MRA, as well a copy of <u>all</u> current SOPs currently in use;
- q. A copy of all internal audits performed in 2020-2021;
- r. A daily schedule of when analyses are typically performed, or if ongoing throughout the day, please let us know;
  - In addition, a request for several dates and time during the next two weeks for both Viridis locations when all technicians/analysts can be available for interview.

A copy of the above requests is attached as **Exhibit N**.

100. On October 19, 2021, Viridis received a returned ticket from METRC stating, "per the MRA, 'Please ask for the equipment maintenance log of all incubators along with least temperature verification performed by an outside company." The MRA has *never* requested this information in the past and is now arbitrarily requesting Viridis perform additional tests by outside vendors without explanation as to why the test is being performed.

- 101. Subsequent to receiving the above requests from the MRA, on October 21, 2021, the MRA indicated in an email to Viridis that it intended to conduct full-day audits at both Viridis Lansing and Viridis Bay City. The MRA intended to "perform audits of the methods and procedures in real time" and to ask "questions related to the method and SOP." A copy of the MRA's email exchange and proposed schedules is attached as Exhibit O.
- 102. Viridis Lansing followed up on the MRA's email request and inquired if the audits were for "quality assurance" or "post-complaint" investigation. The MRA responded that it would be "quality assurance audits, post-complaint audits, and investigatory audits."
  - 103. Some or all of the MRA's "audits" described above are contrary to law.
- 104. Under MAC R. 792.10117, post-complaint fact finding (discovery) (i.e., the MRA's proposed post-complaint and investigatory audits) may only be approved by an administrative law judge. The MRA *has not* obtained such approval and, therefore, is acting contrary to its own regulations and Michigan law.
- 105. MAC R. 420.808(1) also reflects the unremarkable principle that investigations necessarily occur before, not after a complaint is issued. The MRA's attempts to conduct post-complaint discovery here are clearly improper. Viridis has already informed the MRA and its counsel that Viridis will not oppose any requests for reasonable discovery. However, there is no ALJ assigned at this point to decide the proper scope of discovery and/or issue a protective order, as necessary. In other words, Viridis has already articulated its concerns and objections to the MRA and its counsel, and it appears that the MRA is nevertheless deliberately rushing to obtain improper post-complaint discovery before Viridis even has an opportunity to petition an ALJ to better define the scope of discovery and/or implement adequate safeguards.

- 106. On October 25, 2021, the MRA again escalated its disruptive campaign by revealing to Viridis' competitors that it was under investigation relating to the issues stated in this Complaint. The disruptive effect to Viridis' business operations is expected to be substantial.
- 107. The above described requests and conduct are an excessive, unnecessary overreach by the MRA that will significantly disrupt Viridis' business operations and its operations as a marijuana safety compliance facility.
- 108. The above allegations, taken together and under the totality of the circumstances, evidence the MRA has continued to take step after step to interfere with Viridis' business. Viridis attempted to comply with the MRA's request, and in response, the MRA moved the goal posts to make compliance even more arduous and expensive.
- 109. The MRA's actions interfere with or impair the legal rights or privileges of Viridis.
  - 110. The MRA's conduct its contrary to its own regulations and Michigan law.

### **COUNT I**

# INTERFERENCE WITH VIRIDIS' OPERATIONS THROUGH UNNECESSARILY DISRUPTIVE INVESTIGATIVE PROCEDURES

- 111. Viridis reasserts and realleges the preceding paragraphs as if fully set forth herein.
- 112. Viridis has a vested property interest in use of the November SOP, and Viridis reasonably believed that the November SOP was approved by the MRA (in part because the MRA personally observed Viridis using the November SOP at least four times, and the MRA indicated that the November SOP was approved at least 13 times).
- 113. The MRA allowed use of the November SOP to test marijuana products' THC potency levels, specifically through monitoring and approval of the already validated method. In

reliance on the MRA's prior position, Viridis expended substantial time, effort, and resources to perfect the November SOP.

- 114. The MRA witnessed, monitored, and approved the November SOP no less than 13 times between November 2020 and as recently as June 2021.
- 115. The MRA has now attempted to retroactively disapprove or prohibit Viridis from using the November SOP.
- 116. The MRA has undertaken an excessive, unnecessary, and unreasonable campaign to investigate Viridis based on its use of the November SOP despite the fact that the MRA witnessed, monitored, and approved its use on numerous occasions.
- 117. The MRA's campaign to unnecessarily and unreasonably investigate Viridis has now expanded into unrelated and unnecessary areas of Viridis' operations, as described above, and is contrary to Michigan law and its own regulations, specifically MAC R. 792.10117.
- 118. The MRA's investigatory actions have negatively impacted, interfered with, impaired, and disrupted Viridis' business operations and its operations as a marijuana safety compliance facility.
- 119. Among other things, Viridis has had to expend in excess of \$100,000 compiling the MRA's unreasonable and excessive video and information requests discussed above, and expend greater than 25 hours cumulatively in weekly labor hours attempting to comply with the MRA's requests. This has left a substantial backlog of tests that Viridis must complete to satisfy its obligations to its customers.
  - 120. The MRA's campaign was unnecessary and unreasonable.
- 121. Viridis has suffered great economic harm as a result of the MRA's unwarranted activities.

WHEREFORE. Plaintiffs Viridis respectfully requests that the MRA cease its unreasonable and unnecessarily disruptive investigatory efforts, and that Viridis be allowed to continue its work without the MRA's unnecessary, unreasonable, and excessive interference with and disruption to its business operations and its operations as a marijuana safety compliance facility.

Respectfully submitted.

FOSTER, SWIFT, COLLINS & SMITH, P.C. Counsel for Plaintiffs

Dated: October 25, 2021

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Kevin M. Blair (P76927)

Viridis Laboratories, LLC and Viridis North. LLC

Michele Glinn

//Chief Science Officer

Viridis Labora Grica. LLC

Grag Michaud

Thef Executive Officer

Viridis Laboratories. LLC

Todd Welch

Chief Operating Officer

Viridis Laboratories, LLC

# **EXHIBIT D**

#### Outstanding Requests from the MRA to Viridis and Viridis North

### **Currently Outstanding Investigation Requests**

- Video footage of Viridis North. The last video request submitted to the MRA is not able to be viewed.
  - a. Please have Viridis North reach out to their RA and coordinate a time to pick up the requested footage. Please CC mra-scf@michigan.gov on this correspondence.
- 2. Potency prep sheets for all of the following samples:

LN-21-CS-24154,
LN-21-CS-24155
LN-21-CS-24156,
BC-21-CS-24158
BC-21-CS-24159
BC-21-CS-24160

- 3. Follow-up from email sent 10/7/2021
  - a. "Can you please provide your calculation sheets for how you are calculating mold, pests, and powdery mildew. Do you document photographically the amount of total surface area of the sample and the amount which contains foreign matter?"
- 4. Method of analysis added to Certificates of Analysis.

### **Currently Outstanding Method / Validation Requests**

- 5. In order to approve updates made to the potency method (SOP LOM-7.1a Cannabinoid Analysis by HPLC-DAD), that is any updates that alter the method from the reference method, we require a complete validation to AOAC Appendix K. This also includes updates to the prep method that was approved by the MRA in January 2020.
  - a. Submit a validation report, with appropriate experimentation, statistical power, statistical design (e.g. RCBD or CRBD) and statistical analyses (e.g. ANOVA, Tukey HSD or Fisher LSD) to enable acceptance of the null hypothesis (Ho) and rejection of the alternative hypothesis (Ha). If this is the course the laboratory opts to pursue, we recommend that they identify someone who can assist them in the validation process. If there are any questions about the detailed requirements of what the MRA will accept, please contact <a href="mailto:mra-scf@michigan.gov">mra-scf@michigan.gov</a> and all assigned LSS's will provide guidance.
  - b. Alternatively, the laboratory may opt to run the reference method. If the laboratory opts to return to the reference method, they must also adhere to the appropriate SMPRs for the potency.
- 6. Microbiological Testing: In order to receive an approval for the requested microbial SOP matrix expansion, the laboratory must remove the section "Coliform Count using Aria" and the associated data Table 7 (pg. 12). Please reach out to the LSS if you have any additional questions please reach out to both assigned LSSs via mra-scf@michigan.gov

### Outstanding Requests from the MRA to Viridis and Viridis North

- 7. Terpenoid Analysis: In order to receive approval for updates to LOM-7.7b-Terpenoid Analysis by Liquid Injection GC/MS for beverage matrix expansion, the laboratory must provide a reference that contains performance criteria. The method validation provided references a Sigma-Aldrich application note, yet it does not contain expected performance criteria. At minimum, this will be required to approve the method, however, providing this information does not ensure approval if more issues become apparent during the review of the next submission.
- 8. Chemical Residue: In order to receive approval for the requested Chemical Residue SOP matrix expansion, the laboratory must, at minimum, provide acceptable PT results for Diamonozid and Fibronil as well as a corrective action report (CAPA) that addresses the aforementioned failures. Again, there may be additional items requested after subsequent review.

### **New Investigation Requests**

- Initial Demonstration of Capability (IDOC) for all technicians performing foreign matter analysis.
  - a. The document(s) used to train staff about identifying foreign matter as well as how to calculate foreign matter for the entire sample
- 10. All photos of samples which contain foreign matter detected in flower samples for the last 6 months.
- 11. All calculations performed for foreign matter for that past 30 days that determine whether a sample is pass or fail.
- 12. Please tell us how much sample is left in storage for the following Metrc samples (and if that amount is >0, please continue to hold these samples):

1A4050300005E89000000651 1A4050300005E89000000650

- 13. The SOP currently used by staff to complete Foreign Matter analysis
- 14. An instrument read-out of all tests performed on both the gene-up and aria platforms within the past 3 months.
- 15. Incubation logs for all Aspergillus tests performed in the month of September
- 16. A complete list of all currently employed methods, the date of the last update, and the date that the method was approved by the MRA as well as a copy of <u>all</u> SOPs currently in use.
- 17. A copy of all internal audits performed in 2020-2021.
- 18. A daily schedule of when analyses are typically performed, or if ongoing throughout the day, please let us know.

### Outstanding Requests from the MRA to Viridis and Viridis North

a.	In addition, we will need several dates and times during the next two weeks for both
	Viridis locations when all technicians / analysts can be available for interview. We will be
	interviewing them independently to allow operations to continue in the rest of the lab.

# **EXHIBIT E**

From: Gregoire Michaud [mailto:gmichaud@viridisgrp.com]

Sent: Friday, October 22, 2021 4:08 PM

To: Patterson, Claire (LARA)

Cc: Michael LaFramboise; Michele Glinn; Russell, David; Blair, Kevin M.; Kluytman, Julie (LARA)

**Subject:** RE: Tentative Audit Schedule

Here you go...have a nice weekend Claire.

Risa Hunt-Scully (P58239)
Assistant Attorney General
Michigan Department of Attorney General
Licensing & Regulation Division
3rd Floor, G. Mennen Williams Building
525 W. Ottawa Street
Lansing, Michigan 48933
(517) 335-7569
(517) 241-1997

Gregoire P. Michaud CEO/Founder



"Ensuring Health & Safety Within Michigan's Cannabis Industry"

From: Patterson, Claire (LARA) < Patterson C8@michigan.gov >

Sent: Friday, October 22, 2021 4:05 PM

To: Gregoire Michaud <gmichaud@viridisgrp.com>

Cc: Michael LaFramboise <mlaframboise@viridisgrp.com>; Michael Glinn <mglinn@viridisgrp.com>;

drussell@fosterswift.com; Blair, Kevin M. < KBlair@honigman.com >; Kluytman, Julie (LARA)

< KluytmanJ@michigan.gov>

Subject: RE: Tentative Audit Schedule

Hi Greg,

Would you please provide us the name of the AAG that you are working with on this case. We will need to touch base with them about shifting our investigation back, if necessary.

Thank you!

Claire Patterson

Manager, Scientific & Legal Section Enforcement Division Marijuana Regulatory Agency

(517) 230-2097 PattersonC8@michigan.gov www.michigan.gov/MRA



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From: Gregoire Michaud <gmichaud@viridisgrp.com>

Sent: Friday, October 22, 2021 3:51 PM

To: Patterson, Claire (LARA) < Patterson C8@michigan.gov>

Cc: Michael LaFramboise <mlaframboise@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>;

drussell@fosterswift.com; Blair, Kevin M. < KBlair@honigman.com >; Kluytman, Julie (LARA)

<KluytmanJ@michigan.gov>

Subject: RE: Tentative Audit Schedule

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#### Claire,

My apologies for the late request here, but we've been attempting to coordinate a compliance conference with the AG's office which we have tentatively scheduled for November 2<sup>nd</sup> (see attached email). At the request of our legal counsel, we are hoping that you will be okay with rescheduling the audits until after the compliance conference has been held.

Kind regards, Greg

Gregoire P. Michaud CEO/Founder



"Ensuring Health & Safety Within Michigan's Cannabis Industry"

From: Patterson, Claire (LARA) < Patterson C8@michigan.gov>

Sent: Thursday, October 21, 2021 12:10 PM

To: Gregoire Michaud <gmichaud@viridisgrp.com>

Cc: Michael LaFramboise <mlaframboise@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>

Subject: RE: Tentative Audit Schedule

It will be a combination of quality assurance audits, post-complaint audits, and investigatory audits. All will be strictly related to methods, processes, and SOPs. If you have any additional questions, please do not hesitate to ask.

Have a great day!

### Claire Patterson

Manager, Scientific & Legal Section Enforcement Division Marijuana Regulatory Agency

(517) 230-2097 PattersonC8@michigan.gov www.michigan.gov/MRA



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From: Gregoire Michaud <gmichaud@viridisgrp.com>

Sent: Thursday, October 21, 2021 10:33 AM

To: Patterson, Claire (LARA) < Patterson C8@michigan.gov>

Cc: Michael LaFramboise <mlaframboise@viridisgrp.com>; Michael Glinn <mglinn@viridisgrp.com>

Subject: RE: Tentative Audit Schedule

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Yes, it clears up that portion of it, thank you Claire. Is this a quality assurance audit or a post-complaint, investigatory audit?

Gregoire P. Michaud CEO/Founder



"Ensuring Health & Safety Within Michigan's Cannabis Industry"

From: Patterson, Claire (LARA) < Patterson C8@michigan.gov>

Sent: Thursday, October 21, 2021 9:53 AM

To: Gregoire Michaud <gmichaud@viridisgrp.com>; MRA-scf <MRA-scf@michigan.gov>; Michele Glinn

<mglinn@viridisgrp.com>; Michael LaFramboise <mlaframboise@viridisgrp.com>
Cc: Fields, Patrice (LARA) <<u>FieldsP2@michigan.gov</u>>; Rosenzweig, Noah (LARA)

<RosenzweigN@michigan.gov>

Subject: RE: Tentative Audit Schedule

Good morning Greg,

I can jump in on this one, as I just want to make sure we are very clear about our intentions for the onsite event.

The plan is for the LSS staff to perform audits of the methods and procedures for routinely performed work as the work is being performed in real time. We do not plan on removing any staff from the laboratory or any of their duties to perform these audits. We will be asking questions related to the method and SOP, just as you would expect from any ISO audit.

Does that help answer your questions?

Claire Patterson

Manager, Scientific & Legal Section Enforcement Division Marijuana Regulatory Agency

(517) 230-2097 PattersonC8@michigan.gov www.michigan.gov/MRA



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From: Gregoire Michaud <gmichaud@viridisgrp.com>

Sent: Thursday, October 21, 2021 9:36 AM

To: MRA-scf < MRA-scf@michigan.gov >; Michele Glinn < mglinn@viridisgrp.com >; Michael LaFramboise

<mlaframboise@viridisgrp.com>

Cc: Patterson, Claire (LARA) < <u>PattersonC8@michigan.gov</u>>; Fields, Patrice (LARA) < <u>FieldsP2@michigan.gov</u>>; Rosenzweig, Noah (LARA) < <u>RosenzweigN@michigan.gov</u>>

Subject: RE: Tentative Audit Schedule

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Hi Allyson,

Will you be interviewing our team members individually when not observing them during the analytical processes?

Kind regards, Greg

Gregoire P. Michaud CEO/Founder



"Ensuring Health & Safety Within Michigan's Cannabis Industry"

From: MRA-scf < MRA-scf@michigan.gov > Sent: Thursday, October 21, 2021 8:59 AM

To: Michele Glinn < mglinn@viridisgrp.com >; Michael LaFramboise < mlaframboise@viridisgrp.com >;

Gregoire Michaud <gmichaud@viridisgrp.com>

Cc: Patterson, Claire (LARA) < <a href="mailto:PattersonC8@michigan.gov">PattersonC8@michigan.gov</a>; Fields, Patrice (LARA) < <a href="mailto:FieldsP2@michigan.gov">FieldsP2@michigan.gov</a>; Rosenzweig, Noah (LARA) < <a href="mailto:RosenzweigN@michigan.gov">RosenzweigN@michigan.gov</a>>

Subject: Tentative Audit Schedule

Importance: High

Good morning,

Please see attached, if you have questions or concerns, please respond by COB Friday.

#### Allyson

Scientific & Legal Section Enforcement Division Marijuana Regulatory Agency MRA-scf@michigan.gov www.michigan.gov/MRA

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### Tentative Audit schedule for Viridis Lansing

## Audit will occur October 26<sup>th</sup>

8:00:8:15am	Welcome introductions
8:15am-10:30	Quality Systems Review Please have the following documents and records available for review and a staff member who is familiar and able to answer questions related to these items.  • Quality Manual • All Testing SOPs
10:30-12:30	<ul> <li>Observation of Methods</li> <li>Please have all remaining material for the following Metrc samples pulled and set aside.</li> <li>Staff who prepare and run samples should be available for questions.</li> <li>The MRA will be observing and asking questions, please have staff who are knowledgeable about the methods present.</li> <li>Patrice will be observing all chemistry methods</li> <li>Noah will be observing all microbial methods</li> <li>Allyson will be observing foreign matter</li> </ul>
12:30-1:30	lunch
1:30-3:00	Continuation of observation of methods
3:00-4:00	Additional Observation and questions
4:00-4:15	Exit Meeting

Please note that these times are flexible and may go longer or shorter than the timeframe noted.

### Tentative Audit schedule for Viridis North

Audit will occur October 27th.

9:00:9:15am	Welcome introductions
9:15am-11:00	Quality Systems Review Please have the following documents and records available for review and a staff member who is familiar and able to answer questions related to these items.  • Quality Manual • All Testing SOPs
11:00-1:00	Observation of Methods  Please have all remaining material for the following Metrc samples pulled and set aside.  Staff who prepare and run samples should be available for questions.  The MRA will be observing and asking questions, please have staff who are knowledgeable about the methods present.  Patrice will be observing all chemistry methods  Noah will be observing all microbial methods  Allyson will be observing foreign matter
1:00-2:00	lunch
2:00-3:30	Continuation of observation of methods
3:30-4:30	Additional Observation and questions
4:30-4:45	Exit Meeting

Please note that these times are flexible and may go longer or shorter than the timeframe noted.

October 28<sup>th</sup> will be a follow-up day if needed and we will notify at the exit meeting if we will be back and what time we are starting.

# **EXHIBIT F**

Sent: Monday, October 25, 2021 11:46 AM

To: Craig Runk; Linda Palmatier; Michele Glinn; Gregoire Michaud; Erik Nagler; Steven Mayo;

skeeto1515@gmail.com
Cc: MRA-compliance

Subject: Request for Sample audit

Good Afternoon,

The Spott AU-SC-000105

The Marijuana Regulatory Agency (MRA) has selected 3 sample(s) for a safety compliance facility audit

for aspergillus and potency.

### **Selected Packages:**

Licensee #: Viridis Laboratory-Lansing AU-SC-000113

Package Name: Kush Mint Bud Metrc Tags #:

1A4050300009155000001014,1A4050300009155000001015, all remaining sample including extraction

solution from the original testing.

Licensee #: Mitten Canna Co. (AU-G-C-000139)

3734 COMMERCE ST Jackson, MI 49203

Package Name: MacFlurry Bud

Metrc Tag #: 1A4050300009155000000492 Contact Information for Assigned Laboratory: Craig and Linda are included in the email contacts.

This sampling and testing event is being requested as part of MRA oversight authority in accordance with Marihuana Sampling and Testing R. 420.305(17) and (19):

(17) A laboratory shall comply with random quality assurance compliance checks upon the request of the agency. The agency or its authorized agents may collect a random sample of a marihuana product from a laboratory or designate another laboratory to collect a random sample of a marihuana product in a secure manner to test that sample for compliance pursuant to these rules.

(19) A laboratory shall comply with investigations to ensure the health and safety of the public. At the request of the agency, a laboratory may be requested to perform testing as part of an investigation. Your marihuana business should not be charged for this testing event. It is necessary for the laboratory to take 0.5% of the sample from the source package, for the laboratory samples, the laboratory will provide all remaining sample.

Please contact <u>MRA-scf@michigan.gov</u> if you have questions or if the assigned laboratory fails to make contact within 2 business days by replying to this email or if you have questions.

Please reply to this email with the date and time for the sampling event so that the product holds can be lifted.

Best,

Allyson

Scientific & Legal Section

**Enforcement Division** 

Marijuana Regulatory Agency

MRA-scf@michigan.gov

www.michigan.gov/MRA

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Sent: Monday, October 25, 2021 11:52 AM

To: Mike Goldman; Mac Hyman; howard.l@ironlaboratories.com; R Teitel; Seth Tompkins; Michele

Glinn; Gregoire Michaud

Cc: MRA-compliance

Subject: Request for Sample Audit

Good Afternoon,

Iron Laboratories AU-SC-000105

The Marijuana Regulatory Agency (MRA) has selected 3 sample(s) for a safety compliance facility audit for aspergillus and potency.

### **Selected Packages:**

Licensee #: Viridis Laboratory-Lansing AU-SC-000113

Package Name: Blue Nina Flower Metrc Tags #:

1A40503000090EE000004021,1A40503000090EE000004022, all remaining sample including extraction

solution from the original testing.

Licensee #: The Calmic LLC (AU-G-C-000154)

655 Ballard RD Jackson, MI 49201

Package Name: Blue Nina Flower

Metrc Tag #: 1A4050300090EE000003850

Contact Information for Assigned Laboratory:
The contacts for Iron are included on this email.

This sampling and testing event is being requested as part of MRA oversight authority in accordance with Marihuana Sampling and Testing R. 420.305(17) and (19):

(17) A laboratory shall comply with random quality assurance compliance checks upon the request of the agency. The agency or its authorized agents may collect a random sample of a marihuana product from a laboratory or designate another laboratory to collect a random sample of a marihuana product in a secure manner to test that sample for compliance pursuant to these rules.

(19) A laboratory shall comply with investigations to ensure the health and safety of the public. At the request of the agency, a laboratory may be requested to perform testing as part of an investigation. Your marihuana business should not be charged for this testing event. It is necessary for the laboratory to take 0.5% of the sample from the source package, for the laboratory samples, the laboratory will provide all remaining sample.

Please contact MRA-scf@michigan.gov if you have questions or if the assigned laboratory fails to make contact within 2 business days by replying to this email or if you have questions.

Please reply to this email with the date and time for the sampling event so that the product holds can be lifted.

Best,

Allyson

Scientific & Legal Section

**Enforcement Division** 

Marijuana Regulatory Agency

MRA-scf@michigan.gov

www.michigan.gov/MRA

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Sent: Monday, October 25, 2021 12:00 PM

To: Michele Glinn; Gregoire Michaud; Manik; paulhansen@apothecareannarbor.com; Manik

Cc: MRA-compliance

Subject: Request for Sample Audit

Good Afternoon,

Can-Lab AU-SC-000117

The Marijuana Regulatory Agency (MRA) has selected 3 sample(s) for a safety compliance facility audit for aspergillus and potency.

### **Selected Packages:**

Licensee #: Viridis Laboratory-Lansing AU-SC-000113

Package Name: MAC #1 Flower #: 1A40503000090EE000003505, 1A40503000090EE000003506, all

remaining sample including extraction solution from the original testing.

Licensee #: The Calmic LLC (AU-G-C-000154)

655 Ballard RD Jackson, MI 49201

Package Name: MAC #1 Flower

Metrc Tag #: 1A40503000090EE000004806

Contact Information for Assigned Laboratory:

Manik's email is in the contacts.

This sampling and testing event is being requested as part of MRA oversight authority in accordance with Marihuana Sampling and Testing R. 420.305(17) and (19):

(17) A laboratory shall comply with random quality assurance compliance checks upon the request of the agency. The agency or its authorized agents may collect a random sample of a marihuana product from a laboratory or designate another laboratory to collect a random sample of a marihuana product in a secure manner to test that sample for compliance pursuant to these rules.

(19) A laboratory shall comply with investigations to ensure the health and safety of the public. At the request of the agency, a laboratory may be requested to perform testing as part of an investigation. Your marihuana business should not be charged for this testing event. It is necessary for the laboratory to take 0.5% of the sample from the source package, for the laboratory samples, the laboratory will provide all remaining sample.

Please contact <u>MRA-scf@michigan.gov</u> if you have questions or if the assigned laboratory fails to make contact within 2 business days by replying to this email or if you have questions.

Please reply to this email with the date and time for the sampling event so that the product holds can be lifted.

Best,

Allyson

Scientific & Legal Section

**Enforcement Division** 

Marijuana Regulatory Agency

MRA-scf@michigan.gov

www.michigan.gov/MRA

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Sent: Monday, October 25, 2021 12:06 PM

To: howard.l ironlaboratories.com; mike.g ironlaboratories.com; mac.h ironlaboratories.com; rob.t

ironlaboratories.com; Seth Tompkins; Michele Glinn; Gregoire Michaud

Cc: MRA-compliance

Subject: RE: Request for Sample Audit

Hi Howard,

You will make arrangements with Viridis-Lansing to obtain their remaining sample. It does not matter to the MRA if your lab picks up or if their lab drops off to you as long as a manifest is created for the transfer.

You will also make arrangements with the grower listed to sample from the harvest batch.

All samples will be run for aspergillus and potency.

Please let me know if you have additional questions, this is in response to an investigation so if you could make it a priority we would greatly appreciate it. Please send the COAs when complete as a response to this email.

I am available all day if a call is needed. I have included my signature line with my phone number. Allyson

Dr. Allyson L. Chirio DHSc, MPH, BS(MT) (AMT) Laboratory Scientist Specialist Scientific & Legal Section, Enforcement Division Marijuana Regulatory Agency 517-331-7512

ChirioA@michigan.gov

www.michigan.gov/MRA

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From: howard.l ironlaboratories.com

Sent: Monday, October 25, 2021 12:00 PM

To: MRA-scf; mike.g ironlaboratories.com; mac.h ironlaboratories.com; rob.t ironlaboratories.com;

Seth Tompkins; Michele Glinn; Gregoire Michaud

**Cc:** MRA-compliance

Subject: Re: Request for Sample Audit

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Allyson,

Please explain the transport arrangements? I am confused by these instructions.

From: MRA-scf < MRA-scf@michigan.gov > Sent: Monday, October 25, 2021 11:52 AM

To: mike.g ironlaboratories.com <mike.g@ironlaboratories.com>; mac.h ironlaboratories.com <mac.h@ironlaboratories.com>; howard.l ironlaboratories.com <howard.l@ironlaboratories.com>; rob.t ironlaboratories.com>; Seth Tompkins <seth@sethtompkinslaw.com>; Michele Glinn <mglinn@viridisgrp.com>; Gregoire Michaud <gmichaud@viridisgrp.com>

Cc: MRA-compliance < MRA-compliance@michigan.gov>

Subject: Request for Sample Audit

Good Afternoon,

Iron Laboratories AU-SC-000105

The Marijuana Regulatory Agency (MRA) has selected 3 sample(s) for a safety compliance facility audit for aspergillus and potency.

### **Selected Packages**:

Licensee #: Viridis Laboratory-Lansing AU-SC-000113

Package Name: Blue Nina Flower Metrc Tags #:

1A40503000090EE000004021,1A40503000090EE000004022, all remaining sample including extraction

solution from the original testing.

Licensee #: The Calmic LLC (AU-G-C-000154)

655 Ballard RD Jackson, MI 49201

Package Name: Blue Nina Flower

Metrc Tag #: 1A40503000090EE000003850

Contact Information for Assigned Laboratory:
The contacts for Iron are included on this email.

This sampling and testing event is being requested as part of MRA oversight authority in accordance with Marihuana Sampling and Testing R. 420.305(17) and (19):

(17) A laboratory shall comply with random quality assurance compliance checks upon the request of the agency. The agency or its authorized agents may collect a random sample of a marihuana product from a laboratory or designate another laboratory to collect a random sample of a marihuana product in a secure manner to test that sample for compliance pursuant to these rules.

(19) A laboratory shall comply with investigations to ensure the health and safety of the public. At the request of the agency, a laboratory may be requested to perform testing as part of an investigation. Your marihuana business should not be charged for this testing event. It is necessary for the laboratory to take 0.5% of the sample from the source package, for the laboratory samples, the laboratory will provide all remaining sample.

Please contact <u>MRA-scf@michigan.gov</u> if you have questions or if the assigned laboratory fails to make contact within 2 business days by replying to this email or if you have questions.

Please reply to this email with the date and time for the sampling event so that the product holds can be lifted.

Best,
Allyson
Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency
MRA-scf@michigan.gov

# www.michigan.gov/MRA

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From: MRA-scf

Sent: Wednesday, October 27, 2021 12:32 PM

To: Craig Runk; Linda Palmatier; Michele Glinn; Gregoire Michaud; Steven Mayo;

skeeto1515@gmail.com; Patrick Runk

Cc: MRA-compliance

Subject: RE: Request for Sample audit

Thanks Craig. Compliance,

Please make sure to remove the hold prior to the sampling, and reinstate after sample creation.

Scientific & Legal Section

Enforcement Division

Marijuana Regulatory Agency

MRA-scf@michigan.gov

www.michigan.gov/MRA

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Need to file a complaint against a licensee? Click here.



Spread Hope GET VACCINATED

Save Michigan Lives.

From: Craig Runk

Sent: Wednesday, October 27, 2021 10:34 AM

To: MRA-scf; Linda Palmatier; Michele Glinn; Gregoire Michaud; Steven Mayo;

skeeto1515@gmail.com; Patrick Runk

Cc: MRA-compliance

Subject: RE: Request for Sample audit

CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

Hi,

The Spott will collect the specified samples tomorrow, 10/28/2021, between 9AM and 4 PM at the Lansing Viridis lab.

Thank You,

Craig Runk, MS

**Laboratory Manager** 

The Spott

550 East Cork Street

Kalamazoo, MI 49001

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From: MRA-scf < MRA-scf@michigan.gov > Sent: Monday, October 25, 2021 11:46 AM

To: Craig Runk < craigr@mispott.com >; Linda Palmatier < lindap@mispott.com >; Michele Glinn

<mglinn@viridisgrp.com>; Gregoire Michaud <gmichaud@viridisgrp.com>; Erik Nagler<erikn@mispott.com>; Steven Mayo <smayo23@icloud.com>; skeeto1515@gmail.com

Cc: MRA-compliance < MRA-compliance @michigan.gov>

Subject: Request for Sample audit

**Importance:** High Good Afternoon,

The Spott AU-SC-000105

The Marijuana Regulatory Agency (MRA) has selected 3 sample(s) for a safety compliance facility audit

for aspergillus and potency.

**Selected Packages:** 

Licensee #: Viridis Laboratory-Lansing AU-SC-000113

Package Name: Kush Mint Bud Metrc Tags #:

1A4050300009155000001014,1A4050300009155000001015, all remaining sample including extraction

solution from the original testing.

Licensee #: Mitten Canna Co. (AU-G-C-000139)

3734 COMMERCE ST Jackson, MI 49203

Package Name: MacFlurry Bud

Metrc Tag #: 1A4050300009155000000492 Contact Information for Assigned Laboratory: Craig and Linda are included in the email contacts.

This sampling and testing event is being requested as part of MRA oversight authority in accordance

with Marihuana Sampling and Testing R. 420.305(17) and (19):

(17) A laboratory shall comply with random quality assurance compliance checks upon the request of the agency. The agency or its authorized agents may collect a random sample of a marihuana product from a laboratory or designate another laboratory to collect a random sample of a marihuana product in a secure manner to test that sample for compliance pursuant to these rules.

(19) A laboratory shall comply with investigations to ensure the health and safety of the public. At the request of the agency, a laboratory may be requested to perform testing as part of an investigation. Your marihuana business should not be charged for this testing event. It is necessary for the laboratory to take 0.5% of the sample from the source package, for the laboratory samples, the laboratory will provide all remaining sample.

Please contact MRA-scf@michigan.gov if you have questions or if the assigned laboratory fails to make contact within 2 business days by replying to this email or if you have questions.

Please reply to this email with the date and time for the sampling event so that the product holds can be lifted.

Best, Allyson Scientific & Legal Section Enforcement Division Marijuana Regulatory Agency

# MRA-scf@michigan.gov

### www.michigan.gov/MRA

Stay up to date and get vaccinated when it's your turn – for more information, please visit <a href="https://www.michigan.gov/COVIDvaccine">www.michigan.gov/COVIDvaccine</a>.

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# **EXHIBIT G**



GRETCHEN WHITMER GOVERNOR

# STATE OF MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS LANSING

ORLENE HAWKS DIRECTOR

November 15, 2021

Viridis Laboratories, LLC-SC-000009/AU-SC-000113 2827 E. Saginaw Lansing, MI 48912 Date of Audit: 10/26/2021 Compliance Monitoring Tier 4

#### **Onsite Audit Findings**

**Auditors:** Dr. Noah Rosenzweig, Dr. Patrice Fields, Dr. Allyson Chirio & Claire Patterson (oversight)

As requested during the onsite audit by Michele Glinn, at the end of this document, you will find a summary of qualifications for each auditor and the methods they were responsible for reviewing.

Dear Viridis Laboratories, LLC,

An onsite compliance audit was conducted at your facility on 10/26/2021, several non-conformances were identified. The nonconformances are listed below.

#### Nonconformance 1

R. 420.305 (1) A laboratory shall do all of the following: (b) Maintain internal standard operating procedures for the required safety tests in subrule (3) of this rule and for sampling of marihuana and marihuana products that conform to ISO/IEC 17025:2017 standards and have been approved by the agency.

R. 420.305 (1) (c) Maintain a quality control and quality assurance program that conforms to ISO/IEC 17025:2017 standards and meets the requirements established by the agency.

R. 420.305(2) A laboratory shall use analytical testing methodologies for the required safety tests in subrule (3) of this rule that are validated by an independent third party and may be monitored on an ongoing basis by the agency or a third party. In the absence of reference to compendia or published methods, Appendix K of Official Methods of Analysis authored by the Association of Official Analytical Chemists must be published in full. The agency shall approve the validated methodology used by the laboratory and confirm that it produces scientifically accurate results for each safety test it conducts.

Laboratory technicians are not following approved foreign matter SOP - LOM - 7. 11 Foreign Matter Analysis and Photographic Imaging. Laboratory is not failing samples which exceed the 2% action limit.

#### Deviations observed and documented include:

- 1. Dr. Chirio observed samples viewed at only minimal magnification. LSS Chirio did not observe the technician use the dinoscope for higher power viewing for viewing pests, powdery mildew and other organic matter that is not visible on low magnification.
- 2. Dr. Chirio asked the technician (Kylie) performing foreign matter if they ever view samples on the dinoscope which is a higher magnification and she stated "no, we only use it for pictures".
- 3. Dr. Chirio observed visible mold more than 2% in a sample which Laboratory Director Michele Glinn told the laboratory technician Kylie to pass.
- 4. It should be noted that Michele Glinn, laboratory director who per the approved SOP LOM -
- 7. 11 Foreign Matter Analysis and Photographic Imaging is one of the supervisors who can verify foreign matter failures. Michele Glinn was unable to visualize the sample herself, she asked the technician multiple times to point out where the contamination was located.
- 5. She stated that the foreign material was mite poop, not enough to fail and not visible mold.
- 6. When Dr. Chirio asked for clarification on how 2% is calculated for a mold failure, she was told by Michele Glinn the sample containing visible mold would have to cover more than 2 squares on the grid used. The sample was greater than 2 squares and there was additional material that should have been included in the calculation which was not. Please refer to the picture of the sample taken noted as figure 1. Michele Glinn also stated that if mold was present, it would be caught on the total yeast and mold analysis.
- 7. Claire Patterson and Dr. Rosenzweig both with extensive backgrounds in plant biology and pathology confirmed the presence of the mold on the sample.



Figure 1. Sample 26182 Metrc last 4 digits 4884.

#### Nonconformance 2

- R. 420.305 (1) A laboratory shall do all of the following: (b) Maintain internal standard operating procedures for the required safety tests in subrule (3) of this rule and for sampling of marihuana and marihuana products that conform to ISO/IEC 17025:2017 standards and have been approved by the agency.
- R. 420.305 (1) (c) Maintain a quality control and quality assurance program that conforms to ISO/IEC 17025:2017 standards and meets the requirements established by the agency.
- R. 420.305(2) A laboratory shall use analytical testing methodologies for the required safety tests in subrule (3) of this rule that are validated by an independent third party and may be monitored on an ongoing basis by the agency or a third party. In the absence of reference to compendia or published methods, Appendix K of Official Methods of Analysis authored by the Association of Official Analytical Chemists must be published in full. The agency shall approve the validated methodology used by the laboratory and confirm that it produces scientifically accurate results for each safety test it conducts.

#### Deviations observed and documented include:

Viridis laboratories is not adhering to the method specifications. Sample incubation times are not tracked, the laboratory could not provide documentation that the methods were performed as validated.

- 1. The approved SOP LOM 22 Detection of Yeast and Mold by Tempo requires yeast and mold to incubate for 72-76 hours at  $25 \pm 1^{\circ}$ C (24-26°C).
- 2. Incubator I2 identified by Ross White is used for total yeast and mold samples, at the time of inspection the temperature was 25°C, the log sheet (see figure 2 below) provided shows the temperature outside of the manufacture validated specifications exceeding 26°C from 08/10/2021-10/6/2021.
- 3. The approved LOM 21 Detection of Salmonella and STEC by GENE-UP requires samples to be incubated at 41.5°C for 24 28 hours. There are several instances on the incubator log where the incubation temperature exceeds 41.5°C. Refer to figure 2. Below.
- 4. Manager Claire Patterson asked Ross White if incubation time in and time out are recorded and logged, Ross stated that it is not recorded. There is no way to confirm that samples have been incubated the appropriate length of time as samples are not tracked on worklists where the technician could note the last sample placed in incubator and when the run was taken out for testing.
- 5. There are no documented non-conformances or evidence that Viridis is aware of the temperature deviations or has performed any corrective actions or repeat analysis for nonconforming samples, samples which were found to not contain TYM, Salmonella and STEC are not valid (passing samples) due to the deviations from the specific validated temperatures.
- 6. According to SOP-QM 6.3 Facilities and Environmental Conditions "Viridis Laboratories monitors, controls, and records environmental conditions as required by relevant specifications, methods, or procedures or where they may influence the quality of the results." The methods call for strict adherence to temperature and time specifications and continuous

monitoring, which is not being done. Incubator temperatures are only checked once per day in the morning.

- 7. According to SOP QM-8.9 Management Reviews states "Are environmental conditions or facility problems adversely affecting the test results?" Per Dr. Michele Glinn she or her designee review temperature charts not less than monthly, the logs are not signed and the deviations from the approved methods and nonconforming testing results have not been evaluated as far as the MRA is aware. During the audit the MRA did ask to view the Current CAPAs and there were not any internally generated complaints.
- 8. According to SOP QM 7.10 Non-Conforming Work "Viridis Laboratories has a procedure for handling laboratory activities that does not conform to its procedures or to the agreed requirements of the client. (QM 8.7 Corrective Actions) Calibration/test data not conforming to established acceptance criteria are controlled and are not released to the client. Any nonconforming calibration/test items that do not match the requirements are identified, managed and prevented from unintended delivery to the client." Viridis is not adhering to their SOP, results were all released without investigation. As far as the MRA is aware Viridis has not made any attempt to notify clients, the MRA or investigate how many samples are nonconforming.

ncubator Main	tenance / Tempe	OO		Incubator: II, I2, I3, MicroFridge (MF)
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9-2-81 37.0	1.2.21 28.9	1.2.31 41.5	9.32 4.7	9-2-21 IN. 35.0 EX
5321 770	4321 279	972V 413	4321 5.1	450 24-35.02
9/10/21 34.0	9931 285 VIONI 283	9971 41.5	9921 47	9991 14 3500
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0 1/14/21 31.0	HM14 275	11/21 41.4	1/14/21 3.8	9/13/21 I4 - 3510 UN/21 I4 - 345
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9/10/11 37.0	[tall 25,6	4/341 4/50	1/1041 3.9 1/10/21 4.9	9/44/21 =4-34.9 C5
9431121 37.0	918:121 28.9	9/21/01 41.5%	91814 4.0	9/21/2 T4-35.0
1/23/11 37.0	1/121 28.7	1/10/21 415'C	9/27/21 4.4	V2U74 74-74.4
70481 37.0	V25/81 29.0	14421 71.2	4/cih1 4 q	121/21 [4-35.0
4/2410 37.	1174 213	1/241 41 1	1/22/21 4.6	1/13/0 14-35.0
9121/1 37.0	1/11/21 29.4	1010 41.5	1/19/21 4.5	9/21/0 I 4-35.
1/30/21 31.1	/29[d] 27.1 /WI 212	1124/21 41.5 1779/21 41.5	1/21/11 40	1/247 14-75.0
0/1/21 . 370	0/1/21 29.0	10/2 11/5	913071 4.6	113070 24-35.0 14411 14-35.0
10H121 37.0	10/4/28,6	8/4/21 41.6	10/4/21 4.6	1945 H-R0
168/11 37.0	0/571 29.5	2/5/71 UI LI	10/5/71 5.10	418/71 54-25
11.3	0/6/11 227	2111 4,4	16/6/11 5.3	XH-12 G

Figure 2. Viridis Lansing Incubator temperature log

TEMPO® YM (Yeasts Molde) 12594 G - en - 2015/01

#### METICUCIONE FOR USES

For complete instructions, see the TEMPO<sup>®</sup> system User's Menuals.

#### Protocol validated by AOAC Research Institute (Certification No. 041901)

#### Test procedure for food samples

Example for the preparation of a 1/40 dilution enabling enumeration between 10 and 4.9x10<sup>4</sup> CFUIg. The dilution can be modified according to the expected level of contamination.

Please refer to the paragraph "Limitations of the method" for information concerning the primary diluents and recommended dilutions.

- Remove the required number of vials of culture medium (one vial per test sample) and allow to come to room temperature.
- Set the dispenser containing the secondary discent to 3 mL and prime the pump by eliminating the first two volumes dispensed
- 3. Log on to the TEMPO preparation station.
- Following the instructions of the preparation station user interface, identify the sample to be tested, either by manually entering the identifier via the keyboard or using the preparation station bercode reader.
- Reconstitute the culture medium by dispensing 3 mL of secondary diluent per vial using the dispensier.
- Using a storile pipetie, take up 1 mL from the filtered compartment of the TEMPO bag and transfer it into the vial containing the reconstituted culture medium. Homogenize for approximately 3 seconds using a vortex-type mixer. The 4 mit, of inoculated medium obtained corresponds to a 1740 dilution of the sample.
- 7. Remove one card for each vial of inoculated medium. without touching the tip of the transfer tube. Check that the codes (colors and abbreviations) on the card

- 11. Remove the filling rack from the TEMPO Filler Remove the same instrument and visually check that the vials are empty Take the cards out of the rack and transfer them into the incubation racks: insert the cards into the slots, with the label on the card facing the user (towards the rack handle). Cards which are to be incubated at the same temperature should be grouped together on the same rack. Each rack can hold up to 20 cards. Do not insert cards in between the slots
- 12. Dispose of the used vials and transfer tubes into an appropriate receptacle.
- 13. Incubate the cards for 72-76 hours at 25.2.1°C, in order to obtain performance levels similar to the standard EN ISO 21527 (1) and chapter 18 of the BAM (2)

The TEMPS and tool was compared to Compare New State BAM (2). The AOAC study included the following es of lood products

- segones o roco prouces: Iniz (orange juice, apple juice, frozen strawbernes), dairy products (cheddar cheese, frozen yogurt, milk-based infant formule), miscellaneous (flour lortifles, commest, almonds,

Note 1: The incubation time for the test is managed by the TEMPO Read software which integrates a theoretical interval of 15 minutes between the reading of the card barcode and the start of incubation. or the care bactone and the start of inclusions without if the real intervel is greater than 15 minutes (without exceeding 2 hours), this extra time must be added to the remaining incubation time displayed by the TEMPO Read software. Reading must always be performed within the 72-76 hour time limit authorized performed within by the software.

Note 2017he E211 CE leferance Flore the Hearth

Figure 3. Package insert for the Tempo platform

#### DISCUSSION OF MODIFICATION APPROVED NOVEMBER 16, 2020 (14)

The GENEAN Salmonella method successfully detected Salmonella from whole cannabis flower [10 g & 1g] and whole hemp flower (10 g & 1g) after 15 h of primary enrichment. Using POD analysis, no statistically significant differences were observed between the number of positive portions detected by the candidate method presumptive and confirmed results. No discrepant results were obtained with the validation study.

The GENE-UP Salmonella method is quick and simple to perform, providing results in less than 1.5 h post incubation of the selective enrichment for 30 sample replicates. With ready-to-use lyophilized PCR reagents, it allows the user to conduct PCR without an additional step of adding the master mix, reducing the amount of hands-on time during PCR which eliminates the chance of contamination. The GENE-UP software is user friendly with the ability to track lot information and sample identification quickly and with ease.

Matrix/Test Portion	1- n n 1	MPN=/ Test Partion	Nº	Presumptive		Confirmed					
	Inoculum			x*	PODre	95% CI	×	POO <sub>rt</sub> "	95% CI	dPOO <sub>c</sub> s*	95% CP
Whole cannabis flower (10 g)	Sa)monella	N/A'	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
	Typhimurium	0.74 (0.38, 1.28)	20	9	0.45	0.26, 0.66	9	0.45	0.26, 0.66	0.00	-0.13, 0.13
	ATCC* 14028	4.20 (1.71, 10.3)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Whole cannabis flower (1 g)	Salmonella	N/A	5	0	0.00	0.00, 0.43	C	0.00	0.00, 0.43	0.00	-0.47, 0.47
	Typhimurium	0.91 (0.50, 1.54)	20	10	0.50	0.30, 0.70	10	0.50	0.30, 0.70	0.00	-0.13, 0.13
	ATCC 14028	4.20 (1.71, 10.3)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Whole hemp flower (10 g)	Salmonello	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
	EnteritldIs	1.33 (0.86, 2.19)	20	12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.13, 0.13
	ATCC 13076	6.16 (1.91, 19.9)	5	5	1.00	0.57, 1.00	5	1.00	0.57, <b>1.00</b>	0.00	-0.47, 0.47
Whole hemp flower (1 g)	Salmonella	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
	Enteritidis	0.71 (0.41, 1.19)	20	7	0.35	0.18, 0.57	7	0.35	0.18, 0.57	0.00	-0.13, 0.13
	ATCC 13076	4.13 (1.46, 11.7)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47

MPN = Most Probable Number is calculated using the LCF MPN calculator provided by ADAC RI, with 95% confidence interval.

'N/A - Not applicable

Figure 4. Performance tested method specifications for Salmonella these are the same for STEC

<sup>•</sup>N = Number of test portions.

<sup>&#</sup>x27;x = Number of positive test portions.

<sup>&</sup>lt;sup>4</sup>POD<sub>□</sub> = Candidate method presumptive positive outcomes divided by the total number of trials. \*POO<sub>ct</sub> = Candidate method confirmed positive outcomes divided by the total number of trials.

<sup>/</sup>dPOO<sub>OF</sub> Difference between the candidate method presumptive and confirmed POO values.

<sup>955%</sup> CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

<sup>&</sup>quot;ATCC = American Type Culture Collection, Manassas, VA.

MiCROVAL Approved Protocols (2018LR84)		
Matrix	Protocol	
Raw milk products (up to 25 g or 25 mL)	<ul> <li>X g (X mL) of sample.</li> <li>9X mL of buffered peptone water (BPW).</li> <li>Mix using a paddle blender.</li> <li>Incubate at +37°C ± 1°C for 18-26 hours.</li> </ul>	

**Note:** For environmental samples, the collection device should first be dampened with a sterile diluent (for example, buffered peptone water) containing, if necessary, a suitable neutralizing agent (for example, Lecithin-Polysorbate-L. Histidine-Sodium thiosulfate mixture or Dey Engley).

Protocols Outside of Certification			
Matrix	Protocol		
Vegetables (up to 25 g <u>Ţ</u>	X g of sample.  9X mL of buffered peptone water (BPW).  Mix using a paddle blender.  Incubate at +41.5°C ± 1°C for 18-26 hours.		

Note: Incubation conditions may have repercussions on short detection procedures. The temperature conditions indicated must be scrupulously respected. In particular, ensure that the enrichment broth preheating conditions allow for me specified temperature to be reached. The sample preparation time, which is the time octween the end of the enrichment broth preheating phase and the start of the sample incubation phase, must not exceed 45 minutes. It is recommended to use a ventilated incubator for the incubation phase.

Figure 5. Package Insert for STEC

#### Nonconformance 3

420.210 (2) Except for a designated consumption establishment or temporary marihuana event licensed under the Michigan regulation and taxation of marihuana act, a marihuana business must not have any marihuana product without a batch number or identification tag or label pursuant to these rules. A licensee shall immediately tag, identify, or record as part of a batch in the statewide monitoring system any marihuana product as provided in these rules.

Deviations observed and documented include:

Viridis laboratories has marihuana product onsite without Metrc tags.

1. Dr. Chirio observed foreign matter and microbial samples without Metrc tag numbers.



Figure 6. Marihuana Product without Metrc tags.

#### Additional Observations

Deviations observed and documented include:

Viridis laboratories is not adhering to the SOP- LOM - 7. 4 Chemical Residue \_ Pesticide Analysis by LC-MS\_MS and the specific storage requirements for the chemical residue standards used.

1. During the visit to Viridis North, Dr. Fields observed laboratory scientist Ethan preparing to add samples to an existing analysis batch, an analysis batch is a group of samples, sample extracts, or sample digestates (including QC aliquots), that are analyzed together on the same instrument. The analysis batch was started the previous afternoon (10/26/21). Calibration of the instrument only occurs at the start of the testing batch. The calibration curve defines the relationship between the detector response and the concentration of analyte in the sample matrix. Dr. Fields confirmed the calibration curve and quality control checks used to quantitate the samples were prepared 10/26/2021 and were on the instrument overnight at room temperature. Prepared standards if not stored properly can cause inaccurate results. The Restek standards used come frozen and are temperature labile, keeping them on an instrument at room temperature will cause degradation. Degraded standards will cause the responses to be higher for samples since the concentrations of the analytes in the standards will be decreased. Meaning that the laboratory could inaccurately report chemical residues where there are none present or report chemical residues at higher concentrations than what is actually in the sample.

NOTE: This finding is being included on the Lansing findings as the operations were stated to be duplicated. At the time of the Lansing audit, chemical residue samples were not running, so the MRA was not able to review this method. If this same procedure is not occurring at the Lansing location, please respond to this nonconformance with documentation how the procedure differs for the Lansing location.

Oregon Cannabis Peakeide Standards meet the specific cannabis pesticiale residue analysis needs of Oregon-and states with similar pesticide residue regulational/programs. Disassived in actionist the and few middles for stability, the 50 compounds are separated into 6 is 1 int. solutions with individual analyse concentrations of 600 gy/ml. resultant on a convenient 100 gy/ml to solution when blended immediately before use. Designed with quality and convenience in mind, this set of standards eliminates the need for in-house standards representate. Results Oregon Petals leds Standards are certified reference meetable (RSM) manufactured and OC/visted in 150 accretional tales.

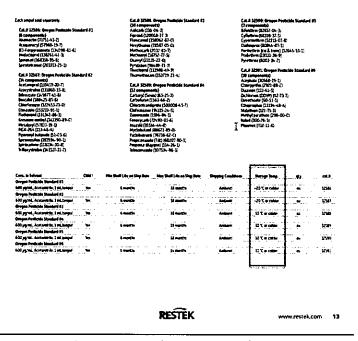


Figure 7. Restek storage conditions

### Corrective actions required to be completed ASAP listed below.

- 1. The laboratory shall immediately log this as a complaint and follow their complaint procedure QM-7.9 Complaints, Non-conforming work QM-7.10 Non-Conforming Work and Corrective action QM-8.7 Corrective Actions.
- 2. Due to the severity and public health implications for the many failures of the existing quality management system, the MRA is requesting a full regulatory audit conducted by the accrediting body or another 3<sup>rd</sup> party accreditor, the results of this audit shall be shared directly with the MRA from the auditor at the same time they are sent to the facility. The MRA would like to be present for this audit, please notify us of the date and time.
- 3. The laboratory shall immediately institute a method for tracking samples in and out of incubators. Management shall review these with the temperature logs before results are reported to ensure accurate results in compliance with their QM-7.7 Ensuring the validity of results SOP.
- 4. The laboratory shall immediately institute continuous temperature monitoring for all incubators and update their current environmental monitoring SOP-QM 6.3 Facilities and Environmental Conditions to include monitoring incubators.
- 5. The laboratory shall immediately revise current temperature logs to include the method specific ranges and corrective actions. At no such time should microbial results be reported if the temperature is outside of the acceptable validated ranges or if the samples have not been incubated within the acceptable timeframes found in the specific method package inserts.
- 6. The laboratory shall immediately assign a manager to review temperature logs, logs shall be signed and dated when reviewed, this should be added to the management review SOP QM-8.9 Management Reviews.
- 7. The laboratory shall compile a list of ALL nonconforming samples and immediately provide the list to the agency. The laboratory should do a look back on all previously reported microbial testing and qualify results where they cannot demonstrate appropriate incubation time.
- 8. The laboratory shall provide all PCR run data directly from the instrument for all microbial methods from 8/10/2021 to current.
- 9. The laboratory shall immediately conduct a thorough root cause analysis for the nonconformances identified in this report and provide all documents to the MRA.
- 10. The laboratory shall immediately correct the foreign matter results of sample 26182 Metrc last 4 digits 4884 to failing. Once this is completed, please send email notification to MRA-SCF@michigan.gov and the hold will be removed.
- 11. The laboratory shall immediately do a look back on samples in current inventory which have been passed for foreign matter and shall repeat the inspection following the approved SOP and additional training provided to staff from Claire Patterson during the Viridis North audit 10/27/2021, Michael Laframboise was present and should be lead on retraining all staff at both locations.
- 12. If non-conforming foreign matter samples are identified, the laboratory will update all test results in Metrc and provide a list of all samples.
- 13. Immediately, Viridis laboratories needs to label marihuana product with the full Metrc tag number assigned in the statewide monitoring system. The only marihuana product onsite that

does not require a Metrc tag number would be any compliantly obtained patient/caregiver material. This finding was observed during the December 2020 semi-annual inspection for Viridis North where Michele Glinn was present and has not been corrected, this needs to be corrected immediately.

14. The MRA is requesting a copy of all complaints and CAPAs for the last year to ensure there are no additional areas of concern.

# **EXHIBIT H**



GRETCHEN WHITMER
GOVERNOR

# STATE OF MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS LANSING

ORLENE HAWKS DIRECTOR

November 15, 2021

Viridis Laboratories North, LLC-SC-000014/AU-SC-000103 1424 Straits Dr, Bay City, 48706-8705, MI Date of Audit: 10/27/2021 Compliance Monitoring Tier 4

#### **Onsite Audit Findings**

Auditors: Dr. Noah Rosenzweig, Dr. Patrice Fields, Dr. Allyson Chirio & Claire Patterson

Dear Viridis Laboratories North, LLC,

An onsite compliance audit was conducted at your facility on 10/27/2021, several non-conformances were identified. The nonconformances are listed below.

#### Nonconformance 1

R. 420.305 (1) A laboratory shall do all of the following: (b) Maintain internal standard operating procedures for the required safety tests in subrule (3) of this rule and for sampling of marihuana and marihuana products that conform to ISO/IEC 17025:2017 standards and have been approved by the agency.

R. 420.305 (1) (c) Maintain a quality control and quality assurance program that conforms to ISO/IEC 17025:2017 standards and meets the requirements established by the agency.

R. 420.305(2) A laboratory shall use analytical testing methodologies for the required safety tests in subrule (3) of this rule that are validated by an independent third party and may be monitored on an ongoing basis by the agency or a third party. In the absence of reference to compendia or published methods, Appendix K of Official Methods of Analysis authored by the Association of Official Analytical Chemists must be published in full. The agency shall approve the validated methodology used by the laboratory and confirm that it produces scientifically accurate results for each safety test it conducts.

Laboratory technicians are not following approved foreign matter SOP - LOM - 7. 11 Foreign Matter Analysis and Photographic Imaging. Laboratory is not failing samples which exceed the 2% action limit.

Deviations observed and documented include:

- 1. Dr. Chirio, Dr. Rosenzweig, Dr. Fields and Claire Patterson all observed samples viewed at only minimal magnification. LSS Chirio did not observe the technician use the dinoscope for higher power viewing for pests, powdery mildew and other organic matter that is not visible on low magnification.
- 2. Dr. Chirio asked Laboratory Manager Michael LaFramboise several questions related to foreign matter, and he was unable to answer specifics but is the supervisor who would confirm the presence of foreign matter. Dr Chirio specifically asked Manager Michael LaFramboise at which power are the technicians viewing samples, she also asked both technicians performing the inspections, none of the staff were able to answer the question. After the finding conference the objective power was determined to be 40x, this is minimal magnification and most foreign matter would not be visualized. The SOP states that staff will review on low power determined to be 40x and then additionally on higher power of at least 100x.
- 3. Dr. Chirio asked the technicians if they view samples using the higher power magnification and the technicians said they only use the higher power for taking photographs of the product.
- 4. Claire Patterson reviewed a sample which contained powdery mildew while onsite, she spent time with the staff showing them powdery mildew and assisting them with being able to identify foreign matter, Manager Michael LaFramboise was present during the short training.



Figure 1. Technician setup for foreign matter under low power

#### Nonconformance 2

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#### Deviations observed and documented include:

Viridis laboratories North is not adhering to the method specifications. Sample incubation times are not tracked, the laboratory could not provide documentation that the methods were performed as validated.

- 1. Dr. Rosenzweig asked Bradley Phelps, while observing him prepping samples for incubation if he had a workorder/worksheets/plate map to ensure chain of custody of samples through the testing process for sample tracking but was not provided one. When asked again how samples were tracked Brandon Lucius responded, "I just have a system".
- 2. Viridis laboratories North is not tracking when samples are placed in incubators or removed from incubators. There is no way for the MRA to know if samples have been incubated the appropriate length of time. Viridis Laboratories North could not provide documentation that samples were incubated the minimum length and did not exceed the maximum length.
- 3. According to SOP-QM 6.3 Facilities and Environmental Conditions "Viridis Laboratories monitors, controls, and records environmental conditions as required by relevant specifications, methods, or procedures or where they may influence the quality of the results."
- 4. During the ISO accreditation audit completed 09/13/2021, Viridis North Laboratories received a deficiency stating the following "The laboratory could not produce records of verification of temperatures in the four different incubators required for its microbial procedures. One incubator did not have a temperature-measuring device in place." Please refer to Figure 1.
- 5. All samples reported when temperatures were not being tracked 8/10/2021-9/14/2021 are non-conforming samples and corrective action should have been taken in compliance with laboratory procedures. As the MRA has not received a list of samples or notification of the nonconformances, it is assumed that the corrective action procedures were not adhered to for these samples. If corrective action procedures were adhered to, please provide those to the MRA as soon as possible.



Figure 2. ISO accreditation audit findings

#### Nonconformance 3

420.210 (2) Except for a designated consumption establishment or temporary marihuana event licensed under the Michigan regulation and taxation of marihuana act, a marihuana business must not have any marihuana product without a batch number or identification tag or label pursuant to these rules. A licensee shall immediately tag, identify, or record as part of a batch in the statewide monitoring system any marihuana product as provided in these rules.

R. 420.305 (1) (c) Maintain a quality control and quality assurance program that conforms to ISO/IEC 17025:2017 standards and meets the requirements established by the agency.

Deviations observed and documented include:

Viridis laboratories North has marihuana product onsite without Metrc tags.

1. Dr. Chirio observed foreign matter and microbial samples without Metrc tag numbers.



Figure 3. Marihuana Product without Metrc tags.

#### Nonconformance 4

R. 420.305 (1) (c) Maintain a quality control and quality assurance program that conforms to ISO/IEC 17025:2017 standards and meets the requirements established by the agency.

Deviations observed and documented include:

Viridis laboratories North has a biochemical hood in use for microbial sample preparation with an expired calibration. This is not in compliance with SOP-6.3 Facilities and Environmental Conditions.

1. Dr. Chirio observed the expired calibration listed below as figure 3.

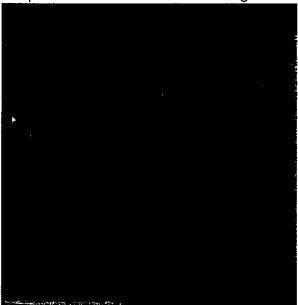


Figure 4. Compliance sticker for biochemical hood in use

#### Additional Observations

Deviations observed and documented include:

Viridis laboratories North is not adhering to the SOP-LOM - 7. 4 Chemical Residue \_ Pesticide Analysis by LC-MS\_MS and the specific storage requirements for the chemical residue standards used.

1. During the visit to Viridis North, Dr. Fields observed laboratory scientist Ethan preparing to add samples to an existing analysis batch, an analysis batch is a group of samples, sample extracts, or sample digestates (including QC aliquots), that are analyzed together on the same instrument. The analysis batch was started the previous afternoon (10/26/21). Calibration of the instrument only occurs at the start of the testing batch. The calibration curve defines the relationship between the detector response and the concentration of analyte in the sample

matrix. Dr. Fields confirmed the calibration curve and quality control checks used to quantitate the samples were prepared 10/26/2021 and were on the instrument overnight at room temperature. Prepared standards if not stored properly can cause inaccurate results. The Restek standards used come frozen and are temperature labile, keeping them on an instrument at room temperature will cause degradation. Degraded standards will cause the responses to be higher for samples since the concentrations of the analytes in the standards will be decreased. Meaning that the laboratory could inaccurately report chemical residues where there are none present or report chemical residues at higher concentrations than what is actually in the sample.

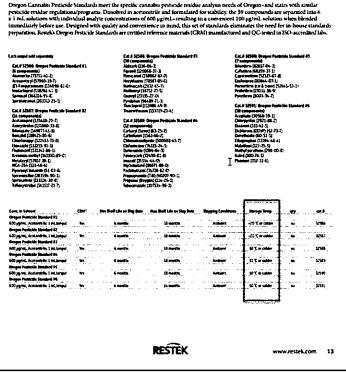


Figure 5. Restek storage conditions

#### Corrective actions required to be completed ASAP listed below.

- 1. The laboratory shall immediately log this as a complaint and follow their complaint procedure QM-7.9 Complaints, Non-conforming work QM-7.10 Non-Conforming Work and Corrective action QM-8.7 Corrective Actions.
- 2. Due to the severity and public health implications for the many failures of the existing quality management system, the MRA is requesting a full regulatory audit conducted by the accrediting body or another 3<sup>rd</sup> party accreditor, the results of this audit shall be shared directly with the

MRA from the auditor at the same time they are sent to the facility. The MRA would like to be present for this audit, please notify us of the date and time.

- 3. The laboratory shall immediately institute a method for tracking samples in and out of incubators. Management shall review these with the temperature logs before results are reported to ensure accurate results in compliance with their QM-7.7 Ensuring the validity of results SOP.
- 4. The laboratory shall immediately institute continuous temperature monitoring for all incubators and update their current environmental monitoring SOP-QM 6.3 Facilities and Environmental Conditions to include monitoring incubators.
- 5. The laboratory shall immediately revise current temperature logs to include the method specific ranges and corrective actions. At no such time should microbial results be reported if the temperature is outside of the acceptable validated ranges or if the samples have not been incubated within the acceptable timeframes found in the specific method package inserts.
- 6. The laboratory shall immediately assign a manager to review temperature logs, logs shall be signed and dated when reviewed, this should be added to the management review SOP QM-8.9 Management Reviews.
- 7. The laboratory shall compile a list of ALL nonconforming TYM samples and immediately provide the list to the agency. The laboratory should do a look back on all previously reported microbial testing and qualify results where they cannot demonstrate appropriate incubation time.
- 8. The laboratory shall provide all PCR run data directly from the instrument for all microbial methods from 8/10/2021 to current.
- 9. The laboratory shall immediately conduct a thorough root cause analysis for the nonconformances identified in this report and provide all documents to the MRA.
- 10. The laboratory shall immediately do a look back on samples in current inventory which have been passed for foreign matter and shall repeat the inspection following the approved SOP and additional training provided to staff from Claire Patterson during the Viridis North audit 10/27/2021, Michael Laframboise was present and should be lead on retraining all staff at both locations.
- 11. If non-conforming foreign matter samples are identified, the laboratory will update all test results in Metrc and provide a list of all samples.
- 12. Immediately Viridis laboratories needs to label marihuana product with the full Metrc tag number assigned in the statewide monitoring system. The only marihuana product onsite that does not require a Metrc tag number would be any compliantly obtained patient/caregiver material. This finding was observed during the December 2020 semi-annual inspection and has not been corrected, this needs to be corrected immediately.
- 13. The MRA is request all complaints and CAPAs for the last year to ensure there are no other issues that have been missed by the failures to the quality systems.
- 14. To protect the health of staff, the biochemical hood used for microbial testing will immediately need servicing to bring the expired certification current.

# **EXHIBIT I**

# Schumacher, Brandon

From: Sent:

Blair, Kevin M. <KBlair@honigman.com> Thursday, November 18, 2021 7:32 PM

To: Kluytman, Julie (LARA); Michele Glinn; Patterson, Claire (LARA); Gregoire Michaud; Todd

Welch; Russell, David; Michael LaFramboise; Mitchell, Desmond (LARA)

**Subject:** RE: Audit follow up

Julie,

This is so incredibly frustrating. I really thought we had turned a corner. Everyone was professional on the Teams meeting and we had what we thought was a productive discussion. But somehow we fell for yet another bait and switch. I promise not to ever surreptitiously record our conversations without your consent, but maybe we should agree to record future conversations so there are no misunderstandings? Because I'm fairly certain no one ever said that Viridis has to complete everything on a list we hadn't even seen yet before resuming testing. You said that there were "more details" on Claire's list that needed to be addressed sometime soon, but the bolded agenda items were all that need to happen before testing resumes. Your response below doesn't even make sense. The whole purpose of that Teams meeting was to go over what needs to happen before testing resumes, and your agenda says "The MRA would expect the items in bold would be corrected prior to resuming testing in those specific areas of concern." So why not share the longer list ahead of the meeting? I had to specifically request it and then you rushed us to end the meeting before we realized that the highlighted list is longer and includes some items that cannot possibly be completed in less than a few days at least. Again, you are effectively shutting down Viridis but deliberately not following the established procedures to do so.

Specifically, I am asking about the items that are impossible to complete by tomorrow morning and whether Viridis is approved to begin testing by showing significant compliance with your arbitrary list. As a regulatory agency, clear communication is paramount and you and your colleagues have purposely continued to speak in vague terms. The MRA represented yesterday that after the logs were approved that Viridis could start testing again. We spent the entire day yesterday going back-and-forth on that single point with no mention of these items other than stating we would have a meeting to discuss on Monday. This morning, you moved the goal posts and immediately put holds on all Viridis items despite your representations. Your actions not only to continue to severely damage Viridis, but also its customers, which has created chaos in the industry. These actions do not further the public health and safety in any way.

Kevin M. Blair

HONIGMAN LLP O 517.377.0716 kblair@honigman.com

From: Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>

Sent: Thursday, November 18, 2021 5:39 PM

**To:** Blair, Kevin M. <KBlair@honigman.com>; Michele Glinn <mglinn@viridisgrp.com>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Gregoire Michaud <gmichaud@viridisgrp.com>; Todd Welch <twelch@viridisgrp.com>; drussell@fosterswift.com; Michael LaFramboise <mlaframboise@viridisgrp.com>; Mitchell, Desmond (LARA)

<MitchellD6@michigan.gov>
Subject: RE: Audit follow up

[EXTERNAL EMAIL]

Kevin,

The agenda states the bold items are a short summary of the corrective actions mentioned in the audit findings. I would not detail all the specific items needed from Claire's corrective action document in an agenda. This was explained in the meeting and the bold items correlate to the audit findings that were provided.

Julie Kluytman, Enforcement Division Director Marijuana Regulatory Agency kluytmanj@michigan.gov

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To: Michele Glinn < mglinn@viridisgrp.com >; Patterson, Claire (LARA) < PattersonC8@michigan.gov >; Gregoire Michaud < michaud@viridisgrp.com >; Todd Welch < twelch@viridisgrp.com >; drussell@fosterswift.com; Michael LaFramboise < mlaframboise@viridisgrp.com >; Mitchell, Desmond (LARA) < MitchellD6@michigan.gov >; Kluytman, Julie (LARA)

< <u>KluytmanJ@michigan.gov</u>>; Patterson, Claire (LARA) < <u>PattersonC8@michigan.gov</u>>

Subject: RE: Audit follow up

# CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

[Removed Kevin King]

Julie and Claire -

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Here is a link to the devices we will order right now. Please confirm this is what you meant. Thank you.

https://www.avogadro-lab-supply.com/products/certified-digital-incubator-thermometer-50-to-70-c-cert-37%C2%BAc?variant=34426410959003&currency=USD&utm\_medium=product\_sync&utm\_source=google&utm\_content=sag\_organic&utm\_campaign=sag\_organic&gclid=Cj0KCQiAkNiMBhCxARIsAIDDKNWDLSAbGAHqW\_Ec1r1Sc-8Lk10UeQbmR320lubhJumkHkMx2dRCSigaAliKEALw\_wcB

Kevin M. Blair	
HONIGMAN LLP O 517.377.0716	

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Sent:

Thursday, November 18, 2021 8:39 PM

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Blair, Kevin M.; Michele Glinn; Patterson, Claire (LARA); Gregoire Michaud; Todd Welch;

Russell, David; Michael LaFramboise; Mitchell, Desmond (LARA)

Subject:

RE: Audit follow up

**Attachments:** 

Viridis Agenda (002).docx

### Kevin,

I am attaching the same agenda that was provided for the meeting, however I have "cut and pasted" directly from Claire's document where the items correlate to the agenda items as they were listed and I have highlighted the terms I used in the agenda so you can understand how I developed the agenda based on the more comprehensive document. To my knowledge, this is typically how agendas are created as they are intended to be lists of focal points for conversation and they don't typically include full conversations or documents.

I recall specifically addressing this in the meeting as Michele asked a question about the PCR and the TYM samples list because they were grouped together. I had placed them together for the agenda because I thought they were of the same topic but it was pointed out that there was some difference. Which is when we clarified again that Claire's document would provide more details and that I had placed these items together for the agenda.

Please let me know if there are any additional questions you have related to the requirements.

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To: Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Michele Glinn <mglinn@viridisgrp.com>; Patterson, Claire

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drussell@fosterswift.com; Michael LaFramboise <mlaframboise@viridisgrp.com>; Mitchell, Desmond (LARA)

< MitchellD6@michigan.gov > Subject: RE: Audit follow up

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Julie Kluytman, Enforcement Division Director Marijuana Regulatory Agency kluytmani@michigan.gov

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< <u>KluytmanJ@michigan.gov</u>>; Patterson, Claire (LARA) < <u>PattersonC8@michigan.gov</u>>

Subject: RE: Audit follow up

November 18, 2021

### Agenda:

Meeting with Viridis and Viridis North

Purpose: Discuss Audit Finding Results and MRA Expectations

Audit Findings that require Corrective Action:

- Log this complaint
- Full audit by accrediting body and the MRA
- The laboratory shall immediately institute a method for tracking samples in and out of ALL incubators.
- Temperature monitoring, revise temperature log, temperature log review
- Nonconforming TYM samples list and PCR run data provided to the agency
- Root cause analysis
- Nonconforming foreign matter samples
- Label products appropriately
- Copy of all complaints sent to MRA

The items listed above are a short summary of the corrective actions mentioned in the audit findings. The MRA would expect the items in bold would be corrected prior to resuming testing in those specific areas of concern.

# Schumacher, Brandon

From:

Blair, Kevin M. <KBlair@honigman.com>

Sent:

Thursday, November 18, 2021 5:12 PM

To:

Michele Glinn; Patterson, Claire (LARA); Gregoire Michaud; Todd Welch; Russell, David;

Michael LaFramboise; Mitchell, Desmond (LARA); Kluytman, Julie (LARA); Patterson,

Claire (LARA)

Subject:

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Kevin M. Blair

HONICMANIII

HONIGMAN LLP
O 517.377.0716
kblair@honigman.com

From: Michele Glinn <mglinn@viridisgrp.com>
Sent: Thursday, November 18, 2021 4:21 PM
To: Blair, Kevin M. <KBlair@honigman.com>

Subject: Fw: Audit follow up

[EXTERNAL EMAIL]

See below.

Best Regards,

Michele A. Glinn, PhD, F-ABFT Chief Science Officer/Founder E: mglinn@viridisgrp.com



From: Patterson, Claire (LARA) < Patterson C8@michigan.gov>

Sent: Thursday, November 18, 2021 4:16 PM

To: Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>; Todd Welch

<twelch@viridisgrp.com>; Kevin King <kevin@dragonflymichigan.com>; drussell@fosterswift.com

<drussell@fosterswift.com>; Michael LaFramboise <mlaframboise@viridisgrp.com>

Cc: Mitchell, Desmond (LARA) < MitchellD6@michigan.gov>; Kluytman, Julie (LARA) < KluytmanJ@michigan.gov>

Subject: Audit follow up

Please see attached.

### Claire Patterson

Manager, Scientific & Legal Section Enforcement Division Marijuana Regulatory Agency

(517) 230-2097 PattersonC8@michigan.gov www.michigan.gov/MRA



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[Removed Kevin King]

Julie and Claire -

I believe you said and confirmed a few times on our Teams meeting just now that Viridis can resume microbial testing as soon as they complete the bolded items from Julie's agenda. Then the document Claire sent says everything highlighted has to be completed before testing resumes. That's exactly why I asked to see Claire's list before we logged off the meeting so there's no confusion about what needs to happen before testing resumes. One example is 4a that says Viridis must "[o]btain continuous, digital data monitoring devices for all incubators." Some of Viridis' incubators already have these, but some do not. We will order them tonight and pay for rush shipping, and provide proof of purchase. Can Viridis please resume testing once all the bolded items from Julie's agenda are completed as you repeatedly said on the Teams meeting, and we will provide proof that we're doing the rest of the highlighted list as fast as possible?

Here is a link to the devices we will order right now. Please confirm this is what you meant. Thank you.

https://www.avogadro-lab-supply.com/products/certified-digital-incubator-thermometer-50-to-70-c-cert-37%C2%BAc?variant=34426410959003&currency=USD&utm\_medium=product\_sync&utm\_source=google&utm\_content=sag\_organic&utm\_campaign=sag\_organic&gclid=Cj0KCQiAkNiMBhCxARIsAIDDKNWDLSAbGAHqW\_Ec1r1Sc-8Lk10UeQbmR320lubhJumkHkMx2dRCSigaAliKEALw\_wcB

# Schumacher, Brandon

From: Blair, Kevin M. < KBlair@honigman.com> Sent: Thursday, November 18, 2021 7:32 PM

To:

Kluytman, Julie (LARA); Michele Glinn; Patterson, Claire (LARA); Gregoire Michaud; Todd

Welch; Russell, David; Michael LaFramboise; Mitchell, Desmond (LARA)

Subject: RE: Audit follow up

Julie,

This is so incredibly frustrating. I really thought we had turned a corner. Everyone was professional on the Teams meeting and we had what we thought was a productive discussion. But somehow we fell for yet another bait and switch. I promise not to ever surreptitiously record our conversations without your consent, but maybe we should agree to record future conversations so there are no misunderstandings? Because I'm fairly certain no one ever said that Viridis has to complete everything on a list we hadn't even seen yet before resuming testing. You said that there were "more details" on Claire's list that needed to be addressed sometime soon, but the bolded agenda items were all that need to happen before testing resumes. Your response below doesn't even make sense. The whole purpose of that Teams meeting was to go over what needs to happen before testing resumes, and your agenda says "The MRA would expect the items in bold would be corrected prior to resuming testing in those specific areas of concern." So why not share the longer list ahead of the meeting? I had to specifically request it and then you rushed us to end the meeting before we realized that the highlighted list is longer and includes some items that cannot possibly be completed in less than a few days at least. Again, you are effectively shutting down Viridis but deliberately not following the established procedures to do so.

Specifically, I am asking about the items that are impossible to complete by tomorrow morning and whether Viridis is approved to begin testing by showing significant compliance with your arbitrary list. As a regulatory agency, clear communication is paramount and you and your colleagues have purposely continued to speak in vague terms. The MRA represented yesterday that after the logs were approved that Viridis could start testing again. We spent the entire day yesterday going back-and-forth on that single point with no mention of these items other than stating we would have a meeting to discuss on Monday. This morning, you moved the goal posts and immediately put holds on all Viridis items despite your representations. Your actions not only to continue to severely damage Viridis, but also its customers, which has created chaos in the industry. These actions do not further the public health and safety in any way.

Kevin M. Blair

**HONIGMAN LLP** 

O 517.377.0716 kblair@honigman.com

From: Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>

Sent: Thursday, November 18, 2021 5:39 PM

To: Blair, Kevin M. <KBlair@honigman.com>; Michele Glinn <mglinn@viridisgrp.com>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Gregoire Michaud <gmichaud@viridisgrp.com>; Todd Welch <twelch@viridisgrp.com>; drussell@fosterswift.com; Michael LaFramboise <mlaframboise@viridisgrp.com>; Mitchell, Desmond (LARA)

<MitchellD6@michigan.gov> Subject: RE: Audit follow up

[EXTERNAL EMAIL]

#### Kevin,

The agenda states the bold items are a short summary of the corrective actions mentioned in the audit findings. I would not detail all the specific items needed from Claire's corrective action document in an agenda. This was explained in the meeting and the bold items correlate to the audit findings that were provided.

Julie Kluytman, Enforcement Division Director Marijuana Regulatory Agency kluytmanj@michigan.gov

From: Blair, Kevin M. < KBlair@honigman.com > Sent: Thursday, November 18, 2021 5:12 PM

To: Michele Glinn < <a href="mailto:mglinn@viridisgrp.com">mglinn@viridisgrp.com</a>; Patterson, Claire (LARA) < <a href="mailto:PattersonC8@michigan.gov">PattersonC8@michigan.gov</a>; Gregoire Michaud <a href="mailto:mglinn@viridisgrp.com">mglinn@viridisgrp.com</a>; Todd Welch <a href="mailto:twelch@viridisgrp.com">twelch@viridisgrp.com</a>; drussell@fosterswift.com; Michael LaFramboise <a href="mailto:mglinn@viridisgrp.com">mglinn@viridisgrp.com</a>; Mitchell, Desmond (LARA) <a href="mailto:MitchellD6@michigan.gov">MitchellD6@michigan.gov</a>; Kluytman, Julie (LARA)

< KluytmanJ@michigan.gov >; Patterson, Claire (LARA) < PattersonC8@michigan.gov >

Subject: RE: Audit follow up

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[Removed Kevin King]

Julie and Claire -

I believe you said and confirmed a few times on our Teams meeting just now that Viridis can resume microbial testing as soon as they complete the bolded items from Julie's agenda. Then the document Claire sent says everything highlighted has to be completed before testing resumes. That's exactly why I asked to see Claire's list before we logged off the meeting so there's no confusion about what needs to happen before testing resumes. One example is 4a that says Viridis must "[o]btain continuous, digital data monitoring devices for all incubators." Some of Viridis' incubators already have these, but some do not. We will order them tonight and pay for rush shipping, and provide proof of purchase. Can Viridis please resume testing once all the bolded items from Julie's agenda are completed as you repeatedly said on the Teams meeting, and we will provide proof that we're doing the rest of the highlighted list as fast as possible?

Here is a link to the devices we will order right now. Please confirm this is what you meant. Thank you.

https://www.avogadro-lab-supply.com/products/certified-digital-incubator-thermometer-50-to-70-c-cert-37%C2%BAc?variant=34426410959003&currency=USD&utm\_medium=product\_sync&utm\_source=google&utm\_content=sag\_organic&utm\_campaign=sag\_organic&gclid=Cj0KCQiAkNiMBhCxARIsAIDDKNWDLSAbGAHqW\_Ec1r1Sc-8Lk10UeQbmR320lubhJumkHkMx2dRCSigaAliKEALw\_wcB

Κe	evin M. Blair	
	ONIGMAN LLP 517.377.0716	

From: Kevin King [mailto:kevin@dragonflymichigan.com]

Sent: Thursday, November 18, 2021 4:19 PM

**To:** Patterson, Claire (LARA)

Cc: Gregoire Michaud; Michele Glinn; Todd Welch; Russell, David; Michael LaFramboise; Mitchell,

Desmond (LARA); Kluytman, Julie (LARA)

Subject: Re: Audit follow up

I believe this was sent to me in error. Is that confirmed?

Regards,

Kevin King
Director of Laboratory Operations
Dragonfly Kitchen II Inc | 26980 County Road 215 | Bangor, MI 49013
C: 708.846.4272
www.dragonflymichigan.com
Kevin@dragonflymichigan.com

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On Thu, Nov 18, 2021 at 4:16 PM Patterson, Claire (LARA) < <u>PattersonC8@michigan.gov</u>> wrote:

Please see attached.

# Claire Patterson

Manager, Scientific & Legal Section

**Enforcement Division** 

Marijuana Regulatory Agency

(517) 230-2097

PattersonC8@michigan.gov

www.michigan.gov/MRA



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## Schumacher, Brandon

From: Schumacher, Brandon

Sent: Monday, November 22, 2021 1:29 PM

To: 'Mains, Douglas E.'; Blair, Kevin M.; Garrison, Emily E.; Russell, David

**Subject:** FW: Follow up & Summary of test results & Draft Recall Bulletin

## Brandon M. H. Schumacher

Attorney Foster Swift Collins & Smith PC 313 South Washington Square Lansing, MI 48933-2193 Office Direct: 517.371.8255

Cell: 517.420.5741

Assistant: Sharla Clements: 517.371.8188

Fax: 517.367.7167

bschumacher@fosterswift.com

www.fosterswift.com

## **FOSTER SWIFT**

From: Russell, David

Sent: Wednesday, November 17, 2021 4:46 PM

To: Schumacher, Brandon

Subject: FW: Follow up & Summary of test results & Draft Recall Bulletin

## David R. Russell

Attorney
Foster Swift Collins & Smith PC
313 S. Washington Square
Lansing, MI 48933
Phone: 517.371.8150
Fax: 517.367.7150
drussell@fosterswift.com

drussell@fosterswift.com www.fosterswift.com

## **FOSTER SWIFT**

**From:** MCINTYRE Maria [mailto:maria.mcintyre@biomerieux.com]

Sent: Wednesday, November 17, 2021 4:03 PM

To: Russell, David; 'Mitchell, Desmond (LARA)'; Blair, Kevin M.

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully,

Risa (AG); Mark Fisk (mfisk@byrumfisk.com); consulting@pmbbiotek.com; MILLS John

Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

Adding John Mills to the conversation.

1. Methods utilized have AOAC approval. This data collection usually includes robustness data that may or may not be a change in temperature. Please know, we are working to confirm if this data is available from

- the work for AOAC. This may take time to capture as I am collaborating with John Mills- Scientific Affairs Manager and Dr. Ron Johnson- former AOAC President.
- ISO 17025 accreditation impacts the discussion as ISO sets the benchmark for the quality standards within
  accredited laboratories. If a recall is generated under these circumstances it's a reflection of a gap in ISO
  accreditation and does not relate to AOAC or the method itself. The lab has completed training on the
  method reflected in the training certificates and demonstrated via the ISO 17025 accreditation process.
- 3. When there is uncertainty in results either retesting or confirmation testing generally holds greater value than a multi-lab study. In such a study, there are many variable in the equation leading to variability.
- 4. The iso files have been reviewed and the assay appears to be running properly. The files have been transferred to the R&D team who created this assay for a 2<sup>nd</sup> opinion and to determine if other areas require addressing.

Kind regards, Maria

Maria McIntyre 425-275-8013

From: Russell, David <DRussell@fosterswift.com> Sent: Wednesday, November 17, 2021 11:59 AM

To: 'Mitchell, Desmond (LARA)' < Mitchell D6@michigan.gov>; Blair, Kevin M. < KBlair@honigman.com>

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson,

Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk

(mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com; MCINTYRE Maria

<maria.mcintyre@biomerieux.com>

Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

You don't often get email from drussell@fosterswift.com. Learn why this is important

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Desmond – I would ask for just a few more minutes. We have spoken with both Ms. McIntyre and Mr. Bird and they are working on sending those now. Thanks.

## David R. Russell

Attorney
Foster Swift Collins & Smith PC
313 S. Washington Square
Lansing, MI 48933
Phone: 517.371.8150
Fax: 517.367.7150
drussell@fosterswift.com
www.fosterswift.com

## **FOSTER SWIFT**

From: Mitchell, Desmond (LARA) [mailto:MitchellD6@michigan.gov]

Sent: Wednesday, November 17, 2021 1:48 PM

To: Blair, Kevin M.; Russell, David

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully,

Risa (AG); Mark Fisk (<u>mfisk@byrumfisk.com</u>); <u>consulting@pmbbiotek.com</u> **Subject:** RE: Follow up & Summary of test results & Draft Recall Bulletin

## Kevin.

I can't wait until tomorrow. I'll give you until 3 pm. Also, you're aware that the absence of the logs is only part of the issue.

Desmond Mitchell, Operations Director Marijuana Regulatory Agency Department of Licensing and Regulatory Affairs

Telephone: (517) 243-9463 Email: mitchelld6@michigan.gov

From: Blair, Kevin M. < KBlair@honigman.com > Sent: Wednesday, November 17, 2021 1:39 PM

To: Mitchell, Desmond (LARA) < Mitchell D6@michigan.gov>; Russell, David < DRussell@fosterswift.com>

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson.

Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk

(mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com

Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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## Desmond -

You said repeatedly yesterday that the absence of logs alone would not justify a recall. You pointed to the test results as the primary basis for warranting a recall. But recall that there are no test results at all related to Viridis North's results. At a minimum, Viridis North should be carved out of this recall. They are a separate licensee, with different ownership, and there is no reason they should get swept into this crippling recall just because their name also includes the word "Viridis."

Also, we are doing all we can to reconnect with Mr. Bird and Ms. McIntyre to get statements from them. They are tied up in other meetings and we haven't been able to reach them, but again, Mr. Bird has been copied on all these emails and we're confident that we have not misrepresented his views. We are asking that you give us until 8:30 tomorrow to get those statements. The stakes here couldn't be any higher, and we urge you not to rush forward with this simply because these folks weren't instantaneously available to drop everything and write statements.

Kevin

Kevin M. Blair

HONIGMAN LLP O 517.377.0716 kblair@honigman.com From: Mitchell, Desmond (LARA) < MitchellD6@michigan.gov>

Sent: Wednesday, November 17, 2021 12:52 PM

To: Russell, David < DRussell@fosterswift.com >; Blair, Kevin M. < KBlair@honigman.com >

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson,

Claire (LARA) < Patterson C8@michigan.gov >; Hunt-Scully, Risa (AG) < HuntScully R@michigan.gov >; Mark Fisk

(<u>mfisk@byrumfisk.com</u>) < <u>mfisk@byrumfisk.com</u>>; <u>consulting@pmbbiotek.com</u>

Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

## [EXTERNAL EMAIL]

Have them submit those exact statements to me in writing and I'll consider discussing it further.

Also, that's not evidence my staff leaked it.

Desmond Mitchell, Operations Director Marijuana Regulatory Agency Department of Licensing and Regulatory Affairs

Telephone: (517) 243-9463 Email: mitchelld6@michigan.gov

From: Russell, David <<u>DRussell@fosterswift.com</u>> Sent: Wednesday, November 17, 2021 12:45 PM

To: Mitchell, Desmond (LARA) < Mitchell D6@michigan.gov >; Blair, Kevin M. < KBlair@honigman.com >

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson,

Claire (LARA) < PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) < HuntScullyR@michigan.gov>; Mark Fisk

(mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com

Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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## Desmond,

I know Kevin is driving, and this is extremely important, so I want to respond immediately. We have Mr. Bird, copied on this e-mail, and Marie McIntyre from bioMeriux that support our position that this recall is not appropriate. We are not sure how there could be any other explanation than retaliation when you have Mr. Bird stating this recall is inappropriate and Ms. McIntrye from the manufacturer of the platform stating that these retests do not support your position and yet the MRA insists on moving forward. We would ask to at least have the opportunity to get everyone on a call to discuss. The stakes are way too big here to risk a miscommunication that you suggest in your e-mail below. Please remember that Mr. Bird has been copied on all of these e-mails. This will destroy Viridis.

We certainly have evidence that there are leaks. There a people that knew the August 10<sup>th</sup> start date from your recall notice, which is not public information, early this morning.

Please let me know if we can set up a call.

#### Dave

David R. Russell

Attorney Foster Swift Collins & Smith PC 313 S. Washington Square Lansing, MI 48933 Phone: 517.371.8150

Fax: 517.367.7150 drussell@fosterswift.com www.fosterswift.com

## **FOSTER SWIFT**

From: Mitchell, Desmond (LARA) [mailto:MitchellD6@michigan.gov]

Sent: Wednesday, November 17, 2021 12:24 PM

To: Blair, Kevin M.

Cc: Russell, David; <a href="mailto:gmichaud@viridisgrp.com">gmichaud@viridisgrp.com</a>; <a href="mailto:mglinn@viridisgrp.com">mglinn@viridisgrp.com</a>; <a href="mailto:Kluytman">Kluytman</a>, Julie (LARA); <a href="mailto:Patterson">Patterson</a>, Claire (LARA);

Hunt-Scully, Risa (AG); Mark Fisk (mfisk@byrumfisk.com); consulting@pmbbiotek.com

Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

Kevin,

As I've repeatedly stated, no one at the MRA is angry with Viridis. We're just following through with our regulatory responsibilities.

As far as your allegation about staff leaking information regarding the recall, do you have any evidence to support it?

Desmond Mitchell, Operations Director Marijuana Regulatory Agency Department of Licensing and Regulatory Affairs

Telephone: (517) 243-9463 Email: mitchelld6@michigan.gov

From: Blair, Kevin M. < KBlair@honigman.com > Sent: Wednesday, November 17, 2021 12:17 PM

To: Mitchell, Desmond (LARA) < MitchellD6@michigan.gov >

**Cc:** Russell, David <<u>DRussell@fosterswift.com</u>>; <u>gmichaud@viridisgrp.com</u>; <u>mglinn@viridisgrp.com</u>; <u>Kluytman</u>, Julie (LARA) <<u>KluytmanJ@michigan.gov</u>>; Patterson, Claire (LARA) <<u>PattersonC8@michigan.gov</u>>; Hunt-Scully, Risa (AG) <<u>HuntScullyR@michigan.gov</u>>; Mark Fisk (<u>mfisk@byrumfisk.com</u>) <<u>mfisk@byrumfisk.com</u>>; <u>consulting@pmbbiotek.com</u>

Subject: Re: Follow up & Summary of test results & Draft Recall Bulletin

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I'm begging you to please get on teams or phone to discuss and try and find a way for cooler heads to prevail. We truly believe this would be a huge mistake. It's one of the biggest recalls ever in the country based on the flimsiest of reasons.

Also, we've heard from countless people in the industry this morning that already know precise details about this recall. They didn't get that info from us so you have at least one staff member so happy about this recall that they're leaking it to the industry beforehand. That alone should give you pause and reconsider the clear biases of some of those who are trying to convince you that this is a safety issue.

Sent from my iPhone

Kevin M. Blair

## HONIGMAN LLP

O 517.377.0716 kblair@honigman.com

On Nov 17, 2021, at 11:46 AM, Mitchell, Desmond (LARA) < <a href="mailto:MitchellD6@michigan.gov">MitchellD6@michigan.gov</a> wrote:

## [EXTERNAL EMAIL]

Good Morning Dave,

Thank you for the feedback. Please note the following:

- 1. Claire also spoke to Mr. Bird and I don't believe your statements are a full and accurate representation of his point of view.
- 2. I'm not comfortable with your proposed revisions. I believe our initial draft provides a more accurate representation of the situation to the public and consumers. As a result, the attached bulletin is the one that will be issued today.
- 3. The investigation is still ongoing. As part of that investigation, we'll determine if the recall should be expanded as you've indicated. If it does, we'll expand the recall. However, as Kevin has pointed out before this is a public health and safety issue and we need to act on this as soon as possible. I believe there is currently sufficient evidence for us to proceed.
- 4. The MRA is also open to and believes it is necessary to continue to have discussions after the recall is issued and hopefully prevent something like this from happening in the future.

Desmond Mitchell, Operations Director Marijuana Regulatory Agency Department of Licensing and Regulatory Affairs

Telephone: (517) 243-9463 Email: mitchelld6@michigan.gov

From: Russell, David < DRussell@fosterswift.com > Sent: Wednesday, November 17, 2021 9:55 AM

**To:** Mitchell, Desmond (LARA) < <u>MitchellD6@michigan.gov</u>>; <u>KBlair@honigman.com</u> **Cc:** gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA)

< <u>KluytmanJ@michigan.gov</u>>; Patterson, Claire (LARA) < <u>PattersonC8@michigan.gov</u>>; Hunt-Scully, Risa (AG) < <u>HuntScullyR@michigan.gov</u>>; Mark Fisk (<u>mfisk@byrumfisk.com</u>) < <u>mfisk@byrumfisk.com</u>>; 'consulting@pmbbiotek.com' < <u>consulting@pmbbiotek.com</u>>

Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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## Good morning, Desmond.

In conversations yesterday and today with Pat Bird, a consultant with the AOAC, Mr. Bird has confirmed to Viridis that not having sample incubation times tracked is not a divergence from the approved AOAC method. Further, Mr. Bird agreed that use of the 10 sample tests sent to five different laboratories is not an appropriate method to confirm Viridis' testing for Apergillus and an improper reason to issue a recall. Additionally, Viridis has had conversations with Marie McIntryre from bioMeriux and she too has opined that the MRA's use of the 10 sample tests in not a proper way to confirm Viridis' retests. I have copied Pat Bird on this e-mail, so he can confirm our conversation if necessary or answer any questions that you may have. It is my understanding that Mr. Bird called Ms. Patterson this morning to discuss this matter and he has indicated a willingness to speak to you as well.

Notwithstanding the fact that Viridis strongly disagrees that any recall is appropriate, at your request, I'm attaching clean and redline versions of your proposed recall bulletin with our proposed changes. While we strongly disagree with your analysis and decision to issue this recall, we respectfully submit that if health and safety is truly your main concern, you can accomplish the exact same result without all the alarmist and defamatory language you included in the first draft. We also truly don't understand why the scope of this recall includes <u>all</u> products (except inhalable concentrates). The proposed recall would encompass approximately 64,489 lbs. of flower (not counting trim, concentrates, etc.) over this period and using the average retail price per lbs. would total \$229,645,329.

All of our discussions thus far have focused on aspergillus, and yet this recall is essentially saying you don't trust any test results at all from Viridis (even products that were tested only for terpenes, potency, or other tests that have nothing to do with aspergillus tests). Therefore, any recall should focus solely on aspergillus results. As we discussed yesterday, 8/10 has no logical connection to the aspergillus test issues, and if the absence of logs alone justifies a recall, this recall should cover everything Viridis has tested for aspergillus since 2019. If, on the other hand, the recall is based on the competitors' test results, then the earliest collection date is 9/13.

Second, we respectfully urge you again to reconsider. This is a truly unprecedented and illogical recall. When Iron Laboratories was caught red handed falsifying records and deceiving consumers about the presence of dangerous pesticides, the MRA said it "has not been made aware of any adverse product reactions in conjunction with product tested by Iron Laboratories and is not recalling any marijuana product at this time." In contrast here, Viridis has been performing these tests for two years with the MRA's full knowledge, the MRA has observed these tests countless times and never said a word about not having incubator timing logs until 10/26/21. As soon as the MRA raised this issue, Viridis agreed to begin keeping these logs. And even after the MRA first raised this on 10/26, you waited another 3 weeks to issue the recall. You said yesterday that you were waiting for test results, but Metrc shows that all but a few of the tests were completed by 11/1. It's hard to understand why the MRA waited 15 days to issue a recall if this was truly a health and safety issue. We also discussed yesterday

how four of the ten labs' results were consistent with Viridis' results, and yet it appears this recall is targeting Viridis only, and not those other labs. At a minimum, this should be a 3-lab recall since The Spot and Can-Lab both got the exact same result as Viridis (passed a sample with two consecutive negative tests after the sample was initially failed and not remediated). Also, we have been in contact with A2LA, AOAC, and bioMerieux, who are all reviewing the data and have expressed serious concerns about your purported basis for this recall. I urge you again to let Viridis re-test these samples, or have an independent third party re-test them, or do an inter-lab test, or a proficiency test, or whatever test you want. Rushing into this recall on such flimsy, ill-advised rationale would be a colossal mistake that would cripple Viridis' business, wreak havoc on the entire industry, and raise serious questions about the MRA's integrity overall.

Finally, while we are sincerely interested in having further discussions and exploring any possible alternatives to this recall, we just want to reiterate that we feel like you've backed Viridis into a corner here and if you issue this recall, they will have no choice but to issue a press release to set the record straight and try to mitigate the damage from this ill-advised and completely illogical recall. We sincerely hope that won't be necessary, but we honestly don't feel like we have any other choice at this point unless the MRA drops this recall threat and starts working with us collaboratively to address the substance of your concerns. (It is well documented that we have been trying to have that dialogue with your staff since August to no avail; instead, it seems some have been spending all their time determined to find any potential reason to justify a recall).

Thank you,

Dave

## David R. Russell

Attorney Foster Swift Collins & Smith PC 313 S. Washington Square Lansing, MI 48933 Phone: 517.371.8150

Fax: 517.367.7150
drussell@fosterswift.com
www.fosterswift.com

**From:** Mitchell, Desmond (LARA) [mailto:MitchellD6@michigan.gov]

Sent: Tuesday, November 16, 2021 4:57 PM

To: KBlair@honigman.com

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA);

Russell, David; Hunt-Scully, Risa (AG)

Subject: FW: Follow up & Summary of test results & Draft Recall Bulletin

Importance: High

## Kevin,

- I apologize for the delay. I've attached the recall bulletin for your review. Please provide any feedback or suggested revisions by 10 am on 11/17/2021. We'll review any proposed revisions and let you know if they will be adopted.
- Please see Claire's responses to your questions below.

If you have any questions, let me know. Thank you.

Desmond Mitchell, Operations Director Marijuana Regulatory Agency Department of Licensing and Regulatory Affairs

Telephone: (517) 243-9463 Email: mitchelld6@michigan.gov

From: Blair, Kevin M. < KBlair@honigman.com > Sent: Tuesday, November 16, 2021 10:58 AM

To: Patterson, Claire (LARA) < Patterson C8@michigan.gov >; Gregoire Michaud

<gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>

Cc: Mitchell, Desmond (LARA) < MitchellD6@michigan.gov >; Kluytman, Julie (LARA)

< <u>KluytmanJ@michigan.gov</u>>; <u>drussell@fosterswift.com</u> **Subject:** RE: Follow up & Summary of test results

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Thank you for correcting that. I mean that sincerely. I appreciate you taking the time to triple check and correct that info. I just want to note, though, that the stakes here couldn't be any bigger. We're talking about health and safety, and we're here on the precipice of an enormous potential recall (that would cripple Viridis and raise serious questions about the integrity of the entire process) and one of the key data points that got us here wasn't just wrong in the initial chart, you also confirmed it again this morning via email. It wasn't until the third check that mistake was finally realized.

Also, I think it's critical to consider how many of the tests corroborate Viridis's samples. Just based on the "pass" results alone, that's 4 out of ten that are consistent with Viridis's results (and several of the other 6 were tested by competitors who have publicly talked about trying to put Viridis out of business, so how do you account for that obvious bias?).

For the retests in question, and for the sake of this conversation, we will exclude the test performed by Infinite because that sample should have been passing. This sample may be viewed as a control, in this case, and should rightly be excluded from any further data analysis.

## With all this considered:

- Viridis performed 8 retests and passed 100% of them, failing 0% of the retests.
- Of the additional 8 retests performed by 4 separate facilities, 6 failed. That leaves us with a 25% passing rate and a 75% failure rate. This level of uncertainty is enough cause for concern.
- Regardless of competition, all scientists should be well versed in the ethical conduct of research. If they are not, they also are aware that all raw data and all data, in fact, is subject to scrutiny by the agency. I have no concerns about bias as the licensees were not told that this investigation had anything to do with Viridis. All labs were simply directed to pick up samples from the lab and from the grow. This is commonplace in all investigations that require retesting and does not single out the lab in particular as being part of the investigation.

Further, if any of the "fail" or "set to fail" cells had any test(s) pass, that's very important information to consider. If there was one pass and one fail, I understand that would be a fail under the rules. But if you're truly making data-driven decisions here, there shouldn't be any hesitation to share the data with us. If there were no negative tests associated with the "fail" or "set to fail" samples, why wouldn't you tell us that? And if there were, we'd like to know how many.

• I am not entirely sure of what you are asking in the case. Aside from the error that was corrected for sample number ending in -1014, all results are correct.

- There is no additional information to be provided here.
- If you are referring to an overall analysis of data, Viridis and Viridis North provide the 1<sup>st</sup> and 3<sup>rd</sup> most tests to the regulated market in Michigan.
- During this time of year, in particular, Aspergillus is incredibly common, with the average percentage of total flower packages tested resulting in an Aspergillus failure 9.43% of the time.
- The mean value on this data set is 7.42%.
- Despite the fact that Viridis and Viridis North perform the 1<sup>st</sup> and 3<sup>rd</sup> most tests in the state, they
  are only reporting aspergillus failures for 0.78% and 4.9% of those samples, respectively. Given
  that they fall well under both the median and average values for reporting, the data is
  considered anomalous and is being treated as such.

Kevin M. Blair

\_\_\_\_\_

## HONIGMAN LLP

O 517.377.0716 kblair@honigman.com

From: Patterson, Claire (LARA) < PattersonC8@michigan.gov>

Sent: Tuesday, November 16, 2021 10:27 AM

To: Blair, Kevin M. < KBlair@honigman.com >; Gregoire Michaud < gmichaud@viridisgrp.com >; Michele

Glinn < mglinn@viridisgrp.com >

Cc: Mitchell, Desmond (LARA) < Mitchell D6@michigan.gov>; Kluytman, Julie (LARA)

< <u>KluytmanJ@michigan.gov</u>>; <u>drussell@fosterswift.com</u>

Subject: RE: Follow up & Summary of test results

## [EXTERNAL EMAIL]

All,

Upon confirmation with COAs and data, I have updated a sample from The Spott to reflect a passing status for package:

1A4050300009155000001014

Please note that package:

1A4050300009155000001015

Is set as fail, and the overall retest result is set to fail.

Thank you,

## Claire Patterson

Manager, Scientific & Legal Section Enforcement Division Marijuana Regulatory Agency

(517) 230-2097

<u>PattersonC8@michigan.gov</u> <u>www.michigan.gov/MRA</u>

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From: Blair, Kevin M. < KBlair@honigman.com > Sent: Tuesday, November 16, 2021 10:00 AM

To: Patterson, Claire (LARA) < Patterson C8@michigan.gov >; Gregoire Michaud

<gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>

Cc: Mitchell, Desmond (LARA) < MitchellD6@michigan.gov >; Kluytman, Julie (LARA)

< < kluytmanl@michigan.gov >; drussell@fosterswift.com

Subject: RE: Follow up & Summary of test results

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#### Claire -

Have you had a chance yet to check whether the first sample retested by The Spott (ending in 1014) was a pass or fail? Your chart shows a fail, but it appears in METRC as a pass.

Also, is there a difference on your chart between the cells that say "fail" vs "set to fail"? For example, does "fail" mean they had two positive tests whereas "set to fail" might mean they had one positive and one negative? If so, that is important information and context for us and Desmond to know (i.e., some of these samples may have tested negative 3 out of 4 times).

Kevin M. Blair

**HONIGMAN LLP** 

O 517.377.0716 kblair@honigman.com

From: Patterson, Claire (LARA) < Patterson C8@michigan.gov >

Sent: Monday, November 15, 2021 1:38 PM

To: Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>; Blair, Kevin

M. < KBlair@honigman.com>

Cc: Mitchell, Desmond (LARA) < <a href="mailto:MitchellD6@michigan.gov">MitchellD6@michigan.gov</a>; Kluytman, Julie (LARA)

<KluytmanJ@michigan.gov>

Subject: Follow up & Summary of test results

## [EXTERNAL EMAIL]

Hi Greg.

As discussed on our call, I am attaching a summary of the test results for the tests in question.

All the best,

## Claire Patterson

Manager, Scientific & Legal Section Enforcement Division Marijuana Regulatory Agency

(517) 230-2097 PattersonC8@michigan.gov www.michigan.gov/MRA

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## Schumacher, Brandon

From: Schumacher, Brandon

Sent: Monday, November 22, 2021 1:29 PM

**To:** 'Mains, Douglas E.'; Garrison, Emily E.; Blair, Kevin M.; Russell, David **Subject:** FW: Follow up & Summary of test results & Draft Recall Bulletin

## Brandon M. H. Schumacher

Attorney Foster Swift Collins & Smith PC 313 South Washington Square Lansing, MI 48933-2193 Office Direct: 517.371.8255

Cell: 517.420.5741

Assistant: Sharla Clements: 517.371.8188

Fax: 517.367.7167

bschumacher@fosterswift.com

www.fosterswift.com

## **FOSTER SWIFT**

From: Russell, David

Sent: Wednesday, November 17, 2021 4:46 PM

To: Schumacher, Brandon

Subject: FW: Follow up & Summary of test results & Draft Recall Bulletin

## David R. Russell

Attorney
Foster Swift Collins & Smith PC
313 S. Washington Square
Lansing, MI 48933
Phone: 517.371.8150
Fax: 517.367.7150
drussell@fosterswift.com

drussell@fosterswift.com www.fosterswift.com

## **FOSTER SWIFT**

From: Russell, David

Sent: Wednesday, November 17, 2021 4:43 PM

To: 'Mitchell, Desmond (LARA)'; MCINTYRE Maria; Blair, Kevin M.

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully,

Risa (AG); Mark Fisk (mfisk@byrumfisk.com); consulting@pmbbiotek.com; MILLS John

Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

Once you have issued the recall the irreparable damage is done to this business. You have two subject matter experts opining that the recall is not appropriate based on your "tests".

## David R. Russell

Attorney Foster Swift Collins & Smith PC 313 S. Washington Square Lansing, MI 48933

Phone: 517.371.8150 Fax: 517.367.7150 drussell@fosterswift.com www.fosterswift.com

## **FOSTER SWIFT**

From: Mitchell, Desmond (LARA) [mailto:MitchellD6@michigan.gov]

**Sent:** Wednesday, November 17, 2021 4:36 PM **To:** Russell, David; MCINTYRE Maria; Blair, Kevin M.

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully,

Risa (AG); Mark Fisk (mfisk@byrumfisk.com); consulting@pmbbiotek.com; MILLS John

Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

We've discussed it enough. We can continue to discuss it as the investigation continues. Also, the statements submitted do not provide any evidence that would support a delay in issuing a recall.

Desmond Mitchell, Operations Director Marijuana Regulatory Agency Department of Licensing and Regulatory Affairs

Telephone: (517) 243-9463 Email: mitchelld6@michigan.gov

From: Russell, David <DRussell@fosterswift.com> Sent: Wednesday, November 17, 2021 4:28 PM

To: Mitchell, Desmond (LARA) < Mitchell D6@michigan.gov>; MCINTYRE Maria < maria.mcintyre@biomerieux.com>; Blair,

Kevin M. <KBlair@honigman.com>

**Cc:** gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson,

Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk

(mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com; MILLS John

<John.MILLS@biomerieux.com>

Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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Desmond – You stated earlier in your e-mail that if you were provided with the requested information that you would consider discussing it further. We have provided the information as requested that clearly shows that your tests do not warrant a recall. This is clearly not a health and safety issue. Please schedule a phone call to discuss with subject matter experts. Dave

David R. Russell

Attorney Foster Swift Collins & Smith PC 313 S. Washington Square Lansing, MI 48933 Phone: 517.371.8150

Fax: 517.367.7150 drussell@fosterswift.com www.fosterswift.com

## **FOSTERSWIFT**

From: Mitchell, Desmond (LARA) [mailto:MitchellD6@michigan.gov]

**Sent:** Wednesday, November 17, 2021 4:23 PM **To:** MCINTYRE Maria; Russell, David; Blair, Kevin M.

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully,

Risa (AG); Mark Fisk (mfisk@byrumfisk.com); consulting@pmbbiotek.com; MILLS John

Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

All,

I appreciate the additional information, but no information has been provided that would prevent the recall. It will be issued today.

Desmond Mitchell, Operations Director Marijuana Regulatory Agency Department of Licensing and Regulatory Affairs

Telephone: (517) 243-9463 Email: <u>mitchelld6@michigan.gov</u>

From: MCINTYRE Maria < maria.mcintyre@biomerieux.com>

Sent: Wednesday, November 17, 2021 4:03 PM

**To:** Russell, David < <a href="mailto:DRussell@fosterswift.com">DRussell@fosterswift.com</a>; Mitchell, Desmond (LARA) < <a href="mailto:MitchellD6@michigan.gov">MitchellD6@michigan.gov</a>; Blair, Kevin M. < <a href="mailto:KBlair@honigman.com">KBlair@honigman.com</a>>

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) < KluytmanJ@michigan.gov >; Patterson, Claire (LARA) < PattersonC8@michigan.gov >; Hunt-Scully, Risa (AG) < HuntScullyR@michigan.gov >; Mark Fisk

(mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com; MILLS John

<John.MILLS@biomerieux.com>

Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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Adding John Mills to the conversation.

Methods utilized have AOAC approval. This data collection usually includes robustness data that may or
may not be a change in temperature. Please know, we are working to confirm if this data is available from
the work for AOAC. This may take time to capture as I am collaborating with John Mills- Scientific Affairs
Manager and Dr. Ron Johnson- former AOAC President.

- 2. ISO 17025 accreditation impacts the discussion as ISO sets the benchmark for the quality standards within accredited laboratories. If a recall is generated under these circumstances it's a reflection of a gap in ISO accreditation and does not relate to AOAC or the method itself. The lab has completed training on the method reflected in the training certificates and demonstrated via the ISO 17025 accreditation process.
- 3. When there is uncertainty in results either retesting or confirmation testing generally holds greater value than a multi-lab study. In such a study, there are many variable in the equation leading to variability.
- 4. The iso files have been reviewed and the assay appears to be running properly. The files have been transferred to the R&D team who created this assay for a 2<sup>nd</sup> opinion and to determine if other areas require addressing.

Kind regards, Maria

Maria McIntyre 425-275-8013

From: Russell, David <<u>DRussell@fosterswift.com</u>> Sent: Wednesday, November 17, 2021 11:59 AM

To: 'Mitchell, Desmond (LARA)' < MitchellD6@michigan.gov >; Blair, Kevin M. < KBlair@honigman.com >

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) < KluytmanJ@michigan.gov >; Patterson,

Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk

(mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com; MCINTYRE Maria

<maria.mcintyre@biomerieux.com>

Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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Desmond – I would ask for just a few more minutes. We have spoken with both Ms. McIntyre and Mr. Bird and they are working on sending those now. Thanks.

## David R. Russell

Attorney
Foster Swift Collins & Smith PC
313 S. Washington Square
Lansing, MI 48933
Phone: 517.371.8150
Fax: 517.367.7150

Fax: 517.367.7150 drussell@fosterswift.com www.fosterswift.com

## FOSTER SWIFT

From: Mitchell, Desmond (LARA) [mailto:MitchellD6@michigan.gov]

Sent: Wednesday, November 17, 2021 1:48 PM

To: Blair, Kevin M.; Russell, David

Cc: qmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully,

Risa (AG); Mark Fisk (<u>mfisk@byrumfisk.com</u>); <u>consulting@pmbbiotek.com</u> **Subject:** RE: Follow up & Summary of test results & Draft Recall Bulletin

Kevin,

I can't wait until tomorrow. I'll give you until 3 pm. Also, you're aware that the absence of the logs is only part of the issue.

Desmond Mitchell, Operations Director Marijuana Regulatory Agency Department of Licensing and Regulatory Affairs

Telephone: (517) 243-9463 Email: mitchelld6@michigan.gov

From: Blair, Kevin M. < KBlair@honigman.com> Sent: Wednesday, November 17, 2021 1:39 PM

To: Mitchell, Desmond (LARA) < Mitchell D6@michigan.gov>; Russell, David < DRussell@fosterswift.com>

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson,

Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk

(mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com

Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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## Desmond -

You said repeatedly yesterday that the absence of logs alone would not justify a recall. You pointed to the test results as the primary basis for warranting a recall. But recall that there are no test results at all related to Viridis North's results. At a minimum, Viridis North should be carved out of this recall. They are a separate licensee, with different ownership, and there is no reason they should get swept into this crippling recall just because their name also includes the word "Viridis."

Also, we are doing all we can to reconnect with Mr. Bird and Ms. McIntyre to get statements from them. They are tied up in other meetings and we haven't been able to reach them, but again, Mr. Bird has been copied on all these emails and we're confident that we have not misrepresented his views. We are asking that you give us until 8:30 tomorrow to get those statements. The stakes here couldn't be any higher, and we urge you not to rush forward with this simply because these folks weren't instantaneously available to drop everything and write statements.

Kevin

Kevin M. Blair

HONIGMAN LLP O 517.377.0716

kblair@honigman.com

From: Mitchell, Desmond (LARA) < MitchellD6@michigan.gov>

Sent: Wednesday, November 17, 2021 12:52 PM

To: Russell, David < DRussell@fosterswift.com >; Blair, Kevin M. < KBlair@honigman.com >

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com

Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

## [EXTERNAL EMAIL]

Have them submit those exact statements to me in writing and I'll consider discussing it further.

Also, that's not evidence my staff leaked it.

Desmond Mitchell, Operations Director Marijuana Regulatory Agency Department of Licensing and Regulatory Affairs

Telephone: (517) 243-9463 Email: mitchelld6@michigan.gov

From: Russell, David < DRussell@fosterswift.com > Sent: Wednesday, November 17, 2021 12:45 PM

To: Mitchell, Desmond (LARA) < MitchellD6@michigan.gov >; Blair, Kevin M. < KBlair@honigman.com >

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson,

Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk

(<u>mfisk@byrumfisk.com</u>) < <u>mfisk@byrumfisk.com</u>>; <u>consulting@pmbbiotek.com</u>

Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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## Desmond,

I know Kevin is driving, and this is extremely important, so I want to respond immediately. We have Mr. Bird, copied on this e-mail, and Marie McIntyre from bioMeriux that support our position that this recall is not appropriate. We are not sure how there could be any other explanation than retaliation when you have Mr. Bird stating this recall is inappropriate and Ms. McIntrye from the manufacturer of the platform stating that these retests do not support your position and yet the MRA insists on moving forward. We would ask to at least have the opportunity to get everyone on a call to discuss. The stakes are way too big here to risk a miscommunication that you suggest in your e-mail below. Please remember that Mr. Bird has been copied on all of these e-mails. This will destroy Viridis.

We certainly have evidence that there are leaks. There a people that knew the August 10<sup>th</sup> start date from your recall notice, which is not public information, early this morning.

Please let me know if we can set up a call.

Dave

David R. Russell

Attorney Foster Swift Collins & Smith PC 313 S. Washington Square Lansing, MI 48933

Phone: 517.371.8150 Fax: 517.367.7150 drussell@fosterswift.com www.fosterswift.com

## **FOSTER SWIFT**

From: Mitchell, Desmond (LARA) [mailto:MitchellD6@michigan.gov]

Sent: Wednesday, November 17, 2021 12:24 PM

To: Blair, Kevin M.

Cc: Russell, David; <a href="mailto:gmichaud@viridisgrp.com">gmichaud@viridisgrp.com</a>; <a href="mailto:mglinn@viridisgrp.com">mglinn@viridisgrp.com</a>; <a href="mailto:Kluytman">Kluytman</a>, Julie (LARA); <a href="mailto:patterson">Patterson</a>, Claire (LARA);

Hunt-Scully, Risa (AG); Mark Fisk (mfisk@byrumfisk.com); consulting@pmbbiotek.com

Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

Kevin,

As I've repeatedly stated, no one at the MRA is angry with Viridis. We're just following through with our regulatory responsibilities.

As far as your allegation about staff leaking information regarding the recall, do you have any evidence to support it?

Desmond Mitchell, Operations Director Marijuana Regulatory Agency Department of Licensing and Regulatory Affairs

Telephone: (517) 243-9463 Email: mitchelld6@michigan.gov

From: Blair, Kevin M. < <u>KBlair@honigman.com</u>>
Sent: Wednesday, November 17, 2021 12:17 PM

To: Mitchell, Desmond (LARA) < MitchellD6@michigan.gov>

Cc: Russell, David <<u>DRussell@fosterswift.com</u>>; <u>gmichaud@viridisgrp.com</u>; <u>mglinn@viridisgrp.com</u>; <u>Kluytman, Julie</u> (LARA) <<u>KluytmanJ@michigan.gov</u>>; <u>Patterson</u>, <u>Claire</u> (LARA) <<u>PattersonC8@michigan.gov</u>>; <u>Hunt-Scully</u>, <u>Risa</u> (AG) <<u>HuntScully</u>R@michigan.gov>; <u>Mark Fisk</u> (<u>mfisk@byrumfisk.com</u>) <<u>mfisk@byrumfisk.com</u>>; <u>consulting@pmbbiotek.com</u>

Subject: Re: Follow up & Summary of test results & Draft Recall Bulletin

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I'm begging you to please get on teams or phone to discuss and try and find a way for cooler heads to prevail. We truly believe this would be a huge mistake. It's one of the biggest recalls ever in the country based on the flimsiest of reasons.

Also, we've heard from countless people in the industry this morning that already know precise details about this recall. They didn't get that info from us so you have at least one staff member so happy about this recall that they're leaking it to the industry beforehand. That alone should give you pause and reconsider the clear biases of some of those who are trying to convince you that this is a safety issue.

Sent from my iPhone

Kevin M. Blair

## HONIGMAN LLP

O 517.377.0716 kblair@honigman.com

On Nov 17, 2021, at 11:46 AM, Mitchell, Desmond (LARA) < MitchellD6@michigan.gov> wrote:

[EXTERNAL EMAIL]

Good Morning Dave,

Thank you for the feedback. Please note the following:

- Claire also spoke to Mr. Bird and I don't believe your statements are a full and accurate representation of his point of view.
- 2. I'm not comfortable with your proposed revisions. I believe our initial draft provides a more accurate representation of the situation to the public and consumers. As a result, the attached bulletin is the one that will be issued today.
- 3. The investigation is still ongoing. As part of that investigation, we'll determine if the recall should be expanded as you've indicated. If it does, we'll expand the recall. However, as Kevin has pointed out before this is a public health and safety issue and we need to act on this as soon as possible. I believe there is currently sufficient evidence for us to proceed.
- 4. The MRA is also open to and believes it is necessary to continue to have discussions after the recall is issued and hopefully prevent something like this from happening in the future.

Desmond Mitchell, Operations Director Marijuana Regulatory Agency Department of Licensing and Regulatory Affairs

Telephone: (517) 243-9463 Email: mitchelld6@michigan.gov

From: Russell, David <DRussell@fosterswift.com> Sent: Wednesday, November 17, 2021 9:55 AM

To: Mitchell, Desmond (LARA) < MitchellD6@michigan.gov >; KBlair@honigman.com

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA)

<KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) < HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) < mfisk@byrumfisk.com>;

'consulting@pmbbiotek.com' < consulting@pmbbiotek.com >

Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

## This message was sent securely using Zix\*

## Good morning, Desmond.

In conversations yesterday and today with Pat Bird, a consultant with the AOAC, Mr. Bird has confirmed to Viridis that not having sample incubation times tracked is not a divergence from the approved AOAC method. Further, Mr. Bird agreed that use of the 10 sample tests sent to five different laboratories is not an appropriate method to confirm Viridis' testing for Apergillus and an improper reason to issue a recall. Additionally, Viridis has had conversations with Marie McIntryre from bioMeriux and she too has opined that the MRA's use of the 10 sample tests in not a proper way to confirm Viridis' retests. I have copied Pat Bird on this e-mail, so he can confirm our conversation if necessary or answer any questions that you may have. It is my understanding that Mr. Bird called Ms. Patterson this morning to discuss this matter and he has indicated a willingness to speak to you as well.

Notwithstanding the fact that Viridis strongly disagrees that any recall is appropriate, at your request, I'm attaching clean and redline versions of your proposed recall bulletin with our proposed changes. While we strongly disagree with your analysis and decision to issue this recall, we respectfully submit that if health and safety is truly your main concern, you can accomplish the exact same result without all the alarmist and defamatory language you included in the first draft. We also truly don't understand why the scope of this recall includes <u>all</u> products (except inhalable concentrates). The proposed recall would encompass approximately 64,489 lbs. of flower (not counting trim, concentrates, etc.) over this period and using the average retail price per lbs. would total \$229,645,329.

All of our discussions thus far have focused on aspergillus, and yet this recall is essentially saying you don't trust any test results at all from Viridis (even products that were tested only for terpenes, potency, or other tests that have nothing to do with aspergillus tests). Therefore, any recall should focus solely on aspergillus results. As we discussed yesterday, 8/10 has no logical connection to the aspergillus test issues, and if the absence of logs alone justifies a recall, this recall should cover everything Viridis has tested for aspergillus since 2019. If, on the other hand, the recall is based on the competitors' test results, then the earliest collection date is 9/13.

Second, we respectfully urge you again to reconsider. This is a truly unprecedented and illogical recall. When Iron Laboratories was caught red handed falsifying records and deceiving consumers about the presence of dangerous pesticides, the MRA said it "has not been made aware of any adverse product reactions in conjunction with product tested by Iron Laboratories and is not recalling any marijuana product at this time." In contrast here, Viridis has been performing these tests for two years with the MRA's full knowledge, the MRA has observed these tests countless times and never said a word about not having incubator timing logs until 10/26/21. As soon as the MRA raised this issue, Viridis agreed to begin keeping these logs. And even after the MRA first raised this on 10/26, you waited another 3 weeks to issue the recall. You said yesterday that you were waiting for test results, but Metrc shows that all but a few of the tests were completed by 11/1. It's hard to understand why the MRA waited 15 days to issue a recall if this was truly a health and safety issue. We also discussed yesterday how four of the ten labs' results were consistent with Viridis' results, and yet it appears this recall is targeting Viridis only, and not those other labs. At a minimum, this should be a 3-lab recall since The Spot and Can-Lab both got the exact same result as Viridis (passed a sample with two consecutive negative tests after the sample was initially failed and not remediated). Also, we have been in contact

with A2LA, AOAC, and bioMerieux, who are all reviewing the data and have expressed serious concerns about your purported basis for this recall. I urge you again to let Viridis re-test these samples, or have an independent third party re-test them, or do an inter-lab test, or a proficiency test, or whatever test you want. Rushing into this recall on such flimsy, ill-advised rationale would be a colossal mistake that would cripple Viridis' business, wreak havoc on the entire industry, and raise serious questions about the MRA's integrity overall.

Finally, while we are sincerely interested in having further discussions and exploring any possible alternatives to this recall, we just want to reiterate that we feel like you've backed Viridis into a corner here and if you issue this recall, they will have no choice but to issue a press release to set the record straight and try to mitigate the damage from this ill-advised and completely illogical recall. We sincerely hope that won't be necessary, but we honestly don't feel like we have any other choice at this point unless the MRA drops this recall threat and starts working with us collaboratively to address the substance of your concerns. (It is well documented that we have been trying to have that dialogue with your staff since August to no avail; instead, it seems some have been spending all their time determined to find any potential reason to justify a recall).

Thank you,

Dave

## David R. Russell

Attorney Foster Swift Collins & Smith PC 313 S. Washington Square Lansing, MI 48933 Phone: 517.371.8150

Fax: 517.367.7150
drussell@fosterswift.com
www.fosterswift.com

From: Mitchell, Desmond (LARA) [mailto:MitchellD6@michigan.gov]

Sent: Tuesday, November 16, 2021 4:57 PM

To: KBlair@honigman.com

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA);

Russell, David; Hunt-Scully, Risa (AG)

Subject: FW: Follow up & Summary of test results & Draft Recall Bulletin

Importance: High

## Kevin,

- I apologize for the delay. I've attached the recall bulletin for your review. Please provide any feedback or suggested revisions by 10 am on 11/17/2021. We'll review any proposed revisions and let you know if they will be adopted.
- Please see Claire's responses to your questions below.

If you have any questions, let me know. Thank you.

Desmond Mitchell, Operations Director Marijuana Regulatory Agency Department of Licensing and Regulatory Affairs Telephone: (517) 243-9463 Email: mitchelld6@michigan.gov

From: Blair, Kevin M. < KBlair@honigman.com > Sent: Tuesday, November 16, 2021 10:58 AM

To: Patterson, Claire (LARA) < Patterson C8@michigan.gov >; Gregoire Michaud

<gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>

Cc: Mitchell, Desmond (LARA) < <a href="mailto:MitchellD6@michigan.gov">MitchellD6@michigan.gov</a>; Kluytman, Julie (LARA)

<<u>KluytmanJ@michigan.gov</u>>; <u>drussell@fosterswift.com</u>

Subject: RE: Follow up & Summary of test results

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Thank you for correcting that. I mean that sincerely. I appreciate you taking the time to triple check and correct that info. I just want to note, though, that the stakes here couldn't be any bigger. We're talking about health and safety, and we're here on the precipice of an enormous potential recall (that would cripple Viridis and raise serious questions about the integrity of the entire process) and one of the key data points that got us here wasn't just wrong in the initial chart, you also confirmed it again this morning via email. It wasn't until the third check that mistake was finally realized.

Also, I think it's critical to consider how many of the tests corroborate Viridis's samples. Just based on the "pass" results alone, that's 4 out of ten that are consistent with Viridis's results (and several of the other 6 were tested by competitors who have publicly talked about trying to put Viridis out of business, so how do you account for that obvious bias?).

For the retests in question, and for the sake of this conversation, we will exclude the test performed by Infinite because that sample should have been passing. This sample may be viewed as a control, in this case, and should rightly be excluded from any further data analysis.

## With all this considered:

- Viridis performed 8 retests and passed 100% of them, failing 0% of the retests.
- Of the additional 8 retests performed by 4 separate facilities, 6 failed. That leaves us with a 25% passing rate and a 75% failure rate. This level of uncertainty is enough cause for concern.
- Regardless of competition, all scientists should be well versed in the ethical conduct of research.
  If they are not, they also are aware that all raw data and all data, in fact, is subject to scrutiny by
  the agency. I have no concerns about bias as the licensees were not told that this investigation
  had anything to do with Viridis. All labs were simply directed to pick up samples from the lab
  and from the grow. This is commonplace in all investigations that require retesting and does not
  single out the lab in particular as being part of the investigation.

Further, if any of the "fail" or "set to fail" cells had any test(s) pass, that's very important information to consider. If there was one pass and one fail, I understand that would be a fail under the rules. But if you're truly making data-driven decisions here, there shouldn't be any hesitation to share the data with us. If there were no negative tests associated with the "fail" or "set to fail" samples, why wouldn't you tell us that? And if there were, we'd like to know how many.

- I am not entirely sure of what you are asking in the case. Aside from the error that was corrected for sample number ending in -1014, all results are correct.
- There is no additional information to be provided here.
- If you are referring to an overall analysis of data, Viridis and Viridis North provide the 1<sup>st</sup> and 3<sup>rd</sup> most tests to the regulated market in Michigan.

- During this time of year, in particular, Aspergillus is incredibly common, with the average percentage of total flower packages tested resulting in an Aspergillus failure 9.43% of the time.
- The mean value on this data set is 7.42%.
- Despite the fact that Viridis and Viridis North perform the 1<sup>st</sup> and 3<sup>rd</sup> most tests in the state, they are only reporting aspergillus failures for 0.78% and 4.9% of those samples, respectively. Given that they fall well under both the median and average values for reporting, the data is considered anomalous and is being treated as such.

## Kevin M. Blair

-...

## HONIGMAN LLP

O 517.377.0716 kblair@honigman.com

From: Patterson, Claire (LARA) < Patterson C8@michigan.gov >

Sent: Tuesday, November 16, 2021 10:27 AM

To: Blair, Kevin M. <KBlair@honigman.com>; Gregoire Michaud <gmichaud@viridisgrp.com>; Michele

Glinn < mglinn@viridisgrp.com >

Cc: Mitchell, Desmond (LARA) < MitchellD6@michigan.gov >; Kluytman, Julie (LARA)

< <u>KluytmanJ@michigan.gov</u>>; <u>drussell@fosterswift.com</u>

Subject: RE: Follow up & Summary of test results

## [EXTERNAL EMAIL]

All,

Upon confirmation with COAs and data, I have updated a sample from The Spott to reflect a passing status for package:

1A4050300009155000001014

Please note that package:

1A4050300009155000001015

Is set as fail, and the overall retest result is set to fail.

Thank you,

## Claire Patterson

Manager, Scientific & Legal Section Enforcement Division Marijuana Regulatory Agency

(517) 230-2097 PattersonC8@michigan.gov www.michigan.gov/MRA CONFIDENTIALITY NOTICE: The information contained in this email message, including any attachments, from the Michigan Department of Licensing and Regulatory Affairs is intended solely for the use of the above named recipient(s) and may contain confidential and/or privileged information. Any unauthorized review, use, disclosure, or distribution of any confidential and/or privileged information contained in this email is expressly prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy any and all of the original message.

From: Blair, Kevin M. < KBlair@honigman.com > Sent: Tuesday, November 16, 2021 10:00 AM

To: Patterson, Claire (LARA) < Patterson C8@michigan.gov >; Gregoire Michaud

<gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>

Cc: Mitchell, Desmond (LARA) < <a href="mailto:MitchellD6@michigan.gov">MitchellD6@michigan.gov</a>; Kluytman, Julie (LARA)

< KluytmanJ@michigan.gov >; drussell@fosterswift.com

Subject: RE: Follow up & Summary of test results

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#### Claire -

Have you had a chance yet to check whether the first sample retested by The Spott (ending in 1014) was a pass or fail? Your chart shows a fail, but it appears in METRC as a pass.

Also, is there a difference on your chart between the cells that say "fail" vs "set to fail"? For example, does "fail" mean they had two positive tests whereas "set to fail" might mean they had one positive and one negative? If so, that is important information and context for us and Desmond to know (i.e., some of these samples may have tested negative 3 out of 4 times).

Kevin M. Blair

HONIGMAN LLP

O 517.377.0716 kblair@honigman.com

From: Patterson, Claire (LARA) < Patterson C8@michigan.gov >

Sent: Monday, November 15, 2021 1:38 PM

To: Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>; Blair, Kevin

M. < KBlair@honigman.com>

Cc: Mitchell, Desmond (LARA) < MitchellD6@michigan.gov >; Kluytman, Julie (LARA)

<KluytmanJ@michigan.gov>

Subject: Follow up & Summary of test results

## [EXTERNAL EMAIL]

Hi Greg,

As discussed on our call, I am attaching a summary of the test results for the tests in question.

All the best,

## Claire Patterson

Manager, Scientific & Legal Section Enforcement Division Marijuana Regulatory Agency

(517) 230-2097 PattersonC8@michigan.gov www.michigan.gov/MRA

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## Russell, David

From:

Patrick Bird <consulting@pmbbiotek.com>

Sent:

Wednesday, November 17, 2021 3:02 PM

To:

Mitchell, Desmond (LARA); Blair, Kevin M.; Russell, David

Cc:

gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson,

Claire (LARA); Hunt-Scully, Risa (AG); Mark Fisk (mfisk@byrumfisk.com)

Subject:

RE: Follow up & Summary of test results & Draft Recall Bulletin

## Good afternoon all.

Apologies for the late response. I've reviewed the email thread and had the opportunity to speak with all parties today (Claire, Desmond, Viridis Group) and have included a statement below summarizing the key points from these conversations. I also want to emphasize that I am a contract employee with AOAC, so I can't speak on their behalf.

- 1. AOAC INTERNATIONAL's role in the cannabis industry is to develop standards and guidance to allow alternative methods to be certified through one of its conformity assessment programs. The certification of the method demonstrates its fit for purpose for use in that industry if the method is performed as written in the validation guidelines. AOAC is not involved in laboratory assessment and/or accreditation.
- 2. Determining if a laboratory is performing a method correctly falls on the accreditation organization that issues the ISO 17025 certificate. If a method is certified during the accreditation it demonstrates that the laboratory is competent to run that method. The MRA's decision to recall these products due to the lack of traceability of the incubation logs indicates an issue with the accreditation process and not AOAC's certification. In this instance, the lab has demonstrated they can competently perform the method through their accreditation, although we all acknowledge there is a gap in the data collection process that fully supports this.
- 3. The additional testing of materials at other labs is not something that I believe supports a recall as there are many factors in play that may have lead to the different results (same batch but different test portions analyzed, time gaps in analysis from one lab to another, etc).

Again I want to reiterate that these statements are on my own accord but the first one is in alignment with AOAC's stated policies and procedures.

Best regards Pat Bird

Patrick M. Bird

Principal Consultant of PMB BioTek Consulting AOAC INTERNATIONAL Technical Consultant 330-730-8741 consulting@pmbbiotek.com



PMB BioTek Consulting

From: Mitchell, Desmond (LARA) < Mitchell D6@michigan.gov>

Sent: Wednesday, November 17, 2021 11:48 AM

To: Blair, Kevin M. <KBlair@honigman.com>; Russell, David <DRussell@fosterswift.com>

## **EXHIBIT J**



# PUBLIC HEALTH AND SAFETY BULLETIN

November 17, 2021

## **Notification of Marijuana Product Recall**

The Marijuana Regulatory Agency (MRA) has identified inaccurate and/or unreliable results of products tested by safety compliance facilities Viridis North, LLC and Viridis Laboratories, LLC.

In the interest of public health and safety, the MRA is issuing this health and safety advisory bulletin for **all** marijuana products tested by Viridis Laboratories, LLC (license numbers SC-000009 and AU-SC-000113) and Viridis North, LLC (license numbers SC-000014 and AU-SC-000103) **except** for inhalable marijuana concentrate products such as:

- Vape carts.
- Live resin.
- Distillate.
- Any other cannabis concentrate created through residual solvent extractions.

The marijuana products impacted have a test date between August 10, 2021 and November 16, 2021. All marijuana product labels are required to list the name and license number of the safety compliance facility that conducted the testing and date the product was tested.

## Note: An MRA investigation is still on-going.

Consumers who have marijuana products in their possession that meet the recall criteria may return the products to the marijuana sales location where they were purchased for proper disposal. Consumers with weakened immune systems or lung disease are at the highest risk for health-related incidents such as aspergillosis, which can impact lung function, if these potentially harmful products are consumed.

Consumers who have experienced adverse reactions after using these products should report their symptoms and product use to their physician. Consumers are requested to report any adverse product reactions to the MRA via email: MRA-Enforcement@michigan.gov or via phone: 517-284-8599.

Marijuana sales locations that sold product covered by this bulletin must display this recall notice on the sales floor, visible to all customers, for 30 days from the date of this



# PUBLIC HEALTH AND SAFETY BULLETIN

November 17, 2021

notice. Marijuana sales locations that receive adverse product reactions from consumers should report the adverse product reactions to the agency at MRA-Enforcement@michigan.gov and document these reports in METRC.

Licensees with products remaining in their inventory that meet the recall criteria have the following options:

- Destroy the product and provide proof of destruction: <u>MRA-Compliance@michigan.gov.</u>
- Have the product retested for the microbials compliance panel.
- Send the product back to the original licensee source so they can destroy or have the product retested as a larger batch.

Licensees that opt to have product sent back or retested will need to create new METRC packages with new METRC identification numbers prior to transferring or submitting the products for testing. Additional guidance can be provided to licensees who need assistance in creating these packages by reaching out to MRA-Compliance@michigan.gov.

Additional questions can be sent to the MRA's Operations Support Section: <u>MRA-Compliance@michigan.gov</u>.

## **EXHIBIT K**

From: Patterson, Claire (LARA) [mailto:PattersonC8@michigan.gov]

Sent: Thursday, November 18, 2021 12:06 PM

To: Blair, Kevin M.; Kluytman, Julie (LARA); Mitchell, Desmond (LARA); MRA-scf

Cc: Todd Welch; Gregoire Michaud; Michele Glinn; Russell, David; Michael LaFramboise

Subject: RE: Tomorrow

The attached approval refers to Aspergillus testing only.

## Claire Patterson

Manager, Scientific & Legal Section Enforcement Division Marijuana Regulatory Agency

(517) 230-2097 PattersonC8@michigan.gov www.michigan.gov/MRA



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From: Blair, Kevin M. < KBlair@honigman.com > Sent: Thursday, November 18, 2021 12:04 PM

To: Kluytman, Julie (LARA) < KluytmanJ@michigan.gov >; Mitchell, Desmond (LARA)

< <u>MitchellD6@michigan.gov</u>>; MRA-scf < <u>MRA-scf@michigan.gov</u>>; Patterson, Claire (LARA)

<PattersonC8@michigan.gov>

**Cc:** Todd Welch <a href="mailto:com">twelch@viridisgrp.com</a>; Gregoire Michaud <a href="mailto:sgrp.com">gmichaud@viridisgrp.com</a>; Michael Glinn <a href="mailto:sgrp.com">mglinn@viridisgrp.com</a>; Russell, David <a href="mailto:DRussell@fosterswift.com">DRussell@fosterswift.com</a>; Michael LaFramboise

<mlaframboise@viridisgrp.com>

Subject: FW: Tomorrow

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Following up on my last email, see highlighted language below as one example when Viridis was explicitly told they could resume testing. Viridis communicated that to customers based on the MRA's assurances and now it seems the MRA is contradicting what you said yesterday. Again, we need to get on the phone ASAP please.

Kevin M. Blair

\_\_\_\_\_

#### HONIGMAN LLP

O 517.377.0716 kblair@honigman.com

From: MRA-scf < MRA-scf@michigan.gov > Sent: Tuesday, November 16, 2021 5:51 PM

To: Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>

Cc: Blair, Kevin M. < KBlair@honigman.com >; Todd Welch < twelch@viridisgrp.com >;

<u>drussell@fosterswift.com</u>; Michael LaFramboise <<u>mlaframboise@viridisgrp.com</u>>; Patterson, Claire (LARA) <<u>PattersonC8@michigan.gov</u>>; Rosenzweig, Noah (LARA) <<u>RosenzweigN@michigan.gov</u>>

Subject: RE: Tomorrow

## [EXTERNAL EMAIL]

Greg,

Thank you and Michele for promptly sharing the incubator log for Viridis. As discussed earlier, Viridis is approved to move forward using the updated LOM-7.20 Gene-Up Aspergillus. A current method approval form for Viridis is attached. We will also cease placing Viridis Aspergillus tests on administrative hold. If outstanding questions remain, please let me know.

## Patrice R. Fields, Ph.D.

Laboratory Scientist Specialist
Scientific & Legal Section, Enforcement Division
Marijuana Regulatory Agency
517-281-3640
FieldsP2@michigan.gov
www.michigan.gov/MRA





Save Michigan Lives.

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From: Gregoire Michaud <gmichaud@viridisgrp.com>

**Sent:** Tuesday, November 16, 2021 4:12 PM **To:** MRA-scf < MRA-scf@michigan.gov>

**Cc:** <u>KBlair@honigman.com</u>; Todd Welch < <u>twelch@viridisgrp.com</u>>; <u>drussell@fosterswift.com</u>; Michele Glinn < <u>mglinn@viridisgrp.com</u>>; Michael LaFramboise < <u>mlaframboise@viridisgrp.com</u>>; Patterson, Claire (LARA) < <u>PattersonC8@michigan.gov</u>>; Rosenzweig, Noah (LARA) < <u>RosenzweigN@michigan.gov</u>>

Subject: RE: Tomorrow

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See attached...thanks Patrice.

From: MRA-scf < MRA-scf@michigan.gov > Sent: Tuesday, November 16, 2021 3:30 PM

To: Gregoire Michaud <gmichaud@viridisgrp.com>

**Cc:** <u>KBlair@honigman.com</u>; Todd Welch < <u>twelch@viridisgrp.com</u>>; <u>drussell@fosterswift.com</u>; Michele Glinn < <u>mglinn@viridisgrp.com</u>>; Michael LaFramboise < <u>mlaframboise@viridisgrp.com</u>>; Patterson, Claire (LARA) < <u>PattersonC8@michigan.gov</u>>; Rosenzweig, Noah (LARA) < <u>RosenzweigN@michigan.gov</u>>

Subject: RE: Tomorrow

Hi Greg,

Thank you for sharing these documents with us. After reviewing the incubator log, corrective action report, and the updated LOM-7.20 Gene-Up Aspergillus, Viridis North is approved to move forward using the SOP approved as of today to test for Aspergillus. We will also cease placing Viridis North Aspergillus tests on administrative hold. An updated method approval form for Viridis North is attached. While most of the same documentation also applies to Viridis, we are concerned that there is no current incubator log showing into and out of incubator times for Aspergillus test samples at that location. Due to this lack of records, we are withholding approval of the updated LOM-7.20 Gene-Up Aspergillus for Viridis and we will continue placing Viridis Aspergillus tests on administrative hold. The administrative holds for Viridis Aspergillus tests will cease once we have received records confirming that the approved SOP is being followed. If you have questions or concerns, please let me know.

## Patrice R. Fields, Ph.D.

Laboratory Scientist Specialist
Scientific & Legal Section, Enforcement Division
Marijuana Regulatory Agency
517-281-3640
FieldsP2@michigan.gov
www.michigan.gov/MRA



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From: Gregoire Michaud <gmichaud@viridisgrp.com>

Sent: Monday, November 15, 2021 11:03 PM

To: Patterson, Claire (LARA) < Patterson C8@michigan.gov>

**Cc:** Blair, Kevin M. < <a href="mailto:KBlair@honigman.com">KBlair@honigman.com</a>; Todd Welch < <a href="mailto:twelch@viridisgrp.com">twelch@viridisgrp.com</a>; drussell@fosterswift.com; Michele Glinn < <a href="mailto:mglinn@viridisgrp.com">mglinn@viridisgrp.com</a>; Michael LaFramboise

<mlaframboise@viridisgrp.com>

Subject: RE: Tomorrow

CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

Good evening Claire,

A little miscommunication at our end on who was going to get you these, sorry. Please find attached our corrective action and the two new logs that were put in place as a result of your audit. Bay City implemented the use of the incubator start/end times last Monday with Lansing starting today. Dr. Glinn was out of the lab all last week and the directive to start using it last Monday did not get relayed. We'll monitor it till the end of the month to ensure compliance is consistent at which point we will close out the corrective action. Also attached is our proposed revisions to the SOP that now reflect the use of the log (revisions highlighted in yellow).

Our apologies again for not getting these to you sooner.

Kind regards, Greg

# **EXHIBIT L**

## STATE OF MICHIGAN IN THE COURT OF CLAIMS

VIRIDIS LABORATORIES, LLC, a Michigan limited liability company, and VIRIDIS NORTH, LLC, a Michigan limited liability company,

Case No. 21-\_\_\_\_-MB

Plaintiffs.

v.

MICHIGAN MARIJUANA REGULATORY AGENCY, a Michigan state agency, ANDREW BRISBO, Individually, JULIE KLUYTMAN, Individually, DESMOND MITCHELL, Individually, CLAIRE PATTERSON, Individually.

Defendants.

David R. Russell (P68568)
Brandon M. H. Schumacher (P82930)
FOSTER, SWIFT, COLLINS & SMITH, P.C.
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EX PARTE ORDER TO SHOW CAUSE WHY WRIT OF MANDAMUS SHOULD NOT BE GRANTED

Plaintiffs Viridis Laboratories, LLC and Viridis North, LLC, filed an Ex Parte Motion for Mandamus on November 22, 2021 (the "Motion"). The Motion having been submitted to the Court as part of Plaintiffs' Verified Complaint pursuant MCR 3.305, and this Court having reviewed the Motion and Verified Complaint;

IT IS HEREBY ORDERED that Defendant Marijuana Regulatory Agency must sho	эw
cause why the requested writ of mandamus compelling Defendant to immediately commence	эa
contested case hearing before an administrative law judge on an expedited basis should not	be
issued, as provided for and permitted by MCR 3.305(C), at a hearing scheduled to	for
, at	
Defendant must file an answer by	
Dated:, 2021	
Hon.	
Court of Claims Judge	

36273:00001:5948388-1

## **EXHIBIT M**



VALIDATION STATUS: (Approved / Not Approved)		1ETHOD NAME / SOP NUMBER: LOM 20 Detection of Aspergillu lp/LOM 21 Detection of Salmonella and STEC by GENE-UP/LOM 22 M/CC			
FACILITY NAME Viridis Lansing	REVIEW DATE 08/05/2021	COUNTY Ingham			INSPECTION NUMBER SC-00009/AU-SC-000113
ADDRESS 2827 E. Saginaw St.	LITY TYPE Safety Compliance Facility/Marihuana Safe Compliance Facility	ety		ASSIGN LSS Ros	IED AGENT senzweig
CITY, STATE ZIP CODE Lansing. MI 48912	EPRESENTATIVE n			ACILITY 33-847-434	

#### **INSPECTOR NOTES:**

- ☐ STATUS (08/10/2021):
  - Approved for all analyses listed below on <u>ALL MATRICES</u> (flower, infused, concentrate):
    - Potency
    - Water Activity
    - Moisture Content
    - Chemical Residue
    - Metals
    - Foreign Matter
    - Microbials
    - Residual Solvent Analysis
    - Target Analytes
    - Terpenes

#### 1. POTENCY

SOP: 7.1a Cannabinoid Analysis by UHPLC-DAD

Matrix: Flower

**Instrument(s):** Thermo Vanquish UHPLC Sytstem with VF-P10-A UHPLC pump and a Diode Array Detector (DAD) Lightpipe<sup>TM</sup> VH-D10, with a Restek sub-2 micron UHPLC column (Raptor ARC-18 LC Column 1.8  $\mu$ m 100 x 3.0 mm)

#### PT Results:

1/03/2020 – External Flower PT – non-matrix match (standard)

1



- Analytes: Delta9THC; CBD; CBDA; Delta9THCA; CBG; Delta8THC; THCV; CBDV; CBGA; CBC;
   CBDVA
- All results ACCEPT

#### 3/12/2020 - External Hemp Oil PT - (standard)

- Analytes: Delta9THC; CBD; CBDA; Delta9THCA; CBG; Delta8THC; THCV; CBDV; CBGA; CBC; CBDVA
- All results ACCEPT

#### **05/12/2020** – Gummy Matrix PT – (standard)

- Analytes: Delta9THC; CBD; CBDA; Delta9THCA; CBN; CBG; Delta8THC; THCV; CBDV; CBGA;
   CBC
- All results ACCEPT

#### Comments (4/16/2020):

- i. Method submitted and accepted on 01/24/2020 for analyses as written on Flower Matrix (ONLY)
- ii. Passing proficiency test submitted to the agency on 4/2/2020 Method Approved for analysis of concentrates.

Updates submitted: 7/08/2020

Potency approved on all matrices

#### 2. WATER ACTIVITY

**SOP:** 7.3 Moisture Content and Water Activity Analysis

Matrix: Flower

#### PT Results:

- PT Flower 01/03/2020 Water Activity ACCEPT
- PT Gummy 03/11/2020 Water Activity ACCEPT

#### Comments (4/10/2020):

iii. Method submitted and accepted on 01/03/2020

Updates submitted:

#### 3. MOISTURE CONTENT

**SOP:** 7.3 Moisture Content and Water Activity Analysis

Matrix: Flower



#### PT Results:

#### Acceptable PT is not required

#### Comments (4/16/2020):

- iv. Method submitted and accepted on 10/25/2019
- v. Not required on concentrates

Updates submitted:

#### 4. CHEMICAL RESIDUE

SOP: 7.4a Chemical Residue / Pesticide Analysis by LC-MS/MS

Matrix: Flower

#### Instruments:

1. ThermoTisher Q Exactive Focus Hybrid Orbi-Trap Mass Spectrometer with Vanquish Binary UHPLC and Tracefinder software

#### August 21, 2020 - Added Instrument:

- AB Sciex 6500 Triple Quadrupole LC-MS/MS with Exion liquid chromatograph and interchangeable ESI and APCI probes
- 3. OS-Q MS Data Analytics processing software

Note: Licensee has submitted appropriate validation and proficiency tests

#### PT Results:

2/21/2020 and 2/22/2020 Analyzed in solvent

All analytes ACCEPT.

4/6/2020 Analyzed in hemp oil matrix – BLIND SAMPLE ANALYSIS

All unknown target analytes ACCEPT.

7/01/2020 Analyzed in gummy matrix

All unknown target analytes ACCEPT.

#### Comments (4/16/2020):

- vi. Method submitted and accepted on 01/24/2020 in Flower Matrix
- vii. Passing PT submitted as Blind Sample analysis, submitted to agency on 4/16/2020. Method approved for analysis of concentrates.



#### 5. METALS

**SOP:** 7.2 Heavy Metal Analysis

Matrix: Flower; Concentrate

Instruments: ThermoFisher iCAP RQ ICP-MS with PrepFast injector port

prepFAST 4DX by Elemental Scientific

MARS6 Microwave-assisted acid digestion extraction system

#### PT Results:

1/03/2020 – External Flower PT – (hemp)

Chromium; Nickel; Arsenic; Cadmium; Mercury; Lead

All results: ACCEPT

3/12/2020 – External Hemp Oil PT – (hemp)

Chromium; Nickel; Copper; Arsenic; Cadmium; Mercury; Lead

All results: ACCEPT

3/24/2020 - Gummy Matrix PT

■ Chromium: Arsenic; Cadmium; Mercury; Lead

All results: ACCEPT

#### Comments:

- viii. 10/25/2019: Method approved as written for flower matrix.
- ix. 01/24/2020: Nickel and Copper added to previously approved method on flower matrix
- x. 04/16/2020: Method approved for use on concentrate matrix
- xi. **04/28/2021** SMPR published 02/11/2021, the current method does not meet the SMPR requirements for the following analytes and will need to be updated: Lead, Mercury, and Cadmium before August 11, 2021.
- xii. 07/2/2021 Under Method Details Specimen Type is cannabis flower, but under Recovery it states: One cannabis flower sample in each run was analyzed in duplicate, with one aliquot used as the unspiked and one as the spiked sample. Gummies were purchased from a local grocery store. Please provide details on cannabis flower and associated metre tag numbers and results from gummy verification if seeking approval.
- xiii. 07/15/2021 Method now meets the SMPR requirements for Lead, Mercury, and Cadmium

Updates submitted:

#### Updates submitted:

07/15/2021 Provided details on cannabis flower and associated metrc tag numbers and removed reference to gummies.



#### 6. RESIDUAL SOLVENTS

SOP: 7.10 Residual Solvent Analysis

Matrix: Concentrate

PT Results:

4/14/2020 – External Hemp Oil PT – (hemp)

All analytes presentAll results: ACCEPT

#### Comments (05/04/2020):

xiv. Method approved as written on concentrate matrix only.

SOP: 7.7 Terpenoid Analysis

Matrix: All

PT Results:

06/18/2020 - External Hemp Oil PT - (hemp)

- xv. a-Bisabolol, a-humulene, a-pinene, a-terpinolene, b-caryophyllene, myrcene, b-pinene, caryophyllene oxide, limonene, linalool.
- xvi. a-pinene, a-terpinolene, b-caryophyllene, myrcene, b-pinene, caryophyllene oxide, limonene:
- xvii. a-Bisabolol, a-humulene, linalool: NOT ACCEPT

#### Comments (09/01/2020): Terpene Analysis Added

- i. Method approved as written for the analysis of all terpenes listed below:
  a-pinene, a-terpinolene, b-caryophyllene, myrcene, b-pinene, caryophyllene oxide, limonene:
  ACCEPT
- ii. The method may be approved for the following terpenes (below) when an acceptable PT is reported. a-Bisabolol, a-humulene, linalool: NOT ACCEPT

**04/28/2021** SMPR published 02/11/2021, the current method does not meet the SMPR requirements for the following analytes and will need to be updated: Ethanol, Heptane, Hexanes all isomers, 2,2-Dimethylbutane, 2,3-Dimethylbutane, 2-Methylpentane, 3-Methylpentane, Isopropyl alcohol, Methanol, Propane, Toluene and Total xylenes (ortho-, meta-, para-) before August 11, 2021.

07/23/2021 Method now meets the SMPR requirements for Ethanol, Heptane, Hexanes all isomers, 2,2-Dimethylbutane, 2,3-Dimethylbutane, 2-Methylpentane, 3-Methylpentane, Isopropyl alcohol, Methanol, Propane, Toluene and Total xylenes (ortho-, meta-, para-).



Updates submitted:

#### Updates submitted:

**07/23/2021** Verification report for recovery of Ethanol, Heptane, Hexanes all isomers, 2,2-Dimethylbutane, 2,3-Dimethylbutane, 2-Methylpentane, 3-Methylpentane, Isopropyl alcohol, Methanol, Propane, Toluene and Total xylenes (ortho-, meta-, para-).

#### 7. MICROBIAL ANALYSIS

SOP: 7.8 Plant-Micro DNA Extraction from Plant Material, LOM - 7.17 Total Yeast and Mold Plating and Count

LOM 20 Detection of Aspergillus by Gene-Up/LOM 21 Detection of Salmonella and STEC by GENE-UP/LOM 22 TEMPO YM/CC

Matrix: Flower

**Instrumentation:** Medicinal Genomics protocol as written and AriaMax

PT Results:

Flower – Hemp flower Matrix

APC (PCR- Quantitative) 10/21/2019 - ACCEPT

Total Coliform (PCR- Quantitative) 10/21/2019 - ACCEPT

E. coli (non-STEC) (PCR- Quantitative) 10/21/2019 – ACCEPT

Enterobacteriaceae (PCR- Quantitative) 10/21/2019 - ACCEPT

Yeast/Mold (PCR- Quantitative) 10/21/2019 - ACCEPT

Yeast and Mold (Plating) 2/01/2021 – ACCEPT

Concentrate – Hemp oil Matrix

Salmonella (PCR- Qualitative) 04/01/2020 – ACCEPT

Coliform (PCR): Externally Graded Not submitted, internal submitted- ACCEPT

Yeast and Mold (PCR): Externally Graded Not submitted, internal submitted—ACCEPT

STEC (PCR- Qualitative) 04/01/2020- ACCEPT

Total Mold (PCR- Qualitative): Externally Graded Not submitted, internal submitted- ACCEPT

Concentrate - Chocolate Matrix

Salmonella (PCR- Qualitative) 05/06/2020 - ACCEPT



## STEC (PCR- Qualitative) 05/06/2020- ACCEPT

#### CMPT-028B Qualitative STEC in Hemp - Viridis Laboratories - NSI Lab Solutions/ FM-PTX1037

Analyte#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Døte	Analyst's Name
Sample 1			<del></del>	<del></del>				
7034	E.coli STEC	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/19/21	David Chalmers
Sample 2								
7034	E.coli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers
Sample 3								
7034	E.coli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers
Sample 4								
7034	E.coli STEC	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/19/21	<b>David Chalmers</b>
Sample 5								
7034	Ecoli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers

#### CIMPT-0298 Qualitative STEC In Edible - Viridis Laboratories - NSI Lab Solutions/ FM-PTX1037

Analyte# Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Dale	Analyst's Name
Sample 1							
7034 Ecoli STEC	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/19/21	David Chalmers
Sample 2							
7034 Ecoli STEC	Gene Up	PCR	ASSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers
Sample 3							
7034 Ecoli STEC	Gane Up	PÇR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers
Sample 4							
7034 Ecoli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers
Sample 5							
7034 Exoli STEC	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/19/21	David Chalmers
	•						

#### CMPT-030B Qualitative STEC in Oil - Viridis Laboratories - NSI Lab Solutions/FM-PTX1037

Analytes	/ Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evoluation	Analysis Date	Analyst's Name
Sample	1		-			••		
7በጓሬ	Fro# STFC	Gene Up	PCR	PRESENT	PRESENT	ACCEPT	07/19/21	David Chairners
Sample.	2							
7034	E.coli STEC	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/19/21	David Chalmers
Sample.	3							
7034	E.coli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers
Sample-	4	•						
7034	E.coli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers
Sample	5							
7034	Ecoli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers



#### CMPT-025B Qualitative Salmonella in Hemp — Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyte#	Analyte	Method Technology	Method Description		Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name	
Sample 1										
	Salmonelia	Gene Up	PCR		PRESENT	PRESENT	ACCEPT.	07/14/21	David Chalmers	
Sample 2						***************************************				
•	Salmonelia	Gene Up	PCR		ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers	
Sample 3										
2057	Salmonella	Gene Up	PCR	517	PRESENT	PRESENT	ACCEPT.	07/14/21	David Chalmers	
Sample 4				$\sim$						
2057	Salmoneila	Gene Up	PCR		ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers	
Sample 5		•								
2057	Salmonelia	Gene Up	PCR		ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers	

#### CMPT-0268 Qualitative Salmonella in Edible — Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analytes	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample	1							
2057	Salmonella	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/14/21	David Chalmers
Sample 2	2							
2057	Salmonella	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers
Sample :	3							
2057	Salmonella	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers
Sample 4	4							
2057	Salmonella	Gene Up	PCR	PRESENT	PRESENT	ACCEPT,	07/14/21	David Chalmers
Sample :	5	•						
2057	Salmonella	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers



#### CMPT-027B Qualitative Salmonella in Oil — Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyte#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample 1			<del></del>	<del></del>				
2057	Salmonella	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers
Sample 2								
	Salmonella	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/14/21	David Chalmers
Sample 3								
2057	Salmonella	Gene Up	PCR	ABSENT	ASSENT	ACCEPT.	07/14/21	David Chalmers
Sample 4								
2057	Salmonella	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/14/21	David Chalmers
Sample 5								
2057	Salmonelia	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers

#### CMPT-031B Qualitative Aspergillus Molds in Hemp - Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyte#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample 1				· · · · ·				· · · · · · · · · · · · · · · · · · ·
6095	Total Mold	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 2								
	Total Mold	Gene Up	PCR	ABSENT	A8SENT	ACCEPT.	07/16/21	David Chalmers
Sample 3								
6095	Total Mold	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 4								
6095	Total Mold	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample S								
6095	Total Mold	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 1								
6096	A. fumagatis	Gene Up	PCR	ABSENT	ABŞENT	ACCEPT,	07/16/21	David Chalmers
Sample 2								
6096	A. furnagatis	Gene Up	PCR	ABSENT	THERE	ACCEPT.	07/16/21	David Chalmers
E olqme2								
	A. fumagatis	Gene Up	PCR	ABSENT	ASSENT	ACCEPT.	07/16/21	David Chaimers
Sample 4								
	A. fumagatis	Gene Up	PCR	<b>A8</b> SENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5								
6096	A. fumagatis	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers



Sample '	1							
	A, flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample :				4 D.C. 1 W			*****	B
Sample :	A flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chairners
	A. flavus	Gene Up	PCR	ARSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4								
6097	A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample :								
6097	A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 1	1							
•	A brasiliensis (Niger)	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 2								
	A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample :								
6098	A brasiliensis (Niger)	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 4 6098	A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample !		Gene op	run	ADSUNI	ROSCII	MUGET I.	01/10/21	David Charliers
6098	A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 1	1							
	A terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample :							0746774	n tanti.
6099 Sample 3	A terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
-	A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4								
	A terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT	07/16/21	David Chalmers
Sample :								
6099	A. terreus	Gene Up	PČR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chairners

#### CMPT-032B Qualitative Aspergillus Molds in Edible - Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyte#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample 1				·		•		
	Total Mold	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmors
Sample 2		e u .	nen					a. trad
Sample 3	Total Mold	Gene Up	PÇR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
	Total Mold	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4		Othe Op		7436.11	PROSERV	ricco i.	27,142.	David Chambers
6095	Total Mold	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5								
6095	Total Mold	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 1								
6096	A fumegatis	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2								
	A. fumagatis	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3		<b>*</b> N-	n.c.n	*****	******			
Sample 4	A. furnagatis	Gene Up	PCR	A8SENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
	A fumagatis	Gene Up	PCR	ABSENT	ANSENT	ACCEPI.	07/16/21	David Chalmers
Sample 5		• · · · · · · · · · · · · · · · · · · ·	. •	7.000.17	,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	0.,,,,,,	
6096	A formagatis	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chaimers
Sample 1								
6097	A flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chairners
Sample 2								
	A flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3		C 11-	000	******			****	
6097 . Sample 4	A navus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
	A flavus	Gene Up	PCR	ASSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5	C. DATAS	Gene op	1.40	7103641	-103E141	MICEL I.	37/10/21	CHAN CHRUMIS
6097	A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT,	07/16/21	David Chalmers



Sample	1							
6098	A brasiliensis (Nigar)	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample :	2							
6098	A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample:								
6098	A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample -								
6098	A brasiliensis (Niger)	Gene Up	PCR	ABŞENT	ABSENT	ACCEPT.	07/15/21	David Chalmers
Sample !								
6096	A brasiliensis (Niger)	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/15/21	David Chalmers
Cample 1								
Sample								
	A terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/15/21	David Chalmers
Sample 2								
6099	A terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT	07/16/21	David Chalmers
Sample 3								
6099	A terreus	Gene Up	PCR	ASSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4								
6099	A terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT,	07/16/21	David Chalmers
Sample :								
6099	A terreus	Gene Up	PCR	ASSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers

#### CMPT-033B Qualitative Aspergillus Molds in Oil – Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

		·····		<del></del>			
Analyte# Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample 1							<del>'.'''</del>
6095 Total Mold	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chairners
Sample 2							
6095 Total Mold	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 3							
6095 Total Mold	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 4							
6095 Total Mold	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5							
609S Total Mold	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers



Sample :	A. fumagatis	Gene Up	PCR		ABSENT	ABSENT	ACCEPT.	07/16/21	David Ch	aimers
	A fumagatis	Gene Up	PCR		PRESENT	PRESENT	ACCEPT.	07/16/21	David Ch	almers
6096	A. fumagatis	Gene Up	PCR		PRESENT	PRESENT	ACCEPT.	07/16/21	David Ch	almers
	A. fumagatis	Gene Up	PCR		ABSENT	ABSENT	ACCEPT.	07/16/21	David Ch	almers
6095	S A fumagatis	Gene Up	PCR		ABSENT	ABSENT	ACCEPT.	07/16/21	David Ch	almers
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6097	A flavus	Gene Up	PCR		ABSENT	ABSENT	ACCEPT.	07/16/21	David Ch	almers
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Comments (4/16/2020):



- iii. 1/03/2020: Method approved as written. NOTE: Please submit upper level of quantitation for quantitative per methodology.
- iv. 1/24/2020: ULOQ submitted in 01/21/2020 remediation response.
- v. 4/16/2020: Method approved as written on concentrate matrix.
- vi. 04/28/2021: The method for Aspergillus, Salmonella, and STEC does not meet the current SMPR's the agency published 02/11/2021, the facility will not be able to use this method after 08/11/2021.
- vii. 7/27/2021: This review is only for the qualitative detection of Aspergillus spp. Salmonella spp. and STEC producing Escherichia coli. Raw data was not included with the validation report. Please include amplification curve and melt-curve raw data. Please include package insert for all assays referenced for MRA review. Please provide detailed information on thermocycler instrumentation, the manufacturer and model number. Humidity and temperature may interfere with the performance of the thermocycler instrument. Please include thermocycler manual to determine temperature range (°C) and relative humidity range (non-condensing). Please include environmental monitoring controls for the room where the testing will be conducted and an acceptable range for each on the log. Additionally, the bench log/worksheet should include information on the PCR plate well ID associated with test samples and controls. Please include the bench log/worksheet. Please include MRA acceptance criteria in SOPs.

This review is only for verification of total Coliform enumeration and total yeast and mold enumeration. Raw data was not included with the validation report. Please include raw data from either a .ted (TEMPO file) converted to .pdf, or .csv (Excel) file type. Please include package insert for all assays referenced for MRA review. Please provide detailed information on TEMPO instrumentation, the manufacturer and model number. If Humidity and temperature may interfere with the performance of the TEMPO instrument, please include TEMPO manual to determine temperature range (°C) and relative humidity range (non-condensing). Please include environmental monitoring controls for the room where the testing will be conducted and an acceptable range for each on the bench log/worksheet. Additionally, the log/worksheet should include information on how ID# associated with test samples and controls are logged. Please include the bench log sheet. Please include MRA acceptance criteria in SOPs.

viii. 8/03/2021: This review is only for the qualitative detection of Aspergillus spp. Salmonella spp. and STEC producing Escherichia coli. Please include amplification curve and melt-curve raw data for the Aspergillus spp. verification, data provided (beverage) was not from the matrices used in the verification study. Please include package insert for all assays referenced for MRA review, these should be available from the manufacturer's website directly. Humidity and temperature may interfere with the performance of the thermocycler instrument. Please include thermocycler manual to determine temperature range (°C) and relative humidity range (non-condensing).

This review is only for verification of total Coliform enumeration and total yeast and mold enumeration. Please provide detailed information on TEMPO instrumentation, specifically if Humidity and temperature may interfere with the performance of the TEMPO instrument, please include TEMPO Reading Station User's Manual (only quick start guides were provided) which includes General Characteristics with Environmental Considerations to determine operational temperature range (°C) and relative humidity range (non-condensing).

ix. **8/10/2021:** The validation submitted for verification for the qualitative detection of *Aspergillus* spp., *Salmonella* spp. and STEC producing *Escherichia coli* method is thorough and satisfactorily addresses all requirements outlined in the Safety Compliance Facility Testing Guide.

The validation submitted for quantitative detection of total yeast and mold method is thorough and satisfactorily addresses all requirements outlined in the Safety Compliance Facility Testing Guide.



These methods are provisionally approved pending the results of the 09/13/2021-09/15/2021 ISO scope expansion.

1 pdates submitted

#### Updates submitted:

8/03/2021: Included environmental monitoring controls for the room where the testing will be conducted and an acceptable range for each on the log. Included information on the PCR plate well ID associated with test samples and controls. Included the bench log/worksheet. Included MRA acceptance criteria in SOPs.

**8/05/2021:** Included amplification raw data for the *Aspergillus* spp. verification, package insert for all assays and thermocycler manual. Provided detailed information on TEMPO Reading Station

#### 8. FOREIGN MATTER

SOP: 7.11 Foreign Matter Analysis and Photographic Imagine

Matrix: Flower

PT Results: 2/27/2020 – External Flower PT – (hemp)

Visual analysis, filth/extraneous material >/< 5% - ACCEPT</li>

#### Comments (4/16/2020):

xx. 4/16/2020: Method Approved: Concentrate and Flower Matrix

Updates submitted:

#### 9. TARGET ANALYTES

SOP: LOM 7.14 Vitamin E Acetate Analysis by UHPLC-DAD

Matrix: Concentrate

#### PT Results:

■ Vitamin E Acetate (05/04/2020)- ACCEPT

#### Comments:

**07/08/2020:** The MRA is notifying the laboratory that analyzing Vitamin E Acetate on UHPLC-DAD has the potential to result in false positive results due to matrix interference and misidentification of peaks. The occurrence of false negative results has not yet been demonstrated but is also hypothesized due to matrix interference. The laboratory is aware of potential interferences.

Updates submitted:

SOP: LOM 7.15 Vitamin E Acetate Analysis by LC-MS/MS

Matrix: Concentrate



#### PT Results:

■ Vitamin E Acetate (10/23/2020)- ACCEPT

#### Comments:

10/30/2020: Laboratory submitted validation documents for addition of Vitamin E Acetate. Approved on 5/20/2020. The laboratory previously performed analysis of Vitamin E Acetate using an HPLC-DAD. The laboratory submitted an alternate protocol to detect Vitamin E Acetate using LC-MS/MS and will use this method going forward and use HPCL-DAD as a backup protocol.

#### ADDITIONAL ANALYSES – NOT REGULATED BY THE MRA

This section serves as acknowledgement that the laboratory has provided the MRA with the appropriate documentation and has notified the agency that they will be performing these analyses. The MRA does not require the following analyses.

1. Plant Gender Identification – Acknowledged.

All changes, updates, or additions to methodology must be submitted to the MRA for review and approval.

#### Assigned MRA Representative:

NAME: Claire T. Patterson, LSS Rosenzweig

ADDRESS: 2407 North Grand River Ave., Lansing, MI 48906

**TELEPHONE**: 517-230-2097, 517-243-4395 **E-MAIL**: RosenzweigN@michigan.gov

Rule 5(1) of the Sampling and Testing rule set (R. 420.305) A laboratory shall do all of the following: (a) Become fully accredited to the International Organization for Standardization (ISO), ISO/IEC 17025:2017 by an International Laboratory Accreditation Cooperation (ILAC) recognized accreditation body or by an entity approved by the agency within 1 year after the date the laboratory license is issued and agree to have the inspections and reports of the International Organization for Standardization made available to the agency.

If any of the methods on this approval report are not accredited by the expiration of the license, the approvals are rescinded in accordance with the rule above.