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EDUCATIONAL RESOURCES

CLINICAL LABORATORY

Proficiency Testing:
Regulations, Changes, and Keys to Success

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Welcome

- So glad you are here!
- Let’s do this workshop!

Objectives

- Upon completion of the presentation, the participant will be able to:
  - Understand which tests are “Regulated” per CLIA.
  - Understand the standards pertaining to Proficiency Testing.
  - Understand the difference between Unsatisfactory PT Performance, Unsuccessful PT Performance, and Unsuccessful PT Participation.
  - Understand when PT Deficiency Investigation reports are required and the keys to successful investigation and documentation.
  - Understand keys to successful Proficiency Testing and preventing PT failures.

Proficiency Testing

- Under CLIA all laboratories that perform non-waived testing are required to enroll in and perform proficiency testing (PT), using one of the CMS approved PT providers.
- Only those laboratories that hold a certificate of waiver are exempt from this requirement to perform and pass PT.

Regulated Analytes

- Regulated Analytes are those tests listed in Subpart I of the CLIA regulations.
- Regulated Analytes require Proficiency Testing enrollment in 3 testing events per year. Each testing event will typically have 5 specimens.
- Failure to enroll in PT for regulated analytes is a CLIA condition level finding. Standard 04.00.00 Enrollment and testing of samples will be cited in these instances.
- In some instances, 02.01.09 Proficiency testing, will also be cited as the laboratory director must ensure that the laboratory is enrolled in a PT program for the testing that is performed.

Immunohematology

- ABO Group
- D(Rho Group)
- Unexpected Antibody Detection
- Compatibility Testing
- Antibody Identification

Hematology

- WBC
- RBC
- Hemoglobin
- Hematocrit
- PT
- PTT
- Fibrinogen
- Cell Identification
- White Blood Cell Differential
- Platelet Count

Routine Chemistry

- ALT (SGPT) & AST(SGOT)
- Cholesterol, Total and HDL
- Albumin
- Sodium, Potassium, and Chloride
- Alkaline Phosphatase
- LDH and LDH isoenzymes
- Amylase
- Magnesium
- Bilirubin, Total
- Total Protein
- Blood Gases (pH, pCO2, pO2)
- Triglyceride
- Calcium, Total
- Uric Acid
- CK and CKMB
- Bun and Creatinine
- Glucose
- Iron

Endocrinology

- Cortisol
- Free Thyroxine (Free T4)
- HCG
- T3 Uptake
- Triiodothyronine (T3)
- TSH
- Thyroxine, total (T4)

Toxicology

- Blood Alcohol
- Procainamide and metabolites
- Blood Lead
- Quinidine
- Carbamazepine
- Theophylline
- Digoxin
- Tobramycin
- Ethosuximide
- Valproic Acid
- Gentamycin
- Lithium
- Phenobarbital
- Phenytoin
- Primidone

Diagnostic Immunology

- Syphilis Serology
- Immunoglobulins, Total, IgA, IgG, IgM, IgE
- Alpha-1 Antitrypsin
- Infectious Mononucleosis
- Alpha Fetoprotein (Tumor Marker)
- Rheumatoid Factor
- ANA
- Rubella
- ASO
- Anti- HIV
- Complement C3
- Complement C4
- Hepatitis B Surface Antigen (HBsAg)
- Hepatitis B Core Antibody (Anti-HBc)
- Hepatitis Be Antigen (HBeAg)

Microbiology

- Bacteriology
  - Aerobic/Anaerobic Culture and Identification
  - Antibiotic Susceptibility testing
  - Direct Bacterial Antigen Detection
  - Gram Stain
- Mycobacteriology
  - Acid Fast Stain
  - Mycobacteriology Identification
  - Mycobacteriology Susceptibility Testing
- Mycology
  - Culture and Identification
- Parasitology
  - Presence or Absence of Parasites
  - Identification of Parasites
- Virology
  - Direct Viral Antigen Detection
  - Viral Isolation and Identification

Reference

CLIA Brochure #8:

Proficiency Testing

www.cms.gov/CLIA/downloads/CLIAbrochure8.pdf

Non- Regulated Analytes

- The remainder of the testing done in the laboratory would be considered non-regulated analytes.
- For those tests not listed in Subpart I (not regulated), the laboratory must verify accuracy of the test or procedure twice annually.
- This can be done with Proficiency testing or an alternate method to validate accuracy.
- Failure to enroll in PT for non-regulated analytes (or validate accuracy) is addressed in Standard 04.01.01 Tests not included in PT.

Alternatives to PT for Non-Regulated Analytes

- Perform blind testing of samples with know values.
- Split Samples- split a patient's specimen with another laboratory that offers the same test(s) or split samples with another instrument or method.
- Comparison of photos or slides from a reference source.

Other Considerations

- 04.00.01 Delegation of Proficiency Testing
- If the laboratory participates in more than one proficiency testing program approved by CMS, the laboratory must designate the program(s) to be used for each specialty, subspecialty, and analyte or test.
- 04.00.02 Change in proficiency testing (PT) program
- For each specialty, subspecialty, analyte or test, the laboratory must participate in an approved proficiency testing program or programs, for one year before designating a different program and must notify ACHC before any change in designation.

Handling and testing of PT Specimens

PT Samples should :

- Be handled like patient specimens.
- Be tested by individuals that normally perform testing and rotated through testing personnel.
- Be tested on the same equipment routinely used for patient testing at the time of the PT event (the primary method).
- Be tested the same number of times as patient samples.
- Not be referred to other laboratories for confirmation testing.

Refer to Standards 04.00.04 Testing of PT samples, 04.00.05 Proficiency Testing-Personnel and 04.00.10 Primary Method.

Additional Standards Pertaining to PT

- Verify that no inter-laboratory communication pertaining to PT has occurred. The laboratory should have policies addressing issues of potential inter-laboratory communication (Standard 04.00.07 Inter-laboratory communication).
- Individuals testing PT samples and the laboratory director must attest to the routine integration of PT samples into the patient workload. Attestation statements must be signed by the testing personnel and director. For moderate complexity testing, the director may delegate the responsibility for signing to a qualified technical consultant. For high complexity testing, the director can delegate the responsibility for signing to a qualified technical supervisor. Note: The technical supervisor for Immunohematology must be an MD or DO licensed in the state where the lab is located and board certified in clinical pathology OR have at least one year training or experience in immunohematology (Standard 04.00.06 Attestation Statements).
- The laboratory must review and evaluate the results obtained on proficiency testing performed. This applies in situations with non-agreement within the testing event, nonparticipation, or late submissions (Standard 04.01.00 Evaluation of Proficiency Testing Performance).

Unsatisfactory PT Performance

Failure to attain the minimum satisfactory score for an analyte, test, subspeciality, or specialty for a single testing event.

- < 80% for regulated analytes.
- < 100% for ABO, Rh, and Compatibility testing.
- < 80% for all other analytes.

Unsatisfactory PT Performance does not require a PT Deficiency Investigation report to be sent to ACHC-even for regulated analytes (this is a change from the previous process). The PT Deficiency Investigation report for unsatisfactory PT performance must be completed and kept onsite for review by the surveyor during the next survey cycle.

Unsuccessful PT Performance

Failure to attain the minimum satisfactory score for a regulated analyte, specialty, or subspecialty for two (2) consecutive or two (2) out of three (3) testing events.

- < 80% for regulated analytes.
- < 100% for ABO, Rh, and Compatibility testing.
- < 80% for all other analytes.

An Unsuccessful Performance Letter will be generated and emailed to the Laboratory Director and Laboratory Manager.

A Proficiency Testing Deficiency Investigation Report must be completed by the organization for each PT failure event and sent to labs@achc.org within 10 business days.

Unsuccessful PT Participation

Repeat Unsuccessful PT Performance (Cease Testing): Failure to attain the minimum satisfactory score for the same regulated analyte, specialty, or subspecialty for three (3) consecutive, three (3) out of four (4), or two (2) sets of two (2) out of three (3) PT events within the most recent 12 PT events.

- < 80% for regulated analytes.
- < 100% for ABO, Rh, and Compatibility testing.

The Program Director will initiate the Unsuccessful PT Participation (Cease Testing) Letter. The letter will be sent to the Laboratory Director and Laboratory Manager.

- Per CLIA, ACHC will report all unsuccessful participation events to CMS within 30 days of the initiation of the action to exclude an analyte, specialty, or subspecialty.
- The laboratory must cease testing for a full 6 months after a cease testing request for a regulated analyte.

Preventing PT Failures (the easy fixes)

- On receipt of the proficiency testing material, validate all specimens are present and store as instructed.
- Follow the directions provided by the PT provider. Follow reconstitution instructions. How long should the PT material sit at room temperature prior to testing? Make sure PT is mixed, handled, and tested as instructed.
- Validate specimens are accurately identified. Many failures occur from running the incorrect specimen or exchanging the identification of 2 PT specimens.
- Validate that the reportable units are correct for the test method.
- Verify the methodology is correct if it is a new analyzer or kit in use.
- Verify no clerical errors have been made during submission.
- Put a system in place to make sure submissions are completed by the deadline.

Save PT specimens for further testing (to investigate PT failures, for staff training and competency).

Completing an In-Depth PT Deficiency Investigation Report

- Completely fill out the Laboratory Information and Survey Information portion of the document, including the survey event test number, analyte(s), and date testing was performed.
- Provide your organization's results and the acceptable ranges for the PT results.
- Choose a deficiency type.
- If yes is marked under Assessment Review, choose all the method histories that were reviewed by circling each option.
- Provide detailed explanation for the Description of the Problem and Investigation Results portion of the PT Investigation report.
- If patient test results were not affected, explain in detail how this was evaluated. If patient test results were affected, what corrective action was taken?
- What Corrective Action was taken to prevent future occurrences?
- Provide documentation of corrective action and a copy of the PT agency evaluation form.
- Document review by staff and Laboratory Director.

PT Deficiency Investigation Report

- “Random error” and “Cause Unknown” are not sufficient explanations for PT Failure. Significant effort should be given to find the root cause. One unexplained PT failure, often leads to a second. Involve the service provider for your analyzer to aid in the investigation.

Successful PT Failure Investigation

Determine the who, what, why, when, and how the failure occurred. Evaluate all phases of testing.

- Pre-analytical: Staff training, Facility (reagent storage, equipment maintenance), SOP, handling of PT specimen.
- Analytical: Environmental Issues, Method Validations, QC, Instrument Issues, Testing Delays.
- Post-Analytical: Clerical Errors, LIS issues, Evaluate Patient Impact.

Use the PT summary report to aid in your investigation. Is there a positive or negative bias to your PT specimens results? If so, this should be investigated. Is calibration necessary to correct this bias?

Questions?

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Thank you

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