

2019 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.

For expert guidance on PT goals, consider the New Poor Lab's Guide to the Regulations

Chemistry

Routine Chemistry CLIA 2019		
Analyte or Test	NEW Criteria for AP	OLD AP
Alanine aminotransferase (ALT/SGPT)	TV \pm 15%	TV \pm 20%
Albumin	TV \pm 8%	TV \pm 10%
Alkaline Phosphatase	TV \pm 20%	TV \pm 30%
Amylase	TV \pm 10%	TV \pm 30%
AST	TV \pm 15%	TV \pm 20%
Bilirubin, total	TV \pm 20%	TV \pm 20% or 0.4 mg/dL (greater)
Blood gas pCO ₂	TV \pm 5mm Hg or \pm 8% (greater)	Same
Blood gas pO ₂	TV \pm 15 mm Hg or \pm 15% (greater)	TV \pm 3SD
Blood gas pH	TV \pm 0.04	Same
B-natriuretic peptide (BNP)	TV \pm 30%	None
Pro B-natriuretic peptide (proBNP)	TV \pm 30%	None
Calcium, total	TV \pm 1.0 mg/dL	Same
Carbon dioxide	TV \pm 20%	None
Chloride	TV \pm 5%	Same
Cholesterol, total	TV \pm 10%	Same
Cholesterol, high density liprotein	TV \pm 20%	TV \pm 30%
Cholesterol, low density lipoprotein (direct)	TV \pm 20%	None

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

Immunology

Immunology CLIA 2019		
Analyte or Test	NEW Criteria for AP	OLD AP
Alpha-1 antitrypsin	TV \pm 20% or positive or negative	TV \pm 3 SD
Alpha-fetoprotein (tumor marker)	TV \pm 20% or positive or negative	TV \pm 3 SD
Antinuclear antibody	TV \pm 3 SD or positive or negative	TV \pm 2 dilutions or pos or neg
Antistreptolysin O	TV \pm 3 SD or positive or negative	TV \pm 2 dilutions or pos or neg
Anti-Human Immunodeficiency virus (HIV)	Reactive (pos) or nonreactive (neg)	Same
Complement C3	TV \pm 15% or positive or negative	TV \pm 3 SD
Complement C4	TV \pm 5 mg/dL or \pm 20% (greater)	TV \pm 3 SD
C-reactive protein (HS)	TV \pm 1 mg/dL or \pm 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)
HB3Ag	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 \pm 15%	TV \pm 3SD
IgE	TV \pm 20%	TV \pm 3SD
IgG	TV \pm 20%	TV \pm 3SD
IgM	TV \pm 20%	TV \pm 3SD
Infectious mononucleosis	Positive or negative	TV \pm 2 dilutions or pos or neg
Rheumatoid factor	TV \pm 3 SD or positive or negative	TV \pm 2 dilutions or pos or neg

Rubella	TV \pm 3 SD or positive or negative	TV \pm 2 dilutions or pos or neg
---------	---------------------------------------	------------------------------------

Endocrinology

Endocrinology CLIA 2019		
Analyte or Test	NEW Criteria for AP	OLD AP
Cancer antigen (CA) 125	TV \pm 20%	None
Carcinoembryonic antigen (CEA)	TV \pm 15%	None
Cortisol	TV \pm 20%	TV \pm 25%
Estradiol	TV \pm 30%	None
Folate, serum	TV \pm 1 ng/mL or \pm 30% (greater)	None
Follicle stimulating hormone	TV \pm 2 IU/L or \pm 18% (greater)	None
Free throxine	TV \pm 0.3 ng/dL or \pm 15% (greater)	TV \pm 3SD
Human chorionic gonadotropin	TV \pm 18% or positive or negative	TV \pm 3SD or positive or negative
Luteinizing hormone	TV \pm 20%	None
Parathyroid hormone	TV \pm 30%	None
Progesterone	TV \pm 25%	None
Prolactin	TV \pm 20%	None
Testosterone	TV \pm 20 ng/dL or \pm 30% (greater)	None
T3 uptake	TV \pm 18%	TV \pm 3SD
Triiodothyronine	TV \pm 30%	TV \pm 3SD
Tyroid stimulating hormone	TV \pm 20% or \pm 2 mIU/L (greater)	TV \pm 3SD
Thyroxine	TV \pm 20% or \pm 1.0 mcg/dL (greater)	Same
Vitamin B12	TV \pm 25%	TV \pm 30%

Toxicology

Toxicology CLIA 2019		
Analyte or Test	NEW Criteria for AP	OLD AP
Acetaminophen	TV \pm 15%	None
Alcohol, blood	TV \pm 20%	TV \pm 25%
Blood lead	TV \pm 10% or 2mcg/dL (greater)	TV \pm 10% or \pm 4 mcg/dL (greater)
Carbamazepine	TV \pm 20%	TV \pm 25%
Digoxin	TV \pm 15% or \pm 2 ng/mL (greater)	None
Gentamicin	TV \pm 25%	Same
Lithium	TV \pm 15%	TV \pm 0.3 mmol/L or 20% (greater)
Phenobarbital	TV \pm 15%	TV \pm 20%
Phenytoin	TV \pm 15% or \pm 2 mcg/dL (greater)	TV \pm 25%
Salicylate	TV \pm 15%	None
Theophylline	TV \pm 20%	TV \pm 25%
Tobramycin	TV \pm 20%	TV \pm 25%
Valproic acid	TV \pm 20%	TV \pm 25%
Vancomycin	TV \pm 15% or \pm 2 mcg/dL (greater)	None

Hematology

Hematology CLIA 2019		
Analyte or Test	NEW Criteria for AP	OLD AP
Cell identification	80% or greater consensus	90% or greater consensus
White blood cell differential	TV \pm 3 SD	Same
Erythrocyte count	TV \pm 4%	TV \pm 6%
Hematocrit	TV \pm 4%	TV \pm 6%
Hemoglobin	TV \pm 4%	TV \pm 7%
Leukocyte count	TV \pm 5%	TV \pm 15%
Platelet count	TV \pm 25%	Same
Fibrinogen	TV \pm 20%	Same

Partial thromboplastin time	$TV \pm 15\%$	Same
Prothrombin time	$TV \pm 15\%$	Same