

## Currently Regulated Analytes and Their Criteria for Acceptable Performance

### Sec. 493.927 General Immunology

Analyte	Criteria for Acceptable Performance
Alpha-1 antitrypsin	Target value $\pm 3$ SD
Alpha-fetoprotein (tumor marker)	Target value $\pm 3$ SD
Antinuclear antibody	Target value $\pm 2$ dilutions or positive or negative
Antistreptolysin O	Target value $\pm 2$ dilution or positive or negative
Anti-Human Immunodeficiency virus	Reactive 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 positive or negative
Rheumatoid Factor	Target value $\pm 2$ dilution or positive or negative
Rubella	Target value $\pm 2$ dilutions or immune or nonimmune or positive or negative

## Currently Regulated Analytes and Their Criteria for Acceptable Performance

### Sec. 493.931 Routine Chemistry

Analyte	Criteria for Acceptable Performance
Alanine aminotransferase (ALT/SGPT)	Target value $\pm$ 20%
Albumin	Target value $\pm$ 10%
Alkaline phosphatase	Target value $\pm$ 30%
Amylase	Target value $\pm$ 30%
Aspartate aminotransferase (AST/SGOT)	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
pCO <sub>2</sub>	Target value $\pm$ 5 mm Hg or $\pm$ 8% (greater)
pH	Target value $\pm$ .04
Calcium, total	Target value $\pm$ 1.0 mg/dL
Chloride	Target value $\pm$ 5%
Cholesterol, total	Target value $\pm$ 10%
Cholesterol, high density lipoprotein	Target value $\pm$ 30%
Creatine kinase	Target value $\pm$ 30%
Creatine kinase isoenzymes	Creatine kinase isoenzymes
Creatinine	Target value $\pm$ 0.3 mg/dL or $\pm$ 15% (greater)
Glucose (excluding monitoring devices cleared by FDA for home use)	Target value $\pm$ 6 mg/dL or $\pm$ 20% (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%

## Currently Regulated Analytes and Their Criteria for Acceptable Performance

### Sec. 493.933 Endocrinology

Analyte	Criteria for Acceptable Performance
Cortisol	Target value $\pm 25\%$
Free Thyroxine	Target value $\pm 3$ SD
Human Chorionic Gonadotropin (excluding urine pregnancy tests done by visual color comparison categorized as waived tests)	Target value $\pm 3$ SD positive or negative
T3 Uptake	Target value $\pm 3$ SD
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)

### Sec. 493.937 Toxicology

Analyte	Criteria for Acceptable Performance
Alcohol, blood	Target value $\pm 25\%$
Blood Lead	Target Value $\pm 10\%$ or 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 $\pm 3$ SD
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 $\pm 25\%$
Tobramycin	Target Value $\pm 25\%$
Theophylline	Target Value $\pm 25\%$
Valproic Acid	Target Value $\pm 25\%$

## Currently Regulated Analytes and Their Criteria for Acceptable Performance

### Sec. 493.941 Hematology

Analyte	Criteria for Acceptable Performance
Cell identification	80% or greater consensus on identification
White blood cell differential	Target $\pm$ 3SD based on the percentage of different types of white blood cells in the samples
Erythrocyte count	Target $\pm$ 6%
Hematocrit (Excluding spun hematocrits)	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%

### Sec. 493.959 Immunohematology

Analyte	Criteria for Acceptable Performance
ABO group	100% accuracy
D (Rho) typing	100% accuracy
Unexpected antibody detection	80% accuracy
Compatibility testing	100% accuracy
Antibody identification	80% accuracy