

# **CLIA Proficiency Testing**

## **PT Workgroup Background Analyte Inclusion and Prioritization**

**CLIAC Meeting**

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# Workgroup Background

- ❑ **CLIAC recommendation: Form a PT workgroup to examine and provide suggestions concerning the need for revisions to the CLIA PT requirements**
  
- ❑ **CMS and CDC organized the workgroup to include stakeholders in the proficiency testing process**
  - Laboratory experts
  - Accreditation organizations
  - State surveyors
  - PT program officials



# Workgroup Members

## WORKGROUP CHAIR

Nichols, James H., PhD, DABCC, FACB

## MICROBIOLOGY CO-CHAIR

Hall, Gerri, PhD, D(ABMM)

## MEMBERS

Breazeale, Ruthi, MMSc, MT(ASCP)

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## EX OFFICIO MEMBERS

Carey, Roberta B., PhD (CDC)

Gutierrez, Alberto, PhD (FDA)

Yost, Judith, MA, MT(ASCP) (CMS)

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Walker, Susan, MLS(ASCP), MA(HEd)

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Winn-Deen, Emily S., PhD

Yamamoto, Gary

Zachary, Andrea A., PhD, D(ABHI)



# Workgroup Charge and Objectives

## Charge:

Provide input to CLIAC for their consideration in making recommendations to HHS regarding the need for revisions to the CLIA requirements for proficiency testing (PT) as specified in subparts H and I of the regulations.

## Objectives:

Provide input to CLIAC regarding changes to subparts H and I of the CLIA regulations:

- Updating the list of CLIA-regulated analytes
- Revising the criteria for acceptable performance (grading criteria), including target values and acceptable limits for current and proposed analytes
- Changes to specialties or subspecialties that do not have regulated analytes, including microbiology
- Clarification of the requirements that address PT referral
- Other changes needed to update and improve required PT



# Statutory PT Requirements

- **CLIA law – Section 353(f)(3)**
  - Requires that a laboratory participate in proficiency testing (PT) for each examination or procedure for which PT can reasonably be developed
  - Standards shall include uniform criteria for acceptable performance based on:
    - Available technology
    - Clinical relevance of the laboratory examination or procedure
  - Standards shall include a system for grading PT



# Regulatory Requirements for Laboratories

- ❑ **42 CFR part 493, Subpart H - requirements for laboratory participation in PT for nonwaived testing**
  - For each regulated analyte or specialty without analytes, laboratories must:
    - Enroll in an approved PT program
    - Analyze 5 challenges per event
    - Obtain 80% for satisfactory score (most analytes)
    - Perform satisfactorily on 2 out of 3 testing events



# Regulatory Requirements for PT Program Approval

- **42 CFR part 493, Subpart I - requirements for proficiency testing program approval and annual reapproval**
  - Specifies the regulated analytes or tests for which PT must be performed, their criteria for acceptable performance, and grading/scoring criteria
  - For each regulated analyte, annual PT must include 5 challenges, 3 times (events) per year



## **Nonwaived Testing for which PT is Required**

- CLIA PT requirements (including regulated analytes) were included in the final CLIA rule published January 28, 1992**
- Required PT for all laboratories (including previously unregulated) was implemented January 1, 1994**
- Regulated analytes and their criteria for acceptable performance have not changed since that time**



# Current Regulated Analytes

- ❑ **Diagnostic Immunology**
  - Syphilis Serology
  - General Immunology – 15 analytes
- ❑ **Chemistry**
  - Routine Chemistry – 25 analytes
  - Endocrinology – 7 analytes
  - Toxicology – 15 analytes
- ❑ **Hematology – 10 analytes**
- ❑ **Immunochemistry – 5 analytes**



## **Current PT Requirements - Nonwaived Microbiology Testing**

- ❑ Does not include regulated analytes**
- ❑ Required PT is specified in Subpart I by “types of services offered by laboratories” for each subspecialty**
  - Laboratory types (levels) are structured based on test procedures performed and extent to which microorganisms are identified (i.e. genus, species)**
  - Lists of example organisms are provided for each subspecialty**
- ❑ 5 samples must be tested per PT event for each subspecialty of patient testing**



## Considerations for Revising the List of Regulated Analytes

- ❑ **Considerations need to reflect statutory and regulatory requirements for having:**
  - Sufficient quantities of stable and reproducible PT samples
  - Ability to establish uniform criteria for acceptable performance for that analyte or test
- ❑ **A process is needed to assess potential factors to identify analytes or tests to add as regulated**
- ❑ **Access to appropriate data is essential to making determinations regarding analyte inclusion and prioritization**



## **Previous CLIAC Deliberations Regarding Adding Analytes**

- CLIAC has considered PT issues on several occasions in the past**
- Their suggestions for potential criteria for adding regulated analytes have included:**
  - Impact on patient care/clinical significance of test
  - Testing problems with specific analytes
  - Cost/benefit analyses for laboratories
- They concluded more data are needed to facilitate future discussions on PT**



# Data and Information Provided for Consideration

- ❑ **CMS PT enrollment data**
- ❑ **Test frequency rankings for different laboratory types**
  - Six-hospital system
  - Large reference laboratories
  - Small hospital/physician office laboratories
  - Health maintenance organization/point-of-care sites
- ❑ **Medicare reimbursement data**
- ❑ **PT program counts for analyte offerings**

