IOWA | State Hygienic Laboratory

CLIA CORNER

State Hygienic Laboratory at The University of Iowa — Second Quarter 2024

In This Issue…

The Proficiency Testing (PT) final rule, CMS-3355-F, was published in the Federal Register on July 11, 2022. Important dates to remember:

- **August 10, 2022:** CMS clarified that PT referral regulations apply to waived testing as well as non-waived testing when a moderate and/or high complexity laboratory chooses to perform PT for waived tests.
- **July 11, 2024:** Effective date for the PT requirement revisions that includes the addition of 29 new regulated analytes, the removal of 5 regulated analytes, and changes to grading and reporting (Regulations 493.2 and 493.801 through 493.959).
- **January 1, 2025:** Implementation date for the PT requirements for both PT program providers and laboratories.

Participation in proficiency testing (PT) is required for laboratories that perform moderate and/or high complexity testing. It evaluates a laboratory's performance through testing unknown samples sent from an outside HHS approved PT provider. The laboratory is to treat the samples the same as it would a patient's samples. The results of the PT samples are submitted to the PT program provider for grading according to the criteria published in Subpart I of the CLIA regulations. The scores for all testing performed are sent to the laboratory, and the scores for all testing of regulated analytes are also sent to the Centers for Medicare and Medicaid Services (CMS). Regulated analytes are those for which a laboratory must enroll in PT and are also listed in Subpart I of the CLIA regulations.

PT participation is a great tool for laboratories to use to monitor the accuracy and reliability of the testing it performs as well as the competency of its testing personnel. The overall quality of the laboratory increases and is maintained with the use of PT.

Final Rule Changes

The CMS-3355-F Final Rule for PT changes includes:

- Microbiology PT changes
- Non-microbiology PT changes
- Addition/deletion of analytes
- Testing of samples, PT referral for waived tests

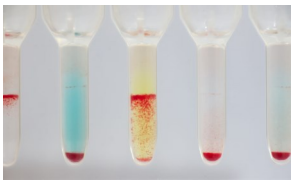
Microbiology PT Changes

The Final Rule includes several changes to microbiology PT, most of which apply to PT providers with reference to PT specimen make-up, grading, and reporting. A few changes laboratories should be aware of include:

- Laboratories must report PT results for microbiology organism identification to the highest level that they report results on patient specimens.
- Bacteriology: Gram stain PT must now include both stain reaction and morphology.
- Laboratories must enroll for the subspecialty that the test system is categorized under, including direct antigen testing.

Non-Microbiology PT Changes

The changes to non-microbiology PT also include updates to grading and reporting, as well as, the addition and revision of definitions related to grading of PT results. In addition, changes to the criteria for acceptable performance for several analytes are included. Additional non-microbiology PT changes laboratories should be aware of include:



Hematology

- Laboratories must report prothrombin time in the same manner as patient results; if a laboratory reports prothrombin time in seconds and INR, it will also need to report both results to the PT provider.
- Laboratories performing both cell counts and differentials must enroll and participate in PT for both.
- Criteria for acceptable performance for "cell identification" changed from 90% to 80%.

Immunohematology

- Criteria for acceptable performance for unexpected antibody detection changed from 80% to 100%

Additional changes can be found under the direct link to the CMS-3355-F, PT Final Rule. In addition, the Division of Clinical Laboratory Improvement and Quality (DCLIQ) summarized changes in a presentation at the Clinical Laboratory Improvement Advisory Committee (CLIAC) meeting in November 2022; the presentation slides can be found here.

Deletion/Addition of Analytes

Subpart I of the CLIA Regulations lists the regulated analytes (those for which a laboratory must enroll in PT) and gives PT providers instructions for grading and reporting results as well as criteria for acceptable PT performance. Subpart I is not included in Appendix C– Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, but can be found here in the Code of Federal Regulations. Five regulated analytes will be removed from Subpart I because they are no longer commonly used. This will be effective July 11, 2024 and includes the following:

- **LDH isoenzymes**
- **Quinidine**
- **Procainamide (and metabolite)**
- **Ethosuximide**
- **Primidone**

29 new analytes have been proposed, bringing the total number of regulated analytes to 105. Following is a list of all regulated analytes, effective July 11, 2024. The newly proposed analytes are in **red**.

GENERAL IMMUNOLOGY			
Alpha-1 Antitrypsin	**Anti-HCV**	HbsAg	IgE
Alpha Fetoprotein (tumor markers)	Anti-Human Immunodeficiency Virus (HIV)	Anti-HBc	IgM
Antinuclear Antibody	**C-reactive protein (high sensitivity)**	HbeAg	Infectious Mononucleosis
Antistreptolysin O	Complement C3	IgA	Rheumatoid Factor
Anti-HBs	Complement C4	IgG	Rubella

ROUTINE CHEMISTRY			
Alanine Aminotransferase (ALT or SGPT)	**Carbon Dioxide**	**Gamma Glutamyl Transferase (GGT)**	Sodium
Albumin	**Carcinoembryonic antigen (CEA)**	Glucose	**Total Iron Binding Capacity (TIBC), direct measurement**
Alkaline Phosphatase	Chloride	**Hemoglobin A1c**	Total Protein
Amylase	Cholesterol, total	Iron, total	Triglycerides
Aspartate Aminotransferase (AST or SGOT)	Cholesterol, HDL	Lactate Dehydrogenase (LDH)	**Troponin I**
B-natriuretic peptide (BNP)	**Cholesterol, LDL, direct measurement**	Magnesium	**Troponin T**
Bilirubin, total	Creatine Kinase, total	**Phosphorus**	Urea Nitrogen (BUN)
Blood Gases (pH/pCO2/pO2)	Creatine Kinase, Isoenzymes (CK-MB)	Potassium	Uric Acid
Calcium, total	Creatinine	**ProBNP**	
Cancer Antigen (CA) 125	**Ferritin**	**Prostate Specific Antigen, total**	

ENDOCRINOLOGY			
Cortisol	Free Thyroxine	**Prolactin**	Triiodothyronine (T3)
Estradiol	Human Chorionic Gonadotropin (hCG)	**Parathyroid Hormone**	Thyroid Stimulating Hormone (TSH)
Folate, serum	**Luteinizing Hormone**	T3 Uptake	Thyroxine, total (T4)
Follicle Stimulating Hormone	**Progesterone**	**Testosterone**	**Vitamin B12**

TOXICOLOGY			
Acetaminophen, serum	Digoxin	Phenytoin	Valproic Acid
Blood Alcohol	Gentamicin	**Salicylate**	**Vancomycin**
Blood Lead	Lithium	Theophylline	
Carbamazepine	Phenobarbital	Tobramycin	
HEMATOLOGY			
Cell Identification	Hematocrit	Platelet Count	Prothrombin Time
WBC Differential (manual & automated)	Hemoglobin	Fibrinogen	
RBC Count	WBC Count	Partial Thromboplastin Time	
IMMUNOHEMATOLOGY			
ABO Group	Unexpected Antibody Detection	Compatibility Testing	Antibody Identification
D (Rho) Typing			

Testing of Samples, PT Referral for Waived Tests

The CMS-3355-F Final Rule aligns the CLIA statute with the PT referral regulations as it pertains to moderate and high complexity laboratories performing waived testing. Laboratories are **not required** to enroll in PT for waived testing. However, those that elect to will be held to the same requirements as non-waived PT testing. This includes PT referral. Please refer to CMS's Proficiency Testing and PT Referral brochure for more information.

Looking for more information about Proficiency Testing? The Iowa State Agency has you covered! The 2018 Third Quarter issue of the CLIA Corner discusses Initial and Non-Initial PT Failures and can be found here.

Still not enough? The 2019 Second Quarter issue discusses PT corrective action, when it is necessary, and what is required; it can be found here.

If you would like your name added to our CLIA Corner Google Group, send an email to:

Kristine-Rotzoll@uiowa.edu or Melinda-Bochmann@uiowa.edu