



# Clinical Laboratory Evaluation Program

## Proficiency Testing Guide

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Department  
of Health

Wadsworth  
Center

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# General Requirements

## Mandatory Proficiency Testing Participation

All laboratories applying for or holding a New York State (NYS) clinical laboratory permit must participate in proficiency testing (PT) as defined by NYS. PT participation through a federal Centers for Medicaid and Medicare Services (CMS) – approved provider acceptable to NYS is required for the tests/analytes offered by the laboratory that are listed in CMS 42 CFR 493 subpart I (CLIA subpart I) or noted in this document as required by NYS (NYS mandated PT; see Appendix for complete listing).

For analytes with NYS mandated PT, an acceptable PT product must include 5 samples per analyte and offer 3 test events per year (2 for Mycobacteriology). Products are approved by CMS and those acceptable to both CMS and NYS can be found on the Wadsworth Center's website:

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

For tests/analytes where PT is not mandated, as determined by NYS, laboratories are required to have an alternate system for verifying the reliability and accuracy of their test results at least twice a year through participation in external proficiency testing programs or through the implementation of an internal proficiency testing program. When external proficiency testing is used as the laboratory's alternate assessment tool for analytes not requiring PT, all NYS Clinical Laboratory Standards of Practice for proficiency testing apply.

All laboratories must disclose to the Clinical Laboratory Evaluation Program (CLEP) the CMS – approved PT provider that is being utilized to fulfill federal proficiency testing requirements. This is accomplished each fall on the Health Commerce System (HCS) using eCLEP (see [PT Designations](#)).

## Rules of PT Participation

Laboratories must adhere to the testing procedures for PT as outlined in this document. Failure to comply with these procedures may result in sanctions being brought against laboratories under state and federal regulations. Laboratories are expected to follow all NYS Clinical Laboratory Standards related to PT.

- Laboratories must authorize their PT provider(s) to send results to NYS (CLEP).
- NYS requires PT for analytes listed as NYS mandated PT even if the laboratory is using a kit listed as CLIA-waived by the federal Food and Drug Administration.
- PT samples must be examined or tested with the laboratory's routine workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods, unless otherwise instructed by the NYS PT program.
- Repeated testing or analysis of proficiency samples is not permitted unless the laboratory performs the same repetitive testing or analysis on patient, donor, insurance applicant or other client samples.
- Laboratories that test proficiency samples must not engage in any inter-laboratory communication or discussion pertaining to the results of test samples until after the date the laboratories are required to report the results to the PT provider.
- Laboratories with multiple testing sites or separate locations cannot participate in any communication or discussion between or among sites/locations concerning test results until after the date the laboratories are required to report the results to the PT provider.
- Laboratories must not send proficiency samples or portions of samples to any other laboratory or location for testing, analysis or review.
- PT samples must not be automatically referred to another laboratory for confirmatory testing, under a reflex testing algorithm or distributive testing algorithm, or for any other purpose.
- PT samples must be tested using the laboratory's primary method. The laboratory cannot test duplicate sets of PT samples using multiple methods/systems unless they routinely test their patient specimens using multiple methods/systems. After the PT due date has passed laboratories may test their PT samples using multiple methods/systems.
- Laboratories that have multiple locations and share a mailroom must have a method in place to ensure the PT samples are received by the correct laboratory location.
- Any laboratory that receives PT samples from another laboratory for testing must notify CLEP within seventy-two hours of receipt or identification of such samples.
- Any laboratory that has referred its proficiency samples to another laboratory for analysis and/or submitted the other laboratory's results as its own will face administrative sanctions and may have its permit revoked and/or denied for at least one year.

# Communication Resources for PT Participation

PT Administration email: [ptadmin@health.ny.gov](mailto:ptadmin@health.ny.gov)

CLEP website: <https://www.wadsworth.org/regulatory/clep>

Search publicly available documents

- Laboratory Standards
- Program Guide
- Permit Modification
- Health Commerce System (HCS)
- Proficiency Testing

PT Survey Search Tool: <https://www.wadsworth.org/regulatory/clep/pt/provider-search>

## HCS Access

The Health Commerce System (HCS) is a restricted website for conducting business with New York State Department of Health.

Refer to the CLEP website (<https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/health-commerce>) for information on obtaining HCS accounts and access to eCLEP, the application tool for laboratories to submit changes to the laboratory's operations as well as the laboratory permit reapplication and designation of required proficiency testing enrollment.

The HCS houses the Program application, eCLEP. eCLEP includes a growing number of modules for the collection of information to include:

- **Permit Materials** module for reporting changes to laboratory operations and completing the annual permit reapplication;
- **Proficiency Testing (PT) module** for reporting the laboratory's chosen provider for each calendar year as well receipt of unsatisfactory performance notifications;
- **Gross Annual Receipts (GAR)** module for annual reporting of GAR;
- **LDT Approval** module for viewing the status of validation packages;
- **Survey** module for accessing the laboratory evaluation reports issued after laboratory surveys and unsuccessful PT participation and submission of plans of correction for any deficiencies.
- Other applications located on the HCS include the Electronic Clinical Laboratory Report System (**ECLRS**) for mandatory reporting of communicable disease testing and the Clinical Laboratory Information Management System (**CLIMS**) for requesting confirmatory communicable disease testing by the Wadsworth Center Public Health Laboratory.

# Approved PT Providers

Laboratories seeking or holding a NYS clinical laboratory permit must successfully participate in proficiency testing for all analytes described as NYS mandated PT. CLEP has screened PT products offered by the CMS-approved PT providers to identify those that meet New York State PT requirements for the NYS mandated PT analytes. **Other products offered by these providers do not meet these requirements but may be used to fulfill requirements for assessment of accuracy and validity for non-subpart I analytes.**

The PT providers listed below have been approved by the CMS as meeting the Clinical Laboratory Improvement Amendments (CLIA) related to PT ([https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency\\_Testing\\_Providers.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html)). They offer PT products that also meet NYS requirements:

- Accutest, Inc. / One World Accuracy
- American Academy of Family Physicians (AAFP) Proficiency Testing
- American Association of Bioanalysts (AAB)
- American Proficiency Institute (API)
- The College of American Pathologists (CAP)
- Medical Laboratory Evaluation (MLE) Program / (American College of Physicians; ACP)
- Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing

A searchable list of NYS approved PT products for NYS mandated PT analytes by permit category is available in the “Proficiency Testing – Survey Search Tool” section of the CLEP website at:

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

## Choosing a PT Product

When selecting a PT product, laboratories should review the statistical analysis of past events to identify products where:

- 1) participants utilize similar methods/instruments; and
- 2) the products are graded by the PT provider.

If using an uncommon method/instrument the laboratory should determine how the provider evaluates methods/instruments without a valid peer group.

Laboratories should also be aware of their provider’s ability to send off-cycle test events should the need arise.



## PT Designations

Laboratories must notify CLEP of the PT provider(s) and product(s) they will be using for all NYS mandated PT analytes via eCLEP on the Health Commerce System (HCS):

- annually during the fall PT designation period
  - eCLEP Proficiency Testing PT Designation module
- when adding a new permit category
  - eCLEP Permit Materials module
- when updating their test menu/PT product choices at other times throughout the year
  - by email to the PT Administration Group at [ptadmin@health.ny.gov](mailto:ptadmin@health.ny.gov)
  - It is not sufficient to notify only the PT provider. **You must also notify CLEP.**

CLEP has screened PT surveys offered by these CMS-approved PT providers and identified those that meet New York State PT requirements for NYS mandated PT analytes. A searchable list of NYS approved PT products for NYS mandated PT analytes by permit category is available in the “Proficiency Testing – Survey Search Tool” section of the CLEP website at:

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

### Instructions for annual PT designation on eCLEP

- In eCLEP, click on “PT Designations”.
- Click on “Step 1. Indicate Tests Offered on NYS patients”.
- Select a permit category from the dropdown menu (only pending or approved permit categories will be displayed) and choose either “Test Offered” or “Test Not Offered” for each NYS mandated PT analyte in the permit category and click “Save”. Do this for all categories that you hold or have requested.
- Click on “Step 2. Designate PT provider and product”, select the permit category from the dropdown menu (only categories which include NYS mandated PT analytes are displayed) and choose the PT provider and product you will enroll in for each test/analyte offered. Do this for all categories that you hold or have requested that include NYS mandated PT analytes.
- Click on “Step 3. View Designations” to review the PT provider and product for tests offered, and any other changes that were made.
- Lastly, click “Step 4. Submit designations”, read the attestation, check the box stating you have read and agree to the attestation and then submit.

Additional help documents can be found on the left side of the screen in eCLEP.

**Laboratories are required to participate in the same PT product for the entire calendar year.**

An exception to this requirement is a change in methodology that necessitates a change in PT product.



## Enrollment

In early January of each year the PT providers send CLEP a file that contains the PT products purchased by all the laboratories holding or requesting a NYS clinical laboratory permit that have enrolled with their program for the coming year. *The Information in this file is used to verify that laboratories have enrolled in all the PT products they designated the previous fall in eCLEP.*

If a laboratory has not enrolled in a PT product they designated the previous fall they will receive a request from CLEP asking for verification that they have enrolled in an acceptable product for the NYS mandated PT analyte(s) in question.

Laboratories must reply to the request by email to [PTAdmin@health.ny.gov](mailto:PTAdmin@health.ny.gov) within 7 days and attach the receipt or confirmation email from the PT provider showing enrollment in an acceptable product. ***An order form is not sufficient proof of enrollment.***

If the analyte(s) is no longer being offered or the laboratory has chosen a different product for PT they must inform [PTAdmin@health.ny.gov](mailto:PTAdmin@health.ny.gov) by email.

Failure to reply to a request for enrollment verification may result in a citation for non-compliance with PT requirements.





## Participation

Throughout the year PT providers electronically send CLEP the results of their PT products (e.g., scores). As results are received CLEP verifies that laboratories have participated in all the PT products that were chosen during the PT designation process.

If results for a designated PT product are not received, the laboratory will receive a request for verification that they participated in the product or an explanation as to why they did not participate. The laboratory's response must be emailed to [PTAdmin@health.ny.gov](mailto:PTAdmin@health.ny.gov) within 7 days.

Failure to reply may result in a score of 0% for non-participation for the analyte(s) in question which puts the laboratory at risk of unsuccessful performance. In addition, failure to reply to a request for participation verification may result in a citation for non-compliance with PT requirements.



Designation

Enrollment

Participation

Performance

## Performance

PT results (e.g., scores) for all NYS mandated PT analytes are made available to CLEP by the CMS-approved PT providers as both electronic files and evaluation reports. After PT results are received at CLEP they are monitored for both participation and performance. The minimum satisfactory score for all analytes is 80%, with the exception of ABO grouping, Rh grouping and compatibility testing where the satisfactory score is 100%.

A 'benefit' PT performance score for a NYS mandated PT analyte cannot be considered in determining eligibility for an initial laboratory permit or new category approval. Benefit scores (i.e., 100% score) may be conferred by the PT provider when PT samples are considered ungradable, most commonly due to a lack of peer group grading. Laboratories should pay particular attention to any exception codes indicated on the PT evaluation reports received from the PT provider.

### PT performance investigation

**Laboratories must investigate all scores less than 100%.** Laboratory investigations into the possible cause(s) for all scores less than 100% should include consideration of critical areas as defined in NYS Clinical Laboratory Standards. Laboratories also need to investigate any result reports where the PT provider notes an unacceptable result, even if the overall score is 100%. This applies to both NYS mandated PT analytes and non-NYS mandated PT analytes.

An appropriate investigation into PT performance issues should contain the following:

- **ROOT CAUSE** – A summary of the root or contributing cause(s) of the deficiency to include what happened, why and how the nonconformity occurred, when the nonconformity began and who was involved.
- **PATIENT IMPACT** – A summary of the impact of this nonconformity on patient results. If there was impact, describe the impact and what actions were taken to remedy the impact. If there was no impact, explain why.
- **CORRECTIVE ACTION** – What change(s) was put in place to ensure there will not be a repeat of this deficiency?

## Documenting the Proficiency Testing Process

Laboratories must maintain the following documentation of the processing of PT materials for review by CLEP staff as required. Review of this documentation may occur during the on-site survey.

Documentation may include:

1. Each step taken in preparing, processing, examining, testing and reporting all results in the proficiency test event.
2. The proficiency testing provider's attestation form completed in accordance with the provider's instructions and requirements.
3. Copies of all testing records, including copies of the PT report forms, for a minimum of two (2) years from the date of the test event for all categories, except Forensic Identity, which requires retention for three (3) years, and Immunohematology, which requires retention for five (5) years.

## Temporary Suspension of Testing

Some circumstances require that a laboratory may not be able to offer a particular test or suite of tests due to backlog of reagents, loss of key personnel, etc. In these instances, laboratories may elect to temporarily suspend the offering of these tests to patients and their participation in proficiency testing. **The laboratory must notify CLEP of their need to temporarily suspend testing. Notification to the laboratory's PT provider does not replace notification to CLEP.**

If the laboratory is unable to participate in two or more consecutive proficiency events for all tests included in a permit category, the category will be deleted from the laboratory permit. To reapply for the category, the laboratory must submit a request to add the category via eCLEP. The laboratory will be required to successfully participate in one PT event for NYS mandated PT analytes. An on-site survey is required for certain high-risk categories prior to permit approval.

## NYS Mandated PT Analytes



### Unsatisfactory Proficiency Testing Performance

Unsatisfactory performance is the failure to attain the minimum satisfactory score (100% for ABO grouping, Rh grouping and compatibility testing; 80% for all others) for the category or test/analyte (NYS mandated PT analytes) for a testing event, including events that are failed for non-technical reasons such as late submission, failure to participate or failure to be graded.

Laboratories receiving an unsatisfactory score are required to investigate the problem(s) that contributed to the unsatisfactory performance and implement corrective action. Laboratories may request additional test samples from their proficiency testing provider to use as part of the remediation.

Formal notification of unsatisfactory performance will be made via email from the PT Administration Group. The laboratory will receive an email which will indicate that a PT document is ready for review and include directions to access the document using eCLEP. A response to CLEP is not required. Documentation of the investigation should be available for review during the on-site survey.

### Unsuccessful Proficiency Testing Performance

Unsuccessful proficiency testing performance is defined as unsatisfactory PT performance for the category or test/analyte (NYS mandated PT analytes) in 2 out of 3 consecutive testing events.

CLEP notifies laboratories following unsuccessful performance via a Laboratory Evaluation Report (LER) similar to the report issued after the on-site survey process. There are two types of LERs that can be issued: a 2-week notification or a cease testing notification. The decision as to whether the laboratory receives a 2-week notification or a cease testing notification is based on past performance, immediate jeopardy to patient care, and root cause of the unsuccessful performance.

Please note, removal of the category or test/analyte from the laboratory's test menu, in and of itself, by either the laboratory or CLEP, is not acceptable remedial action. Remediation programs should be designed based on the nature of the unsatisfactory performances and the area of clinical laboratory medicine involved.

## 2-week notification

The laboratory must:

- investigate and document the problem(s) that contributed to the unsuccessful performance and implement corrective action,
- conduct a retrospective review of patient results to ascertain whether similar error(s) existed in reports of test findings and notify the ordering physician if necessary, and
- reply to the LER within 2 weeks.

The laboratory's remediation must be acceptable to CLEP. If effective corrective action is not implemented and documented to the satisfaction of CLEP, the laboratory will be required to cease testing clinical specimens.

## Cease testing notification

The laboratory must:

- cease testing for the analyte(s) involved in the unsuccessful performance
- identify the permitted laboratory where patient specimens will be sent for such testing
- investigate and document the problem(s) that contributed to the unsuccessful performance and implement corrective action,
- conduct a retrospective review of patient results to ascertain whether similar error(s) existed in reports of test findings and notify the ordering physician if necessary, and
- reply to the LER within 2 weeks.

The laboratory's remediation must be acceptable to CLEP.

Laboratories issued a directive to cease testing clinical specimens due to unsuccessful PT performance will be reinstated after:

- documentation of corrective action has been determined to be acceptable,
- the laboratory demonstrates satisfactory performance in two consecutive test events obtained from the same proficiency test provider (one may be an off-cycle event), and
- at least six months has elapsed since the cease testing order.

## Subsequent Unsuccessful Proficiency Testing Performance

Subsequent unsuccessful proficiency testing performance is defined as unsatisfactory PT performance for the category or test/analyte (NYS mandated PT analytes) in 3 out of 5 consecutive testing events.

Laboratories demonstrating a subsequent unsuccessful PT performance will be instructed to cease testing clinical specimens.

Laboratories issued a directive to cease testing clinical specimens due to subsequent unsuccessful PT performance will be reinstated after:

- documentation of corrective action has been determined to be acceptable,
- the laboratory demonstrates satisfactory performance in two consecutive test events obtained *from the same proficiency test provider* (one may be an off-cycle event), and
- at least six months has elapsed since the cease testing order.

Where performance in PT provides evidence of risk for patient harm as determined by the NYS **Proficiency Testing Standard of Practice 15 (PT S15): Unsuccessful Performance – Department Enforcement**, and the laboratory does not cease testing as directed, the Department will take enforcement action as authorized by Sections 576(3) and 577 of New York State Public Health Law, Article 5, Title V.



# eCLEP Documents

## Documents on Health Commerce System via eCLEP

Laboratories will receive notification by email from the PT Administration Group when they have new PT documents to review on eCLEP. These will include enrollment, participation and performance documents. The document will be viewable by logging into eCLEP through the Health Commerce System and navigating to the PT Documents section within the PT product.

A document may contain the following information:

- NYS Incident Identification Number
- Laboratory name
- CLIA and PFI numbers
- CMS-approved PT provider information, including their name, PT event, test score and PT provider test description.

The types of documents viewable for PT are listed in the table below:

Document	Analyte	PT
Enrollment verification	NYS mandated PT analyte(s)	
Participation verification	NYS mandated PT analyte(s)	
Unsatisfactory PT performance notification	NYS mandated PT analyte	First occurrence
Laboratory evaluation report	NYS mandated PT analyte	2 out of 3 occurrences

## **Responses to PT documents**

### **Enrollment verification**

Laboratories need to reply to the request by email to [PTAdmin@health.ny.gov](mailto:PTAdmin@health.ny.gov) within 7 days and attach the receipt or confirmation email from the PT provider showing enrollment in an acceptable product. An order form is not sufficient proof of enrollment. If the analyte(s) is no longer being offered or the laboratory has chosen a different product for PT they must inform us by email. Failure to reply to a request for enrollment verification may result in a citation for non-compliance with PT requirements.

### **Participation verification**

The laboratory's response must be emailed to [PTAdmin@health.ny.gov](mailto:PTAdmin@health.ny.gov) within 7 days. Failure to reply may result in a score of 0% for non-participation for the analyte(s) in question which puts the laboratory at risk of unsuccessful performance. In addition, failure to reply to a request for participation verification may result in a citation for non-compliance with PT requirements.

### **Performance notification**

The laboratory should investigate the root cause, patient impact and implement corrective action. A response to CLEP is not required. Documentation of the investigation should be available for review during the on-site survey.

### **Investigation of unacceptable PT performance and LER**

The laboratory must investigate the root cause, patient impact and corrective action, and respond to CLEP via the fillable form on eCLEP within 14 days.

# New Laboratories

Laboratories requesting a NYS clinical laboratory permit must meet all requirements for permit issuance including satisfactory (>80%) participation in PT for each NYS mandated PT analyte (100% for ABO grouping, Rh grouping and compatibility testing), for which a permit is being sought.

**PT participation must occur after the date the initial application for a permit was received by CLEP.** Laboratories must authorize their PT provider to release all results to CLEP. Off-cycle PT is acceptable if taken with the PT provider the laboratory is enrolled with for the calendar year. These off-cycle PT performance scores are NOT provided to CLEP as part of the provider's routine data files. Therefore, laboratories should instruct the PT providers to send the evaluation reports directly to the PT Administration Group at [ptadmin@health.y.gov](mailto:ptadmin@health.y.gov).

All laboratories must order their PT using the CLIA number and PFI of the NEW laboratory.

## **We cannot accept:**

**PT reports with an incorrect CLIA number**

**PT reports directly from the laboratory**

Satisfactory PT performance, and continued PT participation with the PT provider on record with NYS, must be maintained to fulfill PT requirements while waiting for all other permit requirements to be met. Satisfactory PT performance is not met if the PT provider does not provide an accurate peer group assessment of the laboratory's PT results. This may include:

- Any PT result with a provider's exception code,
- Any ungraded PT result due to lack of an appropriate peer group,
- Any PT result graded as 100% without consensus, or
- Any PT result that does not allow CLEP to verify the accuracy of the laboratory's performance.

# Addition of Permit Categories

Laboratories holding a NYS clinical laboratory permit that wish to add permit categories must request the category using eCLEP via the eCLEP Permit Materials module.

Satisfactory PT (less than 80% for all analytes except ABO grouping, Rh grouping and compatibility testing which require 100%) is required for all NYS mandated PT analytes requested. Satisfactory PT performance is not met if the PT provider does not provide an appropriate peer group assessment of the laboratory's PT results. This may include:

- Any PT result with a providers' exception code,
- Any ungraded PT result due to lack of an appropriate peer group,
- Any PT result graded as 100% without consensus, or
- Any PT result that does not allow CLEP to verify the accuracy of the laboratory's performance.

# Appendix

## NYS Mandated PT Analytes (includes CLIA Subpart I analytes)

### Bacteriology

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

### Blood pH and Gases

pCO<sub>2</sub>  
pH  
pO<sub>2</sub>

### Clinical Chemistry

alanine aminotransferase (ALT)  
albumin  
alkaline phosphatase  
amylase  
aspartate aminotransferase (AST)  
bilirubin, total  
calcium, total  
chloride  
cholesterol, HDL  
cholesterol, total  
creatinine Kinase  
creatinine Kinase-MB  
creatinine  
glucose  
iron  
lactate dehydrogenase (LDH)  
lactate dehydrogenase isoenzyme 1

## **Clinical Chemistry (continued)**

magnesium  
potassium  
sodium  
total protein  
triglycerides  
urea nitrogen (BUN)  
uric acid

## **Diagnostic Immunology – Diagnostic Services Serology**

alpha 1- antitrypsin (AAT)  
antinuclear antibody (ANA)  
antistreptolysin O (ASO)  
complement component C3  
complement component C4  
hepatitis B core antibody (HBc)  
hepatitis B surface antigen (HBsAg)  
hepatitis Be antigen (HBeAg)  
Heterophile (infectious mono)  
human immunodeficiency virus (HIV)  
IgA  
IgE  
IgG  
IgM  
rheumatoid factor  
rubella  
syphilis

## **Diagnostic Immunology – Donor Services Serology**

hepatitis B core antibody (HBc)  
hepatitis B surface antigen (HBsAg)  
human immunodeficiency virus (HIV)  
syphilis

## **Endocrinology**

cortisol  
human chorionic gonadotropin (hCG), serum  
T3 Uptake/Related Tests  
T4, free  
thyrotropin (TSH)  
thyroxin (T4)  
triiodothyronine (T3)



## **Hematology**

activated partial thromboplastin time (APTT)  
fibrinogen  
hematocrit  
hemoglobin  
platelet count  
prothrombin time (PT)  
red blood cell count (RBC)  
white blood cell count (WBC)  
white cell differential (automated)  
white cell differential (manual)

## **Immunohematology**

ABO grouping  
antibody identification  
compatibility testing  
Rh group  
unexpected antibody detection

## **Mycobacteriology**

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

## **Mycology**

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

## **Oncology – Soluble Tumor Markers**

alpha-fetoprotein tumor markers (AFPTM)

## **Parasitology**

Giardia/Cryptosporidium antigen detection  
Identification of parasites  
Identification of parasites by molecular methods

## **Toxicology – Blood Lead - Comprehensive**

blood lead

## **Toxicology – Blood Lead – ASV Using Screen Printed Sensors**

blood lead (LeadCare)

## **Therapeutic Substance Monitoring / Quantitative Toxicology**

carbamazepine

digoxin

ethanol

ethosuximide

gentamicin

lithium

n-Acetyl-Procaïnamide

phenobarbital

phenytoin

primidone

procainamide

quinidine

theophylline

tobramycin

valproic acid

## **Virology**

Identification of herpes simplex virus (HSV) and related viruses

human papillomavirus (HPV)

Identification of gastrointestinal viruses by molecular methods

Identification of respiratory viruses by molecular methods

Identification of viral meningitis by molecular methods

Identification of virus by culture

Respiratory virus (Influenza and RSV) direct detection\*

Rotavirus direct detection\*

\*Direct detection encompasses both antigen detection and/or molecular detection.