



CLIA REGULATED ANALYTES

The following nonwaived analytes are regulated by the Centers for Medicare and Medicaid Services (CMS) and require enrollment and participation in a proficiency testing (PT) program. Waived methods for regulated analytes (for example, glucose by devices cleared for home use, spun microhematocrit, qualitative urine hCG) do not require PT. If compatible PT samples for a regulated analyte are not offered by more than one PT provider, there may be instances when split-sample analysis is acceptable. Check with your regulatory or accrediting agency for additional information.

SPECIALTY: MICROBIOLOGY

Subspecialty: Bacteriology

- Aerobic/Anaerobic Culture & Identification
- Antibiotic Susceptibility Testing
- Direct Bacterial Antigen Detection
- Gram Stain

Subspecialty: Mycology

- Culture and Identification

Subspecialty: Parasitology

- Presence or Absence of Parasites
- Identification of Parasites

Subspecialty: Virology

- Direct Viral Antigen Detection
- Viral Isolation and Identification

Subspecialty: Mycobacteriology

- Acid Fast Stain
- Mycobacterial Identification
- Antimycobacterial Susceptibility Testing

SPECIALTY: DIAGNOSTIC IMMUNOLOGY

Subspecialty: Syphilis Serology

Subspecialty: General Immunology

- Alpha-1 Antitrypsin
- Alpha Fetoprotein (tumor marker)
- Antinuclear Antibody
- Antistreptolysin O
- Anti-Human Immunodeficiency Virus (HIV)
- Complement C3
- Complement C4
- HbsAg
- Anti-HBc
- Hbe-Ag
- IgA
- IgG
- IgE
- IgM
- Infectious Mononucleosis
- Rheumatoid Factor
- Rubella

SPECIALTY: CHEMISTRY*Subspecialty: Routine Chemistry*

Alanine Aminotransferase (ALT or SGPT)
Albumin
Alkaline Phosphatase
Amylase
Aspartate Aminotransferase (AST or SGOT)
Bilirubin, total
Blood Gases (pH/pCO₂/pO₂)
Calcium, Total
Chloride
Cholesterol, total
Cholesterol, HDL
Creatine Kinase, total
Creatine Kinase, Isoenzyme (CK-MB)
Creatinine
Glucose
Iron, Total
Lactate Dehydrogenase (LDH)
LDH, Isoenzymes (LDH1/LDH2)
Magnesium
Potassium
Sodium
Total Protein
Triglycerides
Urea Nitrogen (BUN)
Uric Acid

Subspecialty: Endocrinology

Cortisol
Free Thyroxine
Human Chorionic Gonadotropin (hCG)
T3 Uptake
Triiodothyronine (T3)
Thyroid Stimulating Hormone (TSH)
Thyroxine, total (T4)

Subspecialty: Toxicology

Blood Alcohol
Blood Lead
Carbamazepine
Digoxin
Ethosuximide
Gentamicin
Lithium
Phenobarbital
Phenytoin
Primidone
Procainamide and Metabolite
Quinidine
Theophylline
Tobramycin
Valproic Acid

SPECIALTY: HEMATOLOGY

Cell Identification
White Blood Cell Differential (manual and automated)
Erythrocyte (RBC) Count
Hematocrit
Hemoglobin
Leukocyte (WBC) Count
Platelet Count
Fibrinogen
Partial Thromboplastin Time
Prothrombin Time

SPECIALTY: IMMUNOHEMATOLOGY

ABO Group
D (Rho) Typing
Unexpected Antibody Detection
Compatibility Testing
Antibody Identification

Reference and Resource:

CLIA Brochure #8: Proficiency Testing

Available at

www.cms.gov/CLIA/downloads/CLIAbrochure8.pdf