DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Quality Safety & Oversight Group

March 15, 2023

Dear PT Program Providers,

The final rule CMS–3355–F, Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance, was published in the Federal Register on July 11, 2022. This final rule will affect laboratories that perform testing for any of the analytes or microbiology subspecialties listed in the CLIA regulations under subpart I. It will also affect any laboratory that participates in PT referral involving waived testing.

This final rule includes:

- the addition and deletion of analytes or tests that require proficiency testing (PT), as well as updates the criteria for acceptable performance and administrative processes for CLIA PT programs.

- an update to align the CLIA regulations with the statute (42 U.S.C. 263a (i)(4)), which does not exclude waived tests from the ban on improper PT referral.

The revisions to PT requirements related to the addition and deletion of analytes or microbiology tests and updates to the criteria for acceptable performance and administrative processes for PT programs (§§ 493.2 and 493.801 through 493.959) are effective on July 11, 2024, two years after the publication date of the final rule in the Federal Register. **The implementation date for the laboratories and PT program providers for these revisions will be January 01, 2025 which is in alignment with our current process for PT program providers and PT enrollment.**

Learn more about the final rule in the *Federal Register*.

If you have any questions, please contact Sarah Bennett and Penny Keller at the following email address:

Sarah.Bennett1@cms.hhs.gov and Penny.Keller@cms.hhs.gov.

Sincerely,

Gregg S. Brandush, RN, JD
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Proficiency Testing Changes for 2025

On July 11, 2022, the Centers for Medicare & Medicaid Services (CMS) published final rule CMS-3355-F. This rule added new regulated analytes to CLIA, revised grading criteria for some current analytes, and made other small changes affecting PT enrollment and grading.

The following tables summarize the changes that will go into effect January 1, 2025. API already offers 5-sample programs for most new analytes, and the associated catalog numbers are shown. If you would like to adjust your proficiency testing enrollments for the 2024 calendar year, please contact us at (800) 333-0958.

Beginning January 1, 2025, labs performing non-waived testing for the analytes below **must** be enrolled in a 5-sample program except in microbiology, where programs can be combined to meet the 5-sample requirement for each subspecialty.

Miscellaneous Changes

HEMATOLOGY
Participants will be required to enroll in proficiency testing for both manual and automated blood cell differentials. Scores for both will be submitted to CMS.
GENERAL IMMUNOLOGY
Qualitative Anti-HBs and Anti-HCV will be considered regulated. The grading criteria is 80% consensus for the targeted result (positive/reactive or negative/nonreactive).
IMMUNOHEMATOLOGY
Antibody Screen (Unexpected Antibody Detection) will no longer use 80% for a passing score. Like most other immunohematology analytes, a score of 100% (all 5 samples acceptable) will need to be obtained in order to pass a test event.

New CMS Regulated Analytes and Grading Criteria

ROUTINE CHEMISTRY			
Analyte	**Catalog #**	**Current API Criteria**	**New CMS Criteria**
BNP	140	± 10 pg/mL or 3 SD (greater)	± 30 percent
NT pro-BNP	140	± 10 pg/mL or 2 SD (greater)	± 30 percent
Cholesterol, LDL (measured)	121, 122	± 2 SD	± 20 percent
CO2	121, 122	± 3 SD	± 20 percent
tCO2	112, 145	± 3 SD	± 20 percent
Ferritin	180	± 3 SD	± 20 percent
GGT	122	± 20 percent	± 5 U/L or 15 percent (greater)
Glycated Hemoglobin (HbA1c)	126, 195	± 3 SD or 20 percent	± 8 percent
Phosphorus	122	± 2 SD	± 0.3 mg/dL or 10 percent (greater)
PSA	180	± 0.4 ng/mL or 3 SD (greater)	± 0.2 ng/mL or 20 percent (greater)
TIBC (measured)	122	± 2 SD	± 20 percent
Troponin I	140	± 0.3 ng/mL or 3 SD (greater)	± 0.9 ng/mL or 30 percent (greater)
Troponin T	140	± 0.1 ng/mL or 2 SD (greater)	± 0.2 ng/mL or 30 percent (greater)
ENDOCRINOLOGY			
Analyte	**Catalog #**	**Current API Criteria**	**New CMS Criteria**
CA 125	183	± 2 SD	± 20 percent
CEA	180, 183	± 3 SD	± 1 ng/mL or 15 percent (greater)
Estradiol	180	± 2 SD	± 30 percent
Folate	180	± 1 ng/mL or 3 SD (greater)	± 1 ng/mL or 30 percent (greater)
FSH	180	± 3 SD	± 2 IU/L or 18 percent (greater)
Luteinizing Hormone	180	± 3 SD	± 20 percent
Parathyroid Hormone	182	± 2 SD	± 30 percent
Progesterone	180	± 3 SD	± 25 percent
Prolactin	180	± 3 SD	± 20 percent
Testosterone	180	± 3 SD	± 0.2 ng/mL or 30 percent (greater)
Vitamin B-12	180	± 3 SD	± 30 pg/mL or 25 percent (greater)
TOXICOLOGY			
Analyte	**Catalog #**	**Current API Criteria**	**New CMS Criteria**
Acetaminophen	132, 136	± 2.5 µg/mL or 3 SD (greater)	± 3 µg/mL or 15 percent (greater)
Salicylates	132, 136	± 2.8 mg/dL or 3 SD (greater)	± 0.2 mg/dL or 15 percent (greater)
Vancomycin	132, 136	± 2 µg/mL or 20 percent (greater)	± 2 µg/mL or 15 percent (greater)
HEMATOLOGY			
Analyte	**Catalog #**	**Current API Criteria**	**New CMS Criteria**
INR	214, 216, 217, 249, 250	± 3 SD	± 15 percent
GENERAL IMMUNOLOGY			
Analyte	**Catalog #**	**Current API Criteria**	**New CMS Criteria**
C-reactive protein (high-sensitivity)	443	± 0.2 mg/dL or 2 SD (greater)	± 0.1 mg/dL or 30 percent (greater)

Revised Grading Criteria for Current Regulated Analytes

ROUTINE CHEMISTRY			
Analyte	**Catalog #**	**Current CMS Criteria**	**New CMS Criteria**
Albumin	121, 122	± 10 percent	± 8 percent
Alkaline phosphatase	122	± 30 percent	± 20 percent
ALT / SGPT	121, 122	± 20 percent	± 6 U/L or 15 percent (greater)
Amylase	122	± 30 percent	± 20 percent
AST / SGOT	121, 122	± 20 percent	± 6 U/L or 15 percent (greater)
Cholesterol, HDL	122	± 30 percent	± 6 mg/dL or 20 percent (greater)
Creatine Kinase / CK	122, 140	± 30 percent	± 20 percent
CK-MB	140	± 3 ng/mL or 3 SD (greater)	± 3 ng/mL or 25 percent (greater)
Creatinine	112, 121, 122, 145	± 0.3 mg/dL or 15 percent (greater)	± 0.2 mg/dL or 10 percent (greater)
Glucose	112, 121, 122, 145	± 6 mg/dL or 10 percent (greater)	± 6 mg/dL or 8 percent (greater)
Iron	122	± 20 percent	± 15 percent
LD / LDH	122	± 20 percent	± 15 percent
Magnesium	122	± 25 percent	± 15 percent
pO2	112, 145	± 3 SD	± 15 mmHg or 15 percent (greater)
Potassium	112, 121, 122, 145	± 0.5 mmol/L	± 0.3 mmol/L
Total Protein	122	± 10 percent	± 8 percent
Triglycerides	121, 122	± 25 percent	± 15 percent
Uric Acid	121, 122	± 17 percent	± 10 percent
ENDOCRINOLOGY			
Analyte	**Catalog #**	**Current CMS Criteria**	**New CMS Criteria**
Cortisol	122, 125	± 25 percent	± 20 percent
Free Thyroxine (FT4)	122, 125, 175	± 3 SD	± 0.3 ng/dL or 15 percent (greater)
HCG (serum-quant)	409	± 10 mIU/mL or 3 SD (greater)	± 3 mIU/mL or 18 percent (greater)
T-Uptake	122, 125, 175	± 3 SD	± 18 percent
Triiodothyronine (T3)	122, 125, 175	± 3 SD	± 30 percent
TSH	122, 125, 175	± 3 SD	± 0.2 mIU/L or 20 percent (greater)
TOXICOLOGY			
Analyte	**Catalog #**	**Current CMS Criteria**	**New CMS Criteria**
Alcohol	137	± 10 mg/dL or 25 percent (greater)	± 20 percent
Blood Lead	172	± 4 µg/dL or 10 percent (greater)	± 2 µg/dL or 10 percent (greater)
Carbamazepine	132, 136	± 25 percent	± 1 µg/mL or 20 percent (greater)
Digoxin	132, 136	± 0.2 ng/mL or 20 percent (greater)	± 0.2 ng/mL or 15 percent (greater)
Lithium	132, 136	± 0.3 mmol/L or 20 percent (greater)	± 0.3 mmol/L or 15 percent (greater)
Phenobarbital	132, 136	± 20 percent	± 2 µg/mL or 15 percent (greater)
Phenytoin	132, 136	± 25 percent	±15% or ± 2 mcg/mL (greater)
Theophylline	132, 136	± 25 percent	± 20 percent
Tobramycin	132, 136	± 25 percent	± 20 percent
Valproic Acid	132, 136	± 25 percent	± 20 percent
HEMATOLOGY			
Analyte	**Catalog #**	**Current CMS Criteria**	**New CMS Criteria**
Hematocrit	See catalog	± 6 percent	± 4 percent
Hemoglobin		± 7 percent	± 4 percent
Red Cell Count		± 6 percent	± 4 percent
White Cell Count		± 15 percent	± 10 percent

GENERAL IMMUNOLOGY			
Analyte	**Cat #**	**Current CMS Criteria**	**New CMS Criteria**
Alpha-1-Antitrypsin	436	± 3 SD	± 20 percent
Complement C3	436	± 3 SD	± 15 percent
Complement C4	436	± 3 SD	± 5 mg/dL or 20 percent (greater)
IgA	436	± 3 SD	± 20 percent
IgE	419, 436	± 3 SD	± 20 percent
IgG	436	± 25 percent	± 20 percent
IgM	436	± 3 SD	± 20 percent

Microbiology Changes for 2025

CLIA requires laboratories performing microbiology tests that are regulated for proficiency testing to test five regulated challenges per test event in each sub-specialty. The five sub-specialties are Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology. The following are new additions to the CLIA Microbiology requirements and will be scored for CMS beginning January 1, 2025.

We have already made changes to Microbiology programs for 2024, as appropriate. Further communications will be forthcoming as the implementation date of January 1, 2025 draws closer. If you have any questions about the new requirements, please contact our Technical Support department at (800) 333-0958 or at TechSupport@api-pt.com.

BACTERIOLOGY	
CLIA Category	**API Analyte**
Gram stain morphology	Gram stain morphology (#320, #328)
Bacterial toxin detection	*C. difficile* toxin (#347, #350) Shiga toxin (#343) Identification of bacterial toxins (#369 – GI Panel)
Antimicrobial susceptibility	Two samples required per event (#314, #321, #328, #924)
MYCOBACTERIOLOGY	
CLIA Category	**API Analyte**
Detection of presence/absence of mycobacteria, without identification	*M. tuberculosis* detection (molecular) (#372)
MYCOLOGY	
CLIA Category	**API Analyte**
Direct fungal antigen detection	Cryptococcal antigen (#345)
Detection of presence/absence of fungi and aerobic actinomycetes, without identification	*Candida* sp. (#324 – Affirm VP)
Identification of fungi and aerobic actinomycetes	Molecular identification of yeasts (#371 – Meningitis Panel, #376 – Vaginal Panel, #389 – UTI Panel, #390 – Joint/Wound Infection Panel) Molecular identification of fungi (#391 – Nail Fungus Panel) *Candida auris* (#393 – new for 2024)
PARASITOLOGY	
CLIA Category	**API Analyte**
Direct parasite antigen detection	Rapid malaria detection (#382)
Identification of parasites	Molecular identification of parasites (#369 – GI Panel, #376 – Vaginal Panel, #392 – STI Panel) *Trichomonas vaginalis* (#324, #362)
VIROLOGY – NO CHANGES	