

Innovative Solutions. Technical Excellence.

# **2024 CATALOG OF PROGRAMS** ACCEPTED BY: CAP, CMS, COLA, TJC

ISO Accredited by A2LA: Cert. #3094.01 - see p. 8

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### Technical expertise. Responsive service. Constant innovation.

### We're proficient at all of them.

When it comes to proficiency testing, reliability is everything. You need a provider that fully supports you with technical expertise and prompt, personal service. At API, we work with over 20,000 laboratories, covering all areas of laboratory medicine. Impressive numbers, for sure. But our reputation as a leader has grown because we are committed to providing the best customer service in the industry. We handle each contact promptly and professionally, so you don't wait for answers. Our technical experts fully understand the laboratory so they can assist you with a wide range of needs. We also provide automated result transmission, creative online services, and free Continuing Education credits.

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## Upload your proficiency testing results without an interface!

- Quantitative & Qualitative results
- Automated mapping of test names
- No middleware or software installation
- No additional cost it's free!

Over 6 million results have been successfully uploaded using this revolutionary technology!

The process is simple:



DataDirect utilizes the ability of your LIS to run a report and create a data file which is uploaded on API's website.

## **API DataDirect**

**Eliminate** the #1 cause of Proficiency Testing failures, **Clerical Errors!** 

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## **Enrollment Information**

#### Enrollment

- 1. Use this catalog to select the programs you need and record the selections on the order form. Please follow the instructions below to complete the form. Make sure to include:
  - a. Shipping Address
  - b. Billing Address (if different than shipping address)
  - c. Regulatory Information (CLIA number, CAP, TJC, or COLA, etc. )
  - d. Payment Method: If paying by check, mail to: American Proficiency Institute P.O. Box 7592 Carol Stream, IL 60197-7592
- 2. Ensure the "TOTAL" includes the \$150 Annual Enrollment fee which covers shipping, administrative costs of setting up customer files, data processing, and reports.

#### 3. To Order:

- a. Email your order to CustomerService@api-pt.com
- b. Fax the order form to us at 855-900-6119
- c. Call us at 800-333-0958 and speak with a Customer Service Representative
- d. Mail orders to: American Proficiency Institute P.O. Box 7592 Carol Stream, IL 60197-7592
- 4. After processing your order, we will send you an "Order Confirmation" showing products ordered and pre-set shipping dates:
  - a. Mark your calendar with the shipment dates. If your kit does not arrive within 3 business days after the shipment date, call us so we can track the kit or issue a replacement.
  - b. Inspect your kit immediately upon receipt. Call us within 3 days if any sample is missing or damaged to request a replacement. Please call prior to discarding any damaged samples or refusing a kit.
  - c. Read the instructions carefully before beginning a test. Some samples require special handling before testing.
  - d. Keep a copy of any result forms mailed to API.

#### **Partial Year Orders**

API makes every effort to accommodate new orders or order changes throughout the year. Except for the annual enrollment fee, we will prorate the prices for orders received after the first shipment.

#### Cancellations

We will credit any charges for unshipped specimens if we receive notification 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.

## International and Non-Continental U.S. Customers

API is able to service many international locations and non-continental U.S. customers. Some locations, including the state of Hawaii, U.S. territories and commonwealths, as well as international locations, may require import permits for API shipments. Local authorities can assist you in determining if any permits are required for your location. *Please note: It is the responsibility of the testing facility to obtain any required import permits.* 

Additional shipping charges for international and noncontinental U.S. locations may apply. Please contact Customer Service at GlobalCustomerService@api-pt.com for more information.

## 2024 Highlights

#### **API Proficiency Testing Programs are CAP Accepted!**

We are pleased to report that the College of American Pathologists continues to accept proficiency testing programs from the American Proficiency Institute. This means CAP accredited laboratories can use API's proficiency testing programs. Please refer to the index on pages 138 through 143 for a complete listing of CAP accepted analytes. API programs are also accepted by CMS, COLA, TJC, and state regulatory agencies including New York state.

#### **API is ISO Accredited!**

We are proud to be accredited as a proficiency testing provider to the requirements of ISO/IEC 17043:2010. We are accredited by the American Association for Laboratory Accreditation (A2LA) under certificate number 3094.01 (www.A2LA.org). A2LA is a signatory to the ILAC Mutual Recognition Arrangement (MRA) which provides global recognition of PT accreditations. Programs included under the scope of this accreditation are marked with a  $\checkmark$  in this catalog.\* Evaluations for accredited analytes can be used by ISO 15189-accredited laboratories to fulfill PT requirements.

\*Printed versions of the catalog may not have the most current scope information; please see online catalog for current status.

#### Track Proficiency Performance using API DataDashboard

With API's DataDashboard, laboratories can quickly and easily view proficiency testing performance over the most recent six test events. The dashboard includes trend data by analyte, percentage of acceptable results compared to all API labs, failure count by test event, and analytes with unsatisfactory performance. Customers can log in to their API Paperless PT account to access their dashboard. Contact us at TechSupport@api-pt.com or call us if you need assistance.

## Automated Proficiency Results with API DataDirect

Using their laboratory information system (LIS) or middleware, laboratories may now transmit proficiency testing results directly to API, a process that revolutionizes proficiency testing for clinical laboratories. No more manual data entry, no more clerical errors, no new technology systems to purchase, and no additional fees! DataDirect is easy to use and saves time! Contact us at DataDirect@api-pt.com or call us for a demonstration and free Test Drive.

#### **2024 Shipping Schedule**

Below is a general shipping schedule. A printable shipping and reporting schedule is available on our website. Shipping dates will also be printed on your order confirmation.

2024 SHIPPING SCHEDULE	1st Event Ship Date	2nd Event Ship Date	3rd Event Ship Date
Chemistry - Core	January 8	May 13	August 19
Chemistry - Miscellaneous	April 15	October 7	-
Hematology	March 4	July 8	October 28
Andrology	March 4	-	October 28
Coagulation	March 4	July 8	October 28
Urinalysis, Microscopy - Misc.	March 4	July 8	October 28
Microbiology	February 5	June 3	September 16
Mycobacteriology	February 26	August 12	-
Mycology	January 8	May 13	August 19
Immunology / Immunohematology	March 25	July 29	November 18

## **New & Enhanced Programs!**

- ANA Educational Pattern ID, Nuclear Titer, Pattern Interpretation added #421\* on page 107.
- Blood Oximetry O2 Saturation (measured) added #114 on page 16.
- Candida auris Compatible with culture and molecular methods #393 on page 89.
- CSF & Body Fluid Chemistry Lactate added #177 on page 32.
- Glycohemoglobin whole blood 5 samples #195 on page 23.
- Hepatitis Be Ag & Ab #449\* on page 110.
- Joint/Wound Infection Panel Acinetobacter baumanii, Klebsiella oxytoca, and Staphylococcus epidermidis added #390 on page 101.
- SARS-CoV-2 Antigen 5 samples CLIA regulated #387 on page 98.
- SARS-CoV-2 (molecular) 5 samples CLIA regulated #394 on page 98.
- STI Panel For use with molecular multiplex methods #392 on page 102.

\*Contains some analytes that are not yet CAP accepted.

#### **Update to SARS Products**

In 2024, API will send PT scores for non-waived SARS antigen and molecular testing to CMS and other regulatory bodies. Laboratories who are performing non-waived testing and have no other regulated virology program will need to enroll in a 5-sample program to maintain compliance. See "SARS-CoV-2 Regulatory Status Update" our website for more details.

> If you have any questions or need assistance with ordering, please email CustomerService@api-pt.com or call us at 800-333-0958. Visit our website, api-pt.com, to view our catalog and full shipping and reporting schedule.

# CHEMISTRY

CHEMISTRY - CORE	1st Event	2nd Event	3rd Event
Ship Dates	January 8	May 13	August 19
Replacement Deadline	January 16	May 21	August 27
PT Results Due Date	January 31	June 5	September 11
Verification Due Date	February 14	June 19	September 25
Evaluations Available Online	February 20	June 25	October 1

CHEMISTRY - MISCELLANEOUS	1st Event	2nd Event
Ship Dates	April 15	October 7
Replacement Deadline	April 23	October 15
PT Results Due Date	May 8	October 30
Verification Due Date	May 15	November 6
Evaluations Available Online	May 28	November 19



#### Alcohol

#### **Program Description**

2 mL serum - For quantitative Alcohol, Ethylene Glycol, Isopropanol, Methanol, and qualitative Acetone (ketone) testing. For quantitative Beta-hydroxybutyrate testing, see #174 - B-Ketone on page 13.

#### **Program Information**

137 Alcohol ✓A37 Alcohol - Verification Program

#### **Analytes**

Acetone	Ethylene Glycol	Methanol
Alcohol	Isopropanol	
Analyte is not CAP accepted.	$\checkmark$ Program is included in our A2LA scope of accreditation	n. See A2LA link on our website for analyte exceptions.
Format		Shipping Dates

5 samples x 3 shipments

**Shipping Dates** Jan. 8, May 13, Aug. 19

#### Ammonia

#### **Program Description**

2 mL serum

#### **Program Information**

138 Ammonia A38 Ammonia - Verification Program

#### **Analytes**

Ammonia

 $\checkmark$  Program is included in our A2LA scope of accreditation.

Format 3 samples x 2 shipments Shipping Dates Apr. 15, Oct. 7 CHEMISTRY

#### Amniotic Fluid pH

#### **Program Description**

0.5 mL simulated amniotic fluid - For Nitrazine methods.

#### **Program Information**

166 Amniotic Fluid pH✓

#### **Analytes**

pH (interpretation)

pH (nitrazine)

✓ Program is included in our A2LA scope of accreditation.

Format

3 samples x 2 shipments

Shipping Dates Apr. 15, Oct. 7

#### Anti-epileptic Drugs

#### **Program Description**

4 mL lyophilized serum

#### **Program Information**

190 Anti-epileptic Drugs

#### **Analytes**

Gabapentin

Levetiracetam

Oxcarbazepine

#### Format

3 samples x 2 shipments

Shipping Dates Apr. 15, Oct. 7

#### Anti-Müllerian Hormone

#### **Program Description**

2 mL liquid

#### **Program Information**

155 Anti-Müllerian Hormone

#### **Analytes**

#### ► AMH

► Analyte is not CAP accepted.

#### Format

3 samples x 2 shipments

Shipping Dates Apr. 15, Oct. 7

#### **Apolipoproteins**

#### **Program Description**

1 mL serum

#### **Program Information**

130 Apolipoproteins

#### **Analytes**

Apolipoprotein A1

Apolipoprotein B

**Format** 3 samples x 2 shipments Lipoprotein (a)

Shipping Dates Apr. 15, Oct. 7

#### **B-Ketone**

#### **Program Description**

1 mL liquid - For quantitative Beta-hydroxybutyrate testing performed on chemistry analyzers or whole blood glucometers. For qualitative testing using Bayer Acetest, see #137 - Alcohol on page 11.

#### **Program Information**

174 B-Ketone√

#### **Analytes**

Beta-hydroxybutyrate

 $\checkmark$  Program is included in our A2LA scope of accreditation.

**Format** 3 samples x 2 shipments **Shipping Dates** Apr. 15, Oct. 7

#### **Blood Gas**

#### **Program Description**

3 mL ampule - For i-STAT see #145 - i-STAT Chemistry on page 24. For competency, see Q11 - Blood Gas - Competency on page 129.

#### **Program Information**

- 187 Additional Blood Gas Ampules
- A11 Blood Gas Verification Program

#### **Analytes**

	pO <sub>2</sub>
$\checkmark$ Program is included in our A2LA scope of accreditation.	
<b>Format</b> 5 samples x 3 shipments	<b>Shipping Dates</b> Jan. 8, May 13, Aug. 19

#### **Blood Gas Plus**

#### **Program Description**

3 mL ampule - For combination blood gas/electrolyte analyzers with or without hematocrit option. For i-STAT see #145 - i-STAT Chemistry on page 24. For competency, see Q11 - Blood Gas - Competency on page 129.

#### **Program Information**

11Z BIOOD Gas Plus	112	Blood Gas Plus ✓
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- 187 Additional Blood Gas Ampules
- A12 Blood Gas Plus Verification Program

#### **Analytes**

BUN Calcium, ionized Chloride Creatinine Glucose	Hematocrit Hemoglobin, calculated Lactate ▶ Magnesium, ionized pCO <sub>2</sub>	pH pO <sub>2</sub> Potassium Sodium tCO <sub>2</sub>
► Analyte is not CAP accepted.	$\checkmark$ Program is included in our A2LA scope of accreditation	n.
<b>Format</b> 5 samples x 3 shipments		<b>Shipping Dates</b> Jan. 8, May 13, Aug. 19

#### Blood Lead - 5

#### **Program Description**

6 mL hemolysate - Designed for LeadCare I, Plus, and Ultra.

#### **Program Information**

172 Blood Lead - 5 samples ✓

#### **Analytes**

#### Lead

✓ Program is included in our A2LA scope of accreditation.

**Format** 5 samples x 3 shipments **Shipping Dates** Jan. 8, May 13, Aug. 19

Blood Lead - 2

#### **Program Description**

6 mL hemolysate - Designed for the LeadCare II.

#### **Program Information**

173 Blood Lead - 2 samples ✓

#### **Analytes**

Lead

✓ Program is included in our A2LA scope of accreditation.

Format

2 samples x 3 shipments

**Shipping Dates** Jan. 8, May 13, Aug. 19 **CHEMISTRY** 

#### **Blood Oximetry**

#### ENHANCED

#### **Program Description**

2 mL ampule - Hemoglobin source is bovine.

#### **Program Information**

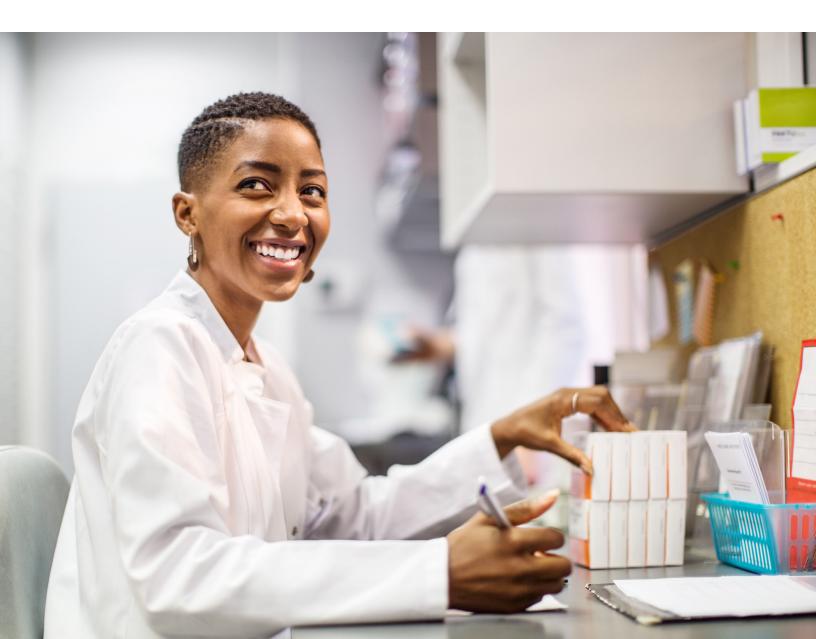
Blood Oximetry ✓A14 Blood Oximetry - Verification Program

#### **Analytes**

O2 Saturation (measured) NEWHematocrit, calculatedCarboxyhemoglobinHemoglobin, total		Methemoglobin Oxyhemoglobin
$\checkmark$ Program is included in our A2LA scope of accreditation.		
Format		Shipping Dates

5 samples x 3 shipments

Shipping Dates Jan. 8, May 13, Aug. 19



# **CHEMISTRY**

#### Cardiac Markers - 5

#### **Program Description**

1.5 mL liquid - CAP accredited labs <u>must</u> test five samples for all Cardiac Markers except D-dimer, Myoglobin, and waived BNP.

#### **Program Information**

- 140 Cardiac Markers 5 samples ✓
- 165 Additional Sample Volume
- A40 Cardiac Markers Verification Program 5 samples

#### Analytes

BNP	Myoglobin	Troponin T (► qualitative)
CK, total	NT pro-BNP	Troponin T (high-sensitivity)
CK-MB	Troponin I	
D-dimer (quant)	Troponin I (high-sensitivity)	
► Analyte is not CAP accepted.	$\checkmark$ Program is included in our A2LA scope of	of accreditation.
Format		Shipping Dates
5 samples x 3 shipments		Jan. 8, May 13, Aug. 19

#### Cardiac Markers - 2

#### **Program Description**

1.5 mL liquid - Please note: CAP accredited labs must test five samples for all Cardiac Markers except D-dimer, Myoglobin, and waived BNP, see #140 - Cardiac Markers - 5.

#### **Program Information**

920 Cardiac Markers - 2 samples ✓

J20 Cardiac Markers - Verification Program - 2 samples

#### **Analytes**

- BNP (► non-waived) D-dimer (quant) Myoglobin
- NT pro-BNP
- Troponin I
- Troponin I (high-sensitivity)

✓ Program is included in our A2LA scope of accreditation.

#### Format

2 samples x 3 shipments

► Analyte is not CAP accepted.

Shipping Dates Jan. 8, May 13, Aug. 19

► Troponin T (high-sensitivity)

► Troponin T

#### **Basic Chemistry**

#### **Program Description**

5 mL serum - Cholestech users see #176/976 - Lipid Plus on page 26. For quantitative HCG, see #409 - Serum HCG on page 29.

#### **Program Information**

121	Basic Chemistry 🗸
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- 141 Additional Sample Volume
- A21 Basic Chemistry Verification Program

#### **Analytes**

ALT (SGPT)	Cholesterol	Potassium
AST (SGOT)	CO <sub>2</sub>	Sodium
Bilirubin, direct	Creatinine	Triglycerides
Bilirubin, total	Glucose	Urea Nitrogen (BUN)
Calcium	HDL Cholesterol	Uric Acid
Chloride	LDL, calculated and measured	
✓ Program is included in our A2LA scope of accreditation	n.	
Format		Shipping Dates
5 samples x 3 shipments		Jan. 8, May 13, Aug. 19

#### **Chemistry - Endocrinology**

#### **Program Description**

5 mL serum - OCD Vitros labs performing thyroid tests, see #175 - Thyroid - Special on page 30. For quantitative HCG, see #409 - Serum HCG on page 29.

#### **Program Information**

125 Chemistry - Endocrinology ✓

#### **Analytes**

Alpha-fetoprotein Cortisol Free T3 Free T4 T Uptake Thyroxine (T4) Triiodothyronine (T3) TSH

✓ Program is included in our A2LA scope of accreditation.

Format

5 samples x 3 shipments

Shipping Dates Jan. 8, May 13, Aug. 19

# **CHEMISTRY**

#### **Comprehensive Chemistry**

#### **Program Description**

5 mL serum - OCD Vitros labs performing thyroid tests, see #175 - Thyroid - Special on page 30. Cholestech users see #176/976 - Lipid Plus on page 26. For quantitative HCG, see #409 - Serum HCG on page 29.

#### **Program Information**

122 Comprehensive Chemistry ✓ 141 Additional Sample Volume A22 Comprehensive Chemistry - Verification Program

#### Analytes

Albumin	Creatine Kinase (CK)	Potassium
Alkaline Phosphatase	Creatinine	Sodium
Alpha-fetoprotein	Free T3	T Uptake
ALT (SGPT)	Free T4	Thyroxine (T4)
Amylase	GGT	TIBC (iron based calculation)
AST (SGOT)	Glucose	TIBC, measured
Bilirubin, direct	HDL Cholesterol	Total Protein
Bilirubin, total	Iron	Triglycerides
Calcium	Lactic Acid	Triiodothyronine (T3)
Calcium, ionized	LDH	ТЅН
Chloride	LDL, calc. and measured	UIBC, measured
Cholesterol	Lipase	Urea Nitrogen (BUN)
► Cholinesterase	Magnesium	Uric Acid
CO <sub>2</sub>	Osmolality	
Cortisol	Phosphorus	
► Analyte is not CAP accepted.	✓ Program is included in our A2LA scope of a	ccreditation. See A2LA link on our website for analyte except

**Format** 

5 samples x 3 shipments

✓ Program is included in our A2LA scope of accreditation. See A2LA link on our website for analyte exceptions.

**Shipping Dates** Jan. 8, May 13, Aug. 19

#### **Chemistry - waived**

#### **Program Description**

5 mL serum - For waived methods. Cholestech users see #976 - Lipid Plus - 2 samples on page 26.

#### **Program Information**

144 Chemistry - waived ✓A44 Chemistry - waived - Verification Program

#### **Analytes**

Albumin	Cholesterol	Phosphorus
Alkaline Phosphatase	CO <sub>2</sub>	Potassium
ALT (SGPT)	Creatine Kinase (CK)	Sodium
Amylase	Creatinine	Total Protein
AST (SGOT)	GGT	Triglycerides
Bilirubin, total & direct	Glucose	Urea Nitrogen (BUN)
Calcium	HDL Cholesterol	Uric Acid
Chloride	LDL, calc. and measured	

✓ Program is included in our A2LA scope of accreditation.

#### Format

2 samples x 3 shipments

#### Cystatin C

#### **Program Description**

1 mL liquid

#### **Program Information**

170 Cystatin C

#### **Analytes**

Cystatin C

#### Format

2 samples x 2 shipments

Shipping Dates Apr. 15, Oct. 7

Shipping Dates

Jan. 8, May 13, Aug. 19

#### **Fetal Fibronectin**

#### **Program Description**

1 mL liquid

#### **Program Information**

142 Fetal Fibronectin 🗸

#### **Analytes**

Fetal Fibronectin

✓ Program is included in our A2LA scope of accreditation.

Format 3 samples x 2 shipments Shipping Dates Apr. 15, Oct. 7

#### **Fetal ROM**

#### **Program Description**

1 mL simulated amniotic fluid for ROM methods. Compatible with Actim Prom, AmniSure ROM, and Clinical Innovations ROM Plus.

#### **Program Information**

131 Fetal ROM✓

#### **Analytes**

Fetal Membranes Rupture Test

 $\checkmark$  Program is included in our A2LA scope of accreditation.

#### Format

3 samples x 2 shipments

Shipping Dates Apr. 15, Oct. 7 CHEMISTRY

#### Fructosamine

#### **Program Description**

1 mL serum

#### **Program Information**

135 Fructosamine

#### **Analytes**

Fructosamine

#### Format

3 samples x 2 shipments

Shipping Dates Apr. 15, Oct. 7

#### Glycohemoglobin

#### **Program Description**

0.7 mL hemolysate - CAP accredited labs using a non-waived method <u>must</u> test five samples for glycohemoglobin. For Afinion see #134 & #195 - Glycohemoglobin - whole blood - on page 23.

#### **Program Information**

126 Glycohemoglobin - 5 samples ✓

- 179 Glycohemoglobin Additional Sample Volume 5 samples
- 127 Glycohemoglobin 2 samples ✓
- 167 Glycohemoglobin Additional Sample Volume 2 samples
- A27 Glycohemoglobin Verification Program 2 samples

#### **Analytes**

Glycohemoglobin (as HbA1c)

 $\checkmark$  Program is included in our A2LA scope of accreditation.

#### Format

3 shipments

**Shipping Dates** Jan. 8, May 13, Aug. 19

#### Glycohemoglobin - whole blood

#### **Program Description**

0.5 mL liquid - For laboratories using Afinion analyzers for HbA1c testing.

#### **Program Information**

- 195 Glycohemoglobin whole blood 5 samples NEW
- 134 Glycohemoglobin whole blood 2 samples  $\checkmark$

#### **Analytes**

Glycohemoglobin (as HbA1c)

 $\checkmark$  Program is included in our A2LA scope of accreditation.

#### Format

3 shipments

Shipping Dates Jan. 8, May 13, Aug. 19

**ENHANCED** 

#### **Program Description**

1 mL hemolysate - For HemoCue 201 Series, HemoCue 301 analyzers, and HemoCue 801.

#### **Program Information**

- 128 HemoCue 5 samples ✓
- 928 HemoCue 2 samples ✓
- J28 HemoCue Verification Program 2 samples

#### **Analytes**

Glucose

Hemoglobin

 $\checkmark$  Program is included in our A2LA scope of accreditation.

#### Format

3 shipments

**Shipping Dates** Jan. 8, May 13, Aug. 19

#### i-STAT Chemistry - 5

#### **Program Description**

3 mL ampule - For ACT testing see #215 - i-STAT ACT on page 59. For BNP, CK-MB, & Troponin I, see #140/920 - Cardiac Markers programs on page 17. For quantitative hCG see #409 - Serum HCG on page 29. For competency, see Q12 - i-STAT Chemistry - Competency on page 132.

#### **Program Information**

145	i-STAT Chemistry $$ - 5 samples $\checkmark$
188	Additional i-STAT Chemistry Ampules

A45 i-STAT Chemistry - Verification Program - 5 samples

#### **Analytes**

Calcium, ionized	Hemoglobin	Potassium
Chloride	Lactate	Sodium
Creatinine	pCO <sub>2</sub>	tCO <sub>2</sub>
Glucose	pН	Urea Nitrogen (BUN)
Hematocrit	pO <sub>2</sub>	
✓ Program is included in our A2LA scope of accreditation.		
Format		Shipping Dates
5 samples x 3 shipments		Jan. 8, May 13, Aug. 19

#### i-STAT Chemistry - 2

#### **Program Description**

3 mL ampule - For i-STAT analyzers for waived testing or non-scored analytes. For competency, see Q12 - i-STAT Chemistry - Competency on page 132.

#### **Program Information**

945 i-STAT Chemistry - 2 samples ✓

J45 i-STAT Chemistry - Verification Program - 2 samples

#### **Analytes**

Calcium, ionized
Chloride
Creatinine
Glucose

Hematocrit Hemoglobin Lactate Potassium Sodium tCO<sub>2</sub> Urea Nitrogen (BUN)

✓ Program is included in our A2LA scope of accreditation.

#### Format

2 samples x 3 shipments

Shipping Dates Jan. 8, May 13, Aug. 19

#### **Program Description**

5 mL serum

#### **Program Information**

180	Immunoassay - 5 samples 🗸
133	Immunoassay - 2 samples 🗸
A33	Immunoassay - Verification Program - 2 samples

#### **Analytes**

11-Deoxycortisol	Folate	Prolactin
► 17-OH-Progesterone	FSH	PSA, total
<ul> <li>Androstenedione</li> </ul>	Growth Hormone	Testosterone
CEA	Homocysteine	TIBC (transferrin based calc)
DHEA-S	LH	Transferrin
Estradiol	► PAP	Vitamin B12
► Estriol	Prealbumin	
Ferritin	Progesterone	
► Analyte is not CAP accepted.	$\checkmark$ Program is included in our A2LA scope of accreditatio	n. See A2LA link on our website for analyte exceptions.
Format		Shipping Dates

#### Format

3 shipments

Jan. 8, May 13, Aug. 19

#### **Immunoassay - Special**

#### **Program Description**

2 mL lyophilized serum

#### **Program Information**

182 Immunoassay - Special - 5 samples ✓ 160 Immunoassay - Special - 2 samples ✓ A60 Immunoassay - Special - Verification Program - 2 samples

#### **Analytes**

3 shipments

1-25-(OH)2 Vitamin D (D3)	<ul> <li>Calcitonin</li> </ul>	Osteocalcin
25-OH Vitamin D	► Gastrin	PTH
► ACTH	► IGF-1	Renin Activity
C-peptide	Insulin	<ul> <li>Renin (Direct Concentration)</li> </ul>
► Analyte is not CAP accepted.	$\checkmark$ Program is included in our A2LA scope of accreditatio	n. See A2LA link on our website for analyte exceptions.
Format		Shipping Dates

All analytes in bold type are regulated for proficiency testing by CMS. Laboratories enrolling in programs to satisfy CMS requirements for PT are responsible for ensuring they are testing five samples, three times per year.

Jan. 8, May 13, Aug. 19

Immunosuppressive Drugs			
<b>Program Description</b> 1 mL whole blood			
Program Information			
189 Immunosuppressive Drugs			
Analytes			
► Cyclosporine	► Tacrolimus		
► Analyte is not CAP accepted.			
Format 3 samples x 2 shipments		<b>Shipping Dates</b> Apr. 15, Oct. 7	

#### Lamellar Body Count

#### **Program Description**

2 mL liquid - For lamellar body counts performed on Hematology analyzers.

#### **Program Information**

208 Lamellar Body Count ✓

#### **Analytes**

Lamellar Body Count

✓ Program is included in our A2LA scope of accreditation.

#### Format

3 samples x 2 shipments

Shipping Dates Apr. 15, Oct. 7

#### **Lipid Plus**

#### **Program Description**

1 mL serum - For laboratories using the Cholestech analyzer. #976 is not scored for CMS.

#### **Program Information**

176 Lipid Plus - 5 samples ✓
976 Lipid Plus - 2 samples ✓

#### **Analytes**

Cholesterol

Glucose

HDL Cholesterol LDL Cholesterol, calc. Triglycerides

 $\checkmark$  Program is included in our A2LA scope of accreditation.

#### Format 3 shipments

**Shipping Dates** Jan. 8, May 13, Aug. 19

#### Neonatal Bilirubin

#### **Program Description**

1 mL serum - Bilirubin levels targeted to be representative for those seen in newborns. #129 is not scored for CMS.

#### **Program Information**

147	Neonatal Bilirubin - 5 samples 🗸	
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- 129 Neonatal Bilirubin 2 samples 🗸
- A29 Neonatal Bilirubin Verification Program 2 samples

#### **Analytes**

Bilirubin, direct

**Bilirubin**, total

 $\checkmark$  Program is included in our A2LA scope of accreditation.

Format	Shipping Dates
3 shipments	Jan. 8, May 13, Aug. 19

#### **POC Glucose A**

#### **Program Description**

1 mL liquid - For waived blood glucose meters. Per CMS, only one set of proficiency results may be reported. Facilities using more than one meter should also enroll in X23, A23, X18, or J18. True Metrix and True Metrix Pro users see #979 - POC Glucose B on page 28.

#### **Program Information**

- 123 POC Glucose A 5 samples ✓
- 192 Additional Volume POC Glucose A 5 samples
- X23 Extra results POC Glucose A Verification Program report results for up to 20 additional meters using #123 samples
- A23 POC Glucose A Verification Program report up to 20 results 5 samples
- 918 POC Glucose A 3 samples ✓
- 992 Additional Volume POC Glucose A 3 samples
- X18 Extra results POC Glucose A Verification Program report results for up to 20 additional meters using #918 samples
- J18 POC Glucose A Verification Program report up to 20 results 3 samples

#### Analytes

Glucose

✓ Program is included in our A2LA scope of accreditation.

Format 2 shipments Shipping Dates Apr. 15, Oct. 7

#### **POC Glucose B**

#### **Program Description**

2 mL liquid - For True Metrix and True Metrix Pro glucose meters. Per CMS, only one set of proficiency results may be reported. Facilities using more than one meter should also enroll in X79 or J79.

#### **Program Information**

- 979 POC Glucose B 3 samples
- X79 Extra results POC Glucose B Verification Program report results for up to 20 additional meters using #979 samples
- J79 POC Glucose B Verification Program report up to 20 results 3 samples

#### **Analytes**

Glucose

Format		
3 samples x 2 shipments		

#### Procalcitonin

#### **Program Description**

2 mL lyophilized samples

#### **Program Information**

169 Procalcitonin√

#### **Analytes**

Procalcitonin

✓ Program is included in our A2LA scope of accreditation.

#### Format

3 samples x 2 shipments

Shipping Dates Apr. 15, Oct. 7

**Shipping Dates** 

Apr. 15, Oct. 7

#### **Psychoactive Drugs**

#### **Program Description**

5 mL lyophilized serum

#### **Program Information**

191 Psychoactive Drugs

#### **Analytes**

► Amitriptyline

Nortriptyline

► Analyte is not CAP accepted.

#### Format

3 samples x 2 shipments

Shipping Dates Apr. 15, Oct. 7

#### Serum HCG

#### **Program Description**

1 mL serum - For quantitative and qualitative serum HCG methods. Due to CLIA regulations, to report results for both quantitative and qualitative serum HCG, order #409 and #D09.

#### **Program Information**

409 Serum HCG ✓D09 Serum HCG - Verification Program

#### **Analytes**

#### HCG

✓ Program is included in our A2LA scope of accreditation.

#### Format

5 samples x 3 shipments

**Shipping Dates** Jan. 8, May 13, Aug. 19

#### **SHBG and Testosterone**

#### **Program Description**

2 mL lyophilized samples

#### **Program Information**

171 SHBG and Testosterone ✓

#### **Analytes**

Andrytes		
Sex Hormone Binding Globulin	Testosterone, free	Testosterone, total
Testosterone, bioavailable		
$\checkmark$ Program is included in our A2LA scope of accreditation.		
Format		Shipping Dates
3 samples x 2 shipments		Apr. 15, Oct. 7

#### **Therapeutic Drugs**

#### **Program Description**

5 mL serum - For Anti-epileptic Drugs, Immunosuppressive Drugs, and Psychoactive Drugs, see #189, #190, #191, on pages 12, 26, and 29.

#### **Program Information**

132 Therapeutic Drugs ✓

136 Therapeutic Drugs - add on option to #121 or  $122\checkmark$ 

A36 Therapeutic Drugs - Verification Program

#### **Analytes**

Acetaminophen	► Lidocaine	Theophylline
Amikacin	Lithium	Tobramycin
► Caffeine	<ul> <li>Methotrexate</li> </ul>	Valproic Acid
Carbamazepine	Phenobarbital	Vancomycin
Digoxin	Phenytoin	
Gentamicin	Salicylates	
► Analyte is not CAP accepted.	✓ Program is included in our A2LA scope o	f accreditation. See A2LA link on our website for analyte exceptions.
Format		Shipping Dates
5 samples x 3 shipments		Jan. 8, May 13, Aug. 19

#### **Thyroid - Special**

#### **Program Description**

0.75 mL serum - Designed for the OCD Vitros analyzers.

#### **Program Information**

175 Thyroid - Special 🗸

#### **Analytes**

Free T3 <b>Free T4</b>	T Uptake Thyroxine (T4)	Triiodothyronine (T3) TSH
✓ Program is included in our A2LA scope of accreditation.		
Format		Shipping Dates
5 samples x 3 shipments		Jan. 8, May 13, Aug. 19

#### **Program Description**

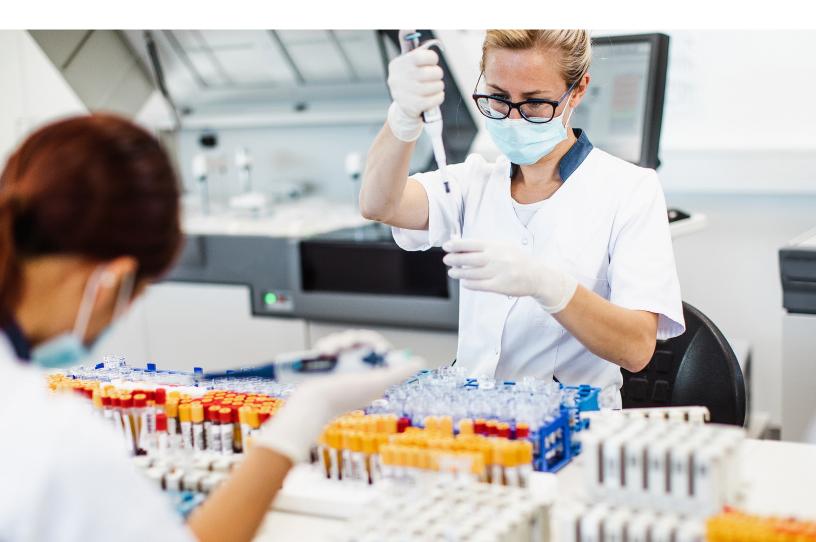
2 mL serum

#### **Program Information**

183 Tumor Markers - 5 samples ✓
150 Tumor Markers - 2 samples ✓

#### **Analytes**

Beta-2 Microglobulin	CA 27.29	PSA, total
CA 125	CEA	PSA (free/total ratio)
CA 15-3	<ul> <li>PSA, complexed</li> </ul>	Thyroglobulin
CA 19-9	PSA, free	
► Analyte is not CAP accepted.	$\checkmark$ Program is included in our A2LA scope of accreditation. See A	2LA link on our website for analyte exceptions.
Format		Shipping Dates
3 shipments		Jan. 8, May 13, Aug. 19



CHEMISTRY

#### URINE CHEMISTRY AND BODY FLUID ANALYSIS

#### **Acute Kidney Injury Risk Assessment**

#### **Program Description**

 $1.5\,\mathrm{mL}$  lyophilized simulated urine - For use with the NEPHROCHECK test system.

#### **Program Information**

186 Acute Kidney Injury Risk Assessment

#### **Analytes**

AKI Risk Score (IGFBP-7 \* TIMP-2)

#### Format

3 samples x 2 shipments

Shipping Dates Apr. 15, Oct. 7

#### **CSF & Body Fluid Chemistry**

#### **Program Description**

2 mL simulated cerebrospinal fluid - 3 samples; 3 mL simulated body fluid - 3 samples. For manual cell count and body fluid crystals see #277 - Cell Count & Body Fluid Crystals on page 46.

#### **Program Information**

177 CSF & Body Fluid Chemistry 🗸

#### **Analytes - CSF Chemistry**

► Albumin	► lgG	Sodium
Chloride	Lactic Acid	Total Protein
Glucose	LDH	

#### **Analytes - Body Fluid Chemistry**

Albumin	Creatinine	Sodium
Alkaline Phosphatase	Glucose	Total Protein
Amylase	Lactate NEW	Triglycerides
Bilirubin, total	LDH	Urea Nitrogen
Calcium	Lipase	Uric Acid
Chloride	pН	
Cholesterol	Potassium	
► Analyte is not CAP accepted.	$\checkmark$ Program is included in our A2LA scope of accredita	tion.
Format		<b>Shipping Dates</b>
6 samples x 2 shipments		Apr. 15, Oct. 7

#### **ENHANCED**

#### **Ethyl Glucuronide**

#### **Program Description**

5 mL urine - For qualitative testing.

#### **Program Information**

148 Ethyl Glucuronide ✓

#### **Analytes**

Ethyl glucuronide (EtG)

✓ Program is included in our A2LA scope of accreditation.

**Format** 3 samples x 2 shipments Shipping Dates Apr. 15, Oct. 7

Microalbumin

#### **Program Description**

3 mL urine - For semi-quantitative dipstick or quantitative analysis. Recommended for Afinion users. If your lab is also performing other urine chemistry tests, see #143 - Urine Chemistry on page 35.

#### **Program Information**

236 Microalbumin√

#### **Analytes**

Microalbumin

Urine Creatinine

✓ Program is included in our A2LA scope of accreditation.

Format		
3 samples x 2 shipments		

CHEMISTRY

**Shipping Dates** Apr. 15, Oct. 7

#### **Sweat Analysis**

#### **Program Description**

3 mL liquid - For sweat analysis.

#### **Program Information**

163 Sweat Analysis

#### Analytes

- Chloride (qualitative)
- ► Chloride (quantitative)

Conductivity
 Osmolality

Sodium

► Analyte is not CAP accepted.

#### Format

3 samples x 2 shipments

Shipping Dates Apr. 15, Oct. 7

**Shipping Dates** 

Apr. 15, Oct. 7

#### **Urea Breath Test**

#### **Program Description**

2 paired sets of air filled sample bags - For the detection of urease associated with H. pylori from breath samples. For use with the Meridian Breath ID platform.

#### **Program Information**

193 Urea Breath Test

#### **Analytes**

Urease

#### Format

2 paired samples x 2 shipments

#### **Urine Adulteration Test**

#### **Program Description**

10 mL urine - Qualitative or quantitative tests for urine adulteration. For Urine Drug Screen see #139 on page 35.

#### **Program Information**

146 Urine Adulteration Test ✓

#### **Analytes**

Creatinine Nitrite	Oxidants pH	Specific Gravity
$\checkmark$ Program is included in our A2LA scope of accreditation.		
<b>Format</b> 3 samples x 2 shipments		<b>Shipping Dates</b> Apr. 15, Oct. 7

#### **Urine Chemistry**

#### **Program Description**

10 mL urine - For quantitative analysis. If your lab is performing <u>only</u> microalbumin and/or creatinine, or for the Afinion microalbumin, see #236 - Microalbumin on page 33.

#### **Program Information**

143 Urine Chemistry ✓

#### **Analytes**

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

✓ Program is included in our A2LA scope of accreditation. See A2LA link on our website for analyte exceptions.

#### Format 3 samples x 2 shipments

#### **Urine Drug Screen**

#### **Program Description**

10 mL urine - Qualitative or quantitative tests for urine drug screen.

#### **Program Information**

139 Urine Drug Screen (qual)
A39 Urine Drug Screen - Verification Programs

#### **Analytes**

6-Acetylmorphine	Cocaine Metabolites	Metham
Acetaminophen	Cotinine	Methaqu
Alcohol	EDDP	Opiates
Amphetamines	Fentanyl	Oxycodo
Barbiturates	Hydrocodone	Phencyc
Benzodiazepines	LSD	Propoxy
Buprenorphine	MDMA	Tramado
Cannabinoids	Meperidine	Tricyclic
Carisoprodol	Methadone	Zolpider

✓Only qualitative testing is included in our A2LA scope of accreditation.

#### Format

3 samples x 2 shipments

Methamphetamines Methaqualone Opiates Oxycodone Phencyclidine Propoxyphene Tramadol Tricyclic Antidepressants Zolpidem

**Shipping Dates** 

Apr. 15, Oct. 7

#### Shipping Dates Apr. 15, Oct. 7

cHEMISTRY

## HEMATOLOGY

HEMATOLOGY	1st Event	2nd Event	3rd Event
Ship Dates	March 4	July 8	October 28
Replacement Deadline	March 12	July 16	November 5
PT Results Due Date	March 27	July 31	November 20
Verification Due Date	April 3	August 7	November 27
Evaluations Available Online	April 16	August 20	December 10



# **INSTRUMENT LIST**

BODY FLUID CELL COUNT METHODS
-------------------------------

Instrument/Method	Program
Abbott Cell-Dyn (all models)	206 - Body Fluid Cell Count - C
Coulter (all models)	206 - Body Fluid Cell Count - C
Iris DxU series	207 - Body Fluid Cell Count - I
Iris iQ® 200	207 - Body Fluid Cell Count - I
Siemens Advia 120/2120	206 - Body Fluid Cell Count - C
Sysmex (all models)	206 - Body Fluid Cell Count - C
Manual Count	277 - Cell Count & Body Fluid Crystals

HEMATOLOGY ANALYZERS & PROGRAMS			
Instrument/Method	Program		
Abbott Cell-Dyn (1600 - 1800)	221 - Hematology - 3		
Abbott Cell-Dyn (3200, 3500, 3700)	242 - Hematology - 5D		
Abbott Cell-Dyn Emerald	221 - Hematology - 3		
Abbott Cell-Dyn Emerald 22, AL	242 - Hematology - 5D		
Abbott Cell-Dyn Ruby, Sapphire	242 - Hematology - 5D		
CDS Medonic CA	221 - Hematology - 3		
CDS Medonic M-Series	227 - Hematology - 3S		
Coulter AcT-5	231 - Hematology - 5A		
Coulter Ac-T (all 3-part differential models)	221 - Hematology - 3		
CoulCoulter HmX	230 - Hematology - 5C		
Coulter LH500	230 - Hematology - 5C		
Coulter LH 750, 755, 780, 785	230 - Hematology - 5C		
Coulter Micro Diff (all models)	221 - Hematology - 3		
Coulter UniCel DxH 500, 520, 560	279 - Hematology - 5H		
Coulter UniCel DxH 600, 690T, 800, 900	230 - Hematology - 5C		
Diatron Abacus 3CP	221 - Hematology - 3		
Diatron Abacus 5	242 - Hematology - 5D		
Drew (Danam) Excell 16	221 - Hematology - 3		
Drew D3, Evolution	221 - Hematology - 3		
HemoCue - for WBC only (all models)	209 - HemoCue White Blood Cell Count		
Horiba ABX Micros (all models)	221 - Hematology - 3		
Horiba ABX Minos	221 - Hematology - 3		
Horiba ABX Pentra (all models)	231 - Hematology - 5A		
Mindray BC-3200, 3600	221 - Hematology - 3		
Pixcell HemoScreen	292 - Hematology - 5P		
Siemens Advia 120, 2120	240 - Hematology - 5B		
Siemens Advia 60, 360	221 - Hematology - 3		
Siemens Advia 560	242 - Hematology - 5D		
Sight OLO	290 - Hematology - 5O		
Sysmex KX Series, pocH-100i, XP-100, & XP-300	227 - Hematology - 3S		
Sysmex XE, XN, XN-L, XS, XT (all models)	238 - Hematology - 5S		
Yumizen H500, H550, H1500, H2500	238 - Hematology - 5S		

SEDIMENTATION RATE METHODS & PROGRAMS		
Instrument/Method	Program	
Alaris ALS-20	228 - Sedimentation Rate - A	
Alcor i-Sed	203 - Sedimentation Rate - D	
Alcor miniiSed	203 - Sedimentation Rate - D	
Alifax ESR	280 - Sedimentation Rate - E	
Chase Westergren 830 SO	228 - Sedimentation Rate - A	
Diesse Mini-Cube, Cube 30	228 - Sedimentation Rate - A	
Dispette, Dispette 2	228 - Sedimentation Rate - A	
Globe Scientific (all methods)	228 - Sedimentation Rate - A	
HemaTech ESR STAT PLUS, STAT 6	202 - Sedimentation Rate - C	
MiniVes	228 - Sedimentation Rate - A	
Polymedco Sedimat 15, 15 Plus	201 - Sedimentation Rate - B	
Polymedco Sedimat/Sediplast	228 - Sedimentation Rate - A	
Sedifast, Sediplast, Sediten, Seditube	228 - Sedimentation Rate - A	
Streck/Analys ESR, Auto ESR Plus (all methods)	228 - Sedimentation Rate - A	
Ves Matic (all models)	228 - Sedimentation Rate - A	
Vital Diagnostic Excyte (all models)	228 - Sedimentation Rate - A	
Winpette	228 - Sedimentation Rate - A	

# **3-PART DIFFERENTIAL PROGRAMS**

## Hematology - 3

## **Program Description**

2 mL simulated whole blood - For automated techniques, including 2 and 3-part differentials or manual techniques for hematocrit, WBC (ammonium oxalate only), and platelet count.

## **Program Information**

221	Hematology - 3✓
B21	Hematology - 3 - Verification Program

## **Analytes**

Automated Differential	MCHC	RBC
Hematocrit	MCV	RDW
Hemoglobin	MPV	WBC
MCH	Platelet Count	

✓ Program is included in our A2LA scope of accreditation.

Format	Shipping Dates
5 samples x 3 shipments	Mar. 4, Jul. 8, Oct. 28

## Hematology - 3S

## **Program Description**

2 mL simulated whole blood - For the CDS Medonic M-Series, Sysmex KX Series, pocH-100i, and XP-300.

## **Program Information**

Hematology - 3 ✓
Hematology - 3S - Verification Program

## **Analytes**

MCHC	RBC
MCV	RDW-CV
MPV	RDW-SD
Platelet Count	WBC
	MCV MPV

✓ Program is included in our A2LA scope of accreditation.

Format	Shipping Dates
5 samples x 3 shipments	Mar. 4, Jul. 8, Oct. 28

# **5-PART DIFFERENTIAL PROGRAMS**

## Hematology - 5A

## **Program Description**

2.5 mL simulated whole blood - For the Horiba Medical Pentra 60, 60+, 80, 120 and the Coulter AcT 5-Diff.

## **Program Information**

231	Hematology - 5A✓
-----	------------------

B31 Hematology - 5A - Verification Program

## **Analytes**

Automated Differential	МСНС	RBC
Hematocrit	MCV	RDW
Hemoglobin	MPV	WBC
MCH	Platelet Count	

✓ Program is included in our A2LA scope of accreditation.

Format	Shipping Dates
5 samples x 3 shipments	Mar. 4, Jul. 8, Oct. 28

# Hematology - 5B

## **Program Description**

4 mL simulated whole blood - For the Siemens Advia 120, 2120, and 2120i.

## **Program Information**

240 Hematology - 5B✓

## **Analytes**

Automated Differential	MCHC	RBC
Hematocrit	MCV	RDW
Hemoglobin	MPV	WBC
MCH	Platelet Count	

✓ Program is included in our A2LA scope of accreditation.

Format	Shipping Dates
5 samples x 3 shipments	Mar. 4, Jul. 8, Oct. 28

HEMATOLOGY

## Hematology - 5C

## **Program Description**

2 mL simulated whole blood - For the Coulter UniCel DxH600, DxH800, DxH900, and LH750, LH755, LH780, LH785.

## **Program Information**

230 Hematology - 5C ✓B30 Hematology - 5C - Verification Program

## **Analytes**

Automated Differential	МСНС	RBC
Hematocrit	MCV	RDW-CV
Hemoglobin	MPV	RDW-SD
IRF	nRBC	Reticulocyte Count
MCH	Platelet Count	WBC
$\checkmark$ Program is included in our A2LA scope of accreditation.		
Format		Shipping Dates

Mar. 4, Jul. 8, Oct. 28

5 samples x 3 shipments

## Hematology - 5D

#### **Program Description**

3 mL simulated whole blood - For the Abbott Cell-Dyn 3000-3700, 4000, Ruby, Sapphire, and the Diatron Abacus 5.

## **Program Information**

242 Hematology - 5D ✓

B42 Hematology - 5D - Verification Program

## **Analytes**

Automated Differential	MCHC	RBC
Hematocrit	MCV	RDW
Hemoglobin	MPV	Reticulocyte Count
IRF	nRBC	WBC
MCH	Platelet Count	

✓ Program is included in our A2LA scope of accreditation.

Format	Shipping Dates
5 samples x 3 shipments	Mar. 4, Jul. 8, Oct. 28

## Hematology - 5H

## **Program Description**

2.5 mL simulated whole blood - For the Coulter DxH500 and DxH520.

## **Program Information**

279	Hematology - 5H ✓
B79	Hematology - 5H - Verification Program

## Analytes

Automated Differential	МСНС	RBC
Hematocrit	MCV	RDW-CV
Hemoglobin	MPV	RDW-SD
MCH	Platelet Count	WBC
$\checkmark$ Program is included in our A2LA scope of accreditatio	n.	
Format		Shipping Dates

5 samples x 3 shipments

# Hematology - 50

## **Program Description**

3 mL simulated whole blood - For the Sight OLO instrument.

## **Program Information**

Hematology - 50

## **Analytes**

Automated Differential	MCHC	RDW
Hematocrit	MCV	WBC
Hemoglobin	Platelet Count	
MCH	RBC	

#### Format

5 samples x 3 shipments

**Shipping Dates** Mar. 4, Jul. 8, Oct. 28

Mar. 4, Jul. 8, Oct. 28

НЕМАТОLOGY

## Hematology - 5P

#### **Program Description**

3 mL simulated whole blood - For the PixCell HemoScreen instrument.

## **Program Information**

292 Hematology - 5P

## **Analytes**

Automated Differential	MCHC	RBC
Hematocrit	MCV	RDW
Hemoglobin	MPV	WBC
MCH	Platelet Count	

Format	Shipping Dates
5 samples x 3 shipments	Mar. 4, Jul. 8, Oct. 28

## Hematology - 5S

#### **Program Description**

2 mL simulated whole blood - For all Sysmex XE, XN, XS, and XT and Yumizen H500, H550, H1500 and H2500 analyzers.

## **Program Information**

238 Hematology - 55 ✓B38 Hematology - 5S - Verification Program

## **Analytes**

Automated Differential	MCHC	RDW-CV
Hematocrit	MCV	RDW-SD
Hemoglobin	MPV	RET-He
IG# and IG%	nRBC#	Reticulocyte Count
IPF	nRBC%	WBC
IRF	Platelet Count	
MCH	RBC	

✓ Program is included in our A2LA scope of accreditation.

Format	Shipping Dates
5 samples x 3 shipments	Mar. 4, Jul. 8, Oct. 28

## **BLOOD CELL IDENTIFICATION**

# For laboratories that perform both Blood Cell Identification and Automated Differentials:

CMS allows for the transmission of only one of these scores each test event. Results for both tests are graded and will appear on your evaluation, but only one score can be sent to CMS. If you would like your score for Blood Cell ID to be sent to CMS, enroll in #224 or #286. If you would like your score for auto differential to be sent to CMS, enroll in #225 or #291.

## **Blood Cell Identification**

## **Program Description**

Two Wright stained peripheral blood smears for blood cell identification. One case study will include 5 annotated cells/objects for identification and will be scored. The second case study is educational and will include 5 cells/objects for identification with a manual 100 WBC differential and platelet estimate. #224 and #225 are virtual programs and do not include printed photographs. To receive printed photographs, order #286 or #291. Please Note: Laboratories ordering only virtual programs must access paperwork and images online. For competency, see Q24 - Blood Cell Identification - Competency on page 129.

## **Program Information**

- 224 Blood Cell ID (CMS Scored) (Virtual only) ✓
- 286 Blood Cell ID (CMS Scored) (#224 + Photos) ✓
- 225 Blood Cell ID (Not CMS Scored) (Virtual only) ✓
- 291 Blood Cell ID (Not CMS Scored) (#225 + Photos) ✓

## **Analytes**

Blood	Cell	Identification
Dioou	CCII	iucilitication

Educational Blood Cell ID

Manual Differential

✓ Program is included in our A2LA scope of accreditation. See A2LA link on our website for analyte exceptions.

**Format** 10 photographs x 3 shipments Shipping Dates Mar. 4, Jul. 8, Oct. 28

## Advanced Blood Cell ID (Virtual only)

#### **Program Description**

One virtual Wright stained peripheral blood smear for blood cell identification. The case study will include seven cells/objects chosen for ID and an educational commentary. This option is designed to offer case studies that are more challenging and complex. Not CMS scored or reported to CAP. Please Note: Laboratories ordering only virtual programs must access paperwork and images online.

## **Program Information**

259 Advanced Blood Cell ID (Virtual only) ✓

## **Analytes**

**Blood Cell Identification** 

✓ Program is included in our A2LA scope of accreditation.

#### Format

7 photographs x 3 shipments

Shipping Dates Mar. 4, Jul. 8, Oct. 28

# **MISCELLANEOUS HEMATOLOGY**

## Advanced Body Fluid Microscopy (Virtual only)

## **Program Description**

One whole slide virtual image of body fluid from various sources. The case study will include five formed elements, cells, or crystals for identification with a manual WBC differential. Please Note: Laboratories ordering only virtual programs must access paperwork and images online.

## **Program Information**

262 Advanced Body Fluid Microscopy (Virtual only)

## **Analytes**

Identification of formed elements

Manual Differential

#### Format

5 photographs x 2 shipments

Shipping Dates Mar. 4, Oct. 28

## **Body Fluid Cell Count - C**

## **Program Description**

3 mL liquid - For Abbott, Coulter, Sysmex and Advia analyzers. For manual cell counts see #277 - Cell Count & Body Fluid Crystals on page 46.

## **Program Information**

206 Body Fluid Cell Count - C✓

## **Analytes**

Mononuclear cells	RBC	WBC
Polymorphonuclear cells	Total Nucleated Cells (TC-BF)	

✓ Program is included in our A2LA scope of accreditation. See A2LA link on our website for analyte exceptions.

Format	Shipping Dates
1 samples x 3 shipments	Mar. 4, Jul. 8, Oct. 28

## **Body Fluid Cell Count - I**

#### **Program Description**

4 mL liquid - For Iris DxU series and Iris IQ<sup>®</sup>. For manual cell counts see #277 - Cell Count & Body Fluid Crystals on page 46.

## **Program Information**

207 Body Fluid Cell Count – I 🗸

#### Analytes

Nucleated Cells

RBC

 $\checkmark$  Program is included in our A2LA scope of accreditation.

#### Format

1 samples x 3 shipments

Shipping Dates Mar. 4, Jul. 8, Oct. 28

## **Body Fluid Microscopy**

#### **Program Description**

Three images for the identification of crystals and other formed elements/cells in various body fluids. This program includes 2 shipments per year. #168 is a virtual program and does not include printed photographs. To receive printed photographs, order #181. Please Note: Laboratories ordering only virtual programs must access paperwork and images online. For Body Fluid competency programs, see pages 128-135.

## **Program Information**

168 Body Fluid Microscopy (Virtual only) ✓

181 Body Fluid Microscopy (#168 + Photos) ✓

#### Analytes

Identification of formed elements

✓ Program is included in our A2LA scope of accreditation.

#### Format

3 photographs x 2 shipments

**Shipping Dates** Mar. 4, Oct. 28

## **Cell Count & Body Fluid Crystals**

#### **Program Description**

Manual Cell Count - 2 samples; Body Fluid Crystals - 2 samples. For CSF and Body Fluid Chemistry, see #177 - CSF & Body Fluid Chemistry on page 32.

## **Program Information**

277 Cell Count & Body Fluid Crystals ✓

## **Analytes**

Crystals	WBC	WBC Differential
RBC		
$\checkmark$ Program is included in our A2LA scope of accreditation.		
Format		Shipping Dates
4 samples x 2 shipments		Mar. 4, Oct. 28

## **Fetal Hemoglobin**

#### **Program Description**

1.2 mL simulated gastric fluid - For qualitative fetal hemoglobin. For Whole Blood Fetal Screen see #515 - Fetal RBC on page 127.

## **Program Information**

210 Fetal Hemoglobin ✓

#### **Analytes**

Fetal Hemoglobin (gastric fluid)

 $\checkmark$  Program is included in our A2LA scope of accreditation.

**Format** 2 samples x 2 shipments **Shipping Dates** Mar. 4, Oct. 28

## **Flow Cytometry**

## **Program Description**

2.5 mL simulated whole blood - For lymphocyte phenotyping.

## **Program Information**

229 Flow Cytometry ✓

## **Analytes**

- ► CD3 (T Cells)
- ► CD4 (T Helper)
- ► Analyte is not CAP accepted.

#### Format

2 samples x 3 shipments

- ► CD8 (T Cytotoxic)
- ► CD19 (B Cells)

 $\checkmark$  Program is included in our A2LA scope of accreditation.

- CD45 (Leukocytes)
- ► CD56 / CD16+56 (NK Cells)

**Shipping Dates** Mar. 4, Jul. 8, Oct. 28

## HemoCue White Blood Cell Count

## **Program Description**

2 mL simulated whole blood - For HemoCue WBC System.

## **Program Information**

209 HemoCue White Blood Cell Count ✓

## Analytes

#### WBC

✓ Program is included in our A2LA scope of accreditation.

#### Format 5 samples x 3 shipm

5 samples x 3 shipments

# Reticulocyte Count

## **Program Description**

1 mL simulated whole blood - For manual (new methylene blue stain only) and automated reticulocyte techniques.

## **Program Information**

223 Reticulocyte Count ✓

#### **Analytes**

Reticulocyte Count

✓ Program is included in our A2LA scope of accreditation.

#### **Format** 2 samples x 3 shipments

**Shipping Dates** Mar. 4, Jul. 8, Oct. 28

**Shipping Dates** 

Mar. 4, Jul. 8, Oct. 28

## Sedimentation Rate - A

#### **Program Description**

5 mL simulated whole blood - For manual methods and most automated methods.

## **Program Information**

228 Sedimentation Rate - A 🗸

## **Analytes**

Sedimentation Rate

✓ Program is included in our A2LA scope of accreditation.

#### Format

2 samples x 3 shipments

Shipping Dates Mar. 4, Jul. 8, Oct. 28

## Sedimentation Rate - B

#### **Program Description**

6 mL simulated whole blood - For Polymedco Sedimat 15, 15 Plus.

#### **Program Information**

201 Sedimentation Rate - B✓

#### **Analytes**

Sedimentation Rate

✓ Program is included in our A2LA scope of accreditation.

#### Format

2 samples x 3 shipments

**Shipping Dates** Mar. 4, Jul. 8, Oct. 28

## Sedimentation Rate - C

#### **Program Description**

6 mL simulated whole blood - For HemaTechnologies ESR STAT Plus and ESR STAT 6.

## **Program Information**

202 Sedimentation Rate - C✓

#### **Analytes**

Sedimentation Rate

✓ Program is included in our A2LA scope of accreditation.

#### Format

2 samples x 3 shipments

Shipping Dates Mar. 4, Jul. 8, Oct. 28

## Sedimentation Rate - D

## **Program Description**

4 mL simulated whole blood - For the Alcor i-SED and Alcor miniiSED.

## **Program Information**

203 Sedimentation Rate - D✓

## **Analytes**

Sedimentation Rate

✓ Program is included in our A2LA scope of accreditation.

#### Format

2 samples x 3 shipments

Shipping Dates Mar. 4, Jul. 8, Oct. 28

## Sedimentation Rate - E

#### **Program Description**

3 mL simulated whole blood - For Alifax ESR analyzers.

## **Program Information**

280 Sedimentation Rate - E

#### **Analytes**

Sedimentation Rate

#### Format

3 samples x 3 shipments

Shipping Dates Mar. 4, Jul. 8, Oct. 28

## **Sickle Cell Screen**

#### **Program Description**

2.5 mL simulated whole blood - For screening kits and electrophoresis screening methods.

## **Program Information**

237 Sickle Cell Screen√

#### **Analytes**

Sickle Cell Screen

✓ Program is included in our A2LA scope of accreditation.

#### Format

2 samples x 3 shipments

**Shipping Dates** Mar. 4, Jul. 8, Oct. 28

# ANDROLOGY

ANDROLOGY	1st Event	3rd Event
Ship Dates	March 4	October 28
Replacement Deadline	March 12	November 5
PT Results Due Date	March 27	November 20
Verification Due Date	April 3	November 27
Evaluations Available Online	April 16	December 10



# ANDROLOGY

## **Antisperm Antibody**

### **Program Description**

0.5 mL serum - Human serum for antisperm antibody.

## **Program Information**

154 Antisperm Antibody 🗸

## **Analytes**

- Antisperm Antibody
- ► Analyte is not CAP accepted.

✓ Program is included in our A2LA scope of accreditation.

Format
2 samples x 2 shipments

Shipping Dates Mar. 4, Oct. 28

## **Automated Post-Vasectomy Sperm Analysis**

#### **Program Description**

1.0 mL stabilized sperm - Designed for automated sperm analyzers.

## **Program Information**

185 Automated Post-Vasectomy Sperm Analysis

## **Analytes**

Sperm Count

Sperm, presence/absence

**Format** 2 samples x 2 shipments

## **Automated Sperm Count**

#### **Program Description**

1.0 mL stabilized sperm - Designed for automated sperm analyzers.

## **Program Information**

184 Automated Sperm Count

## **Analytes**

Sperm Count

► Analyte is not CAP accepted.

#### Format

2 samples x 2 shipments

Shipping Dates Mar. 4, Oct. 28

**Shipping Dates** Mar. 4, Oct. 28

## **Post-Vasectomy Motility (Virtual only)**

#### **Program Description**

Web based video footage for the presence/absence of sperm and sperm motility. Please Note: Laboratories ordering only virtual programs must access paperwork and images online.

#### **Program Information**

194 Post-Vasectomy Motility (Virtual only)

#### **Analytes**

► Sperm, presence/absence

Sperm Motility, presence/absence

► Analyte is not CAP accepted.

#### Format

2 samples x 2 shipments

Shipping Dates Mar. 4, Oct. 28

**Shipping Dates** 

Mar. 4, Oct. 28

## **Post-Vasectomy Sperm Analysis**

#### **Program Description**

0.3 mL stabilized sperm - Designed for manual methods.

#### **Program Information**

162 Post-Vasectomy Sperm Analysis 🗸

#### Analytes

Sperm Count

Sperm, presence/absence

✓ Program is included in our A2LA scope of accreditation.

#### Format

2 samples x 2 shipments

## **Sperm Count**

**Program Description** 0.3 mL stabilized sperm - Designed for manual methods.

## **Program Information**

151 Sperm Count ✓

## **Analytes**

Sperm Count

✓ Program is included in our A2LA scope of accreditation.

**Format** 2 samples x 2 shipments Shipping Dates Mar. 4, Oct. 28

## **Sperm Morphology**

## **Program Description**

1 unstained semen smear and 1 virtual image (online only) for specific sperm morphology.

## **Program Information**

152 Sperm Morphology ✓

## **Analytes**

Sperm Morphology

✓ Program is included in our A2LA scope of accreditation.

#### Format

2 samples x 2 shipments

Shipping Dates Mar. 4, Oct. 28

# Sperm Motility (Virtual only)

#### **Program Description**

Web based video footage for sperm motility and progressive motility. Please Note: Laboratories ordering only virtual programs must access paperwork and images online.

## **Program Information**

161 Sperm Motility (Virtual only) ✓

#### **Analytes**

Sperm Motility

Sperm Progressive Motility

✓ Program is included in our A2LA scope of accreditation.

#### Format

2 samples x 2 shipments

## **Sperm Viability**

#### **Program Description**

Glass slides - Eosin-Nigrosin stained smears.

## **Program Information**

153 Sperm Viability ✓

## **Analytes**

Sperm Viability

✓ Program is included in our A2LA scope of accreditation.

#### **Format** 2 samples x 2 shipments

Shipping Dates Mar. 4, Oct. 28

**Shipping Dates** 

Mar. 4, Oct. 28

# COAGULATION

COAGULATION	1st Event	2nd Event	3rd Event
Ship Dates	March 4	July 8	October 28
Replacement Deadline	March 12	July 16	November 5
PT Results Due Date	March 27	July 31	November 20
Verification Due Date	April 3	August 7	November 27
<b>Evaluations Available Online</b>	April 16	August 20	December 10



# COAGULATION

## Activated Clotting Time (Hemochron/Helena)

#### **Program Description**

3 mL lyophilized samples - For the Hemochron Response, 801, Helena Laboratories Actalyke, and Cascade POC.

## **Program Information**

- 211 Activated Clotting Time 5 samples
- 916 Activated Clotting Time 2 samples
- J16 Activated Clotting Time Verification Program 2 samples

#### **Analytes**

Activated Clotting Time

#### Format

3 shipments

**Shipping Dates** Mar. 4, Jul. 8, Oct. 28

## **Activated Clotting Time (Medtronic)**

#### **Program Description**

3 mL lyophilized samples - For the Medtronic ACT and HMS Plus.

## **Program Information**

- 212 Activated Clotting Time 5 samples
- 917 Activated Clotting Time 2 samples
- J17 Activated Clotting Time Verification Program 2 samples

#### **Analytes**

Activated Clotting Time

#### Format

3 shipments

**Shipping Dates** Mar. 4, Jul. 8, Oct. 28

## Coagulation

#### **Program Description**

1 mL lyophilized plasma - For plasma-based coagulation analyzers.

#### **Program Information**

217	Coa	gulatior	v ر		
	-			 	

B17 Coagulation - Verification Program

### Analytes

APTT	INR	Prothrombin Time
Fibrinogen		
$\checkmark$ Program is included in our A2LA scope of accreditation.		
Format		Shipping Dates
5 samples x 3 shipments		Mar. 4, Jul. 8, Oct. 28

## **Coagulation, Supplemental**

#### **Program Description**

1 mL lyophilized plasma

#### **Program Information**

- 281 Coagulation, Supplemental
- 282 Additional Sample Volume
- 283 Coagulation, Supplemental add on to #217

#### **Analytes**

Antithrombin III Activity Factor II Activity Factor V Activity Factor VII Activity Factor VIII Activity

Factor XII Activity Plasminogen

#### Format

5 samples x 3 shipments

Protein C Protein S Thrombin Time von Willebrand Factor Activity von Willebrand Factor Antigen

#### Shipping Dates Mar. 4, Jul. 8, Oct. 28

All analytes in bold type are regulated for proficiency testing by CMS. Laboratories enrolling in programs to satisfy CMS requirements for PT are responsible for ensuring they are testing five samples, three times per year.

Factor IX Activity

Factor X Activity

Factor XI Activity

## **D-dimer/FDP - Qualitative**

#### **Program Description**

0.5 mL liquid - For qualitative D-dimer and FDP methods.

### **Program Information**

245 D-dimer/FDP - Qualitative ✓

#### Analytes

D-dimer

Fibrin degradation products

✓ Program is included in our A2LA scope of accreditation. See A2LA link on our website for analyte exceptions.

#### Format

2 samples x 3 shipments

**Shipping Dates** Mar. 4, Jul. 8, Oct. 28

## **D-dimer - Quantitative**

#### **Program Description**

0.5 mL plasma - For quantitative D-dimer methods.

## **Program Information**

246 D-dimer - Quantitative ✓

B46 D-dimer - Quantitative - Verification Program

## Analytes

D-dimer

✓ Program is included in our A2LA scope of accreditation.

#### Format

2 samples x 3 shipments

Hemochron Jr. ACT +

#### **Program Description**

0.7 mL lyophilized samples - For the Hemochron Jr., Signature, Signature +, Signature Elite, and IL Gem PCL. For use with ACT + Cuvette.

## **Program Information**

248 Hemochron Jr. ACT +B48 Hemochron Jr. ACT + - Verification Program

## **Analytes**

Activated Clotting Time

Shipping Dates Mar. 4, Jul. 8, Oct. 28

**Shipping Dates** Mar. 4. Jul. 8. Oct. 28

## Hemochron Jr. ACT - LR

#### **Program Description**

0.7 mL lyophilized samples - For the Hemochron Jr., Signature, Signature +, Signature Elite, and IL Gem PCL. For use with ACT-LR cuvette.

### **Program Information**

247 Hemochron Jr. ACT - LR

B47 Hemochron Jr. ACT - LR - Verification Program

## **Analytes**

Activated Clotting Time

#### Format

2 samples x 3 shipments

**Shipping Dates** Mar. 4, Jul. 8, Oct. 28

## Hemochron Jr. Citrate APTT

#### **Program Description**

0.7 mL lyophilized samples - For the Hemochron Jr. II, Signature, Signature +, Signature Elite. For use with Citrate cuvette.

#### **Program Information**

252 Hemochron Jr. Citrate APTT

#### **Analytes**

APTT

#### Format

5 samples x 3 shipments

Shipping Dates Mar. 4, Jul. 8, Oct. 28

## Hemochron Jr. Citrate PT

#### **Program Description**

0.7 mL lyophilized samples - For the Hemochron Jr. Signature, Signature +, Signature Elite, IL Gem PCL, and Gem PCL Plus. For use with Citrate cuvette.

#### **Program Information**

249 Hemochron Jr. Citrate PT

#### **Analytes**

INR

**Prothrombin Time** 

Format	Shipping Dates
5 samples x 3 shipments	Mar. 4, Jul. 8, Oct. 28

## Hemochron Jr. PT

## **Program Description**

0.7 mL lyophilized samples - For the Hemochron Jr. Signature, Signature +, Signature Elite, IL Gem PCL, and Gem PCL Plus. For use with whole blood cuvette.

## **Program Information**

250 Hemochron Jr. PT

## **Analytes**

INR

**Prothrombin Time** 

#### Format

5 samples x 3 shipments

**Heparin Assay** 

## **Program Description**

1.0 mL lyophilized plasma - For testing Low Molecular Weight Heparin (LMWH) and Unfractionated Heparin (UFH) levels. Not CMS scored or reported to CAP.

## **Program Information**

278 Heparin Assay ✓

## **Analytes**

Anti-Xa APTT INR Prothrombin Time Thrombin Time

**Shipping Dates** 

**Shipping Dates** 

Mar. 4, Jul. 8, Oct. 28

 $\checkmark$  Program is included in our A2LA scope of accreditation.

#### Format

2 samples x 3 shipments

## **i-STAT ACT**

## **Program Description**

1 mL lyophilized samples - For the i-STAT analyzer.

## **Program Information**

215 i-STAT ACT ✓
B15 i-STAT ACT - Verification Program

## Analytes

Activated Clotting Time

 $\checkmark$  Program is included in our A2LA scope of accreditation.

# Format

2 samples x 3 shipments

Mar. 4, Jul. 8, Oct. 28

Shipping Dates Mar. 4. Jul. 8. Oct. 28

## **Platelet Function - Aspirin Test**

#### **Program Description**

Pellet - For aspirin-induced inhibition. Designed for use with the Accumetrics VerifyNow System.

#### **Program Information**

255 Platelet Function - Aspirin Test ✓

#### **Analytes**

Aspirin induced inhibition

✓ Program is included in our A2LA scope of accreditation.

**Format** 

2 samples x 3 shipments

**Shipping Dates** Mar. 4, Jul. 8, Oct. 28

**Shipping Dates** 

Mar. 4, Jul. 8, Oct. 28

, Oct. 28

## **Platelet Function - PRUTest**

## **Program Description**

Pellet - For P2Y12 inhibition (Plavix® and Effient®). Designed for use with Accumetrics VerifyNow System.

#### **Program Information**

Platelet Function - PRUTest ✓ 256

#### **Analytes**

P2Y12 inhibition

✓ Program is included in our A2LA scope of accreditation.

#### **Format**

2 samples x 3 shipments

## **POC Coagulation A**

#### **Program Description**

Lyophilized plasma - Point of Care coagulation for CoaguChek XS (INR only), XS Plus, and XS Pro. #914 is not CMS scored or reported to CAP.

#### **Program Information**

- POC Coagulation A 5 samples ✓ 214
- 914 POC Coagulation A - 2 samples ✓
- B14 POC Coagulation A - Verification Program - 5 samples
- J14 POC Coagulation A - Verification Program - 2 samples

#### **Analytes**

INR

**Prothrombin Time** 

 $\checkmark$  Program is included in our A2LA scope of accreditation.

Format	<b>Shipping Dates</b>
3 shipments	Mar. 4, Jul. 8, Oct. 2

## **POC Coagulation B**

## **Program Description**

1 mL lyophilized samples - Point of Care coagulation for i-STAT PCA, i-STAT I, and Coag-Sense (CoaguSense).

## **Program Information**

216 POC Coagulation B✓

B16 POC Coagulation B - Verification Program

## **Analytes**

INR

**Prothrombin Time** 

 $\checkmark$  Program is included in our A2LA scope of accreditation.

**Format** 5 samples x 3 shipments **Shipping Dates** Mar. 4, Jul. 8, Oct. 28

## Thromboelastogram

## **Program Description**

1 mL lyophilized samples - For the Haemonetics TEG 5000, TEG 6s, and ROTEM delta analyzers.

## **Program Information**

244 Thromboelastogram✓

## **Analytes**

Thromboelastometry

✓ Program is included in our A2LA scope of accreditation.

**Format** 3 samples x 3 shipments Shipping Dates Mar. 4, Jul. 8, Oct. 28

# URINALYSIS, MICROSCOPY, & MISCELLANEOUS TESTS

URINALYSIS, MICROSCOPY - MISC	1st Event	2nd Event	3rd Event
Ship Dates	March 4	July 8	October 28
Replacement Deadline	March 12	July 16	November 5
PT Results Due Date	March 27	July 31	November 20
Verification Due Date	April 3	August 7	November 27
Evaluations Available Online	April 16	August 20	December 10



# URINALYSIS, MICROSCOPY, & MISCELLANEOUS TESTS

## Automated Urine Microscopy – I

## **Program Description**

12 mL simulated urine - Designed for Iris DxU series and Iris IQ®.

## **Program Information**

270 Automated Urine Microscopy - I√

## **Analytes**

Crystals	RBC	WBC
Non-Squamous Epithelial Cells		
$\checkmark$ Program is included in our A2LA scope of accreditation.		
Format		Shipping Dates
1 sample x 3 shipments		Mar. 4, Jul. 8, Oct. 28

## Automated Urine Microscopy - S

## **Program Description**

12 mL simulated urine - Designed for Sysmex and the Arkray Aution AU-4050.

## **Program Information**

271 Automated Urine Microscopy - S✓

## **Analytes**

Bacteria	Crystals	RBC
Casts	Epithelial Cells	WBC

✓ Program is included in our A2LA scope of accreditation.

1 sample x 3 shipments Mar. 4, Jul. 8, Oct. 28	Format	Shipping Dates
	1 sample x 3 shipments	Mar. 4, Jul. 8, Oct. 28

## **Fecal Lactoferrin**

#### **Program Description**

0.5 mL simulated stool samples - For qualitative detection of fecal lactoferrin.

#### **Program Information**

261 Fecal Lactoferrin√

#### Analytes

Fecal Lactoferrin

✓ Program is included in our A2LA scope of accreditation.

Format

2 samples x 3 shipments

Shipping Dates Mar. 4, Jul. 8, Oct. 28

## **Fecal Occult Blood**

## **Program Description**

1.5 mL simulated stool samples - For guaiac or immunoassay methods. For competency, see Q22 - Fecal Occult Blood - Competency on page 130.

#### **Program Information**

284 Fecal Occult Blood ✓

285 Fecal Occult Blood - add on option to #232 or 272 ✓

B84 Fecal Occult Blood - Verification Program

#### **Analytes**

Fecal Occult Blood

✓ Program is included in our A2LA scope of accreditation.

Format

2 samples x 3 shipments

Shipping Dates Mar. 4, Jul. 8, Oct. 28

## **Gastric Occult Blood**

#### **Program Description**

2 mL simulated gastric samples - For gastric occult blood and pH.

#### **Program Information**

239 Gastric Occult Blood ✓
B39 Gastric Occult Blood - Verification Program

#### **Analytes**

Gastric Occult Blood

pН

✓ Program is included in our A2LA scope of accreditation.

#### **Format** 2 samples x 3 shipments

**Shipping Dates** Mar. 4, Jul. 8, Oct. 28

## **Microscopy Package**

## **Program Description**

Images for microscopy. For KOH preparations of skin, hair, or nails, see #333 - KOH Preparation on page 91. This program includes two challenges for urine sediment and one challenge for all other analytes. #233 and #B33 are virtual programs and do not include printed photographs. To receive printed photographs, order #287 or #B87. Please Note: Laboratories ordering only virtual programs must access paperwork and images online. For Microscopy competency programs, see pages 128-135.

## **Program Information**

- 233 Microscopy Package (Virtual only) ✓
- 287 Microscopy Package (#233 + Photos) ✓
- B33 Microscopy Package (Virtual only) Verification Program
- B87 Microscopy Package (#B33 + Photos) Verification Program

## **Analytes**

Fecal WBC	Pinworm Preparation	Vaginal Wet Prep
Fern Test	Sperm, pos/neg (► post-vas)	Vaginal Wet Prep (KOH)
Nasal Smear	Urine Sediment	
► Analyte is not CAP accepted.	$\checkmark$ Program is included in our A2LA scope of accreditation.	
Format		Shipping Dates
3 shipments		Mar. 4, Jul. 8, Oct. 28

## **Rapid Urease**

#### **Program Description**

Simulated gastric biopsy samples - For use with CLOtest, PyloriTek, or similar methods.

## **Program Information**

260 Rapid Urease ✓

#### **Analytes**

#### Urease

✓ Program is included in our A2LA scope of accreditation.

#### Format

3 samples x 2 shipments

Shipping Dates Feb. 5, Sep.16 INALYSIS, MICROSCOPY, ISCELLANEOUS TESTS

## **Trichomonas (Virtual only)**

#### **Program Description**

Web based video footage for the presence of *Trichomonas vaginalis*. Please Note: Laboratories ordering only virtual programs must access paperwork and images online.

#### **Program Information**

263 Trichomonas (Virtual only)

## Analytes

Trichomonas vaginalis

#### Format

1 sample x 3 shipments

**Shipping Dates** Mar. 4, Jul. 8, Oct. 28

## Urinalysis & HCG

#### **Program Description**

10 mL urine - For dipstick analysis. HCG is intended for waived methods. For Iris dipsticks, see #272 - Urinalysis & HCG - I on page 67. For automated urine microscopy see #270 and #271 on page 63. For Fecal Occult Blood testing see #285 - Fecal Occult Blood - add on, on page 64. For competency, see Q21 Urinalysis & HCG - Competency on page 134.

#### **Program Information**

232 Urinalysis & HCG ✓B32 Urinalysis & HCG - Verification Program

#### **Analytes**

Bilirubin Bilirubin, confirmatory Blood/Hemoglobin Creatinine Glucose HCG Ketones Leukocyte Esterase Nitrite pH Protein Protein, confirmatory Reducing Substance Specific Gravity Urobilinogen

✓ Program is included in our A2LA scope of accreditation.

Format	Shipping Dates
2 samples x 3 shipments	Mar. 4, Jul. 8, Oct. 28

## Urinalysis & HCG - I

## **Program Description**

10 mL urine - For Iris iChem, iVelocity, and vChem dipstick analysis. HCG is intended for waived methods. For automated urine microscopy see #270 and #271 on page 63. For Fecal Occult Blood testing see #285 - Fecal Occult Blood - add on, on page 64.

## **Program Information**

272 Urinalysis & HCG - I√

## **Analytes**

Bilirubin	Ketones
Bilirubin, confirmatory	Leukocyte Esterase
Blood/Hemoglobin	Nitrite
Glucose	pН
HCG	Protein

✓ Program is included in our A2LA scope of accreditation.

**Format** 2 samples x 3 shipments

## **Urine Crystals**

#### **Program Description**

1.5 mL urine - For identification of urine crystals.

## **Program Information**

273 Urine Crystals ✓

## **Analytes**

Urine Crystal Identification

 $\checkmark$  Program is included in our A2LA scope of accreditation.

#### Format

2 samples x 2 shipments

**Shipping Dates** Mar. 4, Oct. 28

Protein, confirmatory Reducing Substance

Specific Gravity Urobilinogen

**Shipping Dates** 

Mar. 4, Jul. 8, Oct. 28

URINALYSIS, MICROSCOPY, & MISCELLANEOUS TESTS

## **Urine Eosinophils**

#### **Program Description**

One image for the presence or absence of urine eosinophils. #258 is a virtual program and does not include a printed photograph. To receive a printed photograph, order #289. Please Note: Laboratories ordering *only* virtual programs must access paperwork and images online.

## **Program Information**

- 258 Urine Eosinophils (Virtual only) ✓
- 289 Urine Eosinophils (#258 + Photo) ✓

## **Analytes**

Urine Eosinophils

 $\checkmark$  Program is included in our A2LA scope of accreditation.

#### Format

1 photograph x 3 shipments

Shipping Dates Mar. 4, Jul. 8, Oct. 28

## Urine HCG - Qualitative

## **Program Description**

1 mL simulated urine - For non-waived methods such as latex agglutination or FIA. Also may be ordered by laboratories that wish to test 5 samples for waived methods.

## **Program Information**

235 Urine HCG - Qualitative ✓

B35 Urine HCG - Qualitative - Verification Program

## **Analytes**

#### HCG

✓ Program is included in our A2LA scope of accreditation.

Format

5 samples x 3 shipments

**Shipping Dates** Jan. 8, May 13, Aug. 19

## **Urine Sediment**

## **Program Description**

Two images for identification of formed elements in urine sediment. #234 is a virtual program and does not include printed photographs. To receive printed photographs, order #288. Please Note: Laboratories ordering *only* virtual programs must access paperwork and images online. For competency, see Q26 - Urine Sediment - Competency on page 135.

## **Program Information**

- 234 Urine Sediment (Virtual only) ✓
- 288 Urine Sediment (#234 + Photos) ✓

## Analytes

Identification of formed elements

Program is included in our A2LA scope of accreditation.

#### Format

2 photograph x 3 shipments

**Shipping Dates** Mar. 4, Jul. 8, Oct. 28

## Waived & Microscopy Package

## **Program Description**

For waived methods and commonly performed microscopy procedures. HemoCue users see #128/928 on page 23. True Metrix and True Metrix Pro users see #979 - POC Glucose B on page 28. For KOH preparations of skin, hair, or nails, see #333 on page 91. The numbers shown to the right indicate the number of challenges per test event.

## **Program Information**

- 251 Waived & Microscopy Package ✓
- X51 Extra Results WBG Waived Package Verification Program report results for up to 20 additional glucose meters
- B51 Waived & Microscopy Package Verification Program for all analytes listed below

## **Analytes**

Fecal Occult Blood (1) Group A Strep Antigen (2) HCG (1) Hematocrit (2) Hemoglobin (2) Urinalysis (1) Urine Sediment (2) Vaginal Wet Prep (1) Vaginal Wet Prep-KOH (1) Whole Blood Glucose (2)

✓ Program is included in our A2LA scope of accreditation.

Format
3 shipments

**Shipping Dates** Mar. 4, Jul. 8, Oct. 28

# MICROBIOLOGY

MICROBIOLOGY	1st Event	2nd Event	3rd Event
Ship Dates	February 5	June 3	September 16
Replacement Deadline	February 13	June 11	September 24
PT Results Due Date	February 28	June 26	October9
Verification Due Date	March 6	July 3	October 16
<b>Evaluations Available Online</b>	March 19	July 16	October 29
MYCOLOGY	1st Event	2nd Event	3rd Event
Ship Dates	January 8	May 13	August 19
Replacement Deadline	January 16	May 21	August 27
PT Results Due Date	February 28	June 26	October 9
Evaluations Available Online	March 19	July 16	October 29

MYCOBACTERIOLOGY	1st Event	2nd Event
Ship Dates	February 26	August 12
Replacement Deadline	March 5	August 20
PT Results Due Date	May 1	October 16
Evaluations Available Online	May 10	October 25

## **Microbiology Enrollment Requirements**

CLIA requires laboratories performing microbiology tests that are regulated for proficiency testing to test five regulated challenges per test event in each sub-specialty where regulated testing is performed. The five subspecialties are Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology. All non-waived tests in a subspecialty can be combined to meet the five-challenge requirement. For molecular testing of direct specimens, CMS considers only bacteriology, virology, and yeast in blood cultures to be regulated tests. Regulated tests are indicated in bold type.

Challenges tested with waived methods (e.g., Rapid Group A Strep) cannot be included in the five regulated challenges. Furthermore, if one of your methods becomes waived or you change to a waived method mid-year, you are responsible for ensuring you maintain five challenges per test event for the remaining non-waived tests in that sub-specialty.

Programs listed that have fewer than five samples are to be used as add-on options to other programs in the same sub-specialty.

Susceptibility testing counts as one challenge regardless of the number of drugs reported.

Urine colony count is not a regulated test and cannot be included as one of the five challenges.

For assistance, please contact Technical Support at 800-333-0958 or TechSupport@api-pt.com.

# BACTERIOLOGY

## Affirm VP

#### **Program Description**

Swab - For the BD Affirm VP III. For other methods see #362 - Trichomonas on page 93.

## **Program Information**

324 Affirm VP✓

## **Analytes**

Candida sp.

Gardnerella vaginalis

Trichomonas vaginalis

S

p. 16

✓ Program is included in our A2LA scope of accreditation.

Format	Shipping Dates
5 samples x 3 shipments	Feb. 5, Jun. 3, Sep

## **Basic Bacteriology Package**

## **Program Description**

For laboratories performing non-waived Group A Strep Antigen testing, Throat Cultures, and Urine Cultures. The numbers shown to the right of each analyte indicate the number of challenges per test event.

## **Program Information**

321 Basic Bacteriology Package ✓

## Analytes

Group A Strep Antigen (2) Susceptibility Testing, Urine (1) **Throat Culture (2)** Urine Colony Count (1) Urine Culture (1)

✓ Program is included in our A2LA scope of accreditation.

#### Format

5 samples x 3 shipments

**Shipping Dates** Feb. 5, Jun. 3, Sep. 16

# **Bacterial Vaginosis**

### **Program Description**

1 mL liquid - For OSOM BVBlue.

### **Program Information**

359 Bacterial Vaginosis ✓

### Analytes

**Bacterial Vaginosis Screen** 

✓ Program is included in our A2LA scope of accreditation.

Format 2 samples x 3 shipments Shipping Dates Feb. 5, Jun. 3, Sep. 16

### **Blood Culture**

### **Program Description**

Pellet + 12 mL rehydration fluid - For aerobic and anaerobic blood cultures with educational susceptibility testing as indicated. Use as an add on to other Bacteriology programs - 2 shipments per year. For molecular multiplex methods, see #368 - Blood Pathogen Panel on page 100.

# **Program Information**

361 Blood Culture ✓

### **Analytes**

#### **Blood Culture**

Susceptibility Testing (educational)

✓ Program is included in our A2LA scope of accreditation. See A2LA link on our website for analyte exceptions.

### Format

2 samples x 2 shipments

Shipping Dates Feb. 5, Sep. 16

# **Blood Culture Staph aureus (molecular)**

### **Program Description**

Pellet + 12 mL rehydration fluid - For molecular detection of Staphylococcus aureus. Use as add on to other Bacteriology programs.

### **Program Information**

355 Blood Culture Staph aureus (molecular)

# **Analytes**

Methicillin Resistant Staphylococcus aureus

Staphylococcus aureus

**Format** 2 samples x 3 shipments **Shipping Dates** Feb. 5, Jun. 3, Sep. 16 MICROBIOLOGY

### Bordetella pertussis/parapertussis (molecular)

### **Program Description**

1 mL liquid - For molecular methods for *Bordetella pertussis* and *Bordetella parapertussis*. Use as an add on to other Bacteriology programs.

### **Program Information**

363 Bordetella pertussis/parapertussis (molecular) 🗸

### **Analytes**

#### Bordetella parapertussis

Bordetella pertussis

✓ Program is included in our A2LA scope of accreditation.

#### Format

2 samples x 3 shipments

**Shipping Dates** Feb. 5, Jun. 3, Sep. 16

# C. difficile Toxin/Antigen

### **Program Description**

1 mL liquid - For *C. difficile* toxin / antigen test kits and molecular methods.

### **Program Information**

- 350 C. difficile Toxin/Antigen 5 samples ✓
- 347 C. difficile Toxin/Antigen Add on 2 samples ✓
- C47 C. difficile Toxin/Antigen Verification Program 2 samples

### **Analytes**

#### C. difficile Antigen

C. difficile Toxin

✓ Program is included in our A2LA scope of accreditation.

#### Format

3 shipments

# Campylobacter

### **Program Description**

Inocu-Swab II - For detection of *Campylobacter* sp. using antigen or culture methods. Use as an add on to other Bacteriology programs.

### **Program Information**

360 Campylobacter ✓

### **Analytes**

Campylobacter sp.

✓ Program is included in our A2LA scope of accreditation.

**Format** 2 samples x 3 shipments **Shipping Dates** Feb. 5, Jun. 3, Sep. 16

# **Carbapenem-resistant Organisms**

### **Program Description**

Swab - For detection of carbapenem resistant organisms (CRO) using molecular methods.

# **Program Information**

380 Carbapenem-resistant Organisms

### **Analytes**

IMP	NDM	VIM
KPC	OXA	

#### Format

2 samples x 3 shipments

# Chlamydia/GC (molecular)

### **Program Description**

1 mL liquid - For nucleic acid probe or amplification methods.

### **Program Information**

311 Chlamydia/GC (molecular) ✓

### **Analytes**

#### Chlamydia trachomatis

Neisseria gonorrhoeae

✓ Program is included in our A2LA scope of accreditation.

Format

5 samples x 3 shipments

**Shipping Dates** Feb. 5, Jun. 3, Sep. 16

# **Chlamydia Antigen**

### **Program Description**

1 mL liquid - For Chlamydia antigen detection kits.

### **Program Information**

316 Chlamydia Antigen - 5 samples ✓

930 Chlamydia Antigen - Add on - 2 samples 🗸

### **Analytes**

#### Chlamydia Antigen

✓ Program is included in our A2LA scope of accreditation.

Format

3 shipments

# **Comprehensive Bacteriology**

### **Program Description**

For laboratories performing a variety of bacteriology procedures. The numbers to the right of each analyte indicate the total number of challenges sent per <u>year</u>. For molecular methods for Group A Strep see #364/964 - Strep Pharyngeal (molecular) on page 85.

# **Program Information**

328 Comprehensive Bacteriology ✓

### **Analytes**

Blood Culture (w/educ. susceptibility) (1) *Campylobacter* Antigen (2) CSF Culture (w/educ. susceptibility) (1) Ear/Eye Culture (1) Educational Culture & Susc. (3) GC/Group B Strep Culture (2) Gram Stain (15) Group A Strep Antigen (3) Sputum Culture (2) Stool Culture (2) Susceptibility Testing, Urine (3) Throat Culture (1) Urine Culture (3) Urine Colony Count (3) Wound Culture (aerobic & anaerobic) (2)

✓ Program is included in our A2LA scope of accreditation. See A2LA link on our website for analyte exceptions.

Format 3 shipments **Shipping Dates** Feb. 5, Jun. 3, Sep. 16

# **CSF Bacterial Antigen (latex)**

### **Program Description**

1 mL lyophilized samples - For rapid antigen detection of Group B Streptococcus; *Haemophilus influenzae* type b; *Streptococcus pneumoniae*; and *Neisseria meningitidis* group A, C, Y, W135, or N. *meningitidis* group B / E. coli K1 from latex agglutination kit tests. Use as an add on to other Bacteriology programs - 2 shipments per year.

# **Program Information**

318 CSF Bacterial Antigen (latex)

### Analytes

**Bacterial Antigen Detection (CSF)** 

Format

2 samples x 2 shipments

Shipping Dates Feb. 5, Sep. 16



# **Extended Bacteriology - Educational**

### **Program Description**

Inocu-Swab II - Educational culture and susceptibility challenges for laboratories performing complete bacterial identification and susceptibility testing.

### **Program Information**

383 Extended Bacteriology - Educational

### **Analytes**

**Bacterial Identification** 

Susceptibility Testing

### **Format** 3 samples x 3 shipments

**Shipping Dates** Feb. 5, Jun. 3, Sep. 16

### **Gram Stain**

### **Program Description**

Fixed unstained glass slides for Gram stain and morphology. #330 does not include result reporting and is only for use as an add on to #320 - Gram Stain or #328 - Comprehensive Bacteriology.

### **Program Information**

320 Gram Stain ✓

330 Additional Gram Stain Slides

### **Analytes**

Gram Stain

Gram Stain Morphology

✓ Program is included in our A2LA scope of accreditation.

#### Format

5 samples x 3 shipments

# Gram Stain - Direct Smears (Virtual only)

### **Program Description**

Virtual images of Gram stained direct smears from various sources such as blood, sputum, CSF, and wound. Not CMS scored or reported to CAP. Please Note: Laboratories ordering *only* virtual programs must access paperwork and images online. For competency, see Q35 Gram Stain - Competency on page 131

Sputum Quality

# **Program Information**

329 Gram Stain - Direct Smears (Virtual only) ✓

### **Analytes**

Gram Stain Leukocytes

 $\checkmark$  Program is included in our A2LA scope of accreditation.

#### Format

2 samples x 3 shipments

Shipping Dates Feb. 5, Jun. 3, Sep. 16

Stain Quality

# Gram Stain - Vaginitis (Virtual only)

### **Program Description**

Virtual images of Gram stained vaginal smears for the detection of bacterial vaginosis. Not CMS scored or reported to CAP. Please Note: Laboratories ordering only virtual programs must access paperwork and images online.

# **Program Information**

319 Gram Stain - Vaginitis (Virtual only) ✓

### Analytes

Bacterial Vaginosis (Gram stain)

Nugent Score

✓ Program is included in our A2LA scope of accreditation.

Format	
3 samples x 2 shipments	

Shipping Dates Feb. 5, Sep. 16

# **Group A Strep Antigen**

### **Program Description**

Swab - For rapid Group A Strep antigen detection kits. For molecular methods see #364/964 - Strep Pharyngeal (molecular) on page 85. For competency, see Q32 - Group A Strep Antigen - Competency on page 131.

### **Program Information**

- 312 Group A Strep Antigen 5 samples ✓
- 913 Group A Strep Antigen Add on option or waived methods 3 samples 🗸
- 912 Group A Strep Antigen Add on option or waived methods 2 samples 🗸
- J12 Group A Strep Antigen Verification Program 2 samples

### Analytes

#### **Group A Strep Antigen**

✓ Program is included in our A2LA scope of accreditation.

Format	Shipping Dates
3 shipments	Feb. 5, Jun. 3, Sep. 16

### **Group B Strep (molecular)**

### **Program Description**

Swab - For molecular methods for Group B Strep.

### **Program Information**

365 Group B Strep (molecular) - 5 samples  $\checkmark$ 

965 Group B Strep (molecular) - Add on - 2 samples 🗸

### **Analytes**

#### **Group B Strep**

 $\checkmark$  Program is included in our A2LA scope of accreditation.

### Format

3 shipments

# **GC/Group B Strep Culture**

### **Program Description**

Inocu-Swab II - Culture for N. *gonorrhoeae* and Group B Strep. For molecular methods see #365/965 - Group B Strep (molecular) on page 80.

### **Program Information**

315 GC/Group B Strep Culture - 5 samples ✓

929 GC/Group B Strep Culture - Add on - 2 samples ✓

### **Analytes**

#### **Group B Strep Culture**

N. gonorrhoeae Culture

✓ Program is included in our A2LA scope of accreditation.

3 shipments Feb. 5, Jun. 3, Sep. 16	Format	Shipping Dates
	3 shipments	Feb. 5, Jun. 3, Sep. 16

# H. pylori Antigen, Stool

### **Program Description**

0.5 mL fecal suspension - For detection of *H. pylori* antigen. Use as an add on to other Bacteriology programs -2 shipments per year.

# **Program Information**

351 H. pylori Antigen, Stool ✓

### Analytes

#### Helicobacter pylori Antigen

✓ Program is included in our A2LA scope of accreditation.

### Format

2 samples x 2 shipments

Shipping Dates Feb. 5, Sep. 16



# Legionella Antigen

### **Program Description**

0.5 mL liquid - For Legionella antigen detection methods in urine. Use as an add on to other Bacteriology programs..

### **Program Information**

340 Legionella Antigen√

### **Analytes**

#### Legionella Antigen

✓ Program is included in our A2LA scope of accreditation.

**Format** 2 samples x 3 shipments **Shipping Dates** Feb. 5, Jun. 3, Sep. 16

### **MRSA Culture**

### **Program Description**

Swab - For laboratories using culture methods for MRSA. Use as an add on to other Bacteriology programs. For molecular methods see #366 - MRSA/Staph aureus (molecular) on page 83.

### **Program Information**

356 MRSA Culture ✓

### **Analytes**

#### Methicillin Resistant Staphylococcus aureus

✓ Program is included in our A2LA scope of accreditation.

**Format** 2 samples x 3 shipments

# MRSA / Staph aureus (molecular)

### **Program Description**

Swab - For molecular detection of MRSA and Staphylococcus aureus. Use as an add on to other Bacteriology programs.

### **Program Information**

366 MRSA/Staph aureus (molecular) ✓

### Analytes

Methicillin Resistant Staphylococcus aureus

✓ Program is included in our A2LA scope of accreditation.

**Format** 2 samples x 3 shipments Staphylococcus aureus

Shipping Dates Feb. 5, Jun. 3, Sep. 16

# Mycoplasma genitalium (molecular)

### **Program Description**

1 mL liquid - For detection of *Mycoplasma genitalium* using molecular methods. Use as an add on to other Bacteriology programs.

### **Program Information**

384 Mycoplasma genitalium (molecular)

### **Analytes**

Mycoplasma genitalium

**Format** 2 samples x 3 shipments Shipping Dates Feb. 5, Jun. 3, Sep. 16

# Mycoplasma pneumoniae (molecular)

### **Program Description**

1 mL liquid - For detection of *Mycoplasma pneumoniae* using molecular methods. Use as an add on to other Bacteriology programs.

### **Program Information**

374 Mycoplasma pneumoniae (molecular) ✓

### **Analytes**

#### Mycoplasma pneumoniae

✓ Program is included in our A2LA scope of accreditation.

#### Format

2 samples x 3 shipments

**Shipping Dates** Feb. 5, Jun. 3, Sep. 16

# S. pneumoniae Antigen

### **Program Description**

0.5 mL liquid - For *S. pneumoniae* antigen detection methods in urine. Use as an add on to other Bacteriology programs.

### **Program Information**

341 S. pneumoniae Antigen ✓

### **Analytes**

*S. pneumoniae* Antigen

✓ Program is included in our A2LA scope of accreditation.

### Format

2 samples x 3 shipments

### Shiga Toxin

### **Program Description**

1 mL liquid - For detection of Shiga Toxins 1 and 2 using rapid kits.

### **Program Information**

343 Shiga Toxin√

### **Analytes**

Shiga Toxin 1

Shiga Toxin 1 and/or 2

Shiga Toxin 2

✓ Program is included in our A2LA scope of accreditation.

**Format** 2 samples x 2 shipments Shipping Dates Feb. 5, Sep. 16

# **Strep Pharyngeal (molecular)**

### **Program Description**

Swab - For detection of Group A and Group C/G Strep by molecular methods.

### **Program Information**

364	Strep Pharyngeal (molecular) - 5 samples ✓
-----	--

- 964 Strep Pharyngeal (molecular) Add on 2 samples ✓
- C64 Strep Pharyngeal (molecular) Verification Program 2 samples

### **Analytes**

**Group A Strep** 

**Group C/G Strep** 

✓ Program is included in our A2LA scope of accreditation.

#### Format

3 shipments

**Shipping Dates** Feb. 5, Jun. 3, Sep. 16

# **Throat Culture**

### **Program Description**

Inocu-Swab II - For laboratories performing cultures for Group A Strep. For molecular methods see #364/964 - Strep Pharyngeal (molecular) on page 85.

### **Program Information**

313	Throat Culture - 5 samples ✓
-----	------------------------------

- 953 Throat Culture Add on 3 samples ✓
- 952 Throat Culture Add on 2 samples ✓

### **Analytes**

### **Throat Culture**

✓ Program is included in our A2LA scope of accreditation.

### Format

3 shipments

**Shipping Dates** Feb. 5, Jun. 3, Sep. 16

# **Urine Culture**

### **Program Description**

Quantitated pellet and dilution fluid - For culture (including screening tubes, paddles, and agar plates) for bacterial colony count and/or ID. Antimicrobial susceptibility testing can be performed on one sample per test event.

### **Program Information**

314	Urine Culture - 5 samples ✓
014	office culture 5 sumples

924 Urine Culture - Add on - 2 samples ✓

### **Analytes**

Susceptibility Testing	Urine Colony Count	Urine Culture
✓ Program is included in our A2LA scope of accreditation.		
Format		Shipping Dates
3 shipments		Feb. 5, Jun. 3, Sep. 16

### **VRE** Culture

### **Program Description**

Swab - For culture methods for VRE. Use as an add on to other Bacteriology programs. For molecular methods see #367 - VRE (molecular) on page 87.

### **Program Information**

357 VRE Culture ✓

### **Analytes**

#### Vancomycin Resistant Enterococci

✓ Program is included in our A2LA scope of accreditation.

**Format** 2 samples x 3 shipments **Shipping Dates** Feb. 5, Jun. 3, Sep. 16

# VRE (molecular)

### **Program Description**

Swab - For molecular methods for VRE. Use as an add on to other Bacteriology programs.

### **Program Information**

367 VRE (molecular) ✓

### **Analytes**

Vancomycin Resistant Enterococci

✓ Program is included in our A2LA scope of accreditation.

Format 2 samples x 3 shipments Shipping Dates Feb. 5, Jun. 3, Sep. 16

# MYCOBACTERIOLOGY

### **Acid Fast Smears**

### **Program Description**

Fixed unstained glass slides - Shipped two times per year as allowed by CMS.

### **Program Information**

335 Acid Fast Smears ✓

### **Analytes**

#### **Acid Fast Bacilli Smears**

✓ Program is included in our A2LA scope of accreditation.

#### Format

5 samples x 2 shipments

Shipping Dates Feb. 26, Aug. 12

# M. tuberculosis (molecular)

### **Program Description**

1 mL liquid - For detection of *M. tuberculosis* and rifampin resistance using molecular methods.

### **Program Information**

372 M. tuberculosis (molecular) ✓

### **Analytes**

M. tuberculosis detection

Rifampin resistance screen

✓ Program is included in our A2LA scope of accreditation.

Format

5 samples x 2 shipments

Shipping Dates Feb. 26, Aug. 12

# **Mycobacteriology** Culture

### **Program Description**

Liquid samples and lyophilized samples - For culture and identification of mycobacteria. Antimycobacterial susceptibility testing can be performed on one sample per test event. Shipped two times per year as allowed by CMS.

### **Program Information**

344 Mycobacteriology Culture ✓

### **Analytes**

#### Antimycobacterial Susceptibility Testing M

Mycobacteriology Identification

✓ Program is included in our A2LA scope of accreditation.

**Format** 5 samples x 2 shipments Shipping Dates Feb. 26, Aug. 12

# MYCOLOGY

# **Candida auris**

### **Program Description**

Swab - For culture and/or molecular detection of Candida auris. Use as an add on to other Mycology programs. Results for molecular methods are not scored for CMS.

### **Program Information**

393 Candida auris

### **Analytes**

Candida auris

Format 2 samples x 2 shipments

### **Candida Culture**

### **Program Description**

Inocu-Swab II - For Candida culture.

### **Program Information**

Candida Culture ✓ 317

### **Analytes**

#### **Candida** Culture

✓ Program is included in our A2LA scope of accreditation.

Format 5 samples x 3 shipments **Shipping Dates** Feb. 5, Jun. 3, Sep. 16

**Shipping Dates** 

MICROBIOLOGY

All analytes in bold type are regulated for proficiency testing by CMS. Laboratories enrolling in programs to satisfy CMS requirements for PT are responsible for ensuring they are testing five samples, three times per year.

**NEW** 

Feb. 5, Sep. 16

### **Cryptococcal Antigen**

#### **Program Description**

1 mL liquid - For Cryptococcal antigen detection.

### **Program Information**

345 Cryptococcal Antigen✓

### **Analytes**

Cryptococcal Antigen

✓ Program is included in our A2LA scope of accreditation.

Format

5 samples x 3 shipments

**Shipping Dates** Feb. 5, Jun. 3, Sep. 16

### **Dermatophyte Culture**

#### **Program Description**

Inocu-Swab II - For culture methods for dermatophytes.

### **Program Information**

332 Dermatophyte Culture ✓

### **Analytes**

#### **Dermatophyte Culture**

✓ Program is included in our A2LA scope of accreditation.

#### Format

5 samples x 3 shipments

**Shipping Dates** Jan. 8, May 13, Aug. 19

### India Ink

#### **Program Description**

1 mL liquid - For presence or absence of encapsulated yeast using India ink methods.

### **Program Information**

339 India Ink ✓

### **Analytes**

India Ink

✓ Program is included in our A2LA scope of accreditation.

```
Format
```

2 samples x 3 shipments

# **KOH Preparation**

### **Program Description**

Glass slide prepared to represent a KOH examination of skin, nail or hair.

### **Program Information**

333 KOH Preparation ✓

### **Analytes**

**KOH** Preparation

✓ Program is included in our A2LA scope of accreditation.

### Format

2 samples x 3 shipments

**Shipping Dates** Feb. 5, Jun. 3, Sep. 16

# **Mycology and Aerobic Actinomycetes**

### **Program Description**

Inocu-Swab II - For culture and identification of yeasts, molds, and aerobic actinomycetes.

# **Program Information**

Mycology and Aerobic Actinomycetes ✓ 331

### **Analytes**

Antifungal Susceptibility Testing

**Mycology Culture** 

- ► Analyte is not CAP accepted.

# Format

5 samples x 3 shipments

**Shipping Dates** Jan. 8, May 13, Aug. 19

✓ Program is included in our A2LA scope of accreditation. See A2LA link on our website for analyte exceptions.

# PARASITOLOGY

### **Blood Parasites**

### **Program Description**

Two virtual blood smears plus three Giemsa-stained thick and/or thin blood smears for the identification of blood parasites.

### **Program Information**

336 Blood Parasites ✓

### **Analytes**

#### **Blood Parasite Identification**

% Parasitemia

 $\checkmark$  Program is included in our A2LA scope of accreditation. See A2LA link on our website for analyte exceptions.

#### Format

5 samples x 3 shipments

**Shipping Dates** Feb. 5, Jun. 3, Sep. 16

# **Giardia & Cryptosporidium Antigens**

### **Program Description**

1 mL liquid - For EIA & DFA test methods.

### **Program Information**

342	Giardia & Cryptosporidium Antigens - 5 samples ✓
-----	--

932 Giardia & Cryptosporidium Antigens - Add on - 2 samples 🗸

### **Analytes**

#### Cryptosporidium Antigen

Giardia Antigen

✓ Program is included in our A2LA scope of accreditation.

Format	Shipping Dates
3 shipments	Feb. 5, Jun. 3, Sep. 16

# Parasitology

### **Program Description**

Photographs, formalin concentrates for direct examination and modified acid fast stain, and a zinc-based PVA slide. For labs performing a variety of parasitology tests. The numbers shown to the right of each analyte indicate the number of challenges per test event. For *Cryptosporidium* antigen see #342/932 - Giardia & Cryptosporidium Antigens on page 92. For Blood Parasites see #336 on page 92.

### **Program Information**

334 Parasitology ✓

### Analytes

Blood Smear Photo (1) PVA Slide (1) Formalin Concentrates (2)

✓ Program is included in our A2LA scope of accreditation.

**Format** 5 samples x 3 shipments Shipping Dates

**Stool Prep Photo (1)** 

Feb. 5, Jun. 3, Sep. 16

# **Rapid Malaria**

### **Program Description**

0.5 mL stabilized whole blood - For rapid malaria detection. Compatible with methods that detect *Plasmodium falciparum* specific histidine-rich protein 2 (HRP2).

# **Program Information**

382 Rapid Malaria

### **Analytes**

Rapid malaria detection

**Format** 3 samples x 2 shipments

Shipping Dates Feb. 5, Sep. 16

# Trichomonas

### **Program Description**

2 mL liquid - For molecular methods and Sekisui OSOM Rapid Trichomonas test. For laboratories using the BD Affirm VP III see #324 - Affirm VP on page 72.

# **Program Information**

362 Trichomonas ✓

### **Analytes**

Trichomonas vaginalis

✓ Program is included in our A2LA scope of accreditation.

**Format** 5 samples x 3 shipments

# VIROLOGY

### **HBV Viral Load**

### **Program Description**

1.5 mL plasma - For molecular quantification of HBV DNA.

### **Program Information**

442 HBV Viral Load

### **Analytes**

► HBV Viral Load

► Analyte is not CAP accepted.

**Format** 2 samples x 3 shipments **Shipping Dates** Feb. 5, Jun. 3, Sep. 16

# **HCV Viral Load**

### **Program Description**

1.5 mL plasma - For molecular detection and quantification of HCV. #439 is not scored for CMS or CAP.

### **Program Information**

439 HCV Viral Load

### **Analytes**

 HCV, qualitative
 HCV genotyping
 ► HCV viral load

 ► Analyte is not CAP accepted.
 Shipping Dates

 Format
 Shipping Dates

 2 samples x 3 shipments
 Feb. 5, Jun. 3, Sep. 16

# **HIV Viral Load**

### **Program Description**

1.5 mL plasma - For molecular quantification of HIV-1 RNA Viral Load.

### **Program Information**

440 HIV Viral Load

### **Analytes**

HIV-1 RNA Viral Load

► Analyte is not CAP accepted.

#### Format

2 samples x 3 shipments

# HPV (molecular) - 5

### **Program Description**

1 mL liquid - For detection of high risk HPV using molecular methods.

### **Program Information**

375 HPV (molecular) - 5 samples ✓

### Analytes

HPV

HPV genotyping (16, 18, & 18/45)

✓ Program is included in our A2LA scope of accreditation.

#### Format

5 samples x 3 shipments

Shipping Dates Feb. 5, Jun. 3, Sep. 16

# HPV (molecular) - 2

### **Program Description**

1 mL liquid - For detection of high risk HPV using molecular methods. Use as an add on to other Virology programs - 2 shipments per year.

### **Program Information**

975 HPV (molecular) - 2 samples ✓

### **Analytes**

#### HPV

HPV genotyping (16, 18, & 18/45)

 $\checkmark$  Program is included in our A2LA scope of accreditation.

#### Format

2 samples x 2 shipments

**Shipping Dates** Feb. 5, Sep. 16 MICROBIOLOGY

# HSV 1 & 2 (molecular)

### **Program Description**

1 mL liquid - For detection of HSV 1 and 2 using molecular methods.

# **Program Information**

373 HSV 1 & 2 (molecular)  $\checkmark$ 

### Analytes

#### Herpes Simplex Virus Type 1

Herpes Simplex Virus Type 2

✓ Program is included in our A2LA scope of accreditation.

#### Format

5 samples x 3 shipments

Shipping Dates Feb. 5, Jun. 3, Sep. 16

### **Molecular Virology**

### **Program Description**

1 mL liquid - For detection of Cytomegalovirus (CMV), Enterovirus, Human Metapneumovirus (hMPV), and Varicella-zoster virus (VZV) using molecular methods. Use as an add-on option - 2 challenges per analyte.

### **Program Information**

381 Molecular Virology

4 samples x 3 shipments

### **Analytes**

Cytomegalovirus	Human Metapneumovirus	Varicella-zoster virus	
Enterovirus			
Format		Shipping Dates	

### Norovirus

# **Program Description**

1 mL liquid - For detection of Norovirus using molecular methods. Use as an add on to other Virology programs - 2 shipments per year.

Feb. 5, Jun. 3, Sep. 16

### **Program Information**

379 Norovirus

### **Analytes**

#### Norovirus

Format	<b>Shipping Dates</b>
2 samples x 2 shipments	Feb. 5, Sep. 16

# Respiratory Virology SARS/Flu/RSV (molecular)

### **Program Description**

1 mL liquid - For molecular detection of SARS-CoV-2, Influenza A, Influenza B and RSV. For Abbott ID NOW users, see #322 - Virology Package - 5 on page 99 and #394 - SARS-CoV-2 (molecular) - 5 on page 98.

# **Program Information**

388	Respiratory Virology SARS/Flu/RSV (molecular)
C88	$Respiratory\ Virology\ SARS/Flu/RSV\ (molecular)\ -\ Verification\ Program$

### **Analytes**

Influenza A	RSV	SARS-CoV-2
Influenza B		
Format		Shipping Dates

5 samples x 3 shipments

# Rotavirus

# **Program Description**

1 mL liquid - For detection of Rotavirus antigen.

### **Program Information**

- 348 Rotavirus 5 samples ✓
- 349 Rotavirus Add on 3 samples  $\checkmark$

# **Analytes**

#### **Rotavirus Antigen**

 $\checkmark$  Program is included in our A2LA scope of accreditation.

Format		
3 shipments		

**Shipping Dates** Feb. 5, Jun. 3, Sep. 16

Feb. 5, Jun. 3, Sep. 16

### SARS-CoV-2 Antigen

#### 98 | api-pt.com | 800.333.0958

#### **Program Description**

Swab - For detection of SARS-CoV-2 antigen.

### **Program Information**

- 387 SARS-CoV-2 Antigen 5 samples NEW
- 987 SARS-CoV-2 Antigen Add on 2 samples
- C87 SARS-CoV-2 Antigen Verification Program 2 samples

### **Analytes**

SARS-CoV-2

Format	Shipping Dates
3 shipments	Feb. 5, Jun. 3, Sep. 16

### SARS-CoV-2 (molecular)

### **Program Description**

Swab - For detection of SARS-CoV-2 (COVID-19) by molecular methods. Contains the whole genome and includes variants of concern.

### **Program Information**

394 SARS-CoV-2 (molecular) - 5 samples

- 994 SARS-CoV-2 (molecular) Add on 2 samples
- C94 SARS-CoV-2 (molecular) Verification Program 2 samples

### Analytes

SARS-CoV-2

#### Format 3 shipments

**Shipping Dates** Feb. 5, Jun. 3, Sep. 16

# **ENHANCED**

NEW

# Virology Package

### **Program Description**

1 mL liquid - For Influenza A and/or B, RSV, and Adenovirus. Compatible with antigen detection kits and molecular methods. For competency, see Q31 Influenza A&B - Competency on page 132 and Q33 RSV - Competency on page 133.

# **Program Information**

- 322 Virology Package 5 samples ✓
- 942 Virology Package Add on 2 samples 🗸
- C22 Virology Package Verification Program 5 samples

### **Analytes**

Adenovirus	Influenza A or B	RSV
$\checkmark$ Program is included in our A2LA scope of accreditation.		
Format		Shipping Dates
3 shipments		Feb. 5, Jun. 3, Sep. 16

# Virology Package - waived

### **Program Description**

1 mL liquid - For waived Influenza A and/or B, RSV, and Adenovirus. Compatible with antigen detection kits and molecular methods.

# **Program Information**

933	Virology Package - waived methods $\checkmark$	
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J33 Virology Package - waived methods - Verification Program

### **Analytes**

Adenovirus	Influenza A or B	RSV
$\checkmark$ Program is included in our A2LA scope of accreditation.		
Format		Shipping Dates
2 samples x 2 shipments		Feb. 5, Sep. 16



# **MOLECULAR MULTIPLEX PROGRAMS**

For molecular testing of direct specimens, CMS considers bacteriology, virology, and yeast in blood cultures to be regulated tests. If the only regulated bacteriology, virology or mycology testing you perform is using a multiplex analyzer, you are required to participate in five challenges, three times a year for compliance with CLIA. Technical Support is available at 800-333-0958.

### **Blood Pathogen Panel**

### **Program Description**

1 mL liquid - For molecular multiplex panels. A list of targets available for reporting appears on page 104.

### **Program Information**

368 Blood Pathogen Panel ✓

### **Analytes**

Identification of Bacteria	Identification of Yeasts	Resistance Genes
$\checkmark$ Program is included in our A2LA scope of accreditation.		
Format		Shipping Dates
5 samples x 3 shipments		Feb. 5, Jun. 3, Sep. 16

### **GI Panel**

#### **Program Description**

1 mL liquid - For molecular multiplex panels. A list of targets available for reporting appears on page 104.

### **Program Information**

369 GI Panel ✓

### **Analytes**

Identification of Bacteria	Identification of Parasites	Identification of Viruses
Identification of Bacterial Toxins		
$\checkmark$ Program is included in our A2LA scope of accreditation.		
Format		Shipping Dates
5 samples x 3 shipments		Feb. 5, Jun. 3, Sep. 16

### 800.333.0958 | api-pt.com | 101

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# Joint/Wound Infection Panel

### **Program Description**

1 mL liquid - For molecular multiplex panels. Use as an add on to other Bacteriology programs. A list of targets available for reporting appears on page 104.

### **Program Information**

390 Joint/Wound Infection Panel

### Analytes

Format

**Identification of Bacteria** 

2 samples x 3 shipments

Identification of Yeasts

**Resistance Genes** 

**Shipping Dates** 

Feb. 5, Jun. 3, Sep. 16

# Meningitis Panel

### **Program Description**

1 mL liquid - For molecular multiplex panels. A list of targets available for reporting appears on page 104.

### **Program Information**

371 Meningitis Panel ✓

### **Analytes**

Identification of Bacteria	Identification of Viruses	Identification of Yeasts
$\checkmark$ Program is included in our A2LA scope of accreditation.		
Format		Shipping Dates
5 samples x 3 shipments		Feb. 5, Jun. 3, Sep. 16

# Nail Fungus Panel

### **Program Description**

1 mL lyophilized samples- For molecular multiplex panels. Use as an add on to other Bacteriology programs. A list of targets available for reporting appears on page 105.

### **Program Information**

391 Nail Fungus Panel

### **Analytes**

Identification of Bacteria lo

Identification of Fungi

**Resistance Genes** 

Format	Shipping Dates
2 samples x 3 shipments	Feb. 5, Jun. 3, Sep. 2



# ENHANCED

### **Pneumonia Panel**

#### **Program Description**

0.5 mL liquid - For molecular multiplex panels. A list of targets available for reporting appears on page 105.

### **Program Information**

378 Pneumonia Panel

### **Analytes**

Identification of Bacteria	Identification of Viruses	Resistance Genes
-		

**Format** 5 samples x 3 shipments Shipping Dates Feb. 5, Jun. 3, Sep. 16

# **Respiratory Panel**

### **Program Description**

1 mL liquid - For molecular multiplex panels. A list of targets available for reporting appears on page 105.

### **Program Information**

370 Respiratory Panel ✓

### **Analytes**

#### Identification of Bacteria

**Identification of Viruses** 

✓ Program is included in our A2LA scope of accreditation.

#### **Format** 5 samples x 3 shipments

**Shipping Dates** Feb. 5, Jun. 3, Sep. 16

Feb. 5, Jun. 3, Sep. 16

**NEW** 

### **STI Panel**

### **Program Description**

Swab - For molecular multiplex panels. Use as an add on to other Bacteriology and Virology programs. A list of targets available for reporting appears on page 105.

### **Program Information**

392 STI Panel

### **Analytes**

<b>Identification of Bacteria</b> Identification of Parasites	Identification of Spirochetes	Identification of Viruses
Format		Shipping Dates

102 | api-pt.com | 800.333.0958

2 samples x 3 shipments

# **UTI** Panel

### **Program Description**

1 mL lyophilized samples - For molecular multiplex panels. A list of targets available for reporting appears on page 105.

### **Program Information**

389 UTI Panel

### **Analytes**

Identification of Bacteria

Identification of Yeast

**Resistance Genes** 

**Format** 5 samples x 3 shipments **Shipping Dates** Feb. 5, Jun. 3, Sep. 16

# **Vaginal Panel**

### **Program Description**

1 mL liquid - For molecular multiplex panels. Use as an add on to other Bacteriology programs. A list of targets available for reporting appears on page 105.

# **Program Information**

376 Vaginal Panel

### **Analytes**

Detection of Bacterial Vaginosis	Identification of Candida	Identification of Trichomonas
Identification of Bacteria		

**Format** 2 samples x 3 shipments **Shipping Dates** Feb. 5, Jun. 3, Sep. 16

### MULTIPLEX TARGET LIST

The targets shown for each program below are available for reporting. As our multiplex programs cater to many different testing platforms, some of the targets listed may not correspond to your testing platform's menu. Laboratories should only report results for targets they are currently testing at their facility.

, , , , , , , , , , , , , , , , , , , ,	ing platform's menu. Laboratories s	368 - Blood Pathogen Panel	• · · ·	
Malagular Depti Diagd	Cutile station same		Mata and a second and a second and a second and a second	Characteristic announce an alterativity
<u>Molecular Bacti - Blood</u>	Cutibacterium acnes	Fusobacterium nucleatum	Neisseria meningitidis	Stenotrophomonas maltophilia
ACB) complex	Enterobacter sp.	Haemophilus influenzae Klebsiella aerogenes	Proteus sp.	Streptococcus sp.
cinetobacter sp. cinetobacter baumannii	Enterobacter cloacae complex		Pseudomonas aeruginosa	Streptococcus agalactiae
	Enterobacter non cloacae complex	Klebsiella oxytoca	Salmonella sp. Serratia sp.	Streptococcus anginosus group
Bacillus cereus group	Enterobacterales	Klebsiella pneumoniae		Streptococcus pneumoniae
Bacillus subtilis group	Enterococcus sp.	Lactobacillus sp. Listeria sp.	Serratia marcescens	Streptococcus pyogenes
Bacteroides fragilis	Enterococcus faecalis		Staphylococcus sp. Staphylococcus aureus	
Citrobacter sp.	Enterococcus faecium	Listeria monocytogenes		
Corynebacterium sp.	Escherichia coli	Micrococcus sp.	Staphylococcus epidermidis	
Cronobacter sakazakii	Fusobacterium necrophorum	Morganella morganii	Staphylococcus lugdunensis	<b>N</b>
Molecular Mycology - Blood	Candida famata	Candida krusei	Cryptococcus gattii	Rhodotorula
Candida albicans	Candida glabrata	Candida lusitaniae	Cryptococcus neoformans	
Candida auris	Candida guilliermondii	Candida parapsilosis	Cryptococcus neoformans/gattii	
Candida dubliniensis	Candida kefyr	Candida tropicalis	Fusarium	
Molecular Resistance Genes - Blood		mecA	NDM	vanA/B
CTX-M	mcr-1	mecC	vanA	
MP	mecA/C	OXA	vanB	
KPC	mecA/C & MREJ	OXA-48-like	VIM	
		369 - GI Panel		
<u> Molecular Bacti - Gl</u>	Enteropathogenic E. coli (EPEC)	Salmonella	Vibrio	
Campylobacter sp.	E. coli O157	Shigella	Vibrio cholerae	
Enteroaggregative E. coli (EAEC)	Plesiomonas shigelloides	Shigella/Enteroinvasive E. coli (EIEC)	Yersinia enterocolitica	
Molecular Parasite - Gl	Cryptosporidium	Cyclospora cayetanensi	Entamoeba histolytica	Giardia lamblia
<u>Molecular Toxin - Gl</u>	Enterotoxigenic E. coli (ETEC) lt/st	Shiga Toxin 1	Shiga Toxin 2	
C. difficile Toxin A/B	Shiga-like toxin producing E. coli (STEC) stx1/s	tx2		
<u> Molecular Virology - Gl</u>				
Adenovirus F 40/41	Astrovirus	Norovirus GI/GII	Rotavirus A	Sapovirus
		390 - Joint/Wound Infection Pane	I	
<u> Molecular Bacti - Joint</u>	Enterococcus faecalis	Klebsiella oxytoca	Proteus sp.	Streptococcus agalactiae
Acinetobacter baumannii	Enterococcus faecium	Klebsiella pneumoniae group	Pseudomonas aeruginosa	Streptococcus pneumoniae
naerococcus prevotii/vaginalis	Escherichia coli	Morganella morganii	Salmonella sp.	Streptococcus pyogenes
Bacteroides fragilis	Finegoldia magna	Neisseria gonorrhoeae	Serratia marcescens	
Citrobacter sp.	Haemophilus influenzae	Parvimonas micra	Staphylococcus aureus	
Cutibacterium avidum/granulosum	Kingella kingae	Peptoniphilus sp.	Staphylococcus epidermidis	
Enterobacter cloacae complex	Klebsiella aerogenes	Peptostreptococcus anaerobius	Staphylococcus lugdunensis	
Molecular Mycology - Joint	Candida albicans			
Molecular Resistance Genes - Joint	IMP	mecA/C	OXA-48-like	VIM
CTX-M	KPC	MREJ	vanA/B	
		371 - Meningitis Panel		
Molecular Bacti - Meningitis	Haemophilus influenzae	Neisseria meningiti		Streptococcus pneumoniae
ischerichia coli K1	Listeria monocytogenes	Streptococcus agal		
<u> Molecular Virology - Meningitis</u>	Enterovirus	Herpes simplex vi		Human parechovirus
Cytomegalovirus	Herpes simplex virus 1	Human herpesvire	us 6	Varicella zoster virus
<u> Molecular Mycology - Meningitis</u>	Cryptococcus neoformans/gattii			
		391 - Nail Fungus Panel		
<u> Molecular Bacti - Nail</u>	Pseudomonas aeruginosa	Staphylococcus au	eus	Streptococcus pyogenes
<u> Aolecular Mycology - Nail</u>	Acremonium (Sarocladium) strictum	Alternaria sp.		Aspergillus sp.
spergillus fumigatus	Aspergillus niger	Aspergillus terreus		Aspergillus versicolor
andida sp	Candida albicans	Candida dubliniens	is	Candida glabrata
Candida krusei	Candida lusitaniae	Candida parapsilol	osis	Candida tropicalis
ryptococcus sp.	Curvularia sp.	Epidermophyton sp	).	Epidermophyton floccosum
usarium sp.	Fusarium solani	Malassezia sp.		Meyerozyma guilliermondii
Aicrosporum audouinii	Microsporum canis	Microsporum gypse	zum	Microsporum nanum
copulariopsis brevicaulis	Scytalidium (Neoscytalidium) dimidiat	tum Trichophyton sp.		Trichophyton anthropophilic sp.
copular lopsis brevicaalis				
richophyton interdigitale (mentagrophytes)	Trichophyton rubrum	Trichophyton soude	anense	Trichophyton tonsurans
	Trichophyton rubrum Trichosporon sp.	Trichophyton soud Trichosporon beige		Trichophyton tonsurans Trichosporon mucoides
richophyton interdigitale (mentagrophytes)				

### **MULTIPLEX TARGET LIST**

The targets shown for each program below are available for reporting. As our multiplex programs cater to many different testing platforms, some of the targets listed may not correspond to your testing platform's menu. Laboratories should only report results for targets they are currently testing at their facility.

		378 - Pneumonia Panel		
Molecular Bacti - Pneumonia	Escherichia coli	Klebsiella pneumonia group	Proteus sp.	Streptococcus agalactiae
(ACB) complex	Haemophilus influenza	Legionella pneumophila	Pseudomonas aeruginosa	Streptococcus pneumoniae
Chlamydia pneumoniae	Klebsiella aerogenes	Moraxella catarrhalis	Serratia marcescens	Streptococcus pyogenes
Enterobacter cloacae complex	Klebsiella oxytoca	Mycoplasma pneumonia	Staphylococcus aureus	
Molecular Resistance Genes - Pneumonia		КРС	NDM	VIM
СТХ-М	IMP	mecA/C & MREJ	OXA-48-like	
<u> Molecular Virology – Pneumonia</u>	Coronavirus	Human Rhinovirus/Enterovirus	Influenza B	Respiratory Syncytial Virus
Adenovirus	Human Metapneumovirus	Influenza A	Parainfluenza virus	SARS-CoV-2

370 - Respiratory Panel				
Molecular Bacti - Respiratory	Bordetella parapertussis	Bordetella pertussis	Legionella pneumophilia	
Bordetella holmesii	Bordetella parapertussis/bronchiseptica	Chlamydophila pneumoniae	Mycoplasma pneumoniae	
Molecular Virology - Respiratory	Coronavirus HKU1	Human Rhinovirus / Enterovirus	Influenza B	RSV B
Adenovirus	Coronavirus NL63	Influenza A	Parainfluenza 1 - 4	Rhinovirus
Bocavirus	Coronavirus OC43	Influenza A H1	Parainfluenza Virus	SARS-CoV-2
Coronavirus	Human Metapneumovirus (hMPV)	Influenza A H3	Respiratory Syncytial Virus	
Coronavirus 229E	Human Parechovirus	Influenza A / H1-2009	RSV A	

		392 - STI Panel		
Molecular Bacti - STI	Gardnerella vaginalis	Mycoplasma genitalium	Neisseria gonorrhoeae	Ureaplasma urealyticum
Chlamydia trachomatis	Haemophilus ducreyi	Mycoplasma hominis	Ureaplasma parvum	
Molecular Parasite - STI	Trichomonas vaginalis			
Molecular Spirochete - STI	Treponema pallidum			
Molecular Virology - STI	Herpes simplex virus 1	Herpes simplex virus 2		

		389 - UTI Panel		
Molecular Bacti - Urine	Enterobacter cloacae	Klebsiella oxytoca	Proteus vulgaris	Staphylococcus saprophyticus
Acinetobacter baumannii	Enterococcus sp.	Klebsiella pneumoniae	Providencia stuartii	Streptococcus agalactiae
Aerococcus urinae	Enterococcus faecalis	Morganella morganii	Pseudomonas aeruginosa	Streptococcus pneumoniae
Bacteroides fragilis	Enterococcus faecium	Mycoplasma hominis	Serratia marcescens	Streptococcus pyogenes
Citrobacter sp.	Escherichia coli	Peptostreptococcus anaerobius	Staphylococcus sp.	Ureaplasma urealyticum
Citrobacter freundii	Klebsiella sp.	Prevotella sp.	Staphylococcus aureus	
Citrobacter koseri	Klebsiella aerogenes	Proteus mirabilis	Staphylococcus epidermidis	
Molecular Mycology - Urine	Candida albicans	Candida glabrata	Candida lusitaniae	Candida tropicalis
Candida sp.	Candida dubliniensis	Candida krusei	Candida parapsilosis	
Molecular Resistance Genes - Urine	ErmB	mefA	qnrS	vanA
AmpC	ErmC	NDM	SHV	van A/B
СТХ-М	femA	OXA	sul	vanB
CTX-M group 1	IMP	OXA-23	sul1	VIM
CTX-M group 2	IMP-7	OXA-48	sul2	
dfrA	KPC	qnr	TEM	
ErmA	mcr-1	qnrA	TetB	
Erm	mecA	qnrB	Tet M	

	376 - Vaginal Panel	
Molecular Bacti - Vaginitis		
Atopobium vaginae	Gardnerella vaginalis	Lactobacillus sp.
Molecular BV - Vaginitis	Bacterial Vaginosis	BVAB-2
Molecular Parasite - Vaginitis		
Trichomonas vaginalis		
Molecular Mycology - Vaginitis	Candida albicans	Candida dubliniensis
Candida group (albicans, tropicalis, parapsilosis and dubliniensis)	Candida glabrata	Candida glabrata-krusei
Candida krusei	Candida parapsilosis	Candida tropicalis

# IMMUNOLOGY

IMMUNOLOGY	1st Event	2nd Event	3rd Event
Ship Dates	March 25	July 29	November 18
Replacement Deadline	April 2	August 6	November 26
PT Results Due Date	April 10	August 14	December 4
Verification Due Date	April 17	August 21	December 11
<b>Evaluations Available Online</b>	April 30	September 3	December 24



# IMMUNOLOGY

### ANA

### **Program Description**

5 liquid challenges for Screening, Titer, and Pattern Interpretation. One educational case study for pattern identification. Qualitative reporting only. Designed for ANA methods other than latex agglutination. For latex agglutination methods see #429 - ANA (latex kits) on page 107.

### **Program Information**

421 ANA∽

### **Analytes**

### ANA

Anti-DNA (ds, ss) Anti-RNP Anti-RNP / Sm

Anti-Sm
Anti-SSA
Anti-SSA/SSB
Anti-SSB

Antichromatin Antibody Educational Pattern ID NEW Nuclear Titer NEW Pattern Interpretation NEW

**ENHANCED** 

✓ Program is included in our A2LA scope of accreditation. See A2LA link on our website for analyte exceptions.

#### Format

5 samples x 3 shipments

Shipping Dates Mar. 25, Jul. 29, Nov. 18

# ANA (latex kits)

### **Program Description**

0.5 mL serum - Designed for latex agglutination methods.

# **Program Information**

429 ANA (latex kits)

### **Analytes**

ANA

**Format** 5 samples x 3 shipments Shipping Dates Mar. 25, Jul. 29, Nov. 18

### Anti-CCP

### **Program Description**

1 mL serum - For qualitative, quantitative, and semi-quantitative testing.

### **Program Information**

423 Anti-CCP✓

### Analytes

Anti-Cyclic Citrullinated Peptide

✓ Program is included in our A2LA scope of accreditation.

Format

2 samples x 3 shipments

Shipping Dates Mar. 25, Jul. 29, Nov. 18

### ASO

### **Program Description**

1 mL serum - For qualitative, quantitative, and semi-quantitative (titer) methods. Qualitative and titer testing are scored for CMS.

### **Program Information**

424 ASO√

### **Analytes**

#### Anti-Streptolysin O

✓ Program is included in our A2LA scope of accreditation.

Format

5 samples x 3 shipments

Shipping Dates Mar. 25, Jul. 29, Nov. 18

### **C-Reactive Protein**

### **Program Description**

0.5 mL serum - For qualitative and quantitative CRP procedures that measure levels >1.0 mg/dL.

### **Program Information**

431 C-Reactive Protein ✓

### **Analytes**

**C-Reactive Protein** 

✓ Program is included in our A2LA scope of accreditation.

#### Format

2 samples x 3 shipments

Shipping Dates Mar. 25, Jul. 29, Nov. 18

## **Celiac Serology**

#### **Program Description**

0.3 mL serum - For qualitative, quantitative, and screening methods.

#### **Program Information**

448 Celiac Serology

#### **Analytes**

Anti-DGP, qual (IgG & ► IgA) Anti-DGP, quant (IgA & IgG) Anti-DGP, screen (IgA & IgG)

► Analyte is not CAP accepted.

**Format** 2 samples x 3 shipments Anti-DGP/tTG, screen (IgA & IgG) Anti-gliadin Antibody, qual (IgA & IgG) Anti-gliadin Antibody, quant (IgA & IgG) ► Anti-tTG Antibody, IgA, qual & quant Anti-tTG Antibody, IgG, qual & quant

Shipping Dates Mar. 25, Jul. 29, Nov. 18

## **Diagnostic Allergy**

#### **Program Description**

2 mL serum - For quantitative IgE and specific allergens. Specific allergens may be reported qualitatively or quantitatively. Specific Allergens targets will include 3 food, 3 animal, 2 tree, 1 mold, and 1 weed pollen each shipment.

## **Program Information**

419 Diagnostic Allergy ✓

437 Additional Sample Volume

## **Analytes**

Specific Allergens

Total IgE

 $\checkmark$  Program is included in our A2LA scope of accreditation.

#### Format

5 samples x 3 shipments

Shipping Dates Mar. 25, Jul. 29, Nov. 18 IMMUNOLOGY

## H. pylori Antibody

#### **Program Description**

1 mL serum - For kits that detect Helicobacter pylori antibody. For H. pylori antigen see #351 - H. pylori Antigen, Stool on page 81.

#### **Program Information**

420 H. pylori Antibody ✓

#### Analytes

H. pylori Antibody

✓ Program is included in our A2LA scope of accreditation.

#### Format

2 samples x 3 shipments

Shipping Dates Mar. 25, Jul. 29, Nov. 18

**Shipping Dates** 

Mar. 25, Jul. 29, Nov. 18

**NEW** 

## Hepatitis Be Ag & Ab

#### **Program Description**

1 mL serum - For testing Hepatitis Be antigen and/or antibody.

#### **Program Information**

449 Hepatitis Be Ag & Ab

#### Analytes

► Anti-HBe **HBeAg** 

► Analyte is not CAP accepted.

Format

5 samples x 3 shipments

## **High Sensitivity CRP**

#### **Program Description**

0.5 mL serum - For hsCRP procedures that measure levels between 0-1.5 mg/dL.

#### **Program Information**

443 High Sensitivity CRP✓

## **Analytes**

hsCRP

✓ Program is included in our A2LA scope of accreditation.

#### Format

5 samples x 3 shipments

## HSV 1 & 2 Antibody

#### **Program Description**

0.5 mL serum

#### **Program Information**

430 HSV 1 & 2 Antibody ✓

#### **Analytes**

**Format** 

 $\triangle$  HSV-1 Antibody

► HSV-1/2 Antibody

► Analyte is not CAP accepted. △ CAP acceptance pending, fall 2023.

2 samples x 3 shipments

**Shipping Dates** Mar. 25, Jul. 29, Nov. 18

HSV-2 Antibody

## **Immunology Package**

#### **Program Description**

Serum samples - Cost savings for sites that perform all of the included tests - 5 samples per analyte. ASO, Rubella, and Rheumatoid Factor may be reported as qualitative, quantitative, or as a titer; qualitative and titer testing are scored for CMS.

✓ Program is included in our A2LA scope of accreditation. See A2LA link on our website for analyte exceptions.

## **Program Information**

407 Immunology Package ✓

## **Analytes**

Anti-Streptolysin O	<b>Rheumatoid Factor</b>	Rubella	
Infectious Mononucleosis			
✓ Program is included in our A2LA scope of accreditation.			

Format 3 shipments Shipping Dates Mar. 25, Jul. 29, Nov. 18

## Immunoproteins/C3 & C4

#### **Program Description**

1 mL serum - For quantitative testing.

## **Program Information**

436 Immunoproteins/C3 & C4 ✓

## **Analytes**

Alpha-1-Antitrypsin	Haptoglobin	IgG
<ul> <li>Ceruloplasmin</li> </ul>	IgA	IgG Subclass Proteins
Complement C3	lgD	IgM
Complement C4	IgE	Kappa/Lambda ratio
► Analyte is not CAP accepted.	$\checkmark$ Program is included in our A2LA scope of accreditat	tion. See A2LA link on our website for analyte exceptions.
Format		Shipping Dates
5 samples x 3 shipments		Mar. 25, Jul. 29, Nov. 18

## Infectious Disease Serology

#### **Program Description**

0.5 mL lyophilized defibrinated plasma samples - 1 sample per target. Not CMS scored or reported to CAP. Please Note: As a regulated analyte, Rubella also requires enrollment in 5 samples, 3 times per year to meet CMS and CAP requirements. See #415 - Rubella on page 117 or #407 - Immunology Package on page 111.

## **Program Information**

438 Infectious Disease Serology

#### **Analytes**

Cytomegalovirus (IgG & $\triangle$ IgM)	Mumps Virus IgG	Toxoplasma gondii (IgG & IgM)
Epstein-Barr virus (EBV) (Anti-VCA IgG & IgM,	Rubella (IgG & IgM)	Varicella Zoster Virus (VZV) IgG
Anti-EBNA IgG & IgM, Anti-EA IgG & IgM)	Rubeola Virus IgG	<ul> <li>VZV Total Ab</li> </ul>
Analyte is not CAP accepted.	$\Delta\text{CAP}$ acceptance pending, fall 2023.	
Format		Shipping Dates
7 samples x 2 shipments		Mar. 25, Nov. 18

## **Infectious Mononucleosis**

#### **Program Description**

0.6 mL serum - For all Infectious Mononucleosis kits. #910 is not scored for CMS. For multiplex EBV reporting, see catalog #438 – Infectious Disease Serology on page 112.

## **Program Information**

410	Infectious Mononucleosis - 5 samples 🗸

910 Infectious Mononucleosis - waived - 2 samples  $\checkmark$ 

#### **Analytes**

#### Infectious Mononucleosis

✓ Program is included in our A2LA scope of accreditation.

Format	Shipping Dates
3 shipments	Mar. 25, Jul. 29, Nov. 18

## **Infectious Mononucleosis & Rheumatoid Factor**

#### **Program Description**

Serum samples - Cost savings for labs that perform both tests - 5 samples per analyte. Rheumatoid Factor results may be reported as qualitative, quantitative, or as a titer; qualitative and titer testing are scored for CMS.

## **Program Information**

411 Infectious Mononucleosis & Rheumatoid Factor 🗸

#### **Analytes**

#### Infectious Mononucleosis

**Rheumatoid Factor** 

✓ Program is included in our A2LA scope of accreditation.

#### Format 3 shipments

Shipping Dates Mar. 25, Jul. 29, Nov. 18

## Lyme Disease

#### **Program Description**

0.6 mL serum - For IgG and IgM antibody detection to Borrelia burgdorferi.

#### **Program Information**

418 Lyme Disease ✓

## **Analytes**

Lyme Disease Antibody

✓ Program is included in our A2LA scope of accreditation.

Format

2 samples x 3 shipments

**Shipping Dates** Mar. 25, Jul. 29, Nov. 18

## **Mycoplasma Antibody**

#### **Program Description**

0.5 mL serum - For kits that detect Mycoplasma pneumoniae antibody.

#### **Program Information**

428 Mycoplasma Antibody ✓

## **Analytes**

Mycoplasma Antibody

✓ Program is included in our A2LA scope of accreditation.

**Format** 2 samples x 3 shipments

## **Rapid Anti-HCV**

#### **Program Description**

0.5 mL - For rapid or waived methods only.

## **Program Information**

445 Rapid Anti-HCV

#### **Analytes**

∆ Anti-HCV

 $\Delta\,\text{CAP}$  acceptance pending, fall 2023.

**Format** 2 samples x 3 shipments Shipping Dates Mar. 25, Jul. 29, Nov. 18

## **Rapid HIV**

#### **Program Description**

1 mL serum - For laboratories using a rapid method to test for anti-HIV and/or HIV-1 p24 antigen. For other antigen/antibody methods see #417 - Viral Markers on page 119. #433 is not scored for CMS.

## **Program Information**

432 Rapid HIV - 5 samples ✓

- 433 Rapid HIV waived methods 2 samples ✓
- D33 Rapid HIV Verification Program 2 samples

## **Analytes**

Anti-HIV-1/2

HIV-1 p24 Antigen

 $\checkmark$  Program is included in our A2LA scope of accreditation.

#### Format

3 shipments

Shipping Dates Mar. 25, Jul. 29, Nov. 18

## **Rheumatic Disease Serology**

#### **Program Description**

1 mL liquid - 1 sample per analyte.

## **Program Information**

447 Rheumatic Disease Serology

#### **Analytes**

Anti-Jo-1

Anti-Scl-70

**Format** 2 samples x 2 shipments Shipping Dates Mar. 25, Nov. 18

## **Rheumatoid Factor**

#### **Program Description**

1 mL serum - For qualitative, quantitative, and semi-quantitative (titer) methods. Qualitative and titer testing are scored for CMS.

## **Program Information**

408 Rheumatoid Factor ✓

#### **Analytes**

#### **Rheumatoid Factor**

 $\checkmark$  Program is included in our A2LA scope of accreditation.

#### Format

5 samples x 3 shipments

## Rubella

#### **Program Description**

1 mL serum - For qualitative, quantitative, and semi-quantitative (titer) methods. Qualitative and titer testing are scored for CMS.

## **Program Information**

415 Rubella√

#### **Analytes**

Rubella

✓ Program is included in our A2LA scope of accreditation.

**Format** 5 samples x 3 shipments Shipping Dates Mar. 25, Jul. 29, Nov. 18

## SARS-CoV-2 Serology

#### **Program Description**

0.75 mL plasma, non-infectious - For qualitative reporting by methods detecting the presence of antibodies against SARS-CoV-2.

## **Program Information**

444 SARS-CoV-2 SerologyD44 SARS-CoV-2 Serology - Verification Program

## **Analytes**

SARS-CoV-2 (Total Ab, IgG, IgM)

#### Format

2 samples x 3 shipments

Shipping Dates Mar. 25, Jul. 29, Nov. 18

## **Syphilis Serology**

#### **Program Description**

1 mL serum - For qualitative and semi-quantitative (titer) methods for serum and CSF. Designed for RPR, VDRL, FTA, and Treponemal Antibody methods.

#### **Program Information**

416 Syphilis Serology ✓

#### **Analytes**

**Syphilis** 

✓ Program is included in our A2LA scope of accreditation.

**Format** 5 samples x 3 shipments **Shipping Dates** Mar. 25, Jul. 29, Nov. 18

## **Thyroid Antibodies**

## **Program Description**

0.5 mL serum - For quantitative testing.

#### **Program Information**

164 Thyroid Antibodies 🗸

#### **Analytes**

Thyroglobulin Antibody (Anti-TG)

Thyroid Microsomal Antibody (Anti-TPO)

 $\checkmark$  Program is included in our A2LA scope of accreditation.

**Format** 2 samples x 3 shipments

## **Viral Markers**

## **Program Description**

3 mL plasma - For anti-HIV, HIV antigen and/or Hepatitis testing. Anti-HIV and HIV-1 p24 antigen is for standard or confirmatory methods only. For rapid HIV antibody and antigen methods see #432/433 - Rapid HIV on page 115. For rapid Anti-HCV methods see #445 - Rapid Anti-HCV on page 115.

## **Program Information**

417 Viral Markers ✓

#### **Analytes**

Anti-HAV (total & IgM)	Anti-HCV	Anti-HIV-1/2, p24 Antigen
∆ Anti-HAV (IgG)	Anti-HIV-1	Anti-HIV-2
Anti-HBc (total & IgM)	Anti-HIV-1/2	HBsAg
Anti-HBs, qualitative & quantitative	Anti-HIV-1/2 Confirmatory	<b>HBsAg Confirmatory</b>
$\Delta\text{CAP}$ acceptance pending, fall 2023.	$\checkmark$ Program is included in our A2LA scope of acc	creditation.
Format		Shipping Dates
5 samples x 3 shipments		Mar. 25, Jul. 29, Nov. 18

IMMUNOLOGY

# IMMUNOHEMATOLOGY

IMMUNOHEMATOLOGY	1st Event	2nd Event	3rd Event
Ship Dates	March 25	July 29	November 18
Replacement Deadline	April 2	August 6	November 26
PT Results Due Date	April 10	August 14	December 4
Verification Due Date	April 17	August 21	December 11
Evaluations Available Online	April 30	September 3	December 24



## **IMMUNOHEMATOLOGY**

## ABO/Rh

## Program Description

 $3\,mL$  - 4% cell suspensions for ABO/Rh testing.

## **Program Information**

511 ABO/Rh 🗸

#### **Analytes**

ABO Group	ABO Subgroup	D (Rho) Type
$\checkmark$ Program is included in our A2LA scope of accreditation.		
Format		Shipping Dates
5 samples x 3 shipments		Mar. 25. Jul. 29. Nov. 18

## **Antibody Elution**

## **Program Description**

2 mL - 50% cell suspensions for antibody elution for non-ABO antibody testing.

## **Program Information**

516 Antibody Elution ✓

## **Analytes**

Antibody Elution

✓ Program is included in our A2LA scope of accreditation.

**Format** 2 samples x 2 shipments Shipping Dates Mar. 25, Nov. 18 **AMUNOHEMATOLOGY** 

## Antibody Titer - A

#### **Program Description**

2 mL serum for Anti-A titer. One 3 mL red cell sample (4% suspension) to be used as titer cell.

#### **Program Information**

519 Antibody Titer - A 🗸

## **Analytes**

Anti-A (IgM and IgG) titer

✓ Program is included in our A2LA scope of accreditation.

Format

1 samples x 2 shipments

Shipping Dates Mar. 25, Nov. 18

## Antibody Titer - D

#### **Program Description**

2 mL serum for anti-D titer. One 3 mL red cell sample (4% suspension) to be used as titer cell.

#### **Program Information**

520 Antibody Titer - D✓

## **Analytes**

Anti-D titer

✓ Program is included in our A2LA scope of accreditation.

Format	
1 samples x 2 shipments	

**Shipping Dates** Mar. 25, Nov. 18

## Antibody Titer - AD

#### **Program Description**

2 mL serum - One sample each for anti-A and anti-D titer and one 3 mL red cell sample (4% suspension) to be used as titer cell.

#### **Program Information**

521 Antibody Titer - AD ✓

#### **Analytes**

Anti-A (IgM and IgG) titer

Anti-D titer

✓ Program is included in our A2LA scope of accreditation.

**Format** 2 samples x 2 shipments Shipping Dates Mar. 25, Nov. 18

## **Automated Blood Bank**

## **Program Description**

Includes five 4 mL tubes of CPD anticoagulated whole blood. One 2 mL donor red cell suspension is included for compatibility testing and antigen typing which are compatible with Bio-Rad, Grifols, Immucor, and Ortho blood bank analyzers.

## **Program Information**

517 Automated Blood Bank ✓

E17 Automated Blood Bank - Verification Program

#### Analytes

ABO GroupAntibody ScreenABO SubgroupAntigen TypingAntibody IdentificationCompatibility Testing

D (Rho) Type

✓ Program is included in our A2LA scope of accreditation.

#### Format 3 shipments



## Automated Blood Bank with Electronic Crossmatch

#### **Program Description**

Includes five 4 mL tubes of CPD anticoagulated whole blood. One 2 mL donor red cell suspension is included for compatibility testing and antigen typing which are compatible with Bio-Rad, Grifols, Immucor, and Ortho blood bank analyzers. In addition, two donor red cell suspensions with corresponding simulated ISBT donor unit labels are included for electronic crossmatch.

## **Program Information**

537 Automated Blood Bank with Electronic Crossmatch ✓

#### **Analytes**

ABO Group ABO Subgroup Antibody Identification Antibody Screen Antigen Typing Compatibility Testing **D (Rho) Type** Electronic Crossmatch

 $\checkmark$  Program is included in our A2LA scope of accreditation.

Format 3 shipments **Shipping Dates** Mar. 25, Jul. 29, Nov. 18

## **Blood Bank**

#### **Program Description**

Includes five 2 mL samples of a 4% red cell suspension and five 3 mL samples of corresponding serum. One 2 mL donor red cell suspension is included for compatibility testing and antigen typing. For Automated Blood Bank see #517/E17 on page 123.

## **Program Information**

512 Blood Bank ✓

E12 Blood Bank - Verification Program

## **Analytes**

ABO Group	Antibody Screen	D (Rho) type
ABO Subgroup	Antigen Typing	
Antibody Identification	Compatibility Testing	

✓ Program is included in our A2LA scope of accreditation.

Format
3 shipments

Shipping Dates Mar. 25, Jul. 29, Nov. 18

## **Blood Bank with Electronic Crossmatch**

#### **Program Description**

Includes five 2 mL samples of a 4% red cell suspension and five 3 mL samples of corresponding serum. One 2 mL donor red cell suspension is included for compatibility testing and antigen typing. In addition, two donor red cell suspensions with corresponding simulated ISBT donor unit labels are included for electronic crossmatch. For Automated Blood Bank with Electronic Crossmatch see #537 on page 124.

## **Program Information**

532 Blood Bank with Electronic Crossmatch 🗸

## **Analytes**

ABO Group	Antibody Screen
ABO Subgroup	Antigen Typing
Antibody Identification	Compatibility Testing

✓ Program is included in our A2LA scope of accreditation.

Format 3 shipments **D (Rho) Type** Electronic Crossmatch

Shipping Dates Mar. 25, Jul. 29, Nov. 18

## DAT

#### **Program Description**

1 mL - 4% cell suspensions for DAT.

## **Program Information**

514 DAT ✓E14 DAT - Verification Program

## **Analytes**

**Direct Antiglobulin Testing** 

✓ Program is included in our A2LA scope of accreditation.

#### **Format** 2 samples x 3 shipments



## **DAT - Automated**

#### **Program Description**

4 mL - 15% red cell suspensions for automated DAT methods.

#### **Program Information**

534 DAT - Automated ✓

## **Analytes**

**Direct Antiglobulin Testing** 

✓ Program is included in our A2LA scope of accreditation.

Format

2 samples x 3 shipments

**Shipping Dates** Mar. 25, Jul. 29, Nov. 18

## **Educational Blood Bank**

#### **Program Description**

One case study - Sample volume varies by event. 1-2 serum samples and/or 1-2 red cell samples for special challenges that may include ABO Group, D (Rho) Type, Antibody Screen, Antibody Identification, Antigen Typing, or Compatibility Testing.

## **Program Information**

518 Educational Blood Bank 🗸

## **Analytes**

ABO Group Antibody Identification Antibody Screen Antigen Typing Compatibility Testing D (Rho) Type

✓ Program is included in our A2LA scope of accreditation.

Format

3 shipments

Shipping Dates Mar. 25, Jul. 29, Nov. 18

## **Fetal RBC**

## **Program Description**

2 mL simulated whole blood - For fetal screen, Kleihauer-Betke, and flow cytometry.

## **Program Information**

515 Fetal RBC ✓

#### **Analytes**

Fetal Screen

Hemoglobin F, quantitative

✓ Program is included in our A2LA scope of accreditation.

**Format** 2 samples x 3 shipments Shipping Dates Mar. 25, Jul. 29, Nov. 18

**Rh Slide Test** 

## **Program Description**

0.5 mL - 35-45% cell suspensions for sites that use slide methodology or Eldoncards for Rh typing.

## **Program Information**

513 Rh Slide Test ✓

## **Analytes**

D (Rho) Type

✓ Program is included in our A2LA scope of accreditation.

Format

5 samples x 3 shipments



# COMPETENCY



#### Innovative Solutions.

Technical Excellence.

## **Competency Offerings Now Available**

One of the top citations that laboratories receive during an inspection is the lack of competency assessment documentation. API can help laboratories meet this requirement. Our new Competency Programs provide tools to assist with evaluating and documenting the competency of testing personnel. These tools can be utilized in conjunction with the laboratory's established standards to meet the required elements of competency.

Included in Competency Programs:

- Frequent ship dates available to help laboratories stay up to date with competency assessments
- Observation checklists and quizzes to help laboratories ensure they have appropriate documentation to meet the required six elements of competency
- Samples with peer group data comparisons for direct observation of multiple personnel to ensure all members of the laboratory team can demonstrate accurate and reliable patient testing

Let API's Competency Programs provide a pathway for your laboratory to identify quality improvement opportunities, assess workforce development needs, and demonstrate reliable patient testing.

## **Blood Cell Identification - Competency**

#### **Program Description**

One virtual Wright stained peripheral blood smear for blood cell identification. The case study will include 5 annotated cells/objects for identification with a manual 100 WBC differential.

#### **Program Information**

Q24 Blood Cell ID - Competency

#### **Analytes**

**Blood Cell Identification** 

Manual Differential

#### Format

1 virtual image

**Shipping Dates** Available upon request

## **Blood Gas - Competency**

#### **Program Description**

Ten identical 3 mL ampules - For combination blood gas/electrolyte analyzers.

#### **Program Information**

Q11 Blood Gas - Competency

#### Analytes

Format

10 samples

BUN Calcium, ionized Chloride Creatinine Glucose Lactate Magnesium, ionized pCO<sub>2</sub> pH pO<sub>2</sub>

Potassium Sodium tCO<sub>2</sub>

Shipping Dates Available upon request

## **Body Fluid Microscopy - Competency**

#### **Program Description**

Virtual images for the identification of crystals and other formed elements/cells in pleural, peritoneal, or pericardial fluid.

#### **Program Information**

Q13 Body Fluid Microscopy - Competency

#### Analytes

Identification of formed elements

#### Format 2 - 5 targets

COMPETENCY

Shipping Dates

Available upon request

## **CSF - Competency**

#### **Program Description**

Virtual images for the identification of crystals and other formed elements/cells in CSF.

#### **Program Information**

Q14 CSF - Competency

#### Analytes

Identification of formed elements

#### Format

2 - 5 targets

**Shipping Dates** Available upon request

## Fecal Occult Blood - Competency

#### **Program Description**

One 1.5 mL positive simulated stool sample - For guaiac or immunoassay methods.

#### **Program Information**

Q22 Fecal Occult Blood - Competency

#### **Analytes**

Fecal Occult Blood

## Format

1 sample

**Shipping Dates** Available upon request

## Fern Test - Competency

#### **Program Description**

Two virtual images for the presence or absence of ferning.

#### **Program Information**

Q28 Fern Test - Competency

#### **Analytes**

Fern Test

#### Format

2 virtual images

## **Gram Stain - Competency**

#### **Program Description**

Two virtual images of Gram stained direct smears from various sources such as blood, sputum, CSF, and wound.

#### **Program Information**

Q35 Gram Stain - Competency

#### Analytes

Gram Stain Leukocytes Sputum Quality

Stain Quality

#### Format

2 virtual images

**Shipping Dates** Available upon request

## **Group A Strep Antigen - Competency**

## **Program Description**

Ten positive swabs - For rapid Group A Strep antigen detection kits. Program not compatible with molecular methods.

#### **Program Information**

Q32 Group A Strep Antigen - Competency

#### Analytes

Group A Strep Antigen

**Format** 10 samples



## i-STAT Chemistry - Competency

#### **Program Description**

Ten identical 3 mL ampules - For i-STAT analyzers.

#### **Program Information**

Q12 i-STAT Chemistry - Competency

## **Analytes**

Calcium, ionized	Hemoglobin	Potassium
Chloride	Lactate	Sodium
Creatinine	pCO <sub>2</sub>	tCO <sub>2</sub>
Glucose	pH	Urea Nitrogen (BUN)
Hematocrit	pO <sub>2</sub>	

Format

10 samples

**Shipping Dates** Available upon request

## Influenza A&B - Competency

#### **Program Description**

One 1 mL influenza A positive liquid sample and one 1 mL influenza B positive liquid sample - For antigen detection kits and most molecular methods.

## **Program Information**

Q31 Influenza A&B - Competency

## **Analytes**

Influenza A

Influenza B

## Format

2 samples

## **RSV - Competency**

#### **Program Description**

One 1 mL RSV positive liquid sample - For antigen detection kits and most molecular methods.

#### **Program Information**

Q33 RSV - Competency

#### Analytes

RSV

#### Format

1 sample

Shipping Dates Available upon request

## SARS-CoV-2 liquid (molecular) - Competency

#### **Program Description**

One 1.5 mL positive liquid sample. Contains the whole genome, providing sequence targets compatible with liquid based molecular assays. Includes variants of concern.

## **Program Information**

Q34 SARS-CoV-2 liquid (molecular) - Competency

#### **Analytes**

SARS-CoV-2

#### Format 1 sample

1 san

Shipping Dates Available upon request

## **Sperm - Competency**

#### **Program Description**

Two virtual images for the presence or absence of sperm.

#### **Program Information**

Q27 Sperm - Competency

## Analytes

Sperm

Format 2 virtual images

## **Synovial Fluid - Competency**

#### **Program Description**

Virtual images for the identification of crystals and other formed elements/cells in synovial fluid.

#### **Program Information**

Q15 Synovial Fluid - Competency

## Analytes

Identification of formed elements

#### Format

2 - 5 targets

**Shipping Dates** Available upon request

## **Urinalysis & HCG - Competency**

## **Program Description**

One 10 mL urine - For dipstick analysis and urine hCG methods.

## **Program Information**

Q21 Urinalysis & HCG - Competency

#### **Analytes**

Bilirubin
Bilirubin, confirmatory
Blood/Hemoglobin
Creatinine
Glucose

HCG Ketones Leukocyte Esterase Nitrite pH

Protein Protein, confirmatory Reducing Substance Specific Gravity Urobilinogen

Format	Shipping Dates
1 sample	Available upon request

## **Urine Sediment - Competency**

## **Program Description**

Two virtual images for identification of formed elements in urine sediment.

## **Program Information**

Q26 Urine Sediment - Competency

#### **Analytes**

Identification of formed elements

#### Format

2 virtual images

**Shipping Dates** Available upon request

## Vaginal Wet Prep - Competency

## **Program Description**

Two virtual images of Vaginal Wet Prep and two virtual images of Vaginal Wet Prep with KOH.

#### **Program Information**

Q25 Vaginal Wet Prep - Competency

#### **Analytes**

Vaginal Wet Prep

Vaginal Wet Prep (KOH)

#### **Format** 4 virtual images



## CE Credits, Automated Results, and Other Products and Services

## **Free Continuing Education Credits**

Physicians, medical technologists, and technicians enrolled with API are eligible to earn FREE continuing education credit through online self-assessment activities offered in conjunction with the American Society for Clinical Pathology (ASCP). The number of credits that can be earned depends on individual participation. For more information, go to our website at api-pt.com and select "Learn More" under the Continuing Education heading, or call us at 800-333-0958 to speak with a Customer Service Representative.

## **API DataDirect**

Using their own laboratory information system (LIS) or middleware, laboratories may now transmit proficiency testing results directly to API, a process that revolutionizes proficiency testing for clinical laboratories. No more manual data entry, no more clerical errors, no new technology systems to purchase, and no additional fees! Data-Direct is easy to use and saves time! Contact us at DataDirect@api-pt.com or call us for a demonstration.

## **Remedial Proficiency Testing**

Remedial proficiency testing is a service API offers to those who need to test specimens in addition to regular proficiency testing. This is usually required when a laboratory has had poor performance on a particular analyte in two of three test events. If your laboratory encounters a need for this service (which includes a written performance evaluation), call to speak with a Technical Specialist for more details. Remedial evaluations are not included in our A2LA scope of accreditation.

## **Troubleshooting Samples**

Occasionally, laboratories wish to re-test a proficiency testing sample as part of a corrective action plan. Most API samples are available for this purpose at a nominal charge. Our Technical Specialists can give you further information.

## **Supplemental Products**

957 API Binder with Tabs 958 Tabs only

## Verification Programs for Multiple Instruments

CLIA regulations state that if a laboratory uses multiple methods to test an analyte they must designate one instrument/method as primary for the proficiency event and test the PT samples using that instrument/method. Laboratories are not to test proficiency samples during the PT event with more than one instrument unless that is how they test all patient specimens. This restriction also applies to non-regulated analytes and to analytes categorized as waived under CLIA.

Laboratories may test proficiency samples with multiple instruments/methods after the PT due date. API's Verification programs offer the convenience of using proficiency samples and statistics to verify secondary instruments and methods, while remaining compliant with CLIA regulations. Verification samples are shipped along with PT samples. Laboratories are directed to test after the PT due date and submit results for verification samples online. Verification evaluations are available online, when the evaluations for proficiency programs are released.

Where available, verification programs are listed in the main body of the catalog along with regular PT programs. Scores from verification programs are not reported to regulatory agencies such as CMS, CAP, or The Joint Commission. Verification programs are not included in our A2LA scope of accreditation.

# Outstanding Online Features and Services

Paperless Proficiency Testing has unique features that can help you manage your proficiency testing more efficiently. Visit www.api-pt.com to learn more!

- Email is sent with shipping dates, package tracking information, and when your evaluation is ready.
- Submit, review, and print results online.
- DataDashboard trends performance over the most recent six test events.
- Free Continuing Education credits.
- Management reports for multiple labs.

<ul> <li>◊ 1-25-(OH)2 Vitamin D (D3)</li> <li>&gt; 11-Deoxycortisol</li> <li>&gt; 17-OH-Progesterone</li> <li>&gt; 6-Acetylmorphine</li> <li>&gt; A</li> <li>&gt; ABO Group (◊ ABO Subgroup typing)</li> <li>&gt; 121, 123-126</li> <li>&gt; Acetaminophen</li> <li>&gt; Acetone</li> <li>&gt; Acetone</li> <li>&gt; ACTH</li> <li>&gt; ACTH</li> <li>&gt; Adenovirus</li> <li>&gt; 99</li> <li>&gt; Affirm VP</li> <li>&gt; Affirm VP</li> <li>&gt; AKI Risk Score (IGFBP-7 * TIMP-2)</li> <li>&gt; Alcohol</li> <li>&gt; Alpha-1-Antitrypsin</li> <li>&gt; 18, 19</li> </ul>
<ul> <li>▶ 17-OH-Progesterone</li> <li>&gt; 6-Acetylmorphine</li> <li>35</li> <li>A</li> <li>&gt; ABO Group (◊ ABO Subgroup typing)</li> <li>&gt; 121, 123-126</li> <li>&gt; Acetaminophen</li> <li>&gt; 30, 35</li> <li>&gt; Acetone</li> <li>&gt; 11</li> <li>&gt; Acid Fast Smears</li> <li>&gt; ACTH</li> <li>&gt; 25</li> <li>&gt; Adenovirus</li> <li>&gt; 99</li> <li>&gt; Affirm VP</li> <li>&gt; 72</li> <li>&gt; AKI Risk Score (IGFBP-7 * TIMP-2)</li> <li>&gt; Albumin (► CSF, ◊ body fluid)</li> <li>&gt; 19, 20, 32</li> <li>&gt; Alkaline Phosphatase (◊ body fluid)</li> <li>&gt; 19, 20, 32</li> <li>&gt; Alpha-1-Antitrypsin</li> </ul>
<ul> <li>6-Acetylmorphine</li> <li>A</li> <li>ABO Group (&gt; ABO Subgroup typing)</li> <li>121, 123-126</li> <li>Acetaminophen</li> <li>30, 35</li> <li>Acetone</li> <li>11</li> <li>Acid Fast Smears</li> <li>ACTH</li> <li>Activated Clotting Time</li> <li>55, 57-59</li> <li>Adenovirus</li> <li>99</li> <li>Affirm VP</li> <li>72</li> <li>AKI Risk Score (IGFBP-7 * TIMP-2)</li> <li>32</li> <li>Albumin (&gt; CSF, &lt; body fluid)</li> <li>19, 20, 32</li> <li>Alkaline Phosphatase (&lt; body fluid)</li> <li>19, 20, 32</li> <li>Alpha-1-Antitrypsin</li> <li>Air Antitication</li> </ul>
A○ ABO Group (◊ ABO Subgroup typing)121, 123-126○ Acetaminophen30, 35◊ Acetone11○ Acid Fast Smears88▶ ACTH25○ Activated Clotting Time55, 57-59○ Adenovirus99○ Affirm VP72◊ AKI Risk Score (IGFBP-7 * TIMP-2)32○ Albumin (▶ CSF, ◊ body fluid)19, 20, 32○ Alkaline Phosphatase (◊ body fluid)19, 20, 32○ Alpha-1-Antitrypsin112
<ul> <li>ABO Group (\$ ABO Subgroup typing)</li> <li>121, 123-126</li> <li>Acetaminophen</li> <li>30, 35</li> <li>Acetone</li> <li>11</li> <li>Acid Fast Smears</li> <li>ACTH</li> <li>25</li> <li>Activated Clotting Time</li> <li>55, 57-59</li> <li>Adenovirus</li> <li>99</li> <li>Affirm VP</li> <li>72</li> <li>AKI Risk Score (IGFBP-7 * TIMP-2)</li> <li>32</li> <li>Albumin (&gt; CSF, \$ body fluid)</li> <li>19, 20, 32</li> <li>Alkaline Phosphatase (\$ body fluid)</li> <li>19, 20, 32</li> <li>Alpha-1-Antitrypsin</li> </ul>
<ul> <li>Acetaminophen</li> <li>30, 35</li> <li>Acetone</li> <li>11</li> <li>Acid Fast Smears</li> <li>ACTH</li> <li>Activated Clotting Time</li> <li>Activated Clotting Time</li> <li>55, 57-59</li> <li>Adenovirus</li> <li>99</li> <li>Affirm VP</li> <li>72</li> <li>AKI Risk Score (IGFBP-7 * TIMP-2)</li> <li>32</li> <li>Albumin (► CSF, ◊ body fluid)</li> <li>19, 20, 32</li> <li>Alkaline Phosphatase (◊ body fluid)</li> <li>19, 20, 32</li> <li>Alpha-1-Antitrypsin</li> </ul>
<ul> <li>Acetone</li> <li>Acid Fast Smears</li> <li>ACTH</li> <li>Activated Clotting Time</li> <li>Adenovirus</li> <li>Adenovirus</li> <li>Affirm VP</li> <li>AKI Risk Score (IGFBP-7 * TIMP-2)</li> <li>Albumin (► CSF, ◊ body fluid)</li> <li>I9, 20, 32</li> <li>Alcohol</li> <li>I1, 35</li> <li>Alkaline Phosphatase (◊ body fluid)</li> <li>I9, 20, 32</li> </ul>
<ul> <li>Acid Fast Smears</li> <li>ACTH</li> <li>Activated Clotting Time</li> <li>Activated Clotting Time</li> <li>Adenovirus</li> <li>Affirm VP</li> <li>Affirm VP</li> <li>AKI Risk Score (IGFBP-7 * TIMP-2)</li> <li>Albumin (► CSF, ◊ body fluid)</li> <li>I9, 20, 32</li> <li>Alcohol</li> <li>I1, 35</li> <li>Alkaline Phosphatase (◊ body fluid)</li> <li>I9, 20, 32</li> <li>Alpha-1-Antitrypsin</li> </ul>
<ul> <li>ACTH</li> <li>25</li> <li>Activated Clotting Time</li> <li>55, 57-59</li> <li>Adenovirus</li> <li>99</li> <li>Affirm VP</li> <li>72</li> <li>AKI Risk Score (IGFBP-7 * TIMP-2)</li> <li>Albumin (► CSF, ◊ body fluid)</li> <li>19, 20, 32</li> <li>Alcohol</li> <li>11, 35</li> <li>Alkaline Phosphatase (◊ body fluid)</li> <li>19, 20, 32</li> <li>Alpha-1-Antitrypsin</li> </ul>
<ul> <li>Activated Clotting Time</li> <li>Adenovirus</li> <li>Adenovirus</li> <li>Affirm VP</li> <li>AKI Risk Score (IGFBP-7 * TIMP-2)</li> <li>Akbumin (► CSF, ◊ body fluid)</li> <li>19, 20, 32</li> <li>Alcohol</li> <li>11, 35</li> <li>Alkaline Phosphatase (◊ body fluid)</li> <li>19, 20, 32</li> <li>Alpha-1-Antitrypsin</li> </ul>
<ul> <li>Adenovirus</li> <li>Affirm VP</li> <li>AKI Risk Score (IGFBP-7 * TIMP-2)</li> <li>AKI Risk Score (IGFBP-7 * TIMP-2)</li> <li>Albumin (► CSF, ◊ body fluid)</li> <li>19, 20, 32</li> <li>Alcohol</li> <li>11, 35</li> <li>Alkaline Phosphatase (◊ body fluid)</li> <li>19, 20, 32</li> <li>Alpha-1-Antitrypsin</li> </ul>
<ul> <li>Affirm VP</li> <li>AKI Risk Score (IGFBP-7 * TIMP-2)</li> <li>AKI Risk Score (IGFBP-7 * TIMP-2)</li> <li>Albumin (► CSF, ◊ body fluid)</li> <li>19, 20, 32</li> <li>Alcohol</li> <li>11, 35</li> <li>Alkaline Phosphatase (◊ body fluid)</li> <li>19, 20, 32</li> <li>Alpha-1-Antitrypsin</li> </ul>
<ul> <li>♦ AKI Risk Score (IGFBP-7 * TIMP-2)</li> <li>Albumin (► CSF, ♦ body fluid)</li> <li>19, 20, 32</li> <li>Alcohol</li> <li>11, 35</li> <li>Alkaline Phosphatase (♦ body fluid)</li> <li>19, 20, 32</li> <li>Alpha-1-Antitrypsin</li> </ul>
<ul> <li>Albumin (► CSF, ◊ body fluid)</li> <li>Alcohol</li> <li>Alkaline Phosphatase (◊ body fluid)</li> <li>Alpha-1-Antitrypsin</li> </ul>
<ul> <li>Alcohol</li> <li>Alkaline Phosphatase (\$ body fluid)</li> <li>Alkaline Phosphatase</li> <li>Alpha-1-Antitrypsin</li> </ul>
<ul> <li>○ Alkaline Phosphatase (◊ body fluid)</li> <li>○ Alpha-1-Antitrypsin</li> <li>112</li> </ul>
O Alpha-1-Antitrypsin 112
○ Alpha-fetoprotein 18 10
O ALT (SGPT) 18-20
O Amikacin 30
Amitriptyline 29
♦ Ammonia 11
♦ Amniotic Fluid pH 12
O Amphetamines 35
○ Amylase (◊ body fluid) 19, 20, 32, 35
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<ul> <li>Vancomycin</li> <li>VIM</li> <li>Vitamin B12</li> <li>Varicella Zoster Virus (&gt; VZV Total AB)</li> <li>Vitamin D</li> <li>Vitamin D</li> <li>von Willebrand Factor Activity</li> <li>von Willebrand Factor Antigen</li> <li>VRE</li> <li>W</li> <li>WBC Count (blood, manual CSF/BF)</li> <li>WBC Count (auto CSF/BF, urine)</li> <li>WBC Differential (&gt; body fluid, manual CSF/BF)</li> <li>WBC, HemoCue</li> </ul>	30 30 75 25 96,112 25 56 56 56 87 87 38-42,46 44,63 44,63





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