

Guidance Series – GS2107 Testing & Laboratories

The following document includes a summary of relevant regulatory requirements, and also provides examples and recommendations based on program staff research and experience, and shared findings from industry stakeholders including Missouri producers. This document is not a legal interpretation of the law.

This document is intended for Missouri Registered Producers. Registered Producers are responsible for selecting a laboratory that meets all accreditation, testing, and reporting requirements. Compliance of lots may be invalidated if a laboratory is found to not meet all requirements.

For laboratory personnel, please review the Guidelines for Testing Laboratories.

Concepts included in this document are:

- Selecting A Laboratory
- Delivery To The Laboratory
- Interpreting Test Results

- Required Submission Of Test Results
- Retesting
- Preliminary (Non-Compliance) Testing

A. SELECTING A LABORATORY

STEP ONE: Does the laboratory meet the basic qualifications for compliance testing?

You may choose any laboratory that is:

- Accredited to International Organization for Standardization for ISO/IEC 17025; AND
- After December 31, 2022, registered with the Drug Enforcement Agency (DEA) or other requirements established by the United States Department of Agriculture

Laboratories do not have to be within the state of Missouri. Review carrier policies carefully prior to shipping samples.

There is not currently a comprehensive list of qualifying laboratories, but laboratories will often have their qualifications posted online or available upon request. A list of DEA-registered laboratories is available at the following link, and *some* are also ISO 17025 accredited: https://www.ams.usda.gov/rules-regulations/hemp/dea-laboratories

STEP TWO: Does the laboratory complete their required reporting?

All laboratories conducting industrial hemp compliance sampling are *required* to report compliance test results to USDA. It is *your responsibility* as a producer to select a laboratory that fulfills this requirement. More information about this requirement can be found on USDA's website at: https://www.ams.usda.gov/rules-regulations/hemp/information-laboratories

STEP THREE: How does the laboratory calculate and present the Measurement of Uncertainty on their results?

The Measurement of Uncertainty ("MU") is a laboratory-calculated measurement that creates a range for the test result, similar to a margin of error. The way this figure is presented on the Certificate of Analysis may vary, from a simple plusor-minus figure, to a percentage that must be calculated by the reviewer, or may not be included on the Certificate at all. Producers should understand their chosen laboratory's practices prior to submitting a compliance sample. Examples and additional information is available in <u>GS2013</u>: <u>Certificate of Analysis Guide</u>.

*If a laboratory does not include a Measurement of Uncertainty on the Certificate of Analysis, the MU is effectively zero, and the total THC measurement is read as is – there is no margin of error.

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STEP FOUR: Does the laboratory include the required lot information on their Certificates of Analysis?

The Certificate of Analysis (COA) must include, at a minimum:

- Sample ID number as identified on the Chain of Custody form by your Certified Sampler;
 - o Ex: 29_R01930-A4-071819
- Or, <u>both</u> of the following
 - o Lot ID as provided on your Planting Report form (Ex: A4); and,
 - Producer information such as the Registration number (Ex: 29_R01930), or name of the individual or entity responsible for the registration
- Measurement of Uncertainty, if calculated or if needed to be considered a compliant lot

STEP FIVE: Are there any other additional steps or paperwork?

Laboratories will often have additional steps such as account set up, order forms, or additional packaging or shipping requirements for your compliance samples. Ask prior to shipping any samples.

B. DELIVERY TO THE LABORATORY

Once your Certified Sampler has collected your compliance sample(s), the sample(s) may be directly delivered or shipped by the Registered Producer, their authorized agent, or the Certified Sampler. The Chain of Custody form attached to the sample bag must be updated accordingly.

All samples must arrive at the testing laboratory within **four calendar days** (96 hours) of the sample collection. The laboratory may request or require faster shipping speeds. *If your sample(s) will be shipped, carefully review carrier policies in regards to allowance of hemp sample shipments.*

C. INTERPRETING TEST RESULTS

A "pass" test result is a result that is at or below 0.3% Total THC, incorporating the Measurement of Uncertainty. A "fail" test result is a result that exceeds 0.3% Total THC, incorporating the Measurement of Uncertainty. If there is no MU listed on the Certificate of Analysis, the MU is effectively zero, and the total THC result is read as is.

If the Total THC is not directly listed on the Certificate of Analysis, it can also be calculated by the reviewer utilizing the following formula:

Total THC = Measured Delta-9 THC + (Measured THCa * 87.7%)

0.6%
0.5%
0.4%
0.3%
0.2%
0.1%
0.0%
Lot 1 Lot 2 Lot 3

For more information and examples, please review <u>GS2103: Certificate of Analysis Guide</u>.

D. REQUIRED SUBMISSION OF TEST RESULTS

Registered producers must submit Certificates of Analysis for **ALL** compliance samples to the department **within seven** (7) calendar days of receipt, regardless of total THC results. Email submission to reporting.hemp@mda.mo.gov is preferred. Registered Producers **should not** submit any non-compliance results, such as preliminary testing.



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E. RETESTING

If the initial test indicates a "fail" and the lot or a portion of the lot has been harvested, the Registered Producer must submit the results within seven (7) days of receipt, and concurrently notify MDA of the intent to retest, if applicable. If requested by the producer, the laboratory may retest the 'retain specimen' *already in the lab's possession* to check for any testing errors. The duplicate sample retained by the Registered Producer or Certified Sampler cannot be utilized for retest purposes.

If *no portion of the lot has been harvested*, a subsequent compliance sample may be collected at the producer's expense and risk, and the original test is considered preliminary.

F. PRELIMINARY (NON-COMPLIANCE) TESTING

Producers often sample and test their crop as harvest approaches to monitor cannabinoid content. Some producers will do just one preliminary test, and others may check weekly (or more) throughout the floral stage. Some will pull the sample themselves, and some will hire a Certified Sampler. **All** varieties and types of industrial hemp have the potential to "go hot"; make sure you are tracking your crop's progress. Close monitoring will help you maximize profitability, while maintaining compliance.

Certified Samplers are not required to collect preliminary samples, and producers may select any testing laboratory for preliminary testing. However, it is recommended to collect these preliminary samples in accordance with the MDA Sampling Protocol, and to use a qualified testing laboratory to ensure consistency.

Certificates of Analysis for preliminary testing should not be submitted to the Department, and laboratories do not need to report preliminary results to USDA.

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Please contact the program for questions about this document or regulatory topics at hempprogram@mda.mo.gov.

For production or other non-regulatory questions, please contact your local Extension staff:
Lincoln University Hemp Institute: https://bluetigerportal.lincolnu.edu/web/hemp-institute/home
University of Missouri Extension – Industrial Hemp: https://extension2.missouri.edu/programs/industrial-hemp