

## Notification to Add/or Delete FDA-Approved Test(s)

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

### Instructions:

Please refer to the [Comprehensive Test Approval Policy and Submission Guidelines](#) found on our website: [www.wadsworth.org/clep/](http://www.wadsworth.org/clep/) for the proper usage of this form.

Provide the requested information below to apply for the addition/deletion of tests 1) cleared/approved for in vitro diagnostic (IVD) use by the Food and Drug Administration (FDA) and that have not been modified to change intended use; 2) considered standards methods in specific permit categories (see table below); 3) that have been exempted from routine submission in the specific permit category; or 4) as directed by permit category-specific requirements. To request the addition/deletion of a large number of these tests (e.g. > 9), a spreadsheet listing all the required information as indicated below will be accepted in place of multiple forms. A blank [spreadsheet](#) is available on the [Test Approval Policy](#) webpage.

### 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 substantive subcategories. Please refer to the [Program Guide](#) for further information and clarification.

Andrology	Fetal Defect Markers	Parasitology‡
Bacteriology‡	Forensic Identity	Parentage/ Identity testing
Blood pH and Gases	Genetic Testing	Therapeutic Substance Monitoring / Quantitative Toxicology
Blood Services	Hematology‡	Toxicology
Cellular Immunology	Histocompatibility	Trace Elements
Clinical Chemistry	Histopathology‡	Transplant Monitoring
Cytogenetics	HIV testing	Urinalysis
Cytokines	Immunohematology‡	Urine Pregnancy Testing
Cytopathology	Mycobacteriology‡	Virology‡
Diagnostic Immunology	Mycology‡	
Endocrinology	Oncology	

‡Denotes those permit categories that recognize standard methods (e.g. manual differentials, stains, gram stains, culture, tissue processing or provider-performed-microscopy procedures). To add these kinds of tests, please submit the attached form without the FDA Document number.

**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.

**FDA Document Number:** Indicate the PMA or PMN 510(k) document number indicating the FDA status of the test. These documents can be found in the In Vitro Product Database at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfi/d/index.cfm>.

### Signature Requirements:

- The Certificate of Qualification holder for the applicable permit category(ies) must sign for each test being added under that category.
- The laboratory director must sign for all test menu changes.

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Laboratory PFI Number:	Name and Address of Laboratory:

Test Name	Request: <input type="checkbox"/> Add <input type="checkbox"/> Delete
Permit Category Name	FDA/ 510K Document #
Method	
Instrument	
Kit Name	
Specimen type	

Signature of the Assistant Director holding the certificate of qualification for the category, if applicable:  
 \_\_\_\_\_ CQ Code: \_\_\_\_\_ Date: \_\_\_\_\_  
 Signature Name (Print)

Test Name	Request: <input type="checkbox"/> Add <input type="checkbox"/> Delete
Permit Category Name	FDA/ 510K Document #
Method	
Instrument	
Kit Name	
Specimen type	

Signature of the Assistant Director holding the certificate of qualification for the category, if applicable:  
 \_\_\_\_\_ CQ Code: \_\_\_\_\_ Date: \_\_\_\_\_  
 Signature Name (Print)

Test Name	Request: <input type="checkbox"/> Add <input type="checkbox"/> Delete
Permit Category Name	FDA/ 510K Document #
Method	
Instrument	
Kit Name	
Specimen type	

Signature of the Assistant Director holding the certificate of qualification for the category, if applicable:  
 \_\_\_\_\_ CQ Code: \_\_\_\_\_ Date: \_\_\_\_\_  
 Signature Name (Print)

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