

Article 6

Marijuana Testing Facilities

3 AAC 306.600. Applicability

(a) The provisions of 3 AAC 306.600 - 3 AAC 306.675 apply to a person offering a service testing, analyzing, or certifying potency, moisture content, pesticide or solvent residue, mold, mildew, bacteria, or other contaminants in marijuana or a marijuana product to another person including a marijuana establishment or a member of the public, whether for compensation or not, as a independent or third-party testing facility.

(b) The provisions of 3 AAC 306.600 - 3 AAC 306.675 do not apply to a licensed marijuana establishment that controls marijuana testing equipment used solely for its own in-house testing of its own cultivated crop, of products produced or manufactured at its own facility, or of retail products placed or offered for sale in its retail marijuana store.

3 AAC 306.605. Marijuana testing facility license required

(a) A person may not offer or provide a marijuana testing service or test results unless the person has obtained a marijuana testing facility license from the board in compliance with this chapter, or is an employee or agent acting for a licensed marijuana testing facility.

(b) A person seeking a marijuana testing facility license must

(1) submit an application for a marijuana testing facility license on a form the board prescribes, including the information set out under 3 AAC 306.020 and 3 AAC 306.615; and

(2) demonstrate to the board's satisfaction that the applicant

(A) will operate in compliance with each applicable provision of 3 AAC 306.600 - 3 AAC 306.675 and 3 AAC 306.700 - 3 AAC 06.755;

(B) will operate in compliance with each applicable public health, fire, safety, and tax code and ordinance of the state and the local government in which the applicant's proposed licensed premises are located;

(C) does not hold a marijuana establishment license in this state other

than a marijuana testing facility license, or have a financial interest in common with a person who is a licensee of a marijuana establishment in this state other than a marijuana testing facility license; and

(D) meets the board's standards for approval as set out in 3 AAC 306.620 - 3 AAC 306.625.

(c) A licensee of a marijuana testing facility, or an employee or agent of a licensed marijuana testing facility, may not have an ownership interest in or a direct or indirect financial interest in another licensed marijuana establishment.

3 AAC 306.610. Marijuana testing facilities: privileges and prohibitions

(a) A licensed marijuana testing facility may have any amount of marijuana and marijuana products on its premises at any given time if the marijuana testing facility's marijuana inventory tracking system and other records document that all marijuana and marijuana products are on the premises only for the testing purposes described in 3 AAC 306.600 - 3 AAC 06.675.

(b) A licensed marijuana testing facility may not

(1) have a licensee, employee, or agent who holds a type of marijuana establishment license other than a marijuana testing facility license issued under this chapter;

(2) sell, deliver, distribute, or transfer marijuana or a marijuana product to a consumer, with or without compensation; or

(3) allow a person to consume marijuana or a marijuana product on its licensed premises.

3 AAC 306.615. Application for marijuana testing facility license

An applicant for a new marijuana testing facility license must file an application on a form the board prescribes, including

(1) the information required under 3 AAC 306.020; and

(2) the proposed marijuana testing facility's operating plan, including, in addition to the information required under 3 AAC 306.020(c),

(A) each test the marijuana testing facility will offer;

(B) the marijuana testing facility's standard operating procedure for each

test the marijuana testing facility will offer; and

(C) the acceptable range of results for each test the marijuana testing facility will offer.

3 AAC 306.620. Approval of testing facility

(a) A person seeking a marijuana testing facility license must first obtain the approval of the board by showing competence to perform each test the licensee will offer as an independent third-party testing facility, including tests to identify

- (1) THC, THCA, CBD, CBDA and CBN potency;
- (2) Harmful microbials including Escherichia coli (E. Coli) or salmonella;
- (3) residual solvents;
- (4) poisons or toxins;
- (5) harmful chemicals;
- (6) dangerous molds, mildew, or filth;
- (7) pesticides.

(b) In evaluating whether a person has shown competence in testing under this section, the board or the board's contractor may

- (1) conduct an on-site inspection of the applicant's premises;
- (2) require the applicant to demonstrate proficiency in testing; and
- (3) examine compliance with any applicable requirement of 3 AAC 306.630 - 3

AAC 306.675, and 3 AAC 306.700 - 3 AAC 306.755, including

- (A) qualifications of personnel;
- (B) the standard operating procedure for each testing methodology the marijuana testing facility will use;
- (C) proficiency testing results;
- (D) quality control and quality assurance;
- (E) security;
- (F) chain of custody;
- (G) specimen retention;
- (H) space;

- (I) records; and
- (J) reporting of results.

(c) The board will approve a marijuana testing facility license if, after the board or the board's contractor has examined the qualifications and procedures of the marijuana testing facility license applicant, the board finds them generally in compliance with good laboratory practices. Nothing in AS 17.38 or this chapter constitutes a board guarantee that a licensed marijuana testing facility can or will protect the public from all potential hazards of marijuana including microbials, poisons or toxins, residual solvents, pesticides, or other contaminants.

3 AAC 306.622. Marijuana handler permit required

A marijuana testing facility shall ensure that each agent who is required or permitted to be physically present on the licensed premises at any time, each licensee, and each employee

- (1) obtains a marijuana handler permit as provided in 3 AAC 306.700 before being licensed or employed at the marijuana testing facility's licensed premises; and
- (2) has the marijuana handler permit card in the person's immediate possession, or a valid copy on file on the premises, at all times while on the marijuana testing facility's licensed premises.

3 AAC 306.625. Proficiency testing program

(a) When an accredited proficiency testing program becomes available in the state, the board may require an applicant for a marijuana testing facility license to participate successfully in a proficiency testing program not earlier than 12 months before receiving a license. The proficiency testing program must require an applicant for a marijuana testing facility license or a participating licensed marijuana testing facility to analyze test samples using the same procedures with the same number of replicate analyses, standards, testing analysts, and equipment that will be used for product testing. Successful participation is the positive identification of 80 percent of the target analytes that the marijuana testing facility reports, and must include quantitative results when applicable. Any false positive results reported constitute an unsatisfactory score for the proficiency test.

(b) Before renewing the license of a marijuana testing facility, the board may require the facility to participate in a proficiency testing program with documentation of continued

performance satisfactory to the board. The license of a marijuana testing facility may be limited, suspended, or revoked if the facility fails to participate and receive a passing score in a proficiency testing program.

(c) The scientific director employed under 3 AAC 306.630 and each testing analyst of an applicant for a marijuana testing facility license and a licensed marijuana testing facility that participated in a proficiency test shall sign a corresponding attestation statement. The scientific director shall review and evaluate each proficiency test result.

(d) An applicant for a marijuana testing facility license, and a licensed marijuana testing facility participating in the proficiency testing program, shall take and document remedial action when the applicant or the facility meets the standards of (a) of this section, but scores less than 100 percent in a proficiency test. To take and document remedial action, the marijuana testing facility's scientific director shall, at a minimum, review all samples tested and results reported after the date of the marijuana testing facility's last successful proficiency test.

3 AAC 306.630. Scientific director

(a) A marijuana testing facility shall employ a scientific director who must be responsible for

(1) overseeing and directing the scientific methods of the laboratory within the marijuana testing facility;

(2) ensuring that the laboratory achieves and maintains quality standards of practice; and

(3) supervising all staff of the laboratory.

(b) The scientific director of a marijuana testing facility must have

(1) a doctorate degree in chemical or biological sciences from an accredited college or university and have at least two years of post- degree laboratory experience;

(2) a master's degree in chemical or biological sciences from an accredited college or university and have at least four years of post- degree laboratory experience; and

(3) a bachelor's degree in chemical or biological sciences from an accredited college or university and have at least six years of post- degree laboratory experience.

3 AAC 306.635. Testing methodologies

(a) An applicant for a marijuana testing facility license and a licensed marijuana testing facility shall

(1) use as guidelines or references for testing methodologies

(A) the American Herbal Pharmacopoeia's Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control, Revision 2014, adopted by reference; and

(B) the United Nations Office on Drugs and Crime's Recommended Methods for the Identification and Analysis of Cannabis and Cannabis Products: Manual for Use by National Drug Analysis Laboratories, dated 2009 and adopted by reference; and

(2) notify the board of any alternative scientifically valid testing methodology the marijuana testing facility proposes to use for any laboratory test it conducts; the board may require third-party validation of any monograph, peer-reviewed scientific journal article, or analytical method the marijuana testing facility proposes to follow to ensure the methodology produces comparable and accurate results.

(b) An applicant for a marijuana testing facility license and the holder of a marijuana testing facility license shall observe good laboratory practices.

(c) The board or the board's contractor may inspect the practices, procedures, and programs adopted, followed, and maintained by the applicant or the licensed marijuana testing facility and may examine all records of the applicant or the licensed marijuana testing facility that are related to the inspection. The board may require an applicant or a licensed marijuana testing facility to have an independent third party inspect and monitor laboratory operations to assess testing competency and the marijuana testing facility's compliance with its quality program. The board may require random validation of a marijuana testing facility's execution of each testing methodology the facility uses. The marijuana testing facility shall pay all costs of validation.

3 AAC 306.640. Standard operating procedure manual

(a) An applicant for a marijuana testing facility license and a licensed marijuana testing

facility shall have a written manual of standard operating procedures, with detailed instructions explaining how to perform each testing method the applicant or marijuana testing facility uses and minimum standards for each test. The written manual of standard operating procedures must be available to each employee of the marijuana testing facility at all times. The written manual of standard operating procedures must cover at least

- (1) sample preparation for each matrix that will be tested;
- (2) reagent, solution, and reference standard preparation;
- (3) instrument setup, if applicable;
- (4) standardization of volumetric reagent solutions, if applicable;
- (5) data acquisition;
- (6) calculation of results;
- (7) identification criteria;
- (8) quality control frequency;
- (9) quality control acceptance criteria; and
- (10) corrective action protocol.

(b) The scientific director of a marijuana testing facility shall approve, sign, and date each standard operating procedure, and each revision to any standard operating procedure.

3 AAC 306.645. Laboratory testing of marijuana and marijuana products

(a) A marijuana testing facility shall use the general body of required laboratory tests as set out in this section for marijuana plant material, an extract or concentrate of marijuana, and a marijuana product. Required tests may include potency analysis, moisture content, foreign matter inspection, microbial screening, pesticide, other chemical residue, and metals screening, and residual solvents levels. A marijuana testing facility shall establish a schedule of fees required for each test it offers, and shall perform tests using methods in compliance with guidelines prescribed by the board.

(b) The tests required for each marijuana type or marijuana product, are as follows:

(1) potency testing is required on marijuana bud and flower, marijuana concentrate, and a marijuana product, as follows:

(A) the required cannabinoid potency test must at least determine the

concentration of THC, THCA, CBD, CBDA and CBN cannabinoids; a marijuana testing facility may test and report results for any additional cannabinoid if the test is conducted in compliance with a validated method;

(B) a marijuana testing facility shall report potency test results as follows:

(i) for a potency test on marijuana and marijuana concentrate, the marijuana testing facility shall list for each required cannabinoid a single percentage concentration, based on dry weight, that represents an average of all samples within the test batch; additionally, total THC and total CBD shall be reported;

(ii) for a potency test on a marijuana product, whether conducted on each individual production lot or using process validation, the marijuana testing facility shall list for each cannabinoid the total number of milligrams contained within a single retail marijuana product unit for sale;

(iii) testing whether the THC content is homogenous, the marijuana testing facility shall report the THC content of each single serving in a multi-unit package; the reported content must be within 20 percent of the manufacturer's target; for example, in a 25 milligrams total THC package with five servings, each serving must contain between four and six milligrams of THC;

(C) the marijuana testing facility shall determine an edible marijuana product to have failed potency testing if

(i) an individually packaged edible retail marijuana product contained within a test lot is determined to have more than 60 milligrams of THC within it; or

(ii) the THC content of an edible marijuana product is not homogenous;

(2) microbial testing for the listed substances on the listed marijuana and marijuana products is required as follows:

Substance	Acceptable Limits Per Gram	Product to be Tested
-- <i>Shiga</i> -toxin producing <i>Escherichia coli</i> (STEC)- bacteria	Less than 1 colony forming unit (CFU/g)	Marijuana; retail marijuana products; water-and food- based concentrates
<i>Salmonella</i> species-bacteria	Less than 1 colony forming unit (CFU/g)	
Substance	Acceptable Limits Per Gram	Product to be Tested
<i>Aspergillus fumigatus</i> , <i>Aspergillus flavus</i> , <i>Aspergillus</i> <i>niger</i> -fungus	Less than 1 colony forming unit (CFU/g)	Marijuana; retail marijuana products; water-and food- based concentrates

(3) testing for the listed residual solvents and metals on the listed marijuana products is required as follows:

Substance	Acceptable Limits Per Gram	Product to be Tested
butanes	Less than 800 parts per million (PPM)	Solvent-based concentrates
heptanes	Less than 500 parts per million (PPM)	
benzene	Less than 1 part per million (PPM)	
toluene	Less than 1 part per million (PPM)	
hexane	Less than 10 parts per million (PPM)	
Total xylenes (meta-xylenes, para-xylenes, or ortho- xylenes)	Less than 1 part per million (PPM)	

3 AAC 306.650. Chain of custody

A marijuana testing facility shall establish an adequate chain of custody and sample requirement instructions that include

- (1) issuing instructions for the minimum sample requirements 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 sample provided at the time the sample is received at the marijuana testing facility;
- (4) documenting each person handling the original samples, aliquots, and extracts;
- (5) documenting any transfer of samples, aliquots, and extracts to another marijuana testing facility for additional testing or at the request of the marijuana cultivation facility or marijuana product manufacturing facility that provided the testing sample;
- (6) maintaining a current list of authorized persons and restricting entry to the marijuana testing facility to those authorized persons;
- (7) securing the marijuana testing facility during non-working hours;
- (8) securing short-term and long-term storage areas when not in use;
- (9) using a secured area to log in and aliquot samples;
- (10) ensuring samples are stored appropriately; and
- (11) documenting the disposal of samples, aliquots, and extracts.

3 AAC 306.655. Marijuana inventory tracking system

A marijuana testing facility shall use a marijuana inventory tracking system as provided in 3 AAC 306.730 to ensure all marijuana transported to the marijuana testing facility's premises is identified and tracked from the time the marijuana arrives at the marijuana testing facility to the use and destruction of the marijuana in testing, or to disposal in compliance with 3 AAC 306.740.

3 AAC 306.660. Failed materials; retests

- (a) If a sample tested by a marijuana testing facility does not pass the required tests

based on the standards set out in 3 AAC 306.645, including a visual foreign matter inspection, the marijuana establishment that provided the sample shall

(1) dispose of in accordance with 3 AAC 306.740, the entire harvest batch or production lot from which the sample was taken; and

(2) document the disposal of the sample using the marijuana establishment's marijuana inventory tracking system.

(b) If a sample of marijuana fails a required test, any marijuana plant trim, leaf, and other usable material from the same plants automatically fail the required test. The board or director may approve a written request, on a form prescribed by the board, to allow a batch of marijuana that fails a required test to be used to make a carbon dioxide- or solvent-based extract. After processing, the carbon dioxide- or solvent-based extract must pass all required tests.

(c) If a marijuana cultivation facility or a marijuana product manufacturing facility submits a written request, on a form prescribed by the board, for a retest of marijuana or a marijuana product that failed a required test, the board or director may authorize a retest to validate the test results. The marijuana cultivation facility or a marijuana product manufacturing facility shall pay all costs of a retest.

3 AAC 306.665. Supplemental marijuana quality testing

(a) The board or director may at any time determine that the interests of the public require random supplemental testing of marijuana or a marijuana product. When the board or director requires random supplemental testing, the board will or director shall direct the marijuana cultivation facility that produced the marijuana, or the marijuana product manufacturing facility that manufactured the product, to submit a specified sample, batch, or packaged product to a designated marijuana testing facility. The material must be packaged in a manner that ensures the marijuana testing facility will be able to confirm that it has received and is testing the correct supplemental sample.

(b) When a marijuana testing facility receives a sample for random supplemental testing under this section, the marijuana testing facility shall

(1) perform any required laboratory test the board or director requests; and

- (2) report its results to
 - (A) the board or director; and
 - (B) the facility that provided the sample.

(c) A marijuana testing facility that conducts laboratory testing under this section shall bill all costs directly to the marijuana cultivation facility or the marijuana product manufacturing facility that provided the samples for testing.

3 AAC 306.670. Reporting; verification

(a) A marijuana testing facility shall report the result of each required laboratory test directly into its marijuana inventory tracking system not later than 24 hours after the test is completed. A marijuana testing facility shall provide the final report

- (1) in a timely manner to the marijuana establishment that submitted the sample; and
- (2) to the director not later than 72 hours after the marijuana testing facility determines that results of tested samples exceed allowable levels.

(b) A marijuana testing facility shall establish procedures to ensure that reported results are accurate, precise, and scientifically valid. To ensure reported results are valid, a marijuana testing facility shall report results in compliance with guidelines prescribed by the board and include in a final report

- (1) the name and location of the marijuana testing facility;
- (2) the unique sample identifier assigned by the marijuana testing facility;
- (3) the marijuana establishment or other person that submitted the testing sample;
- (4) the sample identifier provided by the marijuana establishment or other person that submitted the testing sample;
- (5) the date the marijuana testing facility received the sample;
- (6) the chain of custody identifier;
- (7) the date of the report;
- (8) the type of marijuana or marijuana product tested;
- (9) the test results;

(10) the units of measure; and

(11) any other information or qualifiers needed for interpretation of the test method and the results being reported, including any identified and documented discrepancy.

(c) A marijuana testing facility may amend a final report for clerical purposes except that test results may not be amended.

(d) A marijuana testing facility shall notify the director in writing not later than 24 hours after a significant equipment malfunction or failure that prevents the completion of required marijuana or marijuana product testing. The licensee shall notify the director of any action the licensee intends to take to provide for re-testing or destruction of the marijuana or marijuana product.

3 AAC 306.675. Records retention

A marijuana testing facility shall maintain the business records required under 3 AAC 306.755 for the period of time specified in that section. The books and records required under 3 AAC 306.755(a)(1) include

- (1) test results;
- (2) quality control and quality assurance records;
- (3) standard operating procedures;
- (4) chain-of-custody records;
- (5) proficiency testing records;
- (6) analytical data to include printouts generated by the instrumentation;
- (7) accession numbers;
- (8) specimen type;
- (9) raw data of calibration standards and curves, controls, and subject results;
- (10) final and amended reports;
- (11) acceptable reference range parameters;
- (12) the identity of the analyst; and
- (13) the date of the analysis.