CLIA '88 AND GRADING

The Clinical Laboratory Improvement Amendment of 1988 (CLIA '88) is a regulation established by the federal government (CMS) to regulate clinical laboratories and proficiency test providers like API.

One of the things specified by CLIA '88 is the way that proficiency test results will be graded. The method by which an analyte is graded depends on whether the test is quantitative (e.g., the amount of Cholesterol in a blood sample) or qualitative (e.g., a blood sample Positive/Negative for Infectious Mono).

HOW YOUR RESULTS ARE GRADED (QUALITATIVE)

Qualitative results are graded based on 80% agreement (called "consensus") of participants giving a particular answer or group of clinically correct answers. The only exception to this is Immunohematology results which are based on 95% consensus. In cases where participants do not reach a consensus, a consensus of referee laboratories will be used. If the proper consensus is not reached, the sample is not graded.

HOW YOUR RESULTS ARE GRADED (QUANTITATIVE)

The criteria used to evaluate your quantitative results are based on a target value (mean) ± a fixed amount. This fixed amount is determined by CLIA '88 for each analyte and is expressed as a percentage, a specific quantity, or a number of standard deviations. The grading criteria are listed below.

The target value is the mean (average) value of your comparison group. A comparison group (peer group) may consist of those laboratories that use the same instrument or reagent as you, or those laboratories that use the same method principle. A comparison group of "All Participants" (all facilities performing that test) may also be used as well as a group of referee laboratories. The comparison group must contain at least 10 laboratories. In cases where an appropriate comparison group cannot be found, no grading criteria is applied. In addition, only samples with at least 80% consensus are graded.

CHEMISTRY Allowed variance from target value

Alpha-fetoprotein	± 3 SD

ENDOCRINOLOGY	Allowed variance from target value
Cortisol	± 25 percent
Free Thyroxine	± 3 SD
HCG	± 3 SD or ± 10 mIU/mL whichever is greater
T-Uptake	± 3 SD
Thyroid Stimulating Hormone	± 3 SD
Thyroxine	± 1 µg/dL or ± 20 percent whichever is greater
Triiodothyronine	± 3 SD

GENERAL IMMUNOLOGY	Allowed variance from target value
Alpha-1-Antitrypsin	± 3 SD
Anti-Streptolysin O	± 2 SD or ± 25 IU/mL whichever is greater
Complement C3	± 3 SD
Complement C4	± 3 SD
IgA	± 3 SD
IgE	± 3 SD
IgG	± 25 percent
IgM	± 3 SD
Rheumatoid Factor	± 3 SD or ± 20 IU/mL whichever is greater
Rubella Antibody	± 3 SD or ± 10 IU/mL whichever is greater

HEMATOLOGY	Allowed variance from target value
Cell ID or White Bld Cell Diff	± 3 SD or ± 1 whichever is greater
Erythrocyte Count	± 6 percent
Fibrinogen	± 20 percent
Hematocrit	± 6 percent
Hemoglobin	± 7 percent
Leukocyte Count	± 15 percent
Partial Thromb. Time (APTT)	± 15 percent

Platelet Count	± 25 percent
Prothrombin Time	± 15 percent

ROUTINE CHEMISTRY	Allowed variance from target value
Albumin	± 10 percent
Alkaline Phosphatase	± 30 percent
ALT / SGPT	± 20 percent
Amylase	± 30 percent
AST / SGOT	± 20 percent
Bilirubin, Total	± 0.4 mg/dL or ± 20 percent whichever is greater
Calcium, Total	± 1 mg/dL
Chloride	± 5 percent
Cholesterol, HDL	± 30 percent
Cholesterol, Total	± 10 percent
Creatine Kinase / CK	± 30 percent
Creatine Kinase, Isoenzyme	± 3 SD or ± 3 ng/mL whichever is greater
Creatine Kinase, Isoenzyme	± 3 SD or ± 3 U/L whichever is greater
Creatinine	± 0.3 mg/dL or ± 15 percent whichever is greater
Glucose	± 6 mg/dL or ± 10 percent whichever is greater
Iron, Total	± 20 percent
LD / LDH	± 20 percent
Magnesium	± 25 percent
pCO2	± 5 mmHg or ± 8 percent whichever is greater
pH	± 0.04
pO2	± 3 SD
Potassium	± 0.5 mmol/L
Sodium	± 4 mmol/L
Total Protein	± 10 percent
Triglycerides	± 25 percent
Urea Nitrogen	± 2 mg/dL or ± 9 percent whichever is greater

Uric Acid	± 17 percent

TOXICOLOGY	Allowed variance from target value
Alcohol	± 10 mg/dL or ± 25 percent whichever is greater
Blood Lead	± 4 µg/dL or ± 10 percent whichever is greater
Carbamazepine	± 25 percent
Digoxin	± 0.2 ng/mL or ± 20 percent whichever is greater
Ethosuximide	± 20 percent
Gentamicin	± 25 percent
Lithium	± 0.3 mmol/L or ± 20 percent whichever is greater
Phenobarbital	± 20 percent
Phenytoin	± 25 percent
Primidone	± 25 percent
Procainamide (and Metabolite)	± 25 percent
Quinidine	± 25 percent
Theophylline	± 25 percent
Tobramycin	± 25 percent
Valproic Acid	± 25 percent

All other analytes are considered 'not scored' by CLIA '88 and are graded using a criteria of Target Value ± 2 SD except as noted below:

NOT SCORED FOR CMS	Allowed variance from target value
Acetaminophen	± 3 SD or ± 2.5 µg/mL whichever is greater
ACT (Hemochron / Helena)	± 3 SD
ACT (Hemochron Jr + / IL +)	± 3 SD
ACT (Hemochron Jr / IL - LR)	± 3 SD
ACT (i-STAT)	± 3 SD
ACT (Medtronic)	± 3 SD
Allergen Specific IgE (quan)	± 3 SD
Alpha (TEG-5000)	± 3 SD

Alpha angles (ROTEM)	± 3 SD
Ammonia	± 2 SD or ± 10 µmol/L whichever is greater
Anti-A Titer (Other, Cut-off)	±
Anti-CCP (quan)	± 3 SD or ± 5 U/mL whichever is greater
Anti-D Titer (Other, Cut-off)	±
Anti-Xa Hybrid curve	± 3 SD
Anti-Xa LMWH curve	± 3 SD
Anti-Xa UFH curve	± 3 SD
APTT (HA)	± 15 percent
Aspirin Induced Inhibition	± 3 SD or ± 50 ARU whichever is greater
Bacteria (UMS)	± 3 SD or ± 5 cells/uL whichever is greater
Basophils (CSF/body fluid)	± 3
Beta-Hydroxybutyrate	± 3 SD or ± 0.2 mmol/L whichever is greater
Bilirubin, Direct	± 2 SD or ± 0.4 mg/dL whichever is greater
Bilirubin, Direct (Neonatal)	± 2 SD or ± 0.4 mg/dL whichever is greater
BNP (CM)	± 3 SD or ± 10 pg/mL whichever is greater
Body Fluid Albumin	± 3 SD or ± 10 percent whichever is greater
Body Fluid Amylase	± 30 percent
Body Fluid Cholesterol	± 3 SD
Body Fluid Creatinine	± 0.3 mg/dL or ± 15 percent whichever is greater
Body Fluid Glucose	± 6 mg/dL or ± 10 percent whichever is greater
Body Fluid LDH	± 20 percent
Body Fluid pH (color comp)	± 1
Body Fluid Total Protein	± 3 SD or ± 10 percent whichever is greater
Body Fluid Triglycerides	± 3 SD or ± 10 mg/dL whichever is greater
Body Fluid Urea Nitrogen	± 2 mg/dL or ± 9 percent whichever is greater
C-Reactive Protein (hs)	± 2 SD or ± 0.2 mg/dL whichever is greater
C-Reactive Protein (quan)	± 2 SD or ± 0.3 mg/dL whichever is greater
Calcium, Ionized (Blood Gas)	± 3 SD or ± 0.05 mmol/L whichever is greater
Calcium, Ionized (i-STAT)	± 3 SD or ± 0.05 mmol/L whichever is greater
Calcium, Ionized (serum)	± 3 SD or ± 0.05 mmol/L whichever is greater

Carbamazepine (Free)	± 25 percent
Carboxyhemoglobin	± 3 SD or ± 3 whichever is greater
Carboxyhemoglobin (Pilot)	± 3 SD
Casts (UMS)	± 3 SD or ± 1 /uL whichever is greater
CEA (Immunoassay)	± 3 SD
CEA (Tumor Markers)	± 3 SD
CFF FLEV (TEG 6s)	± 3 SD
CFF Max Amplitude(MA) (TEG 6s)	± 3 SD
CFT (ROTEM)	± 3 SD
CK Alpha (a) angles (TEG 6s)	± 3 SD
CK K-Time (K) (TEG 6s)	± 3 SD
CK Max Amplitude (MA) (TEG 6s)	± 3 SD
CK R-Time (R) (TEG 6s)	± 3 SD
CKH R-Time (R) (TEG 6s)	± 3 SD
CO2	± 3 SD
Conductivity	± 3 SD
Creatinine (UAD quant)	± 2 SD or ± 20 percent whichever is greater
CRT Max Amplitude(MA) (TEG 6s)	± 3 SD
Crystals (Iris, quan)	± 10
CSF Glucose	± 6 mg/dL or ± 10 percent whichever is greater
CSF Lactic Acid	± 3 SD or ± 0.4 mmol/L whichever is greater
CSF Total Protein	± 3 SD or ± 20 percent whichever is greater
CT (ROTEM)	± 3 SD
Cystatin C	± 3 SD
D-dimer (CM)	± 3 SD
D-dimer (quan)	± 3 SD
D-dimer (quan)	± 3 SD or ± 10 µg/L whichever is greater
Digoxin (Free)	± 0.2 ng/mL or ± 20 percent whichever is greater
Eosinophils (CSF/body fluid)	± 6
Epithelial Cells (UMS)	± 3 SD or ± 1 cells/uL whichever is greater
Estriol (unconjugated)	± 2 SD or ± 0.5 ng/mL whichever is greater

Ferritin	± 3 SD
Folate	± 3 SD
Free PSA	± 3 SD or ± 0.4 ng/mL whichever is greater
Fructosamine	± 2 SD or ± 0.2 mmol/L whichever is greater
FSH	± 3 SD
GGT	± 20 percent
Glucose (HemoCue)	± 10 mg/dL or ± 20 percent whichever is greater
Glucose (WB - Waived Pkg)	± 10 mg/dL or ± 20 percent whichever is greater
Glucose (Whole Blood)	± 10 mg/dL or ± 20 percent whichever is greater
Glycated Hemoglobin	± 3 SD or ± 20 percent whichever is greater
GP IIb / IIIa Inhibition	± 3 SD or ± 30 PAU whichever is greater
Haptoglobin	± 3 SD
HbA1c (Afinion)	± 3 SD or ± 20 percent whichever is greater
Hematocrit (Waived)	± 6 percent
Hematocrit, calculated (Pilot)	± 6 percent
Hemoglobin (Blood Ox Pilot)	± 7 percent
Hemoglobin (HemoCue)	± 7 percent
Hemoglobin (Waived)	± 7 percent
Hemoglobin F, quantitative	± 2 SD or ± 0.6 whichever is greater
Homocysteine	± 3 SD
IG absolute (Hem - 5S)	± 3 SD
IG percent (Hem - 5S)	± 3 SD
Immature Platelet Fraction	± 3 SD
INR	± 3 SD
INR (CoaguChek XS Plus)	± 3 SD
INR (CoaguChek XS)	± 3 SD
INR (CoaguChek)	± 3 SD
INR (HA)	± 3 SD
INR (Hemochron Jr. Cit)	± 3 SD
INR (Hemochron Jr. PT)	± 3 SD
INR (i-STAT/CoaguSense)	± 3 SD

INR (ITC Protime)	± 3 SD
Insulin	± 3 SD
IRF (Hem - 5C)	± 3 SD
IRF (Hem - 5D)	± 3 SD
IRF (Hem - 5S)	± 3 SD
K-Time (K)	± 3 SD
K-Time (K) (TEG-5000)	± 3 SD or ± 0.1 minutes whichever is greater
Lactate (Blood Gas)	± 3 SD or ± 0.4 mmol/L whichever is greater
Lactate (i-STAT)	± 3 SD or ± 0.4 mmol/L whichever is greater
Lactic Acid	± 3 SD or ± 0.4 mmol/L whichever is greater
Lactoferrin	± 30 percent
Lamellar Body Count	± 25 percent
Lidocaine	± 3 SD or ± 10 percent whichever is greater
Lipase	± 2 SD or ± 30 U/L whichever is greater
Luteinizing Hormone	± 3 SD
Lymphocytes (CSF/body fluid)	± 20
Magnesium, Ionized (Blood Gas)	± 3 SD or ± 0.1 mmol/L whichever is greater
Max Amplitude (MA) (TEG-5000)	± 3 SD
MCF (ROTEM)	± 3 SD
MCH (Hem - 3)	± 3 SD
MCH (Hem - 3S)	± 3 SD
MCH (Hem - 5A)	± 3 SD
MCH (Hem - 5B)	± 3 SD
MCH (Hem - 5C)	± 3 SD
MCH (Hem - 5C2)	± 3 SD
MCH (Hem - 5D)	± 3 SD
MCH (Hem - 5E)	± 3 SD
MCH (Hem - 5M)	± 3 SD
MCH (Hem - 5S)	± 3 SD
MCHC (Hem - 3)	± 3 SD
MCHC (Hem - 3S)	± 3 SD

MCHC (Hem - 5A)	± 3 SD
MCHC (Hem - 5B)	± 3 SD
MCHC (Hem - 5C)	± 3 SD
MCHC (Hem - 5C2)	± 3 SD
MCHC (Hem - 5D)	± 3 SD
MCHC (Hem - 5E)	± 3 SD
MCHC (Hem - 5M)	± 3 SD
MCHC (Hem - 5S)	± 3 SD
MCV (Hem - 3)	± 3 SD
MCV (Hem - 3S)	± 3 SD
MCV (Hem - 5)	± 3 SD
MCV (Hem - 5A)	± 3 SD
MCV (Hem - 5B)	± 3 SD
MCV (Hem - 5C)	± 3 SD
MCV (Hem - 5C2)	± 3 SD
MCV (Hem - 5D)	± 3 SD
MCV (Hem - 5E)	± 3 SD
MCV (Hem - 5M)	± 3 SD
MCV (Hem - 5S)	± 3 SD
Methemoglobin	± 2
Microalbumin (quan)	± 3 SD or ± 30 percent whichever is greater
Monocytes (CSF/body fluid)	± 20
Mononuclear (CSF/body fluid)	± 25
MPV (Hem - 3)	± 3 SD
MPV (Hem - 3S)	± 3 SD
MPV (Hem - 5A)	± 3 SD
MPV (Hem - 5B)	± 3 SD
MPV (Hem - 5C)	± 3 SD
MPV (Hem - 5C2)	± 3 SD
MPV (Hem - 5D)	± 3 SD
MPV (Hem - 5E)	± 3 SD

MPV (Hem - 5M)	± 3 SD
MPV (Hem - 5S)	± 3 SD
Myoglobin (CM)	± 2 SD or ± 15 ng/mL whichever is greater
Neutrophils (CSF/body fluid)	± 20
Nitrite (UAD quant)	± 2 SD or ± 30 µg/mL whichever is greater
Non-Squamous Epi (Iris, quan)	± 10
NT pro-BNP (CM)	± 2 SD or ± 10 pg/mL whichever is greater
NUCL (Body Fluid - I)	± 3 SD
Nucleated RBCs (Hem - 5C)	± 3 SD or ± 1 whichever is greater
Nucleated RBCs (Hem - 5D)	± 3 SD or ± 0.01 x 10E9/L whichever is greater
Nucleated RBCs (Hem - 5S)	± 3 SD or ± 0.01 x 10E9/L whichever is greater
Osmolality	± 3 SD
Oxidants (UAD quant)	± 2 SD or ± 30 µg/mL whichever is greater
Oxyhemoglobin	± 3 SD or ± 3 whichever is greater
Oxyhemoglobin (Pilot)	± 3 SD
P2Y12 Inhibition	± 3 SD or ± 30 PRU whichever is greater
PAP	± 2 SD or ± 30 percent whichever is greater
Phenytoin (Free)	± 25 percent
PMN (CSF/body fluid)	± 25
Prealbumin	± 5 mg/dL or ± 25 percent whichever is greater
Procalcitonin	± 3 SD
Progesterone	± 3 SD
Prolactin	± 3 SD
Prothrombin Time (HA)	± 15 percent
PSA	± 3 SD or ± 0.4 ng/mL whichever is greater
PSA (Tumor Markers)	± 3 SD or ± 0.4 ng/mL whichever is greater
R-Time (R)	± 3 SD
R-Time (R) (TEG-5000)	± 3 SD
RBC (Body Fluid - I)	± 3 SD
RBC (Body Fluid-C)	± 3 SD
RBC (Iris, quan)	± 3 SD

RBC (manual - CSF/BF)	± 3 SD
RBC (UMS)	± 3 SD
RBC, CSF (Body Fluid - B)	± 3 SD
RDW (Hem - 3)	± 3 SD
RDW (Hem - 3S)	± 3 SD
RDW (Hem - 5)	± 3 SD
RDW (Hem - 5A)	± 3 SD
RDW (Hem - 5B)	± 3 SD
RDW (Hem - 5C)	± 3 SD
RDW (Hem - 5D)	± 3 SD
RDW (Hem - 5E)	± 3 SD
RDW (Hem - 5S)	± 3 SD
RDW-CV (Hem - 3S)	± 3 SD
RDW-CV (Hem - 5C)	± 3 SD
RDW-CV (Hem - 5C2)	± 3 SD
RDW-CV (Hem - 5M)	± 3 SD
RDW-CV (Hem - 5S)	± 3 SD
RDW-SD (Hem - 3S)	± 3 SD
RDW-SD (Hem - 5C)	± 3 SD
RDW-SD (Hem - 5M)	± 3 SD
RDW-SD (Hem - 5S)	± 3 SD
Reticulocyte Count (Automated)	± 3 SD
Reticulocyte Count (Hem - 5C)	± 3 SD
Reticulocyte Count (Hem - 5D)	± 3 SD
Reticulocyte Count (Hem - 5S)	± 3 SD
Reticulocyte Count (Manual)	± 3 SD
Reticulocyte Hgb (RET-He)	± 3 SD
Salicylates	± 3 SD or ± 2.8 mg/dL whichever is greater
Sedimentation Rate	± 2 SD or ± 3 mm/hr whichever is greater
Sedimentation Rate (HemaTech)	± 2 SD or ± 3 mm/hr whichever is greater
Sedimentation Rate (iSED)	± 2 SD or ± 3 mm/hr whichever is greater

Sedimentation Rate(Sedimat 15)	± 2 SD or ± 3 mm/hr whichever is greater
Sex Hormone Binding Globulin	± 3 SD
Specific Gravity	± 0.01
Specific Gravity (UAI)	± 0.01
Sperm Count (Post-Vasectomy)	± 3 SD
Sperm Morphology (glass slide)	± 20 percent normal
Sperm Morphology (image)	± 20 percent normal
Sperm Viability	± 2 SD or ± 2 percent viable whichever is greater
tCO2 (calculated) (Blood Gas)	± 3 SD
TCO2 (i-Stat Chem 8+)	± 3 SD
Testosterone	± 3 SD
Testosterone (Bioavailable)	± 3 SD
Testosterone (Free)	± 3 SD
Testosterone (SHB)	± 3 SD
Thrombin Time (HA)	± 3 SD
Thyroglobulin Ab (Anti-TG)	± 2 SD or ± 20 IU/mL whichever is greater
Thyroid Microsomal Ab/Anti-TPO	± 2 SD or ± 20 IU/mL whichever is greater
TIBC (iron based calculation)	± 20 percent
TIBC (transferrin based calc.)	± 20 percent
Transferrin	± 20 percent
Troponin I (CM)	± 3 SD or ± 0.3 ng/mL whichever is greater
Troponin T (CM)	± 2 SD or ± 0.1 ng/mL whichever is greater
Urine Amylase	± 3 SD
Urine Calcium	± 3 SD
Urine Chloride	± 3 SD
Urine Creatinine	± 20 percent
Urine Creatinine (quant)	± 20 percent
Urine Glucose	± 3 SD
Urine Magnesium	± 25 percent
Urine Microalbumin	± 3 SD or ± 30 percent whichever is greater
Urine Osmolality	± 3 SD

Urine Phosphorus	± 3 SD
Urine Potassium	± 3 SD
Urine Sodium	± 3 SD
Urine Total Protein	± 3 SD
Urine Urea	± 3 SD
Urine Uric Acid	± 3 SD
Valproic Acid (Free)	± 25 percent
Vancomycin	± 2 µg/mL or ± 20 percent whichever is greater
Vitamin B-12	± 3 SD
WBC (Body Fluid-C)	± 3 SD
WBC (Iris, quan)	± 3 SD
WBC (manual - CSF/BF)	± 3 SD
WBC (UMS)	± 3 SD
WBC, CSF (Body Fluid - B)	± 3 SD

CLOSE WINDOW