Understanding New York Proficiency Testing Requirements
Wednesday, October 18, 2017

The presentation will begin at 2:00 PM
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

- **NO NYS requirements**
  - NO
  - Is the analyte/test offered in NYS or for NYS samples?
    - YES
      - Does NYS require PT for the analyte/test AND specimen type?
        - YES
          - PT required
        - NO
          - Is this your lab’s primary method for the analyte/test?
            - YES
              - Is acceptable PT available?
                - YES

- **PT NOT required**
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
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
- Immunohematology
- 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
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
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/clepclinical-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

Designation Process
Health Commerce System
  ↓
eCLEP
  ↓
Proficiency Testing
  ↓
PT Designation

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
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)

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

**Mobile:**
- Safari (iOS 5.1 or later)
- Google Chrome (iOS 5.1/Android 4.0 or later)

**Unsupported Browsers:**
- Microsoft Internet Explorer Mobile (Windows 8 Phone)
- Safari for Windows (Desktop)
Designate PT

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

Important Health Notifications

<table>
<thead>
<tr>
<th>Posted</th>
<th>Priority</th>
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<th>Source</th>
<th>Audience</th>
<th>Description</th>
<th>Recipients</th>
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<tr>
<td>10/02/17</td>
<td>Drill</td>
<td>Drill</td>
<td>Laboratory Response Network</td>
<td>2017 Ebola Survey</td>
<td>Recipients</td>
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<tr>
<td>10/02/17</td>
<td>Advisory</td>
<td>Influenza</td>
<td>NYSDOH</td>
<td>Influenza Surveillance and Reporting Requirements, 2017-2018</td>
<td>Recipients</td>
<td></td>
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<tr>
<td>09/29/17</td>
<td>Advisory</td>
<td>Commissioner's Letter</td>
<td>NYSDOH</td>
<td>Dr. Zucker's September Physician letter attached</td>
<td>Recipients</td>
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<td>09/26/17</td>
<td>Advisory</td>
<td>NP PA Prescribe Opiateson</td>
<td>NYSDOH</td>
<td>NPs &amp; PAs Can Prescribe Opiateson</td>
<td>Recipients</td>
<td></td>
</tr>
</tbody>
</table>

Showing notifications sent in the past 30 days.
Designate PT
Designate PT
Designate PT

Begin Designation Process

Instructions

Product Help

Category Help
Designate PT

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

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

Step 2. Designate PT provider and product

- Tests listed = “Test Offered” in Step 1.
- You must select a Provider and Product 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**

Step 3. View Pending Designations

Review tests

Review PT Provider and Product
Designate PT

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

Step 4. continued

Director or delegated submitter must attest and submit.

Your designations will not be official – even if saved – until you submit.
Step 1
Select Test Offered for all that apply

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 direct detection
Clostridium difficile direct detection
Group A Streptococcus direct detection
Group B Streptococcus direct detection

Gram stains
Susceptibility (bacterial) testing (AST)

Step 2
Select PT Product

Select most comprehensive product

Identification by Molecular Methods
Select one PT product for each “Test Offered”

Direct Detection
Select one PT product for each “Test Offered”

Select PT product if “Test Offered”
Select PT product if “Test Offered”
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