

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		Unexpected 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	Swab specimen	33
		SARS-CoV-2		
		SARS-CoV-2 Molecular Detection	Swab specimen	33
		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		
		Vaginosis Screen (Antigen/Molecular)	Swab specimen	32
CMS		BV Detection		
		Candida species		
CMS		Gardnerella vaginalis		
		Trichomonas vaginalis		

CMS Regulated	CAP Accepted	Program /Analyte	Specimen Type	Page #
		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
	CAP	Fetal Fibronectin (fFN)		
		Fetal Membrane Rupture Test	0.5 mL liquid specimen	33
	NR	Fetal Membrane Rupture (PAMG-1)		
		IVF Embryo Culture Media	100 mL culture media	33
	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		
		Sperm Motility	Video Image	34
	NR	Sperm Motility		
	NR	Sperm Motility, Forward Progression %		
	NR	Sperm Motility, Forward Progression, semi-quant.		

CMS Regulated	CAP Accepted	Program /Analyte	Specimen Type	Page #
		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
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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

 Δ ETHYL 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	Phosphorus
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	

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.

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)	INR	Prothrombin Time (PT)
Fibrinogen	INR calculation	

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.

Immunoematology**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)

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

For rapid antigen/antibody testing using waived methods:

Anti-HIV1	HIV1 p24 Antigen
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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 eventLiquid 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 eventLiquid 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 Urine Culture |
| 1 Throat Culture | 1 Antimicrobial susceptibility |
| 3 Miscellaneous Cultures* | 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 Gram Stain/Morphology |
| 2 Throat Cultures | 1 Antimicrobial susceptibility |
| 2 Urine Culture | 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 gonorrhoea; 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 Gram Stain/Morphology |
| 1 Antimicrobial susceptibility | |

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	1 Antimicrobial susceptibility
2 Throat Culture identifications	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 gonorrhoea 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
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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*
 Formalized fecal specimens for analysis of Cryptosporidium and Giardia. **CMS reported.**

PARASITOLOGY [691].....\$399 *5 challenges per testing event*
 Specimens include fecal specimens (formalized), 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

SARS-CoV-2 ANTIGEN DETECTION [688].....\$345 *2 challenges per testing event*
 Swab specimens for detection of SARS-CoV-2 by rapid antigen methods.

SARS-CoV-2 MOLECULAR DETECTION [689].....\$354 *2 challenges per testing event*
 Swab specimens for detection of SARS-CoV-2 by molecular methods.

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.

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.

NON-CHEMISTRY PROGRAMS – continued
BOLD analytes are reported to CMS

Δ - denotes Point of Care Testing or Waived Programs

PREIMPLANTATION GENETIC TESTING - ANEUPLOIDY [977] \$980	<i>3 challenges per testing event</i>
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	<i>2 challenges per testing event</i>
Liquid samples of stabilized sperm for qualitative post-vasectomy analysis. Required for CAP accredited laboratories.	
SPERM COUNT, QUANTITATIVE AND QUALITATIVE [980] \$324	<i>2 challenges per testing event</i>
Liquid samples of stabilized sperm for quantitative and qualitative (post-vasectomy) analysis and digital videos for Hemocytometer and Makler methods.	
SPERM MORPHOLOGY [981] \$324	<i>2 challenges per testing event</i>
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	<i>2 challenges per testing event</i>
Digital video for sperm motility	
SPERM VIABILITY [982] \$324	<i>2 challenges per testing event</i>
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	<i>2 challenges per testing event</i>
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.	