



CMS CHANGES TO PROFICIENCY TESTING



The Clinical Laboratory Improvement Amendments (CLIA) requires laboratories performing microbiology tests that are regulated for proficiency testing (PT) to test five regulated challenges per test event in each subspecialty. The five subspecialties are Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology.

Detection (presence or absence) **without identification** will require PT for Bacteria, Mycobacteria, Fungi (**including dermatophytes**), Aerobic Actinomycetes, and Parasites.

The following tables list the new (highlighted in green) and current CMS-regulated analytes and updated criteria for acceptability.

Immunoematology			
Analyte	Current API Criteria	Current CAP Criteria	New CMS Criteria
Unexpected Antibody Detection	80%	80%	100%

Immunology			
Analyte	Current API Criteria	Current CAP Criteria	New CMS Criteria
Alpha-1-Antitrypsin	± 3 SD	± 3 SD	± 20%
Alpha-fetoprotein	± 3 SD	± 3 SD	± 20%
Anti-HBs (HBsAb)	positive/reactive or negative/nonreactive	positive/reactive or negative/nonreactive	positive/reactive or negative/nonreactive
Anti-HCV	positive/reactive or negative/nonreactive	positive/reactive or negative/nonreactive	positive/reactive or negative/nonreactive
C-reactive protein (high-sensitivity)	± 0.2 mg/dL or 2 SD (greater)	± 20%	± 0.1 mg/dL or 30% (greater)
Complement C3	± 3 SD	± 3 SD	± 15%
Complement C4	± 3 SD	± 3 SD	± 5 mg/dL or 20% (greater)
IgA	± 3 SD	± 3 SD	± 20%
IgE	± 3 SD	± 3 SD	± 20%
IgG	± 25%	± 25%	± 20%



Hematology			
Participants must enroll in proficiency testing for both manual and automated blood cell differentials. Scores for both will be submitted to CMS.			
Analyte	Current API Criteria	Current CAP Criteria	New CMS Criteria
Hematocrit	± 6%	± 6%	± 4%
Hemoglobin	± 7%	± 7%	± 4%
INR	± 3 SD	± 20%	± 15%
Red Cell Count	± 6%	± 6%	± 4%
White Cell Count	± 15%	± 15%	± 10%

Routine Chemistry			
Analyte	Current API Criteria	Current CAP Criteria	New CMS Criteria
Albumin	± 10%	± 10%	± 8%
ALKP	± 30%	± 30%	± 20%
ALT / SGPT	± 20%	± 20%	± 6 U/L or 15% (greater)
Amylase	± 30%	± 30%	± 20%
AST / SGOT	± 20%	± 20%	± 6 U/L or 15% (greater)
BNP	± 10 pg/mL or 3 SD (greater)	± 10% or 3 SD (greater)	± 30%
Cholesterol, HDL	± 30%	± 30%	± 6 mg/dL or 20% (greater)
Cholesterol, LDL (measured)	± 2 SD	± 30%	± 20%
Creatinine	± 0.3 mg/dL or 15% (greater)	± 0.3 mg/dL or 15% (greater)	± 0.2 mg/dL or 10% (greater)
Creatine Kinase / CK	± 30%	± 30%	± 20%
CK-MB	± 3 ng/mL or 3 SD (greater)	± 3 SD	± 3 ng/mL or 25% (greater)
CO2	± 3 SD	± 3 SD	± 20%
Ferritin	± 3 SD	± 3 SD	± 20%
GGT	± 20%	± 3 SD	± 5 U/L or 15% (greater)
Glucose	± 6 mg/dL or 10% (greater)	± 6 mg/dL or 10% (greater)	± 6 mg/dL or 8% (greater)
HbA1c	± 3 SD or 20%	± 6%	± 8%
Iron	± 20%	± 20%	± 15%
LD / LDH	± 20%	± 20%	± 15%
Magnesium	± 25%	± 25%	± 15%
NT pro-BNP	± 10 pg/mL or 2 SD (greater)	± 10% or 3 SD (greater)	± 30%



Routine Chemistry			
Analyte	Current API Criteria	Current CAP Criteria	New CMS Criteria
Phosphorus	± 2 SD	± 10.7% or 0.3 mg/dL (greater)	± 0.3 mg/dL or 10% (greater)
Potassium	± 0.5 mmol/L	± 0.5 mmol/L	± 0.3 mmol/L
TIBC (measured)	± 2 SD	± 20%	± 20%
Total Protein	± 10%	± 10%	± 8%
Triglycerides	± 25%	± 25%	± 15%
Troponin I	± 0.3 ng/mL or 3 SD (greater)	± 30% or 3 SD (greater)	± 0.9 ng/mL or 30% (greater)
Uric Acid	± 17%	± 17%	± 10%

Toxicology			
Analyte	Current API Criteria	Current CAP Criteria	New CMS Criteria
Acetaminophen	± 2.5 µg/mL or 3 SD (greater)	± 3 SD or 10% (greater)	± 3 µg/mL or 15% (greater)
Alcohol	± 10 mg/dL or 25% (greater)	± 25%	± 20%
Blood Lead	± 4 µg/dL or 10% (greater)	± 4 µg/dL or 10% (greater)	± 2 µg/dL or 10% (greater)
Carbamazepine	± 25%	± 25%	± 1 µg/mL or 20% (greater)
Digoxin	± 0.2 ng/mL or 20% (greater)	± 0.2 ng/mL or 20% (greater)	± 0.2 ng/mL or 15% (greater)
Lithium	± 0.3 mmol/L or 20% (greater)		± 0.3 mmol/L or 15% (greater)
Phenobarbital	± 20%		± 2 µg/mL or 15% (greater)
Phenytoin	± 25%		± 2 µg/mL or 15% (greater)
Salicylates	± 2.8 mg/dL or 3 SD (greater)	± 3 SD or 10% (greater)	± 0.2 mg/dL or 15% (greater)
Theophylline	± 25%		± 20%
Tobramycin	± 25%		± 20%
Vancomycin	± 2 µg/mL or 20% (greater)	± 3 SD or 10% (greater)	± 2 µg/mL or 15% (greater)



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Endocrinology			
Analyte	Current API Criteria	Current CAP Criteria	New CMS Criteria
CA 125	± 2 SD	± 3 SD	± 20%
CEA	± 3 SD	± 25% or 1.2 ng/mL (greater)	± 1 ng/mL or 15% (greater)
Cortisol	± 25%		± 20%
Estradiol	± 2 SD	± 3 SD	± 30%
Folate	± 1 ng/mL or 3 SD (greater)	± 3 SD	± 1 ng/mL or 30% (greater)
FSH	± 3 SD	± 3 SD	± 2 IU/L or 18% (greater)
Free Thyroxine (FT4)	± 3 SD	± 3 SD	± 0.3 ng/dL or 15% (greater)
HCG (serum-quant)	± 10 mIU/mL or 3 SD (greater)	± 3 SD	± 3 mIU/mL or 18% (greater)
Luteinizing Hormone	± 3 SD	± 3 SD	± 20%
Parathyroid Hormone	± 2 SD	± 3 SD	± 30%
Progesterone	± 3 SD	± 3 SD	± 25%
Prolactin	± 3 SD	± 3 SD	± 20%
Testosterone	± 3 SD	± 3 SD	± 0.2 ng/mL or 30% (greater)
T-Uptake	± 3 SD		± 18%
Triiodothyronine (T3)	± 3 SD		± 30%
Vitamin B-12	± 3 SD	± 3 SD	± 30 pg/mL or 25% (greater)

The final rule may be viewed here: <https://www.federalregister.gov/documents/2022/07/11/2022-14513/clinical-laboratory-improvement-amendments-of-1988-clia-proficiency-testing-regulations-related-to>.

