

Laboratory Testing Guidelines
U.S. Domestic Hemp Production Program
Issued January 15, 2021

Purpose:

1. Standard testing procedures are specified for samples taken in accordance with the Sampling Procedures for the USDA Hemp Production Program to measure the total delta-9 tetrahydrocannabinol (THC) concentration levels of samples on a dry weight basis.
2. The results are intended to measure the total THC concentration of composite hemp samples collected from a “lot” of hemp crop acreage designated by a hemp producer and as reported to USDA as required under the USDA Hemp Production Program. The purpose of the measurements is to determine whether the total THC concentration of the tested material is within the acceptable hemp THC level.

Scope:

1. Hemp grown under a USDA, State, or Tribal hemp production plan is subject to sampling and compliance testing for THC concentration. Certain producers, including research institutions and facilities growing immature plants may have different testing requirements depending on the applicable State or Tribal plan and regulations.
2. Tests shall measure the total THC concentration in a sample submitted to a laboratory for analysis. The laboratory will perform chemical analysis on the sample using post-decarboxylation or other similarly reliable methods where the total THC concentration level considers the potential to convert delta-9-tetrahydrocannabinolic acid (THCA) into THC.
3. The total delta-9 tetrahydrocannabinol concentration level shall be determined and reported on a dry weight basis.
4. Laboratories shall calculate and include the Measurement of Uncertainty (MU) when they report THC concentration test results. “Measurement of uncertainty” is defined as “the parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the particular quantity subject to measurement.” USDA does not establish or standardize an upper or lower boundary for general use by laboratories to calculate a measurement of uncertainty. MU is typically not standardized, but rather is controlled using test methods controlled by performance standards (e.g., AOAC Standard Method Performance Requirements 2019.003 that can be found at <https://www.aoac.org/resources/smpr-2019003/>).
5. Hemp testing laboratories are not required to be ISO accredited, although USDA strongly encourages adherence to the ISO 17025 standard.
6. It is the responsibility of the licensed producer to pay any fees associated with testing or retesting.

Summary of Practice:

1. As required under USDA Hemp Production Program regulations, laboratories that analyze hemp to determine total delta-9 tetrahydrocannabinol THC should meet the following standards:

1.1. Laboratory quality assurance protocols must ensure the validity and reliability of test results;

1.2. Analytical method selection, validation, and verification protocols must ensure that the testing method used is appropriate (fit for purpose) and that the laboratory can successfully perform the testing;

1.3. Protocols for demonstrating testing validity must ensure consistent, accurate analytical performance;

1.4. Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of this part; and

1.5. Testing protocols must include an effective disposal procedure, in accordance with USDA guidelines, for non-compliant samples that do not meet the requirements of this part.

1.6. Measurement of uncertainty (MU) must be estimated and reported with test results. Laboratories shall use appropriate, validated methods and procedures for all testing activities and evaluate measurement of uncertainty.

1.7. Sample preparation of pre- or post-harvest sample shall require grinding of the sample to ensure homogeneity of plant material prior to testing.

1.8 At a minimum, analytical testing of samples for total delta-9 tetrahydrocannabinol concentration levels must use post-decarboxylation or other similarly reliable methods approved by the Secretary in writing. The testing methodology must consider the potential conversion of delta-9 tetrahydrocannabinolic acid (THCA) in hemp into delta-9 tetrahydrocannabinol (THC), and the test result must reflect the total available THC derived from the sum of the THC and THCA content. Current testing methodologies meeting these requirements include gas chromatography and liquid chromatography. Other methods may be approved if they meet the regulatory requirements.

1.9 The total delta-9 tetrahydrocannabinol concentration level shall be determined and reported on a dry weight basis.

2. Laboratories should create an internal SOP specific to testing and retesting hemp and should have the SOP available upon request for inspection. If Sampling Agents are employed,

contracted or utilized by a laboratory, the laboratory shall meet all training requirements under the USDA, State, or Tribal hemp production program.

3. After December 31, 2022, laboratories approved for THC testing must also be registered with DEA to handle controlled substances under the Controlled Substances Act (CSA), 21 CFR part 1301.13.

4. In order to provide flexibility to States and Tribes in administering their own hemp production programs, alternative testing protocols will be considered, if they are comparable and similarly reliable to the baseline mandated by section 297B(a)(2)(ii) of the Agricultural Marketing Act of 1946 and established under the USDA plan and procedures. Approval for alternative testing protocols must be requested of USDA in writing and approved in writing by USDA, provided they meet the requirements of this guidance.

General Guidelines:

General Sample Preparation and Testing Procedures should be conducted as follows:

1. Laboratory receives sample.
2. Dry sample to remove the majority of water.
3. Grind entire sample including leaves, seeds, twigs, and stems.
4. Separate sample into “Test” and “Retain” specimens.
5. Package and store the “Retain” specimen(s) until needed.
6. Analyze the “Test” specimen.
7. Determine moisture content or dry to a consistent weight.
8. Perform chemical analysis.
9. Calculate total THC concentration on a dry weight basis. Test results should be reported on a dry weight basis.

Sample Preparation Guidelines:

Samples should be prepared for testing as follows:

1. Once the composite sample is received by the laboratory, the laboratory should dry the composite sample until brittle in a manner that maintains the THC level of sample.

2. If it is not possible to dry the composite sample within 24 hours from the time of sample arrival, the sample should be held in a freezer at approximate -20°C or lower until the sample is dried.

3. After the initial drying step, the laboratory should grind the entire sample including leaves, seeds, twigs, and stems using centrifugal rotor mill or other method as appropriate. All samples received should be ground, regardless of whether they consist of the initial intact material or “remediated” (shredded or blended) material, as allowed under USDA regulations.

4. The laboratory should create both a “Test Specimen” and a “Retain Specimen for reanalysis and/or confirmation as needed.” One sample part should be selected for analysis and labeled "Test Specimen." The other sample part should be marked "Retain Specimen" and should be packaged and stored in a secured place. The testing laboratory internal SOP should define the sample size and distribution of “Test Specimen” and “Retain Specimen.”

5. Samples should be stored in secured locations, in appropriate containers (e.g., bottles, tubes, vials, etc.).

6. The laboratory should then either determine moisture content or dry the test specimen to a consistent weight. Samples should be dried to a consistent loss (typically 5- 12% moisture content) so that the test can be performed on a dry weight basis, meaning the percentage of THC by weight, after excluding moisture from the sample. The moisture content is expressed as the ratio of the amount of moisture in the sample to the amount of dry solid in the sample.

6.1. The sample can be dried to a consistent weight to remove all water and then be tested on a dry weight basis. If the sample is not to be extracted immediately after drying, it should be stored in a desiccator.

6.2. Alternatively, the sample can be analyzed for moisture content and this moisture content can be factored into the total THC result to give a dry weight basis.

7. Extraction of the sample should occur as soon as possible from the time of sample arrival. Extracts should be stored in secured locations, in appropriate containers (e.g., bottles, tubes, vials, etc.).

Testing Guidelines:

1. The laboratory will perform chemical analysis on the sample using post- decarboxylation or other similarly reliable methods where the total THC concentration level considers the potential to convert delta-9-tetrahydrocannabinolic acid (THCA) into THC.

2. Testing methodologies meeting these requirements include those using gas chromatography and liquid chromatography.

3. The laboratory will then calculate total THC concentration on a dry weight basis.

Testing Methods:

1. The total available THC, derived from the sum of the THC and THCA content, shall be determined and reported on a dry weight basis.

2. Alternative testing protocols will be considered if they are comparable to the baseline mandated by the 2018 Farm Bill and established under the USDA plan and procedures. Approval to use alternative sampling and testing procedures must be requested in writing and approved in writing by USDA.

3. Laboratories shall use appropriate, validated methods and procedures for all testing activities and shall evaluate measurement of uncertainty.

4. Laboratories should meet the AOAC International standard method performance requirements for Quantitation of Cannabinoids in Plant Materials of Hemp (Low THC Varieties Cannabis sp.) (SMPR 2019.003) for selecting an appropriate method.

5. The range of estimated uncertainty is reported as a \pm value and is the same unit as the hemp THC threshold (e.g. ± 0.05), following best practices for significant figures and rounding.

6. There are resources available for defining, guiding, and calculating measurement uncertainty. They include the GUM, ISO, and Eurachem. Once the expanded measurement uncertainty (U) is determined, then the confidence interval can be calculated around a designated threshold. (i.e. the hemp threshold of 0.3% THC.)

Test Results Exceeding 0.3% THC Concentration:

1. Any sample test result where the total THC concentration of the sample is higher than the acceptable hemp THC level shall be conclusive evidence that one or more cannabis plants or plant products from the lot represented by the sample contain a THC concentration in excess of that allowed under the Act.

1.1. If the results of a test conclude that the THC concentration levels of a sample are higher than the acceptable hemp THC level, the laboratory will promptly notify the producer and the State, Tribal, or Federal regulatory licensing body.

2. Retest Procedures.

2.1. Any hemp program licensee may request that the laboratory retest samples if it is believed the original THC concentration level test results were in error.

2.2. If this occurs, the laboratory shall follow the same procedures as to conduct the initial test.

2.3. The licensee requesting the retest of the second sample will pay the cost of the test.

2.4. The retest results shall be issued to the licensee requesting the retest, and a copy shall be provided to USDA or its agent.

Information Sharing:

1. Laboratories performing THC testing for compliance purposes of this program are required to share test results with the licensed producer, the appropriate State Department of Agriculture or Tribe, and USDA. Laboratories shall report all test results, whether passing or failing, to USDA using AMS Form 22 available here: <https://www.ams.usda.gov/rules-regulations/hemp/information-laboratories>.

2. Laboratories shall indicate that a test result is for “official compliance” purposes on lab testing results for compliance purposes. Laboratories shall not mark test results for monitoring of THC levels throughout the growing season as for “official compliance” purposes. Laboratories shall retain a legible copy for inspection upon request of all test results for official compliance purposes for a period of three (3) years from date of analysis.

3. Laboratories may provide test results to licensed producers in whatever manner best aligns with their business practices, but producers must be able to produce a legible copy of test results upon request for inspection purposes. For this reason, providing test results to producers through a web portal or through electronic mail, so the producer will have ready access to print the results when needed, is preferred.

4. Results of testing conducted throughout the growing season for the purposes of monitoring THC concentration should not be submitted to USDA. Only the official test result for compliance testing purposes shall be submitted to the USDA.

Testing Remediated Hemp Samples:

1. Licensees can “remediate” hemp following an initial failed test by shredding plant material in a product called “biomass.” In this instance, laboratories will receive samples of remediated biomass material for retesting.

2. For remediated testing, the laboratory shall follow the same procedures used to conduct an initial test, as described in this document.

3. For remediated testing, the laboratory shall follow the same reporting requirements as described in this document. A licensee must maintain a legible copy of the remediated test results, available for inspection, for a period of three years from receipt of the testing results provided by the laboratory. Therefore, laboratories are encouraged to provide such documentation to licensees.

References:

ISO 17025. General requirements for the complete testing and calibration laboratories. Food and Drug Administration, Office of Regulatory Affairs, ORA Laboratory Manual

Volume III Section 4, Basic Statistics and Data Presentation (current version).

AOAC Standard Method Performance Requirements AOAC SMPR 2019.003; Title: Quantitation of cannabinoids in plant materials of hemp (low THC varieties 4 Cannabis spp.), and Official Method of Analysis 2018.11.

JCGM 100:2008, Evaluation of measurement data – Guide to the expression of uncertainty in measurement (GUM).

ISO/IEC Guide 98, Expression of Uncertainty in Measurement.

EURACHEM/CITAC Guide “Quantifying Uncertainty in Analytical Measurement” Second edition (2000). A Williams, S L R Ellison, M Roesslein (eds.) ISBN 0 948926 15 5. Available from the Eurachem Secretariate

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Note: In accordance with 7 CFR 1.901(e), the contents of this document do not have the force and effect of law and are not meant to bind the public in any way, and the document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.