Effective Date: 09-2024

COLA Technical Bulletin

2024-8: New Proficiency Testing Rules: Reminder

In July of 2022, CMS published Final Rule CMS-3355-F in the Federal Register to implement revisions to the proficiency testing (PT) sections of the CLIA regulations. The Final Rule includes changes to the list of regulated analytes, required content of PT modules and changes in the acceptable ranges used for scoring PT results. The implementation date of those changes is **January 1, 2025**.

The purpose of this Technical Bulletin is to remind laboratories to carefully review their test menus and determine whether there is a need to order additional or different PT modules for next year (2025) to remain compliant with the Final Rule. Please note that this bulletin only provides an **overview** of some of the most significant changes to PT rules and is not comprehensive; refer to the Final Rule[1], linked in the footnote below for more information.

Hematology Changes

With the implementation of the new PT rules, laboratories performing both automated white blood cell (WBC) differentials and manual WBC differentials will be required to enroll in PT for *both* the automated and manual methods. Please consult your PT provider for guidance on selecting appropriate modules.

Microbiology Changes

CMS will require PT for direct antigen testing in the subspecialties of mycology and parasitology; PT is already required for direct antigen testing in both bacteriology and virology. Bacterial toxin detection will now also be included in PT challenges for bacteriology. In addition, PT challenges for Gram stains will now require reporting of the **bacterial morphology** in addition to the Gram reaction.

Laboratories will be required to enroll in PT for organism identification using molecular testing methods under each microbiology subspecialty listed on their test menus.

Chemistry, Toxicology, Endocrinology and Immunology Changes

CMS has approved several additions to the list of regulated analytes for which a laboratory is *required* to enroll in PT. See Table 1 on page 2 of this Technical Bulletin for the list of newly regulated analytes. If your laboratory performs these tests, ensure that you have enrolled with appropriate PT modules.

Changes To Acceptance Limits

The acceptable limits for PT scores for several analytes have been updated to reflect advancements in technology and improvements in analytical accuracy. Please see the Final Rule for more information about new acceptable limits and the rationale behind the updated limits.

Immunohematology Changes

The acceptable score for unexpected antibody detection (antibody screen) will be 100%, where it was previously 80%.

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TABLE 1: Analytes Proposed for Addition to Subpart I

CLIA Regulation	Analytes
General Immunology § 493.927	Anti-HBs Anti-HCV C-reactive protein (high sensitivity)
Routine Chemistry § 493.931	B-natriuretic peptide (BNP) ProBNP Cancer antigen (CA) 125 Carbon dioxide Carcinoembryonic antigen Cholesterol, low density lipoprotein, direct measurement Ferritin Gamma glutamyl transferase Hemoglobin A1c Phosphorus Prostate specific antigen, total Total iron binding capacity (TIBC), direct measurement Troponin I Troponin T
Endocrinology § 493.933	Estradiol Folate, serum Follicle stimulating hormone Luteinizing hormone Progesterone Prolactin Parathyroid hormone Testosterone Vitamin B12
Toxicology § 493.937	Acetaminophen, serum Salicylate Vancomycin

Table 1: New regulated analytes

Note: The following analytes have been removed from the list of regulated analytes: LDH isoenzymes, Ethosuximide, Quinidine, Primidone and Procainamide. You may still want to enroll in PT for these analytes; if you do not, you will still need to evaluate the accuracy twice per year.

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[1] Centers for Medicare & Medicaid Services. Clinical Laboratory Improvement Amendments of 1988 (CLIA) proficiency testing regulations related to analytes and acceptable performance. Federal Register. 2022;87:41194-41242. https://www.federalregister.gov/documents/2022/07/11/2022-14513/clinical-laboratory-improvement-amendments-of-1988-clia-proficiency-testing-regulations-related-to