Quarterly HOT LINE: Effective November 14, 2016

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	2013502	A1 Antigen Typing, Patient											x	
7	2013725	ABCC8-Related Hyperinsulinism, 3 Variants											x	
8	2013605	Adalimumab Activity with Reflex to Antibody											x	
9	2002349	5-a-Dihydrotestosterone by Tandem Mass Spectrometry, Serum				x	x							
9	2002582	Aldosterone and Renin, Direct with Ratio				x								
10	0070073	Aldosterone/Renin Activity Ratio		x		x								
72	0055196	Allergen, Epidermals and Animal Proteins, Pigeon Stools IgE												x
10	0080427	Alpha Fetoprotein (Amniotic Fluid) with Reflex to Acetylcholinesterase and Fetal Hemoglobin				x								
11	2011474	Aminolevulinic Acid (ALA), Random Urine											x	

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11	2005419	Androstanediol Glucuronide Quantitative, Serum or Plasma			x	x								
11	0080001	Angiotensin Converting Enzyme, Serum				x								
12	0060217	Antimicrobial Susceptibility, AFB/Mycobacteria					x							
13	2008467	Anti-Nuclear Antibody (ANA), IgG by IFA with Reflex by IFA Pattern		x			x							
14	2011478	Arsenic, Random Urine with Reflex to Fractionated											x	
15	0051415	Ashkenazi Jewish Diseases, 16 Genes	x	x	x	x		x	x	x				
16	0020399	Basic Metabolic Panel				x								
16	2010445	Benzodiazepines, Serum or Plasma, Quantitative								x				
16	2012225	Benzodiazepines, Urine Screen with Reflex to Quantitation								x				
16	2008291	Benzodiazepines, Urine, Quantitative								x				
17	0051433	Bloom Syndrome (*BLM*), 1 Variant	x	x	x	x		x						
17	2007335	*Borrelia burgdorferi* (Lyme Disease) Reflexive Panel (CSF)		x			x		x					
17	0050254	*Borrelia burgdorferi* Antibodies, IgG and IgM by Immunoblot	x	x		x			x					
18	0055260	*Borrelia burgdorferi* Antibodies, IgG and IgM by Immunoblot (CSF)	x	x					x					
18	0050216	*Borrelia burgdorferi* Antibodies, Total by ELISA			x	x	x	x	x					
19	0050267	*Borrelia burgdorferi* Antibodies, Total by ELISA with Reflex to IgG and IgM by Immunoblot (Early Disease)	x	x		x	x		x					
20	0099483	*Borrelia burgdorferi* Antibodies, Total by ELISA, CSF					x	x	x					
20	0050255	*Borrelia burgdorferi* Antibody, IgG by Immunoblot	x	x					x					
20	0055259	*Borrelia burgdorferi* Antibody, IgG by Immunoblot (CSF)	x	x					x					
21	0050253	*Borrelia burgdorferi* Antibody, IgM by Immunoblot	x	x		x			x					
21	0055258	*Borrelia burgdorferi* Antibody, IgM by Immunoblot (CSF)	x	x					x					
21	0051044	*Borrelia burgdorferi* C6 Peptide Antibodies, Total by ELISA				x								
22	0051043	*Borrelia burgdorferi* C6 Peptide Antibodies, Total by ELISA with Reflex to IgG and IgM by Immunoblot	x	x		x	x		x					
22	0051045	*Borrelia burgdorferi* C6 Peptide Antibodies, Total by ELISA with Reflex to IgG by Immunoblot	x	x		x	x		x					

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23	0050268	*Borrelia burgdorferi* Total Antibodies, IgG and/or IgM by ELISA with Reflex to IgG by Immunoblot (Late Disease)	x	x		x	x		x					
24	2013921	*BRAF* V600E Mutation Detection in Circulating Cell-Free DNA by Digital Droplet PCR											x	
25	2011479	Cadmium, Random Urine											x	
25	2011603	Caffeine, Serum or Plasma					x	x						
26	0051453	Canavan Disease (*ASPA*), 4 Variants	x	x	x	x		x						
26	0070412	Carbohydrate Deficient Transferrin for Alcohol Use			x									
26	2004247	*CEBPA* Mutation Detection								x				
27	2013767	*Chlamydia trachomatis* and *Neisseria gonorrhoeae* by Transcription-Mediated Amplification (TMA) with Reflex to *Chlamydia trachomatis* L serovars (LGV) by PCR											x	
28	2013768	*Chlamydia trachomatis* L serovars (LGV) by PCR											x	
28	0091267	Chloral Hydrate Metabolite, Serum or Plasma		x		x				x				
29	2011311	Chloride, Random Urine											x	
29	0020408	Comprehensive Metabolic Panel				x								
30	2011480	Copper, Random Urine											x	
30	0097222	Cortisol Urine Free by LC-MS/MS						x						
31	0092100	Cortisol/Cortisone Urine Free by LC-MS/MS						x						
31	2013562	C-Peptide, 120 Minutes											x	
32	2013564	C-Peptide, 180 Minutes											x	
32	2013558	C-Peptide, 30 Minutes											x	
33	2013560	C-Peptide, 60 Minutes											x	
33	2013504	Cw Antigen Typing, Patient											x	
34	0051232	Cytochrome P450 2D6 (*CYP2D6*) 14 Variants and Gene Duplication		x	x	x		x						
35	2013098	Cytochrome P450 Genotype Panel		x		x		x						
36	0091258	Diuretic Screen, Urine								x				
36	0092184	Drug Panel 7, Urine - Screen with Reflex to Confirmation/Quantitation								x				
36	0092185	Drug Panel 7A, Urine - Screen with Reflex to Confirmation/Quantitation								x				
36	0092186	Drug Panel 9, Urine - Screen with Reflex to Confirmation/Quantitation								x				
36	0092187	Drug Panel 9A, Urine - Screen with Reflex to Confirmation/Quantitation								x				

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37	0090499	Drug Screen (Nonforensic), Serum								x				
37	0090500	Drug Screen (Nonforensic), Urine, Qualitative								x				
37	0092420	Drug Screen 9 Panel, Serum or Plasma - Immunoassay Screen with Reflex to Mass Spectrometry Confirmation/Quantitation								x				
37	0051463	Dysautonomia, Familial (*IKBKAP*), 2 Variants	x	x	x	x		x						
38	2013906	Epi proColon											x	
38	0090518	Ethanol, Urine, Qualitative - Medical								x				
72	0051220	*EWSR1-FLI1* and *EWSR1-ERG* Translocations by RT-PCR												x
39	0051468	Fanconi Anemia, Group C (*FANCC*), 2 Variants	x	x	x	x		x						
39	2013518	Fatty Acids Profile, Essential Serum or Plasma						x						
39	2012173	Fibrillarin (U3 RNP) Antibody, IgG		x	x		x	x				x		
40	2012678	Gastrointestinal Bacterial Panel by PCR			x									
40	2011660	Gastrointestinal Parasite and Microsporidia by PCR			x									
40	2011150	Gastrointestinal Parasite Panel by PCR			x			x						
40	0051438	Gaucher Disease (*GBA*), 8 Variants	x	x	x	x		x						
41	2013740	Glycogen Storage Disease, Type 1A (*G6PC*), 9 Variants											x	
42	2011304	Heavy Metals Panel 3, Random Urine with Reflex to Arsenic Fractionated											x	
43	2010476	*Helicobacter pylori* Breath Test, Adult				x		x	x					
43	2010925	*Helicobacter pylori* Breath Test, Pediatric				x		x	x					
44	2013881	Hepatitis Delta Virus by Quantitative PCR											x	
44	2012023	Hepatitis E Virus (HEV) Antibodies, IgG and IgM			x									
44	2010151	Hepatitis E Virus (HEV) Antibody, IgG			x									
44	2010156	Hepatitis E Virus (HEV) Antibody, IgM			x									
45	2013897	Herpes Simplex Virus (HSV) Typing											x	
45	0065065	Herpes Simplex Virus Culture with Reflex to HSV Typing										x		
72	0060847	Herpes Simplex Virus Typing												x
45	2007578	High Molecular Weight Kininogen (HMWK)		x		x								
46	2010797	Human Immunodeficiency Virus 1 (HIV-1) by Quantitative PCR with Reflex to HIV PhenoSense GT				x	x							
46	0065999	Human Papillomavirus (HPV), High Risk by Hybrid Capture, Cervical Brush			x	x								

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46	2008404	Human Papillomavirus (HPV), High Risk by Hybrid Capture, ThinPrep			x	x								
47	2013612	Infliximab Activity with Reflex to Antibody											x	
48	2013909	Joubert Syndrome Type 2 (TMEM216), 1 Variant											x	
48	2013690	Kpa Pt Antigen Typing IRL											x	
49	0020045	Lactic Acid, Plasma					x							
49	0090177	Lamotrigine								x				
49	2013802	LANGERIN by Immunohistochemistry											x	
50	2011482	Lead, Random Urine											x	
72	0080200	Lecithin-Sphingomyelin Ratio												x
50	2008003	Leukemia/Lymphoma Phenotyping by Flow Cytometry									x			
51	2013735	Lipoamide Dehydrogenase Deficiency (DLD), 2 Variants											x	
51	2010711	Liver Cytosolic Antigen Type 1 (LC-1) Antibody, IgG		x		x	x					x		
52	2013730	Maple Syrup Urine Disease, Type 1B (*BCKDHB*), 3 Variants											x	
53	2011481	Mercury, Random Urine											x	
53	2013082	*MET* Gene Amplification by FISH				x								
54	2011626	Microsporidia by PCR			x			x						
55	2007967	Motor and Sensory Neuropathy Evaluation with Immunofixation Electrophoresis and Reflex to Titer and Neuronal Immunoblot					x		x	x				
56	2007966	Motor and Sensory Neuropathy Evaluation with Reflex to Titer and Neuronal Immunoblot					x		x	x				
57	0051448	Mucolipidosis Type IV (*MCOLN1*), 2 Variants	x	x	x	x		x						
58	2013805	Natural Killer Cell and Natural Killer T-Cell Panel											x	
72	2004360	Natural Killer Cell Panel												x
59	2013745	NEB-Related Nemaline Myopathy, 1 Variant											x	
59	2001952	Neurofibromatosis Type 1 (NF1) Deletion/Duplication						x						
60	2007159	Neurofibromatosis Type 1 (*NF1*) Sequencing						x						
60	2007154	Neurofibromatosis Type 1 (*NF1*) Sequencing and Deletion/Duplication						x						
61	0051458	Niemann-Pick Type A (*SMPD1*), 4 Variants	x	x	x	x		x						
61	2007190	Occult Blood, Fecal by Immunoassay				x								
61	0098122	Osmolality, Fecal			x									

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61	2012312	Pain Management Panel, Screen with Reflex to Quantitation								x				
62	2007961	Paraneoplastic Antibodies (PCCA/ANNA) by IFA with Reflex to Titer and Immunoblot					x		x	x				
62	2010841	Paraneoplastic Antibodies (PCCA/ANNA) by IFA with Reflex to Titer and Immunoblot, CSF					x		x	x				
72	0040113	*PAX3-FOXO1* and *PAX7-FOXO1* Translocations by RT-PCR												x
62	2008131	Pipecolic Acid, Urine					x							
63	2003040	PM/Scl-100 Antibody, IgG by Immunoblot	x	x	x		x		x	x		x		
63	2011476	Porphobilinogen (PBG), Random Urine											x	
64	2013849	Prenatal Carrier Screening Panel by Next Generation Sequencing											x	
64	0070105	Renin Activity		x		x								
64	2001575	Renin, Direct				x								
65	2012654	*RET* Gene Rearrangements by FISH			x	x								
65	2013506	Sd(a) Antigen Typing, Patient											x	
66	2007965	Sensory Neuropathy Antibody Panel with Reflex to Titer and Neuronal Immunoblot					x		x	x				
72	2003243	Septin 9 (*SEPT9*), Methylated DNA Detection by Real-Time PCR												x
72	0040114	*SS18-SSX* t(X;18) Translocations by RT-PCR												x
67	2013325	Systemic Sclerosis Comprehensive Panel (Pricing Change)	x	x	x		x		x	x	x	x		
68	0051428	Tay-Sachs Disease (*HEXA*), 7 Variants	x	x	x	x		x						
68	0051589	Toll-Like Receptor Function				x								
72	2007064	*Toxoplasma gondii* Antibody, IgA by ELISA												x
69	2013890	*Toxoplasma gondii* Antibody, IgA by ELISA, Serum											x	
72	0070003	Trypsin-Like Immunoreactivity												x
70	2013750	Usher Syndrome, Types 1F and 3 (*PCDH15* and *CLRN1*), 2 Variants											x	
71	2013508	Wr(a) Antigen Typing, Patient											x	
71	0097908	Zonisamide								x				

New Test **2013502** **A1 Antigen Typing, Patient** **A1 AG**
Available Now

Methodology: Hemagglutination
Performed: Monday - Friday
Reported: 1-3 days

Specimen Required: Collect: Lavender (EDTA) or Pink (K_2 EDTA).
Specimen Preparation: Do not freeze. Transport 7 mL whole blood. (Min:1 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): Ambient: 72 hours ; Refrigerated: 1 Week ; Frozen: Unacceptable

Reference Interval: By report

CPT Code(s): 86905

New York DOH approval pending. Call for status update.

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

New Test **2013725** **ABCC8-Related Hyperinsulinism, 3 Variants** **ABCC8**

Additional Technical Information

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Tue, Fri
Reported: 5-10 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Reference Interval: By report

Interpretive Data:
Background Information for *ABCC8*-Related Hyperinsulinism, 3 Variants:
Characteristics: *ABCC8*-related hyperinsulinism is characterized by hypoglycemia varying in severity from mild symptoms to severe neonatal-onset. Infants with the severe neonatal-onset present with hypoglycemia within the first few days of life, which progresses causing seizures, brain damage and death if untreated.
Incidence: 1 in 10,800 in Ashkenazi Jewish individuals.
Inheritance: Autosomal recessive.
Cause: *ABCC8* pathogenic variants.
Variants Tested: p.F1388del (c.4163_4165del), p.V187D (c.560T>A), c.3992-9G>A.
Clinical Sensitivity: 97 percent in Ashkenazi Jewish individuals; unknown in other ethnicities.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Variants other than those tested will not be detected. Diagnostic errors can occur due to rare sequence variations.

See Compliance Statement C: www.aruplab.com/CS

CPT Code(s): 81401

New York DOH approval pending. Call for status update.

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

New Test Available Now **2013605** **Adalimumab Activity with Reflex to Antibody** **ADA DL R**

Supplemental Resources

Methodology: Cell Culture/Quantitative Chemiluminescent Immunoassay/ Semi-Quantitative Chemiluminescent Immunoassay
Performed: Mon,Wed,Thu,Sat
Reported: 2-3 days

Specimen Required: Patient Prep: Collect specimens before adalimumab treatment.
Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.3 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Contaminated, hemolyzed, icteric, or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 4 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval:

Available Separately	Components	Reference Interval
2013605	Adalimunab Activity w/Rflx to Antibody	Not Detected
No	ADA Rlfx to Neutralizing Ab Confirmation	Not Detected

Interpretive Data: This test measures the capacity of Adalimumab to neutralize TNF-alpha activity. Additionally, adalimumab neutralizing antibodies (NAb) are titered (reporting the highest dilution of patient sera in which NAb activity is detected).

This test is used to evaluate secondary response failures to adalimumab therapy. Secondary response failure is defined as loss of clinical response after initial improvement of clinical signs and symptoms. Therapeutic decision should rest on both the clinical response and the knowledge of the fate of the drug including the emergence of immunogenicity in individual patients.

Circulating adalimumab levels have been shown to vary considerably between patients. These differences relate to route and frequency of administration and patient-related features such as age, gender, weight, drug metabolism, and concomitant medications such as methotrexate and other immunosuppressants.

IF Adalimumab Activity is....	AND Adalimumab Neutralizing Ab. Titer is....	THEN....
Not Detected	Not Detected	A higher dosage of adalimumab or shortening the dosing interval may be appropriate.
Not Detected	1:20 or greater	A change to another anti-TNF-alpha drug may be appropriate.
0.65 µg/mL or greater	N/A	A change to another type of therapy (not targeting TNF-alpha) may be appropriate, if the patient did not respond adequately to adalimumab therapy.

See Compliance Statement B: www.aruplab.com/CS

Note: This test is performed pursuant to an agreement with Eurodiagnostica. If Adalimumab drug level is not detected, then Adalimumab Neutralizing Ab Titer will be added. Additional charges apply.

CPT Code(s): 86352, if reflexed add 86352

New York DOH Approved.

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

2002349 5-a-Dihydrotestosterone by Tandem Mass Spectrometry, Serum DHT TMS

Specimen Required: Collect: Plain Red or Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube and freeze immediately. (Min: 0.6 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Hemolyzed or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 5 days; Frozen: 6 months

Reference Interval: Effective November 14, 2016

Males	Females
Premature: 100.0-530.0 pg/mL Full Term: 50.0-600.0 pg/mL 1 week-6 months: 120.0-850.0 pg/mL 7 months-9 years: 0.0-49.9 pg/mL 10-19 years: 0.0-533.0 pg/mL 20 years and older: 106.0-719.0 pg/mL Tanner Stage I: 1.0-47.6 pg/mL Tanner Stage II: 3.5-397.9 pg/mL Tanner Stage III: 14.8-574.6 pg/mL Tanner Stage IV & V: 44.9-511.8 pg/mL	Premature: 20.0-130.0 pg/mL Full Term: 20.0-150.0 pg/mL 1 week-9 years: 0.0-49.9 pg/mL 10-19 years: 50.0-170.0 pg/mL 20 years and older: 24.0-208.0 pg/mL Tanner Stage I: 1.0-64.3 pg/mL Tanner Stage II: 5.5-95.9 pg/mL Tanner Stage III: 11.4-158.3 pg/mL Tanner Stage IV & V: 18.7-193.8 pg/mL

HOT LINE NOTE: Remove information found in the Patient Prep field.

2002582 Aldosterone and Renin, Direct with Ratio A/DR

Specimen Required: Patient Prep: Normal sodium diet (100-200 mEq/day) for at least three days. Receiving no medications known to affect renin-aldosterone system.
Supine: Both specimens should be obtained between 8 a.m. and 10 a.m. (after at least two hours in supine position).
OR
Upright: Both specimens should be obtained before noon (after at least two hours in upright position; seated or standing).
Contact Medical Director if more information is needed.
Collect: From either a supine or upright patient, Serum Separator Tube (SST) **AND** Lavender (EDTA) or Pink (K_2EDTA). Do not collect in refrigerated tubes.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection.
Serum: Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
AND
Plasma: Transfer 2 mL EDTA plasma to an ARUP Standard Transport Tube and freeze immediately. (Min: 1 mL)
Storage/Transport Temperature: Both specimens should be submitted together for testing.
Serum: Frozen. Also acceptable: Refrigerated.
Plasma: CRITICAL FROZEN. Separate specimens must be submitted when additional tests are ordered.
Unacceptable Conditions: Plasma collected in citrate, heparin, or oxalate. Hemolyzed specimens.
Stability (collection to initiation of testing): **Serum:** Ambient: 8 hours; Refrigerated: 5 days; Frozen: 1 month
Plasma: Ambient: 4 hours; Refrigerated: Unacceptable; Frozen: 1 month

0070073 Aldosterone/Renin Activity Ratio A/RA

Methodology: Quantitative Chemiluminescent Immunoassay/Quantitative Enzyme-Linked Immunosorbent Assay

Specimen Required: Patient Prep: Normal sodium diet (100-200 mEq/day) for at least three days. Receiving no medications known to affect renin-aldosterone system.
Supine: Both specimens should be obtained between 8 a.m. and 10 a.m. (after at least two hours in supine position).
OR
Upright: Both specimens should be obtained before noon (after at least two hours in upright position, seated or standing).
Contact Medical Director if more information is needed.
Collect: From either a supine or upright patient, Serum Separator Tube (SST) **AND** Lavender (EDTA) or Pink (K_2EDTA). Do not collect in refrigerated tubes.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection.
Serum: Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
AND
Plasma: Transfer 2 mL EDTA plasma to an ARUP Standard Transport Tube and freeze immediately. (Min: 1.2 mL)
Storage/Transport Temperature: Both specimens should be submitted together for testing.
Serum: Frozen. Also acceptable: Refrigerated.
Plasma: CRITICAL FROZEN. Separate specimens must be submitted when additional tests are ordered.
Unacceptable Conditions: Plasma collected in citrate, heparin, or oxalate. Hemolyzed specimens.
Stability (collection to initiation of testing): **Serum:** Ambient: 8 hours; Refrigerated: 5 days; Frozen: 1 month
Plasma: Ambient: 6 hours; Refrigerated: Unacceptable; Frozen: 1 month

0080427 Alpha Fetoprotein (Amniotic Fluid) with Reflex to Acetylcholinesterase and Fetal Hemoglobin AFP AF

Specimen Required: Patient Prep: Amniocentesis.
Collect: Amniotic fluid.
Specimen Preparation: Transport 2.5 mL amniotic fluid. (Min: 1.5mL)
Storage/Transport Temperature: Room temperature.
Remarks: Include gestational age at time of collection or estimated due date, physician name and phone number on the test request form.
Unacceptable Conditions: Specimens contaminated with fetal blood.
Stability (collection to initiation of testing): Ambient: 1 month; Refrigerated: 3 months; Frozen: 3 months

New Test Available Now **2011474** **Aminolevulinic Acid (ALA), Random Urine** **U ALA RAND**

Methodology: Quantitative Ion Exchange Chromatography/Spectrophotometry
Performed: Mon, Wed, Fri
Reported: 1-4 days

Specimen Required: Patient Prep: Refrain from alcohol consumption 24 hours prior to collection.
Collect: Random urine.
Specimen Preparation: Protect from light. Transfer a 4 mL aliquot from a well-mixed collection to an ARUP Amber Transport Tube. (Min: 1.2 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Body fluids other than urine.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 4 days; Frozen: 1 month

Reference Interval:

Components	Reference Interval
Aminolevulinic Acid - per volume	0-35
ALA, Random Urine - ratio to CRT	By Report

Note: Increased ALA concentration is associated with exposure to alcohol, lead, and a variety of other agents. Massive elevation of ALA occurs in the acute porphyrias and hereditary tyrosinemia.

Specimen preservation with acid or base may interfere with results. If collected urine will be used for additional testing, remove the ALA aliquot **before** adding any acid or base preservatives.

CPT Code(s): 82135

New York DOH Approved.

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

2005419 **Androstanediol Glucuronide Quantitative, Serum or Plasma** **ANDRO GLUC**

Performed: Varies
Reported: 3-17 days

Specimen Required: Collect: Plain Red, Lavender (EDTA), or Serum Separator Tube (SST).
Specimen Preparation: Separate from cells within 1 hour. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Frozen. Also acceptable: Room temperature or refrigerated.
Unacceptable Conditions:
Stability (collection to initiation of testing): Ambient: 6 days; Refrigerated: 6 days; Frozen: 3 years

0080001 **Angiotensin Converting Enzyme, Serum** **ACE**

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: EDTA or heparin plasma. Hemolyzed specimens. CSF (refer to Angiotensin Converting Enzyme, CSF test code 0098974).
Stability (collection to initiation of testing): After separation from cells: Ambient: 1 week; Refrigerated: 1 week; Frozen: 6 months

0060217 Antimicrobial Susceptibility, AFB/Mycobacteria MA AFB

Reference Interval:

Test Number	Test Name	Methodology	Reference Interval/Drugs Tested	CPT Code
0060347	Antimicrobial Susceptibility - AFB/Mycobacterium tuberculosis Primary Panel	MGIT960	The interpretation provided is based on results for the following drugs at the stated concentrations: **Drugs tested:** Ethambutol: 5.0 µg/mL; Isoniazid: 0.1 µg/mL (0.4 µg/mL if resistant to 0.1 µg/mL); Pyrazinamide: 100 µg/mL; Rifampin: 1.0 µg/mL. This procedure screens isolates of *M. tuberculosis* complex for drug resistance. The procedure does not use serial dilutions to provide quantitative MIC values. Single critical concentrations for each antimycobacterial agent used have been defined by the United States Public Health Service.	87188 x4
	Antimicrobial Susceptibility - AFB/*Mycobacterium tuberculosis* Secondary Panel	Agar proportion and Broth dilution	Effective February 21, 2012 **Note:** If *M. tuberculosis* isolate is resistant to rifampin or any two primary drugs, a secondary panel will be performed as a send-out test. The interpretation provided is based on testing for the following drugs at the stated concentrations: **Drugs tested:** Amikacin: 6 µg/mL; capreomycin: 10 µg/mL; cycloserine: 60 µg/mL; ethionamide: 10 µg/mL; kanamycin: 6 µg/mL; PAS: 8 µg/mL; streptomycin at a low level (2.0 µg/mL) and a high level (4.0 µg/mL). Levofloxacin and moxifloxacin are tested at 2, 4 and 8 µg/mL	87190 x6, 87188 x3
	Antimicrobial Susceptibility - AFB/*Mycobacteria*	Broth Microdilution	See organism-specific panels below.	87186
	Mycobacterium avium-intracellularae Complex	Broth Microdilution	Effective 11/14/2016 **Drugs tested:** Amikacin, ciprofloxacin, clarithromycin, doxycycline, ethambutol, ethionamide, isoniazide, linezolid, moxifloxacin, rifabutin, rifampin streptomycin and trimethoprim/sulfamethoxazole (TMP/SXT). Selective reporting by organism. Clarithromycin, moxifloxacin and linezolid are the only drugs for which CLSI provides interpretive guidelines. Clarithromycin results predict azithromycin. For Amikacin, only MIC is reported. Because MIC results do not predict clinical response and may be misleading, rifampin, rifabutin, and ethambutol MICs are not routinely reported and must be specifically requested.	87186
	Rapid Growing *Mycobacteria*	Broth Microdilution	Effective August 17, 2015 **Drugs tested:** Amikacin, cefoxitin, ciprofloxacin, clarithromycin, doxycycline, imipenem, linezolid, minocycline, moxifloxacin, tigecycline, tobramycin (M. chelonae only), and trimethoprim/sulfamethoxazole (TMP/SXT). Selective reporting by organism.	87186
	Other Slowly-Growing Nontuberculosus *Mycobacteria* (NTM)	Broth Microdilution	Effective May 20, 2013 **Drugs tested:** Amikacin, ciprofloxacin, clarithromycin, doxycycline, ethambutol, ethionamide, isoniazide, linezolid, moxifloxacin, rifabutin, rifampin, streptomycin and trimethoprim/sulfamethoxazole (TMP/SXT). Selective reporting by organism. CLSI recommends that isolates of *M. kansasii* be tested against rifampin and clarithromycin only. Rifampin-susceptible isolates are also susceptible to rifabutin. If the isolate is rifampin-resistant, the following secondary drugs will also be reported: Amikacin, ciprofloxacin, ethambutol, linezolid, moxifloxacin, rifabutin, streptomycin and trimethoprim-sulfamethoxazole. *M. marinum* isolates are tested against amikacin, ciprofloxacin, clarithromycin, doxycycline, ethambutol, moxifloxacin, rifabutin, rifampin, and trimethoprim-sulfamethoxazole. Interpretation is based on CLSI guidelines. Slowly-growing NTM other than *M. kansasii* and *M. marinum* are tested against amikacin, ciprofloxacin, clarithromycin, ethambutol, linezolid, moxifloxacin, rifabutin, rifampin, streptomycin, and trimethoprim-sulfamethoxazole. Interpretive criteria are based on CLSI guidelines for *M. kansasii*..	87186

2008467 Anti-Nuclear Antibody (ANA), IgG by IFA with Reflex by IFA Pattern ANA R PAT

Methodology: Semi-Quantitative Indirect Fluorescent Antibody/Qualitative Enzyme-Linked Immunosorbent Assay/Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Semi-Quantitative Multiplex Bead Assay/Qualitative Immunoblot

Reference Interval: **Effective November 14, 2016**

Test Number	Components	Reference Interval
2008467	Anti-Nuclear Antibody (ANA), IgG by IFA with Reflex by IFA Pattern	Less than 1:40
2003040	PM/SCL-100 Antibody, IgG by Immunoblot	Negative
0050215	Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA with Reflex to dsDNA Antibody, IgG by IFA	None Detected
2002693	Double-Stranded DNA (dsDNA) Antibody, IgG by IFA (using *Crithidia luciliae)*	Less than 1:10
2005287	Chromatin Antibody, IgG	19 Units or less: Negative 20-60 Units: Positive 61 Units or greater: Strong Positive
2001601	RNA Polymerase III Antibody, IgG	19 Units or less: Negative 20-39 Units: Weak Positive 40-80 Units: Moderate Positive 81 Units or greater: Strong Positive
0050599	Scleroderma (Scl-70) (ENA) Antibody, IgG	29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive
0050470	RNP (U1) (Ribonucleic Protein) (ENA) Antibody, IgG	29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive
0050085	Smith (ENA) Antibody, IgG	29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive
2012074	SSA 52 and 60 (Ro) (ENA) Antibodies, IgG	

Components	Reference Interval
SSA 52 (Ro) (ENA) Antibody, IgG	29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive
SSA 60 (Ro) (ENA) Antibody, IgG	29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive

0050692	SSB (La) (ENA) Antibody, IgG	29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive

New Test Available Now **2011478** **Arsenic, Random Urine with Reflex to Fractionated** **U ARS RAND**

Patient Demographics Form for Public Health Reporting

Specimen Collection and Handling

Methodology: Quantitative High Performance Liquid Chromatography/Quantitative Inductively Coupled Plasma-Mass Spectrometry
Performed: Mon-Fri
Reported: 1-5 days

Specimen Required: Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, nonessential over-the-counter medications (upon the advice of their physician), and avoid shellfish and seafood for 48 to 72 hours. High concentrations of iodine may interfere with elemental testing. Abstinence from iodine-containing medications or contrast agents for at least 1 month prior to collecting specimens for elemental testing is recommended.
Collect: Random urine.
Specimen Preparation: Transfer an 8 mL aliquot from a well-mixed collection to ARUP Trace Element-Free Transport Tubes (ARUP supply #43116), available online through eSupply using ARUP Connect ™ or contact ARUP Client Services at (800) 522-2787. (Min: 2 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Unacceptable Conditions: Urine collected within 48 hours after administration of a gadolinium (Gd) containing contrast media (may occur with MRI studies). Acid preserved urine.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval:

Test Number	Components	Reference Interval		
	Arsenic, Urine - per volume	0-35.0 µg/L (based on Biological Exposure Index)		
	Arsenic, Urine-ratio to CRT	Less than 30 ug/gCRT		
0020734	Arsenic, Fractionated, Urine	**Test Number**	**Components**	**Reference Interval**
			As Organic	Refer to report
			Arsenic Total Inorganic	Refer to report
			Arsenic, Methylated	Refer to report

Interpretive Data: The ACGIH Biological Exposure Index (BEI) for arsenic in urine is 35 µg/L. The ACGIH BEI is based on the sum of inorganic and methylated species. For specimens with a total arsenic concentration of 35 to 2000 µg/L, fractionation is automatically performed to determine the proportions of inorganic, methylated and organic species. It may be appropriate to request fractionation for specimens with total arsenic greater than 30 µg/gCRT despite a total arsenic concentration less than 35 µg/L. If low-level chronic poisoning is suspected, the µg/gCRT ratio may be a more sensitive indicator of arsenic exposure than the total arsenic concentration.

Note: If total arsenic concentration is between 35-2000 µg/L, then Arsenic, Fractionated, will be added to determine the proportion of organic, inorganic, and methylated forms. Additional charges apply.

CPT Code(s): 82175; if reflexed, add 82175

New York DOH Approved.

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

0051415 Ashkenazi Jewish Diseases, 16 Genes AJP

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Tue, Fri
Reported: 5-10 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Interpretive Data:

Background Information for Ashkenazi Jewish Diseases, 16 Genes:
Overview: This targeted panel detects 51 variants common in the Ashkenazi Jewish population associated with 16 disorders, including *ABCC8*-related hyperinsulinism, Bloom syndrome, Canavan disease, familial dysautonomia, Fanconi anemia group C, Gaucher disease, glycogen storage disease 1A, Joubert syndrome type 2, lipoamide dehydrogenase deficiency, maple syrup urine disease type 1B, mucolipidosis type IV, *NEB*-related nemaline myopathy, Niemann-Pick disease type C, Tay-Sachs disease, Usher syndrome type 1F and type 3.
Inheritance: Autosomal recessive.
Clinical Sensitivity: Among Ashkenazi Jewish individuals:

- 99 percent for Canavan disease, lipoamide dehydrogenase deficiency, familial dysautonomia, Fanconi anemia group C, glycogen storage disease type 1A, Joubert syndrome type 2, maple syrup urine disease type 1B, and NEB-related nemaline myopathy
- 98 percent for Usher syndrome type 3
- 97 percent for ABCC8-related hyperinsulinism and Bloom syndrome
- 95 percent for mucolipidosis type IV;
- 94 percent for Tay-Sachs disease
- 90 percent for Gaucher disease and Niemann-Pick disease type A
- 62 percent for Usher syndrome type 1F

Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring. See table below for specific variants tested.
Analytical Sensitivity and Specificity: 99 percent.
Limitations: Variants other than those tested on this panel will not be detected. Diagnostic errors can occur due to rare sequence variations.

Disease (*Gene*)	Variants Tested	Ashkenazi Disease Incidence	Ashkenazi Pretest Carrier Risk	Ashkenazi Post-test Carrier Risk after Negative Result
ABCC8-related hyperinsulinism (*ABCC8*)	p.F1388del (c.4163_4165del) p.V187D (c.560T>A) c.3992-9G>A	1/7,800	1/52	1/1,700
Bloom syndrome (*BLM*)	p.Y736Lfs (c.2207_2212delinsTAGATTC)	1/40,000	1/100	1/3,300
Canavan disease (*ASPA*)	c.433-2A>G p.Y231X (c.693C>A) p.E285A (c.854A>C) p.A305E (c.914C>A)	1/10,000	1/50	1/4,900
Familial dysautonomia (*IKBKAP*)	p.R696P (c.2087G>C) c.2204+6T>C	1/3,600	1/32	1/3,100
Fanconi anemia group C (*FANCC*)	p.D23Ifs (c.67delG) c.456+4A>T	1/32,000	1/89	1/8,800
Gaucher disease (*GBA*)	p.L29Afs (c.84dupG) c.115+1G>A p.N409S (c.1226A>G) c.1263_1317del55 p.V433L (c.1297G>T) p.D448H (c.1342G>C) p.L483P (c.1448T>C) p.R535H (c.1604G>A)	1/900	1/15	1/141
Glycogen storage disease type 1A (*G6PC*)	p.Q27Rfs (c.79delC) p.Y128Tfs (c.379_380dupTA) p.R83H (c.248G>A) p.R83C (c.247C>T) p.G188R (c.562G>C) p.Q242X (c.724C>T) p.Q347X (c.1039C>T) p.G270V (c.809G>T) p.F327del (c.979_981delTTC)	1/20, 000	1/71	1/7,000
Joubert syndrome type 2 (*TMEM216*)	p.R73L (c.218G>T)	1/34,000	1/92	1/9,100
Lipoamide dehydrogenase deficiency (*DLD*)	p.Y35X (c.104dupA) p.G229C (c.685G>T)	1/35,000	1/94	1/9,300
Maple syrup urine disease type 1B (*BCKDHB*)	p.R183P (c.548G>C) p.G278S (c.832G>A) p.E372X (c.1114G>T)	1/50,000	1/113	1/11,200

Mucolipidosis type IV (*MCOLN1*)	c.406-2A>G g.511_6493del	1/63,000	1/127	1/2,500
NEB-related nemaline myopathy (*NEB*)	exon 55 del (p.R2478_D2512del)	1/47,000	1/108	1/10,700
Niemann-Pick disease type A (*SMPD1*)	p.L304P (c.911T>C) p.F333Sfs (c.996delC) p.R498L (c.1493G>T) p.R610del (c.1829_1831delGCC)	1/32,000	1/90	1/890
Tay-Sachs disease (*HEXA*)	7.6 kb del p.G269S (c.805G>A) c.1073+1G>A p.Y427Ifs (c.1274_1277dup TATC) c.1421+1G>C Pseudodeficiency alleles: p.R247W (c.739C>T) p.R249W (c.745C>T)	1/3,000	1/30	1/480
Usher syndrome type 1F (*PCDH15*)	p.R245X (c.733C>T)	1/20,500	1/72	1/190
Usher syndrome type 3 (*CLRN1*)	p.N48K (c.144T>G)	1/82,000	1/143	1/7,100

See Compliance Statement C: www.aruplab.com/CS

Note: Cystic fibrosis (CF) carrier testing is NOT included as part of this panel. Please order Cystic Fibrosis (*CFTR*) 165 Pathogenic Variants (ARUP test code 2013661) to assess CF carrier status.

CPT Code(s):
81200, 81205, 81209, 81242, 81250, 81251, 81255, 81260, 81290, 81330, 81400, 81401, 81479

0020399 Basic Metabolic Panel — BMP

Specimen Required: Collect: Plasma Separator Tube or Serum Separator Tube (SST).
Specimen Preparation: Allow serum tube to clot completely at room temperature. Separate serum or plasma from cells ASAP or within 30 minutes of collection. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.3 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Specimens collected in EDTA, citrate, or oxalate.
Stability (collection to initiation of testing): After separation from cells: Ambient: Calcium and CO2: 4 hours, All others: 24 hours; Refrigerated: 1 week; Frozen: 2 weeks

2010445 Benzodiazepines, Serum or Plasma, Quantitative — BENZO SP

CPT Code(s): 80346 (Alt code: G0480)

2012225 Benzodiazepines, Urine Screen with Reflex to Quantitation — BENZ RFX U

CPT Code(s): 80301; if positive add 80346 (Alt code: G0479; if positive add G0480)

2008291 Benzodiazepines, Urine, Quantitative — CDCO BENZO

CPT Code(s): 80346 (Alt code: G0480)

0051433 Bloom Syndrome (*BLM*), 1 Variant — BLM

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Tue, Fri
Reported: 5-10 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Interpretive Data:
Background information for Bloom Syndrome (*BLM*), 1 Variant:
Characteristics: Bloom syndrome is characterized by pre- and postnatal growth deficiency, sparse subcutaneous tissue, sun-sensitive telangiectatic hypo- and hyperpigmented skin lesions, chromosome instability causing benign and malignant tumors early in life, and male sterility.
Incidence: 1 in 40,000 in Ashkenazi Jewish individuals.
Inheritance: Autosomal recessive.
Cause: *BLM* pathogenic variants.
Variant Tested: p.Y736Lfs (c.2207_2212delinsTAGATTC).
Clinical Sensitivity: 97 percent in Ashkenazi Jewish individuals, approximately 3 percent in other ethnicities.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical sensitivity and specificity: Greater than 99 percent.
Limitations: Variants other than c.2207_2212delinsTAGATTC will not be detected. Diagnostic errors can occur due to rare sequence variations.

See Compliance Statement C: www.aruplab.com/CS

2007335 *Borrelia burgdorferi* (Lyme Disease) Reflexive Panel (CSF) — LYMECSFR

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Qualitative Immunoblot

Reference Interval:

Test Number	Components	Reference Interval
0099483	*Borrelia burgdorferi* Antibodies, Total by ELISA, CSF	0.99 LIV or less: Negative - Antibody to *B. burgdorferi* not detected. 1.00-1.20 LIV: Equivocal - Repeat testing in 10-14 days may be helpful. 1.21 LIV or greater: Positive - Probable presence of antibody to *B. burgdorferi* detected.
0055259	*Borrelia burgdorferi* Antibody, IgG by Immunoblot (CSF)	Effective August 15, 2011 Negative
0055258	*Borrelia burgdorferi* Antibody, IgM by Immunoblot (CSF)	Effective August 15, 2011 Negative

Note: If *B. burgdorferi* total antibodies by ELISA are 1.00 LIV or greater, then *B. burgdorferi* IgG antibody by immunoblot and IgM antibody by immunoblot will be added. Additional charges apply.

0050254 *Borrelia burgdorferi* Antibodies, IgG and IgM by Immunoblot — LYME WB

Methodology: Qualitative Immunoblot

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.15 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: CSF or plasma. Contaminated, heat-inactivated, hemolyzed, 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)

Note: Per CDC guidelines, if ELISA test result is NEGATIVE, immunoblot should not be performed.

This test should be used for confirmation of an equivocal or positive *B. burgdorferi* total antibodies, IgG and/or IgM test performed on patients less than 4 weeks after appearance of erythema migrans.

0055260 *Borrelia burgdorferi* Antibodies, IgG and IgM by Immunoblot (CSF) LYME WBCSF

Methodology: Qualitative Immunoblot

Note: A negative result indicates that the immunoblot evaluation for *B. burgdorferi* antibody demonstrates no antibodies unique to *B. burgdorferi* and is, therefore, not supportive of Lyme disease.

A positive result indicates that the immunoblot evaluation for Lyme antibody is consistent with the presence of antibody produced by patients in response to infection by *B. burgdorferi* and suggests the presence of Lyme disease. Although the test has been shown to have a high degree of reliability for diagnostic purposes, laboratory data should always be correlated with clinical findings.

Current CDC recommendations for the serological diagnosis of Lyme disease are to screen with a polyvalent ELISA test and confirm equivocals and positives with immunoblot. Both IgM and IgG immunoblots should be performed on samples obtained less than 4 weeks after appearance of erythema migrans. Only IgG immunoblot is to be performed on samples greater than 4 weeks after disease onset. IgM immunoblot in the chronic stage is not recommended and does not aid in the diagnosis of neuroborreliosis or chronic Lyme disease.

0050216 *Borrelia burgdorferi* Antibodies, Total by ELISA LYME EIA

Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.15 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: CSF. Contaminated, heat-inactivated, hemolyzed, 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:

0.99 LIV or less	Negative - Antibody to *B. burgdorferi* not detected.
1.00-1.20 LIV	Equivocal - Repeat testing in 10-14 days may be helpful.
1.21 LIV or greater	Positive - Probable presence of antibody to *B. burgdorferi* detected.

Note: Once this test is performed, if:
a) Negative - no further testing is done;
b) Positive or equivocal - immunoblot testing will be performed on the original sample upon receiving a request. **Sample will be held for 30 days only.**

Current CDC recommendations for the serologic diagnosis of Lyme disease are to screen with a polyvalent ELISA test and confirm equivocal and positive results with Immunoblot. Both IgM and IgG Immunoblots should be performed on specimens less than 4 weeks after appearance of erythema migrans. Only IgG Immunoblot should be performed on specimens greater than 4 weeks after the disease onset. IgM Immunoblot in the chronic stage is not recommended and does not aid in the diagnosis of neuroborreliosis or chronic Lyme disease. Please submit requests for appropriate Immunoblot testing within 10 days.

HOT LINE NOTE: Remove information found in the Interpretive Data field.

0050267 *Borrelia burgdorferi* Antibodies, Total by ELISA with Reflex to IgG and IgM by Immunoblot (Early Disease) LYME ACUTE

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Qualitative Immunoblot

Specimen Required: Patient Prep:
Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.15 mL)
Storage/Transport Temperature: Refrigerated.
Remarks:
Unacceptable Conditions: CSF or plasma. Contaminated, heat-inactivated, hemolyzed, 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:

Test Number	Components	Reference Interval	
0050216	*Borrelia burgdorferi* Antibodies, Total by ELISA		
		0.99 LIV or less	Negative - Antibody to *B. burgdorferi* not detected.
		1.00-1.20 LIV	Equivocal - Repeat testing in 10-14 days may be helpful.
		1.21 LIV or greater	Positive - Probable presence of antibody to *B. burgdorferi* detected.
0050255	*Borrelia burgdorferi* Antibody, IgG by Immunoblot	Effective August 15, 2011 Negative	
0050253	*Borrelia burgdorferi* Antibody, IgM by Immunoblot	Effective August 15, 2011 Negative	

Note: This panel is appropriate for Lyme disease testing less than 4 weeks from erythema migrans or onset of disease symptoms.

A negative result indicates the immunoblot evaluation for *B. burgdorferi* antibody demonstrates no antibodies unique to *B. burgdorferi* and is, therefore, not supportive of Lyme disease.

A positive result indicates that the immunoblot evaluation for *B. burgdorferi* antibody is consistent with the presence of antibody produced by patients in response to infection by *B. burgdorferi* and suggests the presence of Lyme disease. Although the test has been shown to have a high degree of reliability for diagnostic purposes, laboratory data should always be correlated with clinical findings.

Current CDC recommendations for the serological diagnosis of Lyme disease are to screen with a polyvalent ELISA test and confirm equivocals and positives with immunoblot. Both IgM and IgG immunoblots should be performed on specimens obtained less than 4 weeks after appearance of erythema migrans. Only IgG immunoblot is to be performed on specimens greater than 4 weeks after disease onset. IgM immunoblot in the chronic stage is not recommended and does not aid in the diagnosis of neuroborreliosis or chronic Lyme disease.

If ELISA result is 1.00 LIV or greater, then IgG and IgM immunoblot will be added. Additional charges apply.

0099483 *Borrelia burgdorferi* Antibodies, Total by ELISA, CSF — LYME CSF

Reference Interval: 0.99 LIV or less: Negative - Antibody to *B. burgdorferi* not detected.
1.00-1.20 LIV: Equivocal - Repeat testing in 10-14 days may be helpful.
1.21 LIV or greater: Positive - Probable presence of antibody to *B. burgdorferi* detected.

Interpretive Data: The detection of antibodies to *B. burgdorferi* in cerebrospinal fluid may indicate central nervous system infection. However, consideration must be given to possible contamination by blood or transfer of serum antibodies across the blood-brain barrier.

Current CDC recommendations for the serologic diagnosis of Lyme disease are to screen with a polyvalent ELISA test and confirm equivocal and positive results with immunoblot. Both IgM and IgG immunoblots should be performed on samples less than 4 weeks after appearance of erythema migrans. Only IgG immunoblot should be performed on samples greater than 4 weeks after the disease onset. IgM immunoblot in the chronic stage is not recommended and does not aid in the diagnosis of neuroborreliosis or chronic Lyme disease. Please submit requests for appropriate immunoblot testing within 10 days.

See Compliance Statement B: www.aruplab.com/CS

Note: Once this test is performed, if:
a) Negative - no further testing is done.
b) Positive or equivocal - Immunoblot testing will be performed on the original sample upon receiving a request. **Sample will be held for 30 days only.**

0050255 *Borrelia burgdorferi* Antibody, IgG by Immunoblot — LYME G WB

Methodology: Qualitative Immunoblot

Note: This test should be used for confirmation of an equivocal or positive *B. burgdorferi* Total Antibodies, IgG and/or IgM test performed on patients greater than 4 weeks after disease onset. A negative result indicates that the immunoblot evaluation for the Lyme antibody demonstrates no antibodies unique to *B. burgdorferi* and is, therefore, not supportive of Lyme disease.

A positive result indicates that the immunoblot evaluation for *B. burgdorferi* antibody is consistent with the presence of antibody produced by patients in response to infection by *B. burgdorferi* and suggests the presence of Lyme disease. Although the test has been shown to have a high degree of reliability for diagnostic purposes, laboratory data should always be correlated with clinical findings.

Current CDC recommendations for the serological diagnosis of Lyme disease are to screen with a polyvalent ELISA test and confirm equivocals and positives with immunoblot. Both IgM and IgG immunoblots should be performed on samples obtained less than 4 weeks after appearance of erythema migrans. Only IgG immunoblot is to be performed on samples greater than 4 weeks after disease onset. IgM immunoblot in the chronic stage is not recommended and does not aid in the diagnosis of neuroborreliosis or chronic Lyme disease.

0055259 *Borrelia burgdorferi* Antibody, IgG by Immunoblot (CSF) — LYMEGWBCSF

Methodology: Qualitative Immunoblot

Note: A negative result indicates that the immunoblot evaluation for *B. burgdorferi* antibody demonstrates no antibodies unique to *B. burgdorferi* and is, therefore, not supportive of Lyme disease.

A positive result indicates that the immunoblot evaluation for Lyme antibody is consistent with the presence of antibody produced by patients in response to infection by *B. burgdorferi* and suggests the presence of Lyme disease. Although the test has been shown to have a high degree of reliability for diagnostic purposes, laboratory data should always be correlated with clinical findings.

Current CDC recommendations for the serological diagnosis of Lyme disease are to screen with a polyvalent ELISA test and confirm equivocals and positives with immunoblot. Both IgM and IgG immunoblots should be performed on samples obtained less than 4 weeks after appearance of erythema migrans. Only IgG immunoblot is to be performed on samples greater than 4 weeks after disease onset. IgM immunoblot in the chronic stage is not recommended and does not aid in the diagnosis of neuroborreliosis or chronic Lyme disease.

0050253 ***Borrelia burgdorferi* Antibody, IgM by Immunoblot** **LYME M WB**

Methodology: Qualitative Immunoblot

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.15 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: CSF or plasma. Contaminated, heat-inactivated, hemolyzed, 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)

Note: Current CDC recommendations for the serologic diagnosis of Lyme disease are to screen with a polyvalent EIA test and confirm equivocal and positive with immunoblot. Both IgM and IgG immunoblots should be performed on specimens less than 4 weeks after appearance of erythema migrans. Only IgG immunoblot should be performed on specimens greater than 4 weeks after disease onset. IgM immunoblot in the chronic stage is not recommended and does not aid in the diagnosis of neuroborreliosis or chronic Lyme disease. Please submit requests for appropriate immunoblot testing within 10 days.

0055258 ***Borrelia burgdorferi* Antibody, IgM by Immunoblot (CSF)** **LYMEMWBCSF**

Methodology: Qualitative Immunoblot

Note: A negative result indicates that the immunoblot evaluation for *B. burgdorferi* antibody demonstrates no antibodies unique to *B. burgdorferi* and is, therefore, not supportive of Lyme disease.

A positive result indicates that the immunoblot evaluation for Lyme antibody is consistent with the presence of antibody produced by patients in response to infection by *B. burgdorferi* and suggests the presence of Lyme disease. Although the test has been shown to have a high degree of reliability for diagnostic purposes, laboratory data should always be correlated with clinical findings.

Current CDC recommendations for the serologic diagnosis of Lyme disease are to screen with a polyvalent EIA test and confirm equivocal and positive with immunoblot. Both IgM and IgG immunoblots should be performed on specimens obtained less than 4 weeks after appearance of erythema migrans. Only IgG immunoblot should be performed on specimens greater than 4 weeks after disease onset. IgM immunoblot in the chronic stage is not recommended and does not aid in the diagnosis of neuroborreliosis or chronic Lyme disease. Please submit requests for appropriate immunoblot testing within 10 days.

0051044 ***Borrelia burgdorferi* C6 Peptide Antibodies, Total by ELISA** **C6 PEP**

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.15 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: CSF. Contaminated, heat-inactivated, hemolyzed or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

0051043 *Borrelia burgdorferi* C6 Peptide Antibodies, Total by ELISA with Reflex to IgG and IgM by Immunoblot — C6 ACUTE R

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Qualitative Immunoblot

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.15 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: CSF. Contaminated, heat-inactivated, hemolyzed or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval:

Test Number	Components	Reference Interval
0051044	*Borrelia burgdorferi* C6 Peptide Antibodies, Total by ELISA	0.90 LI or less: Negative - C6 peptide antibody to *B. burgdorferi* not detected. 0.91 - 1.09 LI: Equivocal - Repeat testing in 10-14 days may be helpful. 1.10 LI or greater: Positive - C6 peptide antibody to *B. burgdorferi* detected.
0050255	*Borrelia burgdorferi* Antibody, IgG by Immunoblot	Effective August 15, 2011 Negative
0050253	*Borrelia burgdorferi* Antibody, IgM by Immunoblot	Effective August 15, 2011 Negative

Note: If C6 Peptide by ELISA is 0.91 LI or greater, then IgG and IgM immunoblot will be added. Additional charges apply.

0051045 *Borrelia burgdorferi* C6 Peptide Antibodies, Total by ELISA with Reflex to IgG by Immunoblot — C6 CHRON R

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Qualitative Immunoblot

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.15 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: CSF. Contaminated, heat-inactivated, hemolyzed or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval:

Test Number	Components	Reference Interval
0051044	*Borrelia burgdorferi* C6 Peptide Antibodies, Total by ELISA	0.90 LI or less: Negative - C6 peptide antibody to *B. burgdorferi* not detected. 0.91 - 1.09 LI: Equivocal - Repeat testing in 10-14 days may be helpful. 1.10 LI or greater: Positive - C6 peptide antibody to *B. burgdorferi* detected.
0050255	*Borrelia burgdorferi* Antibody, IgG by Immunoblot	Effective August 15, 2011 Negative

Note: If C6 Peptide by ELISA is 0.91 LI or greater, then IgG immunoblot will be added. Additional charges apply.

0050268 *Borrelia burgdorferi* Total Antibodies, IgG and/or IgM by ELISA with Reflex to IgG by Immunoblot (Late Disease) — LYME CHRO

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Qualitative Immunoblot

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.15 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: CSF or plasma. Contaminated, heat-inactivated, hemolyzed, 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:

Test Number	Components	Reference Interval	
0050216	*Borrelia burgdorferi* Antibodies, Total by ELISA		
		0.99 LIV or less	Negative - Antibody to *B. burgdorferi* not detected.
		1.00-1.20 LIV	Equivocal - Repeat testing in 10-14 days may be helpful.
		1.21 LIV or greater	Positive - Probable presence of antibody to *B. burgdorferi* detected.
0050255	*Borrelia burgdorferi* Antibody, IgG by Immunoblot	Effective August 15, 2011 Negative	

Note: This panel is appropriate for Lyme disease testing greater than 4 weeks from erythema migrans or onset of disease symptoms.

A negative result indicates that the immunoblot evaluation for *B. burgdorferi* antibody demonstrates no antibodies unique to *B. burgdorferi* and is, therefore, not supportive of Lyme disease.

A positive result indicates that the immunoblot evaluation for *B. burgdorferi* antibody is consistent with the presence of antibody produced by patients in response to infection by *B. burgdorferi* and suggests the presence of Lyme disease. Although the test has been shown to have a high degree of reliability for diagnostic purposes, laboratory data should always be correlated with clinical findings.

Current CDC recommendations for the serological diagnosis of Lyme disease are to screen with a polyvalent EIA test and confirm equivocal and positive with immunoblot. Both IgM and IgG immunoblots should be performed on specimens obtained less than 4 weeks after appearance of erythema migrans. Only IgG immunoblot is to be performed on specimens greater than 4 weeks after disease onset. IgM immunoblot in the chronic stage is not recommended and does not aid in the diagnosis of neuroborreliosis or chronic Lyme disease. Please submit requests for appropriate immunoblot testing within 10 days.

If ELISA result is 1.00 LIV or greater, then IgG immunoblot will be added. Additional charges apply.

New Test 2013921 ***BRAF* V600E Mutation Detection in Circulating Cell-Free DNA by Digital Droplet PCR** **BRAF CFDNA**

Additional Technical Information

Methodology: Polymerase Chain Reaction
Performed: Varies
Reported: 10-12 days

Specimen Required: Collect: Whole blood in two 10mL Cell-Free DNA (cfDNA) BCT Tubes. Specimens must be collected using the Kit, Cell-Free DNA Blood Collection Tube (ARUP Supply #52358) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Specimen Preparation: Transport 20 mL whole blood in cfDNA BCT Tubes. (Min: 16 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: FFPE tissue. Whole blood collected in non-cfDNA BCT tubes.
Stability (collection to initiation of testing): Ambient: 5 days; Refrigerated: 5 days; Frozen: Unacceptable

Interpretive Data: Refer to report.

See Compliance Statement B: www.aruplab.com/CS

CPT Code(s): 81210

New York DOH approval pending. Call for status update.

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

New Test Available Now **2011479** **Cadmium, Random Urine** **U CAD RAND**

Patient Demographics Form for Public Health Reporting

Specimen Collection and Handling

Methodology: Quantitative Inductively Coupled Plasma-Mass Spectrometry
Performed: Mon-Sat
Reported: 1-3 days

Specimen Required: Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician). High concentrations of iodine may interfere with elemental testing. Abstinence from iodine-containing medications or contrast agents for at least 1 month prior to collecting specimens for elemental testing is recommended.
Collect: Random urine.
Specimen Preparation: Transfer an 8 mL aliquot from a well-mixed collection to ARUP Trace Element-Free Transport Tubes (ARUP supply #43116), available online through eSupply using ARUP Connect ™ or contact ARUP Client Services at (800) 522-2787. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Unacceptable Conditions: Urine collected within 48 hours after administration of a gadolinium (Gd) containing contrast media (may occur with MRI studies). Acid preserved urine.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval:

Components	Reference Interval
Cadmium, Urine - per volume	0.0-2.6 µg/L
Cadmium Rnd Urn ratio/CRT nonoccupation	<2 µg/gCRT

Interpretive Data: Urine cadmium levels can be used to assess cadmium body burden. In chronic exposures, the kidneys are the primary target organ. Symptoms associated with cadmium toxicity vary based upon route of exposure and may include tubular proteinuria, fever, headache, dyspnea, chest pain, conjunctivitis, rhinitis, sore throat and cough. Ingestion of cadmium in high concentration may cause vomiting, diarrhea, salivation, cramps, and abdominal pain.

CPT Code(s): 82300

New York DOH Approved.

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

2011603 **Caffeine, Serum or Plasma** **CAFFEINE S**

Reference Interval: Effective November 14, 2016

Age	1-28 days	29 days and older
Therapeutic Range	8-20 µg/mL	Less than or equal to 20 (not well established)
Toxic:	Greater than 20 µg/mL	Greater than 20 µg/mL

Interpretive Data: Toxic concentrations may cause tremor, cardiac abnormalities and seizures.

0051453 Canavan Disease (*ASPA*), 4 Variants — ASPA

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Tue, Fri
Reported: 5-10 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Interpretive Data:
Background information for Canavan Disease (*ASPA*), 4 Variants:
Characteristics: Canavan Disease is a neurodegenerative brain disorder that results in macrocephaly and lack of head control by 3 to 5 months of age. This progresses to a failure to achieve sitting, ambulation, or speech, and eventually leads to death typically in early childhood to teenage years.
Incidence: 1 in 10,000 Ashkenazi Jewish individuals.
Inheritance: Autosomal recessive.
Cause: *ASPA* pathogenic variants.
Variants Tested: c.433-2A>G, p.Y231X (c.693C>A), p.E285A (c.854A>C), and p.A305E (c.914C>A).
Clinical Sensitivity: 99 percent in Ashkenazi Jewish individuals; 55 percent in other ethnicities.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Variants other than those tested will not be detected. Diagnostic errors can occur due to rare sequence variations.

See Compliance Statement C: www.aruplab.com/CS

0070412 Carbohydrate Deficient Transferrin for Alcohol Use — CDT

Performed: Mon
Reported: 1-8 days

2004247 *CEBPA* Mutation Detection — CEBPA MUT

CPT Code(s): 81218

New Test **2013767** ***Chlamydia trachomatis* and *Neisseria gonorrhoeae* by Transcription-Mediated Amplification (TMA) with Reflex to *Chlamydia trachomatis* L serovars (LGV) by PCR** **CGAMD LGVR**

Specimen Collection and Handling

Methodology: Qualitative Transcription-Mediated Amplification/Qualitative Polymerase Chain Reaction
Performed: Sun-Sat
Reported: 3-8 days

Specimen Required: Collect: Vaginal, rectal, cervical, or male urethral specimen with APTIMA Unisex Swab Specimen Collection kit (ARUP supply #28907) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Also acceptable: First catch urine. Refer to "Sample Collection for the Diagnosis of STD" under Specimen Handling at www.aruplab.com for specific specimen collection and transport instructions.
Specimen Preparation: **APTIMA Swab:** Place blue swab in Swab Specimen Transport Tube, break shaft off at scoreline then recap tube.
First Catch Urine: Transfer 2 mL urine to an APTIMA Urine Specimen Transport Tube (ARUP supply #28908) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. Liquid level must be between fill lines on tube.
Storage/Transport Temperature: Refrigerated.
Remarks: Specimen source is required.
Unacceptable Conditions: Large white swab included in APTIMA Unisex Swab Specimen Collection kit is for preparatory cleaning of the endocervix and is unacceptable for testing. Specimens in swab transport media without a swab.
Stability (collection to initiation of testing): Ambient: 1 month; Refrigerated: 1 month; Frozen: 1 month

Reference Interval:

Test Number	Components	Reference Interval
0060243	*Chlamydia trachomatis* by Transcription-Mediated Amplification (TMA)	Negative
0060244	*Neisseria gonorrhoeae* by Transcription-Mediated Amplification (TMA)	Negative
2013768	*Chlamydia trachomatis* L serovars (LGV) by PCR	Not Detected

Interpretive Data: Refer to report.

Note: If *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by TMA result is positive for *Chlamydia trachomatis*, then *Chlamydia trachomatis* L serovars (LGV) by PCR will be added. Additional charges apply.

CPT Code(s): 87491, 87591; If reflexed, add 87491

New York DOH approval pending. Call for status update.

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

New Test **2013768** ***Chlamydia trachomatis* L serovars (LGV) by PCR** **CT LGVPCR**

Methodology: Qualitative Polymerase Chain Reaction
Performed: Mon, Thu
Reported: 1-5 days

Specimen Required: Collect: Vaginal, rectal, cervical, urethral, genital, or penile swab with APTIMA Unisex Swab Specimen Collection kit (ARUP supply #28907) OR in Viral Transport Media (ARUP supply #12884) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. Also acceptable: Urine. Refer to "Sample Collection for the Diagnosis of STD" under Specimen Handling at www.aruplab.com for specific specimen collection and transport instructions.
Specimen Preparation: **APTIMA Swab:** Place blue swab in Swab Specimen Transport Tube, break shaft off at scoreline then recap tube.
Urine: Transfer 2 mL urine to an APTIMA Urine Specimen Transport Tube (ARUP supply #28908) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. Liquid level must be between fill lines on tube.
Swab in Viral Transport Media (UTM): Transfer swab to viral transport media.
Storage/Transport Temperature: Refrigerated
Remarks: Specimen source required.
Stability (collection to initiation of testing): Ambient: 1 month; Refrigerated: 1 month; Frozen: 1 month

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

Note: This test detects but does not differentiate *Chlamydia trachomatis* L1-L3 serovars. Refer to the CDC website for STD treatment guidelines at: http://www.cdc.gov/std/treatment/default.htm.

CPT Code(s): 87491

New York DOH approval pending. Call for status update.

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

0091267 **Chloral Hydrate Metabolite, Serum or Plasma** **TRICHLOROE**

Methodology: Qualitative Gas Chromatography

Specimen Required: Collect: Plain Red, Lavender (EDTA), or Pink (K_2EDTA). Also acceptable: Gray (sodium fluoride/potassium oxalate).
Specimen Preparation: Separate from cells ASAP or within one hour of collection. Transfer 3 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1.2 mL) Ensure container remains tightly sealed.
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Unacceptable Conditions: Separator tubes.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 14 months

CPT Code(s): 82441 (Alt code: G0480)

New Test Available Now **2011311** **Chloride, Random Urine** **U CL RAND**

Methodology: Quantitative Ion-Selective Electrode
Performed: Sun-Sat
Reported: Within 24 hours

Specimen Required: Collect: Random urine.
Specimen Preparation: Transfer 1 mL aliquot of urine to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 1 week; Frozen: 6 months

Reference Interval:

Components	Reference Interval
Chloride, Urine - ratio to CRT	Male: 23-275 mmol/g CRT Female: 38-318 mmol/g CRT

CPT Code(s): 82436

New York DOH Approved.

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

0020408 **Comprehensive Metabolic Panel** **CMP**

Specimen Required: Collect: Plasma Separator Tube or Serum Separator Tube (SST).
Specimen Preparation: Protect from light. Allow serum tube to clot completely at room temperature. Separate serum or plasma from cells ASAP or within 30 minutes of collection. Transfer 1 mL serum or plasma to an ARUP Amber Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: EDTA, citrate, oxalate, or sodium fluoride/potassium oxalate.
Stability (collection to initiation of testing): After separation from cells: Ambient: Calcium and CO2: 4 hours, All others: 24 hours; Refrigerated: 1 week; Frozen: 2 weeks

New Test Available Now **2011480** **Copper, Random Urine** **U COP RAND**

Specimen Collection and Handling

Methodology: Quantitative Inductively Coupled Plasma-Mass Spectrometry
Performed: Mon-Sat
Reported: 1-3 days

Specimen Required: Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician). High concentrations of iodine may interfere with elemental testing. Abstinence from iodine-containing medications or contrast agents for at least 1 month prior to collecting specimens for elemental testing is recommended.
Collect: Random urine.
Specimen Preparation: Transfer an 8 mL aliquot from a well-mixed collection to ARUP Trace Element-Free Transport Tubes (ARUP supply #43116), available online through eSupply using ARUP Connect ™ or contact ARUP Client Services at (800) 522-2787. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Unacceptable Conditions: Urine collected within 48 hours after administration of a gadolinium (Gd) containing contrast media (may occur with MRI studies). Acid preserved urine.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval:

Components	Reference Interval
Copper, Urine	0.2-8.0 µg/dL
Copper Urine - ratio to CRT	by report

Interpretive Data: Individuals with symptomatic Wilson disease usually excrete more than 100 copper per day. Other conditions associated with elevated urine copper include cholestatic liver disease, proteinuria, some medications, and contaminated specimens.

Although random specimens may contain diagnostic information, 24-hour collection is a more consistent indicator of elevated copper.

See Compliance Statement B: www.aruplab.com/CS

Note: Refer to Copper-Ceruloplasmin Index (Copper Free) (ARUP test code 0025079) for Wilson disease screening test.

CPT Code(s): 82525

New York DOH Approved.

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

0097222 **Cortisol Urine Free by LC-MS/MS** **CORT UF**

Interpretive Data: The optimal specimen for this testing is a 24-hour urine collection. Mass per day calculations are not reported for the following specimen types: a random collection, a collection with duration of less than 20 hours, a collection with duration of greater than 28 hours, or a collection with total volume less than 400 mL or greater than 5000 mL. Ratios to creatinine may be useful for these evaluations.

Baseline urinary free cortisol excretion less than 5 ug/d may be consistent with adrenal insufficiency.

See Compliance Statement B: www.aruplab.com/CS

0092100 **Cortisol/Cortisone Urine Free by LC-MS/MS** **CORTURATIO**

Interpretive Data: The optimal specimen for this testing is a 24-hour urine collection. Mass per day calculations are not reported for the following specimen types: a random collection, a collection with duration of less than 20 hours, a collection with duration of greater than 28 hours, or a collection with total volume less than 400 mL or greater than 5000 mL. Ratios to creatinine may be useful for these evaluations.

Baseline urinary free cortisol excretion less than 5 ug/d may be consistent with adrenal insufficiency.

See Compliance Statement B: www.aruplab.com/CS

New Test **2013562** **C-Peptide, 120 Minutes** **C PEP 120**
Available Now

Methodology: Quantitative Chemiluminescent Immunoassay
Performed: Sun-Sat
Reported: Within 24 hours

Specimen Required: Patient Prep: Fasting specimen preferred.
Collect: Serum Separator Tube (SST) or Plasma Separator Tube (PST). Also acceptable: Green (sodium or lithium heparin), Lavender (EDTA), or Pink (K_2EDTA).
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transport 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Grossly hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 2 days; Frozen: 1 month

Reference Interval: Reference ranges have not been established

Note: To convert to nmol/L, multiply ng/mL by 0.33.

CPT Code(s): 84681

New York DOH Approved.

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

New Test **2013564** **C-Peptide, 180 Minutes** **C PEP 180**
Available Now

Methodology: Quantitative Chemiluminescent Immunoassay
Performed: Sun-Sat
Reported: Within 24 hours

Specimen Required: Patient Prep: Fasting specimen preferred.
Collect: Serum Separator Tube (SST) or Plasma Separator Tube (PST). Also acceptable: Green (sodium or lithium heparin), Lavender (EDTA), or Pink (K_2EDTA).
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transport 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Grossly hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 2 days; Frozen: 1 month

Reference Interval: Reference ranges have not been established

Note: To convert to nmol/L, multiply ng/mL by 0.33.

CPT Code(s): 84681

New York DOH Approved.

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

New Test **2013558** **C-Peptide, 30 Minutes** **C PEP 30**
Available Now

Methodology: Quantitative Chemiluminescent Immunoassay
Performed: Sun-Sat
Reported: Within 24 hours

Specimen Required: Patient Prep: Fasting specimen preferred.
Collect: Serum Separator Tube (SST) or Plasma Separator Tube (PST). Also acceptable: Green (sodium or lithium heparin), Lavender (EDTA), or Pink (K_2EDTA).
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transport 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Grossly hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 2 days; Frozen: 1 month

Reference Interval: Reference Intervals have not been established.

Note: To convert to nmol/L, multiply ng/mL by 0.33.

CPT Code(s): 84681

New York DOH Approved.

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

New Test Available Now **2013560** **C-Peptide, 60 Minutes** **C PEP 60**

Methodology: Quantitative Chemiluminescent Immunoassay
Performed: Sun-Sat
Reported: Within 24 hours

Specimen Required: Patient Prep: Fasting specimen preferred.
Collect: Serum Separator Tube (SST) or Plasma Separator Tube (PST). Also acceptable: Green (sodium or lithium heparin), Lavender (EDTA), or Pink (K_2EDTA).
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transport 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Grossly hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 2 days; Frozen: 1 month

Reference Interval: Reference ranges have not been established

Note:. To convert to nmol/L, multiply ng/mL by 0.33.

CPT Code(s): 84681

New York DOH Approved.

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

New Test Available Now **2013504** **Cw Antigen Typing, Patient** **CW AG**

Methodology: Hemagglutination
Performed: Mon-Fri
Reported: 1-3 days

Specimen Required: Collect: Lavender (EDTA) or Pink (K_2EDTA).
Specimen Preparation: **Do not freeze.** Transport 7 mL whole blood. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Separator tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

CPT Code(s): 86905

New York DOH approval pending. Call for status update.

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

0051232 Cytochrome P450 2D6 (*CYP2D6*) 14 Variants and Gene Duplication — CYP 2D6

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Varies
Reported: 1-2 weeks

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Interpretive Data:

Background Information for Cytochrome P450 2D6 (*CYP2D6*) 14 Variants and Gene Duplication:
Characteristics: The cytochrome P450 (CYP) isozyme 2D6 is involved in the metabolism of many drugs, such as antiestrogens (tamoxifen), alpha-blockers, analgesics, anticonvulsives, antidepressants, antidiabetics, antihypertensives, antipsychotics, antitussives, beta blockers, cardioactives, norepinephrine reuptake inhibitors, and stimulants. Variants of *CYP2D6* will influence pharmacokinetics of CYP2D6 substrates, and may predict non-standard dose requirements.
Inheritance: Autosomal co-dominant.
Cause: *CYP2D6* gene variants.
Variants Tested: (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: Caucasians and Hispanics - 10 percent; African Americans - 2 percent; Asians - 1 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 *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 CYP2D6 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

2013098 Cytochrome P450 Genotype Panel CYP PAN

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring

Specimen Required: Collect: **Whole Blood**: Lavender (EDTA), pink (K_2EDTA), 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.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin.
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: The cytochrome P450 (CYP) isozyme 2D6 is involved in the metabolism of many drugs, such as antiestrogens (tamoxifen), alpha-blockers, analgesics, anticonvulsants, antidepressants, antidiabetics, antihypertensives, antipsychotics, antitussives, beta blockers, cardioactives, norepinephrine reuptake inhibitors, and stimulants. Variants of *CYP2D6* will influence pharmacokinetics of *CYP2D6* substrates, and may predict non-standard dose requirements.
Inheritance: Autosomal co-dominant.
Cause: *CYP2D6* gene variants.
Variants Tested: (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: Caucasians and Hispanics - 10 percent; African Americans - 2 percent; Asians - 1 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 *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 *CYP2D6* 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 Tested: (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:
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

0091258 **Diuretic Screen, Urine** **DIURETIC U**

CPT Code(s): 80377 (Alt code: G0480)

0092184 **Drug Panel 7, Urine - Screen with Reflex to Confirmation/Quantitation** **CDASU 7**

CPT Code(s): 80301; if positive, add appropriate CPT code(s): 80324; 80359; 80353; 80346; 80345; 80349; 80361; 80365; 83992 (Alt code: G0479; if positive, add appropriate CPT code(s): G0480)

0092185 **Drug Panel 7A, Urine - Screen with Reflex to Confirmation/Quantitation** **CDASU 7A**

CPT Code(s): 80301; if positive, add appropriate CPT code(s): 80320; 80324; 80359; 80345; 80346; 80349; 80353; 80361; 80365; 83992 (Alt code: G0479; if positive add appropriate code(s): G0480)

0092186 **Drug Panel 9, Urine - Screen with Reflex to Confirmation/Quantitation** **CDASU 9**

CPT Code(s): 80301; if positive, add appropriate CPT code(s): 80324; 80359; 80345; 80346; 80349; 80353; 80358; 80361; 80365; 80367; 83992 (Alt code: G0479; if positive, add appropriate code(s): G0480)

0092187 **Drug Panel 9A, Urine - Screen with Reflex to Confirmation/Quantitation** **CDASU 9A**

CPT Code(s): 80301; if positive, add appropriate CPT code(s): 80320; 80324; 80359; 80345; 80346; 80349; 80353; 80358; 80361; 80365; 80367; 83992 (Alt code: G0479; if positive, add appropriate code(s): G0480)

0090499	**Drug Screen (Nonforensic), Serum**	**BLD SCREEN**

CPT Code(s): 80301; 80320 (Alt codes: G0479; G0480)

0090500	**Drug Screen (Nonforensic), Urine, Qualitative**	**URN SCREEN**

CPT Code(s): 80301; 80320 (Alt codes: G0479; G0480)

0092420	**Drug Screen 9 Panel, Serum or Plasma - Immunoassay Screen with Reflex to Mass Spectrometry Confirmation/Quantitation**	**DRUG SCRSP**

CPT Code(s): 80301; if positive, add appropriate CPT code(s): 80324; 80359; 80345; 80346; 80349; 80353; 80358; 80361; 80365; 80348; 83992 (Alt code: G0479; if positive, add appropriate CPT code(s): G0480)

0051463	**Dysautonomia, Familial (*IKBKAP*), 2 Variants**	**IKBKAP**

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Tue, Fri
Reported: 5-10 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Interpretive Data:
Background information for Dysautonomia, Familial (*IKBKAP*), 2 Variants:
Characteristics: Familial dysautonomia is a debilitating disease caused by abnormal development and survival of sensory, sympathetic and parasympathetic neurons. Symptoms include gastrointestinal dysfunction, vomiting and autonomic crises, recurrent pneumonia, altered sensitivity to pain and temperature, scoliosis, and cardiovascular instability. Other characteristics include infantile hypotonia, deteriorating wide-based ataxic gait, and decreased life expectancy.
Incidence: 1 in 3,600 Ashkenazi Jewish individuals.
Inheritance: Autosomal recessive.
Cause: *IKBKAP* pathogenic variants.
Variants Tested: p.R696P (c.2087G>C) and c.2204+6T>C.
Clinical Sensitivity: 99 percent in Ashkenazi Jewish individuals, unknown in other ethnicities.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: 99 percent.
Limitations: Variants other than p.R696P (c.2087G>C) and c.2204+6T>C will not be detected. Diagnostic errors can occur due to rare sequence variations.

See Compliance Statement C: www.aruplab.com/CS

New Test Available Now **2013906** **Epi proColon** **EPIPRO**

Additional Technical Information

Methodology: Polymerase Chain Reaction
Performed: Sun, Wed
Reported: 7-10 days

Specimen Required: Collect: Lavender (K_2EDTA). Collect a minimum of 10 mL whole blood. Blood collection tubes should be allowed to complete the evacuated fill**.**
Specimen Preparation: **Plasma preparation should be performed ASAP or within 4 hours of collection. Centrifuge for 12 min at 1350 ± 150 rcf.** Transfer the plasma to a 15 mL conical tube **and centrifuge for an additional 12 minutes at 1350± 150 rcf.** Ensure a minimum of 3.5 mL of plasma is obtained following centrifugation. Transfer entire plasma aliquot to a cryovial tube or any freezable specimen transport tube. (Min: 3.5 mL)
Storage/Transport Temperature: Frozen. Also acceptable: Refrigerated.
Unacceptable Conditions: Serum, stool, or whole blood. Hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 72 hours; Frozen: 2 weeks

Interpretive Data: Refer to report.

Note: This test is not intended to replace a colonoscopy. NOT recommended for pregnant women because of a potential for false-positive results in these individuals.

Accurate test performance requires following the specimen preparation instructions. Minimum volume of 3.5 mL is required for testing without repeats. If a repeat is necessary, an additional specimen will be requested.

CPT Code(s): 81401

New York DOH Approved.

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

0090518 **Ethanol, Urine, Qualitative - Medical** **ETOH URN**

CPT Code(s): 80301 (Alt code: G0479)

0051468 Fanconi Anemia, Group C (*FANCC*), 2 Variants — FANCC

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Tue, Fri
Reported: 5-10 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Interpretive Data:
Background information for Fanconi Anemia, Group C (*FANCC*), 2 Variants:
Characteristics: Fanconi anemia, group C is characterized by the following symptoms: short stature, abnormal skin pigmentation, and multiple malformations that may affect eyes, ears, heart, oral cavity, thumbs, forearms, kidneys, or urinary tract. Other symptoms may include hearing loss, hypogonadism, and developmental delay. Progressive bone marrow failure occurs during the first decade of life. Hematologic malignancies occur in approximately 20 percent of affected individuals. Nonhematologic malignancies occur in approximately 30 percent of affected individuals.
Incidence: 1 in 32,000 Ashkenazi Jewish individuals.
Inheritance: Autosomal recessive.
Cause: *FANCC* pathogenic variants.
Variants Tested: p.D23Ifs (c.67delG) and c.456+4A>T.
Clinical Sensitivity: 99 percent in Ashkenazi Jewish individuals, unknown in other ethnicities.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Variants other than p.D23Ifs (c.67delG) and c.456+4A>T will not be detected. Diagnostic errors can occur due to rare sequence variations.

See Compliance Statement C: www.aruplab.com/CS

2013518 Fatty Acids Profile, Essential Serum or Plasma — FA PRO SP

Interpretive Data: This test does not screen for disorders of peroxisomal biogenesis/function.

See Compliance Statement B: www.aruplab.com/CS

2012173 Fibrillarin (U3 RNP) Antibody, IgG — U3 FIB

Methodology: Qualitative Immunoblot
Performed: Tue, Thu, Sat
Reported: 1-4 days

Reference Interval: Effective November 14, 2016
Negative

Interpretive Data:
The presence of fibrillarin (U3-RNP) IgG antibodies in association with an ANA IFA nucleolar pattern is suggestive of systemic sclerosis (SSc). In SSc, these antibodies are associated with distinct clinical features, such as younger age at disease onset, frequent internal organ involvement (pulmonary hypertension, myositis and renal disease). Fibrillarin antibodies are detected more frequently in African American patients with SSc compared to other ethnic groups. Strong correlation with ANA IFA results is recommended.

In a multi-ethnic cohort of SSc patients (n=98), U3-RNP antibodies detected by immunoblot had an agreement of 98.9 percent with the gold standard immunoprecipitation (IP) assay. Approximately 71 percent (5/7) of the borderline U3-RNP results with ANA nucleolar pattern in this cohort were IP negative.

See Compliance Statement D: www.aruplab.com/CS

HOT LINE NOTE: There is a result type change associated with this test.
Change 2012174 Fibrillarin (U3 RNP) Ab, IgG result type from numeric to alpha.

2012678 Gastrointestinal Bacterial Panel by PCR — GI BACTPCR

Performed: Tue, Thu, Sat
Reported: 2-5 days

2011660 Gastrointestinal Parasite and Microsporidia by PCR — PARAMICPCR

Performed: Tue, Thu, Sat
Reported: 2-5 days

2011150 Gastrointestinal Parasite Panel by PCR — GI PARAPCR

Performed: Tue, Thu, Sat
Reported: 2-5 days

Interpretive Data: A negative result does not rule out the presence of PCR inhibitors in the patient specimen or test-specific nucleic acid in concentrations below the level of detection by this test.

See Compliance Statement B: www.aruplab.com/CS

0051438 Gaucher Disease (*GBA*), 8 Variants — GBA

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Tue, Fri
Reported: 5-10 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Interpretive Data:
Background information for Gaucher Disease (*GBA*), 8 Variants:
Characteristics: Gaucher disease affects lysosomal storage and has extreme symptom variability, ranging from perinatal lethality to asymptomatic individuals. Three Gaucher subtypes have been identified based on symptom characteristics. Type 1 is characterized by bone disease, hepatosplenomegaly, anemia, thrombocytopenia, and lung disease. Individuals with Type 1 disease do not have primary central nervous system (CNS) involvement. Type 2 is characterized by CNS symptoms displaying before age 2, which progresses rapidly resulting in death by age 4. In Type 3 disease, individuals may present as early as age 2 with display CNS symptoms. However, Type 3 disease progresses slowly, usually resulting in death during the third or fourth decade of life.
Incidence: 1 in 900 in Ashkenazi Jewish individuals.
Inheritance: Autosomal recessive.
Cause: *GBA* pathogenic variants.
Variants Tested: c.115+1G>A, p.L29Afs (c.84dupG), p.N409S (c.1226A>G), c.1263_1317del55, p.V433L (c.1297G>T), p.D448H (c.1342G>C), p.L483P (c.1448T>C), and p.R535H (c.1604G>A).
Clinical Sensitivity: 90 percent in Ashkenazi Jewish individuals; 55 percent in other ethnicities.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Variants other than those tested will not be detected. Diagnostic errors can occur due to rare sequence variations.

See Compliance Statement C: www.aruplab.com/CS

New Test **2013740** **Glycogen Storage Disease, Type 1A (*G6PC*), 9 Variants** **G6PC**

Additional Technical Information

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Tue, Fri
Reported: 5-10 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Reference Interval: By report

Interpretive Data:
Background Information for Glycogen Storage Disease, Type 1A (*G6PC*), 9 Variants:
Characteristics: Infants typically present at 3 to 4 months of age with hepatomegaly, lactic acidosis, hyperuricemia, hyperlipidemia, hypertriglyceridemia and/or hypoglycemic seizures. Other characteristics include growth delay leading to short stature, osteoporosis, delayed puberty, renal disease, and hepatic adenomas with potential for malignancy. With treatment, affected individuals often live into adulthood.
Incidence: 1 in 20,000 in Ashkenazi Jewish individuals.
Inheritance: Autosomal recessive.
Cause: *G6PC* pathogenic variants.
Variants Tested: p.Q27Rfs (c.79delC), Y128Tfs (c.379_380dupTA), p.R83H (c.248G>A), p.R83C (c.247C>T), p.G188R (c.562G>C), p.Q242X (c.724C>T), p.Q347X (c.1039C>T), p.G270V (c.809G>T), p.F327del (c.979_981delTTC).
Clinical Sensitivity: 99 percent in Ashkenazi Jewish individuals; varies by ethnicity in non-Ashkenazi Jewish individuals.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Variants other than those tested will not be detected. Diagnostic errors can occur due to rare sequence variations.

See Compliance Statement C: www.aruplab.com/CS

CPT Code(s): 81250

New York DOH approval pending. Call for status update.

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

New Test **2011304** **Heavy Metals Panel 3, Random Urine with Reflex to Arsenic Fractionated** **HYMETU RND**

Available Now

Patient Demographics Form for Public Health Reporting

Specimen Collection and Handling

Methodology: Quantitative Inductively Coupled Plasma-Mass Spectrometry
Performed: Mon-Sat
Reported: 1-4 days

Specimen Required: Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, non-essential over-the-counter medications (upon the advice of their physician), and avoid shellfish and seafood for 48 to 72 hours. High concentrations of iodine may interfere with elemental testing. Abstinence from iodine-containing medications or contrast agents for at least 1 month prior to collecting specimens for elemental testing is recommended.
Collect: Random urine.
Specimen Preparation: Transfer an 8 mL aliquot from a well-mixed collection to ARUP Trace Element-Free Transport Tubes (ARUP supply #43116), available online through eSupply using ARUP Connect ™ or contact ARUP Client Services at (800) 522-2787. (Min: 2 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Unacceptable Conditions: Urine collected within 48 hours after administration of a gadolinium (Gd) containing contrast media (may occur with MRI studies). Acid preserved urine.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval:

Test Number	Components	Reference Interval
	Arsenic, Urine - per volume	0-35.0 µg/L (based on Biological Exposure Index)
	Arsenic Urine - ratio to CRT	Less than 30 µg/gCRT
0020734	Arsenic, Fractionated, Urine	

Test Number	Components	Reference Interval
	As Organic	Refer to report
	Arsenic Total Inorganic	Refer to report
	Arsenic, Methylated	Refer to report

	Lead, Urine - per volume	0-23µg/L
	Lead, Urine - ratio to CRT	Less than 5 µg/gCRT
	Mercury, Urine - per volume	0-10 µg/L
	Mercury, Urine - ratio to CRT	Less than or equal to 35 µg/gCRT

Interpretive Data: Urinary mercury levels predominantly reflect acute or chronic elemental or inorganic mercury exposure. Urine concentrations in unexposed individuals are typically less than 10 µg/L. 24 hour urine concentrations of 30 to 100 µg/L may be associated with subclinical neuropsychiatric symptoms and tremors. Concentrations greater than 100 µg/L can be associated with overt neuropsychiatric disturbances and tremors. Urine mercury levels may be useful in monitoring chelation therapy.

The ACGIH Biological Exposure Index (BEI) for arsenic in urine is 35µg/L. The ACGIH BEI is based on the sum of inorganic and methylated species. For specimens with a total arsenic concentration of 35 to 2000 µg/L, fractionation is automatically performed to determine the proportions of inorganic, methylated and organic species. It may be appropriate to request fractionation for specimens with a total arsenic greater than 30 µg/gCRT, despite a total arsenic concentration less than 35 µg/L. If low-level chronic poisoning is suspected, the µg/gCRT ratio may be a more sensitive indicator of arsenic exposure than the total arsenic concentration.

Note: If total arsenic concentration is between 35-2000 µg/L, then Arsenic, Fractionated, will be added to determine the proportion of organic, inorganic, and methylated forms. Additional charges apply.

CPT Code(s): 82175; 83655; 83825; if reflexed, add 82175

New York DOH Approved.

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

2010476 *Helicobacter pylori* Breath Test, Adult — UBIT

Specimen Required: Patient Prep: This test requires the adult patient (>17 years of age) to fast and abstain from smoking for 1 hour prior to test administration. The patient should not have taken antibiotics, proton pump inhibitors (e.g., Prilosec, Prevacid, Aciphex, Nexium), or bismuth preparations (e.g., Pepto-Bismol) within the previous 14 days. When used to monitor treatment, the test should be performed four weeks after cessation of definitive therapy. The patient should be informed that the Pranactin-Citric drink that will be administered contains phenylalanine. Phenylketonurics restrict dietary phenylalanine.
Collect: BreathTek UBT Kit (ARUP Supply #51124) available online through eSupply using ARUP Connect™ or contact ARUPClient Services at (800) 522-2787.
Specimen Preparation: 1) Label breath collection bags with patient name, MRN, date and time of collection, and indicate Pre (blue) or Post (pink).
2) Collect the baseline (Pre) breath specimen according to the instructions in the BreathTek UBT kit.
3) After the allotted time, collect the Post breath specimen according to the instructions in the kit.
Storage/Transport Temperature: **CRITICAL ROOM TEMPERATURE. Do not freeze.**
Remarks: **For a valid result, the post breath specimen must be collected between 15 and 30 minutes after the patient drinks the Pranactin-Citric solution.**
Unacceptable Conditions: Underinflated bags. Pediatric specimens.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: Unacceptable; Frozen: Unacceptable

Interpretive Data: A negative result does not rule out the possibility of *H. pylori* infection. If clinical signs are suggestive of *H. pylori* infection, retest with a new specimen or an alternate method. Known causes of false negative results include:
1. Use of antibiotics, proton pump inhibitors, and bismuth preparations during the preceding 2 weeks.
2. Administration of the breath test less than 4 weeks after completion of definitive therapy to eradicate *H. pylori.*
3. Premature or late collection of the post-dose specimen.

Known causes of false positive results include:
1. Patients with achlorhydria.
2. Rinsing the testing solution in the mouth, which can allow contact with urease-positive bacteria.
3. The presence of other gastric spiral organisms such as *Helicobacter heilmanii.*

Note: The post-dose sample must be collected between 15 and 30 minutes post-dose to prevent a false negative result.

2010925 *Helicobacter pylori* Breath Test, Pediatric — UBT PED

Specimen Required: Patient Prep: This test requires the pediatric patient (3-17 years old) to fast and abstain from smoking for 1 hour prior to test administration. The patient should not have taken antibiotics, proton pump inhibitors (e.g., Prilosec, Prevacid, Aciphex, Nexium), or bismuth preparations (e.g., Pepto-Bismol) within the previous 14 days. When used to monitor treatment, the test should be performed four weeks after cessation of definitive therapy. The patient should be informed that the Pranactin-Citric drink that will be administered contains phenylalanine. Phenylketonurics restrict dietary phenylalanine.
Collect: BreathTek UBT Kit. (ARUP Supply #51124) Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Specimen Preparation: 1) Label breath collection bags with patient name, MRN, date and time of collection, and indicate Pre (blue) or Post (pink).
2) Collect the baseline (Pre) breath specimen according to the instructions in the BreathTek UBT kit.
3) After the allotted time, collect the Post breath specimen according to the instructions in the kit.
Information required: Record weight, height, gender, and age.
Storage/Transport Temperature: **CRITICAL ROOM TEMPERATURE**. **Do not freeze.**
Remarks: **For a valid result, the post breath specimen must be collected between 15 and 30 minutes after the patient drinks the Pranactin-Citric solution.**
Unacceptable Conditions: Underinflated bags. Specimens from patients younger than 3 years.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: Unacceptable; Frozen: Unacceptable

Interpretive Data: A negative result does not rule out the possibility of *H. pylori* infection. If clinical signs are suggestive of *H. pylori* infection, retest with a new specimen or an alternate method. Known causes of false-negative results include:
1. Use of antibiotics, proton pump inhibitors, and bismuth preparations during the preceding 2 weeks.
2. Administration of the breath test less than 4 weeks after completion of definitive therapy to eradicate *H. pylori.*
3. Premature or late collection of the post-dose specimen.

Known causes of false-positive results include:
1. Patients with achlorhydria.
2. Rinsing the testing solution in the mouth, which can allow contact with urease-positive bacteria.
3. The presence of other gastric spiral organisms such as *Helicobacter heilmanii.*

Note: The post-dose sample must be collected between 15 and 30 minutes post-dose to prevent a false- negative result.

New Test Available Now **2013881** **Hepatitis Delta Virus by Quantitative PCR** **HDV QNT**

Methodology: Quantitative Polymerase Chain Reaction
Performed: Mon, Thu
Reported: 2-5 days

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate serum from cells. Transport 1 mL serum in a sterile container. (Min: 0.5 mL)
Storage/Transport Temperature: Frozen.
Remarks: Specimen source required.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 1 week; Frozen: 4 months

Reference Interval: Not Detected

Interpretive Data: The quantitative range of this assay is 2.1-6.8 log IU/mL (120 – 5,800,000 IU/mL).

A negative result (less than 2.1 log IU/mL or less than 120 IU/mL) does not rule out the presence of PCR inhibitors in the patient specimen or HDV RNA concentrations below the level of detection of the test. Inhibition may also lead to underestimation of viral quantitation.

See Compliance Statement B: www.aruplab.com/CS

Note: The limit of quantification for this test is 2.1 log IU/mL (120 IU/mL). If the test DID NOT DETECT the virus, the result will be reported as "< 2.1 log IU/mL (< 120 IU/mL)." If the test DETECTED the presence of the virus but was not able to accurately quantify the number of copies, the 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.

2012023 **Hepatitis E Virus (HEV) Antibodies, IgG and IgM** **HEV PAN**

Performed: Tue, Fri
Reported: 1-8 days

2010151 **Hepatitis E Virus (HEV) Antibody, IgG** **HEV IGG**

Performed: Tue, Fri
Reported: 1-8 days

2010156 **Hepatitis E Virus (HEV) Antibody, IgM** **HEV IGM**

Performed: Tue, Fri
Reported: 1-8 days

New Test **2013897** **Herpes Simplex Virus (HSV) Typing** **V HSVT**

Methodology: Cell Culture/Immunofluorescence
Performed: Sun-Sat
Reported: 1-5 days (depending on organism growth)

Specimen Required: Patient Prep: Typing may not be requested directly on a specimen.
Collect: Herpes simplex isolate from cell culture with infected cells present.
Specimen Preparation: Harvest positive cells (3-4+ positivity) from actively growing cell culture and acetone fix the infected cells to a two-well slide OR transfer the infected cells with culture media to a sterile, leak-proof container. Place each specimen in an individually sealed bag.
Storage/Transport Temperature: Refrigerated.
Remarks: Specimen source preferred.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 72 hours; Frozen: 1 month

Reference Interval: By report

Note: For culture and typing, refer to Herpes Simplex Virus Culture with Reflex to HSV Typing (ARUP test code 0065065).

CPT Code(s): 87140 x2

New York DOH Approved.

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

0065065 **Herpes Simplex Virus Culture with Reflex to HSV Typing** **V HSVCT**

HOT LINE NOTE: There is a reflexive pattern change associated with this test.
Remove reflex to 0060847 Herpes Simplex Virus Typing and add reflex to 2013897 Herpes Simplex Virus (HSV) Typing.

2007578 **High Molecular Weight Kininogen (HMWK)** **HIGH MOLE**

Methodology: Clotting

Specimen Required: Patient Prep: Do not draw from an arm with a heparin lock or heparinized catheter.
Collect: Light Blue (Sodium Citrate).
Specimen Preparation: Transfer 2 mL plasma to an ARUP Standard Transport Tube. (Min: 1 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions:
Stability (collection to initiation of testing): Ambient: 4 hours; Refrigerated: Unacceptable; Frozen: at -20°C: 2 weeks; Frozen at -70°C: 1 year

2010797 Human Immunodeficiency Virus 1 (HIV-1) by Quantitative PCR with Reflex to HIV PhenoSense GT — HIVQT PR

Specimen Required: Collect: Two Lavender (EDTA) or two Plasma Preparation Tubes (PPT).
Specimen Preparation: Separate plasma from cells within 6 hours of collection. Transfer two 3 mL aliquots (6 mL total) of plasma into individual ARUP Standard Transport Tube(s). (Min: 4.5 mL total) Two tubes are required. One tube will be tested for the HIV by Quantitative PCR assay; if reflexed, the other tube will be tested by HIV PhenoSense GT.
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Serum. Specimens **submitted** in plasma preparation tube. Heparinized specimens.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 2 weeks

Reference Interval:

Available Separately	Components	Reference Interval
0055598	Human Immunodeficiency Virus 1 by Quantitative PCR	Not detected
0092399	HIV PhenoSense GT	By report

0065999 Human Papillomavirus (HPV), High Risk by Hybrid Capture, Cervical Brush — HPV-HI

Performed: Sun-Sat
Reported: 3-10 days

Specimen Required: Patient Prep: Females should avoid high concentrations of antifungal cream, contraceptive jelly, or douche at time of collection.
Collect: Cervical brush in HPV Digene Collection Kit (ARUP supply #12578). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Specimen Preparation: Place each specimen in an individually sealed bag. (Min: 1 mL)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated.
Remarks: Specimen source required.
Unacceptable Conditions: Specimens in any transport media other than indicated above.
For specimens in ThinPrep Pap Test transport media, refer to Human Papillomavirus (HPV), High Risk by Transcription-Mediated Amplification (TMA), ThinPrep (ARUP test code 2007893) or Human Papillomavirus (HPV), High Risk by Hybrid Capture, ThinPrep (ARUP test code 2008404). For specimens in SurePath Pap specimen transport media, refer to Human Papillomavirus (HPV), High Risk by PCR, SurePath (ARUP test code 2011942).
Stability (collection to initiation of testing): Ambient: 2 weeks; Refrigerated: 3 weeks; Frozen: 3 months

2008404 Human Papillomavirus (HPV), High Risk by Hybrid Capture, ThinPrep — TP HPVHI

Performed: Sun-Sat
Reported: 3-10 days

Specimen Required: Patient Prep: Females should avoid high concentrations of antifungal cream, contraceptive jelly, or douche at time of collection.
Collect: Cervical Brush in ThinPrep transport media.
Specimen Preparation: Place each specimen in an individually sealed bag. (Min: 4 mL)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated.
Remarks: Specimen source required.
Unacceptable Conditions: Specimens in any transport media other than indicated above. For specimens in SurePath transport media, refer to Human Papillomavirus (HPV), High Risk by PCR, SurePath (ARUP test code 2011942). For cervical brush specimens in Digene transport media, refer to Human Papillomavirus (HPV), High Risk by Hybrid Capture, Cervical Brush (ARUP test code 0065999). For ThinPrep specimens of less than 4 mL, refer to Human Papillomavirus (HPV), High Risk by Transcription-Mediated Amplification (TMA), ThinPrep (ARUP test code 2007893).
Stability (collection to initiation of testing): Ambient: 3 months; Refrigerated: 3 months; Frozen: Unacceptable

New Test Available Now **2013612** **Infliximab Activity with Reflex to Antibody** **IFX DL R**

Supplemental Resources

Methodology: Cell Culture/Quantitative Chemiluminescent Immunoassay/ Semi-Quantitative Chemiluminescent Immunoassay
Performed: Mon, Wed, Thu, Sat
Reported: 2-3 days

Specimen Required: Patient Prep: Collect specimens before infliximab treatment.
Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.3 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Contaminated, hemolyzed, icteric, or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 4 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval:

Available Separately	Components	Reference Interval
2013612	Infliximab Activity w/Reflex to Antibody	Not Detected
No	IFX Rflx to Neutralizing Ab Confirmation	Not Detected

Interpretive Data: This test measures the capacity of infliximab to neutralize TNF-alpha activity. Additionally, infliximab neutralizing antibodies (NAb) are titered (reporting the highest dilution of patient sera in which NAb activity is detected).

This test is used to evaluate secondary response failures to infliximab therapy. Secondary response failure is defined as loss of clinical response after initial improvement of clinical signs and symptoms. Therapeutic decision should rest on both the clinical response and the knowledge of the fate of the drug including the emergence of immunogenicity in individual patients.

Circulating infliximab levels have been shown to vary considerably between patients. These differences relate to route and frequency of administration and patient-related features such as age, gender, weight, drug metabolism, and concomitant medications such as methotrexate and other immunosuppressants.

IF infliximab Activity is...	AND infliximab Neutralizing Antibody Titer is...	THEN...
Not Detected	Not Detected	A higher dosage of infliximab or shortening the dosing interval may be appropriate.
Not Detected	1:20 or greater	A change to another anti-TNF-alpha drug may be appropriate.
0.65 µg/mL or greater	N/A	A change to another type of therapy (not targeting TNF-alpha) may be appropriate, if the patient did not respond adequately to infliximab therapy.

See Compliance Statement B: www.aruplab.com/CS

Note: This test is performed pursuant to an agreement with Eurodiagnostica. If Infliximab drug level is not detected, then Infliximab Neutralizing Antibody Titer will be added. Additional charges apply.

CPT Code(s): 86352, if reflexed add 86352

New York DOH Approved.

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

New Test 2013909 Joubert Syndrome Type 2 (TMEM216), 1 Variant TMEM216

Additional Technical Information

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Tue, Fri
Reported: 5-10 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Reference Interval: By report

Interpretive Data:
Background Information for Joubert Syndrome Type 2 (*TMEM216*), 1 Variant:
Characteristics: Joubert syndrome, type 2 is characterized by a "molar tooth sign" cerebellar and brain stem malformation, hypotonia and developmental delay. Clinical manifestations and severity of the syndrome vary.
Incidence: 1 in 34,000 in Ashkenazi Jewish individuals.
Inheritance: Autosomal recessive.
Cause: *TMEM216* pathogenic variants.
Variants Tested: p.R73L (c.218G>T).
Clinical Sensitivity: 99 percent in Ashkenazi Jewish individuals; unknown in other ethnicities.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Variants other than p.R73L (c.218G>T) will not be detected. Diagnostic errors can occur due to rare sequence variations.

See Compliance Statement C: www.aruplab.com/CS

CPT Code(s): 81479

New York DOH approval pending. Call for status update.

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

New Test 2013690 Kpa Pt Antigen Typing IRL P-KPA_IRL
Available Now

Methodology: Hemagglutination
Performed: Monday-Friday
Reported: 1-3 days

Specimen Required: Collect: Lavender (EDTA) or Pink (K_2EDTA)
Specimen Preparation: Do not freeze. Transport 7 mL whole blood (Min: 1 mL)
Storage/Transport Temperature: Refrigerated
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 Week; Frozen: Unacceptable

Reference Interval: By Report

CPT Code(s): 86905

New York DOH approval pending. Call for status update.

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

0020045 **Lactic Acid, Plasma** **LA**

Reference Interval: 0.5-2.2 mmol/L

0090177 **Lamotrigine** **LAMOT**

CPT Code(s): 80175 (Alt code: G0480)

New Test **2013802** **LANGERIN by Immunohistochemistry** **LANGER IHC**

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 (ARUP supply #47808 recommended but not required) 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.

New Test Available Now **2011482** **Lead, Random Urine** **U LEADRAND**

Patient Demographics Form for Public Health Reporting

Specimen Collection and Handling

Methodology: Quantitative Inductively Coupled Plasma-Mass Spectrometry
Performed: Mon-Sat
Reported: 1-3 days

Specimen Required: Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician). High concentrations of iodine may interfere with elemental testing. Abstinence from iodine-containing medications or contrast agents for at least 1 month prior to collecting specimens for elemental testing is recommended.
Collect: Random urine.
Specimen Preparation: Transfer an 8 mL aliquot from a well-mixed collection to ARUP Trace Element-Free Transport Tubes (ARUP supply #43116), available online through eSupply using ARUP Connect ™ or contact ARUP Client Services at (800) 522-2787. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Unacceptable Conditions: Urine collected within 48 hours after administration of a gadolinium (Gd) containing contrast media (may occur with MRI studies). Acid preserved urine.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval:

Components	Reference Interval
Lead, Urine	0-23 µg/L
Lead, Urine - ratio to CRT	Less than 5 ug/gCRT

CPT Code(s): 83655

New York DOH Approved.

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

2008003 **Leukemia/Lymphoma Phenotyping by Flow Cytometry** **L/L PANEL**

HOT LINE NOTE: There is a component change associated with this test that affects interface clients only.
Add component 2013914, Leuk/Lymph Phenotype, Source.

New Test 2013735 Lipoamide Dehydrogenase Deficiency (DLD), 2 Variants DLD

Additional Technical Information

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Tue, Fri
Reported: 5-10 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Reference Interval: By report

Interpretive Data:
Background Information for Lipoamide Dehydrogenase Deficiency (*DLD*), 2 Variants:
Characteristics: Lipoamide dehydrogenase deficiency has a variable presentation that ranges from early-onset neurologic disease to adult-onset disease which is primarily hepatic. Early-onset neurologic disease presents in infancy with hypotonia, lethargy, vomiting and progressive encephalopathy resulting in death within the first or second year of life. Adult-onset primarily hepatic disease has a variable onset from infancy to the fourth decade and presents with liver injury or failure that is usually preceded by nausea and vomiting.
Incidence: 1 in 35,000 in Ashkenazi Jewish individuals.
Inheritance: Autosomal recessive.
Cause: *DLD* pathogenic variants.
Variants Tested: p.Y35X (c.104dupA), p.G229C (c.685G>T).
Clinical Sensitivity: 99 percent in Ashkenazi Jewish individuals; unknown in other ethnicities.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Variants other than those tested will not be detected. Diagnostic errors can occur due to rare sequence variations.

See Compliance Statement C: www.aruplab.com/CS

CPT Code(s): 81479

New York DOH approval pending. Call for status update.

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

2010711 Liver Cytosolic Antigen Type 1 (LC-1) Antibody, IgG LC-1

Methodology: Qualitative Immunoblot

Specimen Required: Collect: Serum Separator Tube.
Specimen Preparation: Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.3 mL)
Storage/Transport Temperature: Refrigerated
Unacceptable Conditions: Contaminated, hemolyzed, or severely lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval: Effective November 14, 2016
Negative

HOT LINE NOTE: There is a result type change associated with this test.
Change Liver 2010712 Cytosolic Type 1 IgG from result type numeric to alpha.

New Test **2013730** **Maple Syrup Urine Disease, Type 1B (*BCKDHB*), 3 Variants** **BCKDHB**

Additional Technical Information

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Tue, Fri
Reported: 5-10 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Reference Interval: By report

Interpretive Data:
Background Information for Maple Syrup Urine Disease, Type 1B (*BCKDHB*), 3 Variants:
Characteristics: Maple syrup urine disease (MSUD), type 1B most commonly presents in the first few days of life. Symptoms include irritability, poor feeding, lethargy, intermittent apnea and typically progresses to coma and death within 7 to 10 days if untreated.
Incidence: 1 in 50,000 in Ashkenazi Jewish individuals.
Inheritance: Autosomal recessive.
Cause: *BCKDHB* pathogenic variants.
Variants Tested: p.R183P (c.548G>C), p.G278S (c.832G>A), p.E372X (c.1114G>T).
Clinical Sensitivity: 99 percent in Ashkenazi Jewish individuals; unknown in other ethnicities.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Variants other than those tested will not be detected. Diagnostic errors can occur due to rare sequence variations.

See Compliance Statement C: www.aruplab.com/CS

CPT Code(s): 81205

New York DOH approval pending. Call for status update.

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

New Test Available Now **2011481** **Mercury, Random Urine** **U MERCRAND**

Patient Demographics Form for Public Health Reporting

Specimen Collection and Handling

Methodology: Quantitative Inductively Coupled Plasma-Mass Spectrometry
Performed: Mon-Sat
Reported: 1-4 days

Specimen Required: Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician). High concentrations of iodine may interfere with elemental testing. Abstinence from iodine-containing medications or contrast agents for at least 1 month prior to collecting specimens for elemental testing is recommended.
Collect: Random urine.
Specimen Preparation: Transfer an 8 mL aliquot from a well-mixed collection to ARUP Trace Element-Free Transport Tubes (ARUP supply #43116), available online through eSupply using ARUP Connect ™ or contact ARUP Client Services at (800) 522-2787. (Min: 1 mL).
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Unacceptable Conditions: Urine collected within 48 hours after administration of a gadolinium (Gd) containing contrast media (may occur with MRI studies). Acid preserved urine.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval:

Components	Reference Interval
Mercury, Urine - per volume	0-10 µg/L
Mercury, Urine - ratio to CRT	Less than or equal to 35 µg/gCRT

Interpretive Data: Urinary mercury levels predominantly reflect acute or chronic elemental or inorganic mercury exposure. Urine concentrations in unexposed individuals are typically less than 10 µg/L. 24-hour urine concentrations of 30 to 100 µg/L may be associated with subclinical neuropsychiatric symptoms and tremor while concentrations greater than 100 µg/L can be associated with overt neuropsychiatric disturbances and tremors. Urine mercury levels may be useful in monitoring chelation therapy.

CPT Code(s): 83825

New York DOH Approved.

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

2013082 ***MET* Gene Amplification by FISH** **MET FISH**

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.
Unacceptable Conditions: Specimens fixed or processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). No tumor in tissue. Decalcified specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

2011626 **Microsporidia by PCR** **MICROSPCR**

Performed: Tue, Thu, Sat
Reported: 2-5 days

Interpretive Data: A negative result does not rule out the presence of PCR inhibitors in the patient specimen or test-specific nucleic acid in concentrations below the level of detection by this test.

See Compliance Statement B: www.aruplab.com/CS

2007967 **Motor and Sensory Neuropathy Evaluation with Immunofixation Electrophoresis and Reflex to Titer and Neuronal Immunoblot** **MSNCR**

Reference Interval:

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	Effective February 16, 2016 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	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

Note: Purkinje Cell (PCCA) antibody and Neuronal Nuclear (ANNA) antibody IgG are screened by IFA. If the IFA screen is indeterminate, then a Neuronal Nuclear Antibodies (Hu, Ri, and Yo) IgG by Immunoblot will be added. If the IFA screen is positive at 1:10 or greater, then a PCCA/ANNA antibodies titer and Neuronal Nuclear Antibodies (Hu, Ri, and Yo) IgG by Immunoblot will be added. Additional charges apply.

CPT Code(s): 83516 x 7; 84160; 82784 x3; 84165; 86334; 86255; if reflexed add 83516 and/or 86256

HOT LINE NOTE: Remove data from the Reference Interval table Test Number cell for component Purkinje Cell/Neuronal Nuclear IgG Scrn. This component is not available separately.

2007966 Motor and Sensory Neuropathy Evaluation with Reflex to Titer and Neuronal Immunoblot — MSNER

Reference Interval:

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

Note: Purkinje Cell (PCCA) antibody and Neuronal Nuclear (ANNA) antibody IgG are screened by IFA. If the IFA screen is indeterminate, then a Neuronal Nuclear Antibodies (Hu, Ri, and Yo) IgG by Immunoblot will be added. If the IFA screen is positive at 1:10 or greater, then a PCCA/ANNA antibodies titer and Neuronal Nuclear Antibodies (Hu, Ri, and Yo) IgG by Immunoblot will be added. Additional charges apply.

CPT Code(s): 83516 x 7; 86255; if reflexed add 83516 and/or 86256

HOT LINE NOTE: Remove data from the Reference Interval table Test Number cell for component Purkinje Cell/Neuronal Nuclear IgG Scrn. This component is not available separately.

0051448 Mucolipidosis Type IV (*MCOLN1*), 2 Variants MCOLN1

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Tue, Fri
Reported: 5-10 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Specimens collected in sodium heparin or lithium heparin tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Interpretive Data:
Background information for Mucolipidosis, Type IV (*MCOLN1*), 2 Variants:
Characteristics: Mucolipidosis type IV is characterized by early onset of severe psychomotor delay and progressive visual impairment due to corneal clouding and retinal degeneration. Affected individuals may occasionally learn to say a few words or walk independently. While most affected individuals remain neurologically static until age 30, about 15 percent will display neurological degeneration.
Incidence: 1 in 63,000 Ashkenazi Jewish individuals.
Inheritance: Autosomal recessive.
Cause: *MCOLN1* pathogenic variants.
Variants Tested: g.511_6493del and c.406-2A>G.
Clinical Sensitivity: 95 percent in Ashkenazi Jewish individuals, 6 to 10 percent in other ethnicities.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Variants other than g.511_6493del and c.406-2A>G will not be detected. Diagnostic errors can occur due to rare sequence variations.

See Compliance Statement C: www.aruplab.com/CS

New Test **2013805** **Natural Killer Cell and Natural Killer T-Cell Panel** **NK/NKT**

Time Sensitive

Methodology: Semi-Quantitative Flow Cytometry
Performed: Sun-Sat
Reported: 1-3 days

Specimen Required: Collect: Green (Sodium or Lithium Heparin), Lavender (EDTA), or Pink (K_2EDTA).
Specimen Preparation: Transport 5 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: **CRITICAL ROOM TEMPERATURE.**
Remarks: Specimens must be analyzed within 48 hours of collection.
New York State Clients: EDTA specimens must be analyzed within 30 hours of collection. Heparin specimens must be analyzed within 48 hours of collection.
Unacceptable Conditions: Clotted or hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
New York State Clients: Ambient: EDTA specimens: 30 hours, Heparin specimens: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

Reference Interval:

Available Separately	Component	Reference Interval
No	Pct CD3-CD16-/+CD56br/dim(total NKcells)	3.7 - 27.8 %
No	Abs CD3-CD16-/+CD56br/dim(total NKcells)	75.0 - 559.9 cells/µL
No	Pct CD3-CD16+CD56dim(cytotoxic NK-cells)	50.3 – 100.0 %
No	Abs CD3-CD16+CD56dim(cytotoxic NK-cells)	43.6 - 545.5 cells/µL
No	Pct CD3-CD16-CD56br (cyto secreting NK)	0.7 - 12.5 %
No	Abs CD3-CD16-CD56br (cyto secreting NK)	2.2 - 16.6 cells/µL
No	Pct CD3-CD57+ (CD57 NK-cells)	1.0 - 16.4 %
No	Abs CD3-CD57+ (CD57 NK-cells)	18.0-297.7 cells/µL
No	Pct CD3+CD56+ (CD56 NKT-cells)	1.1 - 11.3 %
No	Abs CD3+CD56+ (CD56 NKT-cells)	16.5-255.9 cells/µL
No	Pct CD3+CD57+ (CD57 NKT-cells)	0.7 - 22.4 %
No	Abs CD3+CD57+ (CD57 NKT-cells)	9.5 - 528.8 cells/µL
No	Pct CD45+CD3+ (T-cells)	56.0 - 86.0 %
No	Abs CD45+CD3+ (T-cells)	687.2 - 2479.9 cells/µL
No	Pct CD45+CD3-(Non T-cells)	13.1 - 42.4 %
No	Abs CD45+CD3-(Non T-cells)	240.7 - 998.0 cells/µL
No	Natural Killer T-cell Panel Interp	See Note

Interpretive Data: Natural killer (NK) cells are identified by the absence of CD3 and the expression of CD16 and/or CD56. NK cells are divided according to the expression of CD16 and CD56 into cytotoxic NK cells (CD3-CD16+CD56dim) that represents approximately 90% of NK cells, and cytokine-secreting or regulatory NK cells (CD3-CD16-CD56bright) that represents approximately 10% of NK cells. NK cells act against virally-infected cells and tumor cells and may be increased or decreased in various immunologic abnormalities. NK cells also have a role in the adaptive immune response through cytokine production. NK-like T-cells have properties of both T-cells and NK-cells, expressing both CD3 and NK-associated antigens. NK-like T-cell subgroup populations reported are CD3+/CD56+ and CD3+/CD57+.

Note: The cytotoxic NK cells (CD3-CD16+CD56dim) and cytokine-secreting or regulatory NK cells (CD3-CD16-CD56bright) are reported as a percentage of the total NK cells. All other populations are reported as a percentage of the total lymphocytes.

See Compliance Statement A: www.aruplab.com/CS

CPT Code(s): 86357 x2, 86356 x14

New York DOH Approved.

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

New Test **2013745** **NEB-Related Nemaline Myopathy, 1 Variant** **NEB**

Additional Technical Information

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Tue, Fri
Reported: 5-10 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Reference Interval: By report

Interpretive Data:
Background Information for *NEB*-Related Nemaline Myopathy, 1 Variant:
Characteristics: *NEB*-related nemaline myopathy typically presents within the first year of life with hypotonia, feeding difficulties and muscle weakness of the face, neck, arms and legs. Muscle weakness is static or progresses very slowly, but lifespan is not usually decreased.
Incidence: 1 in 47,000 in Ashkenazi Jewish individuals.
Inheritance: Autosomal recessive.
Cause: *NEB* pathogenic variants.
Variant Tested: Exon 55 del (p.R2478_D2512del).
Clinical Sensitivity: 99 percent in Ashkenazi Jewish individuals; unknown in other ethnicities.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Variants other than exon 55 del will not be detected. Diagnostic errors can occur due to rare sequence variations.

See Compliance Statement C: www.aruplab.com/CS

CPT Code(s): 81400

New York DOH approval pending. Call for status update.

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

2001952 **Neurofibromatosis Type 1 (NF1) Deletion/Duplication** **NF1 DELDUP**

Interpretive Data:
Background Information for Neurofibromatosis Type 1 (*NF1*) Deletion/Duplication:
Characteristics: Neurofibromatosis type 1 (NF1) demonstrates extreme clinical variability. Features include: cafe au lait macules, axillary or inguinal freckling, dermal fibromas, Lisch nodules (iris hamartomas), optic glioma, specific osseous lesions such as tibial pseudarthrosis or sphenoid dysplasia, learning disabilities (50 percent), scoliosis, vertebral dysplasia, and somatic overgrowth. Large *NF1* locus deletions increase the risk for neurofibroma development, cognitive abnormalities and malignant peripheral nerve sheath tumors (MPNST).
Incidence: 1 in 3000.
Inheritance*:* Autosomal dominant; de novo mutations occur in 50 percent of cases.
Penetrance: 100 percent by adulthood.
Cause: Pathogenic *NF1* mutations.
Clinical Sensitivity: Approximately 5 percent of NF1 is caused by large *NF1* locus deletions and 2 percent due to intragenic deletions.
Methodology: Multiplex ligation-dependent probe amplification (MLPA) to detect large *NF1* locus and intragenic deletions/duplications.
Analytical Sensitivity and Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Single base pair substitutions, small deletions/duplications, regulatory region mutations, and deep intronic mutations will not be detected. Large deletions/duplications of exons 11and 20 will not be detected. The breakpoints for large deletions/duplications will not be determined.

See Compliance Statement C: www.aruplab.com/CS

2007159 Neurofibromatosis Type 1 (*NF1*) Sequencing NF1 FGS

Interpretive Data:
Background Information for Neurofibromatosis Type 1 (*NF1*) Sequencing:
Characteristics: Neurofibromatosis ty1 (NF1) demonstrates extreme clinical variability. Features include: cafe au lait macules, axillary and inguinal freckling, dermal fibromas, Lisch nodules (iris hamartomas), optic glioma, specific osseous lesions such as tibial pseudarthrosis or sphenoid dysplasia, learning disabilities (50 percent), scoliosis, vertebral dysplasia, and somatic overgrowth. Large *NF1* locus deletions increase the risk for neurofibroma development, cognitive abnormalities and malignant peripheral nerve sheath tumors (MPNST).
Incidence: 1 in 3000.
Inheritance: Autosomal dominant; *de novo* mutations occur in 50 percent of cases.
Penetrance: 100 percent by adulthood.
Cause: Pathogenic *NF1* mutations.
Clinical Sensitivity: Approximately 77-86 percent of causative mutations are detected by sequencing.
Methodology: Bidirectional sequencing of the entire coding region and intron-exon boundaries of the *NF1* gene.
Analytical Sensitivity and Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Regulatory region mutations, deep intronic mutations, and large deletions/duplications will not be detected. Mutations in genes other than *NF1* are not evaluated.

See Compliance Statement C: www.aruplab.com/CS

2007154 Neurofibromatosis Type 1 (*NF1*) Sequencing and Deletion/Duplication NF1 FGA

Interpretive Data:
Background Information for Neurofibromatosis Type 1 (*NF1*) Sequencing and Deletion/Duplication:
Characteristics: Neurofibromatosis type 1 (NF1) demonstrates extreme clinical variability. Features include: cafe au lait macules, axillary and inguinal freckling, dermal fibromas, Lisch nodules (iris hamartomas), optic glioma, specific osseous lesions such as tibial pseudarthrosis or sphenoid dysplasia, learning disabilities (50 percent), scoliosis, vertebral dysplasia, and somatic overgrowth. Large *NF1* locus deletions increase the risk for neurofibroma development, cognitive abnormalities and malignant peripheral nerve sheath tumors (MPNST).
Incidence: 1 in 3000.
Inheritance: Autosomal dominant; de novo mutations occur in 50 percent of cases.
Penetrance: 100 percent by adulthood.
Cause: Pathogenic *NF1* mutations.
Clinical Sensitivity: Approximately 84-93 percent; 77-86 percent of causative mutations are detected by sequencing and 7 percent by deletion testing.
Methodology: Bidirectional sequencing of the entire *NF1* coding region and intron-exon boundaries; multiplex ligation-dependent probe amplification (MLPA) to detect large *NF1* locus and intragenic deletions/duplications.
Analytical Sensitivity and Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Regulatory region mutations and deep intronic mutations will not be detected. Large deletions/duplications of exons 11 and 20 will not be detected. The breakpoints of large deletions/duplications will not be determined.

See Compliance Statement C: www.aruplab.com/CS

0051458 Niemann-Pick Type A (*SMPD1*), 4 Variants — SMPD1

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Tue, Fri
Reported: 5-10 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Interpretive Data:
Background information for Niemann-Pick Type A (*SMPD1*), 4 Variants:
Characteristics: Niemann-Pick type A is a lysosomal storage disease causing hepatosplenomegaly, delayed physical and mental development, hypotonia, rigidity, intellectual disability, and death typically by age 3.
Incidence: 1 in 32,000 Ashkenazi Jewish individuals.
Inheritance: Autosomal recessive.
Cause: *SMPD1* pathogenic variants.
Variants Tested: p.L304P (c.911T>C), p.F333Sfs (c.996delC), p.R498L (c.1493G>T), and p.R610del (c.1829_1831delGCC).
Clinical Sensitivity: 90 percent in Ashkenazi Jewish individuals, varies by ethnicity in non-Ashkenazi Jewish individuals.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Variants other than those tested will not be detected. Diagnostic errors can occur due to rare sequence variations.

See Compliance Statement C: www.aruplab.com/CS

2007190 Occult Blood, Fecal by Immunoassay — FOB IA

Specimen Required: Collect: Stool.
Specimen Preparation: **For Clinical Collections:** Dip sampling bottle transfer wand into stool collection and place back into the FOBT-CHEKoc sampling bottle (ARUP Supply #49940) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
For Patient In Home Collection: Patients will dip sampling bottle transfer wand into stool collection and place back into the FOBT-CHEKoc sampling bottle provided in the Patient Take Home Kit (ARUP Supply #49952 which comes with complete patient collection instructions) 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.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Unpreserved stool.
Stability (collection to initiation of testing): Ambient: 15 days; Refrigerated: 1 month; Frozen: Unacceptable

0098122 Osmolality, Fecal — FEC OSMO

Performed: Sun-Sat
Reported: 1-2 days

2012312 Pain Management Panel, Screen with Reflex to Quantitation — PAIN RFX U

CPT Code(s): 80301; 80302 x7; if positive add appropriate CPT: 80324; 80359; 80345; 80346; 80348; 80369; 80353; 80321; 80354; 80362; 80358; 80349; 80361; 80365; 83992; 80367; 80368; 80372; 80373 (Alt code: G0479; if positive, add appropriate CPT code(s): G0480)

2007961 Paraneoplastic Antibodies (PCCA/ANNA) by IFA with Reflex to Titer and Immunoblot — PCCA/ANNA

Reference Interval:

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

Note: Purkinje Cell (PCCA) antibody and Neuronal Nuclear (ANNA) antibody IgG are screened by IFA. If the IFA screen is indeterminate, then a Neuronal Nuclear Antibodies (Hu, Ri, and Yo) IgG by Immunoblot will be added. If the IFA screen is positive at 1:10 or greater, then a PCCA/ANNA antibodies titer and Neuronal Nuclear Antibodies (Hu, Ri, and Yo) IgG by Immunoblot will be added. Additional charges apply.

CPT Code(s): 86255; if reflexed add 83516 and/or 86256

HOT LINE NOTE: Remove data from the Reference Interval table Test Number cell for component Purkinje Cell/Neuronal Nuclear IgG Scrn. This component is not available separately.

2010841 Paraneoplastic Antibodies (PCCA/ANNA) by IFA with Reflex to Titer and Immunoblot, CSF — PCCAANNA C

Reference Interval:

Test Number	Components	Reference Interval
	Paraneoplastic Abs (PCCA/ANNA) IgG, CSF	None Detected
	Neuronal Nuclear Ab Titer, IgG CSF	Less than 1:1
	Purkinje Cell Antibody Titer IgG, CSF	Less than 1:1
2010847	Neuronal Nuclear Abs IgG ImmunoBlot, CSF	None Detected

Note: PCCA/ANNA antibodies are screened by IFA. If the IFA screen is indeterminate then the Immunoblot will be added. If the IFA screen is positive at 1:1, then a specific titer (PCCA or ANNA) and Immunoblot will be added. Additional charges apply.

CPT Code(s): 86255; if reflexed add 83516 and/or 86256

2008131 Pipecolic Acid, Urine — PIPECOL U

Reference Interval: Effective November 14, 2016

Age	Reference Interval
0 - 30 days	Less than or equal to 19.6 mmol/mol creatinine
1 - 5 months	Less than or equal to 12.1 mmol/mol creatinine
6 - 11 months	Less than or equal to 7.2 mmol/mol creatinine
Greater than 1 Year	Less than or equal to 1.2 mmol/mol creatinine

2003040 **PM/Scl-100 Antibody, IgG by Immunoblot** **PM/SCL**

Methodology: Qualitative Immunoblot
Performed: Tue, Thu, Sat
Reported: 1-4 days

Reference Interval: **Effective November 14, 2016**
Negative

CPT Code(s): 86235

HOT LINE NOTE: There is a result type change associated with this test and a reflexive pattern change.
Change 2003041 PM/Scl 100 Antibody, IgG from result type numeric to alpha.
Remove reflex to 0050639 Nuclear Antibody (ANA) by IFA, IgG.
Remove information found in the Note field.

New Test **2011476** **Porphobilinogen (PBG), Random Urine** **UPBGQTRAND**
Available Now

Methodology: Quantitative Ion Exchange Chromatography/Spectrophotometry
Performed: Mon-Fri
Reported: 1-4 days

Specimen Required: Collect: Random urine.
Specimen Preparation: Protect from light. Transfer an 8 mL aliquot from a well-mixed collection to ARUP Amber Transport Tubes. (Min: 3.5 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Body fluids other than urine.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 4 days; Frozen: 1 month

Reference Interval:

Components	Reference Interval
Porphobilinogen (PBG), Urine-per volume	0.0-8.8 µmol/L
Porphobilinogen, Rndm Urn-ratio to CRT	No reference interval (mg/g crt)

Note: Appropriate test to rule out acute intermittent porphyria (AIP) and other acute attacks of other types of porphyrias associated with neurologic and/or psychiatric symptoms.

CPT Code(s): 84110

New York DOH Approved.

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

New Test Available Now **2013849** **Prenatal Carrier Screening Panel by Next Generation Sequencing** **PCS NGS**

Patient History for Prenatal or Expanded Carrier Screening

Additional Technical Information

Methodology: Massively Parallel Sequencing/Polymerase Chain Reaction
Performed: Varies
Reported: Within 3 weeks

Specimen Required: Collect: Lavender (EDTA).
Specimen Preparation: Transport 4 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated
Remarks: Submit Patient History form for Prenatal Carrier Screening with the Electronic Packing List.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

CPT Code(s): 81404, 81405, 81406, 81407, 81408, 81223, 81252, 81479, 81257

New York DOH Approved.

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

0070105 **Renin Activity** **RENIN**

Methodology: Quantitative Enzyme-Linked Immunosorbent Assay

Specimen Required: Patient Prep: Normal sodium diet (100-200 mEq/day) for at least three days. Receiving no medications known to affect renin-aldosterone system.
Supine: Specimen should be obtained between 8 a.m. and 10 a.m. (after at least two hours in supine position).
OR
Upright: Specimen should be obtained before noon (after at least two hours in upright position; seated or standing).
Contact Medical Director if more information is needed.
Collect: From either a supine or upright patient, Lavender (EDTA) or Pink (K_2EDTA). Do not collect in refrigerated tubes.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL plasma to an ARUP Standard Transport Tube and freeze immediately. (Min: 1.2 mL)
Storage/Transport Temperature: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**
Unacceptable Conditions: Serum. Specimens collected in citrate, heparin, or oxalate. Hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 6 hours; Refrigerated: Unacceptable; Frozen: 1 month

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2001575 **Renin, Direct** **RENIND**

Specimen Required: Patient Prep: Normal sodium diet (100-200 mEq/day) for at least three days. Receiving no medications known to affect renin-aldosterone system.
Supine: Specimen should be obtained between 8 a.m. and 10 a.m. (after at least two hours in supine position).
OR
Upright: Specimen should be obtained before noon (after at least two hours in upright position; seated or standing).
Contact Medical Director if more information is needed.
Collect: From either a supine or upright patient, Lavender (EDTA) or Pink (K_2EDTA). Do not collect in refrigerated tubes.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL plasma to an ARUP Standard Transport Tube and freeze immediately. (Min: 1 mL)
Storage/Transport Temperature: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**
Unacceptable Conditions: Serum. Specimens collected in citrate, heparin, or oxalate. Hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 4 hours; Refrigerated: Unacceptable; Frozen: 4 weeks

2012654 ***RET* Gene Rearrangements by FISH** **RET FISH**

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: 2 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.
Unacceptable Conditions: Specimens fixed or processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). No tumor in tissue. Decalcified specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

New Test
Available Now

2013506 **Sd(a) Antigen Typing, Patient** **SDA AG**

Methodology: Hemagglutination
Performed: Mon-Fri
Reported: 1-3 days

Specimen Required: Collect: Lavender (EDTA) or Pink (K_2EDTA).
Specimen Preparation: **Do not freeze.** Transport 7 mL whole blood. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Separator tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

CPT Code(s): 86905

New York DOH approval pending. Call for status update.

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

2007965 Sensory Neuropathy Antibody Panel with Reflex to Titer and Neuronal Immunoblot — SNAP R

Reference Interval:

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

Note: Purkinje Cell (PCCA) antibody and Neuronal Nuclear (ANNA) antibody IgG are screened by IFA. If the IFA screen is indeterminate, then a Neuronal Nuclear Antibodies (Hu, Ri, and Yo) IgG by Immunoblot will be added. If the IFA screen is positive at 1:10 or greater, then a PCCA/ANNA antibodies titer and Neuronal Nuclear Antibodies (Hu, Ri, and Yo) IgG by Immunoblot will be added. Additional charges apply.

CPT Code(s): 83516 x2; 86255; if reflexed add 83516 and/or 86256

HOT LINE NOTE: Remove data from the Reference Interval table Test Number cell for component Purkinje Cell/Neuronal Nuclear IgG Scrn. This component is not available separately.

2013325 Systemic Sclerosis Comprehensive Panel SCL COMP

Methodology: Qualitative Immunoblot/Semi-Quantitative Indirect Fluorescent Antibody/Semi-Quantitative Multiplex Bead Assay/Semi-Quantitative Enzyme-Linked Immunosorbent Assay
Performed: Thu
Reported: 1-8 days

Reference Interval: Effective November 14, 2016

Test Number	Components	Reference Interval
0050599	Scleroderma (Scl-70) (ENA) Antibody, IgG	29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive
0050470	RNP (U1) (Ribonucleic Protein) (ENA) Antibody, IgG	29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive
0050639	Nuclear Antibody (ANA) by IFA, IgG	Less than 1:40
2012173	Fibrillarin (U3 RNP) Antibody, IgG	Negative
2003040	PM/Scl-100 Antibody, IgG by Immunoblot	Negative
2001601	RNA Polymerase III Antibody, IgG	19 Units or less: Negative 20-39 Units: Weak Positive 40-80 Units: Moderate Positive 81 Units or greater: Strong Positive

Note: Panel includes: Anti-Nuclear Ab (ANA) Titer, Anti-Nuclear Ab (ANA) Pattern, Anti-Scl-70, Anti-RNA Polymerase III Ab, Anti-U1 RNP Ab, Anti-Fibrillarin (U3 RNP), Anti-PM/Scl-100 Ab.

CPT Code(s): 86039, 86235 x4, 83516

HOT LINE NOTE: There is a component change, a result type change, and a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional price information.
Remove 0050714 Centromere Ab, IgG.
Change 2012174 Fibrillarin (U3 RNP) Ab, IgG from numeric to alpha.
Change 2003041 PM/Scl 100 Antibody, IgG from numeric to alpha.

0051428 Tay-Sachs Disease (*HEXA*), 7 Variants — HEXA

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Tue, Fri
Reported: 5-10 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Specimens collected in sodium heparin or lithium heparin tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Interpretive Data:
Background information for Tay-Sachs Disease (*HEXA*), 7 Variants:
Characteristics: Tay-Sachs disease is a lysosomal storage disease that, in the most severe childhood-onset form, leads to a loss of motor skills beginning at 3- to 6-months of age and progresses to blindness, seizures, total incapacitation, and eventual death by 4 years of age. Adult-onset Tay-Sachs is a milder disease with later onset and slower progression. In adults, Tay-Sachs disease is associated with variable neurological findings, including progressive dystonia, spinocerebellar degeneration, motor neuron disease, and bipolar form of psychosis.
Incidence: 1 in 3000 Ashkenazi Jewish individuals.
Inheritance: Autosomal recessive.
Cause: *HEXA* gene pathogenic variants.
Variants Tested: Four pathogenic 7.6kb del, c.1073+1G>A, p.Y427Ifs (c.1274_1277dup TATC) c.1421+1G>C; one mild pathogenic p.G269S (c.805G>A); and two pseudodeficiency alleles p.R247W (c.739C>T) and p.R249W (c.745C>T).
Clinical Sensitivity: 94 percent in Ashkenazi Jewish individuals, 59 percent in other ethnicities.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: *HEXA* variants other than those specified above will not be detected. Diagnostic errors can occur due to rare sequence variations.

See Compliance Statement C: www.aruplab.com/CS

0051589 Toll-Like Receptor Function — TLR

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 performance.**
Specimen Preparation: Transport 10 mL whole blood (patient) **AND** 10 mL whole blood (control) in original collection tubes. (Min: 7 mL (patient) **AND** 7 mL (control)) **Do not refrigerate or freeze. LIVE CELLS REQUIRED.**
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).
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
New York State Clients: Ambient 24 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

New Test **2013890** ***Toxoplasma gondii* Antibody, IgA by ELISA, Serum** **TOXOG IGA**

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay
Performed: Varies
Reported: 3-9 days

Specimen Required: Collect: Plain Red or Serum Separator Tube (SST).
Specimen Preparation: Transfer 3 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen.
Unacceptable Conditions: Grossly hemolyzed, icteric, lipemic and bacterially contaminated specimens.
Stability (collection to initiation of testing): Ambient: Undetermined; Refrigerated: 1 week; Frozen: Indefinitely

Reference Interval: By Report

CPT Code(s): 86777

New York DOH Approved.

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

New Test **2013750** **Usher Syndrome, Types 1F and 3 (*PCDH15* and *CLRN1*), 2 Variants** **USHER**

Additional Technical Information

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Tue, Fri
Reported: 5-10 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Reference Interval: By report

Interpretive Data:
Background Information for Usher Syndrome, Types 1F and 3 (*PCDH15* and *CLRN1*), 2 Variants:
Characteristics: Usher syndrome type 1F is characterized by congenital, bilateral, profound sensorineural hearing loss, adolescent-onset retinitis pigmentosa and loss of vestibular function. Usher syndrome type 3 is characterized by post-lingual, progressive hearing loss, late-onset progressive vision loss due to retinitis pigmentosa and variable loss of vestibular function.
Incidence: In Ashkenazi Jewish individuals - 1 in 20,500 for Usher syndrome type 1F; 1 in 82,000 for Usher syndrome type 3.
Inheritance: Autosomal recessive.
Cause: *PCDH15* and *CLRN1* pathogenic variants.
Variants Tested: *PCDH15* p.R245X (c.733C>T), *CLRN1* p.N48K (c.144T>G).
Clinical Sensitivity: In Ashkenazi Jewish individuals - 62 percent for Usher syndrome, type 1F; 98 percent for Usher syndrome, type 3. Sensitivities unknown in other ethnicities.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Variants other than those tested will not be detected. Diagnostic errors can occur due to rare sequence variations.

See Compliance Statement C: www.aruplab.com/CS

CPT Code(s): 81400

New York DOH approval pending. Call for status update.

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

New Test Available Now **2013508** **Wr(a) Antigen Typing, Patient** **WRA AG**

Methodology: Hemagglutination
Performed: Mon-Fri
Reported: 1-3 days

Specimen Required: Collect: Lavender (EDTA) or Pink (K_2EDTA).
Specimen Preparation: **Do not freeze.** Transport 7 mL whole blood. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Separator tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

CPT Code(s): 86905

New York DOH approval pending. Call for status update.

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

0097908 **Zonisamide** **ZONI**

CPT Code(s): 80203 (Alt code: G0480)

Quarterly HOT LINE: Effective November 14, 2016

The following will be discontinued from ARUP's test menu on November 14, 2016.
Replacement test options are supplied if applicable.

Test Number	Test Name	Refer To Replacement
0055196	Allergen, Epidermals and Animal Proteins, Pigeon Stools IgE	
0051220	*EWSR1-FLI1* and *EWSR1-ERG* Translocations by RT-PCR	*EWSR1* (22q12) Gene Rearrangement by FISH (2007225)
0060847	Herpes Simplex Virus Typing	Herpes Simplex Virus (HSV) Typing (2013897)
0080200	Lecithin-Sphingomyelin Ratio	
2004360	Natural Killer Cell Panel	Natural Killer Cell and Natural Killer T-Cell Panel (2013805)
0040113	*PAX3-FOXO1* and *PAX7-FOXO1* Translocations by RT-PCR	*FOXO1* (*FKHR*) (13q14) Gene Rearrangement by FISH (2001497)
2003243	Septin 9 (*SEPT9*), Methylated DNA Detection by Real-Time PCR	Epi proColon (2013906)
0040114	*SS18-SSX* t(X;18) Translocations by RT-PCR	*SS18* (*SYT*) (18q11) Gene Rearrangement by FISH (2007222)
2007064	*Toxoplasma gondii* Antibody, IgA by ELISA	*Toxoplasma gondii* Ab, IgA, ELISA, Serum (2013890)
0070003	Trypsin-Like Immunoreactivity	