

**MEDICARE COVERAGE OF LABORATORY TESTING**

Please remember when ordering laboratory tests that are billed to Medicare/Medicaid or other federally funded programs, the following requirements apply:

1. Only tests that are medically necessary for the diagnosis or treatment of the patient should be ordered. Medicare does not pay for screening tests except for certain specifically approved procedures and may not pay for non-FDA approved tests or those tests considered experimental.
2. If there is reason to believe that Medicare will not pay for a test, the patient should be informed. The patient should then sign an Advance Beneficiary Notice (ABN) to indicate that he or she is responsible for the cost of the test if Medicare denies payment.
3. The ordering physician must provide an ICD-10 diagnosis code or narrative description, if required by the fiscal intermediary or carrier.
4. Organ- or disease-related panels should be billed only when all components of the panel are medically necessary.
5. Both ARUP- and client-customized panels should be billed to Medicare only when every component of the customized panel is medically necessary.
6. Medicare National Limitation Amounts for CPT codes are available through the Centers for Medicare & Medicaid Services (CMS) or its intermediaries. Medicaid reimbursement will be equal to or less than the amount of Medicare reimbursement.

The CPT Code(s) for test(s) profiled in this bulletin are for informational purposes only. The codes reflect our interpretation of CPT coding requirements, based upon AMA guidelines published annually. CPT codes are provided only as guidance to assist you in billing. ARUP strongly recommends that clients reconfirm CPT code information with their local intermediary or carrier. CPT coding is the sole responsibility of the billing party.

Hot Line Page #	Test Number	Summary of Changes by Test Name	Name Change	Methodology	Performed/Reported Schedule	Specimen Requirements	Reference Interval	Interpretive Data	Note	CPT Code	Component Change	Other Interface Change	New Test	Inactive
7	<a href="#">0060997</a>	Acid-Fast Bacillus (AFB) Identification with Reflex to Susceptibility					x							
7	<a href="#">2013015</a>	Adenovirus Antibody, Serum											x	
7	<a href="#">2002582</a>	Aldosterone and Renin, Direct with Ratio				x								
8	<a href="#">2013024</a>	Allergens, Food, Egg Components IgE											x	
49	<a href="#">2007880</a>	Alpha Subunit, Pituitary Glycoprotein Hormones												x
8	<a href="#">2013034</a>	Alpha Subunit, Pituitary Glycoprotein Hormones (PGH)											x	
9	<a href="#">0020506</a>	Amylase, Body Fluid				x		x			x			
9	<a href="#">0060198</a>	Anaerobic Organism Identification with Reflex to Susceptibility							x					
9	<a href="#">2005077</a>	Angelman Syndrome and Prader-Willi Syndrome by Methylation- <b>Sensitive PCR</b>	x											

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9	<a href="#">2012232</a>	Angelman Syndrome and Prader-Willi Syndrome by Methylation- <b>Sensitive PCR</b> , Fetal	x			x								
9	<a href="#">0013006</a>	Antibody Titer				x			x					
9	<a href="#">0060059</a>	Antimicrobial Susceptibility - D-Test (Macrolide, Lincosamide, Streptogramin Resistance)			x									
9	<a href="#">0060708</a>	Antimicrobial Susceptibility - <i>Enterococcus</i>			x									
10	<a href="#">0063999</a>	Antimicrobial Susceptibility - Extended Spectrum Beta Lactamase			x									
10	<a href="#">0060211</a>	Antimicrobial Susceptibility - <i>mecA</i> Gene by PCR			x									
10	<a href="#">0060203</a>	Antimicrobial Susceptibility - MIC/MBC			x									
10	<a href="#">0060193</a>	Antimicrobial Susceptibility - <i>Nocardia</i>			x									
10	<a href="#">0060216</a>	Antimicrobial Susceptibility - Nonfermenter			x									
10	<a href="#">0060200</a>	Antimicrobial Susceptibility - Not Otherwise Specified			x									
10	<a href="#">0060707</a>	Antimicrobial Susceptibility - <i>Staphylococcus</i>			x									
10	<a href="#">0060221</a>	Antimicrobial Susceptibility - <i>Streptococcus pneumoniae</i>			x									
10	<a href="#">0095505</a>	Autoimmune Lymphoproliferative Profile					x					x		
10	<a href="#">2008420</a>	<b>BCR-ABL1</b> Mutation Analysis for <b>Tyrosine Kinase Inhibitor Resistance</b> by Next Generation Sequencing	x											
11	<a href="#">0050388</a>	Beta Globin ( <i>HBB</i> ) Sequencing, Fetal									x			
49	<a href="#">0051288</a>	Beta-2-Adrenergic Receptor ( <i>A2BR2</i> ) Haplotyping												x
11	<a href="#">0020510</a>	Bilirubin, Total, Body Fluid				x		x			x			
11	<a href="#">2012647</a>	Buprenorphine and Metabolites, Serum or Plasma, Quantitative			x		x							
11	<a href="#">2008708</a>	Calculi Risk Assessment, Urine									x			
11	<a href="#">0020746</a>	Cancer Antigen-GI (CA 19-9), Body Fluid				x		x			x			
49	<a href="#">0091166</a>	Carbamazepine - 10,11 Epoxide, Urine												x
11	<a href="#">0091352</a>	Carbidopa and Levodopa Quantitative, Serum or Plasma				x								
12	<a href="#">0020742</a>	Carcinoembryonic Antigen, Fluid				x		x			x			
12	<a href="#">2012844</a>	CD200 by Immunohistochemistry											x	
13	<a href="#">2008114</a>	Celiac Disease Reflexive Cascade					x							
13	<a href="#">2013085</a>	Chikungunya by PCR											x	
49	<a href="#">0090346</a>	Chloramphenicol												x
14	<a href="#">0020163</a>	Chloride, Fluid				x		x			x			
14	<a href="#">0020714</a>	Cholesterol, Fluid				x		x			x			

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14	<a href="#">0020031</a>	Cholesterol, Serum or Plasma							x					
14	<a href="#">2002298</a>	Chromosome FISH, Interphase				x								
14	<a href="#">2002299</a>	Chromosome FISH, Metaphase				x								
14	<a href="#">2003304</a>	Complement Component <b>Level 3a</b>	x									x		
14	<a href="#">2003180</a>	Complement Component <b>Level 4a</b>	x									x		
14	<a href="#">0099072</a>	Complement Component <b>Level 6</b>	x									x		
15	<a href="#">2009416</a>	Complement Factor H <b>Level (B-1H)</b>	x									x		
16	<a href="#">2013098</a>	Cytochrome P450 Genotype Panel											x	
18	<a href="#">0051394</a>	Cytokine <b>Panel</b>	x				x				x			
19	<a href="#">2013111</a>	Cytokine Production by Mononuclear Cells in Response to Antigen and Mitogen Stimulation											x	
20	<a href="#">2013109</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation											x	
49	<a href="#">0051540</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, 12 Cytokines												x
49	<a href="#">0051574</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, Interferon gamma												x
49	<a href="#">0051580</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, Interleukin 1 beta												x
49	<a href="#">0051578</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, Interleukin 10												x
49	<a href="#">0051579</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, Interleukin 13												x
49	<a href="#">0051571</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, Interleukin 2												x
49	<a href="#">0051572</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, Interleukin 2 Receptor (CD25), Soluble												x
49	<a href="#">0051576</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, Interleukin 4												x
49	<a href="#">0051577</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, Interleukin 5												x
49	<a href="#">0051581</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, Interleukin 6												x
49	<a href="#">0051582</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, Interleukin 8												x
49	<a href="#">0051583</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, Tumor Necrosis Factor alpha												x
20	<a href="#">2012166</a>	Dihydropyrimidine Dehydrogenase ( <i>DPYD</i> ), 3 Variants	x	x	x	x					x			

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49	<a href="#">0091467</a>	Dipyridamole, Serum or Plasma												x
21	<a href="#">2006621</a>	Drug Detection Panel, Umbilical Cord Tissue, Qualitative				x	x				x			
49	<a href="#">0090560</a>	Drug Screen (Nonforensic), Comprehensive, Serum and Urine												x
21	<a href="#">0020410</a>	Electrolyte Panel				x								
21	<a href="#">2002902</a>	Epstein-Barr Virus (EBV) by in situ Hybridization, Paraffin									x			
22	<a href="#">2001961</a>	Familial Mutation, Targeted Sequencing								x				
22	<a href="#">2001980</a>	Familial Mutation, Targeted Sequencing, Fetal				x		x	x					
22	<a href="#">0092442</a>	Galactokinase, Blood			x	x								
22	<a href="#">2012678</a>	Gastrointestinal Bacterial Panel by PCR										x		
23	<a href="#">2011470</a>	<i>GLI3</i> -Related Disorders ( <i>GLI3</i> ) Sequencing						x						
23	<a href="#">2011465</a>	<i>GLI3</i> -Related Disorders ( <i>GLI3</i> ) Sequencing and Deletion/Duplication						x						
23	<a href="#">0020503</a>	Glucose, Body Fluid				x	x				x			
23	<a href="#">0092068</a>	Hairstat 5 Reflexive Panel				x								
24	<a href="#">0020053</a>	HDL Cholesterol							x					
49	<a href="#">2008440</a>	Herpesvirus 8 (HHV-8) DNA, Quantitative Real-Time PCR												x
49	<a href="#">2002996</a>	Herpesvirus 8 DNA, Qualitative Real-Time PCR												x
24	<a href="#">2013089</a>	Human Herpesvirus 8 (HHV-8) by Quantitative PCR											x	
25	<a href="#">2013107</a>	Human Immunodeficiency Virus Types 1 and 2 (HIV-1/2) Antibody Differentiation, Supplemental											x	
25	<a href="#">2002896</a>	Human Papillomavirus (HPV) Low Risk by in situ Hybridization, Paraffin									x			
26	<a href="#">0050980</a>	Humoral Immunity Panel I					x							
27	<a href="#">2013101</a>	3-Hydroxy-3-Methylglutaryl Coenzyme A Reductase (HMGCR) Antibody, IgG											x	
27	<a href="#">0050667</a>	Immune Complex Panel				x								
27	<a href="#">0050340</a>	Immunoglobulin A					x							
28	<a href="#">0093149</a>	Immunoglobulin A Subclasses (1 and 2)	x				x							
28	<a href="#">0050576</a>	Immunoglobulin G Subclass 4					x							
29	<a href="#">0050577</a>	Immunoglobulin G Subclasses (1, 2, 3, 4)					x							
29	<a href="#">0050355</a>	Immunoglobulin M					x							
30	<a href="#">0050630</a>	Immunoglobulins (IgA, IgG, IgM), Quantitative					x							
30	<a href="#">2013115</a>	Interleukin 17											x	

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49	<a href="#">0051393</a>	Interleukin-1-Receptor-Associated Kinase-4 (IRAK-4) Deficiency Screen												x
31	<a href="#">2000271</a>	Isohemagglutinin Titer, IgG				x								
31	<a href="#">2000280</a>	Isohemagglutinin Titer, IgG and IgM	x			x								
31	<a href="#">2000270</a>	Isohemagglutinin Titer, IgM				x								
31	<a href="#">2002888</a>	Kappa/Lambda Light Chain Panel by in situ Hybridization, Paraffin									x			
32	<a href="#">2012207</a>	<i>KIT</i> D816V Mutation Detection by PCR for Gleevec Eligibility in Aggressive Systemic Mastocytosis (ASM)											x	
32	<a href="#">0020505</a>	Lactate Dehydrogenase Total, Body Fluid				x	x				x			
33	<a href="#">0020006</a>	Lactate Dehydrogenase, Serum or Plasma				x								
33	<a href="#">0020715</a>	Lipase, Fluid				x	x				x			
49	<a href="#">0091295</a>	Loxapine Quantitative, Serum or Plasma												x
33	<a href="#">0030181</a>	Lupus Anticoagulant Reflexive Panel					x							
34	<a href="#">2013018</a>	Lurasidone Quantitative, Serum or Plasma											x	
35	<a href="#">2013117</a>	Lymphocyte Antigen and Mitogen Proliferation Panel with Cytokine Response											x	
49	<a href="#">0051584</a>	Lymphocyte Antigen and Mitogen Proliferation Panel with Cytokine Response to Mitogens, 12 Cytokines												x
49	<a href="#">0051587</a>	Lymphocyte Antigen and Mitogen Proliferation Panel with Cytokine Response to Mitogens, Monokines												x
49	<a href="#">0051585</a>	Lymphocyte Antigen and Mitogen Proliferation Panel with Cytokine Response to Mitogens, TH1 Cytokines												x
49	<a href="#">0051586</a>	Lymphocyte Antigen and Mitogen Proliferation Panel with Cytokine Response to Mitogens, TH2 Cytokines												x
36	<a href="#">2013082</a>	<i>MET</i> Gene Amplification by FISH											x	
49	<a href="#">0091543</a>	Midazolam Quantitation, Serum or Plasma												x
36	<a href="#">2013014</a>	Mitotane, Serum or Plasma											x	
37	<a href="#">0050615</a>	Monoclonal Protein Detection Quantitation and Characterization, SPEP, IFE, IgA, IgG, IgM, Serum					x							
38	<a href="#">2002715</a>	Monoclonal Protein Detection, Quantitation, Characterization, SPEP, IFE, IgA, IgG, IgM, FLC					x							
39	<a href="#">2007967</a>	Motor and Sensory Neuropathy Evaluation with Immunofixation Electrophoresis and Reflex to Titer and Neuronal Immunoblot					x							

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41	<a href="#">0051225</a>	Motor Neuropathy Panel					x							
41	<a href="#">0081352</a>	Mucopolysaccharides Screen - Electrophoresis and Quantitation, Urine	x							x				
42	<a href="#">2007190</a>	Occult Blood, Fecal by Immunoassay				x								
42	<a href="#">0098834</a>	Oxcarbazepine or Eslicarbazepine Metabolite (MHD)	x									x		
42	<a href="#">2010102</a>	PCA3 - Prostate Cancer Biomarker by Transcription-Mediated Amplification			x	x								
43	<a href="#">2012147</a>	PDGFRB FISH for Gleevec Eligibility in Myelodysplastic Syndrome/Myeloproliferative Disease (MDS/MPD)											x	
44	<a href="#">2013025</a>	Perampanel Quantitative, Serum or Plasma											x	
44	<a href="#">2013008</a>	Periprosthetic Joint Infection (PJI) Detection (Synovasure)											x	
45	<a href="#">2013070</a>	Platelet Surface Glycoprotein Expression (PGE) by Flow Cytometry, Whole Blood											x	
45	<a href="#">0020155</a>	Potassium, Fluid				x		x			x			
45	<a href="#">2008095</a>	14-3-3 Protein Tau/Theta with Reflex to RT-QuIC Analysis, CSF				x								
45	<a href="#">0020502</a>	Protein, Total, Body Fluid				x		x			x			
45	<a href="#">0080312</a>	Pyruvic Acid, CSF				x								
46	<a href="#">0050302</a>	Raji Cell Immune Complex Assay				x								
46	<a href="#">2003347</a>	Rheumatoid Factor, Body Fluid				x		x			x			
46	<a href="#">2012618</a>	Risk of Ovarian Malignancy Algorithm											x	
47	<a href="#">2013011</a>	Selenium, RBCs											x	
47	<a href="#">0020154</a>	Sodium, Fluid				x		x			x			
47	<a href="#">0091100</a>	Sulfonylurea Hypoglycemia Panel, Quantitative, Urine	x											
47	<a href="#">2011134</a>	Thiopurine Drug Metabolites								x				
47	<a href="#">0050920</a>	Treponema pallidum Antibody, IgG by ELISA					x							
47	<a href="#">0050787</a>	Trichinella Antibody, IgG by ELISA	x											
48	<a href="#">0020713</a>	Triglycerides, Fluid				x		x			x			
48	<a href="#">0020040</a>	Triglycerides, Serum or Plasma				x			x					
48	<a href="#">0020513</a>	Uric Acid, Body Fluid				x		x			x			
48	<a href="#">0020026</a>	Uric Acid, Serum or Plasma							x					
48	<a href="#">0095263</a>	VAP Cholesterol, Serum				x								
48	<a href="#">0080380</a>	Vitamin C (Ascorbic Acid), Plasma				x								

Quarterly HOT LINE: Effective February 16, 2016

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49	<a href="#">0091383</a>	Xylenes (Total), Serum or Plasma												x

**[0060997](#) Acid-Fast Bacillus (AFB) Identification with Reflex to Susceptibility MC AFBIS**

**Reference Interval:** Complete identification and susceptibility of clinically significant isolates of *M. tuberculosis* complex, *M. kansasii*, *M. avium-intracellulare* complex, *M. fortuitum* complex, *M. abscessus* complex, *M. chelonae*, *M. immunogenum* and any isolate from a significant source.

**New Test [2013015](#) Adenovirus Antibody, Serum ADENO AB**  
Available January 19, 2016

**Methodology:** Semi-Quantitative Complement Fixation  
**Performed:** Varies  
**Reported:** 3-8 days

**Specimen Required:** Collect: Plain red or serum separator tube (SST).  
Specimen Preparation: Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)  
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.  
Unacceptable Conditions:  
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 1 month

**Reference Interval:** By Report

**CPT Code(s):** 86603

New York DOH Approved.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.

**[2002582](#) Aldosterone and Renin, Direct with Ratio A/DR**

**Specimen Required:**  
Specimen Preparation: Separate from cells ASAP. Transfer 1 mL serum **AND** 2 mL EDTA plasma to individual ARUP Standard Transport Tubes and freeze immediately. (Min: 0.5 mL serum **AND** 1 mL EDTA plasma)

**New Test**     [2013024](#)  
Available January 19, 2016

**Allergens, Food, Egg Components IgE**

**EGG COMP**

**Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay  
**Performed:** Sun-Sat  
**Reported:** 1-2 days

**Specimen Required:** Patient Prep: Multiple patient encounters should be avoided.  
Collect: Serum Separator Tube (SST). Multiple specimen tubes should be avoided.  
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum **plus** 0.1 mL for each additional allergen ordered to an ARUP Standard Transport Tube. (Min: 0.5 mL **plus** 0.04 mL for each allergen ordered)  
Storage/Transport Temperature: Refrigerated.  
Unacceptable Conditions: Hemolyzed, icteric, or lipemic specimens.  
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

**Reference Interval:**

Reporting Range (reported in kU/L)	Probability of IgE Mediated Clinical Reaction	Class Scoring
Less than 0.10	No significant level detected	0
0.10 - 0.34	Clinical relevance undetermined	0/1
0.35 - 0.70	Low	1
0.71 - 3.50	Moderate	2
3.51 - 17.50	High	3
17.51 - 50.00	Very high	4
50.01 - 100.00	Very high	5
Greater than 100.00	Very high	6

**Interpretive Data:** Allergen results of 0.10-0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. Even though increasing ranges are reflective of increasing concentrations of allergen-specific IgE, these concentrations may not correlate with the degree of clinical response or skin testing results when challenged with a specific allergen. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.

**Note:** Allergens included in this panel: Ovomucoid, Ovalbumin, Egg White, and Whole Egg.

**CPT Code(s):** 86003 x4

New York DOH Approved.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.

**New Test**     [2013034](#)  
Available April 4, 2016

**Alpha Subunit, Pituitary Glycoprotein Hormones (PGH)**

**A SUB PGH**

**Methodology:** Quantitative Chemiluminescent Immunoassay  
**Performed:** Varies  
**Reported:** 3-16 days

**Specimen Required:** Collect: Serum Separator Tube (SST) or Plain Red. Also acceptable: Lavender EDTA, pink (K<sub>2</sub> EDTA) or Green (Sodium Heparin).  
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.25 mL) Freeze immediately.  
Storage/Transport Temperature: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**  
Unacceptable Conditions:  
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 24 hours; Frozen: 6 months

**CPT Code(s):** 83520

New York DOH Approved.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.



**0020506 Amylase, Body Fluid AMY-FL**

**Specimen Required:**

Collect: Drain, Pancreatic, or Peritoneal/Ascites fluid.

**Interpretive Data:** For information on body fluid reference ranges and/or interpretive guidance visit <http://aruplab.com/bodyfluids/>

See Compliance Statement B: [www.aruplab.com/CS](http://www.aruplab.com/CS)

**HOT LINE NOTE:** There is a component change associated with this test.

Remove component 0097114, SR Source  
Add component 2013043, Amylase Fluid Source

**0060198 Anaerobic Organism Identification with Reflex to Susceptibility MC ANAIS**

**Note:** Testing performed and associated charges billed depends on specimen source and type of organism suspected. If a significant organism is identified, then the appropriate susceptibility panel will be added. An additional processing fee will be billed for all mixed cultures, as indicated in the specimen requirements. Although, susceptibility testing is not automatically performed on isolates of unknown clinical significance, testing may be requested by contacting the laboratory.

Submission of mixed cultures will result in delayed turnaround time and increased charges. Isolation of organism should be ensured prior to submission. Order a separate test for each organism identification required.

Avoid submission of isolates in liquid media where possible. Submission of liquid media commonly results in mixed and/or non-viable cultures.

Anaerobe susceptibility testing is appropriate in the case of serious infections involving blood, bone, joint, tissue, or brain abscess. (Refer to Antimicrobial Susceptibility – Anaerobe, ARUP test code 0060202).

For identification by 16s rDNA sequencing only, order Organism Identification by 16s rDNA Sequencing (ARUP test code 0060720).

**2005077 Angelman Syndrome and Prader-Willi Syndrome by Methylation-Sensitive PCR AS PWS**

**2012232 Angelman Syndrome and Prader-Willi Syndrome by Methylation-Sensitive PCR, AS PWS FE  
Fetal**

**Specimen Required:**

Collect: **Fetal Specimen:** Four (4) T-25 flasks at 80 percent confluency of cultured amniocytes. **If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787.** Or amniotic fluid.

**AND Maternal Cell Contamination Specimen:** Lavender (EDTA), pink (K<sub>2</sub>EDTA), or yellow (ACD Solution A or B).

Specimen Preparation: **Cultured Amniocytes:** Fill flasks with culture media. Transport four (4) T-25 flasks at 80 percent confluency of cultured amniocytes. Backup cultures must be retained at the client's institution until testing is complete.

**OR Amniotic Fluid:** Transport 20 mL unspun fluid. (Min: 10 mL)

**AND Maternal Cell Contamination Specimen:** Transport 3 mL whole blood. (Min: 1 mL)

**0013006 Antibody Titer IRL-ABTR1**

**Specimen Required:**

Collect: Lavender (EDTA) or Pink K<sub>2</sub>EDTA.

**Note:** Antibody identification must be performed prior to performing this test. Additional charges apply.

**0060059 Antimicrobial Susceptibility - D-Test (Macrolide, Lincosamide, Streptogramin Resistance) MA DTEST**

**Performed:** Sun-Sat

**Reported:** 2-4 days

**0060708 Antimicrobial Susceptibility - Enterococcus MA ENTERO**

**Performed:** Sun-Sat

**Reported:** 2-4 days

Quarterly HOT LINE: Effective February 16, 2016

<a href="#"><u>0063999</u></a>	<b>Antimicrobial Susceptibility - Extended Spectrum Beta Lactamase</b>	<b>MA ESBL</b>
<b>Performed:</b>	Sun-Sat	
<b>Reported:</b>	2-4 days	
<a href="#"><u>0060211</u></a>	<b>Antimicrobial Susceptibility - <i>mecA</i> Gene by PCR</b>	<b>MA MEC</b>
<b>Performed:</b>	Sun-Sat	
<b>Reported:</b>	1-3 days	
<a href="#"><u>0060203</u></a>	<b>Antimicrobial Susceptibility - MIC/MBC</b>	<b>MA MBC</b>
<b>Performed:</b>	Sun-Sat	
<b>Reported:</b>	2-6 days	
<a href="#"><u>0060193</u></a>	<b>Antimicrobial Susceptibility - <i>Nocardia</i></b>	<b>MA NOC</b>
<b>Performed:</b>	Sun-Sat	
<b>Reported:</b>	3-6 days	
<a href="#"><u>0060216</u></a>	<b>Antimicrobial Susceptibility - Nonfermenter</b>	<b>MA NF</b>
<b>Performed:</b>	Sun-Sat	
<b>Reported:</b>	2-4 days	
<a href="#"><u>0060200</u></a>	<b>Antimicrobial Susceptibility - Not Otherwise Specified</b>	<b>MA SENS</b>
<b>Performed:</b>	Sun-Sat	
<b>Reported:</b>	2-4 days	
<a href="#"><u>0060707</u></a>	<b>Antimicrobial Susceptibility - <i>Staphylococcus</i></b>	<b>MA STAPH</b>
<b>Performed:</b>	Sun-Sat	
<b>Reported:</b>	2-4 days	
<a href="#"><u>0060221</u></a>	<b>Antimicrobial Susceptibility - <i>Streptococcus pneumoniae</i></b>	<b>MA SPN</b>
<b>Performed:</b>	Sun-Sat	
<b>Reported:</b>	2-4 days	
<a href="#"><u>0095505</u></a>	<b>Autoimmune Lymphoproliferative Profile</b>	<b>ALPS</b>

**Reference Interval:** Effective February 16, 2016  
Reports include age appropriate reference intervals and interpretation.

Test Number	Components	0-23 months	2 years and older
	% Alpha/Beta+, CD4-, CD8-	0-1.5%	0-1.5%
	Absolute Alpha/Beta+, CD4-, CD8-	0-33 cells/μL	0-33 cells/μL
	% CD5+, CD20+	0-2%	0-4%
	Absolute CD5+, CD20+	0-150 cells/μL	0-100 cells/μL
	% CD3+, HLA-DR+	0-8%	0-11%
	Absolute CD3+, HLA-DR+	0-600 cells/μL	0-320 cells/μL

**HOT LINE NOTE:** There is a numeric map change associated with this test.  
Change the numeric map for component 0095516, % Alpha/Beta+, CD4-, CD8- from XXX to **XX.X**  
Change the numeric map for component 0095517, Absolute Alpha/Beta+, CD4-, CD8- from XXXX to **XXX**

<a href="#"><u>2008420</u></a>	<b>BCR-ABL1 Mutation Analysis for Tyrosine Kinase Inhibitor Resistance by Next Generation Sequencing</b>	<b>BCRABL NGS</b>
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Quarterly HOT LINE: Effective February 16, 2016

**0050388**

**Beta Globin (*HBB*) Sequencing, Fetal**

**BGSEQ FE**

**HOT LINE NOTE:** There is a component change associated with this test.

Remove component 0050578, Beta Globin Full Gene Sequencing  
Add component 2013108, BGSEQ FE, Interpretation

**0020510**

**Bilirubin, Total, Body Fluid**

**TBILI-FL**

**Specimen Required:**

Collect: Biliary/Hepatic, Drain, Peritoneal/Ascites, or Pleural fluid.

**Interpretive Data:** For information on body fluid reference ranges and/or interpretive guidance visit <http://aruplab.com/bodyfluids/>

See Compliance Statement B: [www.aruplab.com/CS](http://www.aruplab.com/CS)

**HOT LINE NOTE:** There is a component change associated with this test.

Remove component 0097114, SR Source  
Add component 2013060, Bilirubin, Total Fluid Source

**2012647**

**Buprenorphine and Metabolites, Serum or Plasma, Quantitative**

**BUPRSP**

**Performed:** Tue, Fri  
**Reported:** 1-5 days

**Reference Interval:** Effective February 16, 2016

Drugs Covered	Cutoff Concentrations
Buprenorphine	1 ng/mL
Norbuprenorphine	1 ng/mL

**2008708**

**Calculi Risk Assessment, Urine**

**CRA**

**HOT LINE NOTE:** There is a component change associated with this test.

Add component 2012774, EER Calculi Risk Assessment Panel, Urine

**0020746**

**Cancer Antigen-GI (CA 19-9), Body Fluid**

**CA-GI FL**

**Specimen Required:**

Collect: Biliary/Hepatic, CSF, Pancreatic, Peritoneal/Ascites, or Pleural fluid.

**Interpretive Data:** The Roche CA 19-9 electrochemiluminescent immunoassay is used. Results obtained with different test methods or kits cannot be used interchangeably. CA 19-9 is useful in monitoring pancreatic, hepatobiliary, gastric, hepatocellular, and colorectal cancer. The CA 19-9 value, regardless of level, should not be interpreted as absolute evidence of the presence or absence of malignant disease.

For information on body fluid reference ranges and/or interpretive guidance visit <http://aruplab.com/bodyfluids/>

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement B: [aruplab.com/CS](http://aruplab.com/CS)

**HOT LINE NOTE:** There is a component change associated with this test.

Remove component 0020777, Source, Fluid  
Add component 2013040, Cancer Antigen-GI(CA19-9), Fluid Source

**0091352**

**Carbidopa and Levodopa Quantitative, Serum or Plasma**

**SINEMET SP**

**Specimen Required:**

Storage/Transport Temperature: **CRITICAL FROZEN**. Separate specimens must be submitted when multiple tests are ordered..  
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 1 month

**0020742**

**Carcinoembryonic Antigen, Fluid**

**CEA FL**

**Specimen Required:**

Collect: CSF, Pancreatic, Pericardial, Peritoneal/Ascites or Pleural fluid.

Specimen Preparation: Centrifuge to remove cellular material. Transfer 1 mL body fluid to an ARUP Standard Transport Tube. (Min: 0.5 mL)

**Interpretive Data:** The Roche CEA electrochemiluminescent immunoassay is used. Results obtained with different assay methods or kits cannot be used interchangeably. Measurements of CEA have been shown to be clinically relevant in the management of patients with colorectal, breast, lung, prostatic, pancreatic, and ovarian carcinomas. Smokers may have slightly elevated levels of CEA. The CEA assay value, regardless of level, should not be interpreted as evidence for the presence or absence of malignant disease and is not recommended for use as a screening procedure to detect the presence of cancer in the general population.

For information on body fluid reference ranges and/or interpretive guidance visit <http://aruplab.com/bodyfluids/>

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement B: [aruplab.com/CS](http://aruplab.com/CS)

**HOT LINE NOTE:** There is a component change associated with this test.

Remove component 0020777, Source, Fluid

Add component 2013044, Carcinoembryonic Antigen Fluid Source

**New Test**

**2012844**

**CD200 by Immunohistochemistry**

**CD200 IHC**

Available January 19, 2016

**Methodology:** Immunohistochemistry

**Performed:** Mon-Fri

**Reported:** 1-3 days

**Specimen Required:** Collect: Tissue.

Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (recommended but not required), (ARUP supply #47808) available online through eSupply using ARUP Connect or contact ARUP Client Services at (800) 522-2787. (Min: 2 slides) If sending precut slides, do not oven bake.

Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.

Unacceptable Conditions: Specimens submitted with non-representative tissue type. Depleted specimens.

Stability (collection to initiation of testing): Ambient: Indefinitely, Refrigerated: Indefinitely, Frozen: Unacceptable

**Note:** All stains will be handled as "Stain and Return" unless a consultation is requested. To request a consultation, submit the pathology report, all associated case materials (clinical history, blocks, slides, etc.), and the Anatomic Pathology requisition form (#32960) in place of the Immunohistochemistry Stain Form.

**CPT Code(s):** 88342

New York DOH approval pending. Call for status update.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.

**2008114**

**Celiac Disease Reflexive Cascade**

**CELIAC REF**

**Reference Interval:** Effective February 16, 2016

Test Number	Components	Reference Interval		
0050340	Immunoglobulin A	<table border="1"> <tr> <td>0-30 days: 1-7 mg/dL 1 month: 1-53 mg/dL 2 months: 3-47 mg/dL 3 months: 5-46 mg/dL 4 months: 4-72 mg/dL 5 months: 8-83 mg/dL 6 months: 8-67 mg/dL 7-8 months: 11-89 mg/dL</td> <td>9-11 months: 16-83 mg/dL 1 year: 14-105 mg/dL 2 years: 14-122 mg/dL 3 years: 22-157 mg/dL 4 years: 25-152 mg/dL 5-7 years: 33-200 mg/dL 8-9 years: 45-234 mg/dL 10 years and older: 68-408 mg/dL</td> </tr> </table>	0-30 days: 1-7 mg/dL 1 month: 1-53 mg/dL 2 months: 3-47 mg/dL 3 months: 5-46 mg/dL 4 months: 4-72 mg/dL 5 months: 8-83 mg/dL 6 months: 8-67 mg/dL 7-8 months: 11-89 mg/dL	9-11 months: 16-83 mg/dL 1 year: 14-105 mg/dL 2 years: 14-122 mg/dL 3 years: 22-157 mg/dL 4 years: 25-152 mg/dL 5-7 years: 33-200 mg/dL 8-9 years: 45-234 mg/dL 10 years and older: 68-408 mg/dL
0-30 days: 1-7 mg/dL 1 month: 1-53 mg/dL 2 months: 3-47 mg/dL 3 months: 5-46 mg/dL 4 months: 4-72 mg/dL 5 months: 8-83 mg/dL 6 months: 8-67 mg/dL 7-8 months: 11-89 mg/dL	9-11 months: 16-83 mg/dL 1 year: 14-105 mg/dL 2 years: 14-122 mg/dL 3 years: 22-157 mg/dL 4 years: 25-152 mg/dL 5-7 years: 33-200 mg/dL 8-9 years: 45-234 mg/dL 10 years and older: 68-408 mg/dL			
0051689	Celiac Disease Dual Antigen Screen	<p>19 Units or less: Negative - No significant level of detectable IgA or IgG antibodies against human tissue transglutaminase or gliadin peptide.</p> <p>20 Units or greater: Positive - Presence of IgA and/or IgG antibodies against human tissue transglutaminase and/or gliadin peptide; suggests possibility of certain gluten sensitive enteropathies such as celiac disease and dermatitis herpetiformis.</p>		
0051357	Deamidated Gliadin Peptide (DGP) Antibody, IgA	<p>19 Units or less: Negative</p> <p>20-30 Units: Weak Positive</p> <p>31 Units or greater: Positive</p>		
0051359	Deamidated Gliadin Peptide (DGP) Antibody, IgG	<p>19 Units or less: Negative</p> <p>20-30 Units: Weak Positive</p> <p>31 Units or greater: Positive</p>		
0097709	Tissue Transglutaminase (tTG) Antibody, IgA	<p>3 U/mL or less: Negative</p> <p>4-10 U/mL: Weak Positive</p> <p>11 U/mL or greater: Positive</p>		
0050736	Endomysial Antibody, IgA by IFA	Less than 1:10		
0056009	Tissue Transglutaminase Antibody, IgG	<p>5 U/mL or less: Negative</p> <p>6-9 U/mL: Weak Positive</p> <p>10 U/mL or greater: Positive</p>		

**New Test**

**2013085**

**Chikungunya by PCR**

**CHIKPCR**

Available January 19, 2016

**Methodology:** Qualitative Polymerase Chain Reaction  
**Performed:** Tue, Fri  
**Reported:** 2-5 days

**Specimen Required:** Collect: Lavender (EDTA), pink (K<sub>2</sub> EDTA), or Serum Separator Tube (SST).  
Specimen Preparation: Separate serum or plasma from cells. Transfer 1 mL serum or plasma to a sterile container. (Min: 0.5 mL)  
Storage/Transport Temperature: Frozen.  
Remarks: Specimen source required.  
Unacceptable Conditions: Heparinized specimens.  
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: 6 months

**Interpretive Data:** See Compliance Statement B: www.aruplab.com/CS

**CPT Code(s):** 87798

New York DOH approval pending. Call for status update.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.

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**0020163 Chloride, Fluid CL FL**

**Specimen Required:**

Collect: CSF, Drain, Pancreatic, Pericardial, Peritoneal/Ascites or Pleural fluid.

**Interpretive Data:** For information on body fluid reference ranges and/or interpretive guidance visit <http://aruplab.com/bodyfluids/>

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement B: [aruplab.com/CS](http://aruplab.com/CS)

**HOT LINE NOTE:** There is a component change associated with this test.

Remove component 0020777, Source, Fluid  
Add component 2013039, Chloride Fluid Source

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**0020714 Cholesterol, Fluid CHOL FL**

**Specimen Required:**

Collect: Drain, Pericardial, Peritoneal/Ascites, or Pleural fluid.

Specimen Preparation: Centrifuge to remove cellular material. Transfer 1 mL body fluid to an ARUP Standard Transport Tube. (Min: 0.5 mL)

**Interpretive Data:** For information on body fluid reference ranges and/or interpretive guidance visit <http://aruplab.com/bodyfluids/>

See Compliance Statement B: [www.aruplab.com/CS](http://www.aruplab.com/CS)

**HOT LINE NOTE:** There is a component change associated with this test.

Remove component 0020777, Source, Fluid  
Add component 2013047, Cholesterol Fluid Source

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**0020031 Cholesterol, Serum or Plasma CHOL**

**Note:** Assay interference (negative) may be observed when high concentrations of N-acetylcysteine (NAC) are present. Negative interference has also been reported with NAPQI (an acetaminophen metabolite), but only when concentrations are at or above those expected during acetaminophen overdose.

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**2002298 Chromosome FISH, Interphase CHR FISHI**

**Specimen Required:**

Remarks: Desired FISH probe and pertinent clinical diagnosis required with test order. **Testing will not be performed until probe and diagnosis are provided;** absence of this information will delay turnaround time.

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**2002299 Chromosome FISH, Metaphase CHR FISHM**

**Specimen Required:**

Remarks: Submit the Patient History for Cytogenetic (Chromosome) Studies form with the electronic packing list (available at <http://www.aruplab.com/genetics/forms.php>).

Desired FISH probe and pertinent clinical diagnosis required with test order. **Testing will not be performed until probe and diagnosis are provided;** absence of this information will delay turnaround time.

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**2003304 Complement Component Level 3a COMP 3A**

**HOT LINE NOTE:** There is a result type change associated with this test.

Change 2003305, 3a Complement Component Level from alpha to numeric

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**2003180 Complement Component Level 4a COMP 4A**

**HOT LINE NOTE:** There is a result type change associated with this test.

Change 2003181, 4a Complement Component Level from alpha to numeric

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**0099072 Complement Component Level 6 COMP 6**

**HOT LINE NOTE:** There is a result type change associated with this test.

Change 0099072, C6 Complement Component Level from alpha to numeric

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2009416

**Complement Factor H Level (B-1H)**

**FACT H**

**HOT LINE NOTE:** There is a result type change associated with this test.  
Change 2009417, Complement Factor H (B-1H) Level from alpha to numeric

**New Test** **2013098**  
Available January 19, 2016

**Cytochrome P450 Genotype Panel**

**CYP PAN**



Additional Technical Information

**Methodology:** Polymerase Chain Reaction/Primer Extension (*CYP2D6*)  
Polymerase Chain Reaction/Fluorescence Monitoring (*CYP2C9*, *CYP2C19*, *CYP3A5*)  
**Performed:** Mon, Thu  
**Reported:** 5-10 days

**Specimen Required:** **Collect:** **Whole Blood:** Lavender (EDTA), pink (K<sub>2</sub>EDTA), or yellow (ACD Solution A or B). OR  
**Saliva:** Collection Device by Spectrum Solutions, LLC (SS-SAL-1, ARUP Supply #52535) available online through eSupply using ARUP Connect™ or by contacting ARUP Client Services at (800) 522-2787.  
**Specimen Preparation:** Transport 3 mL whole blood. (Min: 1 mL) OR Saliva Collection Device.  
**Storage/Transport Temperature:** **Whole Blood:** Refrigerated.  
**Saliva:** Room temperature.  
**Stability (collection to initiation of testing):** **Whole Blood:** Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month  
**Saliva:** Ambient: 2 weeks; Refrigerated: Unacceptable; Frozen: Unacceptable

**Interpretive Data:**

**Background Information for Cytochrome P450 2D6, CYP2D6, 14 Variants and Gene Duplication:**

**Characteristics:** Impaired drug metabolism causing adverse drug reactions or lack of drug response. Drugs metabolized by *CYP2D6* include antiestrogens (tamoxifen), alpha-blockers, analgesics, anticonvulsants, antidepressants, antidiabetics, antihypertensives, antipsychotics, antitussives, beta blockers, cardioactives, norepinephrine reuptake inhibitors, and stimulants. Additionally, many drugs inhibit *CYP2D6* activity, and may affect drug response.

**Inheritance:** Autosomal co-dominant.

**Cause:** *CYP2D6* gene variants.

(Variants are numbered according to M33388 sequence.)

**Functional:** \*2 (2850C>T), \*2A (-1584C>G; 2850C>T).

**Decreased function:** \*9 (2613-5delAGA), \*10 (100C>T), \*17 (1023C>T), \*29 (1659G>A) \*41 (2988G>A).

**Non-functional:** \*3 (2549delA), \*4 (1846G>A), \*5 (gene deletion), \*6 (1707delT), \*7 (2935A>C), \*8 (1758G>T), \*12 (124G>A), \*14 (1758G>A).

**Increased function:** Duplicated functional alleles.

**Negative:** No mutations detected is predictive of \*1 functional alleles.

**Incidence of Poor Metabolizer Phenotype:** 10 percent of Caucasians and Hispanics, 2 percent of African Americans, and 1 percent of Asians.

**Clinical Sensitivity:** Drug-dependent.

**Methodology:** Multiplex polymerase chain reaction and detection primer extension.

**Analytical Sensitivity and Specificity:** Greater than 99 percent.

**Limitations:** Only the targeted *CYP2D6* variants will be detected by this panel. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with *CYP2C9* substrates may be affected by genetic and non-genetic factors that are not detected by this test. This result does not replace the need for therapeutic drug or clinical monitoring.

**Background Information for Cytochrome P450 2C9, CYP2C9, 2 Variants:**

**Characteristics:** The cytochrome P450 (CYP) isozyme 2C9 is involved in the metabolism of many drugs such as warfarin, phenytoin, tolbutamide, glipizide, ibuprofen, and phenobarbital. Variants of *CYP2C9* will influence pharmacokinetics of *CYP2C9* substrates, and may predict non-standard dose requirements.

**Inheritance:** Autosomal co-dominant.

**Cause:** *CYP2C9* gene variants result in decreased or complete deficiency in enzyme activity.

(Variants are numbered according to NM\_000771 transcript)

**Decreased function:** \*2 (rs1799853, c.430C>T).

**Non-functional:** \*3 (rs1057910, c.1075A>C).

**Negative:** No variants detected is predictive of \*1 functional alleles and normal enzymatic activity.

**Allele Frequencies:**

*CYP2C9* \*2: Caucasians – 13 percent, Asians – less than 1 percent, African Americans – 3 percent.

*CYP2C9* \*3: Caucasians – 7 percent, Asians – 4 percent, African Americans – 2 percent.

**Clinical Sensitivity:** Drug-dependent.

**Methodology:** Polymerase chain reaction (PCR) and fluorescence monitoring.

**Analytical Sensitivity and Specificity:** Greater than 99 percent.

**Limitations:** Only the targeted *CYP2C9* variants will be detected by this panel. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with *CYP2C9* substrates may be affected by genetic and non-genetic factors that are not detected by this test. This result does not replace the need for therapeutic drug or clinical monitoring.

**Background Information for Cytochrome P450 2C19, CYP2C19, 9 Variants:**



Quarterly HOT LINE: Effective February 16, 2016

**Characteristics:** The cytochrome P450 (CYP) isozyme 2C19 is involved in the metabolism of many drugs such as clopidogrel, phenytoin, diazepam, R-warfarin, tamoxifen, some antidepressants, proton pump inhibitors, and antimalarials. Variants of *CYP2C19* will influence pharmacokinetics of *CYP2C19* substrates, and may predict non-standard dose requirements.

**Inheritance:** Autosomal co-dominant.

**Cause:** *CYP2C19* gene variants result in increased, decreased, or complete deficiency in enzyme activity.

**Variants Tested:** (Variants are numbered according to NM\_000769 transcript).

**Decreased function:** \*9 (rs17884712, c.431G>A); \*10 (rs6413438, c.680C>T).

**Non-functional:** \*2 (rs4244285, c.681G>A), \*3 (rs4986893, c.636G>A), \*4 (rs28399504, c.1A>G), \*6 (rs72552267, c.395G>A), \*7 (rs72558186, c.819+2T>A), \*8 (rs41291556, c.358T>C).

**Increased function:** \*17 (rs12248560, c.-806C>T).

**Negative:** No variants detected is predictive of \*1 functional alleles and normal enzymatic activity.

**Allele frequencies:**

*CYP2C19*\*2: African American – 18.3 percent, Caucasian – 14.6 percent, Middle Eastern – 13.2 percent, Oceanian – 54.9 percent, South Asian – 34.4 percent.

*CYP2C19*\*3: African American – 0.3 percent, Caucasian – 0.6 percent, Middle Eastern – 2.6 percent, Oceanian – 13.9 percent, East Asian – 8.5 percent.

*CYP2C19*\*17: African American – 19.4 percent, Caucasian – 21.5 percent, Oceanian – 2.5 percent, South Asian – 16.5 percent.

Other alleles are rare, with allele frequencies of less than 1 percent in all populations studied.

**Clinical Sensitivity:** Drug-dependent.

**Methodology:** Polymerase chain reaction (PCR) and fluorescence monitoring.

**Analytical Sensitivity and Specificity:** Greater than 99 percent.

**Limitations:** Only the targeted *CYP2C19* variants will be detected by this panel. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with *CYP2C19* substrates may be affected by genetic and non-genetic factors that are not detected by this test. This result does not replace the need for therapeutic drug or clinical monitoring.

#### Background Information for Cytochrome P450 3A5 Genotyping, *CYP3A5*, 2 Variants:

**Characteristics:** The cytochrome P450 (CYP) 3A subfamily of enzymes is involved in metabolism of many drugs such as immunosuppressants, antibiotics, antivirals, benzodiazepines, and steroids. Nonfunctional variants of *CYP3A5* are common in some populations, preventing expression and function of the *CYP3A5* enzyme, which will influence pharmacokinetics of *CYP3A5* substrates, and may predict non-standard dose requirements.

**Inheritance:** Autosomal co-dominant.

**Cause:** *CYP3A5* gene variants result in enzyme deficiency.

**Variants Tested:** *CYP3A5* non-functional alleles: \*3 (rs776746, c.6986A>G), \*6 (rs10264272, c.14690G>A).

**Negative:** No variants detected is predictive of \*1 functional alleles and normal *CYP3A5* enzyme activity. (Variants are numbered according to NG\_007938.1 transcript)

**Allele Frequencies:**

*CYP3A5*\*3: African – 29.8 percent, Asian – 74.2 percent, Caucasian – 92.1 percent, Latin American – 76.5 percent, Middle Eastern – 88.1 percent.

*CYP3A5*\*6: African – 17.2 percent, Asian – 0.1 percent, Caucasian – 0.1 percent, Latin American – 3.7 percent, Middle Eastern – 1.9 percent.

*CYP3A5*\*7: African – 7.7 percent, Asian – 0 percent, Caucasian – 0 percent, Latin American – 2.5 percent, Middle Eastern – 0.2 percent.

**Clinical Sensitivity:** drug-dependent

**Methodology:** Polymerase chain reaction (PCR) and fluorescence monitoring.

**Analytical Sensitivity and Specificity:** Greater than 99 percent.

**Limitations:** Only the targeted *CYP3A5* variants will be detected by this panel. Diagnostic errors can occur due to rare sequence variations. Many *CYP3A* substrates are also metabolized by *CYP3A4*, for which clinically relevant genetic variation is not recognized to be common. Risk of therapeutic failure or adverse reactions with *CYP3A5* substrates may be affected by genetic and non-genetic factors that are not detected by this test. This result does not replace the need for therapeutic drug or clinical monitoring.

See Compliance Statement C: [www.aruplab.com/CS](http://www.aruplab.com/CS)

**CPT Code(s):** 81225, 81226, 81227, 81401

New York DOH approval pending. Call for status update.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.

Quarterly HOT LINE: Effective February 16, 2016

**0051394**

**Cytokine Panel**

**CYT 12 SE**

**Reference Interval:** Effective February 16, 2016

Test Number	Components	Reference Interval
0051529	Interleukin 2 Receptor (CD25), Soluble	Effective May 19, 2014 1033 pg/mL or less
0051530	Interleukin 12	Effective May 19, 2014 6 pg/mL or less
0051531	Interferon gamma	Effective May 19, 2014 5 pg/mL or less
0051532	Interleukin 4	Effective May 19, 2014 5 pg/mL or less
0051533	Interleukin 5	Effective May 19, 2014 5 pg/mL or less
0051534	Interleukin 10	Effective May 19, 2014 18 pg/mL or less
0051535	Interleukin 13	Effective May 19, 2014 5 pg/mL or less
0051536	Interleukin 1 beta	Effective May 19, 2014 36 pg/mL or less
0051537	Interleukin 6	Effective May 19, 2014 5 pg/mL or less
0051538	Interleukin 8	Effective May 19, 2014 5 pg/mL or less
0051539	Tumor Necrosis Factor - alpha	Effective May 19, 2014 22 pg/mL or less
0051588	Interleukin 2	Effective May 19, 2014 12 pg/mL or less
2013115	Interleukin 17	13 pg/mL or less

**CPT Code(s):** 83520 x13

**HOT LINE NOTE:** There is a component change associated with this test.  
Add component 2013113, Interleukin 17

**New Test**     [2013111](#)

**Cytokine Production by Mononuclear Cells in Response to Antigen and Mitogen Stimulation**

**CYT AM**

Available April 4, 2016



Time Sensitive



Test not New York DOH approved at any laboratory. An approved NPL form must accompany specimen.

**Methodology:** Cell Culture/Quantitative Multiplex Bead Assay

**Performed:** Tue-Fri

**Reported:** 9-10 days

**Specimen Required:** Patient Prep: A control specimen needs to be sent with the patient specimen. The control specimen needs to be drawn from a normal, healthy individual who is not biologically related to the patient, and drawn at approximately the same time as and under similar conditions to the patient specimen.

Collect: Green (sodium heparin) (patient) **AND** green (sodium heparin) (control). Also acceptable: Yellow (ACD Solution A) (patient) **AND** yellow (ACD Solution A) (control). **Patient and control samples must be collected within 48 hours of test performance.**

Specimen Preparation: Transport 10 mL whole blood (patient) **AND** 10 mL whole blood (control) in original collection tubes. (Min: 7 mL whole blood (patient) **AND** 7 mL whole blood (control)) **LIVE CELLS REQUIRED. Do not refrigerate or freeze.**

**Infant Minimum:** 3 mL whole blood (patient) **AND** 7 mL whole blood (control).

Storage/Transport Temperature: **CRITICAL ROOM TEMPERATURE.**

Unacceptable Conditions: Yellow (ACD Solution B). Specimens in transport longer than 48 hours.

Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

**New York State Clients:** Ambient: 24 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

**Reference Interval:** By report

**Interpretive Data:** Antigens (*Candida albicans*, tetanus toxoid) and mitogens (phytohemagglutinin, concanavalin A, pokeweed) are tested independently in lymphocyte culture. Peripheral Blood Mononuclear Cell (PBMC) cytokine production responses to these antigens and mitogens are determined by quantitative multiplex bead assay. Results are used to understand the pathophysiology of immune, infectious, or inflammatory disorders, or may be used for research purposes.

See Compliance Statement B: [www.aruplab.com/CS](http://www.aruplab.com/CS)

**Note:** The following cytokines (and receptor) are reported: IL-2, sIL-2R (sCD25), IL-4, IL-5, IL-10, IL-13, IL-1b, IL-6, IL-17, TNF-a, and IFN-g. Results are reported as pg/mL. Interpretation comparing the patient results to the simultaneously collected client normal control and the laboratory normal control will be provided by an ARUP medical director.

**CPT Code(s):** 86353 x5; 83520 x11

New York DOH approval pending. Call for status update.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.

**New Test**     [2013109](#)     **Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation**     **CYT M**

Available April 4, 2016



Time Sensitive



Test not New York DOH approved at any laboratory. An approved NPL form must accompany specimen.

**Methodology:** Cell Culture/Quantitative Multiplex Bead Assay  
**Performed:** Tue-Fri  
**Reported:** 9-10 days

**Specimen Required:** Patient Prep: A control specimen needs to be sent with the patient specimen. The control specimen needs to be drawn from a normal, healthy individual who is not biologically related to the patient, and drawn at approximately the same time as and under similar conditions to the patient specimen.  
Collect: Green (sodium heparin) (patient) **AND** green (sodium heparin) (control). Also acceptable: Yellow (ACD Solution A) (patient) **AND** yellow (ACD Solution A) (control). **Patient and control samples must be collected within 48 hours of test performance.**  
Specimen Preparation: Transport 10 mL whole blood (patient) **AND** 10 mL whole blood (control) in original collection tubes. (Min: 7 mL whole blood (patient) **AND** 7 mL whole blood (control)) **LIVE CELLS REQUIRED. Do not refrigerate or freeze.**  
**Infant Minimum:** 3 mL whole blood (patient) **AND** 7 mL whole blood (control).  
Storage/Transport Temperature: **CRITICAL ROOM TEMPERATURE.**  
Unacceptable Conditions: Yellow (ACD Solution B). Specimens in transport longer than 48 hours.  
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable  
**New York State Clients:** Ambient: 24 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

**Reference Interval:** By report

**Interpretive Data:** Mitogens (Phytohemagglutinin, concanavalin A, pokeweed) are tested independently in lymphocyte culture. Peripheral Blood Mononuclear Cell (PBMC) cytokine responses to these mitogens are determined by quantitative multiplex bead assay. Results are used to understand the pathophysiology of immune, infectious, or inflammatory disorders, or may be used for research purposes.

See Compliance Statement B: [www.aruplab.com/CS](http://www.aruplab.com/CS)

**Note:** The following cytokines are reported: IL-2, sIL-2R (sCD25), IL-4, IL-5, IL-10, IL-13, IL-1b, IL-6, IL-17, TNF-a, and IFN-g. Results are reported as pg/mL. Interpretation comparing the patient results to the simultaneously collected client normal control and the laboratory normal control will be provided by an ARUP medical director.

**CPT Code(s):** 86353 x3; 83520 x11

New York DOH approval pending. Call for status update.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.

[2012166](#)     **Dihydropyrimidine Dehydrogenase (DPYD), 3 Variants**     **DPYD**

**Methodology:** Polymerase Chain Reaction/Fluorescence Monitoring  
**Performed:** Mon, Thu  
**Reported:** 5-10 days

**Specimen Required:**  
Unacceptable Conditions: Plasma or serum. Heparinized specimens.  
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month.

**HOT LINE NOTE:** There is a component change associated with this test.

- Remove component 2012168, DPYD c.1679T>G
- Remove component 2013169, DPYD c.1905+1G>A
- Remove component 2012170, DPYD c.2846A>T
- Remove component 2012171, DPYD Interpretation
- Add component 2013096, DPYD Genotype
- Add component 2013097, DPYD Phenotype

**2006621**

**Drug Detection Panel, Umbilical Cord Tissue, Qualitative**

**TOF SCR CD**

**Specimen Required:**

**Specimen Preparation:** Drain and discard any blood. Rinse the exterior of the cord segment with normal saline or sterile water. Pat the cord dry and transfer specimens to the appropriate transport device or use the Security Kit for Meconium/Umbilical Drug Detection (ARUP supply #51548) available online through eSupply using ARUP Connect™ or by contacting ARUP Client Services at (800) 522-2787.

**Reference Interval:** Effective February 16, 2015

**Drugs covered and range of cutoff concentrations. Note that some drugs are identified based on the presence of unique drug metabolites not listed below.**

Drugs/Drug Classes	Range of Cutoff Concentrations
<b>Opioids:</b> buprenorphine, codeine, fentanyl, heroin (6-acetylmorphine), dihydrocodeine, hydrocodone, hydromorphone, meperidine, methadone, morphine, naloxone, oxycodone, oxymorphone, propoxyphene, tapentadol, tramadol	1-10 ng/g
<b>Stimulants:</b> amphetamine, cocaine, methamphetamine, MDMA (Ecstasy), phentermine	8 ng/g
<b>Sedatives-hypnotics:</b> alprazolam, butalbital, clonazepam, diazepam, lorazepam, midazolam, nordiazepam, oxazepam, phenobarbital, temazepam, zolpidem	5-75 ng/g
<b>Cannabinoids (11-nor-9-carboxy-THC)</b>	1 ng/g
<b>Phencyclidine (PCP)</b>	4 ng/g

**HOT LINE NOTE:** There is a component change associated with this test.

- Remove component 2006639, Naltrexone (cutoff 8 ng/g)
- Remove component 2006655, MDA (cutoff 8 ng/g)
- Remove component 2006656, MDEA- Eve (cutoff 8 ng/g)
- Remove component 2006666, Flunitrazepam (cutoff 5 ng/g)
- Remove component 2006667, 7-Aminoflunitrazepam (cutoff 5 ng/g)
- Remove component 2006668, Flurazepam (cutoff 5 ng/g)
- Remove component 2006669, Desalkylflurazepam (cutoff 10 ng/g)
- Remove component 2006670, 2-OH-Ethylflurazepam (cutoff 10 ng/g)
- Remove component 2006674, Nitrazepam (cutoff 5 ng/g)
- Remove component 2006678, Secobarbital (cutoff 75 ng/g)
- Remove component 2006680, Triazolam (cutoff 5 ng/g)
- Remove component 2006681, Alpha-OH-Triazolam (cutoff 5 ng/g)
- Add component 2013103, Norbuprenorphine (cutoff 8 ng/g)
- Add component 2013104, Norhydrocodone (cutoff 6 ng/g)
- Add component 2013105, Noroxycodone (cutoff 4 ng/g)
- Add component 2013106, Noroxymorphone (cutoff 4 ng/g)

**0020410**

**Electrolyte Panel**

**LYTES**

**Specimen Required:**

**Unacceptable Conditions:** Specimens collected in sodium citrate, EDTA, potassium oxalate, or sodium fluoride. Hemolyzed specimens.

**2002902**

**Epstein-Barr Virus (EBV) by in situ Hybridization, Paraffin**

**EBV ISH**

**HOT LINE NOTE:** There is a component change associated with this test.

Change component 2003001 H and E Slide Description from a Prompt test to a Resultable test.

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**2001961 Familial Mutation, Targeted Sequencing SEQ FSM**

**CPT Code(s):** 81202 *APC*; 81215 *BRCA1*; 81217 *BRCA2*; 81221 *CFTR*; 81253 *GJB2*; 81293 *MLH1*; 81296 *MSH2*; 81299 *MSH6*; 81303 *MECP2*; 81318 *PMS2*; 81322 *PTEN*; 81402 *MEFV*

81401 if one of the following genes is tested: *ACADM, PRSSI*

81403 if one of the following genes is tested: *ABCD1, ACADVL, ADPKD, ASS1, ATP7B, BMPR2, BTD, CDKL5, CHD7, COL4A5, CYP1B1, DHCR7, ENG, F8, F9, FBNI, GALT, HBA1, HBA2, HBB, HEXA, LMNA, MEN1, MUTYH, NF1, OTC, PTPN11, RET, SDHA, SDHB, SDHC, SDHD, SLC22A5, SMAD4, SOS1, SPINK1, SPRED1, STK11, TGFBRI, TGFBR2, TP53, UBE3A, VHL, VWF*

81479 if one of the following genes is tested: *ACVRL1, ATP7A, BMP9, BMPR1A, CTRC, EIF2AK4, G6PD, GAMT, GATM, GLI3, INSR, KMT2D, MYH3, NAA10, PLOD1, RASA1, SLC25A13, SLC6A8, TNFRSF13B*

Contact ARUP for CPT coding of targeted familial variants in genes not listed here.

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**2001980 Familial Mutation, Targeted Sequencing, Fetal SEQ FSM FE**

**Specimen Required:**  
**Storage/Transport Temperature:** Cultured Amniocytes: **CRITICAL ROOM TEMPERATURE**. Must be received within 48 hours of shipment due to liability of cells.  
**Amniotic fluid:** Room temperature.  
**Maternal Cell Contamination Specimen:** Refrigerated

**Note:** Documentation of the familial gene mutation(s) is required to perform targeted sequencing. Submit a copy of a relative's laboratory test report documenting the gene and specific mutation(s) for which testing is requested.

This test is available for genes currently sequenced at ARUP. **Some genes will require approval before fetal testing can begin. Contact ARUP's Genetic Counselors at (800) 242-2787 extension 2141 prior to test submission.**

Submit a positive control with the patient specimen for appropriate interpretation. Disease-specific patient history forms are available at [www.aruplab.com/Testing-Information/consentforms-patienthistory.jsp](http://www.aruplab.com/Testing-Information/consentforms-patienthistory.jsp)

**CPT Code(s):** 81265 Fetal Cell Contamination; 81202 *APC*; 81215 *BRCA1*; 81217 *BRCA2*; 81221 *CFTR*; 81253 *GJB2*; 81281 *LQTS*; 81402 *MEFV*; 81293 *MLH1*; 81296 *MSH2*; 81299 *MSH6*; 81303 *MECP2*; 81318 *PMS2*; 81322 *PTEN*; 81402 *MEFV*

81401 if one of the following genes is tested: *ACADM, PRSSI*

81403 if one of the following genes is tested: *ABCD1, ACADVL, ADPKD, ASS1, ATP7B, BMPR2, BTD, CDKL5, CHD7, COL4A5, CYP1B1, DHCR7, ENG, F8, F9, FBNI, GALT, HBA1, HBA2, HBB, HEXA, LMNA, MEN1, MUTYH, NF1, OTC, PTPN11, RET, SDHA, SDHB, SDHC, SDHD, SLC22A5, SMAD4, SOS1, SPINK1, SPRED1, STK11, TGFBRI, TGFBR2, TP53, UBE3A, VHL, VWF*

81479 if one of the following genes is tested: *ACVRL1, ATP7A, BMP9, BMPR1A, CTRC, EIF2AK4, G6PD, GAMT, GATM, GLI3, INSR, KMT2D, MYH3, NAA10, PLOD1, RASA1, SLC25A13, SLC6A8, TNFRSF13B*

Contact ARUP for CPT coding of targeted familial variants in genes not listed here.

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**0092442 Galactokinase, Blood GALACTOKI**

**Performed:** Varies  
**Reported:** 21-31 days

**Specimen Required:**  
**Specimen Preparation:** Transport 5 mL whole blood. (Min: 1 mL) **Before sending specimen, contact ARUP Referral Testing at (800) 242-2787, extension 5145 for direct submission instructions. Specimen must be received at performing laboratory within 48 hours of collection.**

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**2012678 Gastrointestinal Bacterial Panel by PCR GI BACTPCR**

**HOT LINE NOTE:** There is a clinically significant charting name change associated with this test. Change the charting name of component 2012679 from *Shigella* species by PCR to *Shigella/Enteroinvasive E. coli* by PCR

**2011470**

**GLI3-Related Disorders (GLI3) Sequencing**

**GLI3 FGS**

**Interpretive Data:**

**Background Information for GLI3-Related Disorders (GLI3) Sequencing:**

**Characteristics:** Mutations in the *GLI3* gene cause multiple disorders. The most common disorders are Pallister-Hall syndrome (PHS) and Greig Cephalopolysyndactyly syndrome (GCPS).

**PHS** is characterized by hypothalamic hamartoma, postaxial/central polydactyly, and bifid epiglottis. Some individuals may exhibit imperforate anus, renal, genitourinary, pulmonary, or non-polydactyly skeletal anomalies.

**GCPS** is characterized by preaxial polysyndactyly, hypertelorism, and macrocephaly. Severe cases may exhibit seizures, hydrocephalus, and/or intellectual disability.

**Inheritance:** Autosomal dominant

**Cause:** Pathogenic germline mutations in the *GLI3* gene.

**Clinical sensitivity:** PHS - 90 percent; GCPS - 70 percent

**Methodology:** Bidirectional sequencing of the entire coding region and intron/exon boundaries of the *GLI3* gene.

**Analytical sensitivity and specificity:** Greater than 99 percent for sequencing.

**Limitations:** Diagnostic errors can occur due to rare sequence variations. Regulatory region mutations, deep intronic mutations, and large deletions/duplications are not detected. Exon 1 is a non-coding region and not covered by this assay. Mutations in genes other than *GLI3* are not detected.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online at [www.aruplab.com](http://www.aruplab.com).

See Compliance Statement C: [www.aruplab.com/CS](http://www.aruplab.com/CS)

**2011465**

**GLI3-Related Disorders (GLI3) Sequencing and Deletion/Duplication**

**GLI3 FGA**

**Interpretive Data:**

**Background Information for GLI3-Related Disorders (GLI3) Sequencing and Deletion/Duplication:**

**Characteristics:** Mutations in the *GLI3* gene cause multiple disorders. The most common disorders are Pallister-Hall syndrome (PHS) and Greig Cephalopolysyndactyly syndrome (GCPS).

**PHS** is characterized by hypothalamic hamartoma, postaxial/central polydactyly, and bifid epiglottis. Some individuals may exhibit imperforate anus, renal, genitourinary, pulmonary, or non-polydactyly skeletal anomalies.

**GCPS** is characterized by preaxial polysyndactyly, hypertelorism, and macrocephaly. Severe cases may exhibit seizures, hydrocephalus, and/or intellectual disability.

**Inheritance:** Autosomal dominant

**Cause:** Pathogenic germline mutations in the *GLI3* gene.

**Clinical sensitivity:** PHS - 90 percent; GCPS - 75-85 percent

**Methodology:** Bidirectional sequencing of the entire coding region and intron/exon boundaries of the *GLI3* gene. Multiplex Ligation-dependent Probe Amplification (MLPA) to detect large exonic *GLI3* deletions and duplications.

**Analytical sensitivity and specificity:** Greater than 99 percent for sequencing; greater than 98 percent for MLPA.

**Limitations:** Diagnostic errors can occur due to rare sequence variations. Regulatory region mutations, deep intronic mutations, and large deletions/duplications are not detected. The breakpoints of large deletions and duplications are not determined. Mutations in genes other than *GLI3* are not detected.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online at [www.aruplab.com](http://www.aruplab.com).

See Compliance Statement C: [www.aruplab.com/CS](http://www.aruplab.com/CS)

**0020503**

**Glucose, Body Fluid**

**GLU-FL**

**Specimen Required:**

Collect: Dialysate, Pericardial, Peritoneal/Ascites, Pleural, or Synovial fluid.

**Interpretive Data:** For information on body fluid reference ranges and/or interpretive guidance visit <http://aruplab.com/bodyfluids/>

See Compliance Statement B: [www.aruplab.com/CS](http://www.aruplab.com/CS)

**HOT LINE NOTE:** There is a component change associated with this test.

Remove component 0097114, SR Source

Add component 2013051, Glucose Fluid Source

**0092068**

**Hairstat 5 Reflexive Panel**

**HAIRSTAT 5**

**Specimen Required:** Patient Prep: Ensure hair is not chemically treated or synthetic. Hair from the beard, underarms, chest, arms, legs or pubic hair may be collected. Body hair from different sites may be combined to get a final volume. Body hair and scalp hair should not be combined.

Unacceptable Conditions: Unsealed specimens.

**0020053**

**HDL Cholesterol**

**CH HDL**

**Note:** Assay interference (negative) may be observed when high concentrations of N-acetylcysteine (NAC) are present. Negative interference has also been reported with NAPQI (an acetaminophen metabolite), but only when concentrations are at or above those expected during acetaminophen overdose.

**New Test**

**2013089**

**Human Herpesvirus 8 (HHV-8) by Quantitative PCR**

**HHV8 QNT**

Available February 16, 2016

**Methodology:** Quantitative Polymerase Chain Reaction

**Performed:** Mon, Thu

**Reported:** 2-5 days

**Specimen Required:** Collect: Lavender (EDTA), Pink (K<sub>2</sub> EDTA), or Serum Separator Tube (SST).

Specimen Preparation: Separate serum or plasma from cells. Transport 1 mL plasma, serum, or whole blood in a sterile container. (Min: 0.5 mL)

Storage/Transport Temperature: Refrigerated.

Remarks: Specimen source required.

Unacceptable Conditions: Heparinized specimens.

Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 1 week; Frozen: 1 year

**Reference Interval:** Not detected

**Interpretive Data:** The quantitative range of this assay is 3.8-8.8 log copies/mL (6,670 - 667,000,000 copies/mL).

A negative result (less than 3.8 log copies/mL or less than 6,670 copies/mL) does not rule out the presence of PCR inhibitors in the patient specimen or HHV8 DNA concentrations below the level of detection of the test. Inhibition may also lead to underestimation of viral quantitation.

No international standard is currently available for calibration of this assay. Caution should be taken when interpreting results generated by different assay methodologies.

See Compliance Statement B: [www.aruplab.com/CS](http://www.aruplab.com/CS)

**Note:** The limit of quantification for this DNA test is 3.8 log copies/mL (6,670 copies/mL). If the test DID NOT DETECT the virus, the test result will be reported as "< 3.8 log copies/mL (< 6,670 copies/mL)." If the test DETECTED the presence of the virus but was not able to accurately quantify the number of copies, the test result will be reported as "Not Quantified."

**CPT Code(s):** 87799

New York DOH approval pending. Call for status update.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.



**New Test**     [2013107](#)     **Human Immunodeficiency Virus Types 1 and 2 (HIV-1/2) Antibody Differentiation, Supplemental**     **HIV AB SUP**

Available January 19, 2016

**Methodology:** Qualitative Immunoassay  
**Performed:** Varies  
**Reported:** 1-2 days

**Specimen Required:** Collect: Lavender (EDTA), or Pink (K<sub>2</sub> EDTA). Also acceptable: Serum Separator Tube (SST).  
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma into an ARUP Standard Transport Tube dedicated only for HIV testing. (Min: 0.5 mL) Remove particulate material.  
Storage/Transport Temperature: Frozen.  
Unacceptable Conditions: Specimens containing particulate material. Severely hemolyzed or heat-inactivated specimens.  
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 1 week; Frozen: Indefinitely (avoid repeated freeze/thaw cycles)

**Reference Interval:**

Test Number	Components	Reference Interval
	HIV-1 Antibody	Negative
	HIV-2 Antibody	Negative

**Interpretive Data:** This test should not be used for blood donor screening, associated re-entry protocols, or for screening Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P).

**Note:** For use ONLY when patient has a repeatedly reactive third- or fourth-generation HIV screen test result. This test discriminates between HIV-1 and HIV-2 antibodies. Results for each type are reported. This test is for use as the antibody differentiation test in the specific multi-test algorithm. If results are negative or indeterminate, this test does NOT reflex to a nucleic acid test.

A multi-test algorithm is recommended by the Centers for Disease Control and Prevention (CDC) and the Clinical Laboratory Standards Institute (CLSI) for the diagnosis of HIV (refer to <http://www.arupconsult.com/Topics/HIV.html>).

**CPT Code(s):** 86701; 86702

New York DOH Approved.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.

[2002896](#)     **Human Papillomavirus (HPV) Low Risk by in situ Hybridization, Paraffin**     **HPVLOW ISH**

**HOT LINE NOTE:** There is a component change associated with this test.  
Change component 2003001 H and E Slide Description from Prompt test to **Resultable test**.

**0050980**

**Humoral Immunity Panel I**

**HUMPAN I**

**Reference Interval:** Effective February 16, 2016

Test Number	Components	Reference Interval		
0050210	Diphtheria Antibody, IgG	Antibody concentration of > 0.1 IU/mL is usually considered protective.		
0050535	Tetanus Antibody, IgG	Antibody concentration of > 0.1 IU/mL is usually considered protective.		
0050725	<i>Streptococcus pneumoniae</i> Antibodies, IgG (14 Serotypes)			
0050340	Immunoglobulin A	<table border="1"> <tr> <td>0-30 days: 1-7 mg/dL 1 month: 1-53 mg/dL 2 months: 3-47 mg/dL 3 months: 5-46 mg/dL 4 months: 4-72 mg/dL 5 months: 8-83 mg/dL 6 months: 8-67 mg/dL 7-8 months: 11-89 mg/dL</td> <td>9-11 months: 16-83 mg/dL 1 year: 14-105 mg/dL 2 years: 14-122 mg/dL 3 years: 22-157 mg/dL 4 years: 25-152 mg/dL 5-7 years: 33-200 mg/dL 8-9 years: 45-234 mg/dL 10 years and older: 68-408 mg/dL</td> </tr> </table>	0-30 days: 1-7 mg/dL 1 month: 1-53 mg/dL 2 months: 3-47 mg/dL 3 months: 5-46 mg/dL 4 months: 4-72 mg/dL 5 months: 8-83 mg/dL 6 months: 8-67 mg/dL 7-8 months: 11-89 mg/dL	9-11 months: 16-83 mg/dL 1 year: 14-105 mg/dL 2 years: 14-122 mg/dL 3 years: 22-157 mg/dL 4 years: 25-152 mg/dL 5-7 years: 33-200 mg/dL 8-9 years: 45-234 mg/dL 10 years and older: 68-408 mg/dL
0-30 days: 1-7 mg/dL 1 month: 1-53 mg/dL 2 months: 3-47 mg/dL 3 months: 5-46 mg/dL 4 months: 4-72 mg/dL 5 months: 8-83 mg/dL 6 months: 8-67 mg/dL 7-8 months: 11-89 mg/dL	9-11 months: 16-83 mg/dL 1 year: 14-105 mg/dL 2 years: 14-122 mg/dL 3 years: 22-157 mg/dL 4 years: 25-152 mg/dL 5-7 years: 33-200 mg/dL 8-9 years: 45-234 mg/dL 10 years and older: 68-408 mg/dL			
0050350	Immunoglobulin G	<table border="1"> <tr> <td>0- 30 days: 611-1542 mg/dL 1 month: 241-870 mg/dL 2 months: 198-577 mg/dL 3 months: 169-558 mg/dL 4 months: 188-536 mg/dL 5 months: 165-781 mg/dL 6 months: 206-676 mg/dL 7-8 months: 208-868 mg/dL</td> <td>9-11 months: 282-1026 mg/dL 1 year: 331-1164 mg/dL 2 years: 407-1009 mg/dL 3 years: 423-1090 mg/dL 4 years: 444-1187 mg/dL 5-7 years: 608-1229 mg/dL 8-9 years: 584-1509 mg/dL 10 years and older: 768-1632 mg/dL</td> </tr> </table>	0- 30 days: 611-1542 mg/dL 1 month: 241-870 mg/dL 2 months: 198-577 mg/dL 3 months: 169-558 mg/dL 4 months: 188-536 mg/dL 5 months: 165-781 mg/dL 6 months: 206-676 mg/dL 7-8 months: 208-868 mg/dL	9-11 months: 282-1026 mg/dL 1 year: 331-1164 mg/dL 2 years: 407-1009 mg/dL 3 years: 423-1090 mg/dL 4 years: 444-1187 mg/dL 5-7 years: 608-1229 mg/dL 8-9 years: 584-1509 mg/dL 10 years and older: 768-1632 mg/dL
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0050355	Immunoglobulin M	<table border="1"> <tr> <td>0-30 days: 0-24 mg/dL 1 month: 19-83 mg/dL 2 months: 16-100 mg/dL 3 months: 23-85 mg/dL 4 months: 26-96 mg/dL 5 months: 31-103 mg/dL 6 months: 33-97 mg/dL 7-8 months: 32-120 mg/dL</td> <td>9-11 months: 39-142 mg/dL 1 year: 41-164 mg/dL 2 years: 46-160 mg/dL 3 years: 45-190 mg/dL 4 years: 41-186 mg/dL 5-7 years: 46-197 mg/dL 8-9 years: 49-230 mg/dL 10 years and older: 35-263 mg/dL</td> </tr> </table>	0-30 days: 0-24 mg/dL 1 month: 19-83 mg/dL 2 months: 16-100 mg/dL 3 months: 23-85 mg/dL 4 months: 26-96 mg/dL 5 months: 31-103 mg/dL 6 months: 33-97 mg/dL 7-8 months: 32-120 mg/dL	9-11 months: 39-142 mg/dL 1 year: 41-164 mg/dL 2 years: 46-160 mg/dL 3 years: 45-190 mg/dL 4 years: 41-186 mg/dL 5-7 years: 46-197 mg/dL 8-9 years: 49-230 mg/dL 10 years and older: 35-263 mg/dL
0-30 days: 0-24 mg/dL 1 month: 19-83 mg/dL 2 months: 16-100 mg/dL 3 months: 23-85 mg/dL 4 months: 26-96 mg/dL 5 months: 31-103 mg/dL 6 months: 33-97 mg/dL 7-8 months: 32-120 mg/dL	9-11 months: 39-142 mg/dL 1 year: 41-164 mg/dL 2 years: 46-160 mg/dL 3 years: 45-190 mg/dL 4 years: 41-186 mg/dL 5-7 years: 46-197 mg/dL 8-9 years: 49-230 mg/dL 10 years and older: 35-263 mg/dL			
0050571	Immunoglobulin G Subclass 1	<table border="1"> <tr> <td>Cord blood: 435-1084 mg/dL 0-2 months: 218-498 mg/dL 3-5 months: 143-394 mg/dL 6-8 months: 190-388 mg/dL 9-23 months: 288-880 mg/dL 2 years: 170-950 mg/dL 3-4 years: 290-1065 mg/dL</td> <td>5-6 years: 330-1065 mg/dL 7-8 years: 225-1100 mg/dL 9-10 years: 390-1235 mg/dL 11-12 years: 380-1420 mg/dL 13-14 years: 165-1440 mg/dL 15 years and older: 240-1118 mg/dL</td> </tr> </table>	Cord blood: 435-1084 mg/dL 0-2 months: 218-498 mg/dL 3-5 months: 143-394 mg/dL 6-8 months: 190-388 mg/dL 9-23 months: 288-880 mg/dL 2 years: 170-950 mg/dL 3-4 years: 290-1065 mg/dL	5-6 years: 330-1065 mg/dL 7-8 years: 225-1100 mg/dL 9-10 years: 390-1235 mg/dL 11-12 years: 380-1420 mg/dL 13-14 years: 165-1440 mg/dL 15 years and older: 240-1118 mg/dL
Cord blood: 435-1084 mg/dL 0-2 months: 218-498 mg/dL 3-5 months: 143-394 mg/dL 6-8 months: 190-388 mg/dL 9-23 months: 288-880 mg/dL 2 years: 170-950 mg/dL 3-4 years: 290-1065 mg/dL	5-6 years: 330-1065 mg/dL 7-8 years: 225-1100 mg/dL 9-10 years: 390-1235 mg/dL 11-12 years: 380-1420 mg/dL 13-14 years: 165-1440 mg/dL 15 years and older: 240-1118 mg/dL			
0050572	Immunoglobulin G Subclass 2	<table border="1"> <tr> <td>Cord blood: 143-453 mg/dL 0-2 months: 40-167 mg/dL 3-5 months: 23-147 mg/dL 6-8 months: 37-60 mg/dL 9-23 months: 30-327 mg/dL 2 years: 22-440 mg/dL 3-4 years: 28-315 mg/dL</td> <td>5-6 years: 57-345 mg/dL 7-8 years: 42-375 mg/dL 9-10 years: 61-430 mg/dL 11-12 years: 73-455 mg/dL 13-14 years: 71-460 mg/dL 15 years and older: 124-549 mg/dL</td> </tr> </table>	Cord blood: 143-453 mg/dL 0-2 months: 40-167 mg/dL 3-5 months: 23-147 mg/dL 6-8 months: 37-60 mg/dL 9-23 months: 30-327 mg/dL 2 years: 22-440 mg/dL 3-4 years: 28-315 mg/dL	5-6 years: 57-345 mg/dL 7-8 years: 42-375 mg/dL 9-10 years: 61-430 mg/dL 11-12 years: 73-455 mg/dL 13-14 years: 71-460 mg/dL 15 years and older: 124-549 mg/dL
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0050576	Immunoglobulin G Subclass 4	<table border="1"> <tr> <td>Cord blood: 1-47 mg/dL 0-2 months: 1-33 mg/dL 3-5 months: 1-14 mg/dL 6-8 months: 1-16 mg/dL 9-23 months: 1-65 mg/dL 2 years: 0-120 mg/dL 3-4 years: 0-90 mg/dL</td> <td>5-6 years: 2-116 mg/dL 7-8 years: 0-138 mg/dL 9-10 years: 1-95 mg/dL 11-12 years: 1-153 mg/dL 13-14 years: 2-143 mg/dL 15 years and older: 1-123 mg/dL</td> </tr> </table>	Cord blood: 1-47 mg/dL 0-2 months: 1-33 mg/dL 3-5 months: 1-14 mg/dL 6-8 months: 1-16 mg/dL 9-23 months: 1-65 mg/dL 2 years: 0-120 mg/dL 3-4 years: 0-90 mg/dL	5-6 years: 2-116 mg/dL 7-8 years: 0-138 mg/dL 9-10 years: 1-95 mg/dL 11-12 years: 1-153 mg/dL 13-14 years: 2-143 mg/dL 15 years and older: 1-123 mg/dL
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Quarterly HOT LINE: Effective February 16, 2016

**New Test**     [2013101](#)     **3-Hydroxy-3-Methylglutaryl Coenzyme A Reductase (HMGCR) Antibody, IgG**     **HMGCR**

Available January 19, 2016

**Methodology:** Semi-Quantitative Enzyme-Linked Immunosorbent Assay  
**Performed:** Fri  
**Reported:** 1-15 days

**Specimen Required:** Collect: Serum Separator Tube (SST).  
Specimen Preparation: Transfer 0.5 mL serum to an ARUP Standard Transport Tube. (Min: 0.15 mL)  
Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen.  
Unacceptable Conditions: Other body fluids. Contaminated, hemolyzed, grossly icteric, or severely lipemic specimens.  
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

**Reference Interval:** 0-19 Units: Negative

**Interpretive Data:** IgG antibodies to 3-hydroxy-3-methylglutaryl-coenzyme A reductase (HMGCR) are mainly associated with necrotizing autoimmune myopathy (NAM) in a subset of statin-treated patients. Although infrequent, these antibodies may also be observed in statin-naïve patients with NAM. Strong clinical correlation is recommended in the absence of muscle fiber necrosis, elevated serum creatinine kinase, perimysial pathology, and/or statin exposure.

See Compliance Statement A: [www.aruplab.com/CS](http://www.aruplab.com/CS)

**CPT Code(s):** 83516

New York DOH approval pending. Call for status update.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.

[0050667](#)     **Immune Complex Panel**     **C1Q/RAJI**

**Specimen Required:** Patient Prep:  
Collect: Plain red or serum separator tube (SST).  
Specimen Preparation: Allow complete clotting of red blood cells (up to 1 hour), then separate serum from cells within 30 minutes and freeze immediately. Transfer **TWO (2)** 1 mL aliquots of serum to individual ARUP Standard Transport Tubes. (Min: 0.5 mL/aliquot)  
Storage/Transport Temperature: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**  
Unacceptable Conditions: Non-frozen specimens. Specimens exposed to repeated freeze/thaw cycles.  
Stability (collection to initiation of testing):  
**Raji:** Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 30 days  
**C1q:** (After separation from cells): Ambient: 2 hours; Refrigerated: Unacceptable; Frozen: 2 weeks (avoid repeated freeze/thaw cycles)

[0050340](#)     **Immunoglobulin A**     **IGA**

**Reference Interval:** Effective February 16, 2016

0-30 days: 1-7 mg/dL	9-11 months: 16-83 mg/dL
1 month: 1-53 mg/dL	1 year: 14-105 mg/dL
2 months: 3-47 mg/dL	2 years: 14-122 mg/dL
3 months: 5-46 mg/dL	3 years: 22-157 mg/dL
4 months: 4-72 mg/dL	4 years: 25-152 mg/dL
5 months: 8-83 mg/dL	5-7 years: 33-200 mg/dL
6 months: 8-67 mg/dL	8-9 years: 45-234 mg/dL
7-8 months: 11-89 mg/dL	10 years and older: 68-408 mg/dL

Quarterly HOT LINE: Effective February 16, 2016

**0093149**

**Immunoglobulin A Subclasses (1 and 2)**

**IGA SUB**

**Reference Interval:** Effective February 16, 2016

Test Number	Components	Reference Interval
0050340	Immunoglobulin A	0-30 days: 1-7 mg/dL 1 month: 1-53 mg/dL 2 months: 3-47 mg/dL 3 months: 5-46 mg/dL 4 months: 4-72 mg/dL 5 months: 8-83 mg/dL 6 months: 8-67 mg/dL 7-8 months: 11-89 mg/dL
		9-11 months: 16-83 mg/dL 1 year: 14-105 mg/dL 2 years: 14-122 mg/dL 3 years: 22-157 mg/dL 4 years: 25-152 mg/dL 5-7 years: 33-200 mg/dL 8-9 years: 45-234 mg/dL 10 years and older: 68-408 mg/dL
	Immunoglobulin A Subclass 1	0-11 months: 1-115 mg/dL 1 year: 3-120 mg/dL 2 years: 7-132 mg/dL 3 years: 11-143 mg/dL 4-7 years: 23-175 mg/dL 8-11 years: 33-204 mg/dL 12-18 years: 47-249 mg/dL Adult: 60-294 mg/dL
	Immunoglobulin A Subclass 2	0-11 months: 0-19 mg/dL 1 year: 0-23 mg/dL 2 years: 1-23 mg/dL 3 years: 1-25 mg/dL 4-7 years: 2-33 mg/dL 8-11 years: 2-37 mg/dL 12-18 years: 4-50 mg/dL Adult: 6-61 mg/dL

**0050576**

**Immunoglobulin G Subclass 4**

**IGG4**

**Reference Interval:** Effective February 16, 2016

Cord blood: 1-47 mg/dL 0-2 months: 1-33 mg/dL 3-5 months: 1-14 mg/dL 6-8 months: 1-16 mg/dL 9-23 months: 1-65 mg/dL 2 years: 0-120 mg/dL 3-4 years: 0-90 mg/dL	5-6 years: 2-116 mg/dL 7-8 years: 0-138 mg/dL 9-10 years: 1-95 mg/dL 11-12 years: 1-153 mg/dL 13-14 years: 2-143 mg/dL 15 years and older: 1-123 mg/dL
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Quarterly HOT LINE: Effective February 16, 2016

**0050577**

**Immunoglobulin G Subclasses (1, 2, 3, 4)**

**IGG SUB**

**Reference Interval:** Effective February 16, 2016

Test Number	Components	Reference Interval
0050571	Immunoglobulin G Subclass 1	Cord blood: 435-1084 mg/dL 0-2 months: 218-498 mg/dL 3-5 months: 143-394 mg/dL 6-8 months: 190-388 mg/dL 9-23 months: 288-880 mg/dL 2 years: 170-950 mg/dL 3-4 years: 290-1065 mg/dL 5-6 years: 330-1065 mg/dL 7-8 years: 225-1100 mg/dL 9-10 years: 390-1235 mg/dL 11-12 years: 380-1420 mg/dL 13-14 years: 165-1440 mg/dL 15 years and older: 240-1118 mg/dL
0050572	Immunoglobulin G Subclass 2	Cord blood: 143-453 mg/dL 0-2 months: 40-167 mg/dL 3-5 months: 23-147 mg/dL 6-8 months: 37-60 mg/dL 9-23 months: 30-327 mg/dL 2 years: 22-440 mg/dL 3-4 years: 28-315 mg/dL 5-6 years: 57-345 mg/dL 7-8 years: 42-375 mg/dL 9-10 years: 61-430 mg/dL 11-12 years: 73-455 mg/dL 13-14 years: 71-460 mg/dL 15 years and older: 124-549 mg/dL
0050573	Immunoglobulin G Subclass 3	Cord blood: 27-146 mg/dL 0-2 months: 4-23 mg/dL 3-5 months: 4-70 mg/dL 6-8 months: 12-62 mg/dL 9-23 months: 13-82 mg/dL 2 years: 4-69 mg/dL 3-4 years: 4-71 mg/dL 5-6 years: 8-126 mg/dL 7-8 years: 9-107 mg/dL 9-10 years: 10-98 mg/dL 11-12 years: 16-194 mg/dL 13-14 years: 12-178 mg/dL 15 years and older: 21-134 mg/dL
0050576	Immunoglobulin G Subclass 4	Cord blood: 1-47 mg/dL 0-2 months: 1-33 mg/dL 3-5 months: 1-14 mg/dL 6-8 months: 1-16 mg/dL 9-23 months: 1-65 mg/dL 2 years: 0-120 mg/dL 3-4 years: 0-90 mg/dL 5-6 years: 2-116 mg/dL 7-8 years: 0-138 mg/dL 9-10 years: 1-95 mg/dL 11-12 years: 1-153 mg/dL 13-14 years: 2-143 mg/dL 15 years and older: 1-123 mg/dL

**0050355**

**Immunoglobulin M**

**IGM**

**Reference Interval:** Effective February 16, 2016

0-30 days: 0-24 mg/dL 1 month: 19-83 mg/dL 2 months: 16-100 mg/dL 3 months: 23-85 mg/dL 4 months: 26-96 mg/dL 5 months: 31-103 mg/dL 6 months: 33-97 mg/dL 7-8 months: 32-120 mg/dL	9-11 months: 39-142 mg/dL 1 year: 41-164 mg/dL 2 years: 46-160 mg/dL 3 years: 45-190 mg/dL 4 years: 41-186 mg/dL 5-7 years: 46-197 mg/dL 8-9 years: 49-230 mg/dL 10 years and older: 35-263 mg/dL
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Quarterly HOT LINE: Effective February 16, 2016

**0050630**

**Immunoglobulins (IgA, IgG, IgM), Quantitative**

**QNTIG**

**Reference Interval:** Effective February 16, 2016

Test Number	Components	Reference Interval
0050340	Immunoglobulin A	0-30 days: 1-7 mg/dL 1 month: 1-53 mg/dL 2 months: 3-47 mg/dL 3 months: 5-46 mg/dL 4 months: 4-72 mg/dL 5 months: 8-83 mg/dL 6 months: 8-67 mg/dL 7-8 months: 11-89 mg/dL
		9-11 months: 16-83 mg/dL 1 year: 14-105 mg/dL 2 years: 14-122 mg/dL 3 years: 22-157 mg/dL 4 years: 25-152 mg/dL 5-7 years: 33-200 mg/dL 8-9 years: 45-234 mg/dL 10 years and older: 68-408 mg/dL
0050350	Immunoglobulin G	0-30 days: 611-1542 mg/dL 1 month: 241-870 mg/dL 2 months: 198-577 mg/dL 3 months: 169-558 mg/dL 4 months: 188-536 mg/dL 5 months: 165-781 mg/dL 6 months: 206-676 mg/dL 7-8 months: 208-868 mg/dL
		9-11 months: 282-1026 mg/dL 1 year: 331-1164 mg/dL 2 years: 407-1009 mg/dL 3 years: 423-1090 mg/dL 4 years: 444-1187 mg/dL 5-7 years: 608-1229 mg/dL 8-9 years: 584-1509 mg/dL 10 years and older: 768-1632 mg/dL
0050355	Immunoglobulin M	0-30 days: 0-24 mg/dL 1 month: 19-83 mg/dL 2 months: 16-100 mg/dL 3 months: 23-85 mg/dL 4 months: 26-96 mg/dL 5 months: 31-103 mg/dL 6 months: 33-97 mg/dL 7-8 months: 32-120 mg/dL
		9-11 months: 39-142 mg/dL 1 year: 41-164 mg/dL 2 years: 46-160 mg/dL 3 years: 45-190 mg/dL 4 years: 41-186 mg/dL 5-7 years: 46-197 mg/dL 8-9 years: 49-230 mg/dL 10 years and older: 35-263 mg/dL

**New Test**

**2013115**

**Interleukin 17**

**IL17**

Available February 16, 2016

**Methodology:** Quantitative Multiplex Bead Assay  
**Performed:** Mon, Wed, Fri  
**Reported:** 1-4 days

**Specimen Required:** Collect: Serum Separator Tube (SST), Plain Red, or Green (Lithium Heparin).  
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.3 mL)  
Storage/Transport Temperature: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**  
Unacceptable Conditions: Contaminated or heat-inactivated specimens.  
Stability (collection to initiation of testing): After separation from cells: Ambient: 30 minutes; Refrigerated: Unacceptable; Frozen: 1 year

**Reference Interval:** 13 pg/mL or less

**Interpretive Data:** Results are used to understand the pathophysiology of immune, infectious, or inflammatory disorders, or may be used for research purposes.

See Compliance Statement B: [www.aruplab.com/CS](http://www.aruplab.com/CS)

**Note:** Lower limit of detection is 5 pg/mL.

**CPT Code(s):** 83520

New York DOH approval pending. Call for status update.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.

Quarterly HOT LINE: Effective February 16, 2016

<a href="#"><u>2000271</u></a>	<b>Isohemagglutinin Titer, IgG</b>	<b>IRL ISO G</b>
Specimen Required: Collect: <b>Lavender</b> (EDTA), or pink (K <sub>2</sub> EDTA).		
<a href="#"><u>2000280</u></a>	<b>Isohemagglutinin Titer, IgG <b>and</b> IgM</b>	<b>IRL ISO MG</b>
Specimen Required: Collect: <b>Lavender</b> (EDTA), or pink (K <sub>2</sub> EDTA).		
<a href="#"><u>2000270</u></a>	<b>Isohemagglutinin Titer, IgM</b>	<b>IRL ISO M</b>
Specimen Required: Collect: <b>Lavender</b> (EDTA), or pink (K <sub>2</sub> EDTA).		
<a href="#"><u>2002888</u></a>	<b>Kappa/Lambda Light Chain Panel by in situ Hybridization, Paraffin</b>	<b>K/L ISH</b>

**HOT LINE NOTE:** There is a component change associated with this test.  
Change component 2003001 H and E Slide Description from Prompt test to **Resultable test**.

**New Test**     [2012207](#)     **KIT D816V Mutation Detection by PCR for Gleevec Eligibility in Aggressive Systemic Mastocytosis (ASM)**     **KIT GLV**

Available January 19, 2016



Additional Technical Information

**Methodology:** Polymerase Chain Reaction  
**Performed:** **DNA isolation:** Sun-Sat  
**Assay:** Mon, Thu  
**Reported:** 2-7 days

**Specimen Required:** Patient Prep: The *KIT* D816V for Gleevec Eligibility in ASM is approved by the FDA as a Humanitarian Use Device for qualitative polymerase chain reaction (PCR) detection of *KIT* D816V mutational status in patients with aggressive systemic mastocytosis (ASM). Testing must be ordered using the following instructions:

1. The ordering physician must register with the Internal Review Board (IRB) for *KIT* D816V for Gleevec Eligibility in ASM testing. Go to <http://www.aruplab.com/KITD816V> to obtain IRB registration online.
2. The test should be ordered using the ARUP test requisition form or via ARUP's web-based ordering interface (available only to existing ARUP clients). The full name of the ordering physician must be included on the ARUP form to ensure timely testing of the specimen. Specimens submitted with incomplete information may delay specimen testing.
3. Physicians are instructed as follows: ARUP does not accept specimens directly from physician offices. ARUP only accepts specimens from established clients. To send a specimen to ARUP, contact your local hospital/reference lab to determine if they are an ARUP client and can send the specimen. If they cannot send the specimens to ARUP, contact ARUP Client Services at (800) 522-2787 to be directed to an alternative ordering mechanism.
4. Information about the *KIT* D816V for Gleevec Eligibility in ASM test and IRB registration may be accessed at <http://www.aruplab.com/KITD816V>.
5. ARUP will receive specimens via usual shipping routes, from designated clients. When the specimen arrives, with an accompanying requisition, the physician's full name will be logged in, if present. If the ordering physician's full name is not present, the specimen is placed on EXCEPT (handled by the Exception Handling services group) after evaluation by the Integrated Oncology and Genetics (IOG) services group. The IOG services group will then attempt to locate the physician for confirmation of IRB registration. Upon confirmation of physician registration, the IOG services group will notify the Molecular Oncology clinical laboratory, and testing will proceed.

Collect: Fresh bone marrow.  
Specimen Preparation: Transfer 3 mL bone marrow to an EDTA tube. (Min: 1 mL)  
Storage/Transport Temperature: Refrigerated.  
Unacceptable Conditions: Whole blood. Paraffin-embedded or clotted specimens.  
Stability (collection to initiation of testing): Specimen must be received and testing initiated within: Ambient: Unacceptable; Refrigerated: 3 days; Frozen: Unacceptable

**Reference Interval:** By report

**Interpretive Data:** Refer to report.

**CPT Code(s):** 81402

New York DOH Approved.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.

[0020505](#)     **Lactate Dehydrogenase Total, Body Fluid**     **LDH-FL**

**Specimen Required:**  
Collect: CSF, Pericardial, Peritoneal/Ascites, Pleural, or Synovial fluid.

**Interpretive Data:** For information on body fluid reference ranges and/or interpretive guidance visit <http://aruplab.com/bodyfluids/>

See Compliance Statement B: [www.aruplab.com/CS](http://www.aruplab.com/CS)

**HOT LINE NOTE:** There is a component change associated with this test.  
 Remove component 0097114, SR Source  
 Add component 2013054, LDH Fluid Source



Quarterly HOT LINE: Effective February 16, 2016

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**0020006 Lactate Dehydrogenase, Serum or Plasma LDH**

**Specimen Required:**

Storage/Transport Temperature: Room temperature.

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**0020715 Lipase, Fluid LIP FL**

**Specimen Required:**

Collect: Biliary/Hepatic, Drain, Pancreatic, Pericardial, Peritoneal/Ascites, Pleural or Synovial fluid.

Specimen Preparation: Centrifuge to remove cellular material. Transfer 1 mL body fluid to an ARUP Standard Transport Tube. (Min: 0.5 mL)

**Interpretive Data:** For information on body fluid reference ranges and/or interpretive guidance visit <http://aruplab.com/bodyfluids/>

See Compliance Statement B: [www.aruplab.com/CS](http://www.aruplab.com/CS)

**HOT LINE NOTE:** There is a component change associated with this test.

Remove component 0020777, Source, Fluid

Add component 2013057, Lipase Fluid Source

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**0030181 Lupus Anticoagulant Reflexive Panel LUPUS R**

**Reference Interval:** Effective February 16, 2016

Test Number	Components	Reference Interval
	Dilute Russell Viper Venom Time (dRVVT)	33-44 seconds
	Dilute Russell Viper Venom (dRVVT) 1:1 Mix (performed if dRVVT > 44 seconds)	33-44 seconds
	Dilute Russell Viper Venom Time (dRVVT) Confirmation Test (performed if dRVVT 1:1 Mix > 44 seconds)	Negative
	Partial Thromboplastin Time	32-48 seconds
	Thrombin Time	14.7-19.5 seconds
	Reptilase Time	Less than 22.0 seconds
	PTT Heparin Neutralized	32-48 seconds
	Partial Thromboplastin Time 1:1 Mix (performed if PTT > 48 seconds)	32-48 seconds
	Platelet Neutralization Procedure (performed if PTT 1:1 Mix > 48 seconds)	Negative
	Hexagonal Phospholipid Neutralization	Negative

**New Test**     **2013018**  
Available January 19, 2016

**Lurasidone Quantitative, Serum or Plasma**

**LURASID**

**Methodology:** Quantitative High Performance Liquid Chromatography/Tandem Mass Spectrometry  
**Performed:** Varies  
**Reported:** 7-10 days

**Specimen Required:** Collect: Plain red, lavender (EDTA), or pink (K<sub>2</sub>EDTA).  
Specimen Preparation: Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.3 mL)  
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.  
Unacceptable Conditions: Separator tubes.  
Stability (collection to initiation of testing): Ambient: 1 month; Refrigerated: 1 month; Frozen: 15 months

**CPT Code(s):** 80342; (Alt code: G0480)  
New York DOH Approved.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.

**New Test**     [2013117](#)     **Lymphocyte Antigen and Mitogen Proliferation Panel with Cytokine Response**     **LAM CYT**

Available April 4, 2016



Time Sensitive



Test not New York DOH approved at any laboratory. An approved NPL form must accompany specimen.

**Methodology:** Cell Culture/Multiplex Bead Assay  
**Performed:** Tue-Fri  
**Reported:** 9-10 days

**Specimen Required:** Patient Prep: Collect control specimen from a healthy individual unrelated to patient at approximately the same time as and under similar conditions to the patient.  
Collect: Green (sodium heparin) (patient) **AND** green (sodium heparin) (control). Also acceptable: Yellow (ACD solution A) (patient) **AND** yellow (ACD solution A) (control). **Patient and control specimens must be collected within 48 hours of test.**  
Specimen Preparation: Transport 20 mL whole blood (patient) **AND** 20 mL whole blood (control) in original collection tubes. (Min: 14 mL (patient) **AND** 14 mL (control)) **Do not refrigerate or freeze. LIVE CELLS REQUIRED.**  
Infant Minimum: 3 mL (patient) **AND** 14 mL (control).  
Storage/Transport Temperature: **CRITICAL ROOM TEMPERATURE.**  
Unacceptable Conditions: Yellow (ACD Solution B). Specimens in transport longer than 48 hours.  
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable  
**New York State Clients:** Ambient 24 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

**Reference Interval:** By report

**Interpretive Data:** Candida and tetanus antigens are tested independently in lymphocyte culture. Lymphocyte proliferation in response to these antigens is determined by 3H-thymidine incorporation.

Phytohemagglutinin, concanavalin A and pokeweed mitogen are tested independently in lymphocyte culture. Lymphocyte proliferation in response to the non-specific mitogens phytohemagglutinin (PHA), concanavalin A (Con A) and pokeweed (PW) are determined by 3H-thymidine incorporation.

Results are reported as counts per minute (CPM) mitogen stimulated versus a control culture and a stimulation Index (SI) which represents the ratio of CPM of the stimulated lymphocytes to the mean CPM of the unstimulated control.

SI\* = Stimulation Index (CPM Mitogen/CPM Media alone)

Antigens (*Candida albicans*, tetanus toxoid) and mitogens (phytohemagglutinin, concanavalin A, pokeweed) are tested independently in lymphocyte culture. Peripheral Blood Mononuclear Cell (PBMC) cytokine production responses to these antigens and mitogens are determined by quantitative multiplex bead assay. Results are used to understand the pathophysiology of immune, infectious, or inflammatory disorders, or may be used for research purposes.

See Compliance Statement B: [www.aruplab.com/CS](http://www.aruplab.com/CS)

**Note:** The following cytokines (and receptor) are reported: IL-2, sIL-2R (sCD25), IL-4, IL-5, IL-10, IL-13, IL-1b, IL-6, IL-8, IL-17, TNF-a, and IFN-g. Interpretation comparing the patient results to the simultaneously collected client normal control and the laboratory normal control will be provided by an ARUP medical director.

**CPT Code(s):** 86353 x5; 83520 x12

New York DOH approval pending. Call for status update.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.

**New Test**     [2013082](#)  
Available January 19, 2016

**MET Gene Amplification by FISH**

**MET FISH**



Additional Technical Information

**Methodology:** Fluorescence in situ Hybridization  
**Performed:** Varies  
**Reported:** 3-7 days

**Specimen Required:** Collect: Tumor tissue.

Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed tumor tissue. Transport tissue block or 4 unstained, consecutively cut, 5-micron thick sections, mounted on positively charged glass slides. (Min: 4 slides) Protect paraffin block and/or slides from excessive heat.

Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated.

Remarks: Include surgical pathology report with reason for referral. The laboratory will not reject specimens that arrive without a pathology report but will hold the specimen until this information is received.

Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

**Reference Interval:** By report

**Interpretive Data:** See Compliance Statement A: [www.aruplab.com/CS](http://www.aruplab.com/CS)

**CPT Code(s):** 88366

New York DOH approval pending. Call for status update.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.

**New Test**     [2013014](#)  
Available January 19, 2016

**Mitotane, Serum or Plasma**

**MITOT SP**

**Methodology:** Quantitative Gas Chromatography  
**Performed:** Varies  
**Reported:** 3-9 days

**Specimen Required:** Collect: Plain red, lavender (EDTA), or pink (K<sub>2</sub>EDTA).

Specimen Preparation: Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.3 mL)

Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.

Unacceptable Conditions: Separator tubes.

Stability (collection to initiation of testing): Ambient: 2 weeks; Refrigerated: 2 weeks; Frozen: 2 weeks

**Reference Interval:** By report

**CPT Code(s):** 80375 (Alt code: G0480)

New York DOH Approved.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.

Quarterly HOT LINE: Effective February 16, 2016

0050615

**Monoclonal Protein Detection Quantitation and Characterization, SPEP, IFE, IgA, IgG, IgM, Serum**

**IFE**

**Reference Interval:** Effective February 16, 2016

Test Number	Components	Reference Interval		
0050640	Protein Electrophoresis, Serum			
		<b>Test Number</b>	<b>Components</b>	<b>Reference Interval</b>
			Total Protein-Electrophoresis, Serum	Refer to report
			Albumin	Refer to report
			Alpha-1 Globulins	Refer to report
			Alpha-2 Globulins	Refer to report
			Beta Globulins	Refer to report
	Gamma	Refer to report		
0050340	Immunoglobulin A	0-30 days: 1-7 mg/dL 1 month: 1-53 mg/dL 2 months: 3-47 mg/dL 3 months: 5-46 mg/dL 4 months: 4-72 mg/dL 5 months: 8-83 mg/dL 6 months: 8-67 mg/dL 7-8 months: 11-89 mg/dL	9-11 months: 16-83 mg/dL 1 year: 14-105 mg/dL 2 years: 14-122 mg/dL 3 years: 22-157 mg/dL 4 years: 25-152 mg/dL 5-7 years: 33-200 mg/dL 8-9 years: 45-234 mg/dL 10 years and older: 68-408 mg/dL	
0050350	Immunoglobulin G	0- 30 days: 611-1542 mg/dL 1 month: 241-870 mg/dL 2 months: 198-577 mg/dL 3 months: 169-558 mg/dL 4 months: 188-536 mg/dL 5 months: 165-781 mg/dL 6 months: 206-676 mg/dL 7-8 months: 208-868 mg/dL	9-11 months: 282-1026 mg/dL 1 year: 331-1164 mg/dL 2 years: 407-1009 mg/dL 3 years: 423-1090 mg/dL 4 years: 444-1187 mg/dL 5-7 years: 608-1229 mg/dL 8-9 years: 584-1509 mg/dL 10 years and older: 768-1632 mg/dL	
0050355	Immunoglobulin M	0-30 days: 0-24 mg/dL 1 month: 19-83 mg/dL 2 months: 16-100 mg/dL 3 months: 23-85 mg/dL 4 months: 26-96 mg/dL 5 months: 31-103 mg/dL 6 months: 33-97 mg/dL 7-8 months: 32-120 mg/dL	9-11 months: 39-142 mg/dL 1 year: 41-164 mg/dL 2 years: 46-160 mg/dL 3 years: 45-190 mg/dL 4 years: 41-186 mg/dL 5-7 years: 46-197 mg/dL 8-9 years: 49-230 mg/dL 10 years and older: 35-263 mg/dL	

Quarterly HOT LINE: Effective February 16, 2016

2002715

**Monoclonal Protein Detection, Quantitation, Characterization, SPEP, IFE, IgA, IgG, IgM, FLC**

**IFE FLC**

**Reference Interval:** Effective February 16, 2016

Test Number	Components	Reference Interval		
0050640	Protein Electrophoresis, Serum			
		<b>Test Number</b>	<b>Components</b>	<b>Reference Interval</b>
			Total Protein-Electrophoresis, Serum	Refer to report
			Albumin	Refer to report
			Alpha-1 Globulins	Refer to report
			Alpha-2 Globulins	Refer to report
			Beta Globulins	Refer to report
	Gamma	Refer to report		
0050340	Immunoglobulin A	0-30 days: 1-7 mg/dL 1 month: 1-53 mg/dL 2 months: 3-47 mg/dL 3 months: 5-46 mg/dL 4 months: 4-72 mg/dL 5 months: 8-83 mg/dL 6 months: 8-67 mg/dL 7-8 months: 11-89 mg/dL	9-11 months: 16-83 mg/dL 1 year: 14-105 mg/dL 2 years: 14-122 mg/dL 3 years: 22-157 mg/dL 4 years: 25-152 mg/dL 5-7 years: 33-200 mg/dL 8-9 years: 45-234 mg/dL 10 years and older: 68-408 mg/dL	
0050350	Immunoglobulin G	0- 30 days: 611-1542 mg/dL 1 month: 241-870 mg/dL 2 months: 198-577 mg/dL 3 months: 169-558 mg/dL 4 months: 188-536 mg/dL 5 months: 165-781 mg/dL 6 months: 206-676 mg/dL 7-8 months: 208-868 mg/dL	9-11 months: 282-1026 mg/dL 1 year: 331-1164 mg/dL 2 years: 407-1009 mg/dL 3 years: 423-1090 mg/dL 4 years: 444-1187 mg/dL 5-7 years: 608-1229 mg/dL 8-9 years: 584-1509 mg/dL 10 years and older: 768-1632 mg/dL	
0050355	Immunoglobulin M	0-30 days: 0-24 mg/dL 1 month: 19-83 mg/dL 2 months: 16-100 mg/dL 3 months: 23-85 mg/dL 4 months: 26-96 mg/dL 5 months: 31-103 mg/dL 6 months: 33-97 mg/dL 7-8 months: 32-120 mg/dL	9-11 months: 39-142 mg/dL 1 year: 41-164 mg/dL 2 years: 46-160 mg/dL 3 years: 45-190 mg/dL 4 years: 41-186 mg/dL 5-7 years: 46-197 mg/dL 8-9 years: 49-230 mg/dL 10 years and older: 35-263 mg/dL	
	Kappa Quantitative Free Light Chains, Serum	0.33 - 1.94 mg/dL		
	Lambda Quantitative Free Light Chains, Serum	0.57-2.63 mg/dL		
	Kappa/Lambda Free Light Chain Ratio, Serum	0.26-1.65		

2007967

**Motor and Sensory Neuropathy Evaluation with Immunofixation Electrophoresis and Reflex to Titer and Neuronal Immunoblot**

**MSNCR**

**Reference Interval:** Effective February 16, 2016

Test Number	Components	Reference Interval		
	Purkinje Cell/Neuronal Nuclear IgG Scrn	None Detected		
	Neuronal Nuclear Antibody (ANNA) IFA Titer, IgG	Less than 1:10		
	Purkinje Cell Antibody, Titer	Less than 1:10		
2007963	Neuronal Nuclear Antibodies (Hu, Ri, Yo) IgG by Immunoblot	None Detected		
0051285	Myelin Associated Glycoprotein (MAG) Antibody, IgM	Less than 1000 TU		
0051284	Sulfate-3-Glucuronyl Paragloboside (SGPG) Antibody, IgM	Less than 1.00 IV		
	Asialo-GM1 Antibodies, IgG/IgM	29 IV or less: Negative 30-50 IV: Equivocal 51-100 IV: Positive 101 IV or greater: Strong Positive		
	GM1 Antibodies, IgG/IgM	29 IV or less: Negative 30-50 IV: Equivocal 51-100 IV: Positive 101 IV or greater: Strong Positive		
	GD1a Antibodies, IgG/IgM	29 IV or less: Negative 30-50 IV: Equivocal 51-100 IV: Positive 101 IV or greater: Strong Positive		
	GD1b Antibodies, IgG/IgM	29 IV or less: Negative 30-50 IV: Equivocal 51-100 IV: Positive 101 IV or greater: Strong Positive		
	GQ1b Antibodies, IgG/IgM	29 IV or less: Negative 30-50 IV: Equivocal 51-100 IV: Positive 101 IV or greater: Strong Positive		
	Total Protein-Electrophoresis, Serum	6.00-8.30 g/dL		
	Albumin	3.75-5.01 g/dL		
	Alpha-1 Globulins	0.19-0.46 g/dL		
	Alpha-2 Globulins	0.48-1.05 g/dL		
	Beta Globulins	0.48-1.10 g/dL		
	Gamma	0.62-1.51 g/dL		
0050340	Immunoglobulin A	<table border="1"> <tr> <td>0-30 days: 1-7 mg/dL 1 month: 1-53 mg/dL 2 months: 3-47 mg/dL 3 months: 5-46 mg/dL 4 months: 4-72 mg/dL 5 months: 8-83 mg/dL 6 months: 8-67 mg/dL 7-8 months: 11-89 mg/dL</td> <td>9-11 months: 16-83 mg/dL 1 year: 14-105 mg/dL 2 years: 14-122 mg/dL 3 years: 22-157 mg/dL 4 years: 25-152 mg/dL 5-7 years: 33-200 mg/dL 8-9 years: 45-234 mg/dL 10 years and older: 68-408 mg/dL</td> </tr> </table>	0-30 days: 1-7 mg/dL 1 month: 1-53 mg/dL 2 months: 3-47 mg/dL 3 months: 5-46 mg/dL 4 months: 4-72 mg/dL 5 months: 8-83 mg/dL 6 months: 8-67 mg/dL 7-8 months: 11-89 mg/dL	9-11 months: 16-83 mg/dL 1 year: 14-105 mg/dL 2 years: 14-122 mg/dL 3 years: 22-157 mg/dL 4 years: 25-152 mg/dL 5-7 years: 33-200 mg/dL 8-9 years: 45-234 mg/dL 10 years and older: 68-408 mg/dL
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0050355	Immunoglobulin M			

Quarterly HOT LINE: Effective February 16, 2016

	<p>0-30 days: 0-24 mg/dL          1 month: 19-83 mg/dL          2 months: 16-100 mg/dL          3 months: 23-85 mg/dL          4 months: 26-96 mg/dL          5 months: 31-103 mg/dL          6 months: 33-97 mg/dL          7-8 months: 32-120 mg/dL</p>	<p>9-11 months: 39-142 mg/dL          1 year: 41-164 mg/dL          2 years: 46-160 mg/dL          3 years: 45-190 mg/dL          4 years: 41-186 mg/dL          5-7 years: 46-197 mg/dL          8-9 years: 49-230 mg/dL          10 years and older: 35-263 mg/dL</p>



**0051225**

**Motor Neuropathy Panel**

**MSN PAN**

Reference Interval: Effective February 16, 2016

Test Number	Components	Reference Interval		
	Asialo-GM1 Antibodies, IgG/IgM	29 IV or less: Negative 30-50 IV: Equivocal 51-100 IV: Positive 101 IV or greater: Strong Positive		
	GM1 Antibodies, IgG/IgM	29 IV or less: Negative 30-50 IV: Equivocal 51-100 IV: Positive 101 IV or greater: Strong Positive		
	GD1a Antibodies, IgG/IgM	29 IV or less: Negative 30-50 IV: Equivocal 51-100 IV: Positive 101 IV or greater: Strong Positive		
	GD1b Antibodies, IgG/IgM	29 IV or less: Negative 30-50 IV: Equivocal 51-100 IV: Positive 101 IV or greater: Strong Positive		
	GQ1b Antibodies, IgG/IgM	29 IV or less: Negative 30-50 IV: Equivocal 51-100 IV: Positive 101 IV or greater: Strong Positive		
	Total Protein-Electrophoresis, Serum	6.00-8.30 g/dL		
	Albumin	3.75-5.01 g/dL		
	Alpha-1 Globulins	0.19-0.46 g/dL		
	Alpha-2 Globulins	0.48-1.05 g/dL		
	Beta Globulins	0.48-1.10 g/dL		
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0051285	Myelin Associated Glycoprotein (MAG) Antibody, IgM	Less than 1000 TU		
0051284	Sulfate-3-Glucuronyl Paragloboside (SGPG) Antibody, IgM	Less than 1.00 IV		

**0081352**

**Mucopolysaccharides Screen - Electrophoresis and Quantitation, Urine**

**MPS SCREEN**

CPT Code(s): 82664; 83864

Quarterly HOT LINE: Effective February 16, 2016

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**2007190**      **Occult Blood, Fecal by Immunoassay**      **FOB IA**

**Specimen Required:**

Specimen Preparation: Patient will dip sampling bottle transfer wand into stool collection and place back into sampling bottle (ARUP Supply #49952) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. **Stool must be transferred to sampling bottle within 4 hours.**

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**0098834**      **Oxcarbazepine or Eslicarbazepine Metabolite (MHD)**      **OXCARB**

**HOT LINE NOTE:** There is a clinically significant charting name change associated with this test.

Change the charting name of component 0098834 from Oxcarbazepine Metabolite to **Oxcarb or Eslicarb Metabolite (MHD)**

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**2010102**      **PCA3 - Prostate Cancer Biomarker by Transcription-Mediated Amplification**      **PCA3 TMA**

**Performed:**      **Thu**  
**Reported:**      **3-8 days**

**Specimen Required:**

Specimen Preparation: Invert urine container 5 times to mix. **Transfer 2.5 mL urine ASAP or within 4 hours of collection into two (2) ProgenSA PCA3 Urine Specimen Transport Tubes (ARUP Supply #45682) available online through eSupply using ARUP Connect or contact ARUP Client Services at (800) 522-2787. (Min: 2.5 mL per tube)** Liquid level must be between black lines on transport tubes. Cap transport tubes and invert 5 times to mix.

**New Test**     [2012147](#)     **PDGFRB FISH for Gleevec Eligibility in Myelodysplastic Syndrome/Myeloproliferative Disease (MDS/MPD)**     **PDGFRB GLV**

Available February 16, 2016



Time Sensitive

**ARUP Consult®**  
Disease Topics

Myelodysplastic syndromes

**Methodology:** Fluorescence in situ Hybridization  
**Performed:** Sun-Sat  
**Reported:** 3-10 days

**Specimen Required:** Patient Prep: *PDGFRB* FISH for Gleevec Eligibility in MDS/MPD is approved by the FDA as a Humanitarian Device for FISH testing of the *PDGFRB* gene to determine mutational status in patients with MDS/MPD. Testing must be ordered using the following instructions:

1. The ordering physician must register with the Internal Review Board (IRB) for *PDGFRB* FISH for Gleevec Eligibility in MDS/MPD testing. Go to <http://www.aruplab.com/PDGFRB> to obtain IRB registration online.
  2. The test should be ordered using the ARUP test requisition form or via ARUP's web-based ordering interface (available only to existing ARUP clients). The full name of the ordering physician must be included on the ARUP form to ensure timely testing of the specimen. Specimens submitted with incomplete information may delay specimen testing.
  3. Physicians are instructed as follows: ARUP does not accept specimens directly from physician offices. ARUP only accepts specimens from established clients. To send a specimen to ARUP, contact your local hospital/reference lab to determine if they are an ARUP client and can send the specimen. If they cannot send the specimens to ARUP, contact ARUP Client Services at (800) 522-2787 to be directed to an alternative ordering mechanism.
  4. Information about the *PDGFRB* FISH for Gleevec Eligibility in MDS/MPD test and IRB registration may be accessed at [www.aruplab.com/PDGFRB](http://www.aruplab.com/PDGFRB).
  5. ARUP will receive specimens via usual shipping routes, from designated clients. When the specimen arrives, with an accompanying requisition, the physician's full name will be logged in, if present. If the ordering physician's full name is not present, the specimen is placed on EXCEPT by the Integrated Oncology and Genetics (IOG) services group. The IOG services group will then attempt to locate the physician for confirmation of IRB registration. Upon confirmation of physician registration, the IOG services group will notify the Cytogenetics clinical laboratory, and testing will proceed.
- Collect: Non-diluted bone marrow aspirate collected in a heparinized syringe. Also acceptable: Green (sodium heparin).  
Specimen Preparation: Transfer 3 mL bone marrow to a green (sodium heparin) tube. (Min: 1 mL)  
Storage/Transport Temperature: Room temperature.  
Unacceptable Conditions: Paraffin-embedded specimens. Clotted specimens.  
Stability (collection to initiation of testing): Specimen must be received and testing initiated within: Ambient: 3 days; Refrigerated: Unacceptable; Frozen: Unacceptable

**Reference Interval:** By report

**Interpretive Data:** Refer to report.

**CPT Code(s):** 88271; 88275; 88291

New York DOH Approved.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.

Quarterly HOT LINE: Effective February 16, 2016

**New Test**     [2013025](#)     **Perampanel Quantitative, Serum or Plasma**     **PERAMP**  
 Available January 19, 2016

**Methodology:**     Quantitative High Performance Liquid Chromatography/Tandem Mass Spectrometry  
**Performed:**         Varies  
**Reported:**          3-9 days

**Specimen Required:** Collect: Plain red, lavender (EDTA), or pink (K<sub>2</sub>EDTA).  
Specimen Preparation: Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.3 mL)  
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.  
Unacceptable Conditions: Separator tubes.  
Stability (collection to initiation of testing): Ambient: 1 month; Refrigerated: 1 month; Frozen: 1 month

**CPT Code(s):**        80339 (Alt code: G0480)

New York DOH Approved.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.

**New Test**     [2013008](#)     **Periprosthetic Joint Infection (PJI) Detection (Synovasure)**     **SYNOVA PJI**  
 Available January 19, 2016

**Methodology:**     Qualitative Enzyme-Linked Immunosorbent Assay  
**Performed:**         Varies  
**Reported:**          3-5 days

**Specimen Required:** Collect: Synovial fluid in plain red. **Specimens must be collected and shipped Monday-Wednesday only and not the day before a holiday.**  
Specimen Preparation: Transport 1 mL synovial fluid. (Min: 0.5 mL)  
Storage/Transport Temperature: Refrigerated.  
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 72 hours; Frozen: Unacceptable

**Reference Interval:** By report

**CPT Code(s):**        86140, 84311, 83516

New York DOH approval pending. Call for status update.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.

**New Test**     [2013070](#)     **Platelet Surface Glycoprotein Expression (PGE) by Flow Cytometry, Whole Blood**     **PGE**

Available January 19, 2016

**Methodology:** Qualitative Flow Cytometry  
**Performed:** Sun-Sat  
**Reported:** 1-3 days

**Specimen Required:** Collect: Lavender (EDTA), pink (K<sub>2</sub> EDTA), or yellow (ACD Solution B).  
Specimen Preparation: Transport 4 mL whole blood. (Min: 0.1 mL)  
Storage/Transport Temperature: Room temperature.  
Stability (collection to initiation of testing): EDTA: Ambient: 72 hours; Refrigerated: 72 hours; Frozen: Unacceptable  
ACD solution B: Ambient: 72 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

**Reference Interval:** Normal

**Interpretive Data:** Refer to report.

**CPT Code(s):** 86022 x3

New York DOH approval pending. Call for status update.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.

[0020155](#)     **Potassium, Fluid**     **K FL**

**Specimen Required:**  
Collect: CSF, Drain, Pancreatic, Pericardial, Peritoneal/Ascites or Pleural fluid.

**Interpretive Data:** For information on body fluid reference ranges and/or interpretive guidance visit <http://aruplab.com/bodyfluids/>

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement B: [aruplab.com/CS](http://aruplab.com/CS)

**HOT LINE NOTE:** There is a component change associated with this test.  
Remove component 0020777, Source, Fluid  
Add component 2013038, Potassium Fluid Source

[2008095](#)     **14-3-3 Protein Tau/Theta with Reflex to RT-QuIC Analysis, CSF**     **14-3-3 CSF**

**Specimen Required:**  
Specimen Preparation: The first 2 mL of CSF that flows from the tap should be discarded. Transfer 5 mL CSF to ARUP Standard Transport Tubes. (Min: 2 mL) **Freeze immediately.**

[0020502](#)     **Protein, Total, Body Fluid**     **TP-FL**

**Specimen Required:**  
Collect: Pericardial, Peritoneal/Ascites, Pleural, or Synovial fluid.

**Interpretive Data:** For information on body fluid reference ranges and/or interpretive guidance visit <http://aruplab.com/bodyfluids/>

See Compliance Statement B: [www.aruplab.com/CS](http://www.aruplab.com/CS)

**HOT LINE NOTE:** There is a component change associated with this test.  
Remove component 0097114, SR Source  
Add component 2013063, Total Protein Fluid Source

[0080312](#)     **Pyruvic Acid, CSF**     **PYRU CSF**

**Specimen Required:**  
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: **2 days**; Frozen: **1 month**

**0050302**

**Raji Cell Immune Complex Assay**

**RAJI**

**Specimen Required:**

**Specimen Preparation:** Allow complete clotting of red blood cells (up to 1 hour), then separate serum from cells within 30 minutes and freeze immediately. Transport 1 mL serum. (Min: 0.5 mL) If ordered in conjunction with a C1q Binding Assay, transfer TWO (2) 1 mL aliquots of serum to individual ARUP Standard Transport Tubes.

**2003347**

**Rheumatoid Factor, Body Fluid**

**RA-FL**

**Specimen Required:**

**Collect:** CSF, Pericardial, Pleural, or Synovial fluid.

**Interpretive Data:** For information on body fluid reference ranges and/or interpretive guidance visit <http://aruplab.com/bodyfluids/>

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement B: [aruplab.com/CS](http://aruplab.com/CS)

**HOT LINE NOTE:** There is a component change associated with this test.

Remove component 0097114, SR Source

Add component 2013048, Rheumatoid Factor Fluid Source

**New Test**

**2012618**

**Risk of Ovarian Malignancy Algorithm**

**ROMA**

Available January 19, 2016

**Methodology:**

Quantitative Enzyme Immunoassay, Electrochemiluminescent Immunoassay

**Performed:**

Thu, Sun

**Reported:**

1-8 days

**Specimen Required:** **Collect:** Plain red or serum separator tube (SST).

**Specimen Preparation:** Allow specimen to clot completely at room temperature. Transfer 1.5 mL serum to an ARUP Standard Transport Tube. (Min: 1 mL)

**Storage/Transport Temperature:** Frozen.

**Unacceptable Conditions:** Hemolyzed or lipemic specimens.

**Stability (collection to initiation of testing):** Ambient: 4 hours; Refrigerated: 72 hours; Frozen: 9 months

**Reference Interval:** By Report

**Interpretive Data:** The Risk of Ovarian Malignancy Algorithm (ROMA) combines the results of HE4, CA125, and menopausal status into a numerical score. If the patient is premenopausal, then a ROMA score of less than 1.31 is consistent with a low likelihood of having a malignancy on surgery. If the patient is postmenopausal, then a ROMA score of less than 2.77 is consistent with a low likelihood of having a malignancy on surgery.

ROMA is intended to aid in assessing whether a premenopausal or postmenopausal woman who presents with an ovarian adnexal mass is at high or low likelihood of having malignancy on surgery. ROMA is indicated for women who meet the following criteria: over age 18; ovarian adnexal mass present for which surgery is planned, and not yet referred to an oncologist. ROMA must be interpreted in conjunction with an independent clinical and radiological assessment. The test is not intended as a screening, stand-alone or tumor-monitoring assay. Tumor monitoring using HE4 and/or CA125 should be ordered separately.

**CPT Code(s):** 86304, 86305 or 81500 (MAAA)

New York DOH approval pending. Call for status update.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.

Quarterly HOT LINE: Effective February 16, 2016

**New Test**     [2013011](#)     **Selenium, RBCs**     **SELENI RBC**  
 Available January 19, 2016

**Methodology:** Quantitative Inductively Coupled Plasma-Mass Spectrometry  
**Performed:** Varies  
**Reported:** 3-11 days

**Specimen Required:** Collect: Royal blue (EDTA).  
Specimen Preparation: Separate cells ASAP or within 2 hours of collection. Transport 1 mL RBCs in the original collection tube. (Min: 0.4 mL)  
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature.  
Stability (collection to initiation of testing): Ambient: 1 month; Refrigerated: 1 month; Frozen: Unacceptable

**Reference Interval:** By Report

**CPT Code(s):** 84255

New York DOH approval pending. Call for status update.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.

[0020154](#)     **Sodium, Fluid**     **NA FL**

**Specimen Required:**  
Collect: CSF, Drain, Pancreatic, Pericardial, Peritoneal/Ascites or Pleural fluid.

**Interpretive Data:** For information on body fluid reference ranges and/or interpretive guidance visit <http://aruplab.com/bodyfluids/>

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement B: [aruplab.com/CS](http://aruplab.com/CS)

**HOT LINE NOTE:** There is a component change associated with this test.  
 Remove component 0020777, Source, Fluid  
 Add component 2013037, Sodium Fluid Source

[0091100](#)     **Sulfonyleurea Hypoglycemia Panel, Quantitative, Urine**     **SULFON UR**

[2011134](#)     **Thiopurine Drug Metabolites**     **THIOPMET**

**CPT Code(s):** 83789

[0050920](#)     ***Treponema pallidum* Antibody, IgG by ELISA**     **SYPH G**

**Reference Interval:** Effective February 16, 2016

Reference Interval	
0.9 IV or Less	Negative - No significant level of <i>Treponema pallidum</i> IgG antibody detected.
1.0 IV	Equivocal - Questionable presence of <i>Treponema pallidum</i> IgG antibody detected. Repeat testing in 10-14 days may be helpful.
1.1 IV or Greater	Positive - Presence of IgG antibody to <i>Treponema pallidum</i> detected, suggestive of current or past infection.

[0050787](#)     ***Trichinella* Antibody, IgG by ELISA**     **TRICH**

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**0020713      Triglycerides, Fluid      TRG FL**

**Specimen Required:**

Collect: Drain, Pericardial, Peritoneal/Ascites, or Pleural fluid.

**Interpretive Data:** For information on body fluid reference ranges and/or interpretive guidance visit <http://aruplab.com/bodyfluids/>

See Compliance Statement B: [www.aruplab.com/CS](http://www.aruplab.com/CS)

**HOT LINE NOTE:** There is a component change associated with this test.

Remove component 0020777, Source, Fluid

Add component 2013066, Triglycerides Fluid Source

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**0020040      Triglycerides, Serum or Plasma      TRG**

**Note:** Assay interference (negative) may be observed when high concentrations of N-acetylcysteine (NAC) are present. Negative interference has also been reported with NAPQI (an acetaminophen metabolite), but only with concentrations at or above those expected during acetaminophen overdose.

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**0020513      Uric Acid, Body Fluid      URIC-FL**

**Specimen Required:**

Collect: Drain, Peritoneal/Ascites, Pleural or Synovial fluid.

**Interpretive Data:** For information on body fluid reference ranges and/or interpretive guidance visit <http://aruplab.com/bodyfluids/>

See Compliance Statement B: [www.aruplab.com/CS](http://www.aruplab.com/CS)

**HOT LINE NOTE:** There is a component change associated with this test.

Remove component 0097114, SR Source

Add component 2013069, Uric Acid Fluid Source

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**0020026      Uric Acid, Serum or Plasma      URIC**

**Note:** Assay interference (negative) may be observed when high concentrations of N-acetylcysteine (NAC) are present. Negative interference has also been reported with NAPQI (an acetaminophen metabolite) but only when concentrations are at or above those expected during acetaminophen overdose.

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**0095263      VAP Cholesterol, Serum      VAP CHOL**

**Specimen Required:** Patient Prep: Fasting specimen is preferred.

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**0080380      Vitamin C (Ascorbic Acid), Plasma      VIT C**

**Specimen Required:**

Specimen Preparation: **Protect from light, centrifuge, transfer plasma and freeze within 1 hour of collection.** Transfer 0.5 mL plasma to an ARUP Amber Transport Tube. (Min: 0.3 mL)



Quarterly HOT LINE: Effective February 16, 2016

**The following will be discontinued from ARUP's test menu on April 4, 2016.  
Replacement test options are supplied if applicable.**

Test Number	Test Name	Refer To Replacement
<a href="#">2007880</a>	Alpha Subunit, Pituitary Glycoprotein Hormones	Alpha Subunit, Pituitary Glycoprotein Hormones (PGH) (2013034)
<a href="#">0051288</a>	Beta-2-Adrenergic Receptor ( <i>A2BR2</i> ) Haplotyping	
<a href="#">0091166</a>	Carbamazepine - 10,11 Epoxide, Urine	
<a href="#">0090346</a>	Chloramphenicol	
<a href="#">0051540</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, 12 Cytokines	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation (2013109)
<a href="#">0051574</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, Interferon gamma	
<a href="#">0051580</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, Interleukin 1 beta	
<a href="#">0051578</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, Interleukin 10	
<a href="#">0051579</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, Interleukin 13	
<a href="#">0051571</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, Interleukin 2	
<a href="#">0051572</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, Interleukin 2 Receptor (CD25), Soluble	
<a href="#">0051576</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, Interleukin 4	
<a href="#">0051577</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, Interleukin 5	
<a href="#">0051581</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, Interleukin 6	
<a href="#">0051582</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, Interleukin 8	
<a href="#">0051583</a>	Cytokine Production by Mononuclear Cells in Response to Mitogen Stimulation, Tumor Necrosis Factor alpha	
<a href="#">0091467</a>	Dipyridamole, Serum or Plasma	
<a href="#">0090560</a>	Drug Screen (Nonforensic), Comprehensive, Serum and Urine	Drug Screen (Nonforensic), Urine, Qualitative (0090500) or Drug Screen (Nonforensic), Serum (0090499)
<a href="#">2008440</a>	Herpesvirus 8 (HHV-8) DNA, Quantitative Real-Time PCR	Human Herpesvirus 8 (HHV-8) by Quantitative PCR (2013089)
<a href="#">2002996</a>	Herpesvirus 8 DNA, Qualitative Real-Time PCR	Human Herpesvirus 8 (HHV-8) by Quantitative PCR (2013089)
<a href="#">0051393</a>	Interleukin-1-Receptor-Associated Kinase-4 (IRAK-4) Deficiency Screen	Toll-Like Receptor Function (0051589)
<a href="#">0091295</a>	Loxapine Quantitative, Serum or Plasma	
<a href="#">0051584</a>	Lymphocyte Antigen and Mitogen Proliferation Panel with Cytokine Response to Mitogens, 12 Cytokines	Lymphocyte Antigen and Mitogen Proliferation Panel with Cytokine Response (2013117)
<a href="#">0051587</a>	Lymphocyte Antigen and Mitogen Proliferation Panel with Cytokine Response to Mitogens, Monokines	
<a href="#">0051585</a>	Lymphocyte Antigen and Mitogen Proliferation Panel with Cytokine Response to Mitogens, TH1 Cytokines	
<a href="#">0051586</a>	Lymphocyte Antigen and Mitogen Proliferation Panel with Cytokine Response to Mitogens, TH2 Cytokines	
<a href="#">0091543</a>	Midazolam Quantitation, Serum or Plasma	
<a href="#">0091383</a>	Xylenes (Total), Serum or Plasma	