



**Department
of Health**

**Wadsworth
Center**

Understanding New York Proficiency Testing Requirements

Wednesday, October 18, 2017

The presentation will begin at 2:00 PM

October 19 2017

A question and answer period will follow the presentation.

- Please save your questions until then.
- Use the WebEx Q/A feature to submit questions in writing.
- We may not be able to answer all questions in the allotted time.

All participants' phones will be muted during the webinar.

Topic: Understanding New York Proficiency Testing Requirements

Presenter: Derek Symula, Ph.D.

Director, Clinical Proficiency Testing Program

Date: Wednesday, October 18, 2017

Time: 2:00 pm, Eastern Daylight Time (New York, GMT-04:00)

This training session will include:

- A review of the NY PT enrollment requirements
- A description of the NY PT designation process
- An explanation of the NY PT policy for molecular microbiology assays

**This training may be used as 1 hour of continuing education to fulfill Human Resources Sustaining Standard of Practice 10 (HR S10): Continuing Education.

NYS Clinical Proficiency Testing Requirements

Laboratories seeking or holding a NYS Clinical Laboratory Evaluation Program (CLEP) permit must enroll in and successfully participate in proficiency testing (PT) for certain analytes/tests.

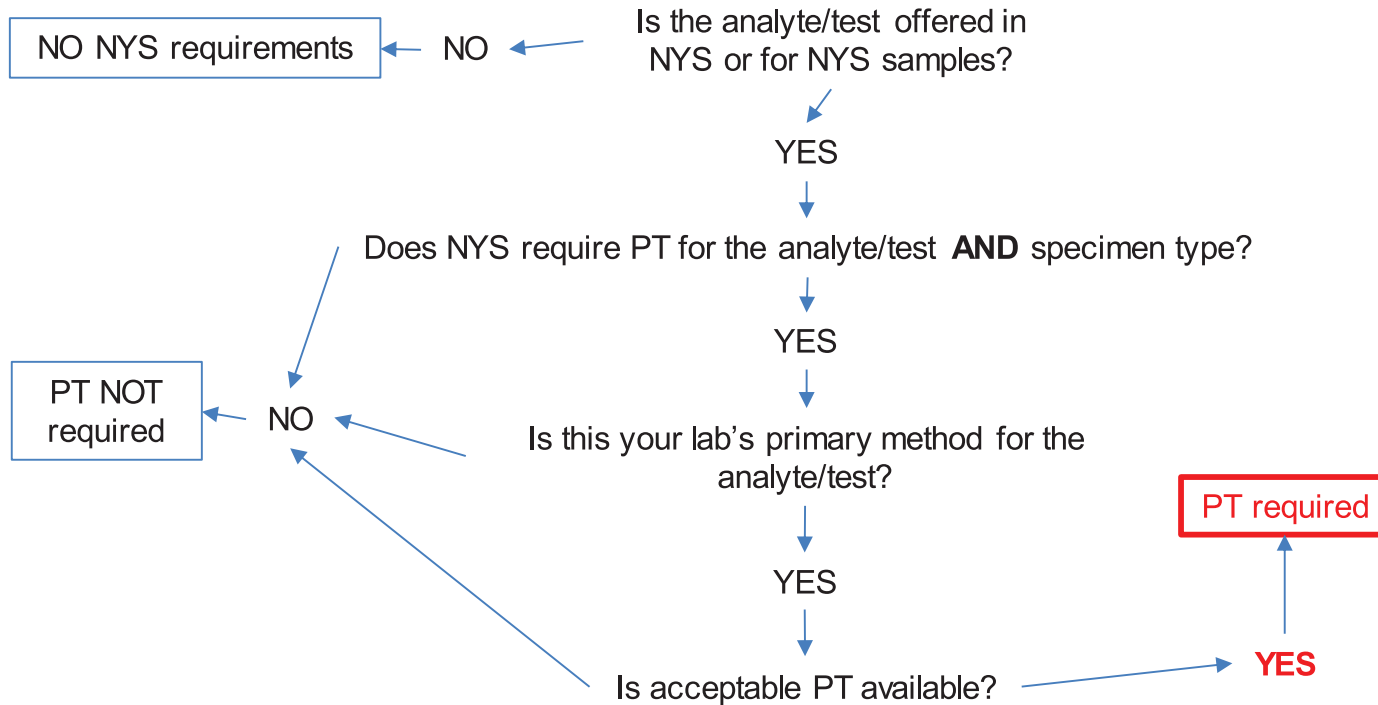
These requirements derive from

- CLIA Subpart H (42 CFR 493 subpart H) – laboratory requirements
- CLIA Subpart I (42 CFR 493 subpart I) – PT program requirements
- NYS clinical laboratory standards of practice PT F1 and PT S1-PT S14*
- NYS clinical laboratory standards of practice DIR S3 (I)*

“Proficiency testing” must be external, graded, and acceptable to NYS.

*Please see current General Systems Standards for exact text and guidance.
<https://www.wadsworth.org/regulatory/clep/clinical-labs/laboratory-standards>

Does NYS Require PT for this Test? – Enrollment Algorithm



Is the analyte/test offered in NYS or for NYS samples?

Did you add the analyte/test to your laboratory's NYS test menu (and haven't deleted it)?

Laboratories located in NYS – test menu

Out of state laboratories – performed on NYS specimens

Special Circumstances

New Permits and New Categories

Once you have applied, your laboratory must enroll in PT for analytes/tests meeting criteria in the enrollment algorithm AND successfully participate in any PT in which it participates.

New tests

Applies to tests added to an existing category and new tests added as part of a new category.

Your laboratory must enroll in PT no later than the date you add the analyte/test to your test menu in eCLEP or add the category (if it meets all other criteria).

Does NYS require PT for the analyte/test AND specimen type?

NYS requires PT for analytes/tests described in CLIA subpart I

Search tests that require PT:

<https://www.wadsworth.org/regulatory/clep/pt/provider-search>

The screenshot shows the website for the Department of Health, Wadsworth Center. At the top left is the New York State logo. A navigation menu includes 'Services', 'News', 'Government', 'Local', 'Location', and 'Translate'. Below this is a dark purple header with 'Department of Health, Wadsworth Center' and a secondary menu with 'Public Health Programs', 'Research', 'Regulatory Programs', 'Education', 'Extramural Funding', and 'About Us'. A search icon is on the right. The main content area features a large image of a multi-well plate with orange liquid. Below the image is the title 'Proficiency Testing - Survey Search Tool'. At the bottom, a breadcrumb trail reads: 'Home > Regulatory Programs > Clinical Laboratory Evaluation Program > Proficiency Testing > Proficiency Testing - Survey'. The footer contains the New York State logo, 'Department of Health', and 'Wadsworth Center'.

Does NYS require PT for the analyte/test AND specimen type?

Bacteriology

Clinical Chemistry

Cytopathology – Gynecological Testing*

Blood pH and Gases

Diagnostic Immunology – Diagnostic Services Serology

Diagnostic Immunology – Donor Services Serology

Endocrinology

Forensic Identity**

Hematology – Cellular Hematology

Hematology - Coagulation

Hematology – Cytohematology Diagnostic

Immunochemistry

Mycobacteriology

Mycology

Oncology – Human Papillomavirus (HPV) Testing

Oncology – Soluble Tumor Markers

Parasitology

Therapeutic Substance Monitoring/Quantitative Toxicology

Toxicology – Blood Lead – Comprehensive

Toxicology – Blood Lead – ASV Using Screen-Printed Sensors

Virology

Tests that require PT
currently fall in these
categories only

These categories ALSO include
tests that DO NOT require PT

*Refer to CLEP Program Guide

**Refer to Forensic Identity requirements



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Does NYS require PT for the analyte/test AND specimen type?

NO TESTS IN THESE CATEGORIES CURRENTLY REQUIRE PT

Andrology
Cellular Immunology – Leukocyte Function
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping
Cellular Immunology – Malignant Leukocyte Phenotyping
Cytogenetics – Cancer
Cytogenetics – Prenatal
Cytogenetics – Restricted
Cytokines
Cytopathology – Non-Gynecological Testing
Fetal Defect Markers
Genetic Testing – Molecular
Genetic Testing – Biochemistry
Histocompatibility General
Histocompatibility HLA Typing Only
Histopathology – General
Histopathology – Oral Pathology
Histopathology – Dermatopathology
Oncology – Molecular and Cellular Tumor Markers
Forensic Toxicology – Initial Testing Only
Forensic Toxicology – Comprehensive
Clinical Toxicology – Qualitative Testing Only
Clinical Toxicology – Comprehensive
Trace Elements
Transplant Monitoring
Wet Mounts

Does NYS require PT for the analyte/test AND specimen type?

Bacteriology tests that require PT for 2018

- Identification of bacteria by culture
- Identification of bacterial meningitis pathogens by molecular methods
- Identification of blood pathogens by molecular methods
- Identification of gastrointestinal pathogens by molecular methods
- Identification of respiratory pathogens by molecular methods
- *Chlamydia/Neisseria gonorrhoeae* by direct detection
- *Clostridium difficile* direct detection
- Group A *Streptococcus* direct detection
- Group B *Streptococcus* direct detection
- Gram stains
- Susceptibility (bacterial) testing (AST)

New for 2018

- Identification of bacteria by culture OR molecular methods requires PT
- Molecular methods include PCR, “NAAT,” sequencing, etc
- Molecular methods – enroll in PT based on specimen source



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Does NYS require PT for the analyte/test AND specimen type?

Mycobacteriology tests that require PT for 2018

- Identification of Mycobacteria by culture
- Identification of Mycobacteria by molecular methods
- Acid fast smears
- Susceptibility (mycobacterial) testing

New for 2018

- Identification of mycobacteria by culture OR molecular methods requires PT
- Molecular methods include PCR, “NAAT,” sequencing, etc
- Susceptibility (mycobacterial) testing by culture OR molecular methods requires PT

Does NYS require PT for the analyte/test AND specimen type?

Mycology tests that require PT for 2018

- Cryptococcal antigen detection
- Identification of fungi by culture
- Identification of fungi by molecular methods

New for 2018

- Identification of fungi by culture OR molecular methods requires PT
- Molecular methods include PCR, “NAAT,” sequencing, etc
- Identification of fungi includes but is not limited to identification of dermatophytes, molds, and yeast

Does NYS require PT for the analyte/test AND specimen type?

Parasitology tests that require PT for 2018

- Giardia/Cryptosporidium antigen detection
 - Identification of parasites
- Identification of parasites using concentration preparations and/or permanent stains requires PT
 - Identification of parasites by molecular methods DOES NOT require PT
 - Identification of parasites includes but is not limited to malarial smears, identification of bloodborne parasites, and identification of tissue parasites.

Does NYS require PT for the analyte/test AND specimen type?

Virology tests that require PT for 2018

- { • Identification of virus by culture
- { • Identification of gastrointestinal viruses by molecular methods
- { • Identification of respiratory viruses by molecular methods
- { • Identification of viral meningitis by molecular methods
- { • Herpes simplex virus (HSV) direct detection
- { • Respiratory virus (influenza and RSV) direct detection
- { • Rotavirus direct detection

New for 2018

- Identification of viruses by culture OR molecular methods requires PT
- Molecular methods include PCR, “NAAT,” sequencing, etc
- Molecular methods – enroll in PT based on specimen source



Does NYS require PT for the analyte/test AND specimen type?

Clinical Chemistry tests that require PT for 2018

- Alanine aminotransferase (ALT)
- Albumin
- Alkaline phosphatase
- **Amylase**
- Aspartate aminotransferase (AST)
- **Bilirubin, total**
- **Calcium, total**
- Chloride
- Cholesterol, HDL
- Cholesterol, total
- Creatine kinase
- Creatine kinase MB
- Creatinine
- Glucose
- Iron
- Lactate dehydrogenase (LDH)
- LDH isoenzymes
- Magnesium
- Potassium
- Sodium
- **Total protein**
- Triglycerides
- Urea nitrogen (BUN)
- Uric acid

Does NYS require PT for the analyte/test AND specimen type?

Clinical Chemistry tests that require PT for 2018

Tests for these analytes/tests in serum, plasma, or blood specimens require PT.

Tests for these analytes/tests in ANY other specimen type, including urine, do NOT require PT.

Tests for ANY other clinical chemistry analytes/tests, regardless of specimen type, do NOT require PT.

Endocrinology* and TSMQT analytes/tests that require PT only require PT if performed on serum, plasma, or blood specimens.

Does NYS require PT for the analyte/test AND specimen type?

Diagnostic Immunology – Diagnostic Services Serology
tests that require PT for 2018

- alpha-1 antitrypsin (AAT)
- **antinuclear antibody (ANA)**
- **antistreptolysin O (ASO)**
- C3
- C4
- Hepatitis B core antibody (anti-HBc)
- Hepatitis Be antigen (HBeAg)
- Hepatitis B surface antigen (HBsAg)*
- **Human immunodeficiency virus***
- IgA
- IgE
- IgG
- IgM
- Heterophile (infectious mono)
- **Rheumatoid Factor**
- Rubella Ab
- Syphilis

*HIV screening AND confirmation each require PT. You must perform confirmation on PT samples as you would for patient samples. Generally, this means confirming just the screen-positive samples. Also applies to HBsAg.

New for 2018

HIV – no longer broken out by screening, confirmation, HIV-1, HIV-2, etc
ANA, ASO, Rheumatoid Factor – no longer broken out by qual, quant, etc.

Does NYS require PT for the analyte/test AND specimen type?

Hematology tests that require PT for 2018

Hematology – Cellular Hematology

- Hematocrit
- Hemoglobin
- Platelet count
- Red blood cell count (RBC)
- White blood cell count (WBC)
- White cell differential (Automated)

Hematology – Cytohematology Diagnostic

- White cell differential (Manual)

Automated differential and manual differential are different tests.
Each requires PT.

Is this your lab's primary method for the analyte/test?

Primary method

The method your laboratory routinely uses to test patient samples for the analyte/test.

Includes:

Tests that have a screening step and a confirmation step – each of these has a primary method.

Not a primary method

A method used when the primary method is not available

Is acceptable PT available?

- Acceptable Providers
- Acceptable Surveys (products)
- Method/sample matrix issues

Is acceptable PT available?

Acceptable PT Providers for satisfying NYS requirements

- ACCUTEST, INC. (aka OneWorld Accuracy)
- AMERICAN ASSOCIATION OF BIOANALYSTS (AAB)
- AMERICAN PROFICIENCY INSTITUTE (API)
- THE COLLEGE OF AMERICAN PATHOLOGISTS (CAP)
- MEDICAL LABORATORY EVALUATION (MLE) PROGRAM (American College of Physicians)
- COMMONWEALTH OF PENNSYLVANIA
- PUERTO RICO PROFICIENCY TESTING SERVICE
- WSLH Proficiency Testing Program

Is acceptable PT available?

Acceptable Surveys for satisfying NYS PT requirements

Mycobacteriology

- Minimum five samples per event
- Minimum two events per year

All other categories (required PT)

- Minimum five samples per event
 - Microbiology – varies by analyte/test
 - All others – five samples for EACH analyte/test
- Minimum three events per year

Is acceptable PT available?

Method/sample matrix issues

Rarely, your laboratory will offer a test that requires PT, but your method will not be compatible with any of the acceptable PT surveys. In that situation, your laboratory is not required to enroll in PT.

- Discuss with ALL of the acceptable PT providers before concluding PT is not available.
- Discuss with NYS

ptadmin@health.ny.gov

518-408-9125

Is acceptable PT available?

Waived Testing

Performed in a comprehensive clinical laboratory?

Requires PT per enrollment algorithm?

If “yes” for both questions, your laboratory **MUST** enroll in acceptable PT.

“PT for waived methods” surveys that are fewer than three events per year and five samples per event do not satisfy NYS requirements.

What if your test does NOT require PT?

Your laboratory must comply with **Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy:**

- Have a system to verify “reliability and accuracy” of tests that don’t require PT
- Verify at least twice annually
- Evaluate verification results
- Perform corrective action under certain circumstances

You may satisfy QA S3 by voluntarily enrolling in external PT.
Regulatory consequences of failure are the same as for required PT.

Please see current General Systems Standards for exact text and guidance.
<https://www.wadsworth.org/regulatory/clep/clinical-labs/laboratory-standards>

What if NYS requires PT for your test?

You must:



- Designate PT
- Enroll in PT
- Successfully participate in PT

Designate = notify NYS of PT provider and product to be used to satisfy PT requirements

Designate PT

Designation period for calendar year 2018
October 23 – November 3, 2017

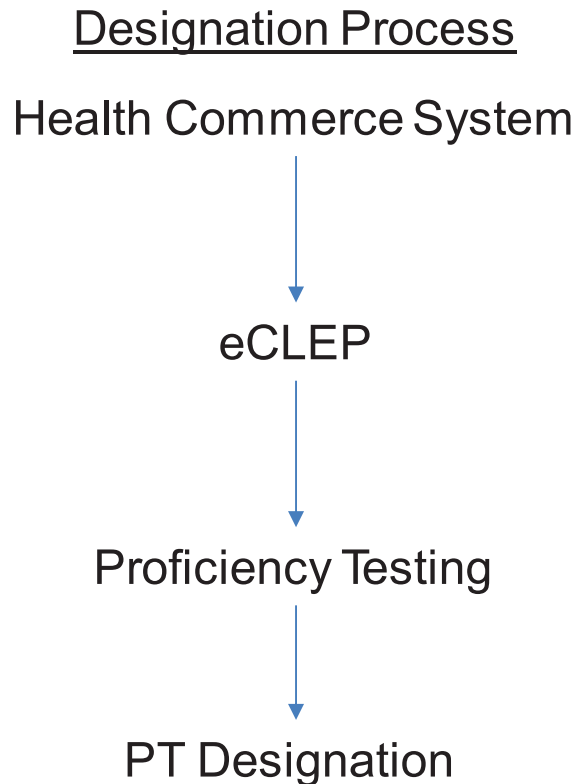
Includes any tests:

- currently on your laboratory's test menu
- in categories that you have applied to add to your permit
- in categories included in a new permit application

For permits, categories, or tests added after the designation period, you will be contacted for designation information.

DESIGNATIONS ARE BINDING. NYS will verify participation.

Designate PT



You must have an HCS account. Laboratory directors have HCS accounts. Others in your laboratory also may have HCS accounts.

HCS questions or password issues?
Commerce Accounts Management Unit (CAMU) - camu@its.ny.gov
or 1-866-529-1890 option 1

You must request access to eCLEP once you have an HCS account.
Contact for eCLEP access:
https://www.wadsworth.org/sites/default/files/WebDoc/delegate_submission_2017_distributed_0.pdf



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Designate PT

Loading...

Most technical issues are due to your web browser. Mozilla Firefox and older versions of Microsoft Internet Explorer are problems. Try a different browser.

Desktop:

- Microsoft Internet Explorer
- Google Chrome
- Safari (Mac OS only)

OK

Mobile:

- Safari (iOS5.1 or later)
- Google Chrome (iOS5.1/Android 4.0 or later)

Limited Support:

- Mozilla Firefox (Desktop/Mobile)
- Most WebKit-based browsers (Android OS 2.3 or later)

not OK

Unsupported Browsers:

- Microsoft Internet Explorer Mobile (Windows 8 Phone)
- Safari for Windows (Desktop)

Designate PT

Health Commerce System

[Home](#) | [My Content](#) | [Print](#) | [Search](#) | [Help](#)

Welcome Dereke J Symula

My Applications

- Acronyms & Abbreviations
- eCLEP
- Emergency Contacts
- EPTRS
- ServNY

Refresh My Applications List

System Notices

- Reminder! The self-service [Forgot your password?](#) and [Forgot your user ID?](#) are now available. You can:
 - reset your password using your NYS driver license or NYS non-driver photo ID or your secret questions/answers.
 - retrieve your user ID via email using your name and email that matches your account information.

Important Health Events

CYBERSECURITY

NYS PMP

ZIKA VIRUS RESPONSE

Important Health Notifications

Posted	Priority	Keyword	Source	Audience	Description	Recipients
10/02/2017	Drill	Drill	Laboratory Response Network		2017 Ebola Survey	Recipients
10/02/2017	Advisory	Influenza	NYSDOH		Influenza Surveillance and Reporting Requirements, 2017-2018	Recipients
09/29/2017	Advisory	Commissioner's Letter	NYSDOH		Dr. Zuckers September Physician letter attached	Recipients
09/26/2017	Advisory	NP PA Prescribe Buprenorphin	NYSDOH		NPs & PAs Can Prescribe Buprenorphine!	Recipients

← Newer
Showing notifications sent in the past 30 days.
Older →

Designate PT

The screenshot shows the Wadsworth Center e-CLEP website. At the top, there is a purple navigation bar with the New York State Health Commerce System logo on the left and links for Home, My Content, Print, Search, and Help on the right. Below this, the page header includes 'Wadsworth Center' and 'e-CLEP' (electronic Clinical Laboratory Evaluation Program). The main content area is divided into two columns. The left column contains a 'Welcome to e-CLEP!' message and a message center table with columns for Date, Priority, and Message. The right column contains several blue boxes with white text: 'Permit Materials' (Laboratory Reapplication, Laboratory Changes), 'Proficiency Testing' (PT Designations), 'LDT Approval' (Test approval materials for permitted and non-permitted laboratories), 'Survey' (Tools and information related to laboratory surveys), and 'Limited Labs' (Limited laboratory forms, etc.). A large blue arrow points to the 'Proficiency Testing' link. At the bottom of the page, there are links for Contact Us, Help, FAQ, Accessibility, and Message Center.

Designate PT

The screenshot shows the Wadsworth Center e-CLEP portal. At the top, there is a navigation bar with 'Home', 'My Content', 'Print', 'Search', and 'Help'. Below this is the 'Wadsworth Center' header with the 'e-CLEP' logo. A breadcrumb trail reads 'home > permit materials > reapplication center'. A menu bar contains 'Permit Materials', 'Proficiency Testing' (circled in red), 'LDT Approval', 'Survey', and 'Limited Labs'. Below the menu, it says 'Reapplication Center' and 'Reapplication Period: Aug 10, 2017 through Aug 12, 2017 at 05:00 PM, EDT'. There are input fields for 'PFI:' and 'Name:'. The main content area is titled 'Read-Only Mode' and contains the following text:

eCLEP access for your facility is currently in read-only mode. Read-only mode is in effect when change notifications made through eCLEP are pending review and approval by the department. Read-only mode may also be in effect when the reapplication period for the succeeding permit year has expired.

While in read-only mode, you may not edit your facility's data. You are, however, able to view a summary of your facility's current data on file with the department. You are also able to view any submissions made during the current application year.

If you believe you have made an error in your submission of a change in notification, or of the permit reapplication, please contact CLEP at CLEP@health.ny.gov to request the edit function be restored to update your facility information.

Current Data on File (without pending changes)

[View Summary](#)

Electronic Submissions

- [Reapplication Submission dated Jun 29, 2017 11:39:24 AM EDT \(PDF\)](#)
- [Reapplication Submission dated Apr 12, 2017 7:20:42 AM EDT \(PDF\)](#)
- [Submission dated May 10, 2016 4:21:03 PM EDT \(PDF\)](#)
- [Reapplication Submission dated Apr 15, 2016 10:02:13 AM EDT \(PDF\)](#)
- [Reapplication Submission dated Apr 1, 2016 12:13:11 PM EDT \(PDF\)](#)

[view all](#)

Designate PT

Wadsworth Center
New York State Department of Health

eCLEP
electronic Clinical Evaluation Program

home > proficiency testing Select Facility

Permit Materials | **Proficiency Testing** | LDT Approval | Survey | Limited Labs

Begin Designation Process
Instructions
Product Help
Category Help

PFI: Name:

Required Proficiency Testing (PT) – Designations

PT designation period is open from 09/01/2016 12:00 till 11/30/2017 17:00.

Use the links at the left to begin or continue the designation process, view instructions, or find additional help regarding specific PT products.

Laboratories seeking or holding a New York State (NYS) comprehensive clinical laboratory permit through the Clinical Laboratory Evaluation Program (CLEP) must enroll in CMS-approved PT Programs for those tests described in CLIA Subpart I, (42 CFR 493 subpart I).

In addition, each laboratory must designate the PT surveys that will be used to satisfy these PT requirements. Laboratories currently holding a NYS CLEP permit or those in applied status for a permit must designate these PT surveys via this website. Laboratories that submitted initial applications and are not currently in applied status will be contacted by CLEP for PT provider information as part of the application review. This process applies ONLY to your laboratory's PRIMARY test method.

This website lists tests that require PT under CLIA subpart I and products offered by CMS-approved PT programs that satisfy these PT requirements. For each test, your laboratory must indicate whether the test is offered in NYS and, if so, indicate a PT provider and product. You must click "submit" on the final page before the notification period ends. You must click on the links at the left side of the page to progress through the process. More detailed instructions can be found [here](#).

DOH will compare your planned enrollment to the PT scores we receive from the PT providers in 2017. Failure to participate in the PT surveys selected here may result in citation under Proficiency Testing Sustaining Standard of Practice 1 (PT S1): Participation. It is important to inform your PT provider(s) that your scores should be released to DOH. Laboratories must participate with their chosen provider(s) for one calendar year before designating a different program.

Note that tests not subject to PT requirements must comply with Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy.

Contact Us | Help | FAQ | Accessibility | Message Center

Begin Designation Process

Instructions

Product Help

Category Help



Department of Health

Wadsworth Center

Designate PT

Home > proficiency testing > test selection

Wadsworth Center
New York State Department of Health

eCLEP
electronic Clinical Evaluation Program

Permit Materials Proficiency Testing Approval Survey Limited Labs

Proficiency Testing Home

Indicate Tests Offered in NYS

PT designation period is open from []

Category: Bacteriology

Help/Instructions

Bacteriology

- Refer to Category Specific Help for additional information
- Laboratories are required to enroll in a program(s) that includes:
 - a minimum of five samples per testing event
 - three shipments per year
 - samples for bacterial isolation and identification (culture and molecular methods), antigen detection, gram stain, and antimicrobial susceptibility testing
- Choose a PT module that best defines the laboratory's level of service for identification. These are defined in the Category Specific Help document.

Show 40 entries

Name	Test Status
Identification of bacterial meningitis pathogens by molecular methods	Test Offered
Identification of bacteria by culture	Test Offered
Identification of blood pathogens by molecular methods	Test Offered
Identification of gastrointestinal pathogens by molecular methods	Test Offered
Identification of respiratory pathogens by molecular methods	Test Offered
Chlamydia/Neisseria gonorrhoeae by direct detection	Test Offered
Clostridium difficile direct detection	Test Offered
Group A Streptococcus direct detection	Test Offered
Group B Streptococcus direct detection	Test Offered
Gram stains	Test Offered
Susceptibility (bacterial) testing (AST)	Test Offered

Showing 1 to 11 of 11 entries (filtered from 26 total entries)

Save Clear

Contact Us Help FAQ Accessibility Message Center

Step 1. Indicate Tests Offered in NYS

- verify laboratory
- choose a category
- only categories that require PT and are held or applied for will appear

“Help Bullets”

dropdown menus

- choose an item
- no free-text

Confirm data entered last year if available. **Enter** new as needed.

Designate PT

The screenshot shows the 'Indicate Tests Offered in NYS' step of the Proficiency Testing process. The main content area displays instructions for Bacteriology and a list of 11 tests. Each test has a 'Test Status' dropdown menu set to 'Test Offered'. The 'Name' and 'Test Status' headers in the list are circled in red. At the bottom of the list, the 'Save' button is also circled in red.

Name	Test Status
Identification of bacterial meningitis pathogens by molecular methods	Test Offered
Identification of bacteria by culture	Test Offered
Identification of blood pathogens by molecular methods	Test Offered
Identification of gastrointestinal pathogens by molecular methods	Test Offered
Identification of respiratory pathogens by molecular methods	Test Offered
Chlamydia/Neisseria gonorrhoeae by direct detection	Test Offered
Clostridium difficile direct detection	Test Offered
Group A Streptococcus direct detection	Test Offered
Group B Streptococcus direct detection	Test Offered
Gram stains	Test Offered
Susceptibility (bacterial) testing (AST)	Test Offered

Step 1 continued

Test Status:
 Select "Test Offered" if your laboratory offers a test in NYS or for NYS samples that meets all criteria in enrollment algorithm.

Select "Test Not Offered" otherwise.

You must select a Test Status for each test.

Don't forget to save!

Designate PT

Wadsworth Center
New York State Department of Health
eCLEP
electronic Clinical Evaluation Program

home > proficiency testing > provider product

Permit Materials | Proficiency Testing | LDT Approval | Survey | Limited Labs

Proficiency Testing Home

Step 1. Indicate Tests Offered in NYS

Step 2. Designate PT provider and product

Step 3. View pending designations

Step 4. Submit designations

View final designations

Instructions

Product Help

Category Help

PFT: [] Name: []

Designate PT provider and product

PT designation period is open from [] to []

Category: Bacteriology

Show 40 entries

PT Designations - PRIMARY METHOD

Test Name	Provider	Product
Identification of bacterial meningitis pathogens by molecular methods	American Proficiency Inst	Meningitis Panel - 371
Identification of bacteria by culture	College of American Path	Vaginits Screen - VS
Identification of blood pathogens by molecular methods		
Identification of gastrointestinal pathogens by molecular methods		
Identification of respiratory pathogens by molecular methods		
Chlamydia/Neisseria gonorrhoeae by direct detection		
Clostridium difficile direct detection		
Group A Streptococcus direct detection	Accutest Inc	Streptococcus A Antigen
Group B Streptococcus direct detection		
Gram stains		
Susceptibility (bacterial) testing (AST)		

Showing 1 to 11 of 11 entries

Your PT Provider will not be saved unless you have also chosen a product.

Save Clear

Contact Us | Help | FAQ | Accessibility | Message Center

Step 2. Designate PT provider and product

- Tests listed = “Test Offered” in Step 1.
- You must select a Provider and Product for for each test offered.
- Complete for each category.
- PRE-SCREENED

Confirm data entered last year if available.

Enter new as needed.

Don't forget to save!

Designate PT

The screenshot shows the 'View Pending Designations' page in the eCLEP system. The page includes a navigation menu with options like 'Permit Materials', 'Proficiency Testing', 'LDT Approval', 'Survey', and 'Limited Labs'. The main content area displays the following information:

View Pending Designations

PT designation period is open from [] 00.

A total of 12 records were modified, with 12 tests offered and 0 tests not offered. Provider Product designations will not appear until Provider Product designations are made on Step 2.

Category	Test	Tests Offered Provider	Product
Bacteriology	Group A Streptococcus direct detection	Accutest Inc	Streptococcus A Antigen - STAA435
	Identification of bacteria by culture	College of American Pathologists	Vaginitis Screen - VS
	Identification of bacterial meningitis pathogens by American Proficiency Institute molecular methods	American Proficiency Institute	Meningitis Panel - 371
Category	Test	Provider	Product
Tests Not Offered			
Category	No Data		Test
Category			Test

At the bottom of the page, there are links for 'Contact Us', 'Help', 'FAQ', 'Accessibility', and 'Message Center'.

Step 3. View Pending Designations

Review tests
Review PT Provider
and Product

Designate PT

The screenshot shows the 'Submit designations' page in the eCLEP system. The page is titled 'Wadsworth Center' and 'eCLEP electronic Clinical Evaluation Program'. It includes a navigation menu with options like 'Permit Materials', 'Proficiency Testing', 'LDT Approval', 'Survey', and 'Limited Labs'. The main content area is titled 'Submit designations' and contains the following elements:

- PFI:** [input field] **Name:** [input field]
- PT designation period is open from** [input field]
- WARNING:** Any tests listed below lack test status information and/or PT designation(s). Please enter this information in order to submit your designations.
- Unassigned Tests / Tests Offered without an assigned product**
- Table of Tests:**

Category	Test Name
Bacteriology	Chlamydia/Neisseria gonorrhoeae by direct detection
	Clostridium difficile direct detection
	Gram Stains
	Group B Streptococcus direct detection
	Identification of blood pathogens by molecular methods
	Identification of gastrointestinal pathogens by molecular methods
Ther. Sub. Mon. Quant. Tox. primidone	Identification of respiratory pathogens by molecular methods
	Susceptibility (bacterial) testing (AST)
- Attestation:** Please read the following attestation carefully. If you agree, signify by clicking the checkbox below (* required), then click Submit.
- Comments:** I understand that signing and submitting this record in this fashion is the legal equivalent of having placed my handwritten signature on the submitted record and this affirmation. I understand and agree that by electronically signing and submitting this record in this fashion I am affirming to the truth of the information contained therein. I, the laboratory director or delegated submitter, attest that my laboratory has enrolled or will enroll in the PT surveys designated here. I understand that these designations are binding for the coming calendar year and that failure to enroll and participate in these surveys for these analytes may result in regulatory sanctions. I further understand that satisfactory PT performance is required to maintain my laboratory's CLEP permit.
- Checkbox:** I have read, and agree with, the above attestation
- Comment field:** Comment [input field] (If you would like to provide a comment, please do so below: (500 characters max))
- Buttons:** Submit, Clear

Step 4. Submit designations

Review your designations before submitting.

eCLEP will not let you submit your designations if you have not selected a Test Status for each test AND selected a PT provider and product for each test offered.

Designate PT

Wadsworth Center
New York State Department of Health

eCLEP
electronic Clinical Evaluation Program

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Proficiency Testing Home

Step 1. Indicate Tests Offered in NYS

Step 2. Designate PT provider and product

Step 3. View pending designations

• Step 4. Submit designations

View final designations

Instructions

Product Help

Category Help

Submit designations

PFI: [] Name: []

PT designation period is open from 0 [] to []

WARNING:
Any tests listed below lack test status information and/or PT designation(s). Please enter this information in order to submit your designations.

Unassigned Tests / Tests Offered without an assigned product

Category	Test Name
Bacteriology	Chlamydia/Neisseria gonorrhoeae by direct detection
	Clostridium difficile direct detection
	Gram stains
	Group B Streptococcus direct detection
	Identification of blood pathogens by molecular methods
	Identification of gastrointestinal pathogens by molecular methods
	Identification of respiratory pathogens by molecular methods
	Susceptibility (bacterial) testing (AST)
Ther. Sub. Mon. Quant. Tox. primidone	

Please read the following attestation carefully. If you agree, signify by clicking the checkbox below (* required), then click Submit

I understand that signing and submitting this record in this fashion is the legal equivalent of having placed my handwritten signature on the submitted record and this affirmation. I understand and agree that by electronically signing and submitting this record in this fashion I am affirming to the truth of the information contained therein.

I, the laboratory director or delegated submitter, attest that my laboratory has enrolled or will enroll in the PT surveys designated here. I understand that these designations are binding for the coming calendar year and that failure to enroll and participate in these surveys for these analytes may result in regulatory sanctions. I further understand that satisfactory PT performance is required to maintain my laboratory's CLEP permit.

I have read, and agree with, the above attestation

Comment

If you would like to provide a comment, please do so below: (500 characters max)

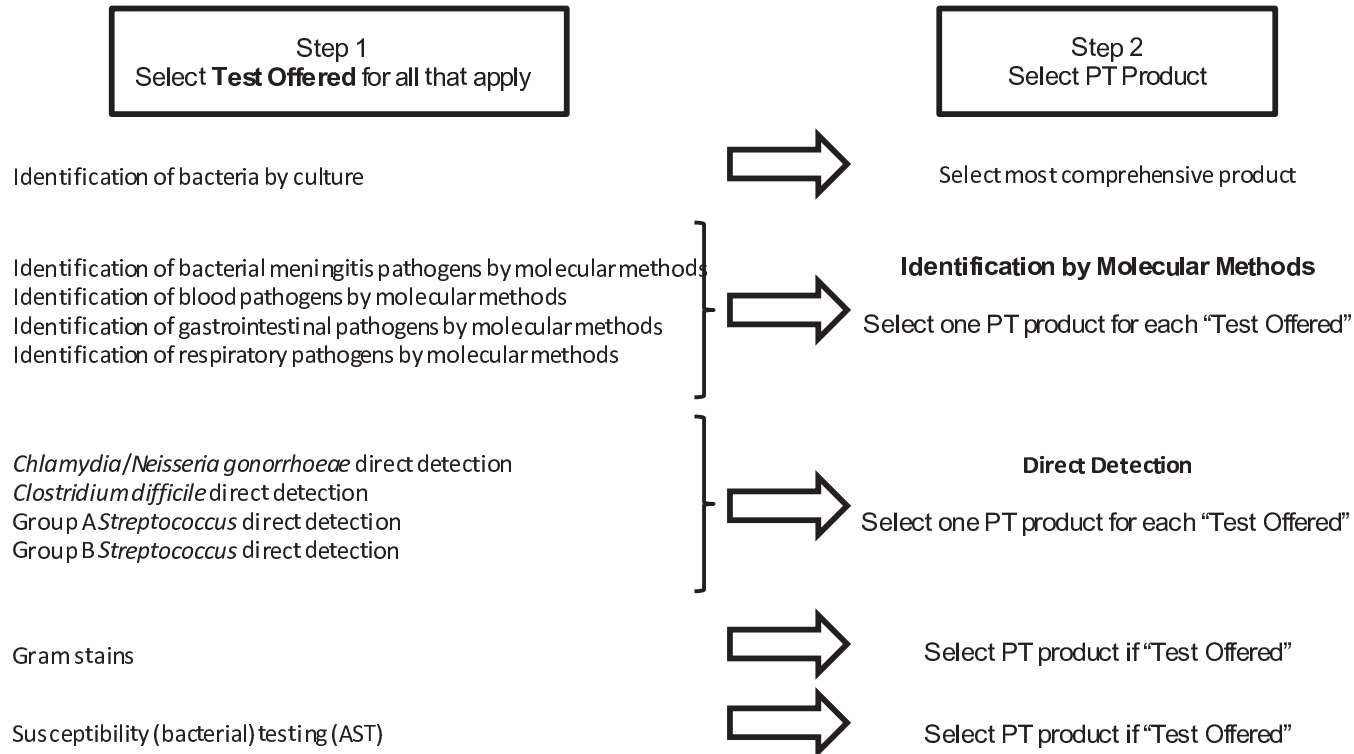
[Submit] [Clear]

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Step 4. continued

Director or delegated submitter must attest and submit.

Your designations will not be official – even if saved – until you submit.



Designate PT

Microbiology – choosing PT products

Bacteriology

You may be able to designate the same PT provider and product for multiple tests.

- Identification of Bacteria -

If there is not a single product available that tests proficiency in all tests, designate the most comprehensive product that allows your laboratory to test ~all culture samples in each event.

Designate PT

Microbiology – choosing PT products

Bacteriology

- Antigen Detection -

Designate a product for each test offered.

- Gram stains -

Designate a product that includes Gram stains.

- Susceptibility (bacterial) testing (AST) -

Designate a product that includes susceptibility testing.

Designate PT

Microbiology – choosing PT products

Bacteriology

Laboratories that offer only Gram stain

- designate a product that requires Gram staining for at least five samples.

Laboratories that offer only Gram stain and ID by culture for throat and urine samples.

- designate a single product (minimum five samples) that requires Gram staining for at least one sample and ID by culture in a least one throat or urine sample (edit: minimum fives samples for ID).

Individual events may include only throat samples or only urine samples and may include different organisms.

Designate PT

Microbiology – choosing PT products

Bacteriology

Laboratories that offer Gram stain, comprehensive ID by culture, direct detection, and susceptibility

– designate a single product (minimum 5 samples) that requires

- Gram staining at least one sample
- ID by culture for a wide variety of sample sources for at least five samples
- direct detection in at least one sample
- susceptibility testing in at least one sample
- Different events may include different sample sources and organisms.
- Designate this product for each analyte/test.

Designate PT

Microbiology – choosing PT products

Bacteriology

OR

- designate a product for Gram stain that requires Gram staining for at least five samples AND
- designate a second product for ID by culture that requires ID by culture for a wide variety of sample sources for at least five samples AND
- Designate a third product for direct detection, five samples AND
- Designate a fourth product for susceptibility, five samples
- Different events may include different sample sources and organisms.

Recurrent issues

Designation ≠ Enrollment

Laboratory doesn't enroll in any PT for the test - citation under PT S1

- Laboratory must enroll later or update test menu

Laboratory enrolls in a different, unacceptable PT - citation under PT S1

- Remember, designations are binding
- Make sure you know you want to enroll in it before designating it
- Be careful of surveys for waived methods

Laboratory enrolls in a different, but acceptable PT - citation under PT S1

Recurrent issues

Additional samples

Some providers allow laboratories to purchase duplicate samples for a product (e.g. two set of the same samples).

- Do not test these samples before the event deadline for an analyte reported for the PT event unless that is what you do for patient samples.
- These duplicate samples can be used after the event deadline for QA S3, competency, etc.

More Frequently Asked Questions

Can I change my PT designation?

- No. PT designations are binding for the calendar year. You can only change them for reasons related to changes in testing. For example, switching to a new method/kit/instrument that is not compatible with your current PT product would justify changing PT.

Can I take off-cycle PT?

- Yes, though this is typically done as remediation. Any off-cycle PT must be provided by the designated provider for that analyte/test.

Do I need to send my enrollment or results to NYS?

- No. You must authorize your PT provider to send results to NYS.

Questions?

ptadmin@health.ny.gov

518-408-9125