

## 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 formerly HCFA) and accepted by Commission on Office Laboratory Accreditation (COLA), Joint Commission on Accreditation of Healthcare Organizations (JCAHO), 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-pts.org](http://www.aab-pts.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. 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 mailed to the participants within 21 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.

A confirmation of your subscription will be sent to you and to the proper regulatory authorities. Notify our office if your confirmation is not received within 21 days of order placement.

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

To place an order, go to our website at [www.aab-mle.org](http://www.aab-mle.org) to use our online ordering tool, or complete an order form and send it 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, thus, no orders will be processed without one of the above payment methods. **Online orders will ONLY be accepted with credit cards and purchase orders. Call 800-234-5315 with credit card information after submitting online order.** Orders may be faxed or emailed if accompanied by a purchase order, credit card payment or letter of authorization. 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**

New account orders must be received by December 2, 2022. 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.

Current 2022 participants will be automatically renewed for 2023 in current year enrollment if renewal order or notification to cancel is not received by September 9, 2022. Autorenewal invoices not paid by January 16, 2023 will not be shipped Q1 2023 samples.

**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 [customerservice@aab-pts.org](mailto:customerservice@aab-pts.org) or [mle@aab-mle.org](mailto: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.”

**2023 Ship Schedule**

Chemistry & Non Chemistry	Shipping Dates	Last Day for Replacement Specimens	Cut-off Date for Results Submission	Evaluations Returned
M1 2023	February 7	February 15	February 24	March 17
M2 2023	May 16	May 24	June 2	June 23
M3 2023	September 12	September 20	September 29	October 20
Andrology, Embryology	Shipping Dates	Last Day for Replacement Specimens	Cut-off Date for Results Submission	Evaluations Returned
S1 2023	April 4	April 12	April 21	May 12
S2 2023	October 24	November 1	November 10	December 1

**Important Information** – Participants are responsible for notifying AAB when the testing kit has not been received **within 3 days** of the shipment date. AAB’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 #
		<b>Adulterated Urine</b>	<b>10 mL liquid specimen</b>	<b>23</b>
		Creatinine, Urine		
		Nitrite, Urine		
		Oxidants		
		pH, Urine		
		Specific Gravity, Urine		
		Interpretation		
		<b>Afinion Glycohemoglobin</b>	<b>0.5 mL liquid hemolysate</b>	<b>23</b>
		Hemoglobin A1c, Afinion (HbA1c)		
		<b>Ammonia</b>	<b>2 mL liquid specimen</b>	<b>23</b>
		Ammonia, Serum		
		<b>Blood Gases</b>	<b>1.7 mL liquid specimen</b>	<b>23</b>
		Calcium, Ionized		
		Chloride		
		Glucose		
		Lactate		
CMS		pCO2		
CMS		pH, Blood Gas		
CMS		pO2		
		Potassium		
		Sodium		
		<b>Blood Lead - Waived</b>	<b>6 mL liquid hemolysate</b>	<b>23</b>
		Lead, Blood		
		<b>Blood Oximetry</b>	<b>1.2 mL liquid specimen</b>	<b>23</b>
		Carboxyhemoglobin		
		Hemoglobin		
		Methemoglobin		
		Oxyhemoglobin		
		<b>BNP/D-Dimer</b>	<b>1.5 mL liquid specimen</b>	<b>23</b>
		BNP		
		NT-proBNP		
		D-Dimer, Qual		
		D-Dimer, Quant, ng/mL		
		D-Dimer, Quant, ugFEU/mL		
		<b>Cardiac Markers</b>	<b>1.5 mL liquid specimen</b>	<b>23</b>
		BNP		
CMS		CK-2/CKMB		
		D-Dimer		

CMS Regulated	CAP Accepted	Program /Analyte	Specimen Type	Page #
		Myoglobin, Quantitative		
		NT-proBNP		
		Troponin I		
		Troponin T		
		<b>Chemistry Module</b>	<b>5 mL liquid specimen</b>	<b>23</b>
CMS		Albumin		
CMS		Alkaline Phosphatase		
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		

CMS Regulated	CAP Accepted	Program /Analyte	Specimen Type	Page #
		TIBC - Direct		
CMS		Triglycerides		
CMS		Triiodothyronine (T3)		
CMS	CAP	TSH		
		UIBC - Direct		
CMS		Urea Nitrogen, Blood		
CMS		Uric Acid		
		<b>Comprehensive Metabolic Panel</b>	<b>5 mL liquid specimen</b>	<b>24</b>
CMS		Albumin		
CMS		Alkaline Phosphatase		
CMS		ALT/SGPT		
CMS		AST/SGOT		
		Bicarbonate (CO2)		
CMS		Bilirubin, Direct		
		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		
		<b>Endocrinology 1</b>	<b>5 mL liquid specimen</b>	<b>24</b>
	CAP	DHEA-S		
	CAP	Estradiol		
		Ferritin		
		Folate		
	CAP	Follicle Stimulating Hormone (FSH)		
		Homocysteine		
	CAP	Luteinizing Hormone (LH)		

CMS Regulated	CAP Accepted	Program /Analyte	Specimen Type	Page #
		Pre-albumin		
	CAP	Progesterone		
	CAP	Prolactin		
	CAP	Testosterone, Total		
		Transferrin		
		Vitamin B12		
		<b>Endocrinology 2</b>	<b>2 mL lyophilized spec.</b>	<b>24</b>
		C-Peptide		
		Insulin		
		PTH (Parathyroid Hormone)		
		Vitamin D		
		<b>Ethyl Glucuronide – Add-On</b>	<b>1 mL liquid specimen</b>	<b>24</b>
		Ethyl glucuronide		
		<b>Fertility Testing</b>	<b>5 mL liquid specimen</b>	<b>24</b>
	CAP	DHEA-S		
	CAP	Estradiol		
	CAP	Follicle Stimulating Hormone (FSH)		
	CAP	Luteinizing Hormone (LH)		
	CAP	Progesterone		
		<b>Fluids Chemistry</b>	<b>10 mL liquid specimen</b>	<b>24</b>
		Albumin, Fluids		
		Amylase, Fluids		
		Chloride, Fluids		
		Cholesterol, Fluids		
		Creatinine, Fluids		
		Glucose, Fluids		
		Lactic Acid, Fluids		
		Lactate Dehydrogenase (LD or LDH), Fluids		
		pH, Fluids		
		Protein, Total, Fluids		
		Sodium, Fluids		
		Uric Acid, Fluids		
		<b>Glycohemoglobin</b>	<b>1 mL liquid hemolysate</b>	<b>24</b>
		Glycohemoglobin		
		<b>Glycohemoglobin, 5-vial</b>	<b>1 mL liquid hemolysate</b>	<b>24</b>
		Glycohemoglobin		
		<b>High Sensitivity C-Reactive Protein</b>	<b>1.5 mL liquid specimen</b>	<b>24</b>
		C-Reactive Protein, high sensitivity (hsCRP)		

CMS Regulated	CAP Accepted	Program /Analyte	Specimen Type	Page #
		<b>Iron Binding Capacity</b>	<b>5 mL liquid specimen</b>	<b>24</b>
		Iron, Binding Capacity, Total (TIBC)		
		Iron, Binding Capacity, Unsaturated (UIBC)		
		Transferrin		
		<b>i-STAT Chemistry</b>	<b>1.7 mL liquid specimen</b>	<b>25</b>
		Calcium, Ionized		
CMS		Chloride		
CMS		Creatinine		
CMS		Glucose		
CMS		Hematocrit		
CMS		Hemoglobin		
CMS		Potassium		
CMS		Sodium		
		tCO2		
CMS		Urea Nitrogen, Blood		
		<b>i-STAT Chemistry - Waived</b>	<b>1.7 mL liquid specimen</b>	<b>25</b>
		Calcium, Ionized		
		Chloride		
		Creatinine		
		Glucose		
		Hematocrit		
		Hemoglobin		
		Potassium		
		Sodium		
		tCO2		
		Urea Nitrogen, Blood		
		<b>Lipid Panel/Glucose—Waived</b>	<b>1.2 ml liquid specimen</b>	<b>25</b>
		Cholesterol, Total		
		Cholesterol, HDL		
		Cholesterol, LDL (Calc)		
		Glucose		
		Triglycerides		
		<b>Lipid Profile</b>	<b>1.2 ml liquid specimen</b>	<b>25</b>
		Apolipoproteins, A1		
		Apolipoproteins, B		
CMS		Cholesterol, HDL		
		Cholesterol, LDL (Direct)		
		Cholesterol, LDL (Calc)		
CMS		Cholesterol, Total		

CMS Regulated	CAP Accepted	Program /Analyte	Specimen Type	Page #
		Lipoprotein (a)		
		<b>Neonatal/Direct Bilirubin</b>	<b>1 mL liquid specimen</b>	<b>25</b>
		Bilirubin, Direct		
CMS		Bilirubin, Neonatal		
CMS		Bilirubin, Total		
		<b>p2PSA</b>	<b>1 mL liquid specimen</b>	<b>25</b>
		p2PSA		
		<b>PSA</b>	<b>1 mL liquid specimen</b>	<b>25</b>
		PSA		
		<b>Serum Alcohol/Ketones</b>	<b>2 mL liquid specimen</b>	<b>25</b>
		Acetone		
CMS		Alcohol (Ethanol)		
		Beta Hydroxybutyrate		
		<b>Serum hCG</b>	<b>1 mL liquid specimen</b>	<b>25</b>
CMS	CAP	Pregnancy Qualitative & Quantitative		
		<b>SHBG/Testosterone</b>	<b>2 mL lyophilized specimen</b>	<b>25</b>
		Sex Hormone Binding Globulin (SHBG)		
		Testosterone, Total		
		Testosterone, Free		
		Testosterone, Bioavailable		
		<b>Therapeutic Drug Monitoring</b>	<b>5 mL liquid specimen</b>	<b>25</b>
		Acetaminophen		
CMS		Carbamazepine		
CMS		Digoxin		
CMS		Gentamicin		
CMS		Lithium		
CMS		Phenobarbital		
CMS		Phenytoin		
		Salicylates -mg/dL		
CMS		Theophylline		
CMS		Tobramycin		
CMS		Valproic Acid		
		Vancomycin		
		<b>Thyroid Antibodies</b>	<b>1 mL liquid specimen</b>	<b>26</b>
		Thyroglobulin Antibody		
		Thyroid peroxidase Antibody (TPO)		



CMS Regulated	CAP Accepted	Program /Analyte	Specimen Type	Page #
		<b>Thyroid Profile</b>	<b>5 mL liquid specimen</b>	<b>26</b>
CMS		Alpha-fetoprotein		
CMS		Cortisol		
		T3, Free		
CMS		T3 - Uptake		
CMS		Thyroxine (T4)		
CMS		Thyroxine (T4), Free		
CMS		Triiodothyronine (T3)		
CMS		TSH		
		<b>Total Protein</b>	<b>3 ml liquid specimen</b>	<b>26</b>
CMS		Total Protein		
		<b>Tumor Markers</b>	<b>2 mL liquid specimen</b>	<b>26</b>
		Beta-2-microglobulin		
		CA 125		
		CA 15-3		
		CA 19-9		
		CA 27.29		
		Carcinoembryonic Antigen (CEA)		
		PSA, Free		
		Prostatic Acid Phosphatase (PAP)		
		Thyroglobulin		
		<b>Urine Chemistry</b>	<b>10 mL liquid specimen</b>	<b>26</b>
		Amylase, Urine		
		Calcium, Urine		
		Chloride, Urine		
		Glucose, Urine		
		Magnesium, Urine		
		Osmolality, Urine		
		Phosphorus, Urine		
		Potassium, Urine		
		Protein, Total, Urine		
		Sodium, Urine		
		Urea Nitrogen, Urine		
		Uric Acid, Urine		
		<b>Urine Drug Screen</b>	<b>10 ml liquid specimen</b>	<b>26</b>
		Acetaminophen		
		Alcohol (Ethanol)		
		Amphetamines		
		Amphetamines/Methamphetamines		

CMS Regulated	CAP Accepted	Program /Analyte	Specimen Type	Page #
		Barbiturates		
		Benzodiazepines		
		Buprenorphine		
		Cannabinoids / Marijuana		
		Carisoprodol		
		Cocaine Metabolites		
		Cotinine		
		Ecstasy (MDMA)		
		Fentanyl		
		Hydrocodone		
		LSD (Lysergic Acid Diethylamide)		
		6-MAM		
		MDMA (Ecstasy)		
		Meperidine		
		Methadone		
		Methadone Metabolite (EDDP)		
		Methamphetamine		
		Methaqualone		
		Opiates		
		Oxycodone		
		Phencyclidine (PCP)		
		Propoxyphene		
		Tramadol		
		Tricyclic Antidepressants (TCA)		
		Zolpidem		
		<b>Waived Chemistry Panel</b>	<b>5 mL liquid specimen</b>	<b>26</b>
		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 or CPK)		

CMS Regulated	CAP Accepted	Program /Analyte	Specimen Type	Page #
		Creatinine		
		Glucose		
		GGT		
		Phosphorus		
		Potassium		
		Protein, Total		
		Sodium		
		Triglycerides		
		Urea Nitrogen, Blood		
		Uric Acid		
		<b>Whole Blood Glucose</b>	<b>1 mL liquid specimen</b>	<b>27</b>
		Glucose, Whole Blood		
		<b>Whole Blood Glucose – Waived</b>	<b>1 mL liquid specimen</b>	<b>27</b>
		Whole Blood Glucose		
<b>PPM &amp; URINALYSIS</b>				
		<b>Fecal Occult Blood</b>	<b>1.5 mL liquid specimen</b>	<b>27</b>
		Fecal Occult Blood		
		<b>Gastric Occult Blood</b>	<b>2 mL liquid specimen</b>	<b>27</b>
		Gastric Occult Blood		
		<b>KOH Slides</b>	<b>KOH Slides</b>	<b>27</b>
		KOH Slides		
		<b>Provider Performed Microscopy</b>	<b>Photos &amp; Digital Image</b>	<b>27</b>
		Fern Test		
		Fecal Leukocytes		
		KOH, Vaginal		
		Nasal Eosinophils		
		Pinworm Preparation		
		Scabies		
		Sperm, Qualitative (Digital Image)		
		Vaginal Wet Mount		
		<b>Urinalysis Dipstick</b>	<b>12 mL liquid specimen</b>	<b>27</b>
		Bilirubin, Urine		
		Creatinine, Urine		
		Glucose, Urine		
		Hemoglobin/Blood, Urine		
		hCG		
		Ketones		
		Leukocyte Esterase		
		Microalbumin		

CMS Regulated	CAP Accepted	Program /Analyte	Specimen Type	Page #
		Nitrite		
		pH, Urine		
		Protein, Total, Urine		
		Specific Gravity, Urine		
		Urobilinogen		
		<b>Urinalysis Module</b>	<b>12 mL liquid specimen</b>	<b>27</b>
		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)		
		Urobilinogen		
		<b>Urine Eosinophils</b>	<b>DigitalScope Images</b>	<b>27</b>
		Eosinophils, Urine		
		<b>Urine hCG</b>	<b>2 mL liquid specimen</b>	<b>27</b>
		Pregnancy, Urine		
		<b>Urine Microalbumin/Creatinine</b>	<b>3 ml liquid specimen</b>	<b>28</b>
		Creatinine, Urine		
		Creatinine, Urine, Semiquantitative		
		Microalbumin, Quantitative		
		Microalbumin, Semiquantitative & Qualitative		
		<b>Urine Pregnancy – 2 vial</b>	<b>2 mL liquid specimen</b>	<b>28</b>
	CAP	Pregnancy, Urine		
		<b>Urine Sediment</b>	<b>Photos</b>	<b>28</b>
		Urine Sediment (Microscopic ID)		
<b>Waived Packages</b>				
		<b>Basic Waived and PPM Package</b>	<b>Multiple sample types</b>	<b>36</b>
		Fecal Occult Blood		
		PPM		
		Strep Antigen Detection		
		Urinalysis		
		Urine Sediment		

CMS Regulated	CAP Accepted	Program /Analyte	Specimen Type	Page #
		Urine hCG		
		Whole Blood Glucose		
		<b>Waived and PPM Package</b>	<b>Multiple sample types</b>	<b>36</b>
		Fecal Occult Blood		
		PPM		
		Strep Antigen Detection		
		Urinalysis		
		Urine Sediment		
		Urine hCG		
		Whole Blood Glucose		
		Hematocrit		
		Hemoglobin		
<b>Coagulation</b>				
		<b>Activated Clotting Time (ACT), 2 vial</b>	<b>2 mL lyophilized specimen</b>	<b>28</b>
		Activated Clotting Time		
		<b>CoaguChek XS Plus Prothrombin Time</b>	<b>.5 ml lyophilized specimen</b>	<b>28</b>
		INR		
CMS		Prothrombin Time		
		<b>CoaguChek XS Plus Prothrombin Time Waived</b>	<b>.5 ml lyophilized specimen</b>	<b>28</b>
		INR		
		Prothrombin Time		
		<b>Coagulation Module</b>	<b>1 mL lyophilized specimen</b>	<b>28</b>
CMS		Activated Partial Thrombin Time (APTT)		
CMS		Fibrinogen		
		INR		
		INR Calculation		
CMS		Prothrombin Time		
		<b>iStat Prothrombin Time</b>		<b>28</b>
CMS		Prothrombin Time		
		INR		
		<b>Roche CoaguChek XS INR - Waived</b>	<b>.5 ml lyophilized specimen</b>	<b>28</b>
		INR		
<b>Hematology</b>				
		<b>Blood Cell Identification</b>	<b>Photomicrographs</b>	<b>28</b>
CMS		Blood Cell Identification		
		Leukocyte (WBC) Differential, Manual		
		Erythrocyte Sedimentation Rate (ESR), Rapid		
		<b>Fluid Cell Count/Crystals</b>	<b>fluid plus micrographs</b>	<b>28</b>
		Erythrocyte (RBC) Count		

CMS Regulated	CAP Accepted	Program /Analyte	Specimen Type	Page #
		Leukocyte (WBC) Count		
		Crystals Identification		
		<b>Hematology Module</b>	<b>3 mL whole blood</b>	<b>29</b>
CMS		Blood Cell Identification		
CMS		Erythrocyte (RBC) Count		
CMS		Hematocrit		
CMS		Hemoglobin		
CMS		Leukocyte (WBC) Count		
CMS		Platelet Count		
		<b>Hematology with 3-part Diff</b>	<b>3 mL whole blood</b>	<b>29</b>
CMS		Erythrocyte (RBC) Count		
CMS		Hematocrit		
CMS		Hemoglobin		
CMS		Leukocyte (WBC) Count		
CMS		Leukocyte (WBC) Differential, Auto		
CMS		Platelet Count		
		<b>Hematology - Sysmex 3-part Diff</b>	<b>3 mL whole blood</b>	<b>29</b>
CMS		Erythrocyte (RBC) Count		
CMS		Hematocrit		
CMS		Hemoglobin		
CMS		Leukocyte (WBC) Count		
CMS		Leukocyte (WBC) Differential, Auto		
CMS		Platelet Count		
		<b>Hematology with 5-part Diff – Abbott Cell-Dyn</b>	<b>3 mL whole blood</b>	<b>29</b>
CMS		Erythrocyte (RBC) Count		
CMS		Hematocrit		
CMS		Hemoglobin		
CMS		Leukocyte (WBC) Count		
CMS		Leukocyte (WBC) Differential, Auto		
CMS		Platelet Count		
		<b>Hematology with 5-part Diff</b>	<b>3 mL whole blood</b>	<b>29</b>
CMS		Erythrocyte (RBC) Count		
CMS		Hematocrit		
CMS		Hemoglobin		
CMS		Leukocyte (WBC) Count		
CMS		Leukocyte (WBC) Differential, Auto		
CMS		Platelet Count		

CMS Regulated	CAP Accepted	Program /Analyte	Specimen Type	Page #
		<b>Hematology with 5 -part Diff – DxH 500 Series</b>	<b>3 mL whole blood</b>	<b>29</b>
CMS		Erythrocyte (RBC) Count		
CMS		Hematocrit		
CMS		Hemoglobin		
CMS		Leukocyte (WBC) Count		
CMS		Leukocyte (WBC) Differential, Auto		
CMS		Platelet Count		
		<b>Hematology with 5 or 6 -part Diff - Sysmex</b>	<b>3 mL whole blood</b>	<b>30</b>
CMS		Erythrocyte (RBC) Count		
CMS		Hematocrit		
CMS		Hemoglobin		
CMS		Leukocyte (WBC) Count		
CMS		Leukocyte (WBC) Differential, Auto		
CMS		Platelet Count		
		<b>Hematology with 5-part Diff – AcT 5 and Pentra</b>	<b>3 mL whole blood</b>	<b>29</b>
CMS		Erythrocyte (RBC) Count		
CMS		Hematocrit		
CMS		Hemoglobin		
CMS		Leukocyte (WBC) Count		
CMS		Leukocyte (WBC) Differential, Auto		
CMS		Platelet Count		
		<b>Hemoglobin/Glucose – Hemocue</b>	<b>2 ml whole blood</b>	<b>29</b>
		Glucose		
		Hemoglobin		
		<b>Hemoglobin/Hematocrit - Waived</b>	<b>3 mL whole blood</b>	<b>29</b>
		Hematocrit		
		Hemoglobin		
		<b>Hemoglobin/Hematocrit/WBC</b>	<b>3 mL whole blood</b>	<b>29</b>
CMS		Hematocrit		
CMS		Hemoglobin		
CMS		WBC count		
		<b>Sedimentation Rate</b>	<b>3 mL whole blood</b>	<b>30</b>
		Erythrocyte Sedimentation Rate (ESR)		
		<b>Rapid Sedimentation Rate</b>	<b>3 mL whole blood</b>	<b>30</b>
		Erythrocyte Sedimentation Rate (ESR), Rapid		
		<b>Reticulocyte Count</b>	<b>1 mL whole blood</b>	<b>30</b>
		Reticulocytes, Automated		
		Reticulocytes, Manual		

CMS Regulated	CAP Accepted	Program /Analyte	Specimen Type	Page #
		<b>Sickle Cell Screen</b>	<b>2 mL whole blood</b>	<b>30</b>
		Sickle Cell Screen		
<b>Immunohematology</b>				
		<b>ABO/Rh Factor</b>	<b>1.5 ml serum &amp; red cells</b>	<b>30</b>
CMS		ABO Typing		
CMS		D (Rh) Typing		
		<b>Blood Bank 1</b>	<b>1.5 ml serum &amp; red cells</b>	<b>30</b>
CMS		ABO Typing		
CMS		D (Rh) Typing		
CMS		Unexpected Antibody Detection		
		<b>Blood Bank 2</b>	<b>1.5 ml serum &amp; red cells</b>	<b>30</b>
CMS		ABO Typing		
CMS		Compatibility Testing (Crossmatch)		
CMS		D (Rh) Typing		
CMS		Unexpected Antibody Detection		
CMS		Unexpected Antibody Identification		
		<b>D (Rh) Typing</b>	<b>1 mL washed red cells</b>	<b>30</b>
CMS		D (Rh) Typing		
		<b>Direct Antiglobulin Test</b>	<b>1 mL washed red cells</b>	<b>30</b>
		Direct Antiglobulin (DAT)		
<b>Immunology/Serology</b>				
		<b>ANA Panel</b>	<b>0.6 mL liquid specimens</b>	<b>30</b>
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		
		<b>C-Reactive Protein (CRP)</b>	<b>0.5 mL liquid specimen</b>	<b>30</b>
		C-Reactive Protein (CRP), Qualitative		
		C-Reactive Protein (CRP), Quantitative		
		<b>Diagnostic Allergy</b>	<b>2 mL liquid specimen</b>	<b>30</b>
		Allergen Specific IgE		
CMS		Total IgE		



CMS Regulated	CAP Accepted	Program /Analyte	Specimen Type	Page #
		<b>H. pylori Antibody Detection</b>	<b>0.5 mL liquid specimen</b>	<b>31</b>
		Helicobacter Pylori Antibody		
		<b>High Sensitivity C-Reactive Protein</b>	<b>1.5 mL liquid specimen</b>	<b>24</b>
		C-Reactive Protein, high sensitivity (hsCRP)		
		<b>HIV Markers</b>	<b>1 mL liquid specimen</b>	
CMS		HIV, Anti-HIV 1 (confirmation)		
CMS		HIV, Anti-HIV 1 or 1/2 (screening)		
		HIV, p24 Antigen		
		<b>HIV Markers - Waived</b>	<b>1 mL liquid specimen</b>	
		HIV, Anti-HIV 1, Waived		
		HIV, p24 Antigen, Waived		
		<b>Immunology Module</b>	<b>Separate vials per analyte</b>	<b>31</b>
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		
		<b>Immunoproteins</b>	<b>1 mL liquid specimen</b>	<b>31</b>
CMS		Complement C3		
CMS		Complement C4		
CMS		IgA		
CMS		IgE		
CMS		IgG		
CMS		IgM		
		<b>Infectious Mononucleosis</b>	<b>0.6 mL liquid specimen</b>	<b>31</b>
CMS		Infectious Mononucleosis		
		<b>Infectious Mononucleosis - Waived</b>	<b>0.6 mL liquid specimen</b>	<b>31</b>
		Infectious Mononucleosis		
		<b>Infectious Mono/Rheumatoid Factor</b>	<b>0.6 mL liquid specimen</b>	<b>31</b>
CMS		Infectious Mononucleosis		
CMS		Rheumatoid Factor (RF)		
		<b>Mycoplasma Antibody</b>	<b>0.5 mL lyophilized specimen</b>	<b>31</b>
		Mycoplasma antibody		
		<b>Oral Fluid HIV Antibodies</b>	<b>1 mL liquid specimen</b>	<b>31</b>
CMS		HIV, Oral Fluids (confirmation)		
CMS		HIV, Oral Fluids (screening)		
		<b>Rheumatoid Factor</b>	<b>1 mL liquid specimen</b>	<b>31</b>
CMS		Rheumatoid Factor (RF), Qualitative		
CMS		Rheumatoid Factor (RF), Quantitative, titer		

CMS Regulated	CAP Accepted	Program /Analyte	Specimen Type	Page #
		Rheumatoid Factor (RF), Quantitative, u/mL		
		<b>Rheumatology Module</b>	<b>1 mL liquid specimen</b>	<b>31</b>
CMS		Rheumatoid Factor (RF), Qualitative		
CMS		Rheumatoid Factor (RF), Quantitative, titer		
		Rheumatoid Factor (RF), Quantitative, u/mL		
		C-Reactive Protein		
		<b>Rubella</b>	<b>1 mL liquid specimen</b>	<b>31</b>
CMS		Rubella, IgG		
		<b>SARS-CoV-2 Serology</b>	<b>1 mL liquid specimen</b>	<b>31</b>
		SARS-CoV-2 Serology		
		<b>Specific Allergen Testing</b>	<b>2 mL liquid specimen</b>	<b>31</b>
		Allergen Specific IgE		
		<b>Syphilis Serology</b>	<b>1 mL liquid specimen</b>	<b>31</b>
CMS		Syphilis, Qualitative		
CMS		Syphilis, Quantitative		
		<b>ToRCH</b>	<b>1 mL liquid specimen</b>	<b>31</b>
		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		
		<b>Viral Markers</b>	<b>1.5 mL liquid specimen</b>	<b>32</b>
		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		
<b>Bacteriology - Cultures</b>				
		<b>Bacteriology 1</b>	<b>Swab specimen &amp; diluent</b>	<b>32</b>
CMS		Antimicrobial Susceptibility		
CMS		Organism Identification, Urine		
CMS		Organism Identification, Throat		
CMS		Organism Identification, Genital		

CMS Regulated	CAP Accepted	Program /Analyte	Specimen Type	Page #
CMS		3 Organism Identification, Misc		
CMS		Gram Stain		
		Gram Stain Morphology		
		<b>Bacteriology 2</b>	<b>Swab specimen &amp; diluent</b>	<b>33</b>
CMS		Antimicrobial Susceptibility		
CMS		Organism Identification, Urine		
CMS		Organism Identification, Throat		
CMS		Organism Identification, Genital		
CMS		Gram Stain		
		Gram Stain Morphology		
		<b>Dermatophyte Culture</b>		<b>35</b>
CMS		Dermatophyte culture		
		<b>Genital Culture</b>	<b>Swab specimen &amp; diluent</b>	<b>33</b>
CMS		Organism Identification, Genital Culture		
CMS		Gram Stain 1		
		Gram Stain Morphology 1		
		<b>Genital/Urine Culture</b>	<b>Swab specimen &amp; diluent</b>	<b>33</b>
CMS		Organism Identification, Genital Culture		
CMS		Organism Identification, Urine Culture		
CMS		Antimicrobial Susceptibility		
CMS		Gram Stain 2		
		Gram Stain Morphology 2		
		<b>Gram Stain and Morphology</b>	<b>5 Glass slides</b>	<b>34</b>
CMS		Gram Stain Identification		
		Gram Stain Organism Morphology		
		<b>Miscellaneous Cultures (Add-On)</b>	<b>Swab specimen &amp; diluent</b>	<b>33</b>
CMS		3 Miscellaneous Cultures (Add-On)		
		<b>MRSA Culture</b>	<b>Swab specimen &amp; diluent</b>	<b>33</b>
CMS		Methicillin Resistant S. aureus		
		<b>MRSA - Add-On</b>	<b>Swab specimen &amp; diluent</b>	<b>33</b>
CMS		MRSA 2 Challenges for probe testing		
		<b>Supplemental Blood Culture</b>	<b>Lyophilized pellet &amp; diluent</b>	<b>33</b>
CMS		Blood Culture, supplemental		
		<b>Throat Culture</b>	<b>Swab specimen &amp; diluent</b>	<b>33</b>
CMS		Organism Identification, Throat Culture		
		<b>Urine Colony Count</b>	<b>Lyophilized pellet &amp; diluent</b>	<b>33</b>
		Colony Count, Urine		
		<b>Urine Culture</b>	<b>Swab specimen &amp; diluent</b>	<b>33</b>
CMS		Antimicrobial Susceptibility		

CMS Regulated	CAP Accepted	Program /Analyte	Specimen Type	Page #
CMS		Organism Identification, Urine Culture		
CMS		Gram Stain 1		
		Gram Stain Morphology 1		
		<b>Urine Presumptive ID/Colony Count</b>	<b>Swab specimen &amp; diluent</b>	<b>33</b>
CMS		Antimicrobial Susceptibility		
CMS		Organism Identification, Urine Culture		
CMS		Gram Stain 1		
		Gram Stain Morphology 1		
		2 Colony Count		
		<b>Urine Presumptive ID/Throat Culture</b>	<b>Swab specimen &amp; diluent</b>	<b>33</b>
CMS		Antimicrobial Susceptibility		
		2 Colony Count		
CMS		Organism Identification, Throat Culture		
CMS		Organism Identification, Urine Culture		
CMS		Gram Stain		
		<b>Urine/Throat Culture</b>	<b>Swab specimen &amp; diluent</b>	<b>33</b>
CMS		Antimicrobial Susceptibility		
CMS		Organism Identification, Urine Culture		
CMS		Organism Identification, Throat Culture		
CMS		Gram Stain 1		
		Gram Stain Morphology 1		
<b>Antigen Testing</b>				
		<b>C. Difficile/Rotavirus Antigen Detection</b>	<b>1 mL lyophilized specimen</b>	<b>34</b>
CMS		C DifficileToxin/Antigen Detection		
CMS		Rotavirus		
		<b>Chlamydia/GC/Strep Group B Antigen Screen</b>	<b>Swab specimen</b>	<b>34</b>
CMS		Chlamydia Antigen Screen		
CMS		GC Antigen Screen		
CMS		Strep Group B, Antigen Screen		
		<b>Cryptosporidium/Giardia lamblia Antigen Detection</b>	<b>Formalin fecal specimen</b>	<b>36</b>
CMS		Cryptosporidium Immunoassay		
CMS		Giardia Immunoassay		
		<b>Legionella Antigen Detection</b>	<b>Swab specimen</b>	<b>34</b>
CMS		Legionella Antigen		
		<b>OSOM Bacterial Vaginosis - Waived</b>	<b>Swab specimen</b>	<b>35</b>
		Bacterioides		
		Gardnerella		
		Mobiluncus		
		Prevotells		

CMS Regulated	CAP Accepted	Program /Analyte	Specimen Type	Page #
		<b>Rapid Urease (CLO)</b>	<b>Simulated tissue specimen</b>	<b>35</b>
		Urease		
		<b>Respiratory Antigen Detection</b>	<b>1 mL liquid specimen</b>	<b>36</b>
CMS		Influenza, Type A. Antigen Screen		
CMS		Influenza, Type B, Antigen Screen		
CMS		Respiratory Syncytial Virus (RSV) Antigen		
		<b>Respiratory Antigen Detection - Waived</b>	<b>1 mL liquid specimen</b>	<b>36</b>
		Influenza, Type A, Antigen Screen, Waived		
		Influenza, Type B, Antigen Screen, Waived		
		Respiratory Syncytial Virus (RSV) Antigen, Waived		
		<b>SARS-CoV-2 Antigen Detection</b>	<b>Swab specimen</b>	<b>36</b>
		SARS-CoV-2		
		<b>SARS-CoV-2 Molecular Detection</b>	<b>Swab specimen</b>	<b>36</b>
		SARS-CoV-2		
		<b>Shiga Toxin</b>	<b>1 mL liquid specimen</b>	<b>36</b>
		Shiga Toxin		
		<b>Strep A Antigen Detection</b>	<b>Swab specimen</b>	<b>36</b>
CMS		Strep Group A Antigen		
		<b>Strep A Antigen Detection - Waived</b>	<b>Swab specimen</b>	<b>36</b>
		Strep Group A Antigen		
		<b>Streptococcus pneumoniae Antigen Detection</b>	<b>Swab specimen</b>	<b>36</b>
CMS		Strep pneumoniae antigen		
		<b>Trichomonas vaginalis - Waived</b>	<b>Swab specimen &amp; diluent</b>	<b>36</b>
		Trichomonas vaginalis Screen		
		<b>Vaginosis Screen</b>	<b>Swab specimen</b>	<b>36</b>
		Candida		
CMS		Gardnerella		
		Trichomonas		
<b>Staining</b>				
		<b>Acid Fast Smears</b>	<b>Glass slides-unstained</b>	<b>35</b>
CMS		Acid-Fast Bacteria/Smears		
		<b>Gram Stain and Morphology</b>	<b>5 Glass slides</b>	<b>34</b>
CMS		Gram Stain Identification		
		Gram Stain Organism Morphology		
<b>Parasitology</b>				
		<b>Parasitology</b>	<b>Formalin</b>	<b>35</b>
CMS		Parasitology		
		<b>PVA Slides - Add On</b>	<b>PVA specimen</b>	<b>35</b>
CMS		Parasitology		

CMS Regulated	CAP Accepted	Program /Analyte	Specimen Type	Page #
<b>Andrology, Embryology</b>				
		<b>Antisperm Antibody</b>	<b>Liquid specimen</b>	<b>36</b>
	NR	Antisperm Antibody		
		<b>Embryo Grading</b>	<b>Video image</b>	<b>36</b>
	NR	Embryo Grading		
		<b>Fetal Fibronectin (fFN)</b>	<b>Liquid specimen</b>	<b>36</b>
	CAP	Fetal Fibronectin (fFN)		
		<b>Fetal Membrane Rupture Test</b>	<b>0.5 mL liquid specimen</b>	<b>36</b>
	NR	Fetal Membrane Rupture (PAMG-1)		
		<b>IVF Embryo Culture Media</b>	<b>100 mL culture media</b>	<b>36</b>
	NR	IVF, Human Sperm Cell Survival, Media Accept		
	NR	IVF, Mouse Embryo, Media Acceptability		
		<b>Preimplantation Genetic Testing - Aneuploidy</b>	<b>5uL liquid specimen</b>	<b>37</b>
		Sex Status		
		Euploid or Aneuploid Status		
		Chromosome addition or deletion		
		<b>Sperm Count - Qualitative/Post Vasectomy</b>	<b>Liquid specimen</b>	<b>37</b>
	CAP	Sperm Count, Qualitative (Post Vasectomy)		
		<b>Sperm Count</b>	<b>Liquid spec. &amp; Digital video</b>	<b>37</b>
	CAP	Sperm Count, Quantitative		
		Sperm Count, Qualitative		
		<b>Sperm Morphology</b>	<b>Glass slide &amp; Digital slide</b>	<b>37</b>
	NR	Sperm Morphology, %		
	NR	Sperm Morphology, Cell ID		
		<b>Sperm Motility</b>	<b>Video Image</b>	<b>37</b>
	NR	Sperm Motility		
	NR	Sperm Motility, Forward Progression %		
	NR	Sperm Motility, Forward Progression, semi-quant.		
		<b>Sperm Viability</b>	<b>Glass slide &amp; Digital slide</b>	<b>37</b>
	CAP	Sperm Viability		
<b>Specialty</b>				
		<b>WB Glucose, EQAS (Multi-site)</b>	<b>1 mL liquid specimen</b>	<b>37</b>
		Glucose, Whole Blood		

**CHEMISTRY PROGRAMS****BOLD analytes are reported to CMS** $\Delta$  - denotes Point of Care Testing or Waived Programs**ADULTERATED URINE [876].....\$204** *2 challenges per testing event*

For use with adulterant detection methods testing the following analytes:

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

**ADULTERATED URINE – ADD-ON [874].....\$99** *2 challenges per testing event*

Same as 876. Available only with 868.

**AFINION GLYCOHEMOGLOGIN [851].....\$234** *2 challenges per testing event*

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

**AMMONIA [836].....\$189** *2 challenges per testing event*

Liquid samples for analysis of Ammonia.

**BLOOD GASES [847].....\$369** *5 challenges per testing event*

Aqueous samples for the following analytes (2 sets):

Chloride	Lactate	pO <sub>2</sub>
Glucose	pCO <sub>2</sub>	Potassium
Ionized Calcium	pH	Sodium

 **$\Delta$  BLOOD LEAD – WAIVED [838].....\$237** *2 challenges per testing event*

Whole blood samples for analysis of blood lead levels using waived methods only.

**For use with waived testing methods only.****BLOOD OXIMETRY [856].....\$381** *5 challenges per testing event*

Compatible with all Oximetry Instruments; liquid specimens for the following analytes:

Carboxyhemoglobin	Oxyhemoglobin
Methemoglobin	Hemoglobin, Total, supplemental

**Must be enrolled in a 5 challenge Hematology or Hemoglobin program.****BNP/D-DIMER [846].....\$258** *2 challenges per testing event*

Liquid samples compatible with the following analytes:

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

**CARDIAC MARKERS [845].....\$381** *5 challenges per testing event*

Samples are compatible with all methods &amp; instruments. Liquid samples for qualitative and quantitative analysis of the following analytes:

BNP	Myoglobin	Troponin T
<b>CK-2/CK-MB</b>	NT-proBNP	
D-Dimer	Troponin I	

**CHEMISTRY MODULE [810].....\$402** *5 challenges per testing event*

Liquid serum samples for the following analytes:

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

**CHEMISTRY PROGRAMS - continued****BOLD analytes are reported to CMS** $\Delta$  - denotes Point of Care Testing or Waived Programs**COMPREHENSIVE METABOLIC PANEL [813].....\$318** *5 challenges per testing event*

Liquid serum samples for analysis of the following analytes:

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

**ENDOCRINOLOGY 1 [860].....\$261** *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].....\$228** *2 challenges per testing event*

Lyophilized samples for the following analytes:

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

 **$\Delta$ ETHYL GLUCORONIDE – ADD-ON [873] .....\$81** *2 challenges per testing event*

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

**FERTILITY TESTING [858].....\$171** *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].....\$258** *2 challenges per testing event*

2 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].....\$219** *2 challenges per testing event*Samples for analysis of glycohemoglobin (Hgb A1c). *Samples are not compatible with the Afinion.***GLYCOHEMOGLOBIN, 5-VIAL [852].....\$387** *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].....\$144** *2 challenges per testing event*

Liquid serum samples. This program targets high sensitivity C-Reactive Protein methods only. For acute inflammatory CRP, please order regular CRP under Immunology section.

**HIGH-SENSITIVITY C-REACTIVE PROTEIN (HS-CRP) – ADD ON [777].....\$72** *2 challenges per testing event*

Same as 765. Only available with 750 and 751.

**IRON BINDING CAPACITY [828].....\$165** *2 challenges per testing event*

Liquid serum samples for the following targeted analytes:

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



**CHEMISTRY PROGRAMS - continued****BOLD analytes are reported to CMS** $\Delta$  - denotes Point of Care Testing or Waived Programs**I-STAT CHEMISTRY [818].....\$288** *5 challenges per testing event*

Liquid samples for the following analytes:

Bicarbonate (TCO <sub>2</sub> )	<b>Glucose</b>	<b>Potassium</b>
Calcium, Ionized	<b>Hematocrit</b>	<b>Sodium</b>
<b>Chloride</b>	<b>Hemoglobin</b>	<b>Urea Nitrogen (BUN)</b>
<b>Creatinine</b>		

 **$\Delta$  I-STAT CHEMISTRY – WAIVED [832].....\$204** *2 challenges per testing event*

Liquid samples for the following analytes using waived methods only:

Bicarbonate (TCO <sub>2</sub> )	Glucose	Potassium
Calcium, Ionized	Hematocrit	Sodium
Chloride	Hemoglobin	Urea Nitrogen (BUN)
Creatinine		

**LIPID PANEL/GLUCOSE – WAIVED [811].....\$201** *2 challenges per testing event*

Liquid serum samples for the following analytes:

Glucose	HDL Cholesterol	LDL Cholesterol (Calc)
Total Cholesterol	Triglyceride	

**LIPID PROFILE [829].....\$246** *5 challenges per testing event*

Liquid serum samples for the following analytes:

Lipoprotein (a)	Apolipoproteins A1 & B	<b>Total Cholesterol</b>
<b>HDL Cholesterol</b>	LDL Cholesterol (Direct)	<b>Triglyceride</b>

**NEONATAL/DIRECT BILIRUBIN [841].....\$243** *5 challenges per testing event*Liquid samples for analysis of **Total/Neonatal Bilirubin** and Direct Bilirubin for those labs needing 5 samples for reporting. This is a targeted program.**p2PSA [869].....\$228** *2 challenges per testing event*

Liquid samples intended for use with the Beckman Coulter p2PSA assay only.

**PSA [861].....\$162** *2 challenges per testing event*

Liquid samples for testing.

**PSA – ADD-ON [859].....\$72** *2 challenges per testing event*

Same as 861. Only available with 860.

**SERUM ALCOHOL/KETONES [835] .....\$264** *5 challenges per testing event*Liquid serum samples for analysis of **Ethanol** and Acetone, including Beta Hydroxybutyrate.**SERUM HCG [865].....\$207** *5 challenges per testing event*Liquid samples for qualitative and quantitative analysis of **serum hCG**.**SERUM HCG – ADD ON [866].....\$102** *5 challenges per testing event*

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

**SHBG/TESTOSTERONE [854].....\$360** *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].....\$237** *5 challenges per testing event*

Liquid serum samples for the following analytes:

Acetaminophen	<b>Lithium</b>	<b>Theophylline</b>
<b>Carbamazepine</b>	<b>Phenobarbital</b>	<b>Tobramycin</b>
<b>Digoxin</b>	<b>Phenytoin</b>	<b>Valproic Acid</b>
<b>Gentamicin</b>	Salicylates	Vancomycin

**CHEMISTRY PROGRAMS - continued****BOLD analytes are reported to CMS** $\Delta$  - denotes Point of Care Testing or Waived Programs**THERAPEUTIC DRUGS – ADD-ON [831].....\$69** *5 challenges per testing event*

Same as 830. Available only with 810.

**THYROID ANTIBODIES [864].....\$273** *2 challenges per testing event*

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

**THYROID PROFILE [824].....\$273** *5 challenges per testing event*

Liquid serum samples for the following analytes:

<b>Alpha-fetoprotein (AFP)</b>	<b>Thyroxine, Free (FT4)</b>	<b>Triiodothyronine, Total (TT3)</b>
<b>Cortisol</b>	<b>Thyroxine, Total (TT4)</b>	<b>TSH</b>
<b>T3 Uptake</b>	<b>Triiodothyronine, Free (FT3)</b>	

**TOTAL PROTEIN [844].....\$246** *5 challenges per testing event*

Liquid samples for Total Protein by refractometer.

**TUMOR MARKERS [862].....\$399** *2 challenges per testing event*

Liquid samples for the following analytes:

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

**URINE CHEMISTRY [872].....\$261** *2 challenges per testing event*

2 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.

 **$\Delta$  URINE DRUG SCREEN [868].....\$255** *2 challenges per testing event*

Liquid samples for the following analytes:

Acetaminophen	Cotinine	Methaqualone
Alcohol (Ethanol)	Fentanyl	Opiates
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	

 **$\Delta$  WAIVED CHEMISTRY PANEL [812].....\$243** *2 challenges per testing event***NOTE: this is for waived methods & instruments only.**

Cholestech Waived users do not need to enroll in separate Lipids analytes program.

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 (CO2)	Creatinine	Urea Nitrogen
Bilirubin, Total	GGT	Uric Acid
Calcium	Glucose	

 **$\Delta$  WAIVED CHEMISTRY PANEL – ADD-ON [833].....\$84**

Same as 812. Only available with 824.

**CHEMISTRY PROGRAMS - continued****BOLD analytes are reported to CMS** $\Delta$  - denotes Point of Care Testing or Waived Programs

**WHOLE BLOOD GLUCOSE [870]**.....\$294    *5 challenges per testing event*  
 For reporting Whole Blood Glucose procedures only.

**$\Delta$  WHOLE BLOOD GLUCOSE – WAIVED [871]**.....\$189    *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**

**$\Delta$  FECAL OCCULT BLOOD [542]**.....\$138    *2 challenges per testing event*  
 Simulated stool samples for analysis of fecal occult blood.

**$\Delta$  FECAL OCCULT BLOOD – ADD ON [537]**.....\$99    *2 challenges per testing event*  
 Same as 542. Only available with 530, 531

**$\Delta$  GASTRIC OCCULT BLOOD [543]**.....\$195    *2 challenges per testing event*  
 Simulated gastric samples for analysis of:

Occult blood	pH
--------------	----

**KOH SLIDES [538]**.....\$192    *2 challenges per testing event*  
 Glass slides to represent a KOH examination.

**$\Delta$  PROVIDER-PERFORMED MICROSCOPY [534]**.....\$150    *1 challenge set per testing event*  
 Each shipment will vary. Each shipment will be a combination of photomicrographs and digital image for the following:

1 Fecal Leukocytes	1 Scabies
1 Fern Test	1 Sperm Qualitative
1 Nasal Eosinophils	1 Vaginal KOH Prep
1 Pinworm Prep	1 Vaginal Wet Mount

**$\Delta$  PPM – ADD-ON [535]**.....\$51    *1 challenge set per testing event*  
 Same as 534. Only available with 530, 531.

**$\Delta$  URINALYSIS DIPSTICK [531]**.....\$120    *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.

**$\Delta$  URINALYSIS MODULE [530]**.....\$144    *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	Ketones	pH
Blood (Hgb)	Leukocyte Esterase	Protein
Creatinine	Microalbumin	Specific Gravity
Glucose	Nitrite	Urobilinogen
Urine Sediment		

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

**$\Delta$  URINE EOSINOPHILS [547]**.....\$81    *1 challenge per testing event*  
 Digital slide image for presence or absence of urine eosinophils for acute nephritis

**$\Delta$  URINE HCG [541]**.....\$105    *1 challenge per testing event*  
 Liquid sample for qualitative analysis of Pregnancy (hCG) and is compatible with all waived urine pregnancy kits.

**$\Delta$  URINE HCG (ADD ON) [540]**.....\$33    *1 challenge per testing event*  
 Form only. Only available with 530, 531

**CHEMISTRY PROGRAMS - continued****BOLD analytes are reported to CMS****Δ - denotes Point of Care Testing or Waived Programs****Δ URINE MICROALBUMIN/CREATININE [539].....\$141** *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].....\$99** *2 challenges per testing event*

Same as 539. Only available with 530, 531

**Δ URINE PREGNANCY – 2 VIAL [550].....\$129** *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].....\$135** *2 challenges per testing event*

Photomicrograph for Urine Sediment Microscopy

**Δ URINE SEDIMENT IDENTIFICATION – ADD-ON [533].....\$39** *2 challenges per testing event*

Same as 532. Available only with 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].....\$282** *2 challenges per testing event*

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

**COAGUCHEK XS PLUS PROTHROMBIN TIME [330].....\$339** *5 challenges per testing event*

Lyophilized samples for Prothrombin Time and INR; this module is compatible with Roche CoaguChek XS, and XS Plus instruments only. This module is NOT compatible with the HemoSense INRatio.

**Δ COAGUCHEK XS PLUS PROTHROMBIN TIME – WAIVED [331].....\$219** *2 challenges per testing event*

Lyophilized samples for Prothrombin Time and INR; this module is compatible with Roche CoaguChek XS, and XS Plus instruments only. This module is NOT compatible with the HemoSense INRatio.

**COAGULATION MODULE [320].....\$240** *5 challenges per testing event*

Lyophilized samples for the following analytes:

**Activated Partial Thromboplastin Time (APTT)**

INR

**Prothrombin Time (PT)****Fibrinogen**

INR calculation

**I-STAT PROTHROMBIN TIME [328].....\$369** *5 challenges per testing event*Lyophilized samples for whole blood **Prothrombin Time** and INR.

This module is ONLY for the Abbott i-Stat instruments.

**Δ ROCHE COAGUCHEK XS INR – WAIVED [324].....\$219** *2 challenges per testing event*Lyophilized samples **for INR only**; this module is compatible with Roche CoaguChek XS, and XS Plus instruments only.**Hematology****BLOOD CELL IDENTIFICATION [231].....\$144** *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].....\$51** *5 challenges per testing event*

Same as 231. Only available with 223 through 229.

**FLUID CELL COUNT/CRYSTALS [250].....\$273** *2 challenges per testing event*

Fluid for Hemocytometer cell count and photographs for identification of crystals.

RBC count, WBC count &amp; Crystal Screening.

**NON-CHEMISTRY PROGRAMS - continued**

BOLD analytes are reported to CMS

Δ - denotes Point of Care Testing or Waived Programs

**HEMATOLOGY MODULE [210]**.....\$294 5 challenges per testing event

Whole blood samples for the following analytes:

<b>Blood Cell Identification</b>	<b>Erythrocyte Count (RBC)</b>	<b>Hematocrit</b>
<b>Hemoglobin</b>	<b>Leukocyte Count (WBC)</b>	<b>Platelet Count</b>

**HEMOGLOBIN/HEMATOCRIT/WBC [212]**.....\$249 5 challenges per testing eventWhole blood samples for **Hemoglobin, Hematocrit and Leukocyte (WBC) count.****Δ HEMOGLOBIN/HEMATOCRIT – WAIVED [213]**.....\$186 2 challenges per testing event

Whole blood samples for waived methods only.

**Δ HEMOGLOBIN/GLUCOSE - HEMOCUE [215]**.....\$195 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. *The following analytes are included in automated differential modules; 3-Part or 5-Part Automated Differential, Erythrocyte Count, Hematocrit, Hemoglobin, Leukocyte Count, Platelet Count.*

**3-part differentials****HEMATOLOGY WITH 3-PART DIFF [225]**.....\$321 5 challenges per testing event

Module is compatible with the following instruments:

- Abbott** Cell-Dyn 610, 1200, 1400, 1500, 1600, 1700, 1800, Emerald
- ABX** all three-part differential models
- Coulter** Ac•T series (excluding Ac•T–5 & 8), J series, MD series, Onyx, S Plus series, ST series, T series
- DANAM/Infolab** – all two-part differential models
- Drew** Evolution
- Mindray** BC-3200
- Nova** Celltrak

**HEMATOLOGY SYSMEX 3-PART DIFF [224]**.....\$330 5 challenges per testing event

Module is compatible with the following instruments:

- Sysmex** E series, F-800, K series, Pochi, KX 21/21N, XP series

**5-part differentials****HEMATOLOGY WITH 5-PART DIFF [226]**.....\$372 5 challenges per testing event

Module is compatible with the following instruments:

- Coulter** DxH 600/800/900, Gen-S, HMX, LH500, LH750/755/780, MAXM, STKS (the VCS series)
- Mindray** BC 5-part

**HEMATOLOGY WITH 5-PART DIFF- ABBOTT CELL-DYN [223]**.....\$372 5 challenges per testing event

Module is compatible with the following instruments:

- Abbott Cell-Dyn** 3000, 3200, 3500, 3700, 4000, Emerald 22, Sapphire, Ruby
- Danam** Excell 22

**HEMATOLOGY WITH 5-PART DIFF – AcT 5 AND PENTRA [228]**.....\$372 5 challenges per testing event

Module G is compatible with the following instruments:

- ABX** Pentra 60 C+, 80, 120
- Coulter** Ac•T 5, Ac•T 8

**HEMATOLOGY WITH 5-PART DIFF – DxH 500 SERIES [227]**.....\$372 5 challenges per testing event

Module is compatible with the following instruments:

- Coulter** DxH 500 series

**NON-CHEMISTRY PROGRAMS - continued**

BOLD analytes are reported to CMS

Δ - denotes Point of Care Testing or Waived Programs

**Hematology****HEMATOLOGY WITH 5 OR 6-PART DIFF – SYSMEX [229].....\$372** 5 challenges per testing event

Module is compatible with the following instruments:

Sysmex NE series, SE series, SF series, XE series, XN/XNL, XS series, XT series

**Miscellaneous Hematology****RETICULOCYTE COUNT [240].....\$255** 2 challenges per testing event

Specimens for all reticulocyte counting methods.

**SEDIMENTATION RATE (ESR) [247].....\$195** 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].....\$195** 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].....\$210** 2 challenges per testing event

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

**Immunochemistry****ABO & Rh FACTOR [451].....\$309** 5 challenges per testing event

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

**BLOOD BANK 1 [452].....\$414** 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].....\$444** 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)

Unexpected Antibody Identification (5 plasma)

**D (RH) TYPING [450].....\$177** 5 Challenges per testing eventThis program is for performing **D (Rh) Typing** only by a slide or tube method.Samples are red cell suspensions for typing. **CMS reported.****DIRECT ANTIGLOBULIN TEST [454].....\$234** 2 challenges per testing event

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

**Immunology****ANA PANEL [782].....\$300** 5 challenges per testing event

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

<b>ANA Screen</b> (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].....\$231** 5 challenges per testing event

Same as 782. Only available with 750 and 751.

**C-REACTIVE PROTEIN [764].....\$132** 2 challenges per testing event

Liquid serum samples for qualitative and quantitative evaluation.

Targeted for non-high sensitivity methods.

**C-REACTIVE PROTEIN (CRP) – ADD-ON [776].....\$66** 2 challenges per testing event

Same as 2939. Only available with 750. Not for high sensitivity methods. See (777)

**DIAGNOSTIC ALLERGY [773].....\$387** 2 challenges per testing event

Liquid sample, a set of challenges for the following:

14 Allergen specific IgE challenges; 5 Total IgE challenges.

**NON-CHEMISTRY PROGRAMS - continued**

BOLD analytes are reported to CMS

Δ - denotes Point of Care Testing or Waived Programs

**IMMUNOLOGY MODULE [750].....\$351** *5 challenges per testing event*

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

<b>Anti-streptolysin O</b>	<b>Infectious Mononucleosis</b>
<b>Rheumatoid Factor</b>	

**IMMUNOPROTEINS [784].....\$249** *5 challenges per testing event*

Liquid serum samples for quantitative evaluation of the following analytes:

<b>C3</b>	<b>IgA</b>	<b>IgG</b>
<b>C4</b>	<b>IgE</b>	<b>IgM</b>

**INFECTIOUS MONONUCLEOSIS [762].....\$213** *5 challenges per testing event*Liquid serum samples for qualitative IgG, IgM or Ig-nonspecific evaluation. **CMS reported.****Δ INFECTIOUS MONONUCLEOSIS – WAIVED [755].....\$135** *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].....\$330** *5 challenges per testing event*Liquid serum samples for infectious mononucleosis and rheumatoid factor. **CMS reported.****RHEUMATOLOGY MODULE [751].....\$264** *5 challenges per testing event*Liquid serum samples for **Rheumatoid Factor** and C-Reactive protein (not for high-sensitivity methods)**RHEUMATOID FACTOR [763].....\$213** *5 challenges per testing event*Liquid serum samples for qualitative evaluation. **CMS reported.****SPECIFIC ALLERGEN TESTING [770].....\$387** *2 challenges per testing event*

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

**Serology****Δ H. PYLORI ANTIBODY DETECTION [780].....\$180** *2 challenges per testing event*

Liquid serum samples for qualitative evaluation.

**HIV MARKERS [791].....\$309** *5 challenges per testing event*

Liquid serum samples for qualitative evaluation of the following analytes:

<b>Anti-HIV1</b>	<b>Anti-HIV1 Confirmation</b>	HIV1 p24 Antigen
------------------	-------------------------------	------------------

**Δ HIV MARKERS – WAIVED [790].....\$192** *2 challenges per testing event*

For rapid antigen/antibody testing using waived methods:

Anti-HIV1	HIV1 p24 Antigen
-----------	------------------

**MYCOPLASMA ANTIBODY [781] .....\$180** *2 challenges per testing event*

Liquid serum samples for qualitative evaluation.

**ORAL FLUID HIV ANTIBODIES [793].....\$396** *5 challenges per testing event*Simulated oral fluid samples for **anti-HIV1 screening and confirmation by Western Blot.****RUBELLA [771].....\$213** *5 challenges per testing event*Liquid serum samples for qualitative IgG, & Ig-nonspecific evaluation. **CMS reported.****SARS-CoV-2 SEROLOGY [792].....\$315** *2 challenges per testing event*

Liquid specimens for SARS-CoV-2 antibody.

**SYPHILIS SEROLOGY [772].....\$234** *5 challenges per testing event*Liquid serum samples for **qualitative/semi-quantitative** evaluation by EIA, FTA, MHA, RPR, TPPA and VDRL.**ToRCH [752].....\$294** *3 challenges per testing event,***Must enroll in Rubella for CLIA reporting;** supplemental for Rubella IgM only:*1st & 3rd events only*

does not meet CLIA Rubella requirements.

Liquid specimens for Serology Testing for:

Cytomegalovirus	Rubella IgM
HSV1; IgG, IgM	Toxoplasma
HSV2; IgG, IgM	



**NON-CHEMISTRY PROGRAMS - continued**

BOLD analytes are reported to CMS

Δ - denotes Point of Care Testing or Waived Programs

**VIRAL MARKERS [775].....\$495**

5 challenges per testing event

Liquid serum samples for qualitative evaluation of the following analytes:

<b>Anti-HBc, Total/IgG</b>	Anti-Hepatitis A, IgM	<b>Anti-HIV1</b>
<b>Anti-HBc, IgM</b>	Anti-Hepatitis A, Total/IgG	
Anti-HBs	<b>HBeAg</b>	
Anti-HCV	<b>HBsAg</b>	

**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.

In order to facilitate selection of methods to cover all aspects of testing performed in your laboratory, the Microbiology Section of the catalog is organized by Sub-Specialty, then by laboratory technique. That is, you will find under Bacteriology programs covering Culture and Identification, Antimicrobial Sensitivity, Gram Stain, Direct Antigen and so on. In order to ensure that you meet the 3 by 5 sample requirement, we typically start the listing with a base program or series of base program options comprising 5 samples and offering one or more testing techniques. You should select one of those base programs that most closely reflect the level of service offered by your laboratory. Once you have established base programs, you should select additional supplemental programs to cover all aspects of testing offered by your laboratory.

If you perform only a limited test menu, please be careful in selecting programs that your selection meets this requirement for reporting five results for each basic laboratory technique and subspecialty. If you do not test all sources in a program, you must select an additional program to insure five reported results. Would Refer does not count. A variety of 5 vial programs and supplemental programs are offered to make meeting this requirement easier.

Unless you are performing waived testing only, typically a supplemental program alone will not be sufficient to meet the CLIA 3 X 5 requirement. If you perform only a limited test menu, please be careful in selecting programs that your selection meets this requirement for each basic laboratory technique and subspecialty. A variety of 5 vial programs are offered to make meeting this requirement easier.

As always, it is ultimately 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.

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.

*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 microorganism.*

**BACTERIOLOGY – Culture and Identification**

**BACTERIOLOGY 1 [630].....\$363**

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.**

<b>1 Throat Culture</b>	<b>1 Urine Culture</b>
<b>1 Genital Culture</b>	<b>3 Miscellaneous Cultures *</b>
<b>1-Antimicrobial susceptibility</b>	<b>2-Gram Stain/Morphology</b>
<b>*Possible sources include Blood, CSF, Ear, Eye Sputum, Stool, Wound</b>	



**NON-CHEMISTRY PROGRAMS - continued**

BOLD analytes are reported to CMS

Δ - denotes Point of Care Testing or Waived Programs

**BACTERIOLOGY 2 [640].....\$348** 5 challenges per testing event

Pure and mixed cultures will be included for identification.

**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.**

Per Event, samples are as follows:

2 Urine Cultures	2-Gram Stain/Morphology
2 Throat Cultures	1-Antimicrobial susceptibility
1 Genital Culture	1-Strep A Antigen Detection

**GENITAL CULTURE [646].....\$333** 5 challenges per testing event

Pure cultures for identification of genital pathogens, Strep Group B and/or Neisseria gonorrhoea; 1 Gram Stain/Morphology.

**CMS reported.****GENITAL/URINE CULTURE [653].....\$336** 5 challenges per testing event

Pure and mixed cultures will be included for identification. Per Event, samples are as follows:

2-Urine Culture identifications	1-Antimicrobial susceptibility
3-Genital Culture identifications	2-Gram Stain/Morphology

**MISCELLANEOUS CULTURES – ADD-ON [651].....\$198** 3 challenges per testing event3 miscellaneous aerobic and anaerobic cultures for identification to include Blood, CSF, Wound, Ear or Stool. Must be enrolled in 640 – 647, 652 or 653. **CMS reported.****MRSA CULTURE [695].....\$312** 5 challenges per testing eventCulture swab samples for the detection Methicillin Resistant *S. aureus* using ChromAgar and molecular probe methods.**MRSA CULTURE – ADD-ON [696].....\$168** 2 challenges per testing event**Same as 695. Must be enrolled in a 5 challenge bacterial culture or antigen program.****SUPPLEMENTAL BLOOD CULTURE [694].....\$159** 2 challenges per testing eventLyophilized pellets with dilution buffer to simulate liquid blood samples. **Must be enrolled in a 5 challenge Bacteriology Culture and Identification program. CMS reported.****THROAT CULTURE [641].....\$333** 5 challenges per testing eventPure and mixed cultures will be included for identification, antigen screen and/or Gram stain. **CMS reported.****URINE COLONY COUNT [648].....\$255** 2 challenges per testing event

Pure and mixed cultures in a lyophilized pellet for bacterial colony count only. For culture and ID, enroll in another 5-challenge CLIA acceptable bacteriology culture and ID program.

**URINE CULTURE [643].....\$333** 5 challenges per testing event

Pure and mixed cultures will be included for identification. Per Event, samples are as follows:

5-Culture identifications	1-Gram Stain/Morphology
1-Antimicrobial susceptibility	

**URINE PRESUMPTIVE ID/COLONY COUNT [647].....\$393** 5 challenges per testing event

Pure and mixed cultures will be included for identification. Per Event, samples are as follows:

5-Urine presumptive ID	1-Gram Stain/Morphology
1-Antimicrobial susceptibility	2-Colony counts

**URINE PRESUMPTIVE ID/THROAT CULTURE [652].....\$381** 5 challenges per testing event

Pure and mixed cultures will be included for identification. Per Event, samples are as follows:

2-Urine presumptive ID	1-Gram Stain/Morphology
3-Throat Cultures	2-Colony Count
1-Antimicrobial susceptibility	

**URINE/THROAT CULTURE [645].....\$336** 5 challenges per testing event

Pure and mixed cultures will be included for identification. Per Event, samples are as follows:

3-Urine Culture identifications	1-Antimicrobial susceptibility
2-Throat Culture identifications	1-Gram Stain/Morphology

**NON-CHEMISTRY PROGRAMS - continued**

BOLD analytes are reported to CMS

Δ - denotes Point of Care Testing or Waived Programs

**BACTERIOLOGY – Antimicrobial Sensitivity****Antimicrobial Applicability**

As indicated in CMS guidelines, participants enrolled in a Microbiology program that perform antimicrobial testing will be flagged for inappropriate selection of antimicrobial agents per CLSI Guidelines (formerly NCCLS) M02-12, M07-A10 and M100 S25.

Inappropriate selection of antimicrobials as indicated by the CLSI guidelines will be scored as misses.

**BACTERIOLOGY 1 [630]**.....\$363      *5 challenges per testing event*

See Culture and ID section above for program description.

**BACTERIOLOGY 2 [640]**.....\$348      *5 challenges per testing event*

See Culture and ID section above for program description.

**GENITAL/URINE CULTURE [653]**.....\$336      *5 challenges per testing event*

See Culture and ID section above for program description.

**URINE/THROAT CULTURE [645]**.....\$336      *5 challenges per testing event*

See Culture and ID section above for program description.

**URINE CULTURE [643]**.....\$333      *5 challenges per testing event*

See Culture and ID section above for program description.

**BACTERIOLOGY – Gram Stain and Morphology**

**GRAM STAIN [650]**.....\$210      *5 challenges per testing event*

Purified bacterial smears for Gram stain. **CMS reported.** Includes two educational DigitalScope™ slide images available online only.

**BACTERIOLOGY 1 [630]**.....\$363      *5 challenges per testing event*

See Culture and ID section above for program description.

**BACTERIOLOGY 2 [640]**.....\$348      *5 challenges per testing event*

See Culture and ID section above for program description.

**GENITAL CULTURE [646]**.....\$333      *5 challenges per testing event*

See Culture and ID section above for program description.

**GENITAL/URINE CULTURE [653]**.....\$336      *5 challenges per testing event*

See Culture and ID section above for program description.

**URINE/THROAT CULTURE [645]**.....\$336      *5 challenges per testing event*

See Culture and ID section above for program description.

**URINE CULTURE [643]**.....\$333      *5 challenges per testing event*

See Culture and ID section above for program description.

**BACTERIOLOGY – Direct Antigen**

**C. DIFFICILE/ROTAVIRUS ANTIGEN DETECTION [682]**.....\$312      *5 challenges per testing event*

Lyophilized vials for detection of C. difficile and Rotavirus antigen. **CMS reported.**

**CHLAMYDIA/GC/STREP B ANTIGEN SCREEN [675]**.....\$399      *5 challenges per testing event*

Swab specimens for Chlamydia trachomatis, Neisseria gonorrhoea and Streptococcus sp., Group B antigen screens; these specimens cannot be cultured. **CMS reported.**

**CHLAMYDIA/GC/STREP B – ADD-ON [673]**.....\$198      *2 challenges per testing event*

Same as 675. **Must enroll in 640 – 647, 652 or 653. CMS reported.**

**LEGIONELLA ANTIGEN DETECTION [686]**.....\$270      *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.**

**NON-CHEMISTRY PROGRAMS - continued**

BOLD analytes are reported to CMS

Δ - denotes Point of Care Testing or Waived Programs

**RAPID UREASE (CLO) [665].....\$174** *2 challenges per testing event*  
 Simulated gastric samples for use with CLOtest, PyloriTek or similar methods.

**STREP A ANTIGEN DETECTION [660].....\$210** *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].....\$132** *2 challenges per testing event*  
 Pre-inoculated swabs for antigen screening using waived methods only.

**STREPTOCOCCUS PNEUMONIAE ANTIGEN DETECTION [687].....\$276** *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.**

**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.**

**BACTERIOLOGY – CLIA Specified Serology - See SEROLOGY Section****MICROBIOLOGY – Molecular**

**CHLAMYDIA/GC/STREP B ANTIGEN SCREEN [675].....\$399** *5 challenges per testing event*  
 See BACTERIOLOGY – Direct Antigen section above for program description.

**CHLAMYDIA/GC/STREP B – ADD-ON [673].....\$198** *2 challenges per testing event*  
 See BACTERIOLOGY – Direct Antigen section above for program description

**OSOM BACTERIAL VAGINOSIS – WAIVED [692].....\$201** *2 challenges per testing event*  
 Swab samples for testing with Sekisui OSOM BVBlue Test.

**TRICHOMONAS VAGINALIS – WAIVED [693].....\$201** *2 challenges per testing event*  
 Lyophilized samples for testing with Sekisui OSOM BVBlue Test.

**VAGINOSIS SCREEN [668].....\$423** *5 challenges per testing event*  
 Swab specimens compatible with all molecular probe and antigen detection methods for the following vaginal pathogens:  
     Candida albicans  
     Trichomonas vaginalis  
     Gardnerella vaginalis

**MYCOBACTERIOLOGY**

**ACID-FAST SMEARS [679].....\$224** *5 challenges per testing event,  
 1st & 3rd events only*  
 Prepared, fixed slides for acid-fast staining

**MYCOLOGY – Microscope Identification**

**KOH SLIDES [538].....\$192** *2 challenges per testing event*  
 Glass slides to represent a KOH examination.

**MYCOLOGY – Culture**

**DERMATOPHYTE CULTURE [678].....\$297** *5 challenges per testing event*  
 Swabs for culture and identification. **CMS reported.**

**MYCOLOGY – Molecular**

**VAGINOSIS SCREEN [668].....\$423** *5 challenges per testing event*  
 See Bacteriology - Molecular section above for program description.

**PARASITOLOGY – Identification (Microscopy)**

**PARASITOLOGY [691].....\$375** *5 challenges per testing event*  
 Specimens include fecal specimens (formalinized), peripheral blood smears and DigitalScope™ slide images. **CMS reported.**

**PVA SLIDES – ADD ON [690].....\$198** *2 challenges per testing event*  
 Slides for staining and identification.

**NON-CHEMISTRY PROGRAMS - continued**

BOLD analytes are reported to CMS

Δ - denotes Point of Care Testing or Waived Programs

**PARASITOLOGY – Direct Antigen/Molecular****CRYPTOSPORIDIUM/GIARDIA LAMBLIA ANTEGEN DETECTION [683]....\$360** *5 challenges per testing event*Formalinized fecal specimens for analysis of Cryptosporidium and Giardia. **CMS reported.****VIROLOGY****SARS-CoV-2 ANTIGEN DETECTION [688].....\$336** *2 challenges per testing event*

Swab specimens for detection of SARS-CoV-2 by rapid antigen methods.

**SARS-CoV-2 MOLECULAR DETECTION [689].....\$345** *2 challenges per testing event*

Swab specimens for detection of SARS-CoV-2 by molecular methods.

**VIROLOGY MARKERS [775].....\$275** *5 challenges per testing event*

See Serology section above for program description.

**HIV MARKERS [791].....\$258** *5 challenges per testing event*

See Serology section above for program description.

**Δ HIV MARKERS – WAIVED [790].....\$192** *2 challenges per testing event*

See Serology section above for program description.

**Δ RESPIRATORY ANTIGEN DETECTION – WAIVED [680].....\$225** *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].....\$336** *5 challenges per testing event*

Lyophilized vials for detection of the following analytes:

- Influenza Type A & Influenza Type B**
- Respiratory syncytial virus (RSV) antigen**

**WAIVED PACKAGES****BASIC WAIVED AND PPM PACKAGE [902].....\$306** *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].....\$351** *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].....\$284** *2 challenges per testing event*

Liquid serum samples for qualitative IgG evaluation.

**EMBRYO GRADING [984].....\$318** *2 challenges per testing event*

Videos for Embryo grading; multiple answers for three different days

**FETAL FIBRONECTIN (FFN) [983].....\$424** *2 challenges per testing event*

Liquid simulated cervicovaginal specimens.

**FETAL MEMBRANE RUPTURE TEST [975].....\$384** *2 challenges per testing event*

Samples for detection of placental alpha-1-microglobulin

**IVF EMBRYO CULTURE MEDIA [976].....\$492** *2 challenges per testing event*

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

**ANDROLOGY AND EMBRYOLOGY AND FETAL PROGRAMS - continued**

**PREIMPLANTATION GENETIC TESTING - ANEUPLOIDY [977].....\$952** *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].....\$274** *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].....\$308** *2 challenges per testing event*  
Liquid samples of stabilized sperm for quantitative and qualitative (post-vasectomy) analysis and digital videos for Hemocytometer and Makler methods.

**SPERM MORPHOLOGY [981].....\$308** *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].....\$320** *2 challenges per testing event*  
Digital video for sperm motility

**SPERM VIABILITY [982].....\$308** *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].....\$243** *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.**