



2024

CATALOG



**MEDICAL
LABORATORY
EVALUATION**

A SERVICE OF THE AMERICAN ASSOCIATION OF BIOANALYSTS

Approved by: CMS

Accepted by: CAP, COLA, TJC, U.S. State Agencies, and A2LA

2024 AAB-MLE Catalog

OVERVIEW

Since 1949, the AAB-MLE Proficiency has made comprehensive external quality control programs available to every individual and clinical laboratory wishing to participate. Updated continuously since their inception, these programs meet the needs of evolving techniques and concepts in the modern laboratory.

Regulatory Agencies—The programs noted in the Analyte Index are approved by Centers for Medicare & Medicaid Services (CMS) and accepted by Commission on Office Laboratory Accreditation (COLA), The Joint Commission (TJC), American Association of Laboratory Accreditation (A2LA), and all state agencies.

The College of American Pathologists has accepted AAB-MLE as an alternative proficiency testing (PT) provider. Be aware that the College of American Pathologists approves alternate PT providers on an analyte-by-analyte basis. Please review the analyte index on the following pages for specific College of American Pathologists accepted analytes. The most current list can be found at www.aab-mle.org. Please verify that you are choosing programs with the College of American Pathologists accepted analytes that you need to meet your College of American Pathologists PT requirements. Any analyte with a NR designation indicates analytes for which CAP does not require proficiency testing. This applies to laboratories being accredited by the College of American Pathologists. AAB-MLE is fully accepted by all other entities and accrediting agencies.

Results of each program are posted to the participant's account on our website within 28 days of the reporting deadline. Cumulative reports demonstrating performance of the past three testing events for CMS-graded analytes are also included. Participant statistics for the entire population of subscribers, segregated according to methodology for most constituents, are available online.

The programs are designed with the flexibility to satisfy the needs of all laboratories ranging from a one-person specialty laboratory to an automated full-service laboratory. We have structured our programs to conform to CLIA '88. We are aware of the economic impact of proficiency testing on the laboratory and we have strived to make our programs as economical as possible.

In selecting programs, one should be aware of federal and state regulatory requirements. Any questions regarding appropriate programs should be addressed to your State Agency or CMS. As detailed further in this catalog, we are offering two basic types of programs:

- Five challenges per testing event which are required for all CMS graded analytes. These analytes are listed in **BOLD** in the catalog program description.
- One, two or three challenges per testing event which are not reported to CMS.

If for a regulated analyte, your laboratory changes mid-year from a non-waived to a waived method, or if the manufacturer is granted waived status, you must maintain enrollment in a five-challenge program for any remaining non-waived tests in the subspecialty as per CMS regulations.

The only programs available are those listed. Special or modified programs cannot be furnished. If you do not perform analysis of a constituent included in our programs, simply do not submit results for that constituent. All specimens with human blood components, except those used in the Viral Markers, HIV Markers & Oral HIV modules, are negative for HIV antibody, HCV antibody and HBsAg at the donor level.

ORDERING INFORMATION

New Participants:

To place an order, go to our website at www.aab-mle.org to download an order form and return the completed form via email to our customer service department at mle@aab-mle.org. Be sure to include a purchase order or credit card information when placing your order.

You may also return the completed form to our mailing address with one of the following:

1. A check for the full amount of the order, or
2. A purchase order with terms of advance payment or net 30 days (payment due 30 days from receipt of order), or
3. Credit Card (American Express, Discover, MasterCard & Visa) information, or
4. Letter of authorization on company letterhead subject to same terms as purchase orders (payment due 30 days from receipt of order).

This is a **prepaid** subscription. No orders will be processed without one of the above payment methods. Credit card payments may be made through our customer service department. Call 800-234-5315 to speak with a representative. The **Annual Registration Fee** is payable each year and is nonrefundable. Enrollment in previous years does not exempt payment of the registration fee.

ORDERING INFORMATION - continued

An Order Verification will be sent to your shipping address. Please allow 2 weeks for order processing; however, if you fail to receive this confirmation, contact our customer service department to ensure your order was received in our office.

New account orders must be received by December 1, 2023; however, we recommend that orders be submitted as soon as possible to guarantee specimen availability. Some programs have limited quantities available. Current participants may be subject to late fees for expedited processing when renewals are submitted past the enrollment deadline.

Attn: Alaska, Hawaii, Canada, Mexico, US Territories and all Foreign participants – these participants will be surcharged for any costs above those normally incurred for delivery in the continental United States. US Territories are not considered part of the continental United States. If submitting a purchase order, please allow for the shipping surcharges. For specific shipping surcharges, please contact our office by calling 800-234-5315 M-F, 8am-5pm Central Time, or email mle@aab-mle.org. All payments are to be in US dollars.

Attn: US Government, State, County, or City Agencies – Programs are subscription products. Please include this clause, if applicable, in your purchase order: “Amount claimed is recommended for payment in advance under the exemption from the provisions of 3 U.S. 530, stated in MP4, Part III, Paragraph 3.02.”

Renewing Participants:

Current participants who have enrolled in our Automatic Renewal Program will be renewed for the 2024 program year based upon their current 2023 order. You will have until November 17, 2023, to cancel your autorenewal without incurring charges. After this date, you will be charged the annual registration fee. All other current participants will receive a 2024 Renewal Form. We encourage renewing participants to return the signed renewal form no later than December 1, 2023, as all products are subject to availability.

All returning participants will receive an invoice by mid-September 2023. Invoices not paid in full by January 16, 2024, will not be shipped the M1 2024 samples.

Cancellations:

We will credit any charges for unshipped specimens if we receive notification in writing **four weeks** prior to the next shipment. In accordance with our cancellation policy, all credits expire within 120 days of the credit memo date. The annual enrollment fee is nonrefundable.

2024 Ship Schedule

| Chemistry & Non-Chemistry | Shipping Dates | Last Day for Replacement Specimens | Cut-off Date for Results Submission | Evaluations Posted |
|---------------------------|----------------|------------------------------------|-------------------------------------|--------------------|
| M1 2024 | February 6 | February 14 | February 23 | March 22 |
| M2 2024 | May 14 | May 22 | May 31 | June 28 |
| M3 2024 | September 10 | September 18 | September 27 | October 25 |
| | | | | |
| Andrology, Embryology | Shipping Dates | Last Day for Replacement Specimens | Cut-off Date for Results Submission | Evaluations Posted |
| S1 2024 | April 9 | April 17 | April 26 | May 24 |
| S2 2024 | October 22 | October 30 | November 8 | December 6 |

Important Information – Participants are responsible for notifying AAB-MLE when the testing kit has not been received **within 3 days** of the shipment date. AAB-MLE’s primary carrier is UPS and the testing kits are **shipped by 2-day service**. Plan accordingly, as alternate shipping dates cannot be provided.

| CMS Regulated | CAP Accepted | Program /Analyte | Specimen Type | Page # |
|---------------|--------------|-----------------------------------|---------------------------------|-----------|
| | | Adulterated Urine – Add-On | 10 mL liquid specimen | 22 |
| | | Creatinine, Urine | | |
| | | Nitrite, Urine | | |
| | | Oxidants | | |
| | | pH, Urine | | |
| | | Specific Gravity, Urine | | |
| | | Interpretation | | |
| | | Afinion Glycohemoglobin | 0.5 mL liquid hemolysate | 22 |
| | | Hemoglobin A1c, Afinion (HbA1c) | | |
| | | Ammonia | 2 mL liquid specimen | 22 |
| | | Ammonia, Serum | | |
| | | Blood Gases | 1.7 mL liquid specimen | 22 |
| | | Calcium, Ionized | | |
| | | Chloride | | |
| | | Glucose | | |
| | | Lactate | | |
| CMS | | pCO2 | | |
| CMS | | pH, Blood Gas | | |
| CMS | | pO2 | | |
| | | Potassium | | |
| | | Sodium | | |
| | | Blood Lead - Waived | 6 mL liquid hemolysate | 22 |
| | | Lead, Blood | | |
| | | BNP/D-Dimer | 1.5 mL liquid specimen | 22 |
| | | BNP | | |
| | | NT-proBNP | | |
| | | D-Dimer, Qual | | |
| | | D-Dimer, Quant, ng/mL | | |
| | | D-Dimer, Quant, ugFEU/mL | | |
| | | Cardiac Markers | 1.5 mL liquid specimen | 22 |
| | | BNP | | |
| CMS | | CK-2/CKMB | | |
| | | D-Dimer | | |
| | | Myoglobin, Quantitative | | |
| | | NT-proBNP | | |
| | | Troponin I | | |
| | | Troponin T | | |
| | | Chemistry Module | 5 mL liquid specimen | 22 |
| CMS | | Albumin | | |
| CMS | | Alkaline Phosphatase | | |

| CMS Regulated | CAP Accepted | Program /Analyte | Specimen Type | Page # |
|---------------|--------------|-----------------------------|---------------|--------|
| CMS | | Alpha-fetoprotein (AFP) | | |
| CMS | | ALT/SGPT | | |
| CMS | | Amylase | | |
| CMS | | AST/SGOT | | |
| | | Bicarbonate (CO2) | | |
| | | Bilirubin, Direct | | |
| CMS | | Bilirubin, Total | | |
| CMS | | Calcium | | |
| CMS | | Chloride | | |
| CMS | | Cholesterol, Total | | |
| CMS | | Cholesterol, HDL | | |
| | | Cholesterol, LDL - Calc | | |
| | | Cholesterol, LDL - Direct | | |
| CMS | | Cortisol | | |
| CMS | | Creatine Kinase (CK) | | |
| CMS | | Creatinine | | |
| | | GGT | | |
| CMS | | Glucose | | |
| CMS | | Iron | | |
| | | Lactate (Lactic Acid) | | |
| CMS | | LDH | | |
| | | Lipase | | |
| CMS | | Magnesium, (mg/dL or mEq/L) | | |
| | | Phosphorus | | |
| CMS | | Potassium | | |
| CMS | | Protein, Total | | |
| CMS | | Sodium | | |
| | | T3, Free | | |
| CMS | | T3 Uptake | | |
| CMS | | Thyroxine (T4) | | |
| CMS | | Thyroxine (T4), Free | | |
| | | TIBC - Calc | | |
| | | TIBC - Direct | | |
| CMS | | Triglycerides | | |
| CMS | | Triiodothyronine (T3) | | |
| CMS | CAP | TSH | | |
| | | UIBC - Direct | | |
| CMS | | Urea Nitrogen, Blood | | |
| CMS | | Uric Acid | | |
| | | | | |

| CMS Regulated | CAP Accepted | Program /Analyte | Specimen Type | Page # |
|---------------|--------------|--------------------------------------|-------------------------------|-----------|
| | | Comprehensive Metabolic Panel | 5 mL liquid specimen | 22 |
| CMS | | Albumin | | |
| CMS | | Alkaline Phosphatase | | |
| CMS | | ALT/SGPT | | |
| CMS | | AST/SGOT | | |
| | | Bicarbonate (CO2) | | |
| | | Bilirubin, Direct | | |
| CMS | | Bilirubin, Total | | |
| CMS | | Calcium | | |
| CMS | | Chloride | | |
| CMS | | Creatinine | | |
| CMS | | Glucose | | |
| CMS | | Iron | | |
| | | Lactate (Lactic Acid) | | |
| CMS | | Magnesium, (mg/dL or mEq/L) | | |
| | | Phosphorus | | |
| CMS | | Potassium | | |
| CMS | | Protein, Total | | |
| CMS | | Sodium | | |
| | | TIBC- Calc | | |
| | | TIBC – Direct | | |
| | | UIBC - Direct | | |
| CMS | | Urea Nitrogen, Blood | | |
| CMS | | Uric Acid | | |
| | | Endocrinology 1 | 5 mL liquid specimen | 23 |
| | CAP | DHEA-S | | |
| | CAP | Estradiol | | |
| | | Ferritin | | |
| | | Folate | | |
| | CAP | Follicle Stimulating Hormone (FSH) | | |
| | | Homocysteine | | |
| | CAP | Luteinizing Hormone (LH) | | |
| | | Pre-albumin | | |
| | CAP | Progesterone | | |
| | CAP | Prolactin | | |
| | CAP | Testosterone, Total | | |
| | | Transferrin | | |
| | | Vitamin B12 | | |
| | | Endocrinology 2 | 2 mL lyophilized spec. | 23 |
| | | C-Peptide | | |

| CMS Regulated | CAP Accepted | Program /Analyte | Specimen Type | Page # |
|---------------|--------------|--|-------------------------------|-----------|
| | | Insulin | | |
| | | PTH (Parathyroid Hormone) | | |
| | | Vitamin D | | |
| | | Ethyl Glucuronide – Add-On | 1 mL liquid specimen | 23 |
| | | Ethyl glucuronide | | |
| | | Fertility Testing | 5 mL liquid specimen | 23 |
| | CAP | DHEA-S | | |
| | CAP | Estradiol | | |
| | CAP | Follicle Stimulating Hormone (FSH) | | |
| | CAP | Luteinizing Hormone (LH) | | |
| | CAP | Progesterone | | |
| | | Fluids Chemistry | 10 mL liquid specimen | 23 |
| | | Albumin, Fluids | | |
| | | Amylase, Fluids | | |
| | | Chloride, Fluids | | |
| | | Cholesterol, Fluids | | |
| | | Glucose, Fluids | | |
| | | Lactic Acid, Fluids | | |
| | | Lactate Dehydrogenase (LD or LDH), Fluids | | |
| | | pH, Fluids | | |
| | | Protein, Total, Fluids | | |
| | | Sodium, Fluids | | |
| | | Uric Acid, Fluids | | |
| | | Glycohemoglobin | 1 mL liquid hemolysate | 23 |
| | | Glycohemoglobin | | |
| | | Glycohemoglobin, 5-vial | 1 mL liquid hemolysate | 23 |
| | | Glycohemoglobin | | |
| | | High Sensitivity C-Reactive Protein | 1.5 mL liquid specimen | 23 |
| | | C-Reactive Protein, high sensitivity (hsCRP) | | |
| | | Iron Binding Capacity | 5 mL liquid specimen | 23 |
| | | Iron, Binding Capacity, Total (TIBC) | | |
| | | Iron, Binding Capacity, Unsaturated (UIBC) | | |
| | | Transferrin | | |
| | | i-STAT Chemistry | 1.7 mL liquid specimen | 23 |
| | | Calcium, Ionized | | |
| CMS | | Chloride | | |
| CMS | | Creatinine | | |
| CMS | | Glucose | | |
| CMS | | Hematocrit | | |
| CMS | | Hemoglobin | | |

| CMS Regulated | CAP Accepted | Program /Analyte | Specimen Type | Page # |
|---------------|--------------|-------------------------------------|-------------------------------|-----------|
| CMS | | Potassium | | |
| CMS | | Sodium | | |
| | | tCO2 | | |
| CMS | | Urea Nitrogen, Blood | | |
| | | i-STAT Chemistry - Waived | 1.7 mL liquid specimen | 24 |
| | | Calcium, Ionized | | |
| | | Chloride | | |
| | | Creatinine | | |
| | | Glucose | | |
| | | Hematocrit | | |
| | | Hemoglobin | | |
| | | Potassium | | |
| | | Sodium | | |
| | | tCO2 | | |
| | | Urea Nitrogen, Blood | | |
| | | Lipid Panel/Glucose - Waived | 5 mL liquid specimen | 24 |
| | | Cholesterol, Total | | |
| | | Cholesterol, HDL | | |
| | | Cholesterol, LDL (Calc) | | |
| | | Glucose | | |
| | | Triglycerides | | |
| | | Lipid Profile | 1.2 mL liquid specimen | 24 |
| | | Apolipoproteins, A1 | | |
| | | Apolipoproteins, B | | |
| CMS | | Cholesterol, HDL | | |
| | | Cholesterol, LDL (Direct) | | |
| CMS | | Cholesterol, Total | | |
| | | Lipoprotein (a) | | |
| CMS | | Triglycerides | | |
| | | Neonatal/Direct Bilirubin | 1 mL liquid specimen | 24 |
| | | Bilirubin, Direct | | |
| CMS | | Bilirubin, Neonatal | | |
| CMS | | Bilirubin, Total | | |
| | | PSA | 5 mL liquid specimen | 24 |
| | | PSA | | |
| | | Serum Alcohol/Ketones | 2 mL liquid specimen | 24 |
| | | Acetone | | |
| CMS | | Alcohol (Ethanol) | | |
| | | Beta Hydroxybutyrate | | |
| | | | | |

| CMS Regulated | CAP Accepted | Program /Analyte | Specimen Type | Page # |
|---------------|--------------|--------------------------------------|----------------------------------|-----------|
| | | Serum hCG | 1 mL liquid specimen | 24 |
| CMS | CAP | Pregnancy Qualitative & Quantitative | | |
| | | SHBG/Testosterone | 2 mL lyophilized specimen | 24 |
| | | Sex Hormone Binding Globulin (SHBG) | | |
| | | Testosterone, Total | | |
| | | Testosterone, Free | | |
| | | Testosterone, Bioavailable | | |
| | | Therapeutic Drug Monitoring | 5 mL liquid specimen | 24 |
| | | Acetaminophen | | |
| CMS | | Carbamazepine | | |
| CMS | | Digoxin | | |
| CMS | | Gentamicin | | |
| CMS | | Lithium | | |
| CMS | | Phenobarbital | | |
| CMS | | Phenytoin | | |
| | | Salicylates -mg/dL | | |
| CMS | | Theophylline | | |
| CMS | | Tobramycin | | |
| CMS | | Valproic Acid | | |
| | | Vancomycin | | |
| | | Thyroid Antibodies | 1 mL liquid specimen | 24 |
| | | Thyroglobulin Antibody | | |
| | | Thyroid peroxidase Antibody (TPO) | | |
| | | Thyroid Profile | 5 mL liquid specimen | 24 |
| CMS | | Alpha-fetoprotein (AFP) | | |
| CMS | | Cortisol | | |
| | | T3, Free | | |
| CMS | | T3 Uptake | | |
| CMS | | Thyroxine (T4) | | |
| CMS | | Thyroxine (T4), Free | | |
| CMS | | Triiodothyronine (T3) | | |
| CMS | | TSH | | |
| | | Total Protein | 5 mL liquid specimen | 25 |
| CMS | | Total Protein | | |
| | | Tumor Markers | 2 mL liquid specimen | 25 |
| | | Beta-2-microglobulin | | |
| | | CA 125 | | |
| | | CA 15-3 | | |
| | | CA 19-9 | | |
| | | CA 27-29 | | |

| CMS Regulated | CAP Accepted | Program /Analyte | Specimen Type | Page # |
|---------------|--------------|----------------------------------|------------------------------|-----------|
| | | Carcinoembryonic Antigen (CEA) | | |
| | | PSA | | |
| | | PSA, Free | | |
| | | Prostatic Acid Phosphatase (PAP) | | |
| | | Thyroglobulin | | |
| | | Urine Chemistry | 10 mL liquid specimen | 25 |
| | | Amylase, Urine | | |
| | | Calcium, Urine | | |
| | | Chloride, Urine | | |
| | | Creatinine, Urine | | |
| | | Glucose, Urine | | |
| | | Magnesium, Urine | | |
| | | Osmolality, Urine | | |
| | | Phosphorus, Urine | | |
| | | Potassium, Urine | | |
| | | Protein, Total, Urine | | |
| | | Sodium, Urine | | |
| | | Urea Nitrogen, Urine | | |
| | | Uric Acid, Urine | | |
| | | Urine Drug Screen | 10 mL liquid specimen | 25 |
| | | Acetaminophen | | |
| | | Alcohol (Ethanol) | | |
| | | Amphetamines | | |
| | | Amphetamines/Methamphetamines | | |
| | | Barbiturates | | |
| | | Benzodiazepines | | |
| | | Buprenorphine | | |
| | | Cannabinoids / Marijuana | | |
| | | Carisoprodol | | |
| | | Cocaine Metabolites | | |
| | | Cotinine | | |
| | | Fentanyl | | |
| | | Hydrocodone | | |
| | | LSD (Lysergic Acid Diethylamide) | | |
| | | 6-MAM | | |
| | | MDMA (Ecstasy) | | |
| | | Meperidine | | |
| | | Methadone | | |
| | | Methadone Metabolite (EDDP) | | |
| | | Methamphetamine | | |

| CMS Regulated | CAP Accepted | Program /Analyte | Specimen Type | Page # |
|-----------------------------|--------------|-------------------------------------|-------------------------------|-----------|
| | | Methaqualone | | |
| | | Opiates (Morphine Trihydrate) | | |
| | | Oxycodone | | |
| | | Phencyclidine (PCP) | | |
| | | Propoxyphene | | |
| | | Tramadol | | |
| | | Tricyclic Antidepressants (TCA) | | |
| | | Zolpidem | | |
| | | Waived Chemistry Panel | 5 mL liquid specimen | 25 |
| | | Albumin | | |
| | | Alkaline Phosphatase | | |
| | | ALT/SGPT | | |
| | | AST/SGOT | | |
| | | Amylase | | |
| | | Bicarbonate (CO2) | | |
| | | Bilirubin, Total | | |
| | | Calcium | | |
| | | Chloride | | |
| | | Cholesterol, HDL | | |
| | | Cholesterol, LDL - Cal | | |
| | | Cholesterol, Total | | |
| | | Creatine Kinase, Total (CK) | | |
| | | Creatinine | | |
| | | Glucose | | |
| | | GGT | | |
| | | Phosphorus | | |
| | | Potassium | | |
| | | Protein, Total | | |
| | | Sodium | | |
| | | Triglycerides | | |
| | | Urea Nitrogen, Blood | | |
| | | Uric Acid | | |
| | | Whole Blood Glucose | 1 mL liquid specimen | 25 |
| CMS | | Glucose, Whole Blood | | |
| | | Whole Blood Glucose – Waived | 1 mL liquid specimen | 25 |
| | | Whole Blood Glucose | | |
| PPM & URINALYSIS | | | | |
| | | Fecal Occult Blood | 1.5 mL liquid specimen | 25 |
| | | Fecal Occult Blood | | |
| | | | | |

| CMS Regulated | CAP Accepted | Program /Analyte | Specimen Type | Page # |
|---------------|--------------|--------------------------------------|---|-----------|
| | | Gastric Occult Blood | 2 mL liquid specimen | 26 |
| | | Gastric Occult Blood | | |
| | | KOH Slides | KOH Slides | 26 |
| | | KOH Slides | | |
| | | Provider Performed Microscopy | Photomicrographs & Digital Image | 26 |
| | | Fern Test | | |
| | | Fecal Leukocytes | | |
| | | KOH Preparation | | |
| | | Nasal Eosinophils | | |
| | | Pinworm Preparation | | |
| | | Scabies | | |
| | | Sperm, Qualitative (Digital Image) | | |
| | | Vaginal Wet Mount | | |
| | | Urinalysis Dipstick | 12 mL liquid specimen | 26 |
| | | Bilirubin, Urine | | |
| | | Creatinine, Urine | | |
| | | Glucose, Urine | | |
| | | Hemoglobin/Blood, Urine | | |
| | | Ketones | | |
| | | Leukocyte Esterase | | |
| | | Microalbumin | | |
| | | Nitrite | | |
| | | pH, Urine | | |
| | | Protein, Total, Urine | | |
| | | Specific Gravity, Urine | | |
| | | Urobilinogen | | |
| | | Urinalysis Module | 12 mL liquid specimen & Photomicrographs | 26 |
| | | Bilirubin, Urine | | |
| | | Creatinine, Urine | | |
| | | Glucose, Urine | | |
| | | Hemoglobin/Blood, Urine | | |
| | | Ketones | | |
| | | Leukocyte Esterase | | |
| | | Microalbumin | | |
| | | Nitrite | | |
| | | pH, Urine | | |
| | | Protein, Total, Urine | | |
| | | Specific Gravity, Urine | | |
| | | Urine Sediment (Microscopic ID) | | |

| CMS Regulated | CAP Accepted | Program /Analyte | Specimen Type | Page # |
|------------------------|--------------|--|------------------------------------|-----------|
| | | Urobilinogen | | |
| | | Urine hCG | 12 mL liquid specimen | 26 |
| | | Pregnancy, Urine | | |
| | | Urine Microalbumin/Creatinine | 3 mL liquid specimen | 26 |
| | | Creatinine, Urine | | |
| | | Creatinine, Urine, Semiquantitative | | |
| | | Microalbumin, Quantitative | | |
| | | Microalbumin, Semiquantitative & Qualitative | | |
| | | Urine Pregnancy – 2 vial | 2 mL liquid specimen | 26 |
| | CAP | Pregnancy, Urine | | |
| | | Urine Sediment | Photomicrographs | 26 |
| | | Urine Sediment (Microscopic ID) | | |
| Waived Packages | | | | |
| | | Basic Waived and PPM Package | Multiple sample types | 33 |
| | | Fecal Occult Blood | | |
| | | PPM | | |
| | | Strep Antigen Detection | | |
| | | Urinalysis | | |
| | | Urine Sediment | | |
| | | Urine hCG | | |
| | | Whole Blood Glucose | | |
| | | Waived and PPM Package | Multiple sample types | 33 |
| | | Fecal Occult Blood | | |
| | | PPM | | |
| | | Strep Antigen Detection | | |
| | | Urinalysis | | |
| | | Urine Sediment | | |
| | | Urine hCG | | |
| | | Whole Blood Glucose | | |
| | | Hematocrit | | |
| | | Hemoglobin | | |
| Coagulation | | | | |
| | | Activated Clotting Time (ACT) | 2 mL lyophilized specimen | 27 |
| | | Activated Clotting Time | | |
| | | CoaguChek XS Plus Prothrombin Time | 0.5 mL lyophilized specimen | 27 |
| | | INR | | |
| CMS | | Prothrombin Time | | |
| | | CoaguChek XS Plus Prothrombin Time - Waived | 0.5 mL lyophilized specimen | 27 |
| | | INR | | |
| | | Prothrombin Time | | |

| CMS Regulated | CAP Accepted | Program /Analyte | Specimen Type | Page # |
|-------------------|--------------|--|------------------------------------|-----------|
| | | Coagulation Module | 1 mL lyophilized specimen | 27 |
| CMS | | Activated Partial Thrombin Time (APTT) | | |
| CMS | | Fibrinogen | | |
| | | INR | | |
| | | INR Calculation | | |
| CMS | | Prothrombin Time | | |
| | | i-STAT Prothrombin Time | 0.5 mL lyophilized specimen | 27 |
| CMS | | Prothrombin Time | | |
| | | INR | | |
| | | Roche CoaguChek XS INR - Waived | 0.5 mL lyophilized specimen | 27 |
| | | INR | | |
| Hematology | | | | |
| | | Blood Cell Identification | Photomicrographs | 27 |
| CMS | | Blood Cell Identification | | |
| | | Hematology with 3-part Diff | 3 mL whole blood | 27 |
| CMS | | Erythrocyte (RBC) Count | | |
| CMS | | Hematocrit | | |
| CMS | | Hemoglobin | | |
| CMS | | Leukocyte (WBC) Count | | |
| CMS | | Leukocyte (WBC) Differential, Auto | | |
| CMS | | Platelet Count | | |
| | | Hematology - Sysmex 3-part Diff | 3 mL whole blood | 28 |
| CMS | | Erythrocyte (RBC) Count | | |
| CMS | | Hematocrit | | |
| CMS | | Hemoglobin | | |
| CMS | | Leukocyte (WBC) Count | | |
| CMS | | Leukocyte (WBC) Differential, Auto | | |
| CMS | | Platelet Count | | |
| | | Hematology with 5-part Diff | 3 mL whole blood | 28 |
| CMS | | Erythrocyte (RBC) Count | | |
| CMS | | Hematocrit | | |
| CMS | | Hemoglobin | | |
| CMS | | Leukocyte (WBC) Count | | |
| CMS | | Leukocyte (WBC) Differential, Auto | | |
| CMS | | Platelet Count | | |
| | | Hematology with 5-part Diff – Abbott Cell-Dyn | 3 mL whole blood | 28 |
| CMS | | Erythrocyte (RBC) Count | | |
| CMS | | Hematocrit | | |
| CMS | | Hemoglobin | | |
| CMS | | Leukocyte (WBC) Count | | |

| CMS Regulated | CAP Accepted | Program /Analyte | Specimen Type | Page # |
|---------------|--------------|--|-------------------------|-----------|
| CMS | | Leukocyte (WBC) Differential, Auto | | |
| CMS | | Platelet Count | | |
| | | Hematology with 5 -part Diff – Act 5 and Pentra | 3 mL whole blood | 28 |
| CMS | | Erythrocyte (RBC) Count | | |
| CMS | | Hematocrit | | |
| CMS | | Hemoglobin | | |
| CMS | | Leukocyte (WBC) Count | | |
| CMS | | Leukocyte (WBC) Differential, Auto | | |
| CMS | | Platelet Count | | |
| | | Hematology with 5-part Diff – DxH 500 Series | 3 mL whole blood | 28 |
| CMS | | Erythrocyte (RBC) Count | | |
| CMS | | Hematocrit | | |
| CMS | | Hemoglobin | | |
| CMS | | Leukocyte (WBC) Count | | |
| CMS | | Leukocyte (WBC) Differential, Auto | | |
| CMS | | Platelet Count | | |
| | | Hematology with 5 or 6 -part Diff - Sysmex | 3 mL whole blood | 28 |
| CMS | | Erythrocyte (RBC) Count | | |
| CMS | | Hematocrit | | |
| CMS | | Hemoglobin | | |
| CMS | | Leukocyte (WBC) Count | | |
| CMS | | Leukocyte (WBC) Differential, Auto | | |
| CMS | | Platelet Count | | |
| | | Hemoglobin/Hematocrit/WBC | 3 mL whole blood | 27 |
| CMS | | Hematocrit | | |
| CMS | | Hemoglobin | | |
| CMS | | WBC count | | |
| | | Hemoglobin/Hematocrit - Waived | 3 mL whole blood | 27 |
| | | Hematocrit | | |
| | | Hemoglobin | | |
| | | Hemoglobin/Glucose – Hemocue | 2 ml whole blood | 27 |
| | | Glucose | | |
| | | Hemoglobin | | |
| | | Reticulocyte Count | 1 mL whole blood | 28 |
| | | Reticulocytes, Automated | | |
| | | Reticulocytes, Manual | | |
| | | Sedimentation Rate | 3 mL whole blood | 28 |
| | | Erythrocyte Sedimentation Rate (ESR) | | |
| | | Rapid Sedimentation Rate | 3 mL whole blood | 28 |
| | | Erythrocyte Sedimentation Rate (ESR), Rapid | | |

| CMS Regulated | CAP Accepted | Program /Analyte | Specimen Type | Page # |
|----------------------------|--------------|--|--------------------------------------|-----------|
| | | Sickle Cell Screen | 2 mL whole blood | 28 |
| | | Sickle Cell Screen | | |
| Immunohematology | | | | |
| | | ABO/Rh Factor | 1.5 mL red cells | 28 |
| CMS | | ABO Typing | | |
| CMS | | D (Rh) Typing | | |
| | | Blood Bank 1 | 1.5 mL plasma & red cells | 28 |
| CMS | | ABO Typing | | |
| CMS | | D (Rh) Typing | | |
| CMS | | Unexpected Antibody Detection | | |
| | | Blood Bank 2 | 1.5 mL plasma & red cells | 28 |
| CMS | | ABO Typing | | |
| CMS | | Compatibility Testing (Crossmatch) | | |
| CMS | | D (Rh) Typing | | |
| CMS | | Unexpected Antibody Detection | | |
| CMS | | Antibody Identification | | |
| | | D (Rh) Typing | 1 mL washed red cells | 28 |
| CMS | | D (Rh) Typing | | |
| | | Direct Antiglobulin Test | 1 mL washed red cells | 29 |
| | | Direct Antiglobulin (DAT) | | |
| Immunology/Serology | | | | |
| | | ANA Panel | 0.6 mL liquid specimens | 29 |
| CMS | | Antinuclear Antibody (ANA) Screen | | |
| | | Anti-dsDNA | | |
| | | Anti-ssDNA | | |
| | | Anti-RNP | | |
| | | Anti-SM | | |
| | | Anti-RNP/SM | | |
| | | Anti-SSA | | |
| | | Anti-SSB | | |
| | | Anti-SSA/SSB | | |
| | | IFA Pattern | | |
| | | Antistreptolysin O (ASO) – Add-On | 1 mL liquid specimen | 29 |
| | | Antistreptolysin O (ASO) | | |
| | | C-Reactive Protein (CRP) | 0.5 mL liquid specimen | 29 |
| | | C-Reactive Protein (CRP), Qualitative | | |
| | | C-Reactive Protein (CRP), Quantitative | | |
| | | Diagnostic Allergy | 2 mL liquid specimen | 29 |
| | | Allergen Specific IgE | | |
| CMS | | Total IgE | | |

| CMS Regulated | CAP Accepted | Program /Analyte | Specimen Type | Page # |
|---------------|--------------|---|-----------------------------------|-----------|
| | | H. pylori Antibody Detection | 0.5 mL liquid specimen | 29 |
| | | Helicobacter Pylori Antibody | | |
| | | HIV Markers | 1 mL liquid specimen | 30 |
| CMS | | HIV, Anti-HIV 1 (confirmation) | | |
| CMS | | HIV, Anti-HIV 1 or 1/2 (screening) | | |
| | | HIV, p24 Antigen | | |
| | | HIV Markers - Waived | 1 mL liquid specimen | 30 |
| | | HIV, Anti-HIV 1, Waived | | |
| | | HIV, p24 Antigen, Waived | | |
| | | Immunology Module | Separate vials per analyte | 29 |
| CMS | | Antistreptolysin O (ASO) | 1 mL liquid specimen | |
| CMS | | Infectious Mononucleosis | 0.6 mL liquid specimen | |
| CMS | | Rheumatoid Factor (RF), Qualitative | 1 mL liquid specimen | |
| CMS | | Rheumatoid Factor (RF), Quantitative, titer | | |
| | | Rheumatoid Factor (RF), Quantitative, u/mL | | |
| | | Immunoproteins | 1 mL liquid specimen | 29 |
| CMS | | Complement C3 | | |
| CMS | | Complement C4 | | |
| CMS | | IgA | | |
| CMS | | IgE | | |
| CMS | | IgG | | |
| CMS | | IgM | | |
| | | Infectious Mononucleosis | 0.6 mL liquid specimen | 29 |
| CMS | | Infectious Mononucleosis | | |
| | | Infectious Mononucleosis - Waived | 0.6 mL liquid specimen | 29 |
| | | Infectious Mononucleosis | | |
| | | Infectious Mono/Rheumatoid Factor | 0.6 mL liquid specimen | 29 |
| CMS | | Infectious Mononucleosis | | |
| CMS | | Rheumatoid Factor (RF) | | |
| | | Mycoplasma Antibody | 0.5 mL liquid specimen | 30 |
| | | Mycoplasma antibody | | |
| | | Oral Fluid HIV Antibodies | 1 mL liquid specimen | 30 |
| CMS | | HIV, Oral Fluids (confirmation) | | |
| CMS | | HIV, Oral Fluids (screening) | | |
| | | Rheumatoid Factor | 1 mL liquid specimen | 29 |
| CMS | | Rheumatoid Factor (RF), Qualitative | | |
| CMS | | Rheumatoid Factor (RF), Quantitative, titer | | |
| | | Rheumatoid Factor (RF), Quantitative, u/mL | | |
| | | Rheumatology Module | 1 mL liquid specimen | 29 |
| CMS | | Rheumatoid Factor (RF), Qualitative | | |

| CMS Regulated | CAP Accepted | Program /Analyte | Specimen Type | Page # |
|--------------------------------|--------------|---|------------------------------------|-----------|
| CMS | | Rheumatoid Factor (RF), Quantitative, titer | | |
| | | Rheumatoid Factor (RF), Quantitative, u/mL | | |
| | | C-Reactive Protein | | |
| | | Rubella | 1 mL liquid specimen | 30 |
| CMS | | Rubella, IgG | | |
| | | SARS-CoV-2 Serology | 1 mL liquid specimen | 30 |
| | | SARS-CoV-2 Serology | | |
| | | Specific Allergen Testing | 2 mL liquid specimen | 29 |
| | | Allergen Specific IgE | | |
| | | Syphilis Serology | 1 mL liquid specimen | 30 |
| CMS | | Syphilis, Qualitative | | |
| CMS | | Syphilis, Quantitative | | |
| | | ToRCH | 1 mL liquid specimen | 30 |
| | | Cytomegalovirus | | |
| | | Herpes Simplex Virus, Type I, IgG | | |
| | | Herpes Simplex Virus, Type I, IgM | | |
| | | Herpes Simplex Virus, Type I/II, IgG | | |
| | | Herpes Simplex Virus, Type I/II, IgM | | |
| | | Rubella, IgM | | |
| | | Toxoplasma | | |
| | | Viral Markers | 1.5 mL liquid specimen | 30 |
| | | Hepatitis, Anti-HAV, IgM | | |
| | | Hepatitis, Anti-HAV, Total/IgG | | |
| CMS | | Hepatitis, Anti-HBc, IgM | | |
| CMS | | Hepatitis, Anti-HBc, Total/IgG | | |
| | | Hepatitis, Anti-HBs | | |
| | | Hepatitis, Anti-HCV | | |
| CMS | | Hepatitis, HBeAg | | |
| CMS | | Hepatitis, HBsAg | | |
| CMS | | Anti-HIV | | |
| Bacteriology - Cultures | | | | |
| | | Bacteriology 1 | Swab specimen & diluent | 31 |
| CMS | | Antimicrobial Susceptibility | | |
| CMS | | Organism Identification, Urine | | |
| CMS | | Organism Identification, Throat | | |
| CMS | | Organism Identification, Genital | | |
| CMS | | Organism Identification, Misc. source (3) | | |
| CMS | | Gram Stain (2) | | |
| | | Gram Stain Morphology (2) | | |
| | | | | |

| CMS Regulated | CAP Accepted | Program /Analyte | Specimen Type | Page # |
|------------------------|--------------|---|---|-----------|
| | | Bacteriology 2 | Swab specimen & diluent | 31 |
| CMS | | Antimicrobial Susceptibility | | |
| CMS | | Organism Identification, Urine | | |
| CMS | | Organism Identification, Throat | | |
| CMS | | Organism Identification, Genital | | |
| CMS | | Gram Stain (2) | | |
| | | Gram Stain Morphology (2) | | |
| CMS | | Strep Group A Antigen | | |
| | | Dermatophyte Culture | Swab specimen & diluent | 32 |
| CMS | | Dermatophyte culture | | |
| | | Genital Culture | Swab specimen & diluent | 31 |
| CMS | | Organism Identification, Genital Culture | | |
| CMS | | Gram Stain (1) | | |
| | | Gram Stain Morphology (1) | | |
| | | Miscellaneous Cultures - Add-On | Swab specimen & diluent | 31 |
| CMS | | Miscellaneous Cultures (3) | | |
| | | MRSA Culture | Swab specimen & diluent | 31 |
| CMS | | Methicillin Resistant S. aureus | | |
| | | Supplemental Blood Culture | Lyophilized pellet & diluent | 31 |
| CMS | | Blood Culture, supplemental | | |
| | | Throat Culture | Swab specimen & diluent | 31 |
| CMS | | Organism Identification, Throat Culture | | |
| | | Urine Colony Count | Lyophilized pellet & diluent | 31 |
| | | Colony Count, Urine | | |
| | | Urine Culture | Swab specimen & diluent | 31 |
| CMS | | Antimicrobial Susceptibility | | |
| CMS | | Organism Identification, Urine Culture | | |
| CMS | | Gram Stain (1) | | |
| | | Gram Stain Morphology (1) | | |
| | | Urine/Throat Culture | Swab specimen & diluent | 32 |
| CMS | | Antimicrobial Susceptibility | | |
| CMS | | Organism Identification, Urine Culture | | |
| CMS | | Organism Identification, Throat Culture | | |
| CMS | | Gram Stain (1) | | |
| | | Gram Stain Morphology (1) | | |
| Antigen Testing | | | | |
| | | C. Difficile/Rotavirus Antigen Detection | 1 mL liquid specimen | 32 |
| CMS | | C DifficileToxin/Antigen Detection | | |
| CMS | | Rotavirus | | |
| | | | | |

| CMS Regulated | CAP Accepted | Program /Analyte | Specimen Type | Page # |
|---------------|--------------|--|----------------------------------|-----------|
| | | Chlamydia/GC/Strep Group B Antigen Screen | Swab specimen | 32 |
| CMS | | Chlamydia Antigen Screen | | |
| CMS | | GC Antigen Screen | | |
| CMS | | Strep Group B, Antigen Screen | | |
| | | Cryptosporidium/Giardia lamblia Antigen Detection | Formalin fecal specimen | 33 |
| CMS | | Cryptosporidium Antigen Screen | | |
| CMS | | Giardia lamblia Antigen Screen | | |
| | | Legionella Antigen Detection | Swab specimen | 32 |
| CMS | | Legionella | | |
| | | OSOM Bacterial Vaginosis - Waived | Swab specimen | 32 |
| | | BV Screen | | |
| | | Rapid Urease (CLO) | Simulated tissue specimen | 32 |
| | | Urease | | |
| | | Respiratory Antigen Detection | 1 mL liquid specimen | 33 |
| CMS | | Influenza, Type A, Antigen Screen | | |
| CMS | | Influenza, Type B, Antigen Screen | | |
| CMS | | Respiratory Syncytial Virus (RSV) Antigen | | |
| | | Respiratory Antigen Detection - Waived | 1 mL liquid specimen | 33 |
| | | Influenza, Type A, Antigen Screen, Waived | | |
| | | Influenza, Type B, Antigen Screen, Waived | | |
| | | Respiratory Syncytial Virus (RSV) Antigen, Waived | | |
| | | SARS-CoV-2 Antigen Detection - Waived | Swab specimen | 33 |
| | | SARS-CoV-2, Waived | | |
| | | SARS-CoV-2 Antigen Detection | Swab specimen | 33 |
| CMS | | SARS-CoV-2 | | |
| | | SARS-CoV-2 Molecular Detection - Waived | Swab specimen | 33 |
| | | SARS-CoV-2, Waived | | |
| | | SARS-CoV-2 Molecular Detection | Swab specimen | 33 |
| CMS | | SARS-CoV-2 | | |
| | | Shiga Toxin | 1 mL liquid specimen | 32 |
| | | Shiga Toxin | | |
| | | Strep A Antigen Detection | Swab specimen | 32 |
| CMS | | Strep Group A Antigen | | |
| | | Strep A Antigen Detection - Waived | Swab specimen | 32 |
| | | Strep Group A Antigen | | |
| | | Streptococcus pneumoniae Antigen Detection | Swab specimen | 32 |
| CMS | | Strep pneumoniae antigen | | |
| | | Trichomonas vaginalis - Waived | Swab specimen | 32 |
| | | Trichomonas vaginalis Screen | | |
| | | | | |

| CMS Regulated | CAP Accepted | Program /Analyte | Specimen Type | Page # |
|-----------------------------|--------------|---|---|-----------|
| | | Vaginosis Screen (Antigen/Molecular) | Swab specimen | 32 |
| CMS | | BV Detection | | |
| | | Candida species | | |
| CMS | | Gardnerella vaginalis | | |
| | | Trichomonas vaginalis | | |
| Staining | | | | |
| | | Acid-Fast Smears | Glass slides-unstained | 32 |
| CMS | | Acid-Fast Bacteria/Smears | | |
| | | Gram Stain and Morphology | 5 Glass slides | 32 |
| CMS | | Gram Stain Identification | | |
| | | Gram Stain Organism Morphology | | |
| Parasitology | | | | |
| | | Parasitology | 0.5 mL fecal suspension and Giemsa stained blood smear | 33 |
| CMS | | Parasitology | | |
| | | PVA Slides - Add On | 2 Glass slides | 33 |
| CMS | | Parasitology | | |
| Andrology/Embryology | | | | |
| | | Antisperm Antibody | Liquid specimen | 33 |
| | NR | Antisperm Antibody | | |
| | | Embryo Grading | Video image | 33 |
| | NR | Embryo Grading | | |
| | | Fetal Fibronectin (fFN) | Liquid specimen | 33 |
| | NR | Fetal Fibronectin (fFN) | | |
| | | Fetal Membrane Rupture Test | 0.5 mL liquid specimen | 34 |
| | NR | Fetal Membrane Rupture (PAMG-1) | | |
| | | IVF Embryo Culture Media | 100 mL culture media | 34 |
| | NR | IVF, Human Sperm Cell Survival, Media Accept | | |
| | NR | IVF, Mouse Embryo, Media Acceptability | | |
| | | Preimplantation Genetic Testing - Aneuploidy | 5uL liquid specimen | 34 |
| | | Sex Status | | |
| | | Euploid or Aneuploid Status | | |
| | | Chromosome addition or deletion | | |
| | | Sperm Count - Qualitative/Post Vasectomy | Liquid specimen | 34 |
| | CAP | Sperm Count, Qualitative (Post Vasectomy) | | |
| | | Sperm Count – Quantitative and Qualitative | Liquid spec. & Digital video | 34 |
| | CAP | Sperm Count, Quantitative | | |
| | | Sperm Count, Qualitative | | |
| | | Sperm Morphology | Glass slide & Digital slide | 34 |
| | NR | Sperm Morphology, % | | |
| | NR | Sperm Morphology, Cell ID | | |

| CMS Regulated | CAP Accepted | Program /Analyte | Specimen Type | Page # |
|------------------|--------------|--|--|-----------|
| | | Sperm Motility | Video Image | 34 |
| | NR | Sperm Motility | | |
| | NR | Sperm Motility, Forward Progression % | | |
| | NR | Sperm Motility, Forward Progression, semi-quant. | | |
| | | Sperm Viability | Glass slide & Digital slide | 34 |
| | CAP | Sperm Viability | | |
| Specialty | | | | |
| | | WB Glucose, EQAS (Multi-site) | 1 mL liquid specimen | 34 |
| | | Glucose, Whole Blood | | |

CHEMISTRY PROGRAMS**BOLD analytes are reported to CMS** Δ - denotes Point of Care Testing or Waived Programs**ADULTERATED URINE – ADD-ON [874].....\$105** *2 challenges per testing event*

Available only with 868. For use with adulterant detection methods testing the following analytes:

| | | |
|-------------------|-------------------------|----------|
| Creatinine, urine | Nitrates, urine | Oxidants |
| pH, urine | Specific Gravity, Urine | |

AFINION GLYCOHEMOGLOBIN [851].....\$243 *2 challenges per testing event*

Samples for Hemoglobin A1C assay (HgbA1c) with the Afinion only

AMMONIA [836].....\$195 *2 challenges per testing event*

Liquid samples for analysis of Ammonia.

BLOOD GASES [847].....\$384 *5 challenges per testing event*

Aqueous samples for the following analytes (2 sets):

| | | |
|-----------------|------------------|-----------------|
| Chloride | Lactate | pO ₂ |
| Glucose | pCO ₂ | Potassium |
| Ionized Calcium | pH | Sodium |

 Δ BLOOD LEAD – WAIVED [838].....\$249 *2 challenges per testing event*Whole blood samples for analysis of blood lead levels. **For use with waived testing methods only.****BNP/D-DIMER [846].....\$270** *2 challenges per testing event*

Liquid samples for the following analytes:

| | | |
|-----|---------|-----------|
| BNP | D-Dimer | NT-proBNP |
|-----|---------|-----------|

CARDIAC MARKERS [845].....\$399 *5 challenges per testing event*

Liquid samples for analysis of the following analytes:

| | | |
|------------|------------|------------|
| BNP | Myoglobin | Troponin T |
| CK-2/CK-MB | NT-proBNP | |
| D-Dimer | Troponin I | |

CHEMISTRY MODULE [810].....\$414 *5 challenges per testing event*

Liquid serum samples for the following analytes:

| | | |
|--------------------------------|---------------------------------|--------------------------------------|
| Albumin | Cortisol | Protein, Total |
| Alkaline Phosphatase | Creatine Kinase (CK/CPK) | Sodium |
| Alpha-fetoprotein (AFP) | Creatinine | T3 Uptake |
| ALT/SGPT | Free T3 | Thyroxine (TT4) |
| Amylase | Free Thyroxine (FT4) | TIBC-calc |
| AST/SGOT | GT/GGT | TIBC-Direct |
| Bilirubin, Direct | Glucose | Triglycerides |
| Bilirubin, Total | Iron | Triiodothyronine, Total (TT3) |
| Calcium | Lactic Acid | TSH |
| Chloride | LD/LDH | UIBC-Direct |
| Cholesterol, HDL | Lipase | Urea Nitrogen (BUN) |
| Cholesterol, LDL Direct/Calc | Magnesium | Uric Acid |
| Cholesterol, Total | Phosphorus | |
| CO ₂ /Bicarbonate | Potassium | |

COMPREHENSIVE METABOLIC PANEL [813].....\$327 *5 challenges per testing event*

Liquid serum samples for analysis of the following analytes:

| | | |
|-----------------------------|------------------------------|----------------------------|
| Albumin | CO ₂ /Bicarbonate | Protein, Total |
| Alkaline Phosphatase | Creatinine | Sodium |
| ALT/SGPT | Glucose | TIBC-calc |
| AST/SGOT | Iron | TIBC-Direct |
| Bilirubin, Direct | Lactic Acid | UIBC-Direct |
| Bilirubin, Total | Magnesium | Urea Nitrogen (BUN) |
| Calcium | Phosphorus | Uric Acid |
| Chloride | Potassium | |

CHEMISTRY PROGRAMS - continued**BOLD analytes are reported to CMS****Δ - denotes Point of Care Testing or Waived Programs****ENDOCRINOLOGY 1 [860].....\$270** *2 challenges per testing event*

Liquid serum samples for the following analytes:

| | | |
|------------------------------------|--------------------------|--------------|
| DHEA-S | Homocysteine | Testosterone |
| Estradiol | Luteinizing Hormone (LH) | Transferrin |
| Ferritin | Prealbumin | Vitamin B12 |
| Folate | Progesterone | |
| Follicle Stimulating Hormone (FSH) | Prolactin | |

ENDOCRINOLOGY 2 [863].....\$237 *2 challenges per testing event*

Lyophilized samples for the following analytes:

| | |
|-----------|-----------------------|
| C-peptide | PTH, Intact |
| Insulin | Vitamin D, 25-Hydroxy |

ΔETHYL GLUCORONIDE – ADD-ON [873]\$87 *2 challenges per testing event*

Liquid serum samples for ethyl glucuronide. Only available with 868.

FERTILITY TESTING [858].....\$180 *2 challenges per testing event*

Liquid serum samples for the following analytes:

| | | |
|-----------|------------------------------------|--------------|
| DHEA-S | Follicle Stimulating Hormone (FSH) | Progesterone |
| Estradiol | Luteinizing Hormone (LH) | |

FLUIDS CHEMISTRY [875].....\$267 *2 challenges per testing event*

Liquid fluids samples for the following analytes:

| | | |
|-------------|--------------------------------|---------------|
| Albumin | Glucose | Sodium |
| Amylase | Lactic Acid | Total Protein |
| Chloride | Lactate Dehydrogenase (LD/LDH) | Uric Acid |
| Cholesterol | pH | |

*Enroll in either the Chemistry Module or Comprehensive Metabolic Panel if CMS reporting is required for the above listed analytes.***GLYCOHEMOGLOBIN [850].....\$228** *2 challenges per testing event*

Samples for analysis of glycohemoglobin (Hgb A1c).

*Samples are **not compatible** with the Afinion.***GLYCOHEMOGLOBIN, 5-VIAL [852].....\$399** *5 challenges per testing event*

Samples for analysis of glycohemoglobin (Hgb A1c).

*Samples are **not compatible** with the Afinion.***HIGH-SENSITIVITY C-REACTIVE PROTEIN (HS-CRP) [765].....\$150** *2 challenges per testing event*

Liquid serum samples. This program targets high sensitivity C-Reactive Protein methods only.

For acute inflammatory phase protein CRP, please order regular CRP under Immunology section.

HIGH-SENSITIVITY C-REACTIVE PROTEIN (HS-CRP) – ADD ON [777].....\$78 *2 challenges per testing event*

Same as 765. Only available with 750 and 751.

IRON BINDING CAPACITY [828].....\$174 *2 challenges per testing event*

Liquid serum samples for the following targeted analytes:

| | |
|------------------------------------|--|
| Transferrin | UIBC (Unsaturated Iron Binding Capacity) |
| TIBC (Total Iron Binding Capacity) | |

I-STAT CHEMISTRY [818].....\$300 *5 challenges per testing event*

Liquid samples for the following analytes:

| | | |
|--------------------|------------|---------------------|
| Bicarbonate (TCO2) | Glucose | Potassium |
| Calcium, Ionized | Hematocrit | Sodium |
| Chloride | Hemoglobin | Urea Nitrogen (BUN) |
| Creatinine | | |

CHEMISTRY PROGRAMS - continued**BOLD analytes are reported to CMS****Δ - denotes Point of Care Testing or Waived Programs****Δ I-STAT CHEMISTRY – WAIVED [832].....\$210***2 challenges per testing event*

Liquid samples for the following analytes using waived methods only:

| | | |
|---------------------------------|------------|---------------------|
| Bicarbonate (TCO ₂) | Glucose | Potassium |
| Calcium, Ionized | Hematocrit | Sodium |
| Chloride | Hemoglobin | Urea Nitrogen (BUN) |
| Creatinine | | |

LIPID PANEL/GLUCOSE – WAIVED [811].....\$210*2 challenges per testing event*

Liquid serum samples for the following analytes:

| | | |
|-------------------|-----------------|------------------------|
| Glucose | HDL Cholesterol | LDL Cholesterol (Calc) |
| Total Cholesterol | Triglyceride | |

LIPID PROFILE [829].....\$258*5 challenges per testing event*

Liquid serum samples for the following analytes:

| | | |
|------------------------|--------------------------|--------------------------|
| Lipoprotein (a) | Apolipoproteins A1 & B | Total Cholesterol |
| HDL Cholesterol | LDL Cholesterol (Direct) | Triglyceride |

NEONATAL/DIRECT BILIRUBIN [841].....\$252*5 challenges per testing event*Liquid samples for analysis of **Total/Neonatal Bilirubin** and Direct Bilirubin**PSA [861].....\$168***2 challenges per testing event*

Liquid samples for testing.

PSA – ADD-ON [859].....\$78*2 challenges per testing event*

Same as 861. Only available with 860.

SERUM ALCOHOL/KETONES [835]\$276*5 challenges per testing event*Liquid serum samples for analysis of **Ethanol** and Acetone, including Beta Hydroxybutyrate.**SERUM HCG [865].....\$216***5 challenges per testing event*Liquid samples for qualitative and quantitative analysis of **serum hCG**.**SERUM HCG – ADD ON [866].....\$108***5 challenges per testing event*

Same as 865. Only available with 810, 813, 818, and 824.

SHBG/TESTOSTERONE [854].....\$369*2 challenges per testing event*

Lyophilized samples for testing the following analytes:

| | |
|------------------------------|---------------------|
| Sex Hormone Binding Globulin | Testosterone, Free |
| Testosterone, Bioavailable | Testosterone, Total |

THERAPEUTIC DRUG MONITORING [830].....\$249*5 challenges per testing event*

Liquid serum samples for the following analytes:

| | | |
|----------------------|----------------------|----------------------|
| Acetaminophen | Lithium | Theophylline |
| Carbamazepine | Phenobarbital | Tobramycin |
| Digoxin | Phenytoin | Valproic Acid |
| Gentamicin | Salicylates | Vancomycin |

THERAPEUTIC DRUGS – ADD-ON [831].....\$69*5 challenges per testing event*

Same as 830. Available only with 810.

THYROID ANTIBODIES [864].....\$282*2 challenges per testing event*

Liquid samples for Thyroglobulin antibody and Thyroid peroxidase antibody (TPO).

THYROID PROFILE [824].....\$285*5 challenges per testing event*

Liquid serum samples for the following analytes:

| | | |
|--------------------------------|-------------------------------|--------------------------------------|
| Alpha-fetoprotein (AFP) | Thyroxine, Free (FT4) | Triiodothyronine, Total (TT3) |
| Cortisol | Thyroxine, Total (TT4) | TSH |
| T3 Uptake | Triiodothyronine, Free (FT3) | |

CHEMISTRY PROGRAMS - continued**BOLD analytes are reported to CMS** Δ - denotes Point of Care Testing or Waived Programs**TOTAL PROTEIN [844].....\$258***5 challenges per testing event*Liquid samples for **Total Protein** by refractometer.**TUMOR MARKERS [862].....\$411***2 challenges per testing event*

Liquid samples for the following analytes:

| | | |
|----------------------|---------------------------------|--|
| Beta-2-microglobulin | CA 27-29 | Prostate-specific Antigen, Free (Free PSA) |
| CA 125 | Carcinoembryonic Antigen (CEA) | Prostatic Acid Phosphatase (PAP) |
| CA 15-3 | Prostate Specific Antigen (PSA) | Thyroglobulin |
| CA 19-9 | | |

URINE CHEMISTRY [872].....\$270*2 challenges per testing event*

Liquid urine samples for the following analytes:

| | | | |
|------------|------------|---------------|-----------|
| Amylase | Glucose | Potassium | Uric Acid |
| Calcium | Magnesium | Sodium | |
| Chloride | Osmolality | Total Protein | |
| Creatinine | Phosphorus | Urea Nitrogen | |

Enroll in either the Chemistry Module or Comprehensive Metabolic Panel if CMS reporting is required for the listed analytes.

 Δ URINE DRUG SCREEN [868].....\$267*2 challenges per testing event*

Liquid samples for the following analytes:

| | | |
|-------------------------------|----------------------------------|-------------------------------|
| Acetaminophen | Cotinine | Methaqualone |
| Alcohol (Ethanol) | Fentanyl | Opiates (Morphine Trihydrate) |
| Amphetamines | Hydrocodone | Oxycodone |
| Amphetamines/Methamphetamines | LSD (Lysergic Acid Diethylamide) | Phencyclidine (PCP) |
| Barbiturates | 6-MAM | Propoxyphene |
| Benzodiazepines | MDMA (Ecstasy) | Tramadol |
| Buprenorphine | Meperidine | Tricyclic Antidepressants |
| Cannabinoids/Marijuana | Methadone | Zolpidem |
| Carisoprodol | Methadone Metabolite (EDDP) | |
| Cocaine Metabolite | Methamphetamines | |

 Δ WAIVED CHEMISTRY PANEL [812].....\$255*2 challenges per testing event***NOTE: this is for waived methods & instruments only.**

Liquid serum samples for the following analytes:

| | | |
|---------------------------------------|-----------------------------|---------------|
| Alanine Aminotransferase (ALT/SGPT) | Chloride | Phosphorous |
| Albumin | Cholesterol, HDL | Potassium |
| Alkaline Phosphatase | Cholesterol, LDL calculated | Sodium |
| Aspartate Aminotransferase (AST/SGOT) | Cholesterol, Total | Total Protein |
| Amylase | Creatine Kinase (CK) | Triglycerides |
| Bicarbonate (CO ₂) | Creatinine | Urea Nitrogen |
| Bilirubin, Total | GGT | Uric Acid |
| Calcium | Glucose | |

 Δ WAIVED CHEMISTRY PANEL – ADD-ON [833].....\$84*2 challenges per testing event*

Same as 812. Only available with 824.

WHOLE BLOOD GLUCOSE [870].....\$309*5 challenges per testing event*For reporting **Whole Blood Glucose** procedures only. **Δ WHOLE BLOOD GLUCOSE – WAIVED [871].....\$198***2 challenges per testing event*For reporting Whole Blood Glucose procedures only. **For multiple analyzer testing, see Specialty Testing section at the end of the catalog.****PPM and Urinalysis** **Δ FECAL OCCULT BLOOD [542].....\$144***2 challenges per testing event*

Simulated stool samples for analysis of fecal occult blood.

CHEMISTRY PROGRAMS - continued**BOLD analytes are reported to CMS****Δ - denotes Point of Care Testing or Waived Programs****Δ FECAL OCCULT BLOOD – ADD ON [537].....\$105** *2 challenges per testing event*

Same as 542. Only available with 530 and 531.

Δ GASTRIC OCCULT BLOOD [543].....\$204 *2 challenges per testing event*

Simulated gastric samples for analysis of:

Occult blood pH

KOH SLIDES [538].....\$201 *2 challenges per testing event*

Glass slides to represent a KOH examination.

Δ PROVIDER-PERFORMED MICROSCOPY [534].....\$159 *1 challenge set per testing event*

Each shipment will vary. Each shipment will be a combination of photomicrographs and digital image for the following:

| | | |
|------------------|-------------------|-------------------|
| Fecal Leukocytes | Nasal Eosinophils | Sperm Qualitative |
| Fern Test | Pinworm Prep | Vaginal Wet Mount |
| KOH Preparation | Scabies | |

Δ PPM – ADD-ON [535].....\$54 *1 challenge set per testing event*

Same as 534. Only available with 530, 531, and 532.

Δ URINALYSIS DIPSTICK [531].....\$126 *1 challenge per testing event*

Liquid sample for the following analytes:

| | | |
|-------------|--------------------|------------------|
| Bilirubin | Ketones | pH |
| Blood (Hgb) | Leukocyte Esterase | Protein |
| Creatinine | Microalbumin | Specific Gravity |
| Glucose | Nitrite | Urobilinogen |

Creatinine is for semi-quantitative dipstick methods only. Quantitative methods should enroll in Urine Microalbumin/Creatinine.

Δ URINALYSIS MODULE [530].....\$150 *1 liquid challenge per testing event****Includes photomicrograph for Urine Sediment Microscopy****2 photo challenges per testing event*

Liquid sample for the following analytes:

| | | |
|-------------|--------------------|-------------------------|
| Bilirubin | Leukocyte Esterase | Protein |
| Blood (Hgb) | Microalbumin | Specific Gravity |
| Creatinine | Nitrite | Urobilinogen |
| Glucose | pH | Urine Sediment (Photos) |
| Ketones | | |

Creatinine is for semi-quantitative dipstick methods only. Quantitative methods should enroll in Urine Microalbumin/Creatinine.

Δ URINE HCG [541].....\$111 *1 challenge per testing event*

Liquid sample for qualitative analysis of Pregnancy (hCG) and is compatible with all waived urine pregnancy kits.

Δ URINE HCG - ADD ON [540].....\$36 *1 challenge per testing event*

Form only. Only available with 530 and 531.

Δ URINE MICROALBUMIN/CREATININE [539].....\$150 *2 challenges per testing event*

Liquid samples for the following analytes:

Creatinine (quantitative/semi-quantitative) Microalbumin (quantitative/semi-quantitative)

Δ URINE MICROALBUMIN/CREATININE – ADD ON [536].....\$105 *2 challenges per testing event*

Same as 539. Only available with 530 and 531.

Δ URINE PREGNANCY – 2 VIAL [550].....\$141 *2 challenges per testing event*

Liquid sample for qualitative analysis of Pregnancy (hCG) and is compatible with all waived urine pregnancy kits.

Δ URINE SEDIMENT IDENTIFICATION [532].....\$141 *2 challenges per testing event*

Photomicrograph for Urine Sediment Microscopy

Δ URINE SEDIMENT IDENTIFICATION – ADD-ON [533].....\$42 *2 challenges per testing event*

Same as 532. Only available with 531 and 534.

NON-CHEMISTRY PROGRAMS**BOLD analytes are reported to CMS****Δ - denotes Point of Care Testing or Waived Programs****Coagulation****Δ ACTIVATED CLOTTING TIME [332].....\$294** *2 challenges per testing event*

Lyophilized samples are compatible with Actalyke, i-Stat, ITC, Medtronic and Quest Instruments.

COAGUCHEK XS PLUS PROTHROMBIN TIME [330].....\$354 *5 challenges per testing event*Lyophilized samples for **Prothrombin Time** and INR. This module is compatible with Roche CoaguChek XS Plus and XS Pro instruments only.**Δ COAGUCHEK XS PLUS PROTHROMBIN TIME – WAIVED [331].....\$231** *2 challenges per testing event*

Lyophilized samples for Prothrombin Time and INR. This module is compatible with Roche CoaguChek XS Plus and XS Pro instruments only.

COAGULATION MODULE [320].....\$252 *5 challenges per testing event*

Lyophilized samples for the following analytes:

Activated Partial Thromboplastin Time (APTT)
FibrinogenINR
INR calculation**Prothrombin Time (PT)****I-STAT PROTHROMBIN TIME [328].....\$384** *5 challenges per testing event*Lyophilized samples for **Prothrombin Time** and INR. This module is compatible with the Abbott i-STAT instrument only.**Δ ROCHE COAGUCHEK XS INR – WAIVED [324].....\$231** *2 challenges per testing event*Lyophilized samples *for INR only*. This module is compatible with Roche CoaguChek XS instrument only.**Hematology****BLOOD CELL IDENTIFICATION [231].....\$150** *5 challenges per testing event*The CMS portion of this program consists of 5 graded photo images of cells or features **for CMS reporting** and 1 ungraded educational photo image.Additionally, 4 DigitalScope™ whole slide images provided for 2 guided or 2 free form manual differentials that can be reported in this program. **Supplemental testing only; not for CMS reporting.****BLOOD CELL IDENTIFICATION – ADD ON [230].....\$54** *5 challenges per testing event*

Same as 231. Only available with 223 through 229.

HEMOGLOBIN/HEMATOCRIT/WBC [212].....\$255 *5 challenges per testing event*Whole blood samples for **Hemoglobin**, **Hematocrit** and **Leukocyte (WBC) count**.**Δ HEMOGLOBIN/HEMATOCRIT – WAIVED [213].....\$192** *2 challenges per testing event*Whole blood samples for *waived* methods only.**Δ HEMOGLOBIN/GLUCOSE - HEMOCUE [215].....\$204** *2 challenges per testing event*

Whole blood samples for testing hemoglobin and glucose on the HemoCue waived method analyzer.

Hematology Automated Differential Instruments

Hematology with automated differential programs are instrument specific. If changes occur during the year, please verify that you are still in the correct program. If you do not see your instrument listed below, consult the most recent instrument and corresponding module list on our website or contact our Technical Support team for assistance.

The following analytes are included in automated differential modules: **3-Part or 5/6-Part Automated Differential, Erythrocyte Count, Hematocrit, Hemoglobin, Leukocyte Count, Platelet Count.****3-part differentials****HEMATOLOGY WITH 3-PART DIFF [225].....\$330** *5 challenges per testing event*

Module is compatible with the following instruments:

Abbott Cell-Dyn 3-part differential models**ABX** all 3-part differential models**Coulter** all 3-part differential models**DANAM** all 3-part differential models**Drew** Evolution**Mindray** all 3-part differential models

NON-CHEMISTRY PROGRAMS – continued**BOLD analytes are reported to CMS** Δ - denotes Point of Care Testing or Waived Programs**HEMATOLOGY SYSMEX 3-PART DIFF [224].....\$339***5 challenges per testing event*

Module is compatible with the following instruments:

Sysmex Pochi, KX 21/21N, XP series

5/6-part differentials**HEMATOLOGY WITH 5-PART DIFF [226].....\$381***5 challenges per testing event*

Module is compatible with the following instruments:

Coulter DxH 600/800/900, Gen-S, HMX, LH500, LH750/755/780

Mindray BC 5-part

HEMATOLOGY WITH 5-PART DIFF- ABBOTT CELL-DYN [223].....\$381*5 challenges per testing event*

Module is compatible with the following instruments:

Abbott Cell-Dyn 3000/4000 series, Emerald 22, Sapphire, Ruby

Danam Excell 22

Diatron Abicus 5

HEMATOLOGY WITH 5-PART DIFF – AcT 5 AND PENTRA [228].....\$381*5 challenges per testing event*

Module is compatible with the following instruments:

ABX Pentra 60 C+, 80, 120

Coulter Ac•T 5

HEMATOLOGY WITH 5-PART DIFF – DxH 500 SERIES [227].....\$381*5 challenges per testing event*

Module is compatible with the following instruments:

Coulter DxH 500 series

HEMATOLOGY WITH 5 OR 6-PART DIFF – SYSMEX [229].....\$381*5 challenges per testing event*

Module is compatible with the following instruments:

Sysmex XE series, XN/XNL, XS series, XT series

Miscellaneous Hematology**RETICULOCYTE COUNT [240].....\$261***2 challenges per testing event*

Specimens for all reticulocyte counting methods.

SEDIMENTATION RATE (ESR) [247].....\$201*2 challenges per testing event*

Specimens for manual and automated systems; samples are not compatible with the ESR Polymedco Sedimat 15 method.

RAPID SEDIMENTATION RATE (ESR) [248].....\$201*2 challenges per testing event*

Specimens are for rapid ESR test systems only (Sedimat-15, Pro-Sed Auto S or equivalent).

SICKLE CELL SCREEN [249].....\$216*2 challenges per testing event*

Whole Blood specimens are for detection of hemoglobin S by insolubility tests and by hemoglobin electrophoresis.

Immunohematology**ABO & Rh FACTOR [451].....\$324***5 challenges per testing event*

Blood Group (ABO) and Rh (D) (5 red cell suspensions)

BLOOD BANK 1 [452].....\$435*5 challenges per testing event*

Blood Group (ABO) and Rh (D) (5 paired red cell suspensions /plasma)

Unexpected Antibody Detection (5 plasma)

BLOOD BANK 2 [453].....\$465*5 challenges per testing event*

Blood Group (ABO) and Rh (D) (5 paired red cell suspensions /plasma)

Compatibility Testing (Crossmatch) (1 donor cells)

Unexpected Antibody Detection (5 plasma)

Antibody Identification (5 plasma)

D (RH) TYPING [450].....\$189*5 Challenges per testing event*This program is for performing **D (Rh) Typing** only by a slide or tube method.Samples are red cell suspensions for typing. **CMS reported.**

NON-CHEMISTRY PROGRAMS – continued**BOLD analytes are reported to CMS****Δ - denotes Point of Care Testing or Waived Programs****DIRECT ANTIGLOBULIN TEST [454].....\$246***2 challenges per testing event*

Suspension of red blood cells for direct anti-globulin testing.

Immunology**ANA PANEL [782].....\$315***5 challenges per testing event*

Liquid serum samples designed for screen methods as well as EIA and IFA methods:

| | |
|--|-------------|
| ANA Screen (for anti-DNA/anti-DNP, or anti-ENA) | Anti-SSA |
| Anti-DNA (ds, ss) | Anti-SSB |
| Anti-RNP | IFA Pattern |
| Anti-Sm | |

ANA PANEL – ADD-ON [783].....\$243*5 challenges per testing event*

Same as 782. Only available with 750 and 751.

Antistreptolysin O (ASO) – ADD-ON [753].....\$93*2 challenges per testing event*Liquid serum samples for qualitative **ASO**. Only available with 751.**C-REACTIVE PROTEIN [764].....\$138***2 challenges per testing event*

Liquid serum samples for qualitative and quantitative evaluation.

Not for high sensitivity methods. See module [765].

C-REACTIVE PROTEIN (CRP) – ADD-ON [776].....\$72*2 challenges per testing event*

Same as 764. Only available with 750.

DIAGNOSTIC ALLERGY [773].....\$399*5 challenges per testing event*

Liquid serum samples for quantitative evaluation of the following analytes:

| | |
|---|------------------|
| Allergen Specific IgE (14 from 2 specimens) | Total IgE |
|---|------------------|

IMMUNOLOGY MODULE [750].....\$375*5 challenges per testing event*

Liquid sample, a set of samples for each of the following analytes:

| | | |
|---------------------------|---------------------------------|--------------------------|
| Antistreptolysin O | Infectious Mononucleosis | Rheumatoid Factor |
|---------------------------|---------------------------------|--------------------------|

IMMUNOPROTEINS [784].....\$264*5 challenges per testing event*

Liquid serum samples for quantitative evaluation of the following analytes:

| | | |
|-----------|------------|------------|
| C3 | IgA | IgG |
| C4 | IgE | IgM |

INFECTIOUS MONONUCLEOSIS [762].....\$222*5 challenges per testing event*Liquid serum samples for qualitative IgG, IgM or Ig-nonspecific evaluation. **CMS reported.****Δ INFECTIOUS MONONUCLEOSIS – WAIVED [755].....\$141***2 challenges per testing event*

Liquid serum samples for qualitative IgG, IgM or Ig-nonspecific evaluation using waived methods only.

INFECTIOUS MONO/RHEUMATOID FACTOR [761].....\$345*5 challenges per testing event*Liquid serum samples for **Infectious Mononucleosis** and **Rheumatoid Factor**.**RHEUMATOLOGY MODULE [751].....\$276***5 challenges per testing event*Liquid serum samples for **Rheumatoid Factor** and C-Reactive protein (not for high-sensitivity methods)**RHEUMATOID FACTOR [763].....\$222***5 challenges per testing event*Liquid serum samples for qualitative evaluation. **CMS reported.****SPECIFIC ALLERGEN TESTING [770].....\$399***2 challenges per testing event*

14 Allergen specific IgE challenges. Does not include total IgE.

Serology**Δ H. PYLORI ANTIBODY DETECTION [780].....\$186***2 challenges per testing event*

Liquid serum samples for qualitative evaluation.

NON-CHEMISTRY PROGRAMS – continued**BOLD analytes are reported to CMS****Δ - denotes Point of Care Testing or Waived Programs****HIV MARKERS [791].....\$318** *5 challenges per testing event*

Liquid serum samples for qualitative evaluation of the following analytes:

Anti-HIV1

Anti-HIV1 Confirmation

HIV1 p24 Antigen

Δ HIV MARKERS – WAIVED [790].....\$201 *2 challenges per testing event*

For rapid antigen/antibody testing using waived methods:

Anti-HIV1

HIV1 p24 Antigen

MYCOPLASMA ANTIBODY [781]\$192 *2 challenges per testing event*

Liquid serum samples for qualitative evaluation.

ORAL FLUID HIV ANTIBODIES [793].....\$402 *5 challenges per testing event*Simulated oral fluid samples for **anti-HIV1 screening and confirmation.****RUBELLA [771].....\$222** *5 challenges per testing event*Liquid serum samples for qualitative IgG, & Ig-nonspecific evaluation. **CMS reported.****SARS-CoV-2 SEROLOGY [792].....\$324** *2 challenges per testing event*

Liquid specimens for SARS-CoV-2 antibody.

SYPHILIS SEROLOGY [772].....\$243 *5 challenges per testing event*Liquid serum samples for **qualitative/semi-quantitative** evaluation by **EIA, FTA, MHA, RPR, TPPA and VDRL.****ToRCH [752].....\$310** *3 challenges per testing event,***Must enroll in Rubella [771] for CLIA reporting;** supplemental for Rubella IgM only:*1st & 3rd events only*

does not meet CLIA Rubella requirements.

Liquid specimens for the following analytes:

Cytomegalovirus

Rubella IgM

HSV1; IgG, IgM

Toxoplasma

HSV2; IgG, IgM

VIRAL MARKERS [775].....\$510 *5 challenges per testing event*

Liquid serum samples for qualitative evaluation of the following analytes:

Anti-HBc, Total/IgG

Anti-Hepatitis A, IgM

Anti-HIV1

Anti-HBc, IgM

Anti-Hepatitis A, Total/IgG

Anti-HBs

HBeAg

Anti-HCV

HBsAg

Microbiology**Proficiency Testing Requirements**

Unlike other specialties under CLIA, Microbiology does not have specific analytes. Instead, laboratories are responsible for selecting Proficiency Testing that covers all aspects of testing offered by their laboratory. The general requirement that Proficiency Testing be comprised of 3 events per year with 5 samples per event applies (with the exception of Acid Fast Smears). The *all aspects of testing offered* requirement means that the laboratory must cover all subspecialties, all basic techniques employed, and all organisms tested by the laboratory.

Federal law requires a minimum of five CMS regulated (non-waived methods) bacteriology challenges per shipment. Individual state laws may differ. When enrolling, ensure your order meets the requirement that is the more stringent of the two. The number of challenges is noted in parentheses. All urine culture specimens are suitable for presumptive identification and/or definitive identification.

To ensure that you meet the 3 by 5 sample requirement, you should select a program that most closely reflects the level of service offered by your laboratory. You may select supplemental programs to cover all aspects of testing offered by your laboratory. If you do not test all sources in a program, you must select an additional program to ensure five reported results. A variety of 5 challenge programs and supplemental programs are offered to make meeting this requirement easier.

It is the responsibility of the laboratory to ensure that they are ordering an adequate selection of Proficiency Testing to meet CLIA requirements. Be aware that Deemed Accrediting Agencies will have their own additional requirements or specific

interpretations of how to meet the proficiency standard. When in doubt you should discuss this with your laboratory's Deemed Accrediting Agency.

Note: The specimens included may contain dangerous pathogens and must be treated with extreme care. These specimens must be handled and disposed of only by personnel trained to work with pathogenic microorganisms.

BACTERIOLOGY – Culture and Identification

Note: CMS requires PT programs to use the CLSI Performance Standards for Antimicrobial Susceptibility Testing. Reporting inappropriate antimicrobials for the intended organism, as indicated by the CLSI guidelines, will be scored as misses.

BACTERIOLOGY 1 [630].....\$381 *6 challenges per testing event*

Pure and mixed cultures will be included for identification. Sources will vary.

Antimicrobial Susceptibility may be performed from the urine culture. For Miscellaneous cultures, all organisms found must be reported. The culture quantities reflect the number of sources per event.

1 Genital Culture

1 Throat Culture

3 Miscellaneous Cultures*

1 Urine Culture

1 Antimicrobial susceptibility

2 Gram Stain/Morphology

**Possible sources include Blood, CSF, Ear, Eye Sputum, Stool, Wound*

BACTERIOLOGY 2 [640].....\$366 *6 challenges per testing event*

Pure and mixed cultures will be included for identification.

Antimicrobial Susceptibility may be performed from the urine culture.

The culture quantities reflect the number of sources per event.

1 Genital Culture

2 Throat Cultures

2 Urine Culture

2 Gram Stain/Morphology

1 Antimicrobial susceptibility

1 Strep A Antigen Detection

GENITAL CULTURE [646].....\$348 *5 challenges per testing event*

Pure and mixed cultures for identification of genital pathogens, Strep Group B and/or Neisseria gonorrhea; 1 Gram Stain/Morphology. **CMS reported.**

MISCELLANEOUS CULTURES – ADD-ON [651].....\$207 *3 challenges per testing event*

3 miscellaneous aerobic and anaerobic cultures for identification to include Blood, CSF, Ear, Eye Sputum, Stool, and Wound.

Only available with 640 through 646. **CMS reported.**

MRSA CULTURE [695].....\$327 *5 challenges per testing event*

Culture swab samples for the detection of Methicillin Resistant *S. aureus*. **CMS reported.**

MRSA CULTURE – ADD-ON [696].....\$174 *2 challenges per testing event*

Same as 695. Only available with 630 through 646. **CMS reported.**

SUPPLEMENTAL BLOOD CULTURE [694].....\$171 *2 challenges per testing event*

Lyophilized pellets with dilution buffer to simulate liquid blood samples.

Only available with 630 through 646. **CMS reported.**

THROAT CULTURE [641].....\$348 *5 challenges per testing event*

Pure and mixed cultures will be included for identification. **CMS reported.**

URINE COLONY COUNT [648].....\$264 *2 challenges per testing event*

Lyophilized pellet for bacterial colony count only. No presumptive identification may be submitted for this module.

Colony Count does not contribute to the minimum of five bacteriology challenges.

URINE CULTURE [643].....\$348 *5 challenges per testing event*

Pure and mixed cultures will be included for identification.

5 Culture identifications

1 Antimicrobial susceptibility

1 Gram Stain/Morphology

NON-CHEMISTRY PROGRAMS – continued**BOLD analytes are reported to CMS****Δ - denotes Point of Care Testing or Waived Programs****URINE/THROAT CULTURE [645].....\$351***5 challenges per testing event*

Pure and mixed cultures will be included for identification. The culture quantities reflect the number of sources per event.

**3 Urine Culture identifications
2 Throat Culture identifications****1 Antimicrobial susceptibility
1 Gram Stain/Morphology****BACTERIOLOGY – Non-culture****C. DIFFICILE/ROTAVIRUS ANTIGEN DETECTION [682].....\$333***5 challenges per testing event*Lyophilized specimens for detection of C. difficile and Rotavirus antigen. **CMS reported.****CHLAMYDIA/GC/STREP B ANTIGEN SCREEN [675].....\$414***5 challenges per testing event*

Swab specimens for Chlamydia trachomatis, Neisseria gonorrhea and Streptococcus Group B antigen screens.

These specimens cannot be cultured. **CMS reported.****CHLAMYDIA/GC/STREP B – ADD-ON [673].....\$207***2 challenges per testing event*Same as 675. Only available with 630 through 646. **CMS reported.****GRAM STAIN [650].....\$252***5 challenges per testing event*Purified bacterial smears for Gram stain. **CMS reported.**

Includes two educational DigitalScope™ slide images available online only.

LEGIONELLA ANTIGEN DETECTION [686].....\$282*5 challenges per testing event*

Swab samples for detection of Legionella antigen. For use with Binax NOW Legionella Urinary Antigen Detection kit only.

CMS reported.**OSOM BACTERIAL VAGINOSIS – WAIVED [692].....\$210***2 challenges per testing event*

Swab samples for testing with Sekisui OSOM BVBlue Test.

RAPID UREASE (CLO) [665].....\$183*2 challenges per testing event*

Simulated gastric samples for use with CLOtest, PyloriTek or similar methods.

SHIGA TOXIN [684].....\$264*2 challenges per testing event*

Specimens for Shiga Toxin 1 and 2.

For supplemental testing only, must addition to another 5-vial CLIA acceptable other Bacteriology antigen programs.**STREP A ANTIGEN DETECTION [660].....\$219***5 challenges per testing event*

Pre-inoculated swabs for antigen screening only.

Any method requiring live bacteria, such as cultures, stains or DNA probe methods should enroll in the Throat Culture or other appropriate Bacteriology Culture and ID module. **CMS reported.****Δ STREP A ANTIGEN DETECTION – WAIVED [662].....\$138***2 challenges per testing event*

Pre-inoculated swabs for antigen screening using waived methods only.

STREPTOCOCCUS PNEUMONIAE ANTIGEN DETECTION [687].....\$288*5 challenges per testing event*Swab samples for detection of Strep pneumoniae antigen. For use with Binax NOW Streptococcus pneumoniae Urinary Antigen Detection kit only. **CMS reported.****TRICHOMONAS VAGINALIS – WAIVED [693].....\$210***2 challenges per testing event*

Lyophilized samples for testing with Sekisui OSOM Test.

VAGINOSIS SCREEN [668].....\$441*5 challenges per testing event*

Swab specimens compatible with all molecular probe and antigen detection methods for the following vaginal pathogens:

BV Detection**Candida albicans****Gardnerella vaginalis****Trichomonas vaginalis****MYCOBACTERIOLOGY****ACID-FAST SMEARS [679].....\$236***5 challenges per testing event,*Prepared, fixed slides for acid-fast staining. **CMS reported.***1st & 3rd events only***MYCOLOGY****DERMATOPHYTE CULTURE [678].....\$312***5 challenges per testing event*Swabs for culture and identification. **CMS reported.**

NON-CHEMISTRY PROGRAMS – continued**BOLD analytes are reported to CMS****Δ - denotes Point of Care Testing or Waived Programs**

KOH SLIDES [538].....\$201 *2 challenges per testing event*
 Glass slides to represent a KOH examination.

PARASITOLOGY

CRYPTOSPORIDIUM/GIARDIA LAMBLIA ANTEGEN DETECTION [683]...\$369 *5 challenges per testing event*
 Formalinized fecal specimens for analysis of Cryptosporidium and Giardia. **CMS reported.**

PARASITOLOGY [691].....\$399 *5 challenges per testing event*
 Specimens include fecal specimens (formalinized), peripheral blood smears and DigitalScope™ slide images. **CMS reported.**

PVA SLIDES – ADD ON [690].....\$207 *2 challenges per testing event*
 Slides for staining and identification. Only available with 691. **CMS reported.**

VIROLOGY

Δ RESPIRATORY ANTIGEN DETECTION – WAIVED [680].....\$234 *2 challenges per testing event*
 Liquid specimens for detection of the following analytes using waived methods only:
 Influenza Type A & Influenza Type B
 Respiratory syncytial virus (RSV) antigen

RESPIRATORY ANTIGEN DETECTION [681].....\$345 *5 challenges per testing event*
 Lyophilized vials for detection of the following analytes:
 Influenza Type A & Influenza Type B
 Respiratory syncytial virus (RSV) antigen

Δ SARS-CoV-2 ANTIGEN DETECTION – WAIVED [688].....\$345 *2 challenges per testing event*
 Swab specimens for the antigen detection of SARS-CoV-2 using waived methods only.

SARS-CoV-2 ANTIGEN DETECTION [697].....\$522 *5 challenges per testing event*
 Swab specimens for detection of SARS-CoV-2 by antigen methods. **CMS reported.**

Δ SARS-CoV-2 MOLECULAR DETECTION – WAIVED [689].....\$354 *2 challenges per testing event*
 Swab specimens for the molecular detection of SARS-CoV-2 using waived methods only.

SARS-CoV-2 MOLECULAR DETECTION [698].....\$531 *5 challenges per testing event*
 Swab specimens for detection of SARS-CoV-2 by molecular methods. **CMS reported.**

WAIVED PACKAGES

BASIC WAIVED AND PPM PACKAGE [902].....\$321 *1-2 challenges per testing event*
 Multiple samples for the following analytes:

| | | |
|---------------------------|----------------|---------------------|
| Fecal Occult Blood | Urinalysis | Whole Blood Glucose |
| PPM | Urine Sediment | |
| Strep A Antigen Detection | Urine hCG | |

WAIVED AND PPM PACKAGE [901].....\$366 *1-2 challenges per testing event*
 Multiple samples for the following analytes:

| | | |
|---------------------------|----------------|---------------------|
| Fecal Occult Blood | Urinalysis | Whole Blood Glucose |
| PPM | Urine Sediment | Hematocrit |
| Strep A Antigen Detection | Urine hCG | Hemoglobin |

ANDROLOGY AND EMBRYOLOGY AND FETAL PROGRAMS

ANTISPERM ANTIBODIES [978].....\$298 *2 challenges per testing event*
 Liquid serum samples for qualitative IgG evaluation.

EMBRYO GRADING [984].....\$334 *2 challenges per testing event*
 Videos for Embryo grading; multiple answers for three different days

FETAL FIBRONECTIN (FFN) [983].....\$446 *2 challenges per testing event*
 Liquid simulated cervicovaginal specimens.

NON-CHEMISTRY PROGRAMS – continued**BOLD analytes are reported to CMS****Δ - denotes Point of Care Testing or Waived Programs****FETAL MEMBRANE RUPTURE TEST [975].....\$404***2 challenges per testing event*

Samples for detection of placental alpha-1-microglobulin

IVF EMBRYO CULTURE MEDIA [976].....\$516*2 challenges per testing event*

Two samples of culture media and one vial of human serum albumin per shipment to challenge the laboratory's ability to test media suitability for in-vitro embryo cultures.

PREIMPLANTATION GENETIC TESTING - ANEUPLOIDY [977].....\$980*3 challenges per testing event*

Samples consists of extracted DNA diluted to the 5 – 6 cell level. The samples will be tested and reported for Sex and Euploid or Aneuploid status and will be graded. Can report chromosome additions or deletions for educational purpose and will not be graded.

SPERM COUNT, QUALITATIVE/POST VASECTOMY [979].....\$288*2 challenges per testing event*Liquid samples of stabilized sperm for qualitative post-vasectomy analysis. **Required for CAP accredited laboratories.****SPERM COUNT, QUANTITATIVE AND QUALITATIVE [980].....\$324***2 challenges per testing event*

Liquid samples of stabilized sperm for quantitative and qualitative analysis and digital videos for Hemocytometer and Makler methods.

SPERM MORPHOLOGY [981].....\$324*2 challenges per testing event*

Unstained semen smears on glass slides and whole slide DigitalScope™ images for sperm morphology analysis.

Samples are not compatible with Testsimplets.

SPERM MOTILITY [985].....\$336*2 challenges per testing event*

Digital video for sperm motility

SPERM VIABILITY [982].....\$324*2 challenges per testing event*

This program is Eosin-Nigrosin stained slides featuring DigitalScope™ images.

SPECIALTY TESTING**This program is designed to meet the laboratory's External Quality Assessment needs in other than the traditional proficiency testing. These are not reported to CMS.****GLUCOSE, WB, EQAS (MULTI-SITE) [903].....\$255***2 challenges per testing event*

This program is WB Glucose testing on multiple glucometers at a facility or institutions. 2 sets of samples shipped.

This allows the participant to challenge up to 20 operators and/or glucometers for testing accuracy.

This is an externally graded program, but for internal use only. **Samples ship with Chemistry/NonChemistry events.**



MEDICAL LABORATORY EVALUATION

A SERVICE OF THE AMERICAN ASSOCIATION OF BIOANALYSTS

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