APA-1

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control: 538

Department or Agency: Alabama Medical Cannabis Commission

Rule No.: Chapter 538-X-10

Rule Title: Regulation of State Testing Laboratories

Intended Action: Amend

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety?	No
Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare?	Yes
Is there another, less restrictive method of regulation available that could adequately protect the public?	No
Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved?	No

To what degree?: N/A

Is the increase in cost more harmful to the public than the harm that might result from the absence of the proposed rule?	NA
Are all facets of the rule-making process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public?	Yes
Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule?	No

Does the proposed rule have an economic impact? No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.

Signature of certifying officer: John McMillan

John McMillan

Date: Tuesday, July 16, 2024

REC'D & FILED

JUL 16, 2024

LEGISLATIVE SVC AGENCY

APA-2

ALABAMA MEDICAL CANNABIS COMMISSION

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Medical Cannabis Commission

RULE NO. & TITLE: Chapter 538-X-10 Regulation of State Testing Laboratories

INTENDED ACTION: Amend

SUBSTANCE OF PROPOSED ACTION:
The proposed action is necessary due to statutory changes in Act 2024-342.

TIME, PLACE AND MANNER OF PRESENTING VIEWS:
A public comment portal will be available on the Commission's website (www.amcc.alabama.gov) between the date of publication (07/31/2024) and for a period of 35 days thereafter (ending on 09/04/2024).

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:
Wednesday, September 4, 2024

CONTACT PERSON AT AGENCY:
Justin Aday

John McMillan

John McMillan

(Signature of officer authorized
to promulgate and adopt
rules or his or her deputy)

ALABAMA MEDICAL CANNABIS COMMISSION
ADMINISTRATIVE CODE

CHAPTER 538-X-10
REGULATION OF STATE TESTING LABORATORIES

TABLE OF CONTENTS

538-X-10-.01	Licensing Applications And Operations Of State Testing Laboratories Generally
538-X-10-.02	Definitions
538-X-10-.03	General Licensing And Regulation Of Medical Cannabis As To State Testing Laboratories
538-X-10-.04	Requirements For State Testing Laboratories
538-X-10-.05	Laboratory Standards
538-X-10-.06	Proficiency Testing
538-X-10-.07	Accreditation
538-X-10-.08	Test Results; Retesting; Challenges To Test Results
538-X-10-.09	Applications and Applications Processing As To State Testing Laboratories
538-X-10-.10	Post-Licensing Inspection Of Facilities Operated By State Testing Laboratories
538-X-10-.11	Investigation Of State Testing Laboratories
538-X-10-.12	Training And Continuing Education Requirements For State Testing Laboratories
538-X-10-.13	State Testing Laboratories' Maintenance Of Proper Technology
538-X-10-.14	State Testing Laboratories' Annual Licensing Fees; Schedule
538-X-10-.15	State Testing Laboratories' Duty To Meet And Maintain Standards, Policies, Procedures And Operations Per Application
538-X-10-.16	State Testing Laboratories' Duty To Notify Or Seek Permission Regarding Material Change In Licensing Information
538-X-10-.17	State Testing Laboratories' Term Of Licenses
538-X-10-.18	State Testing Laboratories' Applications For Renewal Of License

538-X-10-.19	**State Testing Laboratories' Notifications To Apply For Renewal**
538-X-10-.20	**Expiration Of State Testing Laboratories Licenses; Delinquent License Renewal; Failure To Apply For Renewal**
538-X-10-.21	**State Testing Laboratories' License Renewal Process And Procedures; Use Of Independent Third-Party Consultants**
538-X-10-.22	**State Testing Laboratories' License Renewal Fees**
538-X-10-.23	**Non-Renewal Of State Testing Laboratories' Licenses**
538-X-10-.24	**State Testing Laboratories' Transfer Of Licenses; Change Of Ownership**
538-X-10-.25	**Marketing And Advertising By Integrated Facilities**
538-X-10-.26	**Relocation Of State Testing Laboratories' Facilities**
538-X-10-.27	**Material Change In State Testing Laboratories' Information**
538-X-10-.28	**Temporary Licenses For State Testing Laboratories**
538-X-10-.29	**State Testing Laboratories' Surrender Of License; Cessation Of Operations**
538-X-10-.30	**Disciplinary Actions Against State Testing Laboratories**
538-X-10-.31	**State Testing Laboratories' Appeals From Adverse Decisions By The Commission**
538-X-10-A	**Appendix A - Tests and Testing Standards of State Testing Laboratories**

538-X-10-.01 Licensing Applications And Operations Of State Testing Laboratories Generally.

State Testing Laboratories authorized pursuant to §20-2A-66, Code of Ala. 1975, (as amended), shall be located within Alabama and operate in accordance with the provisions of the Act and this Chapter. Except as specifically provided in this Chapter, State Testing Laboratories shall be governed by the General Rules for Licensee Applications (Chapter 3 of these Rules) and the General Rules for Licensee Conduct (Chapter 4 of these Rules).

Author: William H. Webster

Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.

History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-10-.02 Definitions.

As used in this Chapter, the following terms shall have the following meanings:

(1) "Aliquot." A portion of a larger whole, especially a sample taken for chemical analysis or other treatment.

(2) "Chemical Contamination." The presence of inappropriate chemical substances, or appropriate chemical substances in an inappropriately high concentration, in cannabis and medical cannabis.

(3) "Growth Inhibitors/Regulators." Plant growth inhibitors are regulating substances which retard such processes as root and stem elongation, seed germination, and bud opening. Plant growth regulators (PGRs) are chemicals used to modify plant growth such as increasing branching, suppressing shoot growth, increasing return bloom, removing excess fruit, or altering fruit maturity.

(4) "Heavy Metals." Metals of relatively high atomic weight including, but not limited to, arsenic, cadmium, lead and mercury.

(5) "Perform Testing." To conduct tests following approved procedures.

(6) "Private Testing." Testing that is conducted at the instance of a licensee by a third party or outside the official capacity of the State Testing Laboratory.

(7) "Reasonably Free." Falling within anticipated and acceptable levels of defect or chemical presence with respect to a particular standard.

(8) "Residual Pesticides." Detectible levels of any substance or mixture of substances in cannabis or medical cannabis resulting from the use of a pesticide; the term includes derivatives, such as degradation and conversion products, metabolites, reaction products, and impurities that are considered to be of toxicological significance.

(9) "Residual Solvents." The remaining solvent that is present after the medical cannabis extraction process has been completed, usually occurring when the required

processing and solvent-purging methods or steps are not properly utilized.

(10) "Validated Test Methods." A test method that has been validated using ISO/IEC 17025 methodology.

Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: **New Rule:** Published August 31, 2022; effective October 15, 2022.

538-X-10-.03 General Licensing And Regulation Of Medical Cannabis As To State Testing Laboratories.

(1) *License Required.* State Testing Laboratories are required to be licensed as set forth in Rule 2 of Chapter 3 of these Rules; State Testing Laboratories may not act in the capacity as such without a license provided by the Commission in accordance with the Act and this Chapter.

(2) *Number of Licenses to be issued by the Commission.* The number of licenses to be issued to State Testing Laboratories is within the discretion of the Commission, which will award licenses to State Testing Laboratories based on merit, need, and other factors identified generally and specifically by the Act and this Chapter. (See 20-2A-51, Code of Alabama 1975 (as amended)).

(3) *Authority.* A State Testing Laboratory is authorized, without the use of a Secure Transporter, to do the following:

(a) Collect a random sample of cannabis or medical cannabis at the premises of a cultivator, processor, dispensary, or integrated facility for testing.

1. The State Testing Laboratory which performs the test must collect the samples.

2. If the licensee facility has segregated the lot or batch of cannabis or medical cannabis into batches smaller than the entire lot or production run, the State Testing Laboratory must sample and test each batch from the lot.

3. From the time that a lot or production run has been homogenized for sample testing and eventual packaging and sale to a patient or caregiver, the facility which provided the sample shall segregate and withhold from use the entire lot or production run, except the samples that

have been removed by the State Testing Laboratory for testing.

4. During segregation, the facility which provided the sample shall maintain the lot or production run in a secure, cool, and dry location so as to prevent the cannabis or medical cannabis from becoming contaminated or losing its efficacy.

(b) Take cannabis or medical cannabis from, test cannabis or medical cannabis for, and return cannabis or medical cannabis only to a respective licensed facility.

1. At the time of transport, the State Testing Laboratory selecting a sample shall, using tamper-resistant products, record the name of the licensee and facility providing the sample; the batch, lot, or production run number; and the weight or quantity of the sample.

2. The sample shall be sealed into a locked tamper-evident container that shall not be accessible to the State Testing Laboratory transporter during transit.

3. Perform testing and analysis and report on the results of such to the licensee from which the sample was obtained.

4. A single employee may transport samples of cannabis or medical cannabis from or to a State Testing Laboratory for testing; such employees and transport vehicles carrying cannabis or medical cannabis are otherwise subject to the rules and regulations applicable to Secure Transporters as set forth in Chapter 7 of these Rules.

(c) Perform required official testing on behalf of the Commission, the results of which shall fulfill the testing requirements for cannabis and medical cannabis under the Act and these Rules; the results of official testing shall be reported to the Commission and considered dispositive for the purposes of confirming and approving batches of licensee's cannabis and medical cannabis to continue the medical cannabis production process, for ultimate use by patients in this State.

(d) Perform private testing on behalf of a Cultivator, Processor, Secure Transporter, Dispensary, or Integrated Facility; private testing may only occur pursuant to an advance request for a private test by a licensee (made at or before the time of collection of the batch or lot for testing). Unlike an official test, the results of such

private testing shall not fulfill the requirement of testing under the Act and these Rules, and the State Testing Laboratory shall not report the results to the Commission unless a licensee requests that it do so.

(4) *Limitations*.

(a) Under no circumstances shall the licensee which provided the sample sell or transfer the cannabis or medical cannabis to another licensee, patient, or caregiver, unless and until the State Testing Laboratory clears the licensee to do so based on the written results of successfully completed testing.

(b) A licensee shall not use more than one State Testing Laboratory to perform official testing on the same batch or sample of cannabis or medical cannabis except as expressly provided in 538-X-10-.08.

(c) A State Testing Laboratory may subcontract its testing of cannabis and medical cannabis only to another State Testing Laboratory. A transfer of samples pursuant to such a subcontract must be performed directly by the State Testing Laboratories.

(d) A State Testing Laboratory may request additional sample material for the purposes of completing required quality assurance tests but may not use such material for the purposes of resampling or repeating quality assurance tests.

(e) A State Testing Laboratory transporting samples may make multiple stops to collect samples if:

1. Each stop is for the sole purpose of retrieving a sample from a licensee's facility; and

2. All samples are clearly marked, kept separately, and remain secure at all times during transit.

(i) A State Testing Laboratory is not limited in the amount of usable cannabis and medical cannabis it may have on the premises of the laboratory at any given time, but the laboratory must maintain records to prove that all usable cannabis and medical cannabis on the premises are there for testing purposes only.

(ii) A license to operate as a State Testing Laboratory does not authorize the State Testing Laboratory to cultivate, process or dispense

cannabis, nor may a State Testing Laboratory perform the functions of a Secure Transporter (except as specifically stated herein) or an Integrated Facility as defined in the Act and these Rules.

(5) *Restrictions*.

(a) A State Testing Laboratory is not authorized, except at the request of the Commission, to perform testing on behalf of a patient or caregiver.

(b) A State Testing Laboratory may not perform testing for individuals and entities other than licensees under the Act and these Rules, including individuals and entities licensed under the laws of another jurisdiction.

(c) Except as specifically authorized by the Commission, the ability of a State Testing Laboratory to transport cannabis shall be restricted to furthering its function in testing cannabis and medical cannabis; a State Testing Laboratory is prohibited from transporting any cargo except cannabis, medical cannabis and associated products, materials, packages, or containers.

(d) Applicants for a license to operate as a State Testing Laboratory, and any and all investors having any interest in a State Testing Laboratory applicant, are prohibited from having any interest in any applicant for, or a licensee that is, a Cultivator, Secure Transporter, Processor, Dispensary, Integrated Facility, a qualified recommending physician, or another State Testing Laboratory.

Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: **New Rule:** Published August 31, 2022; effective October 15, 2022.

538-X-10-.04 Requirements For State Testing Laboratories.

A State Testing Laboratory must:

(1) Adopt and follow minimum good laboratory practices which must, at a minimum, satisfy the OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring published by the Organization for Economic Co-operation and Development.

(2) Become certified by an accreditation body, such as the American Association for Laboratory Accreditation that

certifies effective implementation of ISO standards and agree to have the inspections and reports of the accreditation testing made available to the Commission.

(3) Maintain equipment and testing facilities sufficient to perform testing as required by the Act and these Rules.

(4) Perform tests per batch on behalf of licensees (scheduled official testing) at least once during each phase of the cannabis production during which testing is required, prior to the cannabis or medical cannabis leaving the cultivation, processing, or dispensing facility (or in the case of an integrated facility, the cultivation, processing or dispensing phase or department); testing also may occur at any time at the request of the Commission (unscheduled official testing) or informally at the request of a licensee (unscheduled unofficial testing).

(5) Perform tests to ensure that all dispensed medical cannabis is reliably high grade and maintains consistency among batches as required by the Act and this Chapter.

(6) Perform tests pursuant to the protocols and corresponding tolerance limits in accordance with the current minimum standards established by the Commission, which shall be available on the Commission's website, including:

(a) Cannabinoid content and potency, including, but not limited to, all of the following:

(i) Total THC (THC+ THCA).

(ii) Total CBD (CBD + CBDA).

(iii) THC/CBD ratio, if applicable.

(iv) Percent of THC relative to original plant material (w/w).

(b) Terpene profiles.

(c) Heavy metals.

(d) Chemical contamination, such as residual solvents remaining after extraction and concentration.

(e) Microbials, including pathogenic microbials.

(f) Mycotoxins.

(g) Residual pesticides: (insecticides, fungicides, herbicides, and growth inhibitors/regulators) used during cultivation as follows:

1. No pesticides or growth regulators may be used in the cultivation or production of cannabis or medical cannabis if the pesticide appears on any list of prohibited pesticides maintained or published by the ~~Department~~Commission.

2. When performing pesticide or growth regulator residue analysis, a State Testing Laboratory shall analyze for any non-prohibited pesticides, to determine whether the test product is reasonably free of residue of such pesticides.

3. If a non-prohibited pesticide or growth regulator **is** detected at a level which exceeds the level specified by the ~~Department or a pesticide prohibited by the Department~~Commission or a pesticide prohibited by the Commission **is** detected in any amount which is positively verified, the pesticide residue analysis is failed, and the product must be recalled.

(h) Residual solvents.

(i) Any other testing protocols as may be required by the current minimum standards established by the Commission, which shall be made available on the Commission's website. (See Appendix A to this Chapter).

(7) Use validated test methods to determine delta-9-tetrahydrocannabinol, tetrahydrocannabinolic acid, cannabidiol, and cannabidiolic acid levels, in accordance with the current minimum standards established by the Commission, which shall be available on the Commission's website.

(8) Perform tests that determine whether cannabis and medical cannabis comply with the current minimum standards for microbial and mycotoxin contents established by the Commission, which shall be available on the Commission's website.

(9) Perform other tests necessary to determine licensees' compliance with good manufacturing practices, including but not limited to the following:

(a) Tests demonstrating that medical cannabis is medical grade.

(b) Tests demonstrating that medical cannabis contains no active ingredients other than cannabis provided by a licensee under the Act and this Chapter.

(c) Tests demonstrating that any excipients are pharmaceutical grade· within safe and effective levels, in accordance with the formulae provided by a Processor or Integrated Facility.

(d) Any other tests as may be reasonable, necessary, and appropriate to demonstrate good manufacturing processes.

(10) Have a secured laboratory space that cannot be accessed by the general public, in accordance with the Security Plan provided by the licensee at the time of licensing or pursuant to an approved amendment, waiver or variance thereto.

(11) Retain and employ at least one staff member (a scientific director) with a relevant advanced degree in a medical or laboratory science from an accredited secondary educational institution.

(a) The scientific director shall:

1. Ensure that the State Testing Laboratory achieves and maintains quality standards of practice as required by the Act and this Chapter; and

2. Supervise all staff of the State Testing Laboratory.

(b) If a scientific director is no longer employed by a State Testing Laboratory, the State Testing Laboratory shall not be permitted to conduct any testing.

(c) Upon the appointment of a new scientific director by a State Testing Laboratory, the State Testing Laboratory shall not resume any testing until the Commission conducts an inspection of the State Testing Laboratory.

(12) A sample of cannabis for testing must be at least ten (10) grams and no more than thirty (30) grams; a sample of a production run of medical cannabis must be the lesser of one percent (1%) of the total product weight of the production run or ten (10) units of product. All samples must be homogenized before testing.

(13) A cultivator or integrated facility shall not submit cannabis (as opposed to medical cannabis) to a State Testing Laboratory for testing unless the cannabis is destined for extraction and weighed within two (2) hours after harvest.

(14) At a minimum, monitor, track, and enter the following information into the Statewide Seed-to- Sale Tracking System as to each sample to be tested, including:

(a) The identity of the licensee for whom testing is to be performed.

(b) Where and how the sample was obtained.

(c) The size, count or weight, as available, of the sample obtained.

(d) The date and time the sample was obtained.

(e) The identity of the transporter, including any Secure Transporter, if any, including the identity of the personnel and vehicle involved in the transport.

(f)) The date and time of the sample's arrival at the State Testing Laboratory.

(g) The tag, lot, or batch number (and any other information contained on the digital or QR code) applicable to the cannabis or medical cannabis, as available, from which each sample was obtained.

(h) The conditions of storage upon arrival at the State Testing Laboratory.

(i) The date and time testing commenced.

(j) The types of tests undertaken by the State Testing Laboratory and the amount of the sample used for each test.

(k) The date and time testing concluded.

(l) The results of testing.

(m) Any steps to be taken as a result of such testing.

(n) Any steps to be taken to dispose of or return any unused sample material.

(o) If returned, the date and time of the sample material's departure from the laboratory.

Author: William H. Webster; Justin C. Aday
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: **New Rule:** Published August 31, 2022; effective October 15, 2022. **Amended:** Published ; effective .

538-X-10-.05 Laboratory Standards.

(1) A State Testing Laboratory must be shown to have met and maintained the requirements for a testing laboratory in international standard ISO/IEC 17025 published by the International Organization for Standardization, a copy of which may be obtained from the American National Standards Institute.

(2) Self-Certification that the State Testing Laboratory is operating according to standards sufficient to meet ISO/IEC 17025 requirements must be provided to the Commission prior to commencing testing on behalf of licensees.

(3) A State Testing Laboratory must follow:

(a) The most current version of the Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control monograph published by the American Herbal Pharmacopoeia, and

(b) "Recommendations for Regulators --Cannabis Operations" published by the American Herbal Products Association, and

(c) "Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals -- An Aid to the Interpretation of ISO/IEC 17025:2005" (2015) published by AOAC International.

(4) A State Testing Laboratory must use, when available, testing methods that have undergone validation by the Official Methods of Analysis of AOAC International, the Performance Tested Methods Program of the Research Institute of AOAC International, the Bacteriological Analytical Manual of the Food and Drug Administration, the International Organization for Standardization, the United States Pharmacopeia, the Microbiology Laboratory Guidebook of the Food Safety and Inspection Service of the United States Department of Agriculture, ~~the Department,~~ or an equivalent third-party validation study approved by the Commission. If no such testing method is available, a State Testing Laboratory may use an alternative testing method, or a testing method developed by the State Testing Laboratory, upon

demonstrating the validity of the testing method to and receiving the approval of the Commission.
Author: William H. Webster; Justin C. Aday
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: **New Rule:** Published August 31, 2022; effective October 15, 2022. **Amended:** Published ; effective .

538-X-10-.06 Proficiency Testing.

In addition to the standard inspection requirements applicable to all licensees pursuant to Rule 538-X-4-.02 of Chapter 4 of these Rules, the Commission may require a State Testing Laboratory, at its own cost, to have an independent third party validate and monitor, on an ongoing basis, the State Testing Laboratory's basic proficiency to correctly execute its analytical testing methodologies.

(1) The Commission will establish a proficiency testing program for State Testing Laboratories. A proficiency testing program must include, without limitation, providing rigorously controlled and standardized proficiency testing samples to State Testing Laboratories for analysis, reporting the results of such analysis and performing a statistical evaluation of the collective demographics and results of all State Testing Laboratories.

(2) Each State Testing Laboratory must participate in the proficiency testing program established pursuant to this section.

(3) If required by the Commission as part of being issued or renewing a license, the State Testing Laboratory must have successfully participated in the proficiency testing program within the preceding 12 months.

(4) To maintain continued registration as a State Testing Laboratory, a laboratory must participate in the designated proficiency testing program with continued satisfactory performance as determined by the Commission.

(5) A State Testing Laboratory must analyze proficiency test samples using the same procedures with the same number of replicate analyses, standards, testing analysts and equipment as used for product testing.

(6) The scientific director of the State Testing Laboratory and all testing analysts that participated in a proficiency test must sign corresponding attestation statements.

(7) The scientific director of the State Testing Laboratory must review and evaluate all proficiency test results.

(8) Successful participation includes the positive identification of eighty percent {80%) of the target analytes that the State Testing Laboratory reports to include quantitative results when applicable. Any false positive or false negative results reported will be considered an unsatisfactory score for the proficiency test.

(9) Unsuccessful participation in a proficiency test may result in limitation, suspension, revocation, or non-renewal of the State Testing Laboratory's license.

(10) The Commission will select a proficiency testing provider to conduct the proficiency testing program and determine the schedule that the proficiency testing provider will follow when sending proficiency testing samples to State Testing Laboratories for analysis.

(11) In addition to achieving the standard required pursuant to paragraph 8. of this Rule, a State Testing Laboratory successfully participates in the proficiency testing program only if the State Testing Laboratory does all of the following:

(a) Obtains single-blind proficiency testing samples from the proficiency testing provider.

(b) Analyzes the proficiency testing sample for all analytes required by the Act and this Chapter.

(c) Reports the results of its analysis to the proficiency testing provider.

(d) Analyzes a proficiency testing sample pursuant to the proficiency testing program not less frequently than once each 12 months.

(e) Pays the costs of subscribing to the proficiency testing program.

(f) Authorizes the proficiency testing provider to submit to the Commission the results of any test performed pursuant to this section.

(12) The performance of a State Testing Laboratory is satisfactory pursuant to paragraph 4. of this Rule if the results of the testing performed pursuant to this Rule are

within the limits of the acceptance range established by the proficiency testing provider.

(13) A State Testing Laboratory that fails to meet the requirements of this Rule may request that the Commission allow the State Testing Laboratory to retest a proficiency testing sample once to establish satisfactory performance. If the Commission denies the request or if the State Testing Laboratory fails to meet the standard on retesting, the Commission may limit, suspend, or revoke the State Testing Laboratory's license.

Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: **New Rule:** Published August 31, 2022; effective October 15, 2022.

538-X-10-.07 Accreditation.

(1) A licensee operating as a State Testing Laboratory must be accredited (or, for new licensees, have at a minimum a plan to achieve accreditation within one year) by an impartial organization that operates in conformance with standard ISO/IEC 17011 of the International Organization for Standardization and is a signatory to the Mutual Recognition Arrangement of the International Laboratory Accreditation Cooperation.

(2) The licensee's scope of accreditation shall demonstrate testing capabilities in the categories of cannabinoids, pesticides, toxins, metals, microbiological bacteria and/or other microbials, including pathogenic microbials.

(3) A State Testing Laboratory is expected to achieve accreditation as set forth in this Rule within one year from the date of licensing by the Commission. The license of a State Testing Laboratory that fails to become accredited within two years from the date of licensing by the Commission shall be non-renewed or revoked.

(4) A State Testing Laboratory that loses accreditation, as set forth in this Rule, must be re-accredited within one year or its license shall be non-renewed or revoked.

Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: **New Rule:** Published August 31, 2022; effective October 15, 2022.

538-X-10-.08 Test Results; Retesting; Challenges To Test Results.

(1) A State Testing Laboratory shall provide the final certificate of analysis containing the results of official testing pursuant to this Chapter to the licensee which provided the sample within two (2) business days after obtaining the results.

(2) If a sample from a batch of cannabis fails an official test conducted by a State Testing Laboratory, the remainder of the batch, including any cannabis plant trim, leaf; and other usable material from the same batch automatically fails the official test.

(a) A batch that fails an official test may be remediated and retested upon the request of the licensee. Initial retesting shall occur using the same sample at the same State Testing Laboratory; however, at the discretion of the licensee, subsequent retesting may occur at a different State Testing Laboratory, if available.

(b) A batch of cannabis that fails a microbial screening may be used to make a CO2 or solvent- based extract. After processing, the CO2 or solvent-based extract must pass all required official tests.

(3) If a sample from a batch in the production of medical cannabis fails an official test conducted by a State Testing Laboratory, the entire batch from which the sample was taken automatically fails the official testing.

(4) A State Testing Laboratory shall, at the time of collection, obtain a sample large enough to undergo two tests; it shall keep any sample which fails testing for 30 days (or longer, at the request of the Commission) pending a request by the licensee to (A) seek retesting, (B) challenge the result, or (C) accept the result and seek remediation of the failed sample and/or the batch from which it was derived. A sample kept by the State Testing Laboratory pursuant to this subsection must be stored in a cool, dry area to prevent or minimize deterioration, and the sample shall be made available to the licensee upon request for further testing in furtherance of any challenge or attempt to remediate. A cannabis testing facility shall dispose of a sample kept pursuant to this subsection after 30 days have elapsed after failure of testing, barring a contrary request by the Commission.

(5) Within seven (7) days following a failed test, a licensee must take at least one of the following actions:

(a) *Accept*. Accept the results of the test and destroy the batch.

(b) *Retest*. Request in writing (with copy to the Commission provided electronically through the Statewide Seed-to-Sale Tracking System) that the State Testing Laboratory retest the sample as to the portion of the test that failed; if the second test of the same sample passes, the sample (if available, otherwise a parallel sample taken by the licensee under subparagraph 6. of this Rule) shall be sent to another State Testing Laboratory, if available, as chosen by the Commission, to provide a tiebreak test (the Commission's function shall not be to gatekeep such a request, but merely to assign the State Testing Laboratory that will administer the subsequent retest). The results of the tiebreak test are final.

(c) *Challenge*. Following a test or failed retest by the State Testing Laboratory, a licensee may challenge the results by a request in writing (with copy to the Commission provided electronically through the Statewide Seed-to-Sale Tracking System) that two additional State Testing Laboratories be chosen by the Commission, if available; the two additional State Testing Laboratories shall provide full testing of the parallel samples taken by the licensee under subparagraph 6. of this Rule (the Commission shall not be to gatekeep such a request, but merely to assign the State Testing Laboratory that will administer the subsequent retest). If both challenge tests are deemed valid and demonstrate that the batch passed, the challenge is successful and the batch is cleared for use; otherwise, the challenge is unsuccessful, and the batch must be destroyed. The Commission shall be the final arbiter of any challenge under this rule.

(d) *Remediate*. Attempt to remediate the batch and request in writing (with copy to the Commission provided electronically through the Statewide Seed-to-Sale Tracking System) that the State Testing Laboratory obtain new samples and retest the remediated batch. Batch Remediation effects a reset of the testing process: testing prior to remediation is not considered, but only the testing of the new, remediated batch.

(6) A licensee may not challenge or request a retest by a State Testing Laboratory pursuant to this rule unless, at the time samples are initially taken for testing, the licensee ensures that three samples are collected at the same time by a State

Testing Laboratory using tamper-resistant containers. One of the samples must be taken by the State Testing Laboratory for testing and the licensee must place the other two samples in a secure quarantine storage area at its facility for further retesting by a secondary State Testing Laboratory. If at any time, further testing cannot be performed due to (A) the lack of available State Testing Laboratories to conduct further or additional tests, or (B) the lack of viable samples from which to perform retesting, tiebreak testing, or challenge testing, the licensee shall have no choice but to accept the result of the failed test and destroy or attempt remediation of the batch as required under this Rule.

(7) A licensee may request a retest as often as it likes, but it may not challenge the results of the test conducted by the State Testing Laboratory more than three (3) times during a one-year period; however, a successful challenge leading to a reversal of the original failed test shall not count toward the three (3) times.

(8) A licensee requesting a retest or challenge, or seeking new testing following remediation, shall be responsible for all costs involved in any testing performed pursuant to this Rule.

(9) Barring contrary results based on a retest or challenge as provided in paragraph 5. of this Rule, if, upon retesting, a sample provided to a State Testing Laboratory sample fails the same official test, the licensee that provided the sample shall destroy and dispose of the entire batch from which the sample was taken and document the destruction and disposal of the batch to the Statewide Seed-to-Sale Tracking System. A batch so destroyed and disposed of must not be recognizable as cannabis or medical cannabis, nor shall it be usable for any legal or illegal purpose.

(10) If a sample provided to a State Testing Laboratory pursuant to this section passes the same official test upon retesting and tiebreak testing by a separate State Testing Laboratory, the licensee need not destroy the entire batch; instead, the State Testing Laboratory shall clear the batch for further processing, packaging, labeling or sale, as appropriate, by means of certificate provided to the licensee and a notation on the Statewide Seed-to-Sale Tracking System.

Author: William H. Webster

Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.

History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-10-.09 Applications and Applications Processing As To State Testing Laboratories.

(1) *Generally*. Applicants for a license to operate as a State Testing Laboratory under the Act and these Rules shall be governed by the Rules for filing applications and seeking a license contained in Chapter 3 (538-X-3-.01, et seq.), except as specifically modified below.

(2) *Procedure for Filing Application Contents of - Application Specific to State Testing Laboratories*. A State Testing Laboratory's application filed with the Commission shall conform to the following requirements for all licensees set forth in 538-X-3-.05 of Chapter 3 of these Rules, except as noted below:

(a) Cover Sheet-as provided in 538-X-3-.0S of Chapter 3 of these Rules.

(b) Summary Sheet- as provided in 538-X-3-.05 of Chapter 3 of these Rules.

(c) Application Information - as provided in 538-X-3-.0S of Chapter 3 of these Rules, except as provided otherwise below:

1. The State Testing Laboratory Applicant's Verification regarding each business entity that has any ownership interest in the applicant shall conform with paragraph 3.a. of Rule 538- x-3-.0S of Chapter 3 of these Rules.

2. The State Testing Laboratory Applicant's Verification regarding individuals having any ownership interest in the applicant, as to the identity, street address and responsible person of all entities with which the individual is connected, to the extent the entity is directly or indirectly involved in the cannabis industry, shall conform with paragraph 3.b. of Rule 538-X-3-.0S of Chapter 3 of these Rules.

3. The State Testing Laboratory Applicant's Verification regarding any criminal history as to any owner, director, board member, or individual with a controlling interest in the applicant shall conform with paragraph 3.c. of Rule 538-X-3-.05 of Chapter 3 of these Rules.

4. The State Testing Laboratory Applicant's verified licensing history, cannabis industry history, and tax history regarding itself or any affiliate shall conform

with paragraphs of 3.d., 3.e., and 3.f. of Rule 538-X-3-.05 of Chapter 3 these Rules.

5. The State Testing Laboratory Applicant's Verification regarding any public officials having any interest in the applicant shall conform with paragraph 3.g. of Rule 538-X-3-.05 of Chapter 3 of these Rules.

6. State Testing Laboratory applicants must:

(i) identify which of the approved types of medical cannabis will be tested at each facility,

(ii) provide a summary of the processes and methods to be utilized to test each product, including the machinery, equipment, materials, and personnel necessary to test each product and

(iii) identify specific plans to ensure safety of personnel, facilities, and products being tested, based on the types of tests proposed to be utilized.

7. The State Testing Laboratory Applicant's statement of the anticipated or actual number of employees shall conform with paragraph 3.h. of Rule 538-X-3-.0S of Chapter 3 of these Rules.

8. The State Testing Laboratory Applicant's statement of the number of days, if awarded a license, within which it will commence operations and reach full capacity shall conform with paragraph 3.i. of Rule 538-X-3-.0S of Chapter 3 of these Rules.

9. The State Testing Laboratory Applicant's consent to the inspections, examinations, searches and seizures contemplated by § 20-2A-52(a)(3), Code of Alabama 1975 (as amended) shall conform with paragraph 3.j. of Rule 538-X-3-.0S of Chapter 3 of these Rules.

10. The State Testing Laboratory Applicant's verification of the permissibility of its facilities' locations and compliance with all State and local laws shall conform with paragraph 3.k. of Rule 538-X-3-.05 of Chapter 3 of these Rules.

11. The State Testing Laboratory Applicant's Verification that it and its leadership have no economic interest in any other license or Applicant for license under the Act or these Rules shall conform with paragraph 3.1. of Rule 538-X-3.05 of Chapter 3 of these Rules.

(3) *Procedure for Filing Application - Exhibits to State Testing Laboratory's Application*. Exhibits to the State Testing Laboratory Applicant's application information shall include all those as provided in subparagraphs 3.m.(1} through 3.m.(16} 538-X-3-.0S of Chapter 3 of these Rules, unless specifically provided otherwise as follows:

(a) State Testing Laboratory applicants must provide, as available, sales contracts and receipts, lease agreements or other documentation demonstrating possessory interest in all machinery and equipment to be used in the testing of cannabis or medical cannabis, as well as specifications and operations manuals of such machinery.

(b) State Testing Laboratory applicants must provide a quality control and quality assurance plan for each type of test to be performed on licensees' cannabis or medical cannabis identifying:

1. A summary of the collection protocols and procedures to be implemented by the State Testing Laboratory to ensure each sample's identity, adequacy, integrity, and freedom from cross-contamination.

2. A summary of the laboratory protocols and procedures to be adopted ensuring proper testing for the required safety, potency, stability, lifespan, and consistency of the cannabis or medical cannabis, whether as required by law or otherwise.

3. An overview of the steps to be taken in the testing process to provide high quality test results and/or to safeguard its testing procedures. The State Testing Laboratory Applicant must identify any specific plans to ensure integrity, consistency, efficacy, efficiency, economy, and accuracy of testing being performed at each facility, including whether and to what extent the State Testing Laboratory intends to implement these plans internally or to rely on any outside source to audit, evaluate and make recommendations to improve testing quality.

4. A summary of the tests that will be conducted, if any, with respect to each type of licensee or product.

5. A plan for reporting the results of testing upon a licensee's product, including the form to be utilized for providing said results to the licensee.

6. A plan for transportation of cannabis and medical cannabis to and from the State Testing Laboratory's facility.

7. Any steps that will be taken to differentiate between official tests and unofficial private testing performed at the request of a licensee.

8. A plan for managing the return and remediation or destruction of any failed test samples, including entry or monitoring the entry of the event on the Statewide Seed-to-Sale Tracking System.

9. Any specific plans to obtain and maintain accreditation as an ISO/IEC 17025 laboratory.

10. A detailed rendering of the information to be entered into the Statewide Seed-to-Sale Tracking System as to each sample obtained for testing.

(c) State Testing Laboratory applicants must provide:

1. A curriculum vitae for the business, demonstrating the education, experience, and other credentials of its leadership, including but not limited to all scientists and engineers employed at each facility.

2. A detailed explanation of the role each leader, scientist or engineer is to have in the processing of medical cannabis at each facility.

3. A 5-year hiring plan for its leaders, scientists, and engineers, identifying the types, positions, required education, required experience, and expected roles of such personnel.

(d) State Testing Laboratory applicants must provide copies of all contracts, contingent contracts, memoranda of understanding (or, if none of the foregoing are available, exemplars) between themselves and:

1. Any Cultivator or prospective Cultivator.

2. Any Processor or prospective Processor.

3. Any Secure Transporter or prospective Secure Transporter.

4. Any Dispensary or prospective Dispensary.

5. Any Integrated Facility or prospective Integrated Facility.

(e) State Testing Laboratory applicants must create a receiving and shipping plan that, at a minimum, ensures the following, in coordination with the contracted licensee:

1. Individual batches of cannabis being received for testing were appropriately prepared, tagged or otherwise identified, and inserted in containers at the time of receipt.

2. Batches and containers arriving from the licensee have been QR coded or otherwise digitally coded to identify, at a minimum, licensee, facility, plant tag identification number, date of harvest or processing, and the date (if any) of the last testing approval by a State Testing Laboratory.

3. Incoming cannabis or medical cannabis is accompanied by a manifest and other appropriate documentation; the information thereon is accurate and has been duly executed by all appropriate parties.

4. All information from the QR code relating to the incoming cannabis or medical cannabis, as well as the date and time of arrival, has been logged into the Statewide-Seed-to-Sale Tracking System.

5. Individual batches of medical cannabis arriving from a dispensary or from a processor after the packaging and labeling process has occurred, have been appropriately packaged, labeled, and inserted in containers prior to transport.

6. Batches and containers being transported back to a licensee from the State Testing Laboratory's facility must be QR coded or otherwise digitally coded to identify, at a minimum, the State Testing Laboratory and facility, the type of product, date of testing, and the date of the State Testing Laboratory's test approving or rejecting the product.

7. Outgoing test material is accompanied by an appropriate manifest and other appropriate documentation; the information thereon is accurate and has been duly executed by all appropriate parties.

8. All information from the QR code relating to the outgoing medical cannabis, as well as the date and time

of shipment, has been logged into the Statewide-Seed-to-Sale Tracking System.

(f) Each State Testing Laboratory must establish policies for an adequate chain of custody and requirements for samples of products provided to the laboratory for testing or research purposes, including, without limitation, policies, and requirements for:

1. Issuing instructions for the minimum sample and storage requirements.

2. Documenting the condition of the external package and integrity seals utilized to prevent contamination of, or tampering with, the sample.

3. Documenting the condition and amount of the sample provided at the time of receipt.

4. Documenting all persons handling the original samples, aliquots, and extracts.

5. Documenting all transfers of samples, aliquots and extracts referred to another State Testing Laboratory for additional testing or whenever requested by a client.

6. Maintaining a current list of authorized medical cannabis establishment agents and restricting entry to the laboratory to only those authorized.

7. Securing the laboratory during nonworking hours.

8. Securing short- and long-term storage areas when not in use.

9. Utilizing a secured area to log-in and aliquot samples.

10. Ensuring samples are stored appropriately.

11. Documenting the disposal or return of samples, aliquots and extracts following the conclusion of testing.

(g) State Testing Laboratory applicants must provide a detailed recall, return and remediation plan that will be followed in the event one or more lots or batches being tested, is determined to require recall. The plan must include, but should not be limited to, the following:

1. Provisions for notifying the licensee of a failed test or other adverse event.

2. Factors about a failed test or adverse event that would likely necessitate a recall, and any potential for retesting or remediation of the product in question, and any guidance that will be offered to assist a notified licensee.

3. Responsible individuals or positions within the State Testing Laboratory who will liaison with the licensee during the recall process.

4. Notification protocols to other licensees and the Commission through the Statewide Seed-to-Sale Tracking System.

5. Processes to help ensure, in cooperation with the notified licensee, that the recalled product is returned, remediated (and approved as safe), or destroyed.

6. Processes to report to the Commission and any other appropriate regulatory body regarding crisis response and steps taken to mitigate or avoid danger to the public.

7. Steps to be taken to assist the notified licensee to avoid further contamination, to preserve and protect uncontaminated cannabis or medical cannabis, and to ensure access to said products by those who depend on it.

8. Any assistance to be provided to the notified licensee to investigate and analyze the factors that led to the need for recall, and the process by which to make any recommendations as to adjustments to the licensee's internal protocols and processes to avoid recurrence.

9. As necessary, any general or specific licensee advisories that should be offered to minimize the likelihood of duplication of the factors that led to the unsafe condition requiring recall.

10. As necessary, any public advisories that should be offered to minimize the risk of harm to patients, caregivers, and other members of the public.

(h) The State Testing Laboratory Applicant's Security Plan must include a plan for security at each facility, including but not limited to the following:

1. Twenty-four-hour alarm systems must be installed in all facilities where cannabis and/or medical cannabis are present.

(i) Such alarms shall be provided and installed by experts in industry-standard commercial-grade alarm systems.

(ii) Alarm systems must be fully operational, securing all entry points and perimeter windows, be equipped with motion detectors and pressure switches, and must cover all areas where cannabis or medical cannabis is delivered, received, handled, stored, prepared, tested, or readied for transport.

2. All ingress and egress points to the facility shall be equipped with digital tag in/tag out systems to preclude unauthorized access by the general public.

3. All ingress and egress points to the testing area shall be equipped with digital tag in/tag out systems to limit access as to all but authorized personnel within the facility.

4. Reception areas and personnel adjacent to ingress and egress points shall have ready access to duress panic and hold-up alarms that may be activated in the event of access by unauthorized personnel or intruders.

5. Broadcast communication devices (cell phones, intercom equipment or the like) must be:

(i) Carried by each employee or installed in all areas of each State Testing Laboratory's facility designed for regular access by humans.

(ii) Accessible for communication by all personnel at all times, and particularly at perimeter ingress/ egress stations, facility reception areas, and the security office.

(iii) Capable of providing information with sufficient clarity to be heard and understood by all personnel and visitors within earshot of the employee receiving the communication.

6. A State Testing Laboratory's facility shall maintain an audio/video surveillance system that shall be in continuous operation 24 hours per day.

(i) Recording devices must be fully functional and fixed in place covering both the interior and exterior of the State Testing Laboratory's facility.

(ii) Recording devices must be in such quantity, with such lighting, and at such resolution as shall allow for the clear identification of individuals and activities in all reasonably accessible areas of the premises, including but not limited to all entrances, exits, parking lots, and any area where medical cannabis or medical cannabis is delivered, received, handled, stored, prepared, tested, or readied for transport.

(iii) Audio/Video surveillance recordings must clearly and accurately display the time and date.

(iv) Audio recordings must clearly and accurately capture conversations and activities to a level of 20 decibels within camera range.

7. The State Testing Laboratory facility's perimeter and any outdoor premises must be surrounded by a sufficient fence or barrier to prevent access by unauthorized persons and must have sufficient lighting to allow for the proper functioning of video surveillance equipment at all times between dusk and dawn or at any other time when ambient lighting requires enhancement to permit identification of individuals or activities upon or immediately adjacent to the premises. Indoor premises must likewise be sufficiently lit to allow for the identification of individuals and activities.

8. The State Testing Laboratory's facility must be housed in a stand-alone building or fully separated portion of a building accessible to and used by only authorized personnel; the area is not to be accessible to or used by scientists, engineers, or lab technicians not employed by the State Testing Laboratory. To the extent the State Testing Laboratory is housed within a larger facility, the portion dedicated to testing cannabis and medical cannabis must be self-contained or, at a minimum, segregated from the remainder of the activities being conducted in the larger facility by separate points of ingress and egress or, at a minimum, separately keyed and electronically protected entryways accessible only to employees of the State Testing Laboratory.

9. Exterior doors of each facility operated by a State Testing Laboratory must be designed or reinforced to

withstand unlawful forcible entry; exterior doors shall remain locked against outside intruders at all times, while allowing free egress by the facility's occupants in the event of an emergency; doors must permit ingress to employees and other appropriate persons only by means of a keycard or other similar electronic access device.

10. Exterior walls of each facility operated by a State Testing Laboratory must be reinforced to withstand unlawful forcible entry. Windows, likewise, must be reinforced to prevent breakage by outside intruders.

11. State Testing Laboratory Facilities must provide and maintain a plan for sufficient staffing of security guards at each facility where cannabis and medical cannabis is present to reasonably ensure the safety of the products stored therein; however, the State Testing Laboratory's plan must provide, at a minimum, one (1) security guard per facility during the facility's business/operating hours.

12. Strict access controls shall protect areas where cannabis or medical cannabis is handled or stored - in a secured, locked room or vault.

13. Records, whether electronic or manual, must be kept of all persons on the premises at a facility at all times, including employees, vendors, transporters or other licensees, and all others, recording the individuals' name, date, time of ingress and egress, and (as to non-employees) the reason for their presence; such records shall be kept for a minimum of two years, and longer at the request of the Commission or law enforcement.

14. Audio/Video surveillance records must be kept for at least 60 days, and longer upon the request of the Commission, its inspectors, or any law enforcement personnel. Audio/Video recordings potentially reflecting an incident of actual or attempted diversion must be kept for the longer of a period of two years, or until resolution of the incident and apprehension and discipline or prosecution of the individuals involved in the actual or attempted diversion.

15. Employees, while on duty, shall wear identification badges that clearly identify them as employees.

16. Visitors, including vendors, other licensees, Commission members, inspection personnel, or other

representatives must wear a "visitor pass" or "AMCC Official" pass, as applicable, at all times while on the premises. The State Testing Laboratory shall not be accessible by the members of the general public at any time.

17. State Testing Laboratories shall maintain, review and update policies to report theft, diversion, or other loss of cannabis or medical cannabis to the Commission and to law enforcement as early as practicable and not more than 24 hours from the event or its discovery.

18. Upon request, a State Testing Laboratory shall make available to the Commission or its inspectors all information relating to the State Laboratory's security plan, including but not limited to its security alarm systems, monitoring, alarm activity, maps of camera locations and camera coverage, audio/video footage, surveillance equipment maintenance logs, authorized use lists, operation instructions, and any other security-related information deemed relevant by the Commission or its inspectors.

(i) The State Testing Laboratory Applicant must provide an affidavit signed by the responsible individual and designated contact person (or, if the State Testing Laboratory is an entity, the duly authorized officer, owner or interest holder and the designated contact person) that the information provided in the Application is true and correct, to the best of the Affiants' knowledge upon a diligent investigation thereof.

(j) The State Testing Laboratory Applicant must provide the appropriate application fee as required by §20-2A-55(f), Code of Ala. 1975, (as amended). The application fee is nonrefundable and must be submitted electronically per instructions in the Application Form received in response to the applicant's Request for Application.

(4) In all other respects except as expressly stated otherwise in this Rule, State Testing Laboratory Applicants shall be governed by the rules for applications and licensing generally pertaining to all applicants (Chapter 3 of these Rules).

Author: William H. Webster

Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.

History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-10-.10 Post-Licensing Inspection Of Facilities Operated By State Testing Laboratories.

Post-Licensing Inspection of State Testing Laboratory facilities under the Act and these Rules shall be governed by Rule 538-X-4-.02 of Chapter 4 of these Rules.
Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-10-.11 Investigation Of State Testing Laboratories.

Investigation of State Testing Laboratory licensees under the Act and these Rules shall be governed by Rule 538-X-4-.03 of Chapter 4 of these Rules.
Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-10-.12 Training And Continuing Education Requirements For State Testing Laboratories.

Training and Continuing education requirements for State Testing Laboratories' owners, officers, administrators, managers, and employees shall be as set forth in Rule 538-X-4-.04 of Chapter 4 of these Rules.
Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-10-.13 State Testing Laboratories' Maintenance Of Proper Technology.

State Testing Laboratories' duty to maintain proper technology shall be governed by Rule 538-X-4-.0S of Chapter 4 of these Rules.
Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.

History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-10-.14 State Testing Laboratories' Annual Licensing Fees; Schedule.

State Testing Laboratories' duty regarding annual license fees shall be as set forth in Rule 538-X-4-.06 of Chapter 4 of these Rules, and the schedule therefor shall be contained on the AMCC website.
Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-10-.15 State Testing Laboratories' Duty To Meet And Maintain Standards, Policies, Procedures And Operations Per Application.

A State Testing Laboratory licensee has an ongoing duty to meet and maintain the standards, policies, procedures, and operations, both at the pre-commencement inspection and at all times thereafter, as it affirmed to the Commission at the time of licensing, as such standards, policies, procedures, and operations may have been amended and updated by the licensee from time to time in accordance with Rules 538-X-4-.08 and 538-X-4-.19., as provided in Rule 538-X-4-.07 of Chapter 4 of these Rules and as modified by Rule 538-X-10-.09 of this Chapter.
Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-10-.16 State Testing Laboratories' Duty To Notify Or Seek Permission Regarding Material Change In Licensing Information.

State Testing Laboratories' duty to notify or seek the Commission's permission regarding any material change in licensing information shall be governed by Rule 538-X-4-.08 of Chapter 4 of these Rules.
Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.

History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-10-.17 State Testing Laboratories' Term Of Licenses.

The term of State Testing Laboratories' licenses shall be governed by Rule 538-X-4-.09 of Chapter 4 of these Rules.
Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-10-.18 State Testing Laboratories' Applications For Renewal Of License.

State Testing Laboratories' applications for renewal of license shall be governed by Rule 538-X-4-.10 of Chapter 4 of these Rules.
Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-10-.19 State Testing Laboratories' Notifications To Apply For Renewal.

State Testing Laboratories' notifications to apply for renewal shall be governed by Rule 538-X-4-.11 of Chapter 4 of these Rules.
Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-10-.20 Expiration Of State Testing Laboratories Licenses; Delinquent License Renewal; Failure To Apply For Renewal.

The expiration of State Testing Laboratories' licenses, renewal of delinquent licenses and consequences for failing to apply for renewal shall be governed by Rule 538-X-4-.12 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: **New Rule:** Published August 31, 2022; effective October 15, 2022.

538-X-10-.21 State Testing Laboratories' License Renewal Process And Procedures; Use Of Independent Third-Party Consultants.

State Testing Laboratories' renewal process and procedures, and the Commission's use of independent third- party consultants to inspect and evaluate State Testing Laboratories, shall be governed by Rule 538-X-4-.13 of Chapter 4 of these Rules.
Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: **New Rule:** Published August 31, 2022; effective October 15, 2022.

538-X-10-.22 State Testing Laboratories' License Renewal Fees.

License renewal fees for State Testing Laboratories shall be governed by Rule 538-X-4-.14 of Chapter 4 of these Rules. License renewal fees shall be set forth on the schedule of fees maintained by the Commission on the AMCC website.
Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: **New Rule:** Published August 31, 2022; effective October 15, 2022.

538-X-10-.23 Non-Renewal Of State Testing Laboratories' Licenses.

Non-renewal of State Testing Laboratories' licenses shall be governed by Rule 538-X-4-.15 of Chapter 4 of these Rules.
Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: **New Rule:** Published August 31, 2022; effective October 15, 2022.

538-X-10-.24 State Testing Laboratories' Transfer Of Licenses; Change Of Ownership.

State Testing Laboratories' transfer of licenses and change of ownership shall be governed by Rule 538-X-4-.16 of Chapter 4 of these Rules.
Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-10-.25 Marketing And Advertising By Integrated Facilities.

State Testing Laboratories' duties with respect to Advertising, except as specifically modified within these Rules, shall be governed by Rule 538-X-4-.17 of Chapter 4 of these Rules.
Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-10-.26 Relocation Of State Testing Laboratories' Facilities.

Relocation of State Testing Laboratories' facilities shall be governed by Rule 538-X-4-.18 of Chapter 4 of these Rules.
Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-10-.27 Material Change In State Testing Laboratories' Information.

Rules regarding a material change in State Testing Laboratories' Information previously provided to the Commission shall be governed by Rule 538-X-4-.19 of Chapter 4 of these Rules.
Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.

History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-10-.28 Temporary Licenses For State Testing Laboratories.

Rules regarding temporary licenses for State Testing Laboratories shall be governed by Rule 538-X-4-.20 of Chapter 4 of these Rules.
Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-10-.29 State Testing Laboratories' Surrender Of License; Cessation Of Operations.

A State Testing Laboratory's surrender of license and/or cessation of operations shall be governed by Rule 538-X-4-.21 of Chapter 4 of these Rules.
Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-10-.30 Disciplinary Actions Against State Testing Laboratories.

Disciplinary Actions against State Testing Laboratories shall be governed by Rule 538-X-4-.22 of Chapter 4 of these Rules.
Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-10-.31 State Testing Laboratories' Appeals From Adverse Decisions By The Commission.

State Testing Laboratories' appeals from adverse decisions by the Commission shall be governed by Rule 538-X-4-.23 of Chapter 4 of these Rules.
Author: William H. Webster

Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended. **History: New Rule:** Published August 31, 2022; effective October 15, 2022.

538-X-10-A **Appendix A - Tests and Testing Standards of State Testing Laboratories.**

The tests required by a State Testing Laboratory, by product, shall be as follows:

Product	Tests Required	Detectible Levels
In-process medical cannabis and crude collected resins, as received	1. Moisture content	1. < 15%
	2. Potency analysis	2. N/A
	3. Terpene analysis	3. N/A
	4. Foreign matter inspection	4. None detected
	5. Mycotoxin screening	5. < 20 Ã‚µg/kg for the total of Aflatoxins B1, B2, G1 and G2 combined and < 20 Ã‚µg/kg for Ochratoxin A
	6. Heavy metal screening	6. Arsenic: < 2 ppm Cadmium: < 0.82 ppm Lead: < 1.2 ppm Mercury: < 0.4 ppm
	7. Pesticide residue analysis	7. See Rule 538-x-10-.04 of this Chapter
	8. Herbicide screening	8. See Rule 538-x-10-.04 of this Chapter
	9. Growth regulator screening	9. See Rule 538-x-10-.04 of this Chapter
	10. Total yeast and mold	10. < 10,000 colony forming units per gram
	11. Total Enterobacteriaceae	11. < 1,000 colony forming units per gram
	12. Salmonella	12. None detected per gram
	13. Pathogenic E. coli	13. None detected per gram
	14. Aspergillus fumigatus	14. None detected per gram
	15. Aspergillus flavus	15. None detected per gram
	16. Aspergillus terreus	16. None detected per gram
	17. Aspergillus niger	17. None detected per gram
	18. Total coliform	18. < 1,000 colony-forming units per gram

Cannabis, as received, which is destined for extraction	1. Potency analysis	1. N/A
	2. Terpene analysis	2. N/A
	3. Foreign matter inspection	3. None detected
	4. Mycotoxin screening	4. < 20 Ã‚µg/kg for the total of Aflatoxins B1, B2, G1 and G2 combined and < 20 Ã‚µg/kg for Ochratoxin A
	5. Heavy metal screening	5. Arsenic: < 2 ppm Cadmium: < 0.82 ppm Lead: < 1.2 ppm Mercury: < 0.4 ppm
	6. Pesticide residue analysis	6. See Rule 538-x-10-.04 of this Chapter
	7. Herbicide screening	7. See Rule 538-x-10-.04 of this Chapter
	8. Growth regulator screening	8. See Rule 538-x-10-.04 of this Chapter
	9. Total yeast and mold	9. < 10,000 colony forming units per gram
	10. Total Enterobacteriaceae	10. < 1,000 colony forming units per gram
	11. Salmonella	11. None detected per gram
	12. Pathogenic E. coli	12. None detected per gram
	13. Aspergillus fumigatus	13. None detected per gram
	14. Aspergillus flavus	14. None detected per gram
	15. Aspergillus terreus	15. None detected per gram
	16. Aspergillus niger	16. None detected per gram
	17. Total coliform	17. < 1,000 colony forming units per gram
Fully processed extract of cannabis, including mixtures of extracted products or oils or fats derived from natural sources, including concentrated cannabis extracted with CO2	1. Potency analysis	1. N/A
	2. Foreign matter inspection	2. None detected
	3. Terpene analysis	3. N/A
	4. Mycotoxin screening	4. < 20 Ã‚µg/kg for the total of Aflatoxins B1, B2, G1 and G2

		combined and < 20 Ã,µg/kg for Ochratoxin A
	5. Heavy metal screening	5. Arsenic: < 2 ppm Cadmium: < 0.82 ppm Lead: < 1.2 ppm Mercury: < 0.4 ppm
	6. Pesticide residue analysis	6. See Rule 538-x-10-.04 of this Chapter
	7. Total yeast and mold	7. < 1,000 colony forming units per gram
	8. Total Enterobacteriaceae	8. < 100 colony forming units per gram
	9. Salmonella	9. None detected per gram
	10. Pathogenic E. coli	10. None detected per gram
	11. Aspergillus fumigatus	11. None detected per gram
	12. Aspergillus flavus	12. None detected per gram
	13. Aspergillus terreus	13. None detected per gram
	14. Aspergillus niger	14. None detected per gram
Extract of cannabis (solvent-based) made with any approved solvent, including concentrated cannabis extracted by means other than with CO2	1. Potency analysis	1. N/A
	2. Terpene analysis	2. N/A
	3. Foreign matter inspection	3. None detected
	4. Residual solvent test	4. < 500 ppm
	5. Mycotoxin screening	5. < 20 Ã,µg/kg for the total of Aflatoxins B1, B2, G1 and G2 combined and < 20 Ã,µg/kg for Ochratoxin A
	6. Heavy metal screening	6. Arsenic: < 2 ppm Cadmium: < 0.82 ppm Lead: < 1.2 ppm Mercury: < 0.4 ppm
	7. Pesticide residue analysis	7. See Rule 538-x-10-.04 of this Chapter
	8. Total yeast and mold	8. < 1,000 colony forming units per gram
	9. Total Enterobacteriaceae	9. < 100 colony forming units per gram
	10. Salmonella	

	11. Pathogenic E. coli 12. Aspergillus fumigatus 13. Aspergillus flavus 14. Aspergillus terreus 15. Aspergillus niger	10. None detected per gram 11. None detected per gram 12. None detected per gram 13. None detected per gram 14. None detected per gram 15. None detected per gram
Topical cannabis-infused product, including a product which contains concentrated cannabis	1. Potency analysis 2. Terpene analysis	1. N/A 2. N/A

As used in this Appendix A, "as received" means the unaltered state in which a sample was collected, without any processing or conditioning, which accounts for all mass, including moisture content.

Author: William H. Webster
Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.
History: **New Rule:** Published August 31, 2022; effective October 15, 2022. **Amended:** Published ; effective .