



**Pennsylvania Department of Health
Office of Medical Marijuana**

**Application to Become an Approved Laboratory
for Medical Marijuana Testing**

Publication Release Date: May 11, 2017

**For additional information, please contact:
The Pennsylvania Department of Health
Office of Medical Marijuana
RA-DHMedMarijuana@pa.gov**

Application to Become an Approved Laboratory for Medical Marijuana Testing

Generally

A laboratory may not identify, collect, handle or conduct tests on samples from a grower/processor or conduct tests on test samples for the Department of Health (Department) unless the laboratory has been approved by the Department under 28 Pa. Code § 1171.22 (relating to laboratories generally) and has a written contract with the grower/processor under 28 Pa. Code § 1171.29 (relating to testing requirements).

An approved laboratory may not test any samples when there is evidence of improper collection, improper preservation, apparent spoilage, excessive time lapse between collection of the sample and testing, or any other factor sufficient to render the findings of questionable validity. (28 Pa. Code § 1171.29(f) (relating to testing requirements)).

The Department may issue a laboratory approval if the Department determines that the laboratory applicant is financially and professionally suitable to conduct the testing required under the Medical Marijuana Act (35 P.S. §§ 10231.101-10231.2110) and its regulations.

By submitting an Application to Become an Approved Laboratory for Medical Marijuana Testing to the Department, a laboratory applicant consents to an investigation, to the extent deemed appropriate by the Department, of the laboratory applicant's ability to meet the approved laboratory requirements under the Medical Marijuana Act and its regulations. (28 Pa. Code § 1171.23(c) (relating to approval of laboratories)).

An approval issued by the Department to a laboratory is valid for 2 years from the date of issuance and is valid only for the laboratory location specified in the approval. (28 Pa. Code § 1171.22 (relating to approval of laboratories)).

Completing the Application

Complete every section of the application.

The application and any supporting documentation must be saved as PDF files on a single USB drive, external hard drive, CD-ROM, or DVD, in accordance with the following file naming format: *Laboratory Approval Application.pdf*.

Please make sure the application is properly signed and dated. A laboratory owner's signature must be scanned and provided electronically in a pdf file.

Submitting the Application

Applications must be mailed to the following address:

PA Department of Health
Office of Medical Marijuana
Laboratory Approval
Room 628, Health and Welfare Building
625 Forster Street Harrisburg, PA 17120

Application to Become an Approved Laboratory for Medical Marijuana Testing Citation Table		
Application Section	Topic	Regulatory Citation
General Information	Laboratory Owner's information	28 Pa. Code § 1171.23(b)(3)
Laboratory Director	Information and credentials	28 Pa. Code § 1171.22(c)
Technical Personnel	Information and credentials	28 Pa. Code § 1171.23(b)(3)
Accreditation Documentation	Laboratory applicant's most recent certificate of accreditation or a copy of the contract with an accreditation body.	28 Pa. Code § 1171.23(b)(4) 28 Pa. Code § 1171.23(e)
Scope of Accreditation Documentation	Laboratory applicant is accredited to perform testing of medical marijuana.	28 Pa. Code § 1171.23(b)(4) 28 Pa. Code § 1171.23(e)
Standard Operating Procedures	Standard operating procedures and sampling procedures.	28 Pa. Code § 1171.23(b)(5)
Specialized Laboratory Equipment	List of the specialized laboratory equipment utilized or to be utilized by the laboratory applicant.	28 Pa. Code § 1171.23(b)(6)
Quality Assurance Program	Description of the laboratory applicant's quality assurance program.	28 Pa. Code § 1171.23(b)(3) 28 Pa. Code § 1171.32
Chain of Custody Procedures	Procedures for collecting samples from grower/processors.	28 Pa. Code § 1171.23(b)(9)
Signature	A false statement made in the Application to Become an Approved Laboratory for Medical Marijuana Testing is punishable under the applicable provisions of 18 Pa. C.S. Ch. 49 (relating to falsification and intimidation).	28 Pa. Code § 1171.23(d)

Application to Become an Approved Laboratory for Medical Marijuana Testing

General Information

Laboratory Applicant's Name:		
Laboratory Owner's Name:		
Laboratory Owner's License Numbers: <small>(Provide which one is applicable)</small>	Medical License Number:	Pharmacist License Number:
Laboratory Owner's Business Address:		
City, State and Zip Code:		
Telephone Number:		
Fax Number:		

Contact Person

Laboratory Contact Person's Name:	
Title:	
Address:	
City, State and Zip Code:	
Telephone Number:	
Email Address:	

Laboratory Director

Name:		
Please provide one or more of the following:		
Professional License(s):	Medical License Number:	Pharmacist License Number:
Title:		

Technical Personnel

Name:
Professional Training:
Title:

Technical Personnel

Name:
Professional Training:
Title:

Technical Personnel

Name:
Professional Training:
Title:

If necessary, attach additional pages for technical personnel.

Please attach to the application all requested documentation. Failure to include the requested documentation may result in the application being rejected by the Department.

Accreditation Documentation

A copy of the laboratory applicant's most recent certificate of accreditation for the Pennsylvania-based laboratory. If the laboratory applicant is applying to the Department for the first time and has not been issued a certificate of accreditation as a Pennsylvania-based laboratory, please submit the following:

1. A copy of the laboratory applicant's contract with an accreditation body for the Pennsylvania-based laboratory seeking to become approved, and
2. Evidence that the Pennsylvania-based laboratory seeking approval has been accredited by the accreditation body in another jurisdiction.

Scope of Accreditation Documentation

A copy of the laboratory applicant's Scope of Accreditation for the location to be approved that includes evidence that the laboratory applicant is accredited to perform testing of medical marijuana. If the laboratory applicant has not been issued a certificate of accreditation as a Pennsylvania-based laboratory, please submit a copy of the proposed scope of accreditation provided with the contract submitted to an accreditation body for the Pennsylvania-based laboratory seeking to become approved by the Department. Please highlight the list of all tests submitted as part of the scope of accreditation or included as part of the laboratory applicant's contract for accreditation. The laboratory applicant must also highlight the evaluation process that will be used to determine employee competency for conducting tests according to the scope of accreditation.

Standard Operating Procedures

A copy of the standard operating procedures and sampling procedures adopted by the laboratory applicant, which are part of the laboratory's quality assurance system as required by the accreditation body issuing the certificate of accreditation to the laboratory applicant.

Specialized Laboratory Equipment

A list of the specialized laboratory equipment utilized or to be utilized by the laboratory applicant in its testing operations, including the manufacturer's name, the serial and model number(s) of the equipment and the date each piece of equipment was last inspected.

Quality Assurance Program

Attach a description of the laboratory applicant's quality assurance program, which must comply with 28 Pa. Code § 1171.32 (relating to quality assurance program).

Chain of Custody Procedures

An outline of the steps and procedures to be followed to establish chain of custody when collecting samples for a grower/processor or test samples for the Department.

Signature Section

I hereby certify that I am authorized to sign this Application to Become an Approved Laboratory for Medical Marijuana Testing, that the information contained herein is true and correct and that there is no misrepresentation, falsification or omissions in this application.

I also acknowledge that I have reviewed and will comply with the Medical Marijuana Act (35 P.S. §§ 10231.101-10231.2110) and the Laboratories regulations in 28 Pa. Code Chapter 1171.

A false statement made in this Application to Become an Approved Laboratory for Medical Marijuana Testing is punishable under the applicable provisions of 18 Pa. C.S. Ch. 49 (relating to falsification and intimidation).

Laboratory Owner's Signature:

Date:

Printed Name:

Title:

A photocopy or other electronic version of this document shall be accepted as an original signature.