

June 30, 2025

Assured Testing Laboratories, LLC 300 Potash Hill Road, Suite A Tyngsborough, Massachusetts 01879 License no. IL281360 Case No. ENF-2025-1858

### SUMMARY SUSPENSION ORDER

G.L. c. 94G, §§ 4(a)(xi) and (a½)(xi) 935 CMR 500.350

Pursuant to its authority under G.L. c. 94G, §§ 4(a)(xi) and (a½)(xi) and 935 CMR 500.350, the Commonwealth of Massachusetts Cannabis Control Commission (the "Commission"), acting through its Executive Director, issues this Summary Suspension Order (the "Order") requiring the immediate suspension of License no. IL281360 held by Assured Testing Laboratories, LLC (the "Respondent"), the immediate suspension of all agent registrations associated with Respondent, and the cessation of all licensed operations having determined that Respondent established a pattern of failing to accurately report Total Yeast and Mold test results to the Commission and in the Seed-to-Sale System of Record, Metrc (herein, "Metrc"). Respondent's noncompliance poses an immediate and serious threat to the public health, safety, or welfare of the Commonwealth and undermines the Commission's confidence in Respondent's ability to uphold its regulatory obligations.

The Order shall be effective upon Respondent and shall take effect on <u>July 4, 2025, at 12:00</u> **A.M.** (the "Effective Date and Time").

# I. STATUTORY AND REGULATORY AUTHORITY

- 1. The Commission is charged with the administration and enforcement of laws regulating and licensing Marijuana Establishments and maintains jurisdiction over the conduct of licensed entities including their compliance with the Commonwealth's marijuana laws, G.L. c. 94G, and regulations, 935 CMR 500.000 *et seq. See* G.L. c. 94G, § 4(a), (a½);
- 2. Independent Testing Laboratories are a type of Marijuana Establishment, defined as "a laboratory that is licensed by the Commission and is: (i) accredited to the most current International Organization for Standardization 17025 by a third-party accrediting body that is a signatory to the International Laboratory Accreditation Cooperation mutual recognition arrangement or that is otherwise approved by the Commission; (ii) independent financially from any medical marijuana treatment center or any licensee or marijuana establishment for which it conducts a test; and (iii) qualified to test marijuana



in compliance with regulations promulgated by the commission pursuant to [G.L. c. 94G]." G.L. c. 94G, § 1;

- 3. The Commission possesses all powers necessary or convenient to carry out and effectuate its purposes including, but not limited to:
  - a. the power to conduct investigations into qualifications for licensure. G.L. c. 94G, § 4(a)(xv);
  - b. the power to revoke or suspend a license. See G.L. c. 94G, § 4(a)(xi);
  - c. the power to gather facts and information applicable to the Commission's obligation to suspend or revoke licenses for a violation of G.L. c. 94G, or any regulation adopted by the Commission. G.L. c. 94G, § 4(a)(xiv);
  - d. the power to impose...penalties and sanctions for a violation of [G.L. c. 94G] or any regulations promulgated by the Commission. *See* G.L. c. 94G, § 4(a)(xxii); and
  - e. the power to conduct adjudicatory proceedings in accordance with chapter 30A. G.L. c. 94G, § 4(a)(xxiv);
- 4. The Commission also has the power to promulgate regulations and to adopt, amend, or repeal regulations for the implementation, administration, and enforcement of G.L. c. 94G. See G.L. c. 94G, § 4(a)(xxiv), (xxviii);
- 5. In accordance with G.L. c. 94G, § 15, the Commission has adopted regulations for the administration, clarification and enforcement of laws regulating and licensing Marijuana Establishments which include:
  - Requiring testing of Marijuana and Marijuana Products to be performed by an Independent Testing Laboratory in compliance with protocols. See 935 CMR 500.160(1) and 501.160(1);
  - b. Requiring the reporting of results that indicate contamination levels are acceptable limits established in protocols. *See* 935 CMR 500.160(4)(b) and 501.160(4)(b); and
  - c. Grounds for the summary suspension of a license prior to a hearing to protect the public health, safety, or welfare. *See* 935 CMR 500.350(1) and 501.350(1);
- 6. If based on inspection, affidavits, or other credible evidence, the Commission or Commission Delegee determines that a Licensee or Registrant poses an immediate or serious threat to the public health, safety or welfare, the Commission or Commission Delegee's may issue a Summary Suspension Order that requires the immediate suspension of a License and its associated registrations and cessation of all operations. 935 CMR 500.350(2)(b);
- 7. On receipt of a Summary Suspension Order, the Licensee and its associated Marijuana Establishment Agents must immediately comply with the requirements of the order and, if requested, post notice at public entrances to the establishment. 935 CMR 500.350(4);

#### II. FACTUAL BASIS

In making this determination, the Commission finds as follows:

- 8. Respondent is an operational Independent Testing Laboratory located at 300 Potash Hill Road, Suite A in Tyngsborough, Massachusetts 01879, with a final license to test Marijuana and Marijuana Products for Marijuana Establishments and Medical Marijuana Treatment Centers under License no. IL281360;
- 9. On October 13, 2022, the Commission issued Respondent its Final License to operate as an Independent Testing Laboratory;
- 10. After receiving Commission authorization, Respondent commenced operations on February 16, 2023;
- 11. In its application for licensure, Respondent disclosed Dimitrios Pelekoudas, PhD ("Dr. Pelekoudas") and Linda Pelekoudas as Persons Having Direct or Indirect Authority;
- 12. According to the Massachusetts Cannabis Industry Portal (MassCIP), there are 33 active, registered Laboratory Agents ("Agents") that work for Respondent;
- 13. Respondent is accredited in accordance with ISO/IEC 17025:2017 by Perry Johnson Laboratory Accreditation, Inc.;
- 14. Section 5.4 of ISO/IEC 17025:2017, states that "Laboratory activities shall be carried out in such a way as to meet the requirements of [ISO/IEC 17025], the laboratory's customers, regulatory authorities and organizations providing recognition. This shall include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility";
- 15. Respondent's accredited method for testing Total Yeast and Mold is described in its standard operating procedures (SOP) titled Sample Preparation and Processing to Quantify and Qualify Microbiological Organisms in Cannabis, Doc. No. SOP-006 (herein, "Sample Preparation SOP") and Quantitative Detection of Fungal Organisms in Cannabis and Cannabis Products, Doc. No. SOP-007 (herein, "Detection of Fungal Organisms SOP");

16.	Pursuant to its Detection of Fungal Organisms SOP, Respondent measures T	otal Yeast
	and Mold in Marijuana and Marijuana Product lab samples through the	
	;	

17. The laboratory techniques and processes	utilizes to generate a numerical result for
Total Yeast and Mold include nucleic aci	d extraction, polymerase chain reaction (PCR),



microarray hybridization, and scanning of sample wells. These processes are described in further detail in the Sample Preparation and the Detection of Fungal Organisms SOP;

- 18. According to the company that manufactures the effective limit of detection (LOD) of the six between 100-100,000 colony forming units per gram (CFU/g) with Association of Analytical Collaboration International (AOAC) certification between 100-10,000 CFU/g;
- 19. According to Section 3.1 and 3.2 of Respondent's standard operating procedure titled Data Reporting, Doc. No. P-042 (herein, "Data Reporting SOP"), "results in the form of a Certificate of Analysis, and case records, are reviewed and authorized prior to release." The Data Reporting SOP specifically directs the authorizer of results to "review the technical record and document the review";
- 20. Further, Section 3.3 of the Data Reporting SOP states that "the results of each test or series of tests carried out by the trained analyst shall be reported accurately, clearly, unambiguously, and objectively, and in accordance with applicable procedures incorporated in its manuals. All issued reports are retained as technical records" and are reviewed and signed by the Quality Manager or their designee once complete;
- 21. The individuals working for Respondent that sign Certificates of Analyses, verifying and attesting to the accuracy and the information presented, are the Quality Managers, as well as the Owner and Chief Executive Officer Dr. Pelekoudas;
- 22. According to data from Confident Cannabis, Respondent's Laboratory Information Management System (LIMS), from April 1, 2024, to April 15, 2025, Respondent processed 22,531 Marijuana and Marijuana Product laboratory samples (herein "lab samples") from 61 different Marijuana Establishments and Medical Marijuana Treatment Centers;
- 23. Respondent performed microbial panel testing, including analysis for Total Yeast and Mold, on 18,246 of the 22,531 lab samples;
- 24. Respondent's tests represented approximately 25% of all the Total Yeast and Mold tests analyzed by Independent Testing Laboratories in the Commonwealth of Massachusetts;
- 25. During that same timeframe, Respondent reported in Metrc that only 0.05% of lab samples it tested for Total Yeast and Mold—10 out of 17,565 lab samples—failed due to contamination results exceeding the regulatory limit;
- 26. According to data retrieved from Metrc, from April 1, 2024, to April 15, 2025, 4.5% of Marijuana and Marijuana Products tested for Total Yeast and Mold industry-wide failed due to contamination results exceeding 10,000 CFU/g—the Commission's threshold for safe Marijuana and Marijuana Products;



- 27. According to the data provided by Respondent, 7,183 lab samples it analyzed had microbial panels that produced a numerical value for Total Yeast and Mold that was above zero and under 10,000 CFU/g but Respondent reported those results in Confident Cannabis, Certificates of Analysis, or Metrc as zero or non-detect, rather than the true value;
- 28. 544 lab samples had microbial panels that indicated a Total Yeast and Mold value of over 10,000 CFU/g, the Commission's threshold for Total Yeast and Mold contamination. Respondent did not report any of those failures to the Commission or input them into Metrc for the associated lab sample;
- 29. 160 lab samples were subject to multiple microbial panels after testing indicated Total Yeast and Mold contamination levels exceeded 10,000 CFU/g. These Total Yeast and Mold failures were either omitted from data entry by Respondent in Confident Cannabis or reported as non-detect on Certificates of Analysis and zero in Metrc;
- 30. Pursuant to Respondent's standard operating procedure titled Internal Validation, Doc. No. P-048 (herein, "Internal Validation SOP"), Respondent established a process of "performing internal validation when test results for cannabis or cannabis products indicate a potential exceedance of regulatory limits established by the [Commission]";
- 31. Section 3.0 of the Internal Validation SOP defines the following two terms, relevant to this matter:
  - a. "Internal Validation: The internal process initiated when test data suggests a sample may exceed CCC-established failure limits. Internal validation involves additional sample preparation, analysis, and/or data review to verify the accuracy of the initial result"; and
  - b. "Potential failure: An initial analytical result indicating that a sample may not comply with CCC regulatory thresholds. This applies to analysis of microbial and heavy metal samples."
- 32. Section 5.0 of the Internal Validation SOP included steps to inform the client, requesting new sample material, performing testing and analysis of that new material, and reporting the results of those new tests in Metrc rather than the original tests;

#### III. COMMISSION FINDINGS AND VIOLATIONS OF LAW

- 33. The facts set forth in Paragraphs 1 through 32 warrant the issuance of a Summary Suspension Order;
- 34. G.L. c. 94G, § 15(a)(3) requires that an "Independent Testing Laboratory shall report any results indicating contamination to the commission within 72 hours of identification";



- 35. Both Independent Testing Laboratories and Marijuana Establishments are required to "have a written policy for responding to laboratory results that indicate contaminant levels are above acceptable limits established in the protocols identified in 935 CMR 500.160(1)...the notifications shall be from both the Marijuana Establishment and the Independent Testing Laboratory, separately and directly." 935 CMR 500.160(4)(b) and 501.160(4)(b);
- 36. The Commission has established that the contamination limit for Total Yeast and Mold in processed and unprocessed material is 10,000 CFU/g, and 1,000 CFU/g for CO<sub>2</sub> and Solvent-based Extracts. *See* Exhibit 6 of the Protocol for the Sampling and Analysis of Finished Marijuana and Marijuana Products for Marijuana Establishments, Medical Marijuana Treatment Centers, and Colocated Marijuana Operations (the "Protocol");
- 37. A Licensee that receives notice that Marijuana or a Marijuana Product it has submitted for testing has failed any test for contaminants shall either reanalyze the Marijuana or Marijuana Product without remediation, take steps to remediate the identified contaminants, or dispose of the Marijuana or Marijuana Product. 935 CMR 500.160(13) and 501.160(13);
- 38. If the Licensee chooses to reanalyze the sample, a sample from the same batch shall be submitted for reanalysis at the ITL that provided the original failed result. If the sample passes all previously failed tests at the initial ITL, a sample from the same batch previously tested shall be submitted to a second ITL other than the initial ITL for a Second Confirmatory Test. To be considered passing and therefore safe for sale, the sample shall have passed the Second Confirmatory Test at a second ITL. Any Marijuana or Marijuana Product that fails the Second Confirmatory Test may not be sold, transferred or otherwise dispensed to Consumers, Patients or Licensees without first being remediated. Otherwise, the Marijuana Establishment shall dispose of any such product. 935 CMR 500.160(13)(a) and 501.160(13)(a);
- 39. Commission regulations authorize the Commission, or a Commission delegee, to issue a Summary Suspension Order on the receipt of credible information that a licensee poses an immediate or serious threat to the public health, safety, or welfare. *See* 935 CMR 500.350(2);
- 40. Violations of statute and Commission regulations casting doubt on the veracity and accuracy of Marijuana and Marijuana Product testing constitute violations that pose an immediate or serious threat to the public health, safety, or welfare;
- 41. From April 1, 2024, to April 15, 2025, Respondent's tests represented approximately 25% of all the Total Yeast and Mold tests analyzed by Independent Testing Laboratories but had a failure rate for Total Yeast and Mold of 0.05%;



- 42. When compared to the industry average, lab samples analyzed by Respondent were ninety times less likely to fail for the presence of Total Yeast and Mold;
- 43. According to Respondent's Data Reporting SOP, review of the technical record is required which should include a review of data from each applicable testing platform, such as data generated from for determining Total Yeast and Mold results for compliance testing. Analysts are then required to report the results from each test "accurately, clearly, unambiguously, and objectively";
- 44. Respondent failed to report to the Commission the true value of 7,183 lab samples—39% of the lab samples performed microbial panel tested—it analyzed that produced a numerical value for Total Yeast and Mold that was above zero and under 10,000 CFU/g in violation of G.L. c. 94G, § 15(a)(3);
- 45. Respondent failed to report to the Commission the results of 544 lab samples it analyzed that produced a numerical value for Total Yeast and Mold that exceeded 10,000 CFU/g in violation of G.L. c. 94G, § 15(a)(3), 935 CMR 500.160(4)(b) and 501.160(4)(b);
- 46. The Commission relies on the truthfulness of information input by Independent Testing Laboratories into Metrc and represented on Certificates of Analysis to facilitate its testing protocols and permit the legalized sale and safe consumption of Marijuana and Marijuana Products in the Commonwealth of Massachusetts;
- 47. Respondent's practice of misreporting Total Yeast and Mold under 10,000 CFU/g as zero or non-detect rather than the measured value falsely represents to the Commission, Patients and Consumers that there is no presence of microbial contaminants, and posed an immediate or serious threat to public health, safety or welfare;
- 48. Respondent's failure to report test results showing contamination exceeding 10,000 CFU/g for Total Yeast and Mold—as required by statute and regulation—and its decision to report favorable retest results at zero or non-detect undermines the Commission's ability to ensure compliance, and posed an immediate or serious threat to public health, safety or welfare;
- 49. The procedure described in Section 5.0 of the Internal Validation SOP for lab samples exceeding 10,000 CFU/g is incompatible with the requirements of G.L. c. 94G, § 15(a)(3), 935 CMR 500.160(4)(b) or 501.160(4)(b) and subverts the reanalysis process outlined in 935 CMR 500.160(13) or 501.160(13);
- 50. Respondent subjected 160 lab samples to multiple rounds of reanalysis that did not comply with 935 CMR 500.160(13) or 501.160(13), following initial test results indicating Total Yeast and Mold contamination levels exceeded 10,000 CFU/g;

- 51. Respondent's practices and activities related to Total Yeast and Mold testing do not comply with its obligations to its regulatory authority Commission in accordance with Section 5.4 of ISO/IEC 17025:2017;
- 52. Respondent's practice of requesting additional Marijuana lab sample submissions for failing Total Yeast and Mold results is an intentional effort to conceal those failing results and only report the favorable results on behalf of its clients contradicts Commission regulations and the Protocol putting the health of Patients and Consumers at risk. These actions posed an immediate or serious threat to public health, safety or welfare;
- 53. Respondent's failure to accurately report Total Yeast and Mold test results undermines public confidence in the regulated Marijuana industry. Further, through its conduct, Respondent has disadvantaged other Independent Testing Laboratories that report accurate test results in accordance with applicable statutory and regulatory requirements as well as Marijuana Establishments that rely upon Respondent to produce accurate test results. This conduct poses an immediate or serious threat to the public welfare; and
- 54. Individually each of Respondent's actions regarding the failure to report Total Yeast and Mold contamination results pose an immediate or serious threat to the public health, safety, or welfare. Taken together, Respondent's conduct and practices poses an immediate or serious threat to the public health, safety, and welfare, as well as an existential threat to the regulated Marijuana industry.

### IV. ORDER

Based on the above factual findings and violations of law, and Respondent's disregard of Commission regulations and its obligations to accurately and truthfully report results of Total Yeast and Mold tests, Respondent's continued operations pose an immediate or serious threat to the public health, safety, or welfare.

55. Accordingly, the Commission, acting through its Executive Director, <u>suspends and</u> <u>requires the immediate cessation of operations</u> associated with the licenses stated below subject to the conditions of Paragraph 57, effective July 4, 2025, at 12:00 AM;

Final License IL281360 Independent Testing Laboratory Tyngsborough, MA

- 56. Accordingly, the Commission, acting through its Executive Director, <u>suspends</u> all agent registrations and any other agent registrations affiliated with IL281360 subject to the conditions of Paragraph 57, effective <u>July 4, 2025, at 12:00 AM</u>:
- 57. Further, the Commission, acting through its Executive Director, hereby orders:
  - a. Respondent **shall** post and maintain a copy of the Order, in its entirety, on the outside of all public entrances to its establishment throughout the term of the suspension;



- b. Respondent may finalize the testing of any in-progress lab samples in its inventory prior to the effective date of the suspension. Respondent **shall** report the true and accurate value of Total Yeast and Mold results for any in-progress lab samples to the Commission and provide the underlying data from for those lab samples to <a href="mailto:Testing@CCCMass.com">Testing@CCCMass.com</a> Attn: Director of Testing, within 72 hours of analysis;
- c. Marijuana or Marijuana Product lab samples that are not completed by the effective date of the Order **shall** be returned to the Marijuana Establishment or Medical Marijuana Treatment Center of origin or wasted by Respondent. Respondent **shall** notify the Commission at least 24 hours in advance of any Marijuana or Marijuana Product destruction;
- d. Respondent **shall** identify agents essential for the security and general maintenance of the laboratory and provide the names of those agents to <a href="Testing@CCCMass.com">Testing@CCCMass.com</a>
  Attn: Director of Testing. Upon satisfactory review of the agents proposed by Respondent, the Commission may approve reinstatement of their Agent Registrations for that limited purpose;
- e. Respondent **shall** make available, during regular business hours, agents to respond to inquiries from client licensees regarding Marijuana Product samples tested by Assured;
- f. Respondent **shall** not allow anyone other than those identified in subparagraph d to access the Premises with the exception of Commission staff, local law enforcement, or emergency personnel. Limited exceptions for other individuals, including, but not limited to, third-party contractors, consultants or visitors, will be considered on a case-by-case basis as outlined below:
  - (i) Respondent shall provide notice of other individuals to the Director of Investigations, at least 24 hours in advance of an expected visit and such request shall include the name(s) of the visitor(s), expected date of visit, purpose of the visit, and name(s) of the Registered Agent(s) who will escort the visitor(s). Visitors may access the facility only on approved dates and may only be present for the purposes stated. All approved visitors shall be signed in and out as Visitors and must be accompanied by a Registered Agent;
- g. Respondent **shall** cooperate with the Commission as necessary and to facilitate any inspections by Commission staff on the Premises;

Notice is provided pursuant to 935 CMR 500.350(3)(a)5. and 500.500(3)(b)4. that the Order shall take effect on <u>July 4, 2025, at 12:00 A.M</u>. Failure to comply with the conditions of the Order may result in further enforcement action against Respondent up to and including the issuance of a monetary penalty, suspension or revocation of licensure.

Nothing herein should be construed as precluding or limiting Commission authority to take additional administrative action to protect the public health, safety, and welfare.

The Commission reserves the right to modify, amend, or rescind the order or take additional enforcement action permitted pursuant to 935 CMR 500.350 and 500.500. The Order shall

remain in effect until the Commission rescinds or amends the order or until such other time as specified in 935 CMR 500.500.

Respondent may request a hearing no later than 21 calendar days after the Effective Date of the Order by making such request by email to <a href="Hearings@CCCMass.com">Hearings@CCCMass.com</a>, Attn: Legal Department, for it to be considered timely under 935 CMR 500.350(5)(a). Respondent may appear *pro se* or be represented by counsel in the administrative hearing process. <a href="The hearing will be subject to the Standard Adjudicatory Rules of Practice and Procedure, which includes 801 CMR 1.01, 801 CMR 1.02, and 801 CMR 1.03.

The requirements of an order issued under 935 CMR 500.350(2) shall remain in effect until one of the following events has occurred: (a) the Commission modifies, amends or rescinds the order; (b) there is a Final Decision on the merits of a Commission order, including judicial review of the order, unless the order is vacated or modified by a court of competent jurisdiction or rescinded by the Commission; (c) there is a Final Decision on the merits of a subsequently issued Order to Show Cause under 935 CMR 500.370 including judicial review of the order, unless the order is vacated or modified by a court of competent jurisdiction or rescinded by the Commission; or (d) until such time as is otherwise established under the procedures set forth in 935 CMR 500.000. 935 CMR 500.350(6).

Signed this 30 day of June 2025:

**Commonwealth of Massachusetts Cannabis Control Commission** 

Travis Ahern, Executive Director

To de

Copy to:

Nomxolisi K. Jones, Chief of Investigations and Enforcement Katherine Binkoski, Director of Investigations Timothy Barwise, Interim Director of Testing and Investigations Manager Timothy Goodin, Enforcement Counsel Jacob Nielson, First Assistant Enforcement Counsel Tiixa Chukwuezi, Associate Enforcement Counsel



# **CERTIFICATE OF SERVICE**

I,Timothy Goodin, hereby certify that on this 30<sup>th</sup> day of June 2025, I served a copy of this Summary Suspension Order on Assured Testing Laboratories, LLC, by electronic mail to the owner of record Dimitrios Pelekoudas, PhD at d.pelekoudas@assuredtestinglab.com.

Timothy Goodin

Enforcement Counsel

MA BBO # 698182

Timothy.Goodin@CCCMass.com

**Union Station** 

2 Washington Square

Worcester, Massachusetts 01609

774-337-2120

Jacob Nielson

First Assistant Enforcement Counsel

MA BBO # 692153

Jacob.Nielson@CCCMass.com

**Union Station** 

2 Washington Square

Worcester, Massachusetts 01609

774-670-4091