


COLA PRIMER 7

Regulated Analytes

● Introduction ●

The following analytes are designated by the Centers for Medicare and Medicaid Services (CMS) as **regulated analytes** and thereby require enrollment in an approved proficiency testing (PT) program. Unregulated analytes not enrolled in a PT program require split specimen testing. Proficiency testing is not required for waived methods but it is considered good laboratory practice.

| Key  | SPECIALTY | Subspecialty | Analyte |
|---|-----------|--------------|---------|
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● MICROBIOLOGY ●

Bacteriology

Detection or Identification of Bacteria
Antimicrobial Susceptibility Testing
Gram Stain including bacterial morphology
Direct Bacterial Antigen Detection
Bacterial Toxin Detection

Mycology

Detection or Identification of Fungi
Direct Fungal Antigen Detection

Parasitology

Detection or Identification of Parasites
Presence or Absence of Parasites
Direct Parasite Antigen Detection

Virology

Detection or Identification of Viruses
Direct Viral Antigen Detection

Mycobacteriology

Detection or Identification of Mycobacteria
Acid Fast Stain

● DIAGNOSTIC IMMUNOLOGY ●

Syphilis Serology

Treponema pallidum (syphilis) antibody

General Immunology

Alpha-1 Antitrypsin
Alpha Fetoprotein (tumor marker)
Antinuclear Antibody
Antistreptolysin O (ASO), qualitative
Anti-Human Immunodeficiency Virus (Anti-HIV)
C-reactive protein (high sensitivity)
Complement C3
Complement C4
Hepatitis B Surface Antibody (anti-HBs)
Hepatitis B Surface Antigen (HBsAG)
Hepatitis B Core Antibody (Anti-HBc)
Hepatitis Be Antigen (HBeAg)
Hepatitis C Antibody (anti-HCV)
Immunoglobulins, total: IgA, IgG, IgM, IgE
Infectious Mononucleosis
Rheumatoid factor, qualitative
Rubella, qualitative

● HEMATOLOGY ●

Blood Cell Identification (manual)
White Blood Cell Differential (automated)
Erythrocyte Count
Hematocrit
Hemoglobin
Leukocyte Count
Platelet Count
Fibrinogen
Partial Thromboplastin Time
Prothrombin Time (seconds or INR)

● IMMUNOHEMATOLOGY ●

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

● CHEMISTRY ●

Routine Chemistry

Alanine Aminotransferase (ALT/SGPT)
 Albumin
 Alkaline Phosphatase
 Amylase
 Aspartate Aminotransferase (AST/SGOT)
 B-natriuretic peptide (BNP)
 Bilirubin, total
 Blood Gases (pH, PO₂, PCO₂)
 Calcium, total
 Carbon Dioxide
 Chloride
 Cholesterol, total
 Cholesterol, HDL
 Cholesterol, LDL
 Creatine Kinase, total
 Creatine Kinase, Isoenzyme (CK-MB)
 Creatinine
 Ferritin
 Gamma-glutamyl Transferase (GGT)
 Glucose
 Glycohemoglobin (Hemoglobin A1c)
 Iron, total
 Lactate Dehydrogenase (LDH), total
 Magnesium
 Phosphorous
 Potassium
 ProBNP
 Prostate Specific Antigen (PSA total)
 Sodium
 Total Iron Binding Capacity (TIBC), direct measurement
 Total Protein
 Triglycerides
 Troponin I
 Troponin T
 Urea Nitrogen (BUN)
 Uric Acid

Endocrinology

Cortisol
 Cancer Antigen (CA) 125
 Carcinoembryonic Antigen (CEA)
 Estradiol
 Folate, serum
 Follicle Stimulating Hormone (FSH)
 Human Chorionic Gonadotropin (hCG), excluding urine qualitative hCG
 Luteinizing Hormone (LH)
 Parathyroid Hormone
 Progesterone
 Prolactin
 Testosterone
 T3 Uptake
 Triiodothyronine, total (T3)
 Thyroid Stimulating Hormone (TSH)
 Thyroxine, free (FT4)
 Thyroxine, total (T4)
 Vitamin B12

● CHEMISTRY ●

Toxicology

Acetaminophen, serum
 Alcohol, blood
 Lead, blood
 Carbamazepine
 Digoxin
 Gentamicin
 Lithium
 Phenobarbital
 Phenytoin
 Salicylate
 Theophylline
 Tobramycin
 Valproic Acid
 Vancomycin

● PATHOLOGY ●

Histopathology (NOTE: Although not mandated by CMS, COLA requires that PT be performed for the tests listed below.)

Breast HER2 IHC Breast Her2 ISH
Breast ER IHC and ISH Breast PR IHC and ISH

Cytology

Gynecologic Cytology

Laboratories must ensure that the laboratory and each individual engaged in the examination of gynecologic preparations is enrolled in a proficiency testing program approved by CMS, in the State in which he or she is employed. The laboratory must ensure that each individual is tested at least once per year and obtains a passing score.

● REFERENCES ●

- <https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/cliabrochure8.pdf>
- <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CytologyProficiencyTesting>
- COLA Laboratory Accreditation Manual