Proficiency Testing (PT) Program Content

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PT Program Approval Process

- An organization, Federal, or State program seeking approval or reapproval for its program for the next calendar year must submit an application providing the required information by July 1 of the current year. (§ 493.901 Approval of proficiency testing programs.)
- CMS partners with CDC to approve PT programs annually.
  - In general, CMS focuses on evaluating the information about program administration and proposed content for the upcoming calendar year, while CDC focuses on analyzing the data from the PT program's previous year's offerings to ensure they met the regulatory guidelines.

PT Program Content Requirements

- The annual program must provide samples that cover the **full range of reactivity** from highly reactive to non-reactive. (Syphilis serology § 493.923(a) and general immunology § 493.927(a))

- The annual program must provide samples that cover the **clinically relevant range** of values that would be expected in patient specimens. (Routine chemistry § 493.931(a) and endocrinology § 493.933(a))

- The annual program must provide samples that cover the full range of values that could occur in patient specimens and that cover the **level of clinical significance** for the particular drug. (Toxicology § 493.937(a))

PT Program Content Requirements (cont.)

- The annual program must provide samples that cover the **full range of values** that would be expected in patient samples. (Hematology § 493.941(a))

- The annual program must provide samples that cover the **full range of interpretation** that would be expected in patient samples. (Immunohematology § 493.959(b))

Challenges for PT Programs

- Providing samples on the low-end of the range.
  - Examples: Alanine aminotransferase (ALT), Alkaline Phosphatase, Aspartate aminotransferase (AST), blood urea nitrogen (BUN), creatine kinase, creatinine, Thyroid Stimulating Hormone (TSH), T3 uptake, protime, partial thromboplastin time, carbamazepine, valproic acid.
- Samples need to cover multiple instruments, methodologies, reagents, and analytes.

Division of Laboratory Systems

Proficiency Testing (PT) Program Evaluation: Selection and Use of Reference Ranges

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Reference Ranges

- Reference ranges are used to determine if analyte challenges are provided across the relevant range of reactivity, values, interpretation, clinical significance, or clinical relevance

- For each analyte, the values from the total population of laboratories or the largest number of laboratories are recorded and compared to the reference range

CDC expects that of the 15 annual challenges, at least one is within 10% of the lowest or highest reference value to be considered compliant

Most reference ranges are from the Mayo Clinic Test Menu website (Home - Mayo Clinic Laboratories)

For the five analytes not found on the Mayo Clinic Test Menu website, other public access websites were searched

- The five analytes not found on the Mayo Clinic Test Menu:
  - Blood gases - medlineplus./gov/encyclopedia.html
  - Creatine Kinase MB - www.aruplab.com/testing
  - Lactate Dehydrogenase Isoenzymes - www.labcorp.com/test-menu/search
  - T3 Uptake - www.labcorp.com/test-menu/search
  - White blood cell differential

- White blood cell differential
  - No specific laboratory reference range used
  - Different sets of challenges are sent based on the instrument used
  - Analysis used values from the instrument operated by most laboratories
    - The average of each analyte from each PT program was calculated
    - Reference range was the span of the average values

Thank you!

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For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Discussion Questions

Discussion questions for CLIAC on this topic:

- How should we determine the sample range for each analyte that a PT program should cover?
  - Clinically relevant range
  - Full range of reactivity
  - Level of clinical significance
  - Full range of values
- What are acceptable limitations to proficiency testing programs meeting these ranges?