

Florida Department of Agriculture and Consumer Services Division of Plant Industry

DESIGNATED LABORATORY COMPLIANCE AGREEMENT

Section 581.217, F.S. / 5B-57.014(2), F.A.C. Post Office Box 147100, Gainesville, FL 32614-7100 / (352)395-4700

This AGREEMENT, made and entered into on	R SERVICES
LABORATORY wishes to be placed on DEPARTMENT'S designated	d laboratory list.
In consideration of the mutual covenants set forth, the parties agree as	follows:
ARTICLE 1: TERM	

- 1.1 The term of this Agreement shall commence on the Effective Date and shall continue for a period of one (1) year, subject to termination provision(s).
- 1.2 Extension of this agreement shall be in writing for a single period only not to exceed six (6) months and shall be subject to the same terms and conditions set forth in the initial contract. There shall be only one extension of a contract unless the failure to meet the criteria set forth in the contract for completion of the contract is due to events beyond the control of the LABORATORY.

ARTICLE 2: SAMPLE COLLECTION AND TESTING

2.1 <u>Sample Collection.</u> LABORATORY agrees to collect samples in accordance with the Pre-Harvest Sampling Manual, FDACS – 08127, Rev. 06/21.

ARTICLE 3: GENERAL PROVISIONS

To determine the Total delta-9 tetrahydrocannabinol concentration in hemp samples the LABORATORY agrees to the following:

- 3.1 LABORATORY shall be accredited to the International Organization for Standardization (ISO) 17025:2017.
- 3.2 LABORATORY shall be registered with Drug Enforcement Administration (DEA) in accordance with 21 CFR 1301.13.
- 3.3 The Cannabinoid Analysis method utilized for Total delta-9 tetrahydrocannabinol concentration must be included within the ISO17025:2017 scope of accreditation.
- 3.4 LABORATORY shall notify the Department in writing within three (3) business days if there is a change in its accreditation status or scope of accreditation. This notification must be made to DPIHemp@FDACS.gov.
- 3.5 LABORATORY shall use its best efforts to ensure that its turn around time for delivering laboratory results to the DEPARTMENT shall not exceed two business days from the time of sample receipt at the LABORATORY'S location.

- 3.6 LABORATORY shall provide documentation to DEPARTMENT identifying that it has adequate redundancy in equipment and resources to meet the sample turnaround time specified above.
- 3.7 LABORATORY shall maintain copies of all proficiency testing program sample results for three (3) years from the date the results are finalized and provide to the DEPARTMENT upon request.
- 3.8 LABORATORY shall notify DEPARTMENT within 3 (three) business days if it will not be able to meet the sample turnaround time identified in this agreement.

ARTICLE 4: Sample Custody and Records

- 4.1 Upon receipt by LABORATORY, the sample collection bag seal must be inspected for tampering or damage.
- 4.2 LABORATORY must notify DEPARTMENT if the sample collection bag seal is damaged as resampling will be required for any samples that do not have an intact seal. This notification must be made to DPIHemp@FDACS.gov.
- 4.3 LABORATORY must sign and date the Cannabis Sample Submission Form FDACS 08114, Rev. 04/21 upon receipt. A copy of the signed form must accompany the laboratory report.
- 4.4 LABORATORY must assign a unique identification number to each sample which links it to Cannabis Sample Submission Form, FDACS-08114, Rev. 04/21
- 4.5 LABORATORY must maintain all records associated with the receipt, preparation, analysis, reporting, and disposal of the samples for three (3) years from the date of disposal of the samples and provide to the DEPARTMENT upon request.
- 4.6 LABORATORY must maintain, and provide to the DEPARTMENT upon request, standard operating procedures (SOPs) that accurately reflect all procedures utilized, including the testing requirements specified in this document.

ARTICLE 5: Drying and Homogenization

- 5.1 After LABORATORY receipt and login, the samples must be dried at a temperature not to exceed 85°C until brittle or a consistent weight is achieved.
- 5.2 Samples must then be homogenized in a manner that produces homogeneous particle sizes that fit through a wire screen no larger than 1.5 x 1.5mm.
- 5.3 After homogenization, the sample must be separated into test and retain portions.

ARTICLE 6: Extraction

- 6.1 A portion of the homogenized sample must be extracted in an organic solvent that is suitable for recovering cannabinoids.
- 6.2 The preparation method utilized must be the one specified in the ISO17025:2017 scope of accreditation for cannabinoid analysis.
- 6.3 A hemp Certified Reference Material (CRM) should be processed with each analytical batch.

ARTICLE 7: Analysis

- 7.1 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 USDA. 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 reflect the total available THC derived from the sum of the THC and THCA content. Testing methodologies meeting these requirements include, but are not limited to, gas chromatography and high-performance liquid chromatography.
 - Total delta-9 tetrahydrocannabinol concentration = [delta-9 tetrahydrocannabinol] + $(0.877 \times [\text{tetrahydrocannabinolic acid}])$.
- 7.2 The analysis method must also be the one specified in the ISO17025:2017 scope of accreditation for cannabinoid analysis. The method must be sensitive enough to be able to report delta-9 THC and THCA at a minimum of 0.30%.
- 7.3 BAEL methods PREP 240 (sample preparation) and METHOD 711 (analysis method) are hereby listed as reference methods.
- 7.4 Retest. Any hemp program licensee may request that the laboratory retest the retained samples if the initial report indicates the sample did not have an Acceptable THC level. If this occurs, the laboratory shall follow the same procedures that were followed to conduct the initial test. The licensee requesting the retest of the second sample will pay the cost of the test. The retest shall be done on the retain portion described in the Drying and Homogenization section above.

ARTICLE 8: Reporting

- 8.1 The Total delta-9 tetrahydrocannabinol concentration level shall be determined and reported on a dry weight basis.
- 8.2 The percent Total delta-9 tetrahydrocannabinol concentration shall be reported to two decimal places (example: 0.XX%). Results below the method detection limit shall be reported as not detected or <MDL. The MDL shall be listed on the laboratory report.
- 8.3 The testing measurement of uncertainty shall be reported as a ± value in the same units as the result on each laboratory report. LABORATORY's measurement uncertainty shall be calculated following JCGM 100:2008, Evaluation of Measurement Data-Guide to the expression of uncertainty in measurement (GUM) or the LABORATORY'S ISO17025:2017 approved procedure.
- 8.4 Laboratory reports must be issued to DPIHemp@FDACS.gov within one business day after the completion of the analysis.
- 8.5 Any modifications to LABORATORY'S SOPs must be documented and included on the laboratory report.

ARTICLE 9: Termination

9.1 <u>For Convenience</u>. DEPARTMENT or LABORATORY may terminate this AGREEMENT in whole or in part for its convenience by giving at least forty-five (45) days written notice by electronic or registered mail to the other party, specifying the effective date of termination.

- 9.2 <u>For Cause</u>. DEPARTMENT may terminate this AGREEMENT for cause; provided, however, no right of default shall accrue until thirty (30) days after the defaulting party is notified in writing of the reason(s) for termination and has failed to cure or give adequate assurances of performance within the thirty (30) day period after notice of termination.
 - 9.2.1 For cause termination shall be defined as default, breach or failure of the LABORATORY to fulfill any of its obligations hereunder.
 - 9.2.2 Opportunity to cure. Prior to the exercise of any remedy provided for herein, DEPARTMENT shall provide thirty (30) calendar days written notice of default and shall provide LABORATORY the opportunity to cure such failure or default within said thirty (30) day period. Upon the failure or inability to cure, DEPARTMENT shall have all rights and remedies provided at law or in equity.

Signed by parties to this AGREEMENT:	
LABORATORY	FLORIDA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES
Signature	Signature
Title	Title
Date	Date