Department of Health, Wadsworth Center

Test Approval

The Application Procedures section below describes the types of tests that require specific review and approval from the Department and provides forms and instructions for submitting test validation materials.

Laboratories must establish the analytic and clinical performance characteristics of all tests performed. If these characteristics have been defined by the test manufacturer, the laboratory must verify those characteristics at the site where the test will be performed.

Application Procedures

FDA-approved assays, Standard Methods and Legacy Assays

Modifications to Approved Assays

Tests using commercially distributed assays or test kits NOT cleared/approved by the FDA

Laboratory-developed tests (LDTs)

LDTs used in Clinical Trials

LDTs used for Lifestyle Testing

LDTs used in Research Testing

Requests for Exemption from Comprehensive Submissions

Adding LDTs Under an Approved Exemption

LDTs with at-home Collected Specimens

Tiered Evaluation of Laboratory Developed Tests Policy

Features of the tiered evaluation review process

Classifications

Review the full Tiered Evaluation of Laboratory Developed Tests Policy.

Making a Submission

If a full method validation submission is required as described above, please select the appropriate checklist for your category from the following:

Obtain a Permit

Health Commerce System

On-Site Survey Process

Test Approval

Lifestyle and Wellness Tests

Patient Service Centers & Health Fairs

Clinical Laboratory Evaluation Program

United States
See map: Google Maps
P: (518) 485-5378
F: (518) 485-5414
clep@health.ny.gov

US Postal Service

Clinical Laboratory Evaluation Program
Biggs Laboratory
Wadsworth Center
NYS Department of Health
Empire State Plaza
Albany, NY 12237

UPS, FedEx, Courier

Clinical Lab Eval Program
Biggs Lab – Wadsworth Center
NYS Department of Health
Dock J – P1, Empire State Plaza
Albany, NY 12237

- Cellular Immunology Checklist
- Cytogenetics FISH Checklist
- Forensic Identity Checklist
- Genetic Testing Molecular Checklist
  - Guidelines for Germline Variant Detection Using Next Generation Sequencing (NGS)
- Microbiology Molecular Checklist
  - MALDI-TOF Assays in Microbiology Checklist
  - Validation of Next Generation Sequencing (NGS) Methods for Identification and/or Characterization of Infectious Agents
- Oncology Molecular Checklist
  - Frequently Asked Questions for Third Party Review Process for Next Generation Sequencing Oncology Panels
  - Guidelines for Somatic Variant Detection Using Next Generation Sequencing (NGS)
- Toxicology Checklist
- Trace Elements Checklist

If you do not see your category listed, please use the General Checklist. Compile all requested documentation and index the documents as requested.

Complete the Risk Attestation Form to accompany the submission. The test classification of the assay will be assigned by the Clinical Laboratory Reference System. The assigned risk classification will define the mode of review the submission will receive:

Category	Submission Required	Initial Approval	Review Required	Review Priority
High	Yes	None	Yes	High[1]
Moderate	Yes	Conditional[2,3]	Yes	Medium
Low	Yes	Full[2,3]	No[4]	--
Clinical Trial	Yes	N/A[2,4]	No[4]	--
Lifestyle	Yes	N/A[4]	N/A[4]	--

[1] Submissions for laboratories pending a permit or permit category are automatically assigned High Risk, except for packages that qualify for Clinical Trials or Lifestyle status.
[2] Provided the laboratory holds the appropriate permit category.
[3] The Department reserves the right to withhold approval at its discretion.
[4]The Department reserves the right to review all applications at its discretion.

Submit all documents in both hard copy and one identical electronic copy (provided as a pdf on a CD or flash drive) to the address provided on the first page of the appropriate Submission checklist. The electronic version must follow the Digital Submission Guidelines below.

Mark the cover page of each unit of material with the words “proprietary”, “confidential” or similar to indicate the desire to protect these documents from immediate release based on a Freedom of Information Law (FOIL) request. If so marked, the laboratory will be advised of any FOIL requests for those documents and will be provided an opportunity to block release by presenting evidence that the materials contain trade secrets.

DO NOT include additional items not requested or not needed to provide context of the assay procedure, reporting or how the analytic and clinical performance was established.

Digital Submission Guidelines

Laboratories must comply with the digital submission requirements set forth below. Laboratories are required to submit both paper and PDF electronic versions of complete validation packages. The electronic version (CD or flash drive joined securely to the hard copy) is expected to be an exact duplicate of the paper submission.

Differences between the paper and electronic copy are allowable, provided the electronic copy is more inclusive. In some cases, paper submission of certain material is not feasible (e.g., raw data and statistical analysis program data). The electronic copy must contain all the elements/data required for the submission as defined in each submission checklist, while the paper copy may include a placeholder that cross-references the location of that information in the electronic copy.

- Paper and electronic copies must be organized in the manner required in the appropriate submission checklist.
- Electronic copies must be limited to **as few files as possible**.
- For PDF documents generated from a scanned copy rather than from the source document, optical character recognition (OCR) must be performed. We recognize that use of OCR may not be feasible in some cases for documents with figures and images.
- A single PDF document cannot exceed 50 MB in size.
- Submit only one PDF document to address all the elements of the submission checklist. Raw data should be submitted in separate files, with up to five files total to be submitted. If additional files are required, please contact clepval@health.ny.gov.
- A project ID (PID) will be assigned to the submission by CLEP staff and this PID will be appended to the filename(s). The laboratory will be notified of the PID by email confirming receipt of the submission.

Tracking a Submission

Laboratories can track the progress of test approval submissions via the Test Approval Status link on the eCLEP home page available on the Department's Health Commerce System (HCS). Approved methods are shared with referring laboratories, consumers, and health care providers upon request, so it is important to regularly review your list of approved methods to ensure a method is still being offered by your laboratory. Once a submission is received and logged, it is assigned a Project ID (PID) number and included in the Test Approval Status list showing the current status. If a test or test method has been discontinued, you may send an email as described below.

To inquire about a submission, you can send an email the CLEP Validation Unit. Please reference your laboratory's four-digit permanent facility identifier (PFI) and the PID number in the subject line of your email.

Deleting a Test

To delete a test considered to be an LDT from the test approval listing, email the CLEP Validation Unit.

Non-Permitted Laboratory Test Requests

- Instructions
- Application

New York State Public Health Law (Article 5, Title V, Section 574) and regulations (Subsection 58-1.10 (g) of 10NYCRR) require that all specimens obtained within New York State be tested by a laboratory that holds a New York State clinical laboratory permit, including test-specific approval when required. Explicit test-specific approval is not required for tests designated as FDA-cleared, approved or exempt. Notification to add such tests to the laboratory's test menu is still required. Due to the rarity of many diseases, testing for all potential conditions may not be available from permit-holding laboratories or there may be adequate justification for use of a specific laboratory that does not hold a permit. In these cases, the department's approval must be received prior to submitting a specimen collected in New York State for testing by a non-permitted laboratory or a permitted laboratory that does not hold approval for that particular test. All laboratories performing testing, however, must hold a valid CLIA number. The Clinical Laboratory Evaluation Program (CLEP) administers this process and monitors the volume and frequency of requests.

Print

REGULATORY PROGRAMS

Clinical Laboratory Evaluation Program
Environmental Laboratory Approval Program
Physician Office Laboratory Evaluation Program
Breath & Blood Alcohol Testing
Blood Resources Program
Tissue Resources Program
Regulated Medical Waste Program
Laboratory Investigations Unit

EDUCATION

Wadsworth Center Fellowship Program
APHL/CDC Fellowships
NIH Biodefense & Emerging Infectious Diseases Training Program
Postdoctoral & Visiting Scientists
Graduate
Research Experience for Undergraduates
Student Volunteers

EXTRAMURAL FUNDING

Breast Cancer Research & Education
Multiple Sclerosis
New York State Stem Cell Science
Spinal Cord Injury Research

ABOUT US

Affiliations
Director's Office
Employment Opportunities
History
Landmark Achievements
News and Events
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NYS Department of Health