

# 2020 Catalog

A PROFICIENCY TESTING PROGRAM FOR LABORATORIES





The right choice for proficiency testing.

aafp.org/pt



## AT A GLANCE

## ORDER INFORMATION

AAFP-PT accepts enrollments throughout the year. If you are enrolling for the entire 2020 program year, you must enroll by November 1, 2019 to guarantee specimen availability.

Go to www.aafp.org/pt to order. Further details on page 1.



Proficiency Testing (PT) is an external quality control process. It is the practice of testing unknown specimens from an outside source to assure quality laboratory testing results.

# WHY SHOULD MY LAB DO PROFICIENCY TESTING?

While internal quality controls are performed daily in laboratories with known controls, PT provides an important comparison. Unknown specimen values provide an objective assessment of the accuracy of your laboratory staff and equipment.

Some laboratories are required to complete proficiency testing in order to comply with Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). Under CLIA '88, laboratory sites performing moderate or high complexity testing on human samples must enroll in a PT program.

Many laboratories provide waived testing and are not required under CLIA '88 to complete PT. However, many waived laboratories choose to complete PT in order to assure high quality and accurate laboratory results for their patients.

## WHY SHOULD I CHOOSE AAFP-PT?

AAFP-PT provides:

- Comprehensive list of specimens appropriate for testing in waived and high complexity laboratories
- Three shipments per year
- No annual registration fee for COLA member laboratories
- 10% discount on orders with three or more laboratory locations
- Friendly and fast customer service and technical support from our team of experienced laboratorians
- Free handbook binder cover, spine inserts, and tabs to help organize PT materials

- Convenient customer service available through PT Central, email, or phone
- 24/7 online access to current enrollment status, evaluations, and forms through PT Central
- Email reminders of all important reporting deadlines, including notifications of missing data in results submissions
- Automatic email confirmation when results have been received
- Evaluation report provided by email
- Continuing education credit through ASCLS P.A.C.E.®

ACCURATE LAB RESULTS
ARE CRUCIAL TO PATIENT
CARE. YOU CAN RELY
ON AAFP PROFICIENCY
TESTING TO HELP YOU
MAINTAIN LABORATORY
EXCELLENCE.



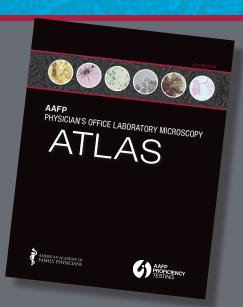
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Shipment Schedule inside back cover

All regulated analytes are in **RED** and are provided at five challenges per shipment.

## AAFP's THE POL MICROSCOPY ATLAS

- More than 150 color photos
- Includes all PPM specimen types, plus blood cell identification and Gram stains
- Concise, easy-to-follow descriptions, clinical associations, and procedures
- Suitable for training and competency assessment





TO ORDER: www.aafp.org/microscopy (800) 274-2237



## **Order Information**

AAFP-PT accepts enrollments throughout the year. If you are enrolling for the entire 2020 program year, you must enroll by November 1, 2019 to guarantee specimen availability. Orders during the program year (including orders for fewer than three events) have prorated pricing available. Please call or email the AAFP-PT team for a quote. All orders, full and partial year, include an \$87 non-refundable annual registration fee.

To place your order, go to www.aafp.org/pt. Our team is ready to assist you in selecting the appropriate modules for your laboratory. Contact us at (800) 274-7911 or pt@aafp.org.

An order form must accompany all purchase orders.

## **SHIPPING**

Domestic kits are shipped 2nd Day Federal Express for participants in the continental United States. Participants in Alaska, Hawaii, and the U.S. Territories should expect their specimens by the third day after the ship date. Please make arrangements for your specimens to be signed for and refrigerated upon receipt. International participants may incur additional shipping fees.

## CANCELATIONS/REFUNDS/ADDITIONS

Cancelations must be submitted by email or through PT Central four weeks prior to an event ship date. Credits will be applied to the following year's PT order, if requested. If no order is being placed for the next year, a refund check will be issued upon request at the end of the current program year. The annual registration fee is not prorated and is non-refundable.

Additions must be requested by completing the Additional Information/Change Form found at www.aafp.org/pt. Any module may be added to an existing order depending on material availability. A \$35 shipping charge will be applied if a separate shipment is required. The module cost will be prorated according to the number of shipments remaining in the program year.

## OFF-SCHEDULE/REINSTATEMENT TESTING

Subject to product availability, PT specimens may be purchased throughout the program year. Typically specimens are received within one week. The evaluation will be completed within 10 business days after results are received. AAFP-PT reports reinstatement testing performance to state agencies or COLA for regulated analytes. Go to www.aafp.org/pt for reinstatement prices, process, and the Reinstatement Order Form.

## SUBMITTING RESULTS FOR MULTIPLE INSTRUMENTS OR METHODS

Under CLIA '88 regulations, laboratories are only permitted to submit results for one instrument or method per analyte per testing event. Laboratories wishing to perform PT on additional methods or instruments as part of their in-house quality assurance program must notify AAFP-PT in advance. These laboratories must delay testing for the secondary methods until after the event deadline. At that time, the laboratory will receive an email notification indicating a limited time period for performing testing and submitting results from additional instruments. The graded results for the additional instruments/methods will appear on the Evaluation Report, but will not be transmitted to accrediting agencies.

## **Continuing Education Information**

Laboratorians can earn up to 12 hours of continuing education credit for participation in the AAFP-PT program. The POL Insight is available on the PT Central home page three times per year. AAFP-PT is an approved provider of continuing education by ASCLS P.A.C.E.®. This is a benefit offered to all participants at no additional cost.

## POL Microscopy Atlas, 4th Edition

Developed by AAFP-PT, the Atlas contains more than 150 photos of cellular elements including urine sediments, vaginal wet preps, skin preps, nasal smears, stools for fecal leukocytes, stools for pinworms, peripheral bloods, fern test, and Gram stains. Each photo has a matching description and clinical associations. The Atlas also contains procedures such as urine sediment, vaginal wet prep, and manual differentials. To purchase this valuable resource, useful for training, continuing education, and as a benchtop reference, go to www.aafp.org/microscopy.

Cost: \$49 (AAFP member) | \$59 (nonmember)

## **CHEMISTRY**

## Apolipoproteins and Lp(a) - 2 specimens (LP)

Three shipments per year - 2 specimens per event

Module 712

\$162

**Product Information** – For quantitative methods. 1.2 mL liquid specimens.

Compatible with automated methods including: Abbott, Beckman Coulter, Roche, Siemens, Vitros, and Alfa Wassermann.

Analytes:

Apolipoprotein A1 Apolipoprotein B Apolipoprotein C Apolipoprotein E Lp(a)

β-hCG Quantitative (Serum) – 5 specimens (CH)

Three shipments per year – 5 specimens per event Module 719 \$141

**Product Information** – For quantitative methods. 5.0 mL liquid specimens.

Analyte: hCG

β-hCG Qualitative (Serum) – 5 specimens (HCG)

Three shipments per year – 5 specimens per event Module 678 \$147

Product Information - For qualitative serum pregnancy methods. 1.0 mL liquid specimens.

Analyte: hCG

Blood Lead - 1 specimen (LE)

Three shipments per year – 1 specimen per event Module 716 \$198

Note: Module 716 intended for waived methods such as Lead Care.

Three shipments per year – 5 specimens per event Module 709 \$402

**Product Information** – For quantitative waived methods. Whole blood specimens. Intended for use with instruments

such as Lead Care®.

Analyte: Lead

Blood Gases - 5 specimens (BG)

Three shipments per year – 5 specimens per event Module 702 \$402

**Product Information** – For quantitative methods. 2.0 mL liquid specimens that are compatible with all blood gas analyzers, except Abbott I-Stat® (see Module 723).

Analytes:

ionized Calcium pCO2 pH pO2 Hemoglobin Hematocrit

Blood Oximetry - 5 specimens (COX)

Three shipments per year – 5 specimens per event Module 659 \$312

**Product Information** – For quantitative methods. 1.2 mL liquid specimens.

**Analytes:** 

Carboxyhemoglobin Hematocrit (calculated) Hemoglobin (total) Methemoglobin Oxyhemoglobin

### CHEMISTRY CONTINUED >>>

## Cardiac Markers - 2 specimens (CDM)

## Three shipments per year - 2 specimens per event

Module 720 \$192

**Product Information** – For quantitative methods. 1.5 mL liquid specimens.

Compatible with automated methods including: Abbott, Alere Triage, Beckman Coulter, Roche, Siemens, and Vitros.

**Analytes:** 

BNP D-Dimer Myoglobin NT proBNP Troponin I

## Cardiac Markers II - 5 specimens (CDM)

## Three shipments per year - 5 specimens per event

**Product Information** – For quantitative methods. 1.5 mL liquid specimens.

Compatible with automated methods including: Abbott, Alere Triage, Beckman Coulter, Roche, Siemens, and Vitros.

Basic Cardiac Markers Module 715 \$231

**Analytes:** 

**CKMB** Myoglobin Troponin I

Complete Cardiac Markers Module 714 \$294

Analytes:

BNP CKMB D-Dimer Myoglobin NT proBNP Troponin I

## Cholestech LDX - 2 specimens (CT)

### Three shipments per year - 2 specimens per event

Module 600 \$183

**Product Information** – For quantitative waived methods. 1.0 mL liquid specimen. Intended for use only with Cholestech LDX® instruments.

Analytes:

Cholesterol Glucose HDL Cholesterol LDL Cholesterol Triglyceride

## Endocrinology - 5 specimens (CH)

### Three shipments per year - 5 specimens per event

Module 676 \$231

**Product Information** – For quantitative methods. 5.0 mL liquid specimens.

Compatible with automated methods including: Alfa Wassermann, Beckman Coulter, NanoEnTek Frend, Qualigen FastPak, Roche, Siemens, Tosoh, and Vitros.

Analytes:

Cortisol Free T3 Free T4 hCG T3 Uptake T3 T4 (Thyroxine) TSH

## Fetal Membrane Rupture - 2 specimens (ROM)

## Three shipments per year - 2 specimens per event

Module 645 \$294

Product Information - For quantitative methods. 0.5 mL liquid specimens. Intended for use only with Amnisure ROM.

**Analyte:** Fetal Membranes Rupture PAMG-1

### Gastric Occult Blood & pH - 2 specimens (GOB)

#### Three shipments per year - 2 specimens per event

Module 630 \$147

**Product Information** – For qualitative methods. 2.0 mL liquid specimens.

**Analytes:** 

Gastric Occult Blood pH

## CHEMISTRY CONTINUED >>>

## Glucose - Whole Blood (WBG)

Three shipments per year - 2 specimens per event

Module 664

Note: Module 664 is intended for waived methods only.

Three shipments per year - 5 specimens per event

Module 669 \$243

\$141

**Product Information** – For quantitative methods. 3.0 mL whole blood specimens. For use only with hand-held whole blood glucose monitors. Specimens are not compatible with the HemoCue glucose instruments (see Module 608).

Analyte: Glucose whole blood

## Glucose/Hemoglobin, HemoCue – 2 specimens (HQ)

Three shipments per year - 2 specimens per event

Module 608 \$147

**Product Information** – For quantitative methods. 2.0 mL liquid specimens. Intended for use only with the HemoCue (waived) instruments.

Analytes: Glucose whole blood Hemoglobin

## Glycohemoglobin, Afinion (Waived) - 2 specimens (AFF)

Three shipments per year - 2 specimens per event

Module 666 \$192

**Product Information** – For quantitative waived method. 0.5 mL whole blood specimen. Intended for use only with Alere Afinion (waived) instrument.

Analyte: Glycohemoglobin

## Glycohemoglobin - 2 specimens (GH)

Three shipments per year - 2 specimens per event

Module 672 \$192

**Product Information** – For quantitative methods. 1.0 mL whole blood specimen. Intended for use with instruments using immunochemical methods. See module 666 for Alere Afinion Glycohemoglobin.

Analyte: Glycohemoglobin

## i-STAT® Blood Gases - 5 specimens (IST)

Three shipments per year - 5 specimens per event

Module 723 \$234

Product Information - For quantitative methods. Intended for use only with Abbott i-STAT® cartridges.

Analytes/Panels: CG4+ G3+

## i-STAT® Chemistry (IST)

Three shipments per year - 2 specimens per event

Module 722 \$192

Three shipments per year - 5 specimens per event

Module 700 \$294

**Product Information** – For quantitative methods. Intended for use only with Abbott i-STAT® cartridge.

All cartridges listed below are waived.

Analytes/Panels:

6+ Cartridges CHEM 8+ Crea E3+ EC4+ G

## i-STAT® Chemistry/Blood Gas Combo – 5 specimens (IST)

Three shipments per year - 5 specimens per event

Module 721 \$312

Product Information - For quantitative methods. Intended for use only with Abbott i-STAT® cartridge.

Analytes/panels:

CG8+ EC8+ EG6+ EG7+

## MultiChem - 5 specimens (CH)

#### Three shipments per year - 5 specimens per event

**Product Information** – For quantitative methods. 5.0 mL liquid specimens.

Compatible with automated methods including: Abaxis, Abbott, Alfa Wassermann, Beckman Coulter, Clinical Data Envoy, Horiba, NanoEnTek Frend, Qualigen FastPak, Roche, Siemens, and Vitros.

 MultiChem 5, 1-5 analytes
 Module 612
 \$243

 MultiChem 10, 6-10 analytes
 Module 616
 \$255

 MultiChem 15, 11-15 analytes
 Module 617
 \$294

 MultiChem 20, 16-20 analytes
 Module 618
 \$354

 MultiChem 21+, 21+ analytes
 Module 619
 \$402

Analytes: See MultiChem Analytes chart below

#### MultiChem Package Analytes

All MultiChem modules include five specimens per shipment. Order packages 612, 616, 617, 618, or 619 according to the number of chemistry analytes tested in your lab. The chemistry analytes included in these packages are:

Cholesterol, HDL Iron Theophylline Acetominophen Phosphorous **AFP** Cholesterol, LDL Lactic Acid Potassium **TIBC** Albumin Cholesterol, Total LDH Primidone Tobramycin Alkaline Phosphatase CK Procainamide **Total Protein** Lidocaine CO Quinidine ALT/SGPT Lipase Triglyceride **UIBC** Amikacin Cortisol Lithium Salicvlate Amylase Creatinine Magnesium Sodium Urea Nitrogen (BUN) AST/SGOT Digoxin N-acetyl Procainamide *T*3 Uric Acid (NAPA) Bilirubin, Direct Ethosuximide T3, Free Valproic Acid Osmolality Bilirubin, Total Gentamicin T3 Uptake Vancomycin Phenobarbital Calcium **GGT** T4, (thyroxine) Phenylalanine Carbamazepine Glucose T4, Free Phenytoin Chloride hCG (Quant.) **TSH** 

## Neonatal Bilirubin - 2 specimens (NB)

### Three shipments per year - 2 specimens per event

ADD-ON - Module 663

\$132

Note: Module 663 is an ADD-ON module and can only be ordered when multi-chem modules 612-619 are ordered.

**Product Information** – For quantitative methods. 1.0 mL liquid specimens.

**Analytes:** Neonatal total bilirubin Neonatal direct bilirubin

### Neonatal Bilirubin - 5 specimens (NB)

Three shipments per year - 5 specimens per event

Module 662 \$192

**Product Information** - For quantitative methods. 1.0 mL liquid specimens.

Compatible with automated methods including: Beckman Coulter, Roche, Siemens, Vitros, and Alfa Wassermann.

**Analytes:** *Total bilirubin* Neonatal direct bilirubin

Note: Total bilirubin will be reported as a regulated analyte to CMS if not tested within modules 612-619.

### PSA - 1 specimen (SC)

### Three shipments per year - 1 specimen per event

ADD-ON - Module 667

\$36

Note: Module 795 is an ADD-ON module and can only be ordered when multi-chem modules 612-619 are ordered.

**Product Information** – For quantitative methods. 5.0 mL liquid specimen.

Analytes: PSA

### CHEMISTRY CONTINUED >>>

## SHBG and Testosterone – 2 specimens (SHT)

Three shipments per year - 2 specimens per event

\$402 Module 688

**Product Information** – For quantitative methods. 2.0 mL liquid specimens.

Analytes:

Sex Hormone Binding Globulin (SHBG) Free testosterone Total testosterone

## Special Chemistry – 2 specimens (SC)

#### Three shipments per year - 2 specimens per event

Module 686 \$276

**Product Information** – For quantitative methods. 5.0 mL liquid specimen.

Compatible with automated methods such as: Abbott, Alfa Wassermann, Beckman Coulter, NanoEnTek Frend, Qualigen FastPak, Roche, Siemens, Tosoh, and Vitros.

Analytes:

CEA DHEA Sulfate Estradiol Estriol Ferritin Folate **FSH** PAP Prealbumin Homocysteine IΗ Progesterone

Prolactin **PSA** Testosterone Transferrin Vitamin B12

## Special Chemistry II - 2 specimens (SPC)

#### Three shipments per year - 2 specimens per event

Module 685 \$162

**Product Information** – For quantitative methods. 2.0 mL lyophilized specimens.

Compatible with automated methods such as: Abbott, Beckman Coulter, Horiba, NanoEnTek Frend, Qualigen FastPak, Roche, Siemens, Tosoh, and Vitros.

Analytes:

C-peptide Insulin Parathyroid hormone (PTH) Vitamin D

## Thyroid Antibodies - 2 specimens (THY)

Three shipments per year - 2 specimens per event

Module 677 \$276

**Product Information** – For quantitative methods. 3.0 mL liquid specimens.

**Analytes:** Thyroglobulin antibody (Anti-TG) Thyroid Microsomal antibody (Anti-TPO)

### Tumor Markers – 5 specimens (TM)

Three shipments per year - 5 specimens per event

Module 708 \$402

**Product Information** – For quantitative methods. 3.0 mL liquid specimens.

Analytes:

**AFP** CA-19-9 Beta-2 Microglobulin CA 125 CA 15-3 CA-27/29

CEA PSA (Free) PSA (Total) Thyroglobulin Total protein

## Waived Chemistry – 2 specimens (CH)

## Three shipments per year - 2 specimens per event

Module 717 \$183

Product Information - For quantitative waived methods. 5.0 mL liquid specimen for the Abaxis Piccolo® reagent discs, and CardioChek. Not compatible with the Abbott i-Stat.

Abaxis Analytes/Panels:

Basic Metabolic Comprehensive Metabolic Panel Electrolytes General Chemistry 13 Lipid Panel Plus

General Chemistry 6 Kidney Check Lipid Panel

Liver Panel Plus Renal Panel Metlyte 8

CardioChek Panels/Analytes: Smart Bundle Lipid Panel

## **COAGULATION**

## CoaguChek XS, XS Plus, & XS Pro (CXP)

Three shipments per year - 2 specimens per event

Module 763

\$183

Note: Module 763 intended for waived methods only.

Three shipments per year - 5 specimens per event

Module 764

\$243

Product Information - For quantitative methods. Lyophilized plasma specimens. Not compatible with the Abbott i-Stat®.

Analyte: INR Protime

## Coagulation - Plasma - 5 specimens (CG)

Three shipments per year - 5 specimens per event

Module 680

\$162

**Product Information** – For quantitative methods. Lyophilized plasma specimens.

For use on all plasma coagulation except for whole blood instruments such as CoaguChek® or i-Stat®.

**Analytes:** 

APTT (Activated Partial Thromboplastin Time)

Fibrinogen

INR

**Protime** 

## D-Dimer - 2 specimens (CDM)

Three shipments per year - 2 specimens per event

Module 740

\$147

Product Information - For qualitative/quantitative methods. 1.5 mL liquid specimen.

Analyte: D-dimer

## i-Stat® Protime - 5 specimens (PTI)

Three shipments per year - 5 specimens per event

Module 748

\$231

**Product Information** – For qualitative methods. Lyophilized plasma specimens. For use only with i-Stat® or CoaguSense® instruments.

Analyte: INR

**Protime** 

## **HEMATOLOGY**

## **Blood Cell Identification (ID)**

Three shipments per year - images provided on paper and online

ADD-ON - Module 603

\$42

Note: Available when ordered in combination with modules 611, 613, 614, 745, 746, 747, or 752.

Product Information - 5 regulated and 1 educational microscopic images for red blood cell identification, including clinical history.

## Erythrocyte Sedimentation Rate (ESR, Sed. Rate) – 1 specimen (ES)

Three shipments per year - 1 specimen per event

Module 730 \$162

Product Information - For quantitative methods. 3.0 mL whole blood specimen.

Compatible with manual and most automated erythrocyte sedimentation rate methods. Not compatible with the Polymedco Sedimat-15.

**Analytes:** Sed Rate erythrocyte sedimentation rate

## Hematology and Blood Cell ID Package - (CBC without AutoDiff) - 5 specimens (HD, ID)

Three shipments per year - 5 specimens per event

Module 610 \$249

**Product Information** – For quantitative methods. 3.0 mL whole blood specimens. Compatible with all traditional methods including the hemocytometer, microhematocrit, and StatCrit. Does not include an automated differential.

**Analytes:** 

Blood Cell ID Photographs Hematocrit Hemoglobin Platelet count RBC WBC

## **Hematology CBC Modules - 5 Specimens**

Complete Blood Count (CBC) with 3 & 5 part differentials, see table

**Product information:** For quantitative methods. 3.0 mL whole blood specimens with pierceable caps.

Analytes:

Red Blood Cell White Blood Cell Hemoglobin Hematocrit MCV Platelet Count

RDW Automated Differential

	Module and Price					
	SYX	HD	DIF	CL	всх	SXT
HEMATOLOGY CBC - SELECT MODULE BY INSTRUMENT	613 \$243	614 <b>\$243</b>	745 \$294	746 \$294	747 \$294	752 \$294
	3 pa	rt diff		5 par	t diff	
Abbott Cell-Dyn 1700, 1800		Х				
Abbott Cell-Dyn 3000, 3200, 3500/3700, 4000				Х		
Abbott Emerald		Х				
Abbott Sapphire, Ruby, Emerald 22				Х		
Bayer (Siemens) ADVIA 60		Х				
Beckman-Coulter AcT, AcT Diff2		Х				
Beckman-Coulter AcT 5 Diff					Х	
Beckman-Coulter HmX, LH Series, DXH600			Х			
CDS Medonic & M series		Х				
Drew Scientific D3, Evolution		Х				
Horiba Micros/45/60		Х				
Horiba Pentra 60, 60C+, 80					Х	
Mindray 3000/3200 series		Х				
Siemens Advia 560				Х		
Sysmex CC, E, F, K, NE, R Series, XP-300	Х					
Sysmex pocH-100i	Х					
Sysmex XE 2100 series, XT 1800i, XT2000i, XS series, SE 5000, XNSeries, XT400i						Х

### **HEMATOLOGY CONTINUED >>>**

## HemoCue WBC - 5 specimens (HQW)

Three shipments per year - 5 specimens per event

Module 606 \$231

**Product Information** – For quantitative methods. 2.0 mL whole blood specimens.

**Analytes: White Blood Cells** 

## Hemoglobin/Glucose, HemoCue - 2 specimens (HQ)

Three shipments per year - 2 specimens per event

Module 608 \$147

Product Information - For quantitative methods. 2.0 mL whole blood specimens. For use only with waived HemoCue instruments.

Analytes: Glucose Hemoglobin

## Hemoglobin/Hematocrit - 2 specimens (HD)

Three shipments per year - 2 specimens per event

Module 602 \$147

**Product Information** – For quantitative methods. 3.0 mL whole blood specimens. Intended for use with waived methods only. Not suitable for HemoCue instruments.

Analytes: Hematocrit Hemoglobin

## Sickle Cell Screen - 2 specimens (SS)

Three shipments per year - 2 specimens per event

Module 739 \$162

Product Information - For quantitative methods. 1.0 mL RBC specimen. Suitable for all screening methods.

Analyte: Sickle cell screen

## **IMMUNOLOGY/VIROLOGY**

## Anti-CCP - 2 specimens (CCP)

Three shipments per year - 2 specimens per event

Module 931

\$294

Product Information - For qualitative/quantitative methods. 1.0 mL liquid specimen.

Analyte: Anti-CCP

## Anti-nuclear Antibodies (ANA) – 5 specimens (AE)

Three shipments per year - 5 specimens per event

Module 760

\$147

Product Information - For quantitative ELISA methods. 1.0 mL liquid specimen.

Analyte: ANA

## Antistreptolysin O (ASO) – 5 specimens (AS)

Three shipments per year - 5 specimens per event

Module 683

\$192

Product Information - For quantitative/qualitative methods. 1.0 mL liquid specimens.

Analyte: ASO Antibody

## C-Reactive Protein (CRP) - 2 specimens (CR)

Three shipments per year - 2 specimens per event

Module 684

\$141

Product Information - For qualitative/quantitative methods. 1.0 mL liquid specimens.

Analyte: CRP

## C-Reactive Protein, High Sensitivity CRP - 2 specimens (HCR)

Three shipments per year - 2 specimens per event

Module 761 \$141

**Product Information** – For quantitative methods. 0.5 mL liquid specimen.

Analyte: hsCRP

## Hepatitis C Antibody (Waived) - 2 specimens (VM)

Three shipments per year - 2 specimens per event

Module 932

\$312

Product Information - For qualitative waived methods. 1.0 mL liquid specimens.

Analyte: Anti-HCV

## Hepatitis Markers – 5 specimens (VM)

Three shipments per year - 5 specimens per event

Module 767

\$462

**Product Information** – For qualitative methods. 1.0 mL liquid specimens.

Analytes:

Anti-HAV Anti-HBc Anti-HBs Anti-HCV **HBeAg HBsAg** 

## **HIV Antibody/Antigen Combo (HIV)**

Three shipments per year - 2 specimens per event

Module 933 \$249

Note: Module 933 is intended for waived methods only.

Three shipments per year - 5 specimens per event

Module 934

\$354

**Product Information** – For qualitative methods. 0.5 mL liquid specimens.

Analytes: HIV Antibody HIV Antigen (p24)

2020 SHIP DATES: MARCH 2 | JUNE 1 | OCTOBER 5

## IMMUNOLOGY/VIROLOGY CONTINUED >>>

## H. pylori - 2 specimens (HP)

Three shipments per year - 2 specimens per event

Module 644 \$147

**Product Information** – For qualitative methods. 1.0 mL liquid blood specimen.

Analytes: H. pylori Antibody

## Infectious Mononucleosis (IM)

Three shipments per year - 2 specimens per event

Module 753

\$90

Note: Module 753 is intended for waived methods only.

Module 675

\$147

Three shipments per year - 5 specimens per event

**Product Information** – For qualitative methods. 0.6 mL liquid specimens.

Analyte: Infectious Mononucleosis

## Infectious Mono / RF Combo Pkg - 5 specimens (IM, RF)

Three shipments per year - 5 specimens per event

Module 754 \$231

**Product Information** – For qualitative methods. 1.0 mL liquid specimens.

**Analytes:** *Infectious Mononucleosis* Rheumatoid Factor

## Lyme Serology - 2 specimens (LY)

Three shipments per year - 2 specimens per event

Module 654

\$192

Product Information - For qualitative methods. 0.6 mL liquid specimen.

Analyte: Lyme Serology

## Mycoplasma Antibody - 2 specimens (MY)

Three shipments per year - 2 specimens per event

Module 758

\$183

**Product Information** – For qualitative methods. 0.5 mL liquid specimen.

**Analyte:** Mycoplasma Antibody

## Rheumatoid Factor - 5 specimens (RF)

Three shipments per year - 5 specimens per event

Module 653

\$147

**Product Information** – For qualitative methods. 1.0 mL liquid specimens.

Analyte: Rheumatoid Factor

## Syphilis Serology - 5 specimens (SY)

Three shipments per year - 5 specimens per event

Module 679

\$171

Product Information - For semi-quantitative/semi-qualitative methods. 1.0 mL liquid specimens.

Analytes: RPR **VDRL** 

## **MICROBIOLOGY**

#### **MODULE INFORMATION**

The specialty of microbiology has unique CLIA '88 PT performance requirements specified in the regulations: Five challenges three times per year must be performed. These challenges can be all one type of testing or a combination of several types of testing. Bacterial cultures and antigen detection methods are both classified as testing procedures in bacteriology and can each be counted together toward these challenge requirements. Viral antigen detection should be considered separately at five challenges three times per year. AAFP-PT has constructed several modules designed to provide your laboratory with the number of challenges required by CLIA '88 at the lowest cost.

#### ANTIGEN DETECTION PACKAGES

When selecting your test packages, please remember that CLIA '88 regulations require five challenges of both bacterial and viral specimens three times per year.

#### **CULTURE PACKAGES**

These packages are designed for laboratories performing cultures (and susceptibilities if applicable) from one or more sources. You should select the package that covers all or most of the sources tested in your lab.

## Bacterial Vaginosis - 2 specimens (BV)

## Three shipments per year - 2 specimens per event

Module 975 \$171

**Product Information** – For detection of elevated vaginal fluid sialidase activity, an enzyme produced by bacterial pathogens associated with bacterial vaginosis including *Gardnerella*, *Bacteriodes*, *Prevotella*, and *Mobiluncus*. Intended for use with OSOM® BVBlue-Detects®.

Procedure - Bacterial vaginosis screen detection

## Complete Bacteriology - 7 specimens (BA, UC, TC, GC)

## Three shipments per year - 7 specimens per event

Module 782 \$276

**Product Information** – For performing cultures on all or most body sites. Sources covered throughout the year include blood, CSF, ear, eye, genital, respiratory/sputum, skin, stool, throat, urine, and wounds. Does not include Gram stain (see Module 668).

#### **Procedures**

Aerobic/Anaerobic bacterial culture Antimicrobial susceptibility Organism identification

## C. difficile Toxin/Ag (CDF)

## Three shipments per year - 2 specimens per event

Module 964 \$132

Note: Module 964 is intended for waived methods only.

Three shipments per year – 5 specimens per event

Module 963 \$192

**Product Information** – Stool specimen for detection of Clostridium difficile toxin and/or antigen. Compatible with molecular methods.

**Procedures** - *C. difficile Antigen* and/or Toxin

## Dermatophyte Screen - 5 specimens (DM)

## Three shipments per year - 5 specimens per event

Module 772 \$243

**Product Information** – Designed for dermatophyte screening only. Reported as present/absence. A non-regulated procedure. Specimens are suitable for culture method including DTM or other selective media.

Procedure - Dermatophyte screen - qualitative reporting only

#### MICROBIOLOGY CONTINUED > > >

## Gastrointestinal Viral Detection – 5 specimens (GVD)

Three shipments per year - 5 specimens per event

Module 978 \$294

**Product Information** – For qualitative methods. 1.0 mL liquid specimen.

**Procedures** 

Rotavirus

## Genital Culture - 5 specimens (GC)

Three shipments per year - 5 specimens per event

Module 777

\$255

**Product information** – Intended for performing only genital cultures.

Procedures - Organism identification

## Genital Viral Detection – 5 specimens (HVD)

Three shipments per year - 5 specimens per event

Module 929

\$312

**Product Information** – For qualitative methods. 1.0mL liquid specimen.

Procedures - Herpes Simplex 1 Herpes Simplex 2

## Gential Viral Detection II - 5 Specimens (PVD)



Three shipments per year - 5 specimens per event

Module 936 \$402

**Product Information** – For qualitative methods for *human papillomavirus*. 1.0mL liquid specimen.

Procedures - HPV genotyping (16,18,45)

### Giardia/Cryptosporidum Antigen – (GCA)

Three shipments per year - 2 specimens per event

ADD-ON - Module 972

\$147

Note: Module 972 intended for waived methods or as an ADD-ON module and can be ordered when culture modules 775-782 are ordered.

Three shipments per year - 5 specimens per event

\$255

Product Information - Intended for performing Giardia/Cryptosporidium screening on stool specimens.

Procedures - Giardia and/or Cryptosporidium Antigen

## Gram Stain (Glass Slides) - 5 specimens (GS)

Three shipments per year - 5 specimens per event

Module 668 \$147

**Product Information** – Methanol-fixed slides for Gram staining.

Procedures - Gram reaction Organism morphology

## **Group A Strep (RS)**

Three shipments per year - 2 specimens per event

Module 665

\$90

Note: Module 665 intended for waived methods only.

Three shipments per year - 2 specimens per event

ADD-ON - Module 783

\$60

Note: Module 783 is an ADD-ON module and can only be ordered when culture modules 775-782 are ordered.

Three shipments per year - 5 specimens per event

Module 691

\$183

Product Information - Intended for Group A Streptococci antigen detection (rapid strep). Compatible with molecular methods.

Procedure - Strep A Antigen

#### MICROBIOLOGY CONTINUED > > >

## Group B Screen - 5 Specimens (AD)

Three shipments per year - 5 specimens per event

Module 789 \$276

Product Information - Swab specimen for detection of Group B Streptococcus by culture screen or antigen methods. Compatible with molecular methods.

Procedures - Group B Strep

## Legionella Antigen – 2 specimens (LEG)

### Three shipments per year - 2 specimens per event

ADD-ON - Module 961

\$123

Note: Module 961 is an ADD-ON module and can only be ordered when culture modules 775-782 are ordered.

**Product Information** – Intended for Legionella antigen detection.

Procedure - Legionella Antigen

## MRSA Molecular (MRSA)

Three shipments per year - 2 specimens per event

ADD-ON - Module 768

\$105

Note: Module 768 is an ADD-ON module and can only be ordered when culture modules 775-782 are ordered.

Three shipments per year - 5 specimens per event

Module 690

\$276

Product Information - Compatible with molecular methods for qualitative reporting. 1mL liquid specimens.

Procedure - Methicillin-resistant Staphylococcus aureus

## Presumptive ID/Colony Count – Urine 5 specimens (CC)

Three shipments per year - 5 specimens per event

\$276 Module 784

Product Information - Dehydrated bacteria specimens which require preparation prior to plating and testing. Specimens are suitable for paddle, tube cultures, or agar plated with calibrated loop. Identification to the Gram reaction or genus of the organisms (presumptive identification) and colony count.

Procedures - Colony count

Organism identification

## Rapid Urease - 2 specimens (RUR)

Three shipments per year - 2 specimens per event

Module 924

Product information - Specimens are supplied on paper disk and ready for use. The disk has viable microorganisms for use with various bench top urease detection methods such as CLOtest®, PlyoriTek®, or similar methods.

Procedure - Urease

## Respiratory Viral Antigen Detection – (VAD)

Two shipments per year - 2 specimens per event

Module 792

\$147

\$132

Note: Module 792 is intended for waived methods and ships A and C events only.

Three shipments per year - 5 specimens per event

Module 770 \$294

**Product Information** – For qualitative methods. 1.0 mL liquid specimen.

Procedures - Adenovirus Influenza A Influenza B RSV

## Strep pneumoniae (PNU)

Three shipments per year - 2 specimens per event

Module 962

\$123

Note: Module 962 is intended for waived methods only

Three shipments per year - 5 specimens per event

Module 974 \$231

**Product Information** – Intended for *Streptococcus pneumoniae* detection. Compatible with molecular methods.

Procedure - Strep pneumoniae

#### MICROBIOLOGY CONTINUED > > >

## Trichomonas Detection, Rapid - 2 specimens (CGT)

Three shipments per year - 2 specimens per event

Module 977 \$162

**Product information** – Swabs for detections of Trichomonas used with OSOM® Trichomonas Rapid Test.

Procedure - Trichomonas detection

## Throat Culture - 5 specimens (TC)

Three shipments per year - 5 specimens per event

Module 776 \$255

**Product information** – Intended for throat cultures only.

Procedure - Organism identification

## Throat & Genital Culture – 5 specimens (TC/GC)

Three shipments per year - 3 throat specimens and 2 genital specimens per event

Module 780 \$255

**Product information** – Intended for throat and genital cultures only.

Procedure - Organism identification

## **Urine Colony Count - 1 specimen (CC)**

### Three shipments per year - 1 specimen per event

Module 661 \$171

Note: If your laboratory performs presumptive IDs, refer to Presumptive ID/Colony Count module 784.

**Product Information** – Dehydrated bacteria specimens which require preparation prior to plating and testing. Specimens are suitable for paddle, tube cultures, or agar plated with calibrated loop. Urine colony count is a non-regulated procedure.

Procedure - Colony count

### Urine Culture - 5 specimens (UC)

#### Three shipments per year - 5 specimens per event

Module 775 \$255

Note: If your laboratory performs only colony counts, refer to Presumptive ID/Colony Count module 784.

Product information - Intended for only urine culture with organism identification and/or susceptibility testing.

Procedures - Antimicrobial susceptibility Organism identification

## Urine & Genital Culture - 5 specimens (UC/GC)

#### Three shipments per year - 3 urine specimens and 2 genital specimens per event

Module 779 \$255

Note: If your laboratory performs only colony counts, refer to Presumptive ID/Colony Count module 784.

Product information - Intended for urine and genital cultures only with organism identification and/or susceptibility testing.

Procedures - Antimicrobial susceptibility Organism identification

### Urine & Throat Culture – 5 specimens (UC/TC)

### Three shipments per year - 3 urine specimens and 2 throat specimens per event

Module 778 \$255

Note: If your laboratory performs only colony counts, refer to Presumptive ID/Colony Count module 784.

Product information - Intended for urine and throat cultures only with organism identification and/or susceptibility testing.

Procedures - Antimicrobial susceptibility Organism identification

## Urine, Throat, and Genital Culture – 5 specimens (UC/TC/GC)

Three shipments per year – 2 urine specimens, 2 throat specimens, and 1 genital specimen per event Module 781 \$255

Product information - Intended for urine, throat, and genital cultures with organism identification and/or susceptibility testing.

Procedures - Antimicrobial susceptibility Organism identification

## MICROBIOLOGY CONTINUED >>>

## Urine Susceptibility - 1 specimen (UC or CC)

#### Three shipments per year - 1 specimen per event

ADD-ON - Module 790

\$36

Note: Module 790 is an ADD-ON module and can only be ordered when culture modules 661 or 784 are ordered.

Product Information - Intended for urine susceptibility testing. This procedure is regulated and will be reported to CLIA '88.

Procedure - Antimicrobial susceptibility

## Vaginal Pathogens – 5 specimens (VP)

Three shipments per year - 5 specimens per event

Module 771

\$354

**Product Information** – Swab specimens to be used for DNA probe testing for Candida sp., *Gardnerella vaginalis*, and/or *Trichomonas vaginalis*.

**Procedures** 

Candida detection

Gardnerella detection

Trichomonas detection

## Vaginal Pathogens II (CGT)

### Three shipments per year - 2 specimens per event

ADD-ON - Module 795

\$105

Note: Module 795 is an ADD-ON module and can only be ordered when culture modules 775-782 are ordered.

Note: Modules 794 and 795 replace GenProbe GC/Chlamydia Module 774.

#### Three shipments per year - 5 specimens per event

Module 794

\$312

**Product Information** – Swab specimen for detection of *Chlamydia trachomatis, Neisseria gonorrhoeae*, and/or *Trichomonas vaginalis*. Specimens contain human DNA and are intended for DNA probe techniques and other molecular methods.

Procedures - Chlamydia trachomatis

Neisseria gonorrhoeae

Trichomonas detection

## VRE Molecular (VRE)

#### Three shipments per year - 2 specimens per event

ADD-ON - Module 976

\$105

Note: Module 976 is an ADD-ON module and can only be ordered when culture modules 775-782 are ordered.

Three shipments per year - 5 specimens per event

Module 958

\$276

**Product Information** – Compatible with molecular methods for qualitative reporting. Not intended for methods that screen for specific VRE genes.

Procedure - Vancomycin-resistant Enterococcus

## **MICROSCOPY**

## Clinical Microscopy (CM)

Three shipments per year - 1 photo sheet per event

Module 641 \$147

**Product Information** – 6 photographs representing a selection from the following sources:

Fecal Leukocytes . . . . 1 time per year Stool for Pinworms . . . 1 time per year Fern Testing . . . . . 2 times per year Urine Sediment . . . . . 3 times per year KOH-Skin Scraping . . . 3 times per year Vaginal Wet Prep . . . . 3 times per year

Nasal Smears ..... 2 times per year

## KOH (glass slides) - 2 specimens (KOH)

Three shipments per year - 2 specimens per event

Module 637 \$171

Product Information - Microscopic exam on glass slides for fungal elements in hair, nails, or skin. Not intended for vaginal wet preps.

## Post Vasectomy Sperm Analysis - 2 specimens (PVAS)

Three shipments per year - 2 specimens per event

Module 950 \$249

Product Information - Microscopic exam intended for presence or absence of sperm. 1.5 mL liquid specimen.

## **Urine Sediment Microscopy (CM)**

Three shipments per year - 1 photo sheet per event

Module 638 \$60

Analyte: Urine Sediment

## **URINALYSIS**

## Complete Urinalysis Package - 1 specimen (CM, UA)

#### Three shipments per year - 1 of each specimen per event

Module 639 \$171

Product Information - For qualitative/semi-quantitative methods. 10.0 mL liquid specimen. 1 photo sheet.

#### **Analytes:**

Clinical Microscopy (photosheet)

Urinalysis components (dipstick): Bilirubin, Blood/HgB, Glucose, Leukocyte Esterase, Ketones, Microalbumin (qualitative), Nitrite, pH, Protein, Specific Gravity, Urobilinogen

Urine hCG

## Urine Adulteration - 2 specimen (UAD)

Three shipments per year - 2 specimen per event

Module 940 \$183

**Product Information** – For semi-quantitative methods. 10.0 mL liquid specimen.

Analyte:

Creatinine Nitrite (Oxidants) pH Sp Gravity

## **Urine Chemistry - 2 specimens (URC)**

Three shipments per year - 2 specimens per event

Module 728 \$276

Product Information - For quantitative methods. 10.0 mL liquid specimen.

**Analytes:** 

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

## Urine Drug Screen - 10mL - 2 specimens (UDS)

Three shipments per year - 2 specimens per event

Module 703 \$231

**Product Information** – For qualitative methods. 10.0 mL liquid specimen.

**Analytes:** 

Acetaminophen **Amphetamines** Barbiturates Benzodiazepines Buprenorphine Cotinine Cannabinoids (THC) Cocaine Metabolites **EDDP** Ethanol Hydrocodone LSD MDMA (Ecstasy) Meperidine Fentanyl Methadone Methamphetamine Methaqualone Opiates Oxycodone **PCP** Propoxyphene 6-monoacetylmorphine Tramadol Tricyclic Anti-depressants

## Urine Drug Screen - 50 mL - 2 specimens (UDS)

Three shipments per year - 2 specimens per event

Module 713 \$294

**Product Information** – For qualitative methods. 50.0 mL liquid specimen.

Analytes:

Buprenorphine Acetaminophen **Amphetamines** Barbiturates Benzodiazepines Cotinine **EDDP** Ethanol Cannabinoids (THC) Cocaine Metabolites MDMA (Ecstasy) Fentanyl Hydrocodone LSD Meperidine Methamphetamine Methadone Methaqualone Opiates Oxycodone

PCP Propoxyphene 6-monoacetylmorphine Tramadol Tricyclic Anti-depressants

#### **URINALYSIS CONTINUED > > >**

## Urinalysis - 2 specimens (UA)

Three shipments per year - 2 specimens per event

Module 640 \$105

Product Information - For qualitative/semi-quantitative methods. 10.0 mL liquid specimen.

**Analytes:** 

Urinalysis components (dipstick): Bilirubin, Blood/HgB, Glucose, Leukocyte Esterase, Ketones, Microalbumin (qualitative), Nitrite, pH, Protein, Specific Gravity, Urobilinogen

Fluid pH

## Urinalysis/hCG - 2 specimens (UA)

Three shipments per year - 2 specimens per event

Module 642 \$123

Product Information - For qualitative/semi-quantitative methods. 10.0 mL liquid specimen.

**Analytes:** 

Urine hCG

Urinalysis components (dipstick): Bilirubin, Blood/HgB, Glucose, Leukocyte Esterase, Ketones, Microalbumin (qualitative), Nitrite, pH, Protein, Specific Gravity, Urobilinogen

## Urinalysis/hCG/Fecal Occult Blood – 1 specimen (UA,OC)

Three shipments per year - 1 of each specimen per event

Module 647 \$123

Product Information - For qualitative / semi-quantitative methods. 10.0 mL liquid specimen.

**Analytes:** 

Fecal Occult Blood Urine hCG

Urinalysis components (dipstick): Bilirubin, Blood/HgB, Glucose, Leukocyte Esterase, Ketones, Microalbumin (qualitative), Nitrite, pH, Protein, Specific Gravity, Urobilinogen

### Urine Microalbumin & Creatinine - 2 specimens (UM)

Three shipments per year - 2 specimens per event

Module 705 \$162

**Product Information** – For quantitative/semi-quantitative methods. 10.0 mL liquid specimen.

**Analytes:** Creatinine Microalbumin

## **Urine Sediment Microscopy (CM)**

Three shipments per year - 1 photo sheet per event

Module 638 \$60

Analyte: Urine Sediment

## WAIVED/PPM

All modules in this section are for waived instruments or non-regulated analytes only. Consult index for other waived tests not found in this section.

## Blood Lead - 1 specimen (LE)

### Three shipments per year - 1 specimen per event

Module 716 \$198

**Product Information** – For quantitative waived methods. Whole blood specimens. Intended for use with instruments such as Lead Care<sup>®</sup>.

Analyte: Lead

## Cholestech LDX - 2 specimens (CT)

## Three shipments per year - 2 specimens per event

Module 600 \$183

**Product Information** – For quantitative waived methods. 0.5 mL liquid specimen. Intented for use only with Cholestech LDX® instrument.

**Analytes:** 

Cholesterol Glucose LDL Cholesterol HDL Cholesterol Triglyceride

## Clinical Microscopy (CM)

## Three shipments per year - 1 photo sheet per event

Module 641 \$147

Product Information - 6 photographs representing a selection from the following sources:

Fecal Leukocytes . . . . . 1 time per year Stool for Pinworms . . . . 1 time per year Fern Testing . . . . . . 2 times per year Urine Sediment . . . . . 3 times per year KOH -Skin Scraping . . . 3 times per year Vaginal Wet Prep . . . . 3 times per year

Nasal Smears . . . . . . 2 times per year

## CoaguChek XS, XS Plus, & XS Pro - 2 specimens (CXP)

#### Three shipments per year - 2 specimens per event

Module 763 \$183

**Product Information** – For quantitative waived methods. Lyophilized plasma specimens. Intended for use with CoaguChek XS, CoaguChek XS Plus, and CoaguChek XS Pro instruments. Not compatible with the Abbott iStat<sup>®</sup>.

Analyte: INR Protime

## Complete Urinalysis Package - 1 specimen (CM, UA)

### Three shipments per year - 1 of each specimen per event

Module 639 \$171

Product Information - For qualitative/semi-quantitative methods. 10.0 mL liquid specimen. 1 photo sheet.

#### Analytes:

Clinical Microscopy (photosheet)

Urinalysis components (dipstick): Bilirubin, Blood/HgB, Glucose, Leukocyte Esterase, Ketones, Microalbumin (qualitative), Nitrite, pH, Protein, Specific Gravity, Urobilinogen

Urine hCG

### Fecal Occult Blood – 1 specimen (OC)

#### Three shipments per year - 1 specimen per event

ADD-ON - Module 791

\$36

Note: Module 791 is an add-on module and can only be ordered when Modules 639-642 are ordered.

Product Information - For qualitative Guaiac or Immunochemical waived methods. 1.5 mL liquid specimen.

Analyte: Fecal Occult Blood

## **WAIVED/PPM CONTINUED >>>**

## Glycohemoglobin, Afinion (Waived) - 2 specimens (AFF)

#### Three shipments per year - 2 specimens per event

Module 666 \$192

**Product Information** – For quantitative waived method. 0.5 mL whole blood specimen. Intended for use only with Alere Afinion (waived) instrument.

Analyte: Glycohemoglobin

## Glycohemoglobin - 2 specimens (GH)

#### Three shipments per year - 2 specimens per event

Module 672 \$192

**Product Information** – For quantitative methods. 1.0 mL whole blood specimen. Intended for use with instruments using immunochemical methods. See module 666 for Alere Afinion Glycohemoglobin.

Analyte: Glycohemoglobin

## Group A Strep - 2 specimens (RS)

#### Three shipments per year - 2 specimens per event

Module 665 \$90

Product Information - For qualitative waived methods. Intended for Group A Streptococci antigen detection (Rapid strep).

Analyte: Strep A Antigen

## Glucose, Whole Blood (WBG)

Three shipments per year - 2 specimens per event

Module 664 \$141

Three shipments per year - 5 specimens per event

Module 669 \$243

**Product Information** – For quantitative waived methods. 3.0 mL whole blood specimens. For use only with hand-held whole blood glucose monitors. Specimens are not compatible with the HemoCue glucose instruments (see Module 608).

Analyte: Glucose whole blood

## Glucose/Hemoglobin, HemoCue - 2 specimens (HQ)

For HemoCue instruments only

#### Three shipments per year - 2 specimens per event

Module 608 \$147

**Product Information** – For quantitative waived methods. 2.0 mL liquid specimens. Intended for use only with the HemoCue (waived) instruments.

Analyte: Glucose Hemoglobin

## Hemoglobin/Hematocrit - 2 specimens (HD)

## Three shipments per year - 2 specimens per event

Module 602 \$147

Product Information - For quantitative waived methods. 3.0 mL whole blood specimens. Not suitable for HemoCue instruments.

**Analyte:** Hematocrit Hemoglobin

## Hepatitis C Antibody (Waived) - 2 specimens (VM)

## Three shipments per year - 2 specimens per event

Module 932 \$312

**Product Information** – For quantitative waived methods. 1.0 mL liquid specimens.

Analyte: Anti-HCV

## HIV Antibody/Antigen Combo - 2 specimens (HIV)

#### Three shipments per year - 2 specimens per event

Module 933

\$249

Note: Module 933 is inteneded for waived methods only.

Product Information - For quantitative waived methods. 0.5 mL liquid specimens.

**Analyte:** HIV Antibody HIV Antigen (p24)

### 2020 SHIP DATES: MARCH 2 | JUNE 1 | OCTOBER 5

## WAIVED/PPM CONTINUED >>>

## i-STAT® Chemistry - 2 specimens (IST)

Three shipments per year - 2 specimen pers event

Module 722

\$192

**Product Information** – For quantitative methods. All cartridges listed below are waived. Intended for use with Abbott i-STAT® cartridges.

**Analytes:** 

6+ Cartridges CHEM 8+ Crea E3+ EC4+ G

Infectious Mononucleosis (IM)

Three shipments per year – 2 specimens per event Module 753 \$90

Three shipments per year – 5 specimens per event Module 675 \$147

**Product Information** – For qualitative waived methods. 0.6 mL liquid specimens.

Analyte: Infectious Mononucleosis

## KOH (glass slides) - 2 specimens (KOH)

Three shipments per year - 2 specimens per event

Module 637 \$171

**Product Information** - Microscopic exam on glass slides for fungal elements in hair, nails, or skin. Not intended for vaginal wet preps.

## Respiratory Viral Detection – 2 specimens (VAD)

Two shipments per year - 2 specimens per event

Module 792 \$147

Note: Module 792 ships A and C events only.

**Product Information** – For qualitative waived methods. 1.0 mL liquid specimen.

**Procedures** 

Adenovirus Influenza A Influenza B RSV

### Urinalysis - 2 specimens (UA)

Three shipments per year - 2 specimens per event

Module 640 \$105

Product Information - For qualitative/semi-quantitative methods. 10.0 mL liquid specimen.

Analytes:

Urinalysis components (dipstick): Bilirubin, Blood/HgB, Glucose, Leukocyte Esterase, Ketones, Microalbumin (qualitative), Nitrite, pH, Protein, Specific Gravity, Urobilinogen

Fluid pH

## Urinalysis/ hCG - 2 specimens (UA)

Three shipments per year - 2 specimens per event

Module 642 \$123

Product Information - For qualitative/ semi-quantitative waived methods. 10.0 mL liquid specimen.

**Analytes:** 

Urine hCG

Urinalysis components (dipstick): Bilirubin, Blood/HgB, Glucose, Leukocyte Esterase, Ketones, Microalbumin (qualitative), Nitrite, pH, Protein, Specific Gravity, Urobilinogen

## WAIVED/PPM CONTINUED >>>

## Urinalysis/hCG/Fecal Occult Blood - 1 specimen (UA,OC)

Three shipments per year - 1 specimen per event

Module 647 \$123

Product Information - For qualitative/ semi-quantitative methods. 10.0 mL liquid specimen.

Analytes:

Fecal Occult Blood Urine hCG

Urinalysis components (dipstick): Bilirubin, Blood/HgB, Glucose, Leukocyte Esterase, Ketones, Microalbumin (qualitative),

Nitrite, pH, Protein, Specific Gravity, Urobilinogen

## **Urine Sediment Microscopy (CM)**

Three shipments per year - 1 photo sheet per event

Module 638

\$60

Analyte: Urine Sediment

## Waived Chemistry - 2 specimens (CH)

Three shipments per year - 2 specimens per event

Module 717 \$183

**Product Information** – For quantitative waived methods. 5.0 mL liquid specimen for the Abaxis Piccolo® reagent discs, and CardioChek. Not compatible with the Abbott i-Stat®.

Abaxis Analytes/Panels:

Basic Metabolic Comprehensive Metabolic Panel Electrolytes General Chemistry 13

General Chemistry 6 Kidney Check Lipid Panel Lipid Panel Plus

Liver Panel Plus Metlyte 8 Renal Panel

CardioChek Panels/Analytes: Smart Bundle Lipid Panel

## Waived/PPM Tests I - 1 specimen

Three shipments per year - 1 of each specimen per event

Module 609 \$294

Product Information - For qualitative/semi-quantitative methods used on waived instruments/kits.

Includes:

Clinical Microscopy (CM)

Urinalysis components – dipstick (UA): Bilirubin, Blood/

HgB, Glucose, Leukocyte Esterase, Ketones, Microalbumin

Group A Strep Antigen (RS) (qualitative), Nitrite, pH, Protein, Specific Gravity, Urobilinogen

Hematocrit (HD)

Urine hCG (UA)

Hemoglobin (including HemoCue) (HD)

Whole Blood Glucose (WBG) (Hand-Held methods only –

NOT HemoCue, see module 608)

Infectious Mono (IM)

## Waived/PPM Tests II

Three shipments per year Module 601 \$312

Product Information – For qualitative/semi-quantitative methods used on waived instruments/kits. Does not include Infectious Mono.

**Includes:** Number in parentheses ( ) indicates specimens received per shipment.

Clinical Microscopy (CM) (1)

Urinalysis components – dipstick (UA) (1): Bilirubin, Blood/
Fecal Occult Blood (OC) (1)

HgB, Glucose, Leukocyte Esterase, Ketones, Microalbumin

Group A Strep Antigen (RS) (2) (qualitative), Nitrite, pH, Protein, Specific Gravity, Urobilinogen

Hematocrit (HD) (2)

Urine hCG (UA) (1)

Hemoglobin (including HemoCue) (HD) (2) Whole Blood Glucose (WBG) (2) (Hand-Held methods only –

NOT HemoCue, see module 608)

## **ANALYTE INDEX**

All regulated analytes are in **RED** and are provided at five challenges per shipment.

A	Chlamydia Antigen Detection
6-MAM (monoacetylmorphine) (urine)	Chlamydia by Molecular Method
Acetaminophen (urine)	<b>Chloride</b>
Acetaminophen5	Chloride (urine)
Adenovirus 14	Cholesterol, HDL
Adenovirus	Cholesterol, HDL (waived)
Aerobic/Anaerobic culture	Cholesterol, LDL (Calculated and Direct)
AFP (Alpha fetoprotein)	Cholesterol, Total (waived)
Albumin	Cholesterol, Total
ALP (Alkaline Phosphatase)	CK (Creatine Kinase)
ALT/SGPT (Alanine Aminotransferase)	<b>CK-MB</b>
Amikacin	Clinical Microscopy
Amphetamines (urine)	CO <sub>2</sub>
Amylase (urine)	Cocaine Metabolites (urine)
Amylase	Colony Count, Urine
ANA (Anti-Nuclear Antibody) (ELISA)	Cortisol 3,5
ANTI-CCP	Cotinine (urine)
ANTI-HAV	C-Peptide
ANTI-HBc 10	Creatinine (urine)
ANTI-HBs 10	Creatinine
ANTI-HCV	CRP (C-Reactive Protein) (qual. & quant)
Antimicrobial susceptibility 12,15,16	CRP, high sensitivity
Apolipoprotein A1	Cryptosporidium Antigen
Apolipoprotein B	Culture, Genital. 13,15
Apolipoprotein C	Culture, Throat
Apolipoprotein E	Culture, Urine
APTT (Activated Partial Thromboplastin Time)	Cultures, Miscellaneous (Blood, CSF, Eye, Ear, Skin, Sputum,
ASO (Antistreptolysin 0) 10	Stool, Wound)
AST/SGOT (Aspartate Aminotransferase) 5	otooi, would)
AS1/SGOT (Aspartate Animotransierase)	D
В	_
Bacterial Vaginosis	D-Dimer
Beta-2 Microglobulin	Dermatophyte Screen
Barbiturates (urine)	DHEAS (DHEA Sulfate)
Benzodiazepines (urine)	Differential, Automated 1-3-part
Bilirubin, Direct	Differential, Automated 5-part
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Bilirubin, Total	Drug Screen (urine)
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Blood Gases	Ecstasy (see MDMA)
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BNP	Estradiol6
	Estriol
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	Ethosuximide
C	
C. difficile Antigen/Toxin	F
CA 125	Fecal Leukocytes
CA 15-3	Fecal Occult Blood. 19.20,23
CA 19-9	Fentanyl (urine)
	Fern Testing
CA 27/29	Ferritin
Calcium, ionized	Fetal Membranes Rupture
Calcium (urine)	Fibrinogen
Calcium, Total	Fluid pH
Candida species	Folate
Cannabinoids (THC) (urine)	FSH (Follicle Stimulating Hormone)
Carbamazepine	r orr (i olliole otilitulating riolfflorle)
Carboxyhemoglobin	
CBC8	
CEA6	

All CLIA '88 regulated analytes are provided at five challenges per event.

## **ANALYTE INDEX**

All regulated analytes are in **RED** and are provided at five challenges per shipment.

G	K
Gardnerella vaginalis	KOH (glass slides-hair/skin/nails)
Gastric Occult Blood	KOH Skin Scraping (photograph)
Gastric pH	rice i cital cotaping (protograpil)
GC by Molecular method	L
Gentamicin	Lactic Acid
GGT	
Giardia Antigen Detection	LDH (Lactate Dehydrogenase)
Glucose	Lead, whole blood
Glucose, whole blood	Lead, whole blood
Glucose (urine)	Legionella Antigen
Glycohemoglobin4,21	LH (Lutenizing Hormone)
Gram Stain (includes morphology)	Lidocaine5
Group A Strep Antigen	Lipase5
Group A Strep Antigen	Lithium5
Group B Strep	Lp(a)
Gloup B Stiep	LSD (urine)
••	Lyme Serology
Н	
H. pylori Antibody11	M
HAV (Antibody)10	<b>Magnesium</b>
<b>HBeAg</b>	Magnesium (urine)
HBs Antibody10	MCV
HBsAg	MDMA (Ecstasy) (urine)
hCG (Quantitative, serum)	Meperidine (urine)
hCG (Qualitative, serum)	Methadone (urine)
hCG (Urine)	Methamphetamine (urine)
HCV Antibody	Methagualone (urine)
Hematocrit (calculated)	Methemoglobin2
Hematocrit	Microalbumin (urine)
Hematocrit, waived9,21,23	MRSA-Molecular method
<b>Hemoglobin</b>	Mycoplasma Antibody
Hemoglobin (Total)	Myoglobin
Hemoglobin, waived	7.0
HIV Antibody/Antigen (waived)10,21	N
HIV Antibody/Antigen	N-acetyl Procainamide (NAPA)
Homocysteine	Nasal Smear, Eosinophils
HPV (Human Papillomavirus)	Neisseria gonorrhoeae (GC) Culture
HSV (Herpes Simplex Virus)	Neisseria gonorrhoeae (GC) by molecular method. 16
Hydrocodone (urine)	Nitrite (Oxidants) (urine)
I	NTproBNP
Infectious Mononucleosis	
Infectious Mononucleosis	0
Influenza A	Opiates (urine)
Influenza A	Osmolality
Influenza A/B	Oxycodone (urine)
Influenza A/B	Oxyhemoglobin2
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Insulin	
Iron	
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i-STAT® Blood Gases	
i-STAT® Chemistry	
i-STAT® Chemistry	

## **ANALYTE INDEX**

All regulated analytes are in  $\ensuremath{\textbf{RED}}$  and are provided at five challenges per shipment.

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PCP (urine)
pH, (gastric)3
pH, Blood gas
pH (urine or Fluid)
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Phenylalanine
Phenytoin
Phosphorous5
Phosphorous (urine)
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Platelet Count
pO2, Blood gas
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Primidone
Procainamide
Progesterone6
Prolactin6
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Protime
Protime
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RBC (Red Blood Cell Count). 8 RDW 8
RBC (Red Blood Cell Count). 8 RDW 8 Rheumatoid factor. 11
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RBC (Red Blood Cell Count).       8         RDW       8         Rheumatoid factor       11         Rotavirus.       13         RPR       11
RBC (Red Blood Cell Count).       8         RDW       8         Rheumatoid factor       11         Rotavirus       13         RPR       11         RSV (Respiratory Syncytial Virus) Antigen Detection       14
RBC (Red Blood Cell Count).       8         RDW       8         Rheumatoid factor       11         Rotavirus.       13         RPR       11
RBC (Red Blood Cell Count).       8         RDW       8         Rheumatoid factor       11         Rotavirus       13         RPR       11         RSV (Respiratory Syncytial Virus) Antigen Detection       14
R         RBC (Red Blood Cell Count).         8           RDW         8           Rheumatoid factor         11           Rotavirus         13           RPR         11           RSV (Respiratory Syncytial Virus) Antigen Detection         14           RSV (Respiratory Syncytial Virus) Antigen Detection         22           S
RBC (Red Blood Cell Count).       8         RDW       8         Rheumatoid factor       11         Rotavirus.       13         RPR       11         RSV (Respiratory Syncytial Virus) Antigen Detection       14         RSV (Respiratory Syncytial Virus) Antigen Detection       22
R       RBC (Red Blood Cell Count).       8         RDW       8         Rheumatoid factor       11         Rotavirus.       13         RPR       11         RSV (Respiratory Syncytial Virus) Antigen Detection       14         RSV (Respiratory Syncytial Virus) Antigen Detection       22         S       Salicylate       5         Sedimentation Rate (ESR)       8
RBC (Red Blood Cell Count).       8         RDW       8         Rheumatoid factor       11         Rotavirus.       13         RPR       11         RSV (Respiratory Syncytial Virus) Antigen Detection       14         RSV (Respiratory Syncytial Virus) Antigen Detection       22         S       Salicylate
R       RBC (Red Blood Cell Count).       8         RDW       8         Rheumatoid factor       11         Rotavirus.       13         RPR       11         RSV (Respiratory Syncytial Virus) Antigen Detection       14         RSV (Respiratory Syncytial Virus) Antigen Detection       22         S       Salicylate       5         Sedimentation Rate (ESR)       8         Sex Hormone Binding Globulin (SHBG)       6         Sickle Cell       9
R       RBC (Red Blood Cell Count).       8         RDW       8         Rheumatoid factor       11         Rotavirus.       13         RPR       11         RSV (Respiratory Syncytial Virus) Antigen Detection       14         RSV (Respiratory Syncytial Virus) Antigen Detection       22         S       Salicylate       5         Sedimentation Rate (ESR)       8         Sex Hormone Binding Globulin (SHBG)       6
R       RBC (Red Blood Cell Count).       8         RDW       8         Rheumatoid factor       11         Rotavirus.       13         RPR       11         RSV (Respiratory Syncytial Virus) Antigen Detection       14         RSV (Respiratory Syncytial Virus) Antigen Detection       22         S       Salicylate       5         Sedimentation Rate (ESR)       8         Sex Hormone Binding Globulin (SHBG)       6         Sickle Cell       9
R       RBC (Red Blood Cell Count).       8         RDW       8         Rheumatoid factor       11         Rotavirus.       13         RPR       11         RSV (Respiratory Syncytial Virus) Antigen Detection       14         RSV (Respiratory Syncytial Virus) Antigen Detection       22         S       Salicylate       5         Sedimentation Rate (ESR)       8         Sex Hormone Binding Globulin (SHBG)       6         Sickle Cell       9         Skin Scraping, fungal/scabies       17,20
R         RBC (Red Blood Cell Count).         8           RDW         8           Rheumatoid factor         11           Rotavirus.         13           RPR         11           RSV (Respiratory Syncytial Virus) Antigen Detection         14           RSV (Respiratory Syncytial Virus) Antigen Detection         22           S         Salicylate         5           Sedimentation Rate (ESR)         8           Sex Hormone Binding Globulin (SHBG)         6           Sickle Cell         9           Skin Scraping, fungal/scabies         17,20           Sodium         5
R         RBC (Red Blood Cell Count).         8           RDW         8           Rheumatoid factor         11           Rotavirus.         13           RPR         11           RSV (Respiratory Syncytial Virus) Antigen Detection         14           RSV (Respiratory Syncytial Virus) Antigen Detection         22           S         Salicylate         5           Sedimentation Rate (ESR)         8           Sex Hormone Binding Globulin (SHBG)         6           Sickle Cell         9           Skin Scraping, fungal/scabies         17,20           Sodium         5           Sodium (urine)         17
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R         RBC (Red Blood Cell Count).         8           RDW         8           Rheumatoid factor         11           Rotavirus.         13           RPR         11           RSV (Respiratory Syncytial Virus) Antigen Detection         14           RSV (Respiratory Syncytial Virus) Antigen Detection         22           S         Salicylate         5           Sedimentation Rate (ESR)         8           Sex Hormone Binding Globulin (SHBG)         6           Sickle Cell         9           Skin Scraping, fungal/scabies         17,20           Sodium         5           Sodium (urine)         17           Sperm analysis (post-vasectomy)         17           SP Gravity         17
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R         RBC (Red Blood Cell Count).       8         RDW       8         Rheumatoid factor       11         Rotavirus.       13         RPR       11         RSV (Respiratory Syncytial Virus) Antigen Detection       14         RSV (Respiratory Syncytial Virus) Antigen Detection       22         S       Salicylate       5         Sedimentation Rate (ESR)       8         Sex Hormone Binding Globulin (SHBG)       6         Sickle Cell       9         Skin Scraping, fungal/scabies       17,20         Sodium       5         Sodium (urine)       17         Sperm analysis (post-vasectomy)       17         Strep Antigen (Group A)       13         Strep Antigen (Group A)       13         Strep Antigen (Group B)       13         Strep pneumoniae       14
RBC (Red Blood Cell Count).       8         RDW       8         Rheumatoid factor       11         Rotavirus.       13         RPR       11         RSV (Respiratory Syncytial Virus) Antigen Detection       14         RSV (Respiratory Syncytial Virus) Antigen Detection       22         S       Salicylate       5         Sedimentation Rate (ESR)       8         Sex Hormone Binding Globulin (SHBG)       6         Sickle Cell       9         Skin Scraping, fungal/scabies       17,20         Sodium       5         Sodium (urine)       17         Sperm analysis (post-vasectomy)       17         Sperm analysis (post-vasectomy)       17         Strep Antigen (Group A)       13         Strep Antigen (Group A)       13         Strep Antigen (Group B)       13         Strep pneumoniae       14         Susceptibility, Urine       15,16
R         RBC (Red Blood Cell Count).       8         RDW       8         Rheumatoid factor       11         Rotavirus.       13         RPR       11         RSV (Respiratory Syncytial Virus) Antigen Detection       14         RSV (Respiratory Syncytial Virus) Antigen Detection       22         S       Salicylate       5         Sedimentation Rate (ESR)       8         Sex Hormone Binding Globulin (SHBG)       6         Sickle Cell       9         Skin Scraping, fungal/scabies       17,20         Sodium       5         Sodium (urine)       17         Sperm analysis (post-vasectomy)       17         Strep Antigen (Group A)       13         Strep Antigen (Group A)       13         Strep Antigen (Group B)       13         Strep pneumoniae       14
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T3 Uptake       3,5         T3, Free       3,5         T4 (Thyroxine)       3,5         T4, Free (Free Thyroxine)       3,5         Testosterone, Free       6         Testosterone, Total       6         Theophylline       5         Thyroglobulin Antibody (Anti-TG)       6         Thyroglobulin       6         Thyroglo Microsomal Antibody (Anti-TPO)       6         TIBC (Total Iron Binding Capacity)       5         Tobramycin       5         Total Protein       5         Total Protein (urine)       18         Tramadol (urine)       18         Transferrin       6         Trichomonas detection       15,17         Trichomonas vaginalis       1.7         Tricyclic Antidepressants (urine)       18         Triglyceride       5         Triglyceride (waived)       3,19         Troponin I       3         TSH (Thyroid Stimulating Hormone)       3,5
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V         Vaginal Wet Prep/KOH       17,20         Valproic Acid       5         Vancomycin       5         VDRL       11         Vitamin B12       6         Vitamin D       6         VRE-(Vancomycin-resistant Enterococcus) molecular       16         VRE-(Vancomycin-resistant Enterococcus) molecular       16         W-Z

## SHIPMENT SCHEDULE

Please examine your kit upon receipt. If you have incomplete or damaged PT material, please contact AAFP-PT. Although every effort is made to assure that your kit arrives cool, please refrigerate the specimens overnight before testing. Every effort is made to accommodate replacement requests depending on the availability of testing material at that time. If you have guestions concerning your PT materials, please contact the AAFP at (800) 274-7911 or pt@aafp.org.

## Kit 2020 - A

- March 2 Kit Shipment
- March 6 please call if kit not received
- March 16 Last day for replacements
- March 25 Results submission deadline
- April 17 Evaluations available



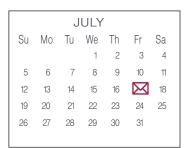


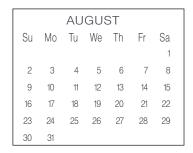
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24	25	26	27	28	29	30	
31							

## Kit 2020 - B

- June 1 Kit Shipment
- June 5 please call if kit not received
- June 15 Last day for replacements
- June 24 Results submission deadline
- July 17 Evaluations available





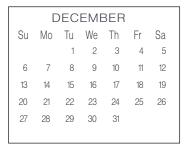


## Kit 2020 - C

- October 5 Kit Shipment
- October 9 please call if kit not received
- October 19 Last day for replacements
- October 28 Results submission deadline
- November 13 Evaluations available

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18	I	20		22	23	24		
25	26	27	1	29	30	31		





🔶 Kit Shipment | 🥿 Call if kit not received | 📕 Replacements deadline | 🖰 Results deadline | 🖂 Evaluations available



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