

Sun Diagnostics has compiled this list of Total Allowable Error limits for a variety of laboratory tests as defined by CLIA or other industry standards. This list is intended as a reference only.

**Laboratories are responsible for setting their own performance criteria.**

<b>Chemistry Analyte</b>	<b>Limit</b>	<b>Source</b>
Albumin (ALB)	± 10%	CLIA
Alkaline Phosphatase (ALP)	± 30%	CLIA
Alanine Aminotransferase (ALT)	± 20%	CLIA
Amylase (AMY)	± 30%	CLIA
Aspartate Aminotransferase (AST)	± 20%	CLIA
Bilirubin, Total (TBILI)	± 0.4 mg/dL or 20% (greater)	CLIA
Calcium (CA)	± 1.0 mg/dL	CLIA
Cholesterol, Total (CHOL)	± 10%	CLIA
	± 9%	NCEP
HDL Cholesterol (HDL-C)	± 30%	CLIA
	± 13%	NCEP
LDL Cholesterol (LDL-C)	± 12%	NCEP
Chloride (CL)	± 5%	CLIA
Creatine Kinase (CK)	± 30%	CLIA
Creatinine (CREA)	± 0.3 mg/dL or 15% (greater) ± 7.6% (desirable), ± 11.4% (minimum)	CLIA NKDEP
Glucose (GLU)	± 6 mg/dL or 10% (greater)	CLIA
Hemoglobin A1c (HbA1c)	± 6%	NGSP
IRON (FE)	± 20%	CLIA
Lactate Dehydrogenase (LDH)	± 20%	CLIA
Magnesium (MG)	± 25%	CLIA
PCO <sub>2</sub>	± 5 mmHg or 8% (greater)	CLIA
pH	± 0.04	CLIA
PO <sub>2</sub>	± 3 SD	CLIA
Potassium (K)	± 0.5 mmol/L	CLIA
Protein, Total (TP)	± 10%	CLIA
Sodium (NA)	± 4 mmol/L	CLIA
Triglycerides (TRIG)	± 25%	CLIA
	± 15%	NCEP
Urea (UREA)	± 2 mg/dL or 9% (greater)	CLIA
Uric Acid (UA)	± 17%	CLIA

**RECOMMENDED  
TOTAL ALLOWABLE ERROR LIMITS**

Therapeutic Drugs and Drugs of Abuse	Limit	Source
Ethanol	± 25% ± 10%	CLIA NYS
Acetaminophen	± 15%	NYS
Carbamazepine	± 25% ± 15%	CLIA NYS
Digoxin	± 0.2 ng/mL or 20% (greater) ± 0.2 ng/mL or 15% (greater)	CLIA NYS
Gentamicin	± 25% ± 15%	CLIA NYS
Lithium	± 0.3 mmol/L or 20% (greater) ± 0.3 mmol/L or 15% (greater)	CLIA NYS
NAPA	± 25%	NYS
Phenobarbital	± 20% ± 15%	CLIA NYS
Phenytoin	± 25% ± 15%	CLIA NYS
Primidome	± 25% ± 15%	CLIA NYS
Procainamide	± 25%	CLIA
Quinidine	± 25% ± 15%	CLIA NYS
Theophylline	± 25% ± 15%	CLIA NYS
Tobramycin	± 25% ± 15%	CLIA NYS
Valproic acid	± 25% ± 15%	CLIA NYS
Vancomycin	± 15%	NYS

<b>Endocrinology and Immunology Analytes</b>	<b>Limit</b>	<b>Source</b>
IgG	± 25%	CLIA
Cortisol	± 25%	CLIA
Free Thyroxine (FT4)	± 3 SD	CLIA
Human Chorionic Gonadotropin (HCG)	± 3 SD	CLIA
Triiodothyronine (T3)	± 3 SD	CLIA
T3 Uptake	± 3 SD	CLIA
Thyroxine (T4)	± 1.0 µg/dL or 20% (greater)	CLIA
Thyroid Stimulating Hormone (TSH)	± 3 SD	CLIA
Free Triiodothyronine (FT3)	± 0.5 pg/mL or 25% (greater)	NYS
Vitamin B12	± 25%	NYS
Folic Acid	± 2.0 ng/mL or 30% (greater)	NYS
Insulin	± 3.0 µU/mL or 25% (greater)	NYS
Free Estriol	± 3.0 ng/mL or 25% (greater)	NYS
Estradiol	± 15 pg/mL or 25% (greater)	NYS
Testosterone	± 20 ng/mL or 25% (greater)	NYS
Progesterone	± 1.0 ng/mL or 25% (greater)	NYS
Dehydroepiandrosterone sulfate (DHEA-S)	± 15 µg/dL or 25% (greater)	NYS
Luteinizing Hormone (LH)	± 1.5 mIU/mL or 25% (greater)	NYS
Follicle Stimulating Hormone (FSH)	± 2.0 mIU/mL or 25% (greater)	NYS
Prolactin	± 2.0 µg/dL or 25% (greater)	NYS
25-OH Vitamin D	± 3.0 ng/mL or 25% (greater)	NYS
Parathyroid Hormone, Intact (PTH)	± 10 pg/mL or 30% (greater)	NYS

<b>Hematology Analytes</b>	<b>Limit</b>	<b>Source</b>
Activated Partial Thromboplastin Time (APTT)	± 15%	CLIA
Erythrocyte Count (RBC)	± 6%	CLIA
Fibrinogen	± 20%	CLIA
Hematocrit (HCT)	± 6%	CLIA
Hemoglobin (HGB)	± 7%	CLIA
Platelet Count (PLT)	± 25%	CLIA
Prothrombin Time (PT)	± 15%	CLIA
Leukocyte Count (WBC)	± 15%	CLIA

Note: Sources are not listed if they agree with CLIA.

**SOURCES:**

1. CLIA, CFR Part 439
  - a. Routine Chemistry: [http://www.cdc.gov/clia/regs/subpart\\_i.aspx](http://www.cdc.gov/clia/regs/subpart_i.aspx)
  - b. Toxicology: [http://www.cdc.gov/clia/regs/subpart\\_i.aspx](http://www.cdc.gov/clia/regs/subpart_i.aspx)
2. New York State Dept. of Health (NYSDOH) Clinical Laboratory Evaluation Program.
  - a. Clinical Chemistry: <http://www.wadsworth.org/chemheme/chem/genc/ccpt.htm>
  - b. Therapeutic Substances: <http://www.wadsworth.org/chemheme/chem/tsm/tsmpt.htm>
  - c. Endocrinology: <http://www.wadsworth.org/chemheme/chem/endo/endo.htm>
2. National Cholesterol Education Program: Recommendations for improving cholesterol measurement. a report from the Laboratory Standardization Panel of the National Cholesterol Education Program. NIH Publication No. 90-2964, Bethesda, Maryland, February, 1990.
3. Bachorik PS, Ross JW, for the NCEP Working Group on Lipoprotein Measurement. National Cholesterol Education Program recommendations for measurement of low-density lipoprotein cholesterol: executive summary. Clin Chem 1995;41:1414-20.
4. Stein EA, Myers GL, for the NCEP Working Group on Lipoprotein Measurement. National Cholesterol Education Program recommendations for triglyceride measurement: executive summary. Clin Chem 1995;41:1421-6.
5. Warnick GR, Wood PD, for the NCEP Working Group on Lipoprotein Measurement. National Cholesterol Education Program recommendations for measurement of high-density lipoprotein cholesterol: executive summary. Clin Chem 1995;41:1427-33.
6. National Glycohemoglobin Standardization Program (NGSP), [www.ngsp.org](http://www.ngsp.org).
7. Myers GL, Miller WG, Coresh J, Fleming J, Greenberg N, Greene T, et al. Recommendations for improving serum creatinine measurement: a report from the Laboratory Working Group of the National Kidney Disease Education Program. Clin Chem 2006; 52: 5-18.