

Notification to Delete FDA-Approved Test(s)

Telephone: (518) 485-5378 Fax: (518) 449-6904
E-mail: CLEPCERT@health.state.ny.us
Web: www.wadsworth.org/regulatory/clep

Instructions:

Please provide the requested information below to delete tests from your test menu for New York state specimens that cannot be deleted via eCLEP.

For deletion of non-FDA approved/cleared tests from your test menu for which method validation has been approved or submitted to the Method Validation Unit, please send an e-mail to clepval@health.state.ny.us with the laboratory's PFI number and project identification number (PID), if known, in the subject line.

Definitions:

Name of Test: Provide a descriptive name to identify the test, for example: Group A Strep antigen.

Permit Category: Below is a general listing of the permit categories recognized by New York State. Please note that these category names are different from the specialty names recognized by CMS/CLIA. Several categories have subcategories. Please refer to the [Program Guide](#) for further information and clarification.

Andrology
Bacteriology
Blood pH and Gases
Blood Services
Cellular Immunology
Clinical Chemistry
Cytogenetics
Cytokines
Cytopathology
Diagnostic Immunology

Endocrinology
Fetal Defect Markers
Forensic Identity
Genetic Testing
Hematology
Histocompatibility
Histopathology
Immunohematology
Mycobacteriology
Mycology

Oncology
Parasitology
Parentage/ Identity testing
Therapeutic Substance Monitoring /
Quantitative Toxicology
Toxicology
Trace Elements
Transplant Monitoring
Urinalysis
Urine Pregnancy Testing
Virology

Note: if all tests are being deleted from a category, the entire category can be deleted via eCLEP.

Method: Indicate the underlying methodology, for example: chemiluminescent immunometric assay (CIA) or real-time polymerase chain reaction (real-time PCR).

Instrument: Indicate the type, brand and model of the instrument used for detection, if applicable.

Kit Name: Indicate the name of the commercially-available test, if applicable.

Specimen type: Indicate the bodily specimen the testing is performed on.

Signature Requirements:

- The laboratory director must sign for test menu changes.

NEW YORK STATE DEPARTMENT OF HEALTH
WADSWORTH CENTER
CLINICAL LABORATORY EVALUATION PROGRAM
EMPIRE STATE PLAZA, P.O. BOX 509
ALBANY, NEW YORK 12201-0509

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Notification to Delete Test(s)

**Note: Please submit by one method only:
e-mail, fax or postal service.**

Laboratory PFI:

Name and Address of Laboratory:

Test Name

Permit Category
Name

Method

Instrument

Kit Name

Specimen type

Test Name

Permit Category
Name

Method

Instrument

Kit Name

Specimen type

Test Name

Permit Category
Name

Method

Instrument

Kit Name

Specimen type

Test Name

Permit Category
Name

Method

Instrument

Kit Name

Specimen type

NOTE: All signatures must be original. SIGNATURE STAMPS WILL NOT BE ACCEPTED.

Date

Signature, Laboratory Director

Name, Laboratory Director (Print)

CQ Code