PERFORMANCE EVALUATION

The Clinical Laboratory Improvement Amendments (CLIA) were established by the U.S. government and are administered by the Centers for Medicare & Medicaid Services (CMS) to regulate U.S. clinical laboratories and PT providers like API. One of the subjects governed by the CLIA regulations is the evaluation of PT results for analytes listed in CLIA, called “regulated” analytes. The general process required for regulated analytes is described below, and is used for both regulated and non-regulated analytes. Some details depend on whether analytes are quantitative (reported as a specific numeric value) or qualitative (reported as a characteristic, such as positive or negative).

Comparison Groups

Results for each participant are evaluated in comparison to a group of participants reporting on the same sample and analyte. The comparison group may be all laboratories reporting the same analyte, or a subset of laboratories (peer group) using the same method (e.g., instrument, reagent, kit) or method principle. Peer group comparisons are generally preferred to provide the most accurate comparison with the least possible method bias.

Comparison groups must meet certain requirements to be used to evaluate each participant’s performance. First, a comparison group must contain at least 10 laboratories. Second, a comparison group must reach "consensus" on the acceptable results for that analyte in that sample, defined by CLIA as having 80% of participant results within the range of acceptable results. One exception is regulated immunohematology analytes, which require 95% consensus. If the smallest peer group for a certain participant does not meet these two requirements, the next larger comparison group meeting the requirements is used, with the largest possible group being “All Participants.” For regulated analytes, if no comparison group reaches consensus for an analyte/sample combination, performance is based on the results of expert/referee laboratories. For any analyte, if an appropriate comparison group cannot be found, performance is listed as "Not Graded" and statistics are provided for participants to determine their own performance.

Expected Results

For quantitative analytes, API evaluates participants against a target value, which is the mathematical mean of participant results after outlier removal. If an analyte is regulated, CLIA specifies the criteria for acceptable performance as a range above and below the mean, calculated as either a fixed amount, a percentage of the mean, or a number of standard deviations. For non-regulated analytes, API determines the criteria that will be used to calculate the acceptable range. Criteria for acceptable performance for quantitative analytes are listed below.

Qualitative analytes are those reported as a characteristic like positive/negative or as a cell/species identification. For these analytes, the expected result is the most common response from participants or a group of responses that are clinically equivalent. The expected result should match the planned target for the sample, as supported by an independent reference value. Clinically equivalent responses include responses such as those in microbiology that reflect different extents of testing or identification performed in different laboratories.

For semi-quantitative analytes reported as a category or estimate rather than a single measured quantity, the group of expected results includes the most common response plus one response lower and one response higher, to accommodate differences in interpretation that will not affect patient care. For regulated titer analytes (Anti-Streptolysin O and Rheumatoid Factor), CLIA requires the most common response ± two dilutions be considered acceptable.

For qualitative and semi-quantitative analytes, both negative and positive responses are not accepted for the same method on the same sample. In addition, the expected response(s) must reflect agreement of participants, as described above under Comparison Groups, in order for a sample to be evaluated.

Performance

Results agreeing with the expected result(s) for the comparison group are labeled “Acceptable”; other results are “Unacceptable”. If a challenge was not intended to be evaluated (educational) or an appropriate comparison group could not be found, results are labeled “Not Graded” and information is provided in the online Participant Data Summary for participants to determine their own performance.

For a description of how scores are calculated, refer to the Performance Evaluation section of our User Guide, which is available from the teal menu on the left side our website. In microbiology, scores are available for each analyte, but reported for regulatory purposes as an average of regulated tests performed in each sub-specialty (i.e., bacteriology, mycology, mycobacteriology, parasitology, or virology).

CRITERIA FOR ACCEPTABLE PERFORMANCE

Criteria for acceptable performance for quantitative analytes appear in the tables below, divided into regulated and non-regulated analytes. Since some regulated analytes are qualitative, this is not a comprehensive list of regulated analytes. Please note:

- For qualitative analytes, the criterion for acceptable performance is agreement with other participants performing the same test. Therefore, these analytes are not listed in the tables below.
- Our User Guide contains a complete list of all analytes and criteria organized by program, with bold text indicating regulated analytes.
- The following criteria apply to evaluations released in 2025 or later. For criteria used in earlier evaluations, contact TechSupport@api-pt.com.

CLIA Regulated Analytes – Criteria for Acceptable Performance	
General Chemistry	**Allowed Variance from the Target Value**
Albumin	± 8%*
Alkaline Phosphatase	± 20%*
ALT/SGPT	± 6 U/L or ± 15% (greater)*
Amylase	± 20%*
AST/SGOT	± 6 U/L or ± 15% (greater)*
Bilirubin, Total	± 0.4 mg/dL or ± 20% (greater)
BNP^	± 30%
Calcium, Total	± 1 mg/dL
Chloride	± 5%
Cholesterol, Total	± 10%
Cholesterol, HDL	± 6 mg/dL or ± 20% (greater)*
Cholesterol, LDL (measured)^	± 20%
Creatine Kinase (CK), total	± 20%
Creatine Kinase, Isoenzyme (CK-MB)	± 3 ng/mL or ± 25% (greater)*
Creatinine	± 0.2 mg/dL or ± 10% (greater)*
CO_2^	± 20%
Ferritin^	± 20%
GGT^	± 5 U/L or ± 15% (greater)
Glucose	± 6 mg/dL or ± 8% (greater)*
Glycated Hemoglobin (HbA1c)^	± 8%
Iron	± 15%
LD/LDH	± 15%
Magnesium	± 15%
NT pro-BNP^	± 30%
pCO_2	± 5 mmHg or ± 8% (greater)
pH	± 0.04

^ New CMS regulated analyte and criteria for acceptable performance due to 2025 CLIA changes.
* Revised criteria for acceptable performance due to 2025 CLIA changes.

CLIA Regulated Analytes – Criteria for Acceptable Performance	
General Chemistry (continued)	**Allowed Variance from the Target Value**
Phosphorus^	± 0.3 mg/dL or ± 10% (greater)
pO_2	± 15 mmHg or ± 15% (greater)
Potassium	± 0.3 mmol/L*
PSA, total^	± 0.2 ng/mL or ± 20% (greater)
Sodium	± 4 mmol/L
tCO_2, calculated & measured^	± 20%
TIBC (measured)^	± 20%
Total Protein	± 8%*
Triglycerides	± 15%*
Troponin I^ ◊	± 0.9 ng/mL or ± 30% (greater)
Urea Nitrogen (BUN)	± 2 mg/dL or ± 9% (greater)
Uric Acid	± 10%*
Endocrinology	**Allowed Variance from the Target Value**
Alpha-fetoprotein^	± 20%
CA 125^	± 20%
CEA^	± 1 ng/mL or ± 15% (greater)
Cortisol	± 20%*
Estradiol^	± 30%
Folate^	± 1 ng/mL or ± 30% (greater)
Free Thyroxine (Free T4)	± 0.3 ng/dL or ± 15% (greater)*
FSH^	± 2 IU/L or ± 18% (greater)
HCG (serum, quantitative)	± 3 mIU/mL or ± 18% (greater)*
Luteinizing Hormone^	± 20%
Parathyroid Hormone^	± 30%
Progesterone^	± 25%
Prolactin^	± 20%
T3-Uptake	± 18%
Testosterone^	± 0.2 ng/mL or ± 30% (greater)
Thyroid Stimulating Hormone	± 0.2 mIU/L or ± 20% (greater)*
Thyroxine (T4)	± 1 µg/dL or ± 20% (greater)
Triiodothyronine (T3)	± 30%*
Vitamin B-12^	± 30 pg/mL or ± 25% (greater)
Toxicology	**Allowed Variance from the Target Value**
Acetaminophen^	± 3 µg/mL or ± 15% (greater)
Alcohol	± 20%*
Blood Lead	± 2 µg/dL or ± 10% (greater)*
Carbamazepine	± 1 µg/mL or ± 20% (greater)*
Digoxin	± 0.2 ng/mL or ± 15% (greater)*
Gentamicin	± 25%
Lithium	± 0.3 mmol/L or ± 15% (greater)*
Phenobarbital	± 2 µg/mL or ± 15% (greater)*
Phenytoin	± 2 µg/mL or ± 15% (greater)*
Salicylates^	± 0.2 mg/dL or ± 15% (greater)

◊ High-sensitivity Troponin I and Troponin T are not regulated. See page 5 for criteria for acceptable performance.
^ New CMS regulated analyte and criteria for acceptable performance due to 2025 CLIA changes.
* Revised criteria for acceptable performance due to 2025 CLIA changes.

CLIA Regulated Analytes – Criteria for Acceptable Performance

Toxicology (continued)	Allowed Variance from the Target Value
Theophylline	± 20%*
Tobramycin	± 20%*
Valproic Acid	± 20%*
Vancomycin^	± 2 µg/mL or ± 15% (greater)
Hematology and Coagulation	**Allowed Variance from the Target Value**
Automated White Blood Cell Differential	± 3 SD or ± 1 unit (%) (greater)
Erythrocyte (Red Blood Cell) Count	± 4%*
Fibrinogen	± 20%
Hematocrit	± 4%*
Hemoglobin	± 4%*
INR^	± 15%
Leukocyte (White Blood Cell) Count	± 10%*
Partial Thromboplastin Time (APTT)	± 15%
Platelet Count	± 25%
Prothrombin Time (PT)	± 15%
General Immunology	**Allowed Variance from the Target Value**
Alpha-1-Antitrypsin	± 20%*
Complement C3	± 15%*
Complement C4	± 5mg/dL or ± 20% (greater)*
C-Reactive Protein (high-sensitivity)^	± 0.1 mg/dL or ± 30% (greater)
IgA	± 20%*
IgE	± 20%*
IgG	± 20%*
IgM	± 20%*

^ New CMS regulated analyte and criteria for acceptable performance due to 2025 CLIA changes.
* Revised criteria for acceptable performance due to 2025 CLIA changes.

Non-Regulated Analytes – Criteria for Acceptable Performance

Many quantitative analytes not regulated under CLIA are evaluated using the Target Value ± 2 SD.
Analytes with other performance criteria are noted below:

Chemistry – Core	Allowed Variance from the Target Value
11-Deoxycortisol	± 3 SD
17-OH-Progesterone	± 3 SD
ACTH	± 3 SD
Androstenedione	± 3 SD
Bilirubin, Direct	± 2 SD or ± 0.4 mg/dL (greater)
Caffeine	± 3 SD or ± 10% (greater)
Calcitonin	± 3 SD
Calcium, Ionized	± 3 SD or ± 0.05 mmol/L (greater)
Carboxyhemoglobin	± 3 SD or ± 3 units (%) (greater)
Estriol (unconjugated)	± 2 SD or ± 0.5 ng/mL (greater)
Free PSA/Total PSA ratio	± 3 SD or ± 0.1 units (%) (greater)
Growth Hormone	± 3 SD or ± 0.2 ng/mL (greater)
Homocysteine	± 3 SD
IGF-1	± 3 SD or ± 0.2 ng/mL (greater)
Insulin	± 3 SD

Non-Regulated Analytes – Criteria for Acceptable Performance	
Chemistry – Core (continued)	**Allowed Variance from the Target Value**
Lactate (Lactic Acid)	± 3 SD or ± 0.4 mmol/L (greater)
LDL Cholesterol (calculated)	± 2 SD
Lidocaine	± 3 SD or ± 10% (greater)
Lipase	± 2 SD or ± 30 U/L (greater)
Magnesium, Ionized (Blood Gas)	± 3 SD or ± 0.1 mmol/L (greater)
Methemoglobin	± 2 units (%)
Methotrexate	± 3 SD or ± 10% (greater)
Myoglobin	± 2 SD or ± 15 ng/mL (greater)
O_2 Saturation (measured)	± 3 SD or ± 3 units (%) (greater)
Osmolality	± 3 SD
Osteocalcin	± 3 SD
Oxyhemoglobin	± 3 SD or ± 3 units (%) (greater)
PAP	± 2 SD or ± 30% (greater)
Prealbumin	± 5 mg/dL or ± 25% (greater)
PSA, free	± 3 SD or ± 0.4 ng/mL (greater)
Renin Activity	± 3 SD
Renin (Direct Concentration)	± 3 SD
Sex Hormone Binding Globulin	± 3 SD
TIBC (all)	± 20%
Transferrin	± 20%
Troponin I (high-sensitivity)	± 3 SD or ± 30% (greater)
Troponin T (high-sensitivity)	± 3 SD or ± 30% (greater)
Chemistry – Miscellaneous	**Allowed Variance from the Target Value**
Anti-CCP	± 3 SD or ± 5 U/mL (greater)
Beta-Hydroxybutyrate	± 3 SD or ± 0.2 mmol/L (greater)
Body Fluid Albumin	± 3 SD or ± 10% (greater)
Body Fluid ALP	± 30%
Body Fluid Amylase	± 30%
Body Fluid Bilirubin, Total	± 0.4 mg/dL or ± 20% (greater)
Body Fluid Calcium	± 1 mg/dL
Body Fluid Chloride	± 2 SD or ± 5% (greater)
Body Fluid Cholesterol	± 3 SD
Body Fluid Creatinine	± 0.3 mg/dL or ± 15% (greater)
Body Fluid Glucose	± 6 mg/dL or ± 10% (greater)
Body Fluid LDH	± 20%
Body Fluid Lipase	± 2 SD or ± 30% (greater)
Body Fluid pH (color comparison)	± 1
Body Fluid Potassium	± 0.5 mmol/L
Body Fluid Sodium	± 4 mmol/L
Body Fluid Total Protein	± 3 SD or ± 10% (greater)
Body Fluid Triglycerides	± 3 SD or ± 10 mg/dL (greater)
Body Fluid Urea Nitrogen	± 2 mg/dL or ± 9% (greater)
Body Fluid Uric Acid	± 17%
Conductivity	± 3 SD
CSF Glucose	± 6 mg/dL or ± 10% (greater)
CSF Lactic Acid	± 3 SD or ± 0.4 mmol/L (greater)
CSF Total Protein	± 3 SD or ± 20% (greater)

Non-Regulated Analytes – Criteria for Acceptable Performance	
Chemistry – Miscellaneous (continued)	**Allowed Variance from the Target Value**
Cyclosporine	± 3 SD
Cystatin C	± 3 SD
Ethylene Glycol	± 25%
Fructosamine	± 2 SD or ± 0.2 mmol/L (greater)
Gabapentin	± 3 SD
Glucose (whole blood, waived)	± 10 mg/dL or ± 20% (greater)
Isopropanol	± 25%
Levetiracetam	± 3 SD
Methanol	± 25%
Microalbumin	± 3 SD or ± 30% (greater)
Microalbumin/Creatinine Ratio	± 3 SD
Oxcarbazepine	± 3 SD
Oxidants, quantitative	± 2 SD or ± 30 µg/mL (greater)
Procalcitonin	± 3 SD
Tacrolimus	± 3 SD
Testosterone, bioavailable	± 3 SD
Testosterone, free	± 3 SD
Testosterone, total	± 3 SD
Urine Amylase	± 3 SD
Urine Calcium	± 3 SD
Urine Chloride	± 3 SD
Urine Creatinine	± 20%
Urine Glucose	± 3 SD
Urine Magnesium	± 25%
Urine Microalbumin	± 3 SD or ± 30% (greater)
Urine Osmolality	± 3 SD
Urine Phosphorus	± 3 SD
Urine Potassium	± 3 SD
Urine Sodium	± 3 SD
Urine Total Protein	± 3 SD
Urine Total Nitrogen	± 3 SD
Urine Urea (BUN)	± 3 SD
Urine Uric Acid	± 3 SD
Hematology and Coagulation	**Allowed Variance from the Target Value**
Activated Clotting Time	± 3 SD
Antithrombin III Activity	± 3 SD
Anti-Xa (Hybrid, LMWH, UFH curves)	± 3 SD
Aspirin Induced Inhibition	± 3 SD or ± 50 ARU (greater)
Bacteria (Urine Microscopic System)	± 3 SD or ± 5 cells/µL (greater)
Basophils (CSF/Body Fluid)	± 3 units (%)
Casts (Urine Microscopic System)	± 3 SD or ± 1 cast/µL (greater)
Creatinine (UAD quantitative)	± 2 SD or ± 20% (greater)
Crystals (Iris, quantitative)	± 10
D-Dimer	± 3 SD
Eosinophils (CSF/Body Fluid)	± 6 units (%)
Epithelial Cells (Urine Microscopic System)	± 3 SD or ± 1 cell/µL (greater)

Non-Regulated Analytes – Criteria for Acceptable Performance	
Hematology and Coagulation (continued)	**Allowed Variance from the Target Value**
Factor II, IX, V, VII, VIII, X, XI, XII	± 3 SD
Glucose (whole blood, waived)	± 10 mg/dL or ± 20% (greater)
Hematocrit (waived)	± 4%
Hemoglobin (waived)	± 4%
IG absolute	± 3 SD
IG %	± 3 SD
Immature Platelet Fraction (IPF)	± 3 SD
Immature Reticulocyte Fraction (IRF)	± 3 SD
K-Time (K)	± 3 SD or ± 0.1 (greater)
Lymphocytes (CSF/Body Fluid)	± 20 units (%)
MCH	± 3 SD
MCHC	± 3 SD
MCV	± 3 SD or ± 3 fL (greater)
Monocytes (CSF/Body Fluid)	± 20 units (%)
Mononuclear (CSF/Body Fluid)	± 25 units (%)
MPV	± 3 SD
Neutrophils (CSF/Body Fluid)	± 20 units (%)
Nitrite	± 2 SD or ± 30 µg/mL (greater)
Non-Squamous Epithelial Cells (Iris, quantitative)	± 10
NUCL (Body Fluid - Iris)	± 3 SD
Nucleated RBCs (Hem - 5C)	± 3 SD or ± 1% (greater)
Nucleated RBCs (Hem - 5D & Heme - 5S)	± 3 SD or ± 0.01 x 10^9/L (greater)
P2Y12 Inhibition	± 3 SD or ± 30 PRU (greater)
Plasminogen	± 3 SD
Polymorphonuclear (CSF/Body Fluid)	± 25 units (%)
Protein C Activity	± 3 SD
Protein S - Activity, Free Antigen, and Total Antigen	± 3 SD
RBC (Body Fluid, automated)	± 3 SD
RBC, Iris (quantitative)	± 3 SD or ± 2 (greater)
RBC, Sysmex (quantitative)	±3 SD or ± 2 cells/µL (greater)
RDW (including CV and SD)	± 3 SD
Reticulocyte Count	± 3 SD
Reticulocyte Hgb	± 3 SD
Sedimentation Rate	± 2 SD or ± 3 mm/hr (greater)
Specific Gravity, UA (quantitative)	± 0.01
Sperm Count (Post-Vasectomy) (manual and automated)	± 3 SD
Sperm Morphology	± 20 units (% normal)
Sperm Viability	± 2 SD or ± 2% viable (greater)
Thrombin Time	± 3 SD
Thromboelastometry [excluding K Time (K)]	± 3 SD
Total Nucleated Cell Count	± 3 SD
von Willebrand Factor Activity/Antigen	± 3 SD
WBC (Body Fluid automated)	± 3 SD
WBC differential, manual (educational)	± 3 SD or ± 1 unit (%) (greater)
WBC, Iris (quantitative)	± 3 SD or ± 3 (greater)
WBC, Sysmex (quantitative)	± 3 SD or ± 3 cells/µL (greater)

Non-Regulated Analytes – Criteria for Acceptable Performance	
Immunology	**Allowed Variance from the Target Value**
Allergen Specific IgE	± 3 SD or ± 0.18 kUA/L (greater)
Anti-HBs, quantitative	± 3 SD or ± 3 mIU/mL (greater)
Anti-Streptolysin O, quantitative	± 2 SD or ± 25 IU/mL (greater)
C-Reactive Protein (quantitative)	± 2 SD or ± 0.3 mg/dL (greater)
Celiac Serology, quantitative	± 3 SD
Ceruloplasmin	± 3 SD
Haptoglobin	± 3 SD
HBV Viral Load	± 3 SD
HCV Viral Load	± 3 SD
Hemoglobin F, quantitative	± 2 SD or ± 0.6 units (%) (greater)
HIV-1 RNA Viral Load	± 3 SD
IgD	± 3 SD
IgG Subclass Proteins	± 3 SD
Kappa/Lambda ratio	± 3 SD
Kappa Light Chain	± 3 SD
Lambda Light Chain	± 3 SD
Rheumatoid Factor, quantitative	± 3 SD or ± 20 IU/mL (greater)
Rubella, quantitative	± 3 SD or ± 10 IU/mL (greater)
Thyroglobulin Ab (Anti-TG)	± 2 SD or ± 20 IU/mL (greater)
Thyroid Microsomal Ab (Anti-TPO)	± 2 SD or ± 20 IU/mL (greater)