

On July 11, 2022, the Centers for Medicare & Medicaid Services (CMS) published final rule CMS-3355-F. This rule introduces new regulated analytes to CLIA, updates grading criteria for some existing analytes, and implements additional changes that impact PT enrollment and grading.

Prepare your laboratory for the upcoming changes in CLIA proficiency testing (PT) regulations, which will be implemented on January 1, 2025. Refer to the table below, to review the new CMS regulated analytes, their acceptance limits, and corresponding program codes.

Contact us for assistance. contactcenter@cap.org 800-323-4040, Option 1 | +1-847-832-7000, Option 1.

New CMS Regulated Analytes			
Analyte	Program Code(s)	Current Criteria	New CMS Criteria
CHEMISTRY			
BNP	BNP5, PCARM, PCARMX	Target value \pm 3 SD or 10% (greater)	Target value \pm 30%
NT pro-BNP	BNP5, PCARM, PCARMX	Target value \pm 3 SD or 10% (greater)	Target value \pm 30%
CO ₂ , total	AQ, AQH, AQIS, C1/C3/C3X/C4/CZ/CZ X/CZ2X	Target value \pm 3 SD	Target value \pm 20%
LDL Cholesterol, measured	C1/C3/C3X/C4/CZ/CZ X/CZ2X	Target value \pm 30%	Target value \pm 20%
Ferritin	C1/C3/C3X/CZ/CZX/C Z2X, K/KK	Target value \pm 3 SD	Target value \pm 20%
Gamma glutamyl transferase (GGT)	C1/C3/C3X/CZ/CZX/C Z2X	Target value \pm 3 SD	Target value \pm 15% or 5 U/L (greater)
Hemoglobin A1c	GH5, GH5I	Target value \pm 6%	Target value \pm 8%*
Phosphorus	C1/C3/C3X/CZ/CZX/C Z2X	Target value \pm 10.7% or 0.3 mg/dL (greater)	Target value \pm 10% or 0.3 mg/dL (greater)
Prostate-specific antigen (PSA), total	K/KK	Target value \pm 3 SD or 0.2 ng/mL (greater)	Target value \pm 20% or 0.2 ng/mL (greater)
Iron-binding capacity, total (TIBC), measured	C3/C3X/CZ/CZX/CZ2X	Target value \pm 20%	Target value \pm 20%
Troponin I	CRT, CRTI, PCARM, PCARMX	Target value \pm 3 SD or 30% (greater)	Target value \pm 30% or 0.9 ng/mL (greater)
ENDOCRINOLOGY			
Cancer antigen (CA) 125	K/KK	Target value \pm 3 SD	Target value \pm 20%
Carcinoembryonic antigen (CEA)	K/KK	Target value \pm 25% or 1.2 ng/mL (greater)	Target value \pm 15% or 1 ng/mL (greater)
Estradiol	Y/YY	Target value \pm 3 SD	Target value \pm 30%
Folate	K/KK	Target value \pm 3 SD	Target value \pm 30% or 1 ng/mL (greater)
Follicle-stimulating hormone (FSH)	Y/YY	Target value \pm 3 SD	Target value \pm 18% or 2 IU/L (greater)
Luteinizing hormone (LH)	Y/YY	Target value \pm 3 SD	Target value \pm 20%
Parathyroid hormone (PTH)	PTH	Target value \pm 3 SD	Target value \pm 30%
Progesterone	Y/YY	Target value \pm 3 SD	Target value \pm 25%
Prolactin	Y/YY	Target value \pm 3 SD	Target value \pm 20%
Testosterone	Y/YY	Target value \pm 3 SD	Target value \pm 30% or 20 ng/dL (greater)
Vitamin B12	K/KK	Target value \pm 3 SD	Target value \pm 25% or 30 pg/mL (greater)
TOXICOLOGY			
Acetaminophen	CZ/CZX/CZ2X/Z	Target value \pm 3 SD or 10% (greater)	Target value \pm 15% or 3 mcg/mL (greater)
Salicylate	CZ/CZX/CZ2X/Z	Target value \pm 3 SD or 10% (greater)	Target value \pm 15% or 2 mcg/mL (greater)
Vancomycin	CZ/CZX/CZ2X/Z	Target value \pm 3 SD or 10% (greater)	Target value \pm 15% or 2 mcg/mL (greater)
HEMATOLOGY (including Coagulation)			
INR	CGB, CGL, WP3, WP4, WP6, WP9	Target value \pm 20%	Target value \pm 15%
IMMUNOLOGY			
CRP, high sensitivity	HSCR	Target value \pm 30%	Target value \pm 30% or 1 mg/L (greater)
Anti-HBs (HBsAb)	VM1	Reactive (positive) or non-reactive (negative)	Reactive (positive) or non-reactive (negative)
Anti-HCV	VM1	Reactive (positive) or non-reactive (negative)	Reactive (positive) or non-reactive (negative)

*CAP-accredited laboratories that use accuracy-based proficiency testing for hemoglobin A1c will be required to evaluate results based on acceptable performance criteria of \pm 6% in 2025. Therefore, the CAP will provide two evaluations starting with the GH5-A 2025 mailing to meet CLIA (Target value \pm 8%) and CAP checklist (Target value \pm 6%) requirements.

Revised Scoring Criteria for Currently Regulated Analytes			
CHEMISTRY			
Analyte	Program Code(s)	Current CMS Criteria	New CMS Criteria
Alanine aminotransferase (ALT/SGPT)	C1/C3/C3X/CZ/CZX/C Z2X	Target value \pm 20%	Target value \pm 15% or 6 U/L (greater)

Albumin	C1/C3/C3X/CZ/CZX/CZ2X	Target value ± 10%	Target value ± 8%
Alkaline Phosphatase	C1/C3/C3X/CZ/CZX/CZ2X	Target value ± 30%	Target value ± 20%
Amylase	C1/C3/C3X/CZ/CZX/CZ2X	Target value ± 30%	Target value ± 20%
Aspartate aminotransferase (AST/SGOT)	C1/C3/C3X/CZ/CZX/CZ2X	Target value ± 20%	Target value ± 15% or 6 U/L (greater)
pO2	AQ, AQH, AQIS	Target value ± 3 SD	Target value ± 15% or 15 mmHg (greater)
HDL Cholesterol	C1/C3/C3X/C4/CZ/CZX/CZ2X	Target value ± 30%	Target value ± 20% or 6 mg/dL (greater)
Creatine Kinase (CK)	C1/C3/C3X/CZ/CZX/CZ2X	Target value ± 30%	Target value ± 20%
CK-MB isoenzyme	CRT, CRTI, HCRT, HCRTI	Target value ± 3 SD	Target value ± 25% or 3 ng/mL (greater)
Creatinine	AQ, AQH, AQIS, C1/C3/C3X/C4/CZ/CZX/CZ2X, WBCR	Target value ± 15% or 0.3 mg/dL (greater)	Target value ± 10% or 0.2 mg/dL (greater)
Glucose	AQ, AQH, AQIS, C1/C3/C3X/C4/CZ/CZX/CZ2X	Target value ± 10% or 6 mg/dL (greater)	Target value ± 8% or 6 mg/dL (greater)
Iron	C1/C3/C3X/CZ/CZX/CZ2X	Target value ± 20%	Target value ± 15%
Lactate dehydrogenase (LD)	C1/C3/C3X/CZ/CZX/CZ2X	Target value ± 20%	Target value ± 15%
Magnesium	C1/C3/C3X/CZ/CZX/CZ2X	Target value ± 25%	Target value ± 15%
Potassium	AQ, AQH, AQIS, C1/C3/C3X/CZ/CZX/CZ2X	Target value ± 0.5 mmol/L	Target value ± 0.3 mmol/L
Protein, total	C1/C3/C3X/CZ/CZX/CZ2X	Target value ± 10%	Target value ± 8%
Triglycerides	C1/C3/C3X/C4/CZ/CZX/CZ2X	Target value ± 25%	Target value ± 15%
Uric Acid	C1/C3/C3X/C4/CZ/CZX/CZ2X	Target value ± 17%	Target value ± 10%
ENDOCRINOLOGY			
Analyte		Current CMS Criteria	New CMS Criteria
Alpha-fetoprotein (AFP)	K/KK, FP/FPX	Target value ± 3 SD	Target value ± 20%
Cortisol	C1/C3/C3X/C4/CZ/CZX/CZ2X, K/KK	Target value ± 25%	Target value ± 20%
Thyroxine (T4), free	C1/C3/C3X/C4/CZ/CZX/CZ2X, K/KK	Target value ± 3 SD	Target value ± 15% or 0.3 ng/dL (greater)
hCG serum	C1/C3/C3X/C4/CZ/CZX/CZ2X, FP/FPX/FP1T, HCG, IL, K/KK	Target value ± 3 SD	Target value ± 18% or 3 mIU/mL (greater)
T3 Uptake and related tests	C1/C3/C3X/C4/CZ/CZX/CZ2X, K/KK	Target value ± 3 SD	Target value ± 18%
Triiodothyronine (T3)	C1/C3/C3X/C4/CZ/CZX/CZ2X, K/KK	Target value ± 3 SD	Target value ± 30%
Thyroid-stimulating hormone (TSH)	C1/C3/C3X/C4/CZ/CZX/CZ2X, K/KK	Target value ± 3 SD	Target value ± 20% or 0.2 mIU/L (greater)
TOXICOLOGY			
Analyte		Current CMS Criteria	New CMS Criteria
Alcohol	AL1, AL2	Target value ± 25%	Target value ± 20%
Blood Lead	BL	Target value ± 10% or 4 mcg/dL (greater)	Target value ± 10% or 2 mcg/dL (greater)
Carbamazepine	CZ/CZX/CZ2X/Z	Target value ± 25%	Target value ± 20% or 1 mcg/mL (greater)
Digoxin	CZ/CZX/CZ2X/Z	Target value ± 20% or 0.2 ng/mL (greater)	Target value ± 15% or 0.2 ng/mL (greater)
Lithium	C1/C3/C3X/CZ/CZX/CZ2X/Z	Target value ± 20% or 0.3 mmol/L (greater)	Target value ± 15% or 0.3 mmol/L (greater)
Phenobarbital	CZ/CZX/CZ2X/Z	Target value ± 20%	Target value ± 15% or 2 mcg/mL (greater)
Phenytoin	CZ/CZX/CZ2X/Z	Target value ± 25%	Target value ± 15% or 2 mcg/mL (greater)
Theophylline	CZ/CZX/CZ2X/Z	Target value ± 25%	Target value ± 20%
Tobramycin	CZ/CZX/CZ2X/Z	Target value ± 25%	Target value ± 20%
Valproic Acid	CZ/CZX/CZ2X/Z	Target value ± 25%	Target value ± 20%
HEMATOLOGY			
Analyte		Current CMS Criteria	New CMS Criteria
Red blood cell count	FH1, FH2, FH3, FH4, FH9, FH10, FH13, FH16, FH17, HE	Target value + 6%	Target value ± 4%
Hematocrit	AQH, AQIS, FH1, FH2, FH3, FH4, FH9, FH10, FH13, FH16, FH17, HE, SO	Target value + 6%	Target value ± 4%

Hemoglobin	AQH, AQIS, FH1, FH2, FH3, FH4, FH9, FH10, FH13, FH16, FH17, HE, SO	Target value + 7%	Target value ± 4%
WBC count	FH1, FH2, FH3, FH4, FH9, FH10, FH13, FH16, FH17, HE	Target value + 15%	Target value ± 10%
Participants will be required to enroll in proficiency testing for both manual and automated blood cell differentials.			
IMMUNOLOGY			
Analyte		Current CMS Criteria	New CMS Criteria
Alpha-1-Antitrypsin	IG/IGX	Target value ± 3 SD	Target value ± 20%
Complement C3	IG/IGX	Target value ± 3 SD	Target value ± 15%
Complement C4	IG/IGX	Target value ± 3 SD	Target value ± 20% or 5 mg/dL (greater)
IgA	IG/IGX	Target value ± 3 SD	Target value ± 20%
IgE	IG/IGX, K/KK, SE	Target value ± 3 SD	Target value ± 20%
IgG	IG/IGX	Target value ± 25%	Target value ± 20%
IgM	IG/IGX	Target value ± 3 SD	Target value ± 20%
TRANSFUSION MEDICINE			
Unexpected antibody detection	J, JAT	Passing Score of 80%	Passing Score of 100%

Microbiology Specialty			
	Analyte/Method	Program Code(s)	
BACTERIOLOGY			
Antimicrobial Susceptibility Testing changing to 2 challenges per mailing		D, D2, RMC	
	<i>C. difficile</i>	CDF5, D, GIP5	
Bacterial Toxin Detection	Shigatoxin	GIP5	
Gram Stain Morphology		D, D2, D3, D5, RMC	
Detection of the Presence or Absence of Bacteria without Identification	For the subspecialty of Bacteriology, a reporting option of presence or absence of bacteria without identification will be allowed		
MYCOBACTERIOLOGY			
Mycobacteriology Identification	Molecular	MTR5	
Detection of the Presence or Absence of Mycobacteria without Identification	For the subspecialty of Mycobacteriology, a reporting option of presence or absence of mycobacteria without identification will be allowed		
MYCOLOGY			
Fungal Identification	Molecular	IDM5, MVP, VS, YBC	
Direct Fungal Antigen Detection		CRYP, F, F1	
Detection of the Presence or Absence of Fungi and Aerobic Actinomycetes without Identification	For the subspecialty of Mycology, a reporting option of presence or absence of fungi or aerobic actinomycetes without identification will be allowed		
PARASITOLOGY			
Identification of Parasites	Molecular	GIP5, MVP, STIM, TVG5, VS	
Direct Parasite Antigen Detection		P, P3, P4, P5, RML5	
Detection of the Presence or Absence of Parasites without Identification	For the subspecialty of Parasitology, a reporting option of presence or absence of parasites without identification will be allowed		
VIROLOGY			
No changes			