



2025

CATALOG



**MEDICAL
LABORATORY
EVALUATION**

A SERVICE OF THE AMERICAN ASSOCIATION OF BIOANALYSTS

APPROVED BY CMS, COLA, TJC, U.S. State Agencies, A2LA, and International regulatory bodies.
CAP accepted analytes offered.

2025 AAB-MLE CATALOG

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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 its 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 COLA, The Joint Commission (TJC), American Association of Laboratory Accreditation (A2LA), and all state agencies.

The College of American Pathologists (CAP) 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. Analytes accepted by the College of American Pathologists are indicated with an asterisk under each applicable program. The most current list of these accepted analytes can be found at www.aab-mle.org. 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.

Results of each program are posted to the participant's account on our website within 30 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 regulated 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 shipped 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.

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 should be received by December 2, 2024, to ensure availability for the first event; 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 2025 program year based upon their current 2024 order. You will have until November 15, 2024, 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 2025 Renewal Form. We encourage renewing participants to return the signed renewal form no later than December 2, 2024, as all products are subject to availability.

All returning participants will receive an invoice by mid-September 2024. Invoices not paid in full by January 13, 2025, will not be shipped the M1 2025 samples.

ORDERING INFORMATION

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.

2025 Ship Schedule

Chemistry & Non-Chemistry	Shipping Dates	Last Day for Replacement Specimens	Cut-off Date for Results Submission	Evaluations Posted
M1 2025	February 4	February 12	February 21	March 21
M2 2025	May 13	May 21	May 30	June 27
M3 2025	September 9	September 17	September 26	October 24
Andrology, Embryology	Shipping Dates	Last Day for Replacement Specimens	Cut-off Date for Results Submission	Evaluations Posted
S1 2025	April 8	April 16	April 25	May 23
S2 2025	October 21	October 29	November 7	December 5

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.

WHAT'S NEW IN 2025

NEW MODULES

MODULE	DESCRIPTION	PAGE
766	Antinuclear Antibody (ANA) Latex Methods	18
671	Strep Complete – Molecular Methods	25
685	Viral Respiratory Panel – Molecular Methods	27
857	Anti-Müllerian Hormone (AMH) (1 st and 3 rd events only)	5

RECONFIGURED MODULES *

MODULE	DESCRIPTION	CHANGES	PAGE
630	Bacteriology 1	Now includes 2 urine samples per event	23
640	Bacteriology 2	Strep A Antigen Detection removed	23
684	Shiga Toxin	5 challenges per testing event	24
752	ToRCH	5 challenges per testing event – all 3 events. (Now includes Rubella IgG testing)	21
765	High Sensitivity C-Reactive Protein	5 challenges per testing event	18
854	SHBG/Testosterone	SHBG/Free Testosterone (No longer includes Total Testosterone – see module 860)	9
858	Fertility	5 challenges per testing event	7
860	Endocrinology 1	5 challenges per testing event (Now includes Total PSA)	6
861	PSA	5 challenges per testing event	8
862	Tumor Markers	5 challenges per testing event	10
863	Endocrinology 2	5 challenges per testing event	7

*Changes made to maintain compliance with updated CLIA regulations for 2025

CHEMISTRY

CMS regulated analytes for CLIA purposes are in bold

* - CAP accepted analyte

Δ - Waived Program or Point of Care Testing

ADULTERATED URINE – ADD-ON [874] \$117*2 challenges per testing event*

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

Creatinine	Oxidants	Specific Gravity
Nitrates	pH	

AMMONIA [836] \$213*2 challenges per testing event*

Liquid samples for analysis of Ammonia.

ANTI-MÜLLERIAN HORMONE (AMH) [857] \$674*3 challenges per testing event - 1st & 3rd events only*

Lyophilized samples for analysis of Anti-Müllerian hormone.

These samples contain all three isomers that constitute the bioactive form of Anti-Müllerian hormone.

BLOOD GASES [847] \$405*5 challenges per testing event*

Aqueous samples for the following analytes (2 sets):

Chloride	Lactate	pO2
Glucose	pCO2	Potassium
Ionized Calcium	pH	Sodium

Δ BLOOD LEAD – WAIVED [838] \$261*2 challenges per testing event*

Whole blood samples for analysis of blood lead levels. For use with waived testing methods only.

CARDIAC MARKERS [845] \$417*5 challenges per testing event*

Liquid samples for analysis of the following analytes:

BNP	Myoglobin	Troponin I, HS
CK-MB	NT-proBNP	Troponin T
D-Dimer	Troponin I	Troponin T, HS

CHEMISTRY

CMS regulated analytes for CLIA purposes are in bold

* - CAP accepted analyte

Δ - Waived Program or Point of Care Testing

CHEMISTRY MODULE [810] \$450

5 challenges per testing event

Liquid samples for the following analytes:

Albumin	Cholesterol, Total	Potassium
Alkaline Phosphatase	Cortisol	Protein, Total
Alpha-fetoprotein (AFP)	Creatine Kinase (CK)	Sodium
ALT (SGPT)	Creatinine	T3 Uptake
Amylase	Free T3	Thyroxine, (T4)
AST (SGOT)	Free Thyroxine (FT4)	TIBC (Calc)
Bilirubin, Direct	GGT	TIBC (Direct)
Bilirubin, Total	Glucose	Triglyceride
Calcium	Iron	Triiodothyronine (T3)
Carbon Dioxide (CO2)	Lactate	TSH *
Chloride	LDH	UIBC (Direct)
Cholesterol, HDL	Magnesium	Uric Acid
Cholesterol, LDL (Calc)	Lipase	Urea Nitrogen (BUN)
Cholesterol, LDL (Direct)	Phosphorus	

COMPREHENSIVE METABOLIC PANEL [813] \$345

5 challenges per testing event

Liquid samples for analysis of the following analytes:

Albumin	Chloride	Protein, Total
Alkaline Phosphatase	Creatinine	Sodium
ALT (SGPT)	Glucose	TIBC (Calc)
AST (SGOT)	Iron	TIBC (Direct)
Bilirubin, Direct	Lactate	UIBC (Direct)
Bilirubin, Total	Magnesium	Urea Nitrogen (BUN)
Calcium	Phosphorus	Uric Acid
Carbon Dioxide (CO2)	Potassium	

ENDOCRINOLOGY 1 [860] \$420

5 challenges per testing event

Liquid samples for the following analytes:

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

CHEMISTRY

CMS regulated analytes for CLIA purposes are in bold

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Δ - Waived Program or Point of Care Testing

ENDOCRINOLOGY 2 [863] \$357

5 challenges per testing event

Lyophilized samples for the following analytes:

C-peptide

Insulin

PTH, Intact

Vitamin D, 25-Hydroxy

ETHYL GLUCURONIDE – ADD-ON [873] \$99

2 challenges per testing event

Liquid urine samples for Ethyl Glucuronide. Only available with 868.

FERTILITY TESTING [858] \$330

5 challenges per testing event

Liquid samples for the following analytes:

DHEA-S *

Estradiol ***Follicle Stimulating Hormone (FSH) *****Luteinizing Hormone (LH) *****Progesterone *****FLUIDS CHEMISTRY [875] \$279**

1 challenge per testing event

Liquid fluids samples for the following analytes:

Albumin

Amylase

Chloride

Cholesterol

Glucose

Lactate

LDH

pH

Protein, Total

Sodium

Uric Acid

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

Δ GLYCOHEMOGLOBIN, AFINION [851] \$255

2 challenges per testing event

Samples for Hemoglobin A1c assay for Afinion only

GLYCOHEMOGLOBIN [852] \$420

5 challenges per testing event

Samples for analysis of glycohemoglobin (**Hemoglobin A1c**).Samples are **not compatible** with the Afinion.

CHEMISTRY

CMS regulated analytes for CLIA purposes are in bold

* - CAP accepted analyte

Δ - Waived Program or Point of Care Testing

Δ GLYCOHEMOGLOBIN - WAIVED [850] \$240

2 challenges per testing event

Samples for analysis of glycohemoglobin (Hemoglobin A1c).

Samples are **not compatible** with the Afinion.**I-STAT CHEMISTRY [818] \$315**

5 challenges per testing event

Liquid samples for the following analytes:

Calcium, Ionized
Chloride
Creatinine
Glucose

Hematocrit
Hemoglobin
 Magnesium, Ionized
Potassium

Sodium
TCO2
Urea Nitrogen (BUN)

Δ I-STAT CREATININE – WAIVED [832] \$216

2 challenges per testing event

Liquid samples for waived methods only.

Δ LIPID PANEL/GLUCOSE – WAIVED [811] \$219

2 challenges per testing event

Liquid samples for the following analytes:

Glucose
 Cholesterol, HDL

Cholesterol, LDL (Calc)
 Cholesterol, Total

Triglyceride

LIPID PROFILE [829] \$294

5 challenges per testing event

Liquid samples for the following analytes:

Apolipoproteins A1 & B
Cholesterol, HDL

Cholesterol, LDL (Direct)
Cholesterol, Total

Lipoprotein (a)
Triglyceride

NEONATAL/DIRECT BILIRUBIN [841] \$264

5 challenges per testing event

Liquid samples for analysis of **Total/Neonatal Bilirubin** and Direct Bilirubin**PSA [861] \$267**

5 challenges per testing event

Liquid samples for testing of **Prostate Specific Antigen (PSA)**.

CHEMISTRY

CMS regulated analytes for CLIA purposes are in bold

* - CAP accepted analyte

Δ - Waived Program or Point of Care Testing

SERUM ALCOHOL/KETONES [835] \$294

5 challenges per testing event

Liquid samples for analysis of **Alcohol** and Acetone, including Beta Hydroxybutyrate.*** SERUM HCG [865] \$225**

5 challenges per testing event

Liquid samples for qualitative and quantitative analysis of **serum hCG**.*** SERUM HCG – ADD ON [866] \$120**

5 challenges per testing event

Liquid samples for qualitative and quantitative analysis of **serum hCG**.

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

SHBG/FREE TESTOSTERONE [854] \$387

2 challenges per testing event

Lyophilized samples for testing the following analytes:

Sex Hormone Binding Globulin (SHBG)	Testosterone, Free
Testosterone, Bioavailable	

THERAPEUTIC DRUG MONITORING [830] \$273

5 challenges per testing event

Liquid samples for the following analytes:

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

THERAPEUTIC DRUGS – ADD-ON [831] \$99

5 challenges per testing event

Same as 830. Available only with 810.

THYROID ANTIBODIES [864] \$297

2 challenges per testing event

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

CHEMISTRY

CMS regulated analytes for CLIA purposes are in bold

* - CAP accepted analyte

Δ - Waived Program or Point of Care Testing

THYROID PROFILE [824] \$297

5 challenges per testing event

Liquid samples for the following analytes:

Alpha-fetoprotein (AFP)**Cortisol**

Free T3 (FT3)

Free Thyroxine, (FT4)**T3 Uptake****Thyroxine, (T4)****Triiodothyronine, (T3)****TSH *****TOTAL PROTEIN [844] \$285**

5 challenges per testing event

Liquid samples for **Total Protein** by refractometer.**TUMOR MARKERS [862] \$549**

5 challenges per testing event

Liquid samples for the following analytes:

Beta-2-microglobulin

CA 125

CA 15-3

CA 19-9

CA 27-29

CEA**PSA**

Prostate Specific Antigen, Free

Prostatic Acid Phosphatase (PAP)

Thyroglobulin

URINE CHEMISTRY [872] \$279

2 challenges per testing event

Liquid urine samples for the following analytes:

Amylase

Calcium

Chloride

Creatinine

Glucose

Magnesium

Osmolality

Phosphorus

Potassium

Protein, Total

Sodium

Urea Nitrogen
(BUN)

Uric Acid

CHEMISTRY

CMS regulated analytes for CLIA purposes are in bold

* - CAP accepted analyte

Δ - Waived Program or Point of Care Testing

Δ URINE DRUG SCREEN [868] \$285

2 challenges per testing event

Liquid samples for the following analytes:

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

Δ WAIVED CHEMISTRY PANEL [812] \$267

2 challenges per testing event

NOTE: this is for waived methods & instruments only.

Liquid samples for the following analytes:

Albumin	Chloride	Phosphorus
Alkaline Phosphatase	Cholesterol, HDL	Potassium
ALT (SGPT)	Cholesterol, LDL (Calc)	Protein, Total
AST (SGOT)	Cholesterol, Total	Sodium
Amylase	Creatine Kinase (CK)	Triglycerides
Bilirubin, Total	Creatinine	Urea Nitrogen (BUN)
Calcium	GGT	Uric Acid
Carbon Dioxide (CO2)	Glucose	

Δ WAIVED CHEMISTRY PANEL – ADD-ON [833] \$99

2 challenges per testing event

Same as 812. Only available with 824.

WHOLE BLOOD GLUCOSE [870] \$324

5 challenges per testing event

For reporting **Whole Blood Glucose** procedures only.**Δ WHOLE BLOOD GLUCOSE – WAIVED [871] \$207**

2 challenges per testing event

For reporting Whole Blood Glucose procedures only. **For multiple analyzer testing, see Specialty Testing section on page 28.**

Δ PROVIDER-PERFORMED MICROSCOPY [534] \$165

1 challenge each per testing event

Each shipment will contain color photographs depicting microscopic fields for the examination of:

Fecal Leukocytes	Nasal Eosinophils	Sperm Detection
Fern Test	Pinworm Prep	Vaginal Wet Mount
KOH Preparation	Scabies Detection	

Δ PPM – ADD-ON [535] \$57

1 challenge each per testing event

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

KOH SLIDES [538] \$216

2 challenges per testing event

Glass slides to represent a KOH examination.

Δ URINALYSIS DIPSTICK [531] \$138

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

NOTE: Microalbumin and Creatinine are for semi-quantitative dipstick methods only. For quantitative methods, enroll in Urine Microalbumin/Creatinine.

Δ URINALYSIS MODULE [530] \$165

1 liquid challenge per testing event

2 photomicrographs for Urine Sediment Microscopy per event

Liquid sample for the following analytes:

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

NOTE: Microalbumin and Creatinine are for semi-quantitative dipstick methods only. For quantitative methods, enroll in Urine Microalbumin/Creatinine.

*** Δ URINE HCG [541] \$120**

1 challenge per testing event

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

*** Δ URINE HCG - ADD ON [540] \$39**

1 challenge per testing event

Only available with 530 and 531.

Δ URINE MICROALBUMIN/CREATININE [539] \$165

2 challenges per testing event

Liquid samples for the following analytes:

Creatinine (quantitative/semi-quantitative)	Microalbumin (quantitative/semi-quantitative)
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Δ URINE MICROALBUMIN/CREATININE – ADD ON [536] \$117

2 challenges per testing event

Same as 539. Only available with 530 and 531.

*** Δ URINE PREGNANCY – 2 VIAL [550] \$159**

2 challenges per testing event

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

Δ URINE SEDIMENT IDENTIFICATION [532] \$147

2 challenges per testing event

Photomicrograph for Urine Sediment Microscopy

Δ URINE SEDIMENT IDENTIFICATION – ADD-ON [533] \$45

2 challenges per testing event

Same as 532. Only available with 531 and 534.

Δ FECAL OCCULT BLOOD [542] \$159

2 challenges per testing event

Simulated stool samples for analysis of fecal occult blood.

Δ FECAL OCCULT BLOOD – ADD ON [537] \$117

2 challenges per testing event

Same as 542. Only available with 530 and 531.

COAGULATION

CMS regulated analytes for CLIA purposes are in bold

* - CAP accepted analyte

Δ - Waived Program or Point of Care Testing

COAGUCHEK XS PLUS PROTHROMBIN TIME [330] \$363

5 challenges per testing event

Lyophilized samples for **Prothrombin Time (PT)** and **INR**.

This module is compatible with Roche CoaguChek XS Plus and XS Pro instruments only.

Δ COAGUCHEK XS PLUS PROTHROMBIN TIME – WAIVED [331] \$237

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] \$261

5 challenges per testing event

Lyophilized samples for the following analytes:

Activated Partial Thromboplastin Time (APTT) **INR**
Fibrinogen**Prothrombin Time (PT)****Δ ROCHE COAGUCHEK XS INR – WAIVED [324] \$237**

2 challenges per testing event

Lyophilized samples for *INR* only.

This module is compatible with Roche CoaguChek XS instrument only.

HEMATOLOGY

CMS regulated analytes for CLIA purposes are in bold

* - CAP accepted analyte

Δ - Waived Program or Point of Care Testing

BLOOD CELL IDENTIFICATION [231] \$1565 graded photo challenges for **Blood Cell Identification** and 1 ungraded educational photo challenge per testing event.

Includes 4 DigitalScope™ whole slide images for 2 guided or 2 free form manual differentials. Supplemental testing only; not CMS reported.

BLOOD CELL IDENTIFICATION – ADD ON [230] \$57

Same as 231. Only available with 223 through 229.

HEMOGLOBIN/HEMATOCRIT/WBC [212] \$273

5 challenges per testing event

Whole blood samples for **Hemoglobin**, **Hematocrit** and **Leukocyte (WBC) Count**.

HEMATOLOGY

CMS regulated analytes for CLIA purposes are in bold

* - CAP accepted analyte

Δ - Waived Program or Point of Care Testing

Δ HEMOGLOBIN/HEMATOCRIT – WAIVED [213] \$201

2 challenges per testing event

Whole blood samples for *waived* methods only.

Δ HEMOGLOBIN/GLUCOSE - HEMOCUE [215] \$213

2 challenges per testing event

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

Hematology Differential Instruments

The following analytes are included in automated differential modules: **3-Part or 5/6-Part Automated Differential, Erythrocyte (RBC) Count, Hematocrit, Hemoglobin, Leukocyte (WBC) Count, Platelet Count.**

As these modules are **instrument specific**, please verify that you are still in the correct program when changes occur during the year. 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.

NOTE: Per new CLIA regulations, if you perform both automated and manual differentials, you must also enroll in the blood cell identification module to be compliant. **AAB-MLE will submit scores to regulatory agencies for both the automated and manual differentials beginning in 2025.**

HEMATOLOGY WITH 3-PART DIFF [225] \$345

5 challenges per testing event

Module is compatible with the following instruments:

Abbott Cell-Dyn 3-part differential models

ABX 3-part differential models

Coulter 3-part differential models

Drew Evolution

Mindray 3-part differential models

HEMATOLOGY SYSMEX 3-PART DIFF [224] \$357

5 challenges per testing event

Module is compatible with the following instruments:

Sysmex Pochi, KX 21/21N, XP series

HEMATOLOGY WITH 5-PART DIFF [226] \$399

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

CMS regulated analytes for CLIA purposes are in bold

* - CAP accepted analyte

Δ - Waived Program or Point of Care Testing

HEMATOLOGY WITH 5-PART DIFF- ABBOTT CELL-DYN [223] \$399*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** Abacus 5**HEMATOLOGY WITH 5-PART DIFF – AcT 5 AND PENTRA [228] \$399***5 challenges per testing event*

Module is compatible with the following instruments:

ABX Pentra 60 C+, 80, 120**Coulter** AcT 5**HEMATOLOGY WITH 5-PART DIFF – DxH 500 SERIES [227] \$399***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] \$399***5 challenges per testing event*

Module is compatible with the following instruments:

Sysmex XE series, XN/XNL series, XS series, XT series**RETICULOCYTE COUNT [240] \$273***2 challenges per testing event*

Specimens for all reticulocyte counting methods.

SEDIMENTATION RATE (ESR) [247] \$213*2 challenges per testing event*

Specimens for manual and automated systems. Not compatible with the Polymedco Sedimat-15 or the Alcor iSed.

RAPID SEDIMENTATION RATE (ESR) [248] \$213*2 challenges per testing event*

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

HEMATOLOGY

CMS regulated analytes for CLIA purposes are in bold

* - CAP accepted analyte

Δ - Waived Program or Point of Care Testing

SICKLE CELL SCREEN [249] \$228*2 challenges per testing event*

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

IMMUNOHEMATOLOGY

CMS regulated analytes for CLIA purposes are in bold

* - CAP accepted analyte

Δ - Waived Program or Point of Care Testing

ABO & Rh FACTOR [451] \$384*5 challenges per testing event*

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

BLOOD BANK 1 [452] \$540*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] \$597*5 challenges per testing event*

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

Compatibility Testing (Crossmatch) (1 donor cells)

Unexpected Antibody Detection (5 plasma)

Antibody Identification (5 plasma)

D (RH) TYPING [450] \$330*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.

DIRECT ANTIGLOBULIN TEST [454] \$291*2 challenges per testing event*

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

ANA PANEL [782] \$324*5 challenges per testing event*Liquid samples for Screening and Pattern Interpretation for **non**-latex agglutination methods.**Antinuclear Antibody (ANA) Screen**

Anti-DNA (ds, ss)

Anti-RNP

Anti-Sm

Anti-SSA

Anti-SSB

IFA Pattern

ANTINUCLEAR ANTIBODY (ANA) – LATEX METHODS [766] \$240*5 challenges per testing event.*Liquid samples for **ANA Screen** for latex agglutination methods only.**ANTISTREPTOLYSIN O (ASO) – ADD-ON [753] \$123***5 challenges per testing event*Liquid samples for qualitative **ASO**. Only available with 751.**C-REACTIVE PROTEIN [764] \$150***2 challenges per testing event*

Liquid samples for qualitative and quantitative evaluation.

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

C-REACTIVE PROTEIN (CRP) – ADD-ON [776] \$90*2 challenges per testing event*

Same as 764. Only available with 750.

DIAGNOSTIC ALLERGY [773] \$399*5 IgE challenges and 14 Allergen Specific IgE challenges per testing event*

Liquid samples for quantitative evaluation of the following analytes:

Allergy Testing

Total IgE

HIGH-SENSITIVITY C-REACTIVE PROTEIN (HS-CRP) [765] \$270*5 challenges per testing event*Liquid samples. This program targets **high sensitivity C-Reactive Protein** methods only.

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

IMMUNOLOGY MODULE [750] \$450*5 challenges per testing event*

Liquid samples for each of the following analytes:

Antistreptolysin O (ASO)	Infectious Mononucleosis	Rheumatoid Factor
		(qualitative/quantitative)

IMMUNOPROTEINS [784] \$276*5 challenges per testing event*

Liquid samples for quantitative evaluation of the following analytes:

C3	IgA	IgG
C4	IgE	IgM

INFECTIOUS MONONUCLEOSIS [762] \$240*5 challenges per testing event*Liquid samples for qualitative **Infectious Mononucleosis** (IgG, IgM or Ig-nonspecific) evaluation.**Δ INFECTIOUS MONONUCLEOSIS – WAIVED [755] \$150***2 challenges per testing event*

Liquid samples for qualitative Infectious Mononucleosis (IgG, IgM or Ig-nonspecific) evaluation for waived methods only.

INFECTIOUS MONO/RHEUMATOID FACTOR [761] \$405*5 challenges per testing event*Liquid samples for **Infectious Mononucleosis** and **Rheumatoid Factor** (qualitative/quantitative).**RHEUMATOLOGY MODULE [751] \$351***2 C-Reactive Protein challenges per testing event**5 Rheumatoid Factor challenges per testing event*Liquid samples for **Rheumatoid Factor** (qualitative/quantitative) and C-Reactive protein (not for high-sensitivity methods)**RHEUMATOID FACTOR [763] \$240***5 challenges per testing event*Liquid samples for **qualitative** and/or quantitative evaluation.**SPECIFIC ALLERGEN TESTING [770] \$399***2 challenges per testing event*

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

SEROLOGY

CMS regulated analytes for CLIA purposes are in bold

* - CAP accepted analyte

Δ - Waived Program or Point of Care Testing

H. PYLORI ANTIBODY DETECTION [780] \$195*2 challenges per testing event*

Liquid samples for qualitative evaluation.

HIV MARKERS [791] \$345*5 challenges per testing event*

Liquid samples for qualitative evaluation of the following analytes:

Anti-HIV**Anti-HIV/p24 Antigen (not differentiated)****Anti-HIV Confirmation**

p24 Antigen

Δ HIV MARKERS – WAIVED [790] \$216*2 challenges per testing event*

For rapid antigen/antibody testing using waived methods:

Anti-HIV

p24 Antigen

MYCOPLASMA ANTIBODY [781] \$204*2 challenges per testing event*

Liquid samples for qualitative evaluation.

ORAL FLUID HIV ANTIBODIES [793] \$414*5 challenges per testing event*Simulated oral fluid samples for **anti-HIV screening and confirmation.****RUBELLA [771] \$240***5 challenges per testing event*Liquid samples for **qualitative/quantitative Rubella** (IgG, & Ig-nonspecific) evaluation.**SARS-CoV-2 SEROLOGY [792] \$339***2 challenges per testing event*

Liquid specimens for SARS-CoV-2 antibody.

SYPHILIS SEROLOGY [772] \$261*5 challenges per testing event*Liquid samples for **qualitative/semi-quantitative** evaluation of **Syphilis Serology** by EIA, FTA, MHA, RPR, TPPA and VDRL.

SEROLOGY

CMS regulated analytes for CLIA purposes are in bold

* - CAP accepted analyte

Δ - Waived Program or Point of Care Testing

ToRCH [752] \$522

5 challenges per testing event

Liquid specimens for qualitative evaluation of the following analytes:

Cytomegalovirus IgG, IgM	HSV-1 / 2 IgM
HSV-1 IgG, IgM	Rubella IgG , IgM
HSV-2 IgG, IgM	Toxoplasma IgG, IgM

VIRAL MARKERS [775] \$519

5 challenges per testing event

Liquid samples for qualitative evaluation of the following analytes:

Anti-HBc, Total/IgG	Anti-HAV, IgM	Anti-HIV
Anti-HBc, IgM	Anti-HAV, Total/IgG	
Anti-HBs	HBeAg	
Anti-HCV	HBsAg	

MICROBIOLOGY

CMS regulated analytes for CLIA purposes are in bold

* - CAP accepted analyte

Δ - Waived Program or Point of Care Testing

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). 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. If 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

BACTERIOLOGY 1 [630] \$417

7 culture challenges per testing event

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

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

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

BACTERIOLOGY 2 [640] \$384

5 culture challenges per testing event

Pure and mixed cultures will be included for identification.

Antimicrobial Susceptibility is performed from urine culture samples.

The culture quantities reflect the number of sources per event.

- | | |
|--------------------------|---------------------------------------|
| 1 Genital Culture | 2 Antimicrobial Susceptibility |
| 2 Throat Cultures | 2 Gram Stain/Morphology |
| 2 Urine Culture | |

GENITAL CULTURE [646] \$366

5 challenges per testing event

Pure and mixed **Genital cultures** for identification of genital pathogens; **1 Gram Stain/Morphology**.

MISCELLANEOUS CULTURES – ADD-ON [651] \$219

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.

MRSA CULTURE [695] \$375*5 challenges per testing event*Swab samples for the culture of **Methicillin Resistant S. aureus**.**MRSA CULTURE – ADD-ON [696] \$216***2 challenges per testing event*Culture swab samples for the detection of **Methicillin Resistant S. aureus**.

Same as 695. Only available with 630 through 646.

SUPPLEMENTAL BLOOD CULTURE [694] \$189*2 Blood Culture challenges per testing event*

Lyophilized pellets with dilution buffer to simulate liquid blood samples.

Only available with 630 through 646.

THROAT CULTURE [641] \$366*5 challenges per testing event*Pure and mixed **Throat cultures** will be included for identification.**URINE COLONY COUNT [648] \$276***2 challenges per testing event*

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

*Colony Count does not contribute to the required minimum of five bacteriology challenges.***URINE CULTURE [643] \$366***5 challenges per testing event*

Pure and mixed cultures will be included for identification.

5 Urine Cultures**2 Antimicrobial Susceptibility****2 Gram Stain/Morphology****URINE/THROAT CULTURE [645] \$369***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 Cultures**2 Antimicrobial Susceptibility****2 Throat Cultures****2 Gram Stain/Morphology**

BACTERIOLOGY NON-CULTURE

C. DIFFICILE/ROTAVIRUS DETECTION [682] \$342

5 challenges per testing event

Lyophilized specimens for detection of **C. difficile Antigen/Toxin** and **Rotavirus antigen**.

CHLAMYDIA/GC/STREP B ANTIGEN SCREEN [675] \$414

5 challenges per testing event

Swab specimens for **Chlamydia trachomatis**, **Neisseria gonorrhoeae** and **Streptococcus Group B** for antigen detection only.

GRAM STAIN [650] \$264

5 challenges per testing event

Purified bacterial smears for **Gram stain/Morphology**.

Includes two educational DigitalScope™ slide images available online only.

LEGIONELLA ANTIGEN DETECTION [686] \$360

5 challenges per testing event

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

Δ OSOM BACTERIAL VAGINOSIS – WAIVED [692] \$234

2 challenges per testing event

Swab samples for testing with Sekisui OSOM BVBlue Test.

RAPID UREASE (CLO) [665] \$201

2 challenges per testing event

Simulated gastric samples for use with CLOtest, PyloriTek or similar methods. Not compatible with breath test methods.

SHIGA TOXIN [684] \$414

5 challenges per testing event

Specimens for **Shiga Toxin 1 and 2**.

STREP A ANTIGEN DETECTION [660] \$228

5 challenges per testing event

Pre-inoculated swabs for **Strep A** antigen screening only.

Δ STREP A ANTIGEN DETECTION – WAIVED [662] **\$147**
2 challenges per testing event
Pre-inoculated swabs for antigen screening using waived methods only.

STREP COMPLETE – MOLECULAR METHODS [671] **\$345**
5 challenges per testing event
Swab samples for detection of Strep Groups A, C/G.

Strep Group A

Strep Group C/G

STREPTOCOCCUS PNEUMONIAE ANTIGEN DETECTION [687] **\$360**
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.

VAGINOSIS SCREEN [668] **\$459**
5 challenges per testing event
Swab specimens compatible with all molecular probe and antigen detection methods for the following vaginal pathogens:

Bacterial Vaginosis Detection

Candida glabrata-krusei

Candida group

Candida sp.

Gardnerella vaginalis

Trichomonas vaginalis

MYCOBACTERIOLOGY

ACID-FAST SMEARS [679] **\$262**
5 challenges per testing event - 1st & 3rd events only
Prepared, fixed slides for **Acid-Fast** staining.

MYCOLOGY

DERMATOPHYTE CULTURE [678] \$366

5 challenges per testing event

Swabs for detection or culture and identification of **Dermatophytes**.

KOH SLIDES [538] \$216

2 challenges per testing event

Glass slides to represent a KOH examination.

PARASITOLOGY

CRYPTOSPORIDIUM/GIARDIA LAMBLIA ANTIGEN DETECTION [683]..... \$384

5 challenges per testing event

Formalinized fecal specimens for analysis of **Cryptosporidium** and **Giardia lamblia**.

PARASITOLOGY [691] \$414

4 **fecal suspension** (formalinized) challenges per testing event

1 **peripheral blood smear** challenges per testing event

PVA SLIDES – ADD ON [690] \$216

2 **Parasitology** challenges per testing event

Slides for staining and identification. Only available with 691.

Δ TRICHOMONAS VAGINALIS – WAIVED [693] \$234

2 challenges per testing event

Lyophilized samples for testing with Sekisui OSOM Test.

VIROLOGY

Δ RESPIRATORY ANTIGEN DETECTION – WAIVED [680] \$243

2 challenges per testing event

Liquid specimens for detection of the following analytes using waived methods only:

Influenza A

Influenza B

Respiratory syncytial virus (RSV)

RESPIRATORY ANTIGEN DETECTION [681] \$360*5 challenges per testing event*

Lyophilized vials for detection of the following analytes:

Influenza A**Respiratory syncytial virus (RSV)****Influenza B****Δ SARS-CoV-2 ANTIGEN DETECTION – WAIVED [688] \$366***2 challenges per testing event*

Swab specimens for the antigen detection of SARS-CoV-2 using waived methods only.

SARS-CoV-2 ANTIGEN DETECTION [697] \$537*5 challenges per testing event*Swab specimens for detection of **SARS-CoV-2** by antigen methods.**Δ SARS-CoV-2 MOLECULAR DETECTION – WAIVED [689] \$375***2 challenges per testing event*

Swab specimens for the molecular detection of SARS-CoV-2 using waived methods only.

SARS-CoV-2 MOLECULAR DETECTION [698] \$546*5 challenges per testing event*Swab specimens for detection of **SARS-CoV-2** by molecular methods.**VIRAL RESPIRATORY PANEL – MOLECULAR METHODS [685] \$675***5 challenges per testing event*

Swabs for detection of the following analytes:

Influenza A**Respiratory syncytial virus (RSV)****Influenza B****SARS-CoV-2**

BASIC WAIVED AND PPM PACKAGE [902] **\$336**

Number of challenges per testing event noted in parentheses.
Multiple samples for the following analytes:

Fecal Occult Blood (2)	Urinalysis (1)	Whole Blood Glucose (2)
PPM (6)	Urine hCG (1)	
Strep A Antigen Detection (2)	Urine Sediment (2)	

WAIVED AND PPM PACKAGE [901] **\$384**

Number of challenges per testing event noted in parentheses.
Multiple samples for the following analytes:

Fecal Occult Blood (2)	PPM (6)	Urine hCG (1)
Hematocrit (2)	Strep A Antigen Detection (2)	Urine Sediment (2)
Hemoglobin (2)	Urinalysis (1)	Whole Blood Glucose (2)

SPECIALITY 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] **\$270**

2 challenges per testing event
This program is WB Glucose testing on multiple glucometers at a facility or institutions. Two 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.

ANTISPERM ANTIBODIES [978] \$312

2 challenges per testing event

Liquid samples for qualitative IgG evaluation.

EMBRYO GRADING [984] \$350

2 challenges per testing event

Videos for Embryo grading; multiple answers for three different days.

FETAL FIBRONECTIN (FFN) [983] \$468

2 challenges per testing event

Liquid simulated cervicovaginal specimens.

FETAL MEMBRANE RUPTURE TEST [975] \$424

2 challenges per testing event

Samples for detection of placental alpha-1-microglobulin.

IVF EMBRYO CULTURE MEDIA [976] \$542

2 challenges per testing event

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

PREIMPLANTATION GENETIC TESTING - ANEUPLOIDY [977] \$1030

3 challenges per testing event

Samples consist of extracted DNA diluted to the 5 – 6 cell level. The Sex and Euploid or Aneuploid status will be graded. Chromosome additions or deletions for educational purposes will not be graded.

*** SPERM COUNT, QUALITATIVE/POST VASECTOMY [979] \$312**

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] \$340**

2 challenges per testing event

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

SPERM MORPHOLOGY [981] \$346

2 challenges per testing event

Unstained semen smears on glass slides and whole slides DigitalScope™ images for sperm morphology analysis. Samples are not compatible with Testsimplets.

SPERM MOTILITY [985] \$352

2 challenges per testing event

Digital video for Sperm Motility

*** SPERM VIABILITY [982] \$346**

2 challenges per testing event

Eosin-Nigrosin stained slides and DigitalScope™ images.

OTHER PRODUCTS AND SERVICES

CONTINUING EDUCATION..... FREE

Continuing education is offered free of charge to all AAB-MLE participants through the following:

AAB-MLE LMS portal: To access AAB-MLE LMS, email us at techsupport@aab-pts.org or request a token online at www.aab-mle.org.

AAB-MLE LABU: To access AAB-MLE LABU email us at mle@aab-mle.org or call 1-800-234-5315. Additional information is available at www.labuniversity.org/learn-with-labu. Email info@labu.org or call 877-234-8193.

G2'S LAB INDUSTRY ADVISOR SUBSCRIPTION..... \$260

Biweekly newsletter covering government policy for diagnostic testing and related medical services.

OFF-CYCLE PROFICIENCY TESTING..... Starting at \$225

Off-cycle proficiency testing (PT) provides laboratories with immediate, on-demand, customized proficiency testing for prelicensure, reinstatement, or remedial purposes; a complement to the regularly scheduled PT program. AAB-MLE's off-cycle proficiency testing service is available to every laboratory, regardless of AAB-MLE enrollment status. Contact AAB-MLE Technical Support at 800-234-5315 or techsupport@aab-pts.org

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