

QUALITY REQUIREMENTS

2024 CLIA Proposed Acceptance Limits for Proficiency Testing

In 2019 CLIA proposed a new set of quality requirements for proficiency testing. Here's what was listed in the Federal Register for public comment. **UPDATED! July 11, 2022: new goals slated for implementation in 2024! 23 changes for the 2024 goals - highlight in bold!!**

[For expert guidance on PT goals, consider the New Poor Lab's Guide to the Regulations](#)

Chemistry

Routine Chemistry CLIA 2024		
Analyte or Test	NEW Criteria for AP	OLD AP
Alanine aminotransferase (ALT/SGPT)	TV ± 15% or ± 6 U/L (greater)	TV ± 20%
Albumin	TV ± 8%	TV ± 10%
Alkaline Phosphatase	TV ± 20%	TV ± 30%
Amylase	TV ± 10%	TV ± 30%
AST	TV ± 15% or ± 6 U/L (greater)	TV ± 20%
Bilirubin, total	TV ± 20% or 0.4 mg/dL (greater)	Same
Blood gas pCO ₂	TV ± 5 mm Hg or ± 8% (greater)	Same
Blood gas pO ₂	TV ± 15 mm Hg or ± 15% (greater)	TV ± 3SD
Blood gas pH	TV ± 0.04	Same
B-natriuretic peptide (BNP)	TV ± 30%	None
Pro B-natriuretic peptide (proBNP)	TV ± 30%	None
Calcium, total	TV ± 1.0 mg/dL	Same
Carbon dioxide	TV ± 20%	None
Chloride	TV ± 5%	Same
Cholesterol, total	TV ± 10%	Same

Cholesterol, high density lipoprotein	TV ± 20% TV or ± 6 mg/dL (greater)	TV ± 30%
Cholesterol, low density lipoprotein (direct)	TV ± 20%	None
Creatine kinase (CK)	TV ± 20%	TV ± 30%
CK-MB isoenzymes	TV ± 25% TV or ± 3 ng/mL (greater) or MB elevated (presence or absence)	MB elevated (presence or absence)
Creatinine	TV ± 0.2 mg/dL or ± 10% (greater)	TV ± 0.2 mg/dL or ± 15% (greater)
Ferritin	TV ± 20%	None
Gamma glutamyl transferase	TV ± 5 U/L or ±15% (greater)	None
Glucose (excluding FDA home use)	TV ± 6 mg/dL or ± 8% (greater)	TV ± 6 mg/dL or ± 10% (greater)
Hemoglobin A1c	TV ± 8%	None
Iron, total	TV ± 15%	TV ± 20%
Lactate dehydrogenase (LDH)	TV ± 15%	TV ± 20%
Magnesium	TV ± 15%	TV ± 25%
Phosphorus	TV ± 0.3 mg/dL or 10% (greater)	None
Potassium	TV ± 0.3 mmol/L	TV ± 0.5 mmol/L
Prostate Specific Antigen, total	TV ± 0.2 ng/dL or 20% (greater)	None
Sodium	TV ± 4 mmol/L	Same
Total Iron Binding Capacity (direct)	TV ± 20%	None
Total Protein	TV ± 8%	TV ± 10%
Triglycerides	TV ± 15%	TV ± 25%
Troponin I	TV ± 0.9 ng/mL or 30% (greater)	None
Troponin T	TV ± 0.2 ng/mL or 30% (greater)	None
Urea Nitrogen	TV ± 2 mg/dL or ± 9% (greater)	Same
Uric Acid	TV ± 10%	TV ± 17%

Immunology

Immunology CLIA 2019-2024		
Analyte or Test	NEW Criteria for AP	OLD AP
Alpha-1 antitrypsin	TV ± 20% or positive or negative	TV ± 3 SD
Alpha-fetoprotein (tumor marker)	TV ± 20% or positive or negative	TV ± 3 SD
Antinuclear antibody	TV ± 2 dilutions or pos or neg	same

Antistreptolysin O	TV ± 2 dilutions or pos or neg	same
Anti-Human Immunodeficiency virus (HIV)	Reactive (pos) or nonreactive (neg)	Same
Complement C3	TV ± 15%	TV ± 3 SD
Complement C4	TV ± 5 mg/dL or ± 20% (greater)	TV ± 3 SD
C-reactive protein (HS)	TV ± 1 mg/dL or ± 30% (greater)	None
HBsAg	Reactive (pos) or nonreactive (neg)	Reactive (pos) or nonreactive (neg)
anti-HBc	Reactive (pos) or nonreactive (neg)	Reactive (pos) or nonreactive (neg)
HBeAg	Reactive (pos) or nonreactive (neg)	Reactive (pos) or nonreactive (neg)
Anti-HBs	Reactive (pos) or nonreactive (neg)	Reactive (pos) or nonreactive (neg)
Anti-HCV	Reactive (pos) or nonreactive (neg)	Reactive (pos) or nonreactive (neg)
IgA	TV ± 20%	TV ± 3SD
IgE	TV ± 20%	TV ± 3SD
IgG	TV ± 20%	TV ± 3SD
IgM	TV ± 20%	TV ± 3SD
Infectious mononucleosis	TV ± 2 dilutions or pos or neg	same
Rheumatoid factor	TV ± 2 dilutions or pos or neg	same
Rubella	TV ± 2 dilutions or pos or neg or immune or nonimmune	same

Endocrinology

Endocrinology CLIA 2024		
Analyte or Test	NEW Criteria for AP	OLD AP
Cancer antigen (CA) 125	TV ± 20%	None
Carcinoembryonic antigen (CEA)	TV ± 15% or ± 1 ng/dL (greater)	None
Cortisol	TV ± 20%	TV ± 25%
Estradiol	TV ± 30%	None
Folate, serum	TV ± 1 ng/mL or ± 30% (greater)	None
Follicle stimulating hormone	TV ± 2 IU/L or ± 18% (greater)	None
Free throxine	TV ± 0.3 ng/dL or ± 15% (greater)	TV ± 3SD

Human chorionic gonadotropin	TV ± 18% or ± 3 mIU/mL (greater) or positive or negative	TV ± 3SD or positive or negative
Luteinizing hormone	TV ± 20%	None
Parathyroid hormone	TV ± 30%	None
Progesterone	TV ± 25%	None
Prolactin	TV ± 20%	None
Testosterone	TV ± 20 ng/dL or ±30% (greater)	None
T3 uptake	TV ± 18%	TV ± 3SD
Triiodothyronine	TV ± 30%	TV ± 3SD
Thyroid stimulating hormone	TV ± 20% or ± 2 mIU/L (greater)	TV ± 3SD
Thyroxine	TV ± 20% or ± 1.0 mcg/dL (greater)	Same
Vitamin B12	TV ± 25% or ± 30 pg/mL (greater)	TV ± 30%

Toxicology

Toxicology CLIA 2024		
Analyte or Test	NEW Criteria for AP	OLD AP
Acetaminophen	TV ± 15% or or ± 3 mcg/dL (greater)	None
Alcohol, blood	TV ± 20%	TV ± 25%
Blood lead	TV ± 10% or 2mcg/dL (greater)	TV ± 10% or ±4 mcg/dL (greater)
Carbamazepine	TV ± 20% or ± 1.0 mcg/dL (greater)	TV ± 25%
Digoxin	TV ± 15% or ± 0.2 ng/mL (greater)	None
Gentamicin	TV ± 25%	Same
Lithium	TV ± 15% or ± 0.3 mmol/L (greater)	TV ± 0.3 mmol/L or 20% (greater)
Phenobarbital	TV ± 15% or ± 2 mcg/mL (greater)	TV ± 20%
Phenytoin	TV ± 15% or ± 2 mcg/dL (greater)	TV ± 25%
Salicylate	TV ± 15% or ± 2 mcg/dL (greater)	None
Theophylline	TV ± 20%	TV ± 25%
Tobramycin	TV ± 20%	TV ± 25%
Valproic acid	TV ± 20%	TV ± 25%
Vancomycin	TV ± 15% or ± 2 mcg/dL (greater)	None