

# CLIA Proficiency Testing criteria

The tables below contain information on CLIA proficiency testing criteria for acceptable analytical performance, as printed in the Federal Register February 28, 1992;57(40):7002-186. These guidelines for acceptable performance can be used as Analytical Quality Requirements in the Westgard QC Design and Planning process.



## CLIA Final Rules for Quality System

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**You can skip ahead to specific areas of laboratory tests by clicking on the listed items:**

- [Routine Chemistry](#)
- [Toxicology](#)
- [Hematology](#)
- [Endocrinology](#)
- [General Immunology](#)

<b>Routine Chemistry</b>	
Test or Analyte	Acceptable Performance
Alanine aminotransferase	Target value $\pm$ 20%
Albumin	Target value $\pm$ 10%
Alkaline phosphatase	Target value $\pm$ 30%
Amylase	Target value $\pm$ 30%
Aspartate aminotransferase (AST)	Target value $\pm$ 20%
Bilirubin, total	Target value $\pm$ 0.4 mg/dL or $\pm$ 20% (greater)
Blood gas pO <sub>2</sub>	Target value $\pm$ 3 SD
Blood gas pCO <sub>2</sub>	Target value $\pm$ 5 mm Hg or $\pm$ 8% (greater)
Blood gas pH	Target value $\pm$ 0.04
Calcium, total	Target value $\pm$ 1.0 mg/dL
Chloride	Target value $\pm$ 5%
Cholesterol, total	Target value $\pm$ 10%
Cholesterol, high dens. lipoprotein	Target value $\pm$ 30%
Creatine kinase	Target value $\pm$ 30%
Creatine kinase isoenzymes	MB elevated (present or absent) or Target value $\pm$ 3 SD Creatinine
Creatinine	Target value $\pm$ 0.3 mg/dL or $\pm$ 15% (greater)
Glucose	Target value $\pm$ 6 mg/dL or $\pm$ 10% (greater)
Iron, total	Target value $\pm$ 20%
Lactate dehydrogenase (LDH)	Target value $\pm$ 20%
LDH isoenzymes	LDH1/LDH2 (+ or -) or Target value $\pm$ 30%
Magnesium	Target value $\pm$ 25%
Potassium	Target value $\pm$ 0.5 mmol/L
Sodium	Target value $\pm$ 4 mmol/L
Total protein	Target value $\pm$ 10%
Triglycerides	Target value $\pm$ 25%
Urea Nitrogen	Target value $\pm$ 2 mg/dL or $\pm$ 9% (greater)
Uric acid	Target value $\pm$ 17%

<b>Toxicology</b>	
Alcohol, blood	Target value $\pm$ 25%
Blood lead	Target value $\pm$ 10% or $\pm$ 4 mcg/dL (greater)
Carbamazepine	Target value $\pm$ 25%
Digoxin	Target value $\pm$ 20% or $\pm$ 0.2 ng/mL (greater)
Ethosuximide	Target value $\pm$ 20%
Gentamicin	Target value $\pm$ 25%
Lithium	Target value $\pm$ 0.3 mmol/L or $\pm$ 20% (greater)
Phenobarbital	Target value $\pm$ 20%
Phenytoin	Target value $\pm$ 25%
Primidone	Target value $\pm$ 25%
Procainamide (and metabolite)	Target value $\pm$ 25%
Quinidine	Target value $\pm$ 25%
Theophylline	Target value $\pm$ 25%
Tobramycin	Target value $\pm$ 25%
Valproic acid	Target value $\pm$ 25%

<b>Hematology</b>	
Test or Analyte	Acceptable Performance
Cell identification	90% or greater consensus on identification
White cell differentiation	Target $\pm$ 3 SD based on percentage of different types of white cells
Erythrocyte count	Target $\pm$ 6%
Hematocrit	Target $\pm$ 6%
Hemoglobin	Target $\pm$ 7%
Leukocyte count	Target $\pm$ 15%
Platelet count	Target $\pm$ 25%
Fibrinogen	Target $\pm$ 20%
Partial thromboplastin time	Target $\pm$ 15%
Prothrombin time	Target $\pm$ 15%

<b>Endocrinology</b>	
Test or Analyte	Acceptable Performance
Cortisol	Target value $\pm$ 25%
Free thyroxine	Target value $\pm$ 3 SD
Human chorionic gonadotropin	Target value $\pm$ 3 SD or (positive or negative)
T3 uptake	Target value $\pm$ 3 SD by method
Triiodothyronine	Target value $\pm$ 3 SD
Thyroid stimulating hormone	Target value $\pm$ 3 SD
Thyroxine	Target value $\pm$ 20% or 1.0 mcg/dL (greater)

<b>General immunology</b>	
Test or Analyte	Acceptable Performance
Alpha-1 antitrypsin	Target value $\pm$ 3 SD
Alpha-fetoprotein	Target value $\pm$ 3 SD
Antinuclear antibody	Target value $\pm$ 2 dilution or (pos. or neg.)
Antistreptolysin O	Target value $\pm$ 2 dilution or (pos. or neg.)
Anti-Human Immunodeficiency virus	Reaction or nonreactive
Complement C3	Target value $\pm$ 3 SD
Complement C4	Target value $\pm$ 3 SD
Hepatitis (HBsAg, anti-HBc, HBeAg)	Reactive (positive) or nonreactive (negative)
IgA	Target value $\pm$ 3 SD
IgE	Target value $\pm$ 3 SD
IgG	Target value $\pm$ 25%
IgM	Target value $\pm$ 3 SD
Infectious mononucleosis	Target value $\pm$ 2 dilution or (pos. or neg.)
Rheumatoid factor	Target value $\pm$ 2 dilution or (pos. or neg.)
Rubella	Target value $\pm$ 2 dilution or (pos. or neg.)