Quarterly HOT LINE: Effective May 18, 2015

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-9 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
6	2011902	Adrenoleukodystrophy, X- Linked (*ABCD1*) Sequencing Available Date 4/20/2015											x	
6	2011880	Adrenoleukodystrophy, X-Linked (*ABCD1*) Deletion/Duplication Available Date 4/20/2015											x	
7	2011906	Adrenoleukodystrophy, X-Linked (*ABCD1*) Sequencing and Deletion/Duplication Available Date 4/20/2015											x	
7	0020008	Alanine Aminotransferase, Serum or Plasma										x		
8	0080137	Amino Acids Quantitative by LC-MS/MS, CSF	x	x			x				x	x		
8	0060347	Antimicrobial Susceptibility, AFB/*Mycobacterium tuberculosis* Primary Panel								x				

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
9	0050317	Anti-Nuclear Antibodies (ANA), IgG by ELISA with Reflexes to ANA, IgG by IFA and to dsDNA, RNP, Smith, SSA 52, SSA 60, and SSB Antibodies, IgG	x				x		x	x	x			
10	2008467	Anti-Nuclear Antibody (ANA), IgG by IFA with Reflex by IFA Pattern					x		x	x	x			
11	2011890	Arginase 1 by Immunohistochemistry Available Date 4/20/2015											x	
11	0025000	Arsenic, Urine with Reflex to Fractionated					x	x						
11	0020007	Aspartate Aminotransferase, Serum or Plasma										x		
12	2011411	Bath Salts Panel, Serum or Plasma							x					
12	0099410	Bismuth, Urine					x	x				x		
12	2002926	*Blastomyces dermatitidis* Antigen EIA				x				x				
12	0060060	Blood Culture, Acid-Fast Bacillus (AFB)								x				
12	0060024	Blood Culture, AFB and Fungal								x				
12	0060070	Blood Culture, Fungal								x				
13	0049003	Blood Smear – with Interpretation											x	
39	2008710	BRAF V600E by Immunohistochemistry												x
14	2012026	Breast and Ovarian Hereditary Cancer Panel, Sequencing and Deletion/Duplication, 20 Genes Available Date 4/20/2015											x	
15	2012002	Bruton Tyrosine Kinase (BTK) Protein Expression by Flow Cytometry Available Date 4/20/2015											x	
39	0091520	Butorphanol, Urine - Screen with Reflex to Confirmation/Quantitation												x
15	2010757	Cancer Panel, Hereditary, Deletion/Duplication, 46 Genes	x						x					
16	2012032	Cancer Panel, Hereditary, Sequencing and Deletion/Duplication, 47 Genes											x	
16	0093399	Circulating Tumor Cell Count			x	x								
16	0020408	Comprehensive Metabolic Panel					x					x		
17	0051668	Connective Tissue Diseases Profile					x			x	x	x		
39	0091485	Cresols, Urine												x
17	0050195	*Cryptococcus* Antigen, CSF							x					
17	0060045	*Cryptosporidium* Antigen by EIA				x			x					
18	0051813	Cytomegalovirus by Quantitative PCR				x					x			
39	0091356	Dantrolene, Serum or Plasma												x
18	0070212	Deoxypyridinoline Crosslinks, Urine					x					x		

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
18	0050757	DNA Extraction and Storage Available Date 4/20/2015											x	
18	0050220	DNase-B Antibody			x									
39	2007785	ERBB2 (*HER2/neu*) (HercepTest) by Immunohistochemistry, Tissue with Reflex to Dual ISH if 2+												x
39	2007410	ERBB2 (HER2/neu) Gene Amplification by Dual in-situ Hybridization												x
39	0050653	Extractable Nuclear Antigen Antibodies (RNP, Smith, Scleroderma, SSA, & SSB)												x
19	0050652	Extractable Nuclear Antigen Antibodies (RNP, Smith, SSA 52, SSA 60, and SSB)	x				x			x	x	x		
19	0050791	Extractable Nuclear Antigen Antibodies (SSA 52, SSA 60, and SSB)	x				x			x	x	x		
19	0091341	Fluoride Quantitative, Serum or Plasma		x	x									
19	2005633	Genomic SNP Microarray, Products of Conception			x									
20	0060048	*Giardia* Antigen by EIA				x								
20	2011925	Glypican 3 by Immunohistochemistry Available Date 4/20/2015											x	
21	0099475	Heavy Metals Panel 3, Urine with Reflex to Arsenic Fractionated					x							
21	0020572	Heavy Metals Panel 4, Urine with Reflex to Arsenic Fractionated					x							
22	0025055	Heavy Metals Panel 6, Urine with Reflex to Arsenic Fractionated					x							
22	0049020	Hemoglobin, Unstable			x									
22	0020416	Hepatic Function Panel					x					x		
23	2012023	Hepatitis E Virus (HEV) Antibodies, IgG and IgM Available Date 4/20/2015											x	
23	2012052	Hereditary Hemolytic Anemia Sequencing, 28 Genes Available Date 4/20/2015											x	
39	0091175	Hippuric Acid, Urine												x
24	2007894	Human Papillomavirus (HPV) Genotypes 16 and 18/45 by Transcription-Mediated Amplification (TMA), ThinPrep												
24	2002896	Human Papillomavirus (HPV) Low Risk by in situ Hybridization, Paraffin				x		x						
24	2002899	Human Papillomavirus (HPV), High Risk by in situ Hybridization, Paraffin				x		x						
24	0020642	Human T-Lymphotropic Virus Types I/II Antibodies, Western Blot				x								

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
39	0091207	Hydroxyzine and Metabolite Quantitative, Serum or Plasma												x
24	0050157	Hypersensitivity Pneumonitis Extended Panel (Farmer's Lung Panel)				x								
24	0050676	Immunoglobulin G, CSF Index				x								
25	2012085	*JAK2* Gene, V617F Mutation, Qualitative with Reflex to *JAK2* Exon 12 Mutation Analysis by PCR Available Date 4/20/2015											x	
25	2012084	*JAK2* Gene, V617F Mutation, Qualitative with Reflex to *CALR* (Calreticulin) Exon 9 Mutation Analysis by PCR with Reflex to *MPL* codon 515 Mutation Detection by Pyrosequencing, Quantitative Available Date 4/20/2015											x	
25	0020843	Kidney Stone Risk Panel, Urine				x								
26	2007935	Lactate to Pyruvate Ratio, Whole Blood	x											
26	0025016	Lead, Industrial Exposure Panel, Adults						x						
27	0025060	Lead, Urine					x	x						
27	0049000	Leukocyte Alkaline Phosphatase				x		x						
27	2005661	Liver Fibrosis, Chronic Viral Hepatitis (Echosens FibroMeter)				x						x		
27	0050119	Lupus Comprehensive Reflexive Panel							x	x	x			
28	2012039	Lysozyme, Serum											x	
39	0050367	Lysozyme, Serum or Body Fluid												x
39	0050368	Lysozyme, Urine												x
28	0098819	Melanocyte Stimulation Hormone, Alpha (a-MSH)				x								
39	0091477	Methylhippuric Acid, Urine												x
28	2011998	MITF by Immunohistochemistry Available Date 4/20/2015											x	
29	2006878	Mitochondrial Disorders (121 Nuclear Genes by Sequencing, 119 Nuclear Genes by Deletion/Duplication)	x						x	x				
29	2006050	Mitochondrial Disorders (121 Nuclear Genes) Sequencing	x						x	x		x		
29	2006061	Mitochondrial Disorders (mtDNA and 119 Nuclear Genes) Deletion/Duplication	x						x	x		x		
30	2006054	Mitochondrial Disorders Panel (mtDNA by Sequencing and Deletion/Duplication, 121 Nuclear Genes by Sequencing, 119 Nuclear Genes by Deletion/Duplication)	x						x	x				
30	2010851	Myositis Antibody Comprehensive Panel					x		x	x	x	x		

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
39	0091486	Nalbuphine, Urine - Screen with Reflex to Confirmation/Quantitation												x
31	0020482	Oxalate, Urine				x			x					
31	2007949	Paliperidone, Serum or Plasma						x						
31	2002528	Pancreatobiliary FISH											x	
39	2002461	Pancreatobiliary FISH												x
32	2012043	Parvovirus B19 by Quantitative PCR Available Date 4/20/2015											x	
32	2009451	Phosphatidylserine and Prothrombin Antibodies, IgG and IgM				x								
39	2004103	*Pneumocystis jiroveci* by Immunohistochemistry												x
32	2010248	Prosigna Breast Cancer Prognostic Gene Signature				x								
32	0070213	Pyridinium Crosslinks (Total), Urine					x					x		
33	2008418	ROS1 by FISH Available Date 4/20/2015											x	
33	2012007	Skeletal Dysplasia Panel, Deletion/Duplication, 35 Genes Available Date 4/20/2015											x	
34	2012015	Skeletal Dysplasia Panel, Sequencing (39 Genes) and Deletion/Duplication (35 Genes) Available Date 4/20/2015											x	
35	2012010	Skeletal Dysplasia Panel, Sequencing (39 Genes) and Deletion/Duplication (35 Genes), Fetal Available Date 4/20/2015											x	
36	2012018	Skeletal Dysplasia Panel, Sequencing, 39 Genes Available Date 4/20/2015											x	
39	0050691	SSA (Ro) (ENA) Antibody, IgG												x
37	2012074	SSA 52 and 60 (Ro) (ENA) Antibodies, IgG											x	
37	0061162	*Streptococcus pneumoniae* Antigen, CSF							x					
38	2012057	Systemic Sclerosis Panel											x	
39	0091534	Tolbutamide, Serum or Plasma												x
38	0060132	Wound Culture and Gram Stain				x								
38	0020462	Zinc, Urine						x						

New Test **2011902** **Adrenoleukodystrophy, X- Linked (*ABCD1*) Sequencing** **ABCD1 FGS**
Available April 20, 2015


Patient History For Adrenoleukodysrophy, X-linked (*ABCD1*) Genetic Testing


Additional Technical Information

Methodology: Polymerase Chain Reaction/Sequencing
Performed: Sun-Sat
Reported: Within 3 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.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data: Refer to Report
See Compliance Statement C: www.aruplab.com /CS

CPT Code(s): 81405

New York DOH approval pending. Call for status update.

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

New Test **2011880** **Adrenoleukodystrophy, X-Linked (*ABCD1*) Deletion/Duplication** **ABCD1 DD**
Available April 20, 2015


Patient History For Adrenoleukodysrophy, X-linked (*ABCD1*) Genetic Testing


Additional Technical Information

Methodology: Multiplex Ligation-dependent Probe Amplification
Performed: Varies
Reported: Within 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.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data: Refer to Report
Counseling and informed consent are recommended for genetic testing. Consent forms are available online at www.aruplab.com.
Refer to Statement C under Testing Information at http://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 **2011906** **Adrenoleukodystrophy, X-Linked (*ABCD1*) Sequencing and Deletion/Duplication** **ABCD1 FGA**

Available April 20, 2015

Patient History For Adrenoleukodysrophy, X-linked (*ABCD1*) Genetic Testing

Additional Technical Information

Methodology: Polymerase Chain Reaction/Sequencing/Multiplex Ligation-dependent Probe Amplification
Performed: Sun-Sat
Reported: 3-4 weeks

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 2 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data: Refer to Report
See Compliance Statement C: www.aruplab.com/CS

CPT Code(s): 81405, 81479

New York DOH approval pending. Call for status update.

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

0020008 **Alanine Aminotransferase, Serum or Plasma** **ALT**

HOT LINE NOTE: There is a unit of measure change associated with this test.
For all clients except the University of Utah Hospital, there is a unit of measure change associated with this test.
Change Unit of measure for component 0020008, Alanine Aminotransferase, from U/L to IU/L

0080137 Amino Acids Quantitative by LC-MS/MS, CSF — CSFAA QNT

Methodology: Quantitative Liquid Chromatography/Tandem Mass Spectrometry

Reference Interval:
Effective May 18, 2015

Components	Reference Interval
α-Aminoadipic acid	0.0 - 2.0 µmol/L
α-Amino-n-butyric acid	0.0 - 6.5 µmol/L
Alanine	12.5 - 47.3 µmol/L
Alloisoleucine	0.0 - 2.0 µmol/L
Anserine	0.0 - 7.0 µmol/L
Arginine	5.9 - 30.6 µmol/L
Argininosuccinic acid	0.0 - 2.0 µmol/L
Asparagine	0.0 - 23.6 µmol/L
Aspartic acid	0.0 - 5.8 µmol/L
β-Alanine	2.7 - 21.7 µmol/L
β-Aminoisobutyric acid	0.0 - 2.0 µmol/L
Citrulline	0.0 - 5.6 µmol/L
Cystathionine	0.0 - 3.0 µmol/L
Cystine	0.0 - 5.0 µmol/L
Ethanolamine	3.8 - 29.0 µmol/L
γ-Amino-n-butyric acid	0.0 - 2.0 µmol/L
Glutamic acid	0.0 - 15.0 µmol/L
Glutamine	230.7 - 637.4 µmol/L
Glycine	3.1 - 21.0 µmol/L
Histidine	5.0 - 24.0 µmol/L
Homocitrulline	0.0 - 4.0 µmol/L
Homocystine	0.0 - 2.0 µmol/L
Hydroxylysine	0.0 - 5.0 µmol/L
Hydroxyproline	0.0 - 8.0 µmol/L
Isoleucine	1.0 - 11.0 µmol/L
Leucine	3.4 - 25.9 µmol/L
Lysine	7.8 - 40.8 µmol/L
Methionine	0.0 - 10.0 µmol/L
Ornithine	2.0 - 12.0 µmol/L
Phenylalanine	6.9 - 25.1 µmol/L
Proline	0.0 - 8.0 µmol/L
Sarcosine	0.0 - 2.0 µmol/L
Serine	18.0 - 73.0 µmol/L
Taurine	2.7 - 16.2 µmol/L
Threonine	10.0 - 60.0 µmol/L
Tryptophan	0.0 - 6.0 µmol/L
Tyrosine	5.4 - 23.7 µmol/L
Valine	7.0 - 37.1 µmol/L

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

Add component 2011976, Homocitrulline, CSF
Add component 2011988, Anserine, CSF
Add component 2011977, Hydroxylysine, CSF
Add component 2011986, Allo-isoleucine, CSF
Add component 2011983, Sarcosine, CSF
Add component 2011994, Gamma-amino butyric acid, CSF
Add component 2011985, Alpha-amino butyric acid, CSF
Add component 2011984, Tryptophan, CSF
Add component 2011989, Argininosuccinic Acid, CSF
Add component 2011992, Cystathionine, CSF
Add component 2011993, Ethanolamine, CSF
Add component 2011990, Beta-alanine, CSF
Add component 2011991, Beta-amino isobutyric acid, CSF
Add component 2011987, Alpha-aminoadipic acid, CSF
Change the charting name of component 0080142 from Aspartate, CSF to Aspartic Acid, CSF

0060347 Antimicrobial Susceptibility, AFB/*Mycobacterium tuberculosis* Primary Panel — MA MTBPRIM

CPT Code(s): 87188 x4. CPT codes vary based on method.

0050317 **Anti-Nuclear Antibodies (ANA), IgG by ELISA with Reflexes to ANA, IgG by IFA and to dsDNA, RNP, Smith, SSA 52, SSA 60, and SSB Antibodies, IgG** **ANA REF**

Reference Interval:
Effective May 18, 2015

Test Number	Components	Reference Interval	
	Anti-Nuclear Antibodies (ANA), IgG by ELISA	None Detected	
0050639	Nuclear Antibody (ANA) by IFA, IgG	Effective May 18, 2015 Less than 1:40	
	Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA	None Detected	
2002693	Double-Stranded DNA (dsDNA) Antibody, IgG by IFA (using *Crithidia luciliae*)	Less than 1:10	
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	

Note: ANA are not specific for systemic lupus erythematosus (SLE) but are found in a variety of rheumatic or connective tissue diseases. When cell culture substrates (HEp-2 cells) are used, the ANA incidence is greater than 90 percent in systemic lupus erythematosus (SLE), 80 percent in Sjögren syndrome and scleroderma, and 40 percent in juvenile idiopathic arthritis.

ARUP uses anti-human IgG-specific conjugate since many (20-77 percent) normal individuals have low levels (1:10 to 1:80) of ANA-IgM. Conversion of ANAs from IgM to IgG generally precedes the onset of autoimmune disease states. If clinical presentation is inconsistent with the ANA IFA result, consult ARUP for alternative testing.

Specimens are screened for ANA using ELISA. If ANA IgG is detected by ELISA, then ANA IgG by IFA (using HEp-2 substrate) will be added. If ANA, IgG by IFA is confirmed positive with a titer of 1:40 or greater, then a titer and pattern will be reported. In addition, samples positive for ANA, IgG by IFA will reflex to Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA, RNP (U1) (Ribonucleic Protein) (ENA) Antibody, IgG, Smith (ENA) Antibody, IgG, SSA 52 and 60 (Ro) (ENA) Antibodies, IgG, and SSB (La) (ENA) Antibody, IgG. If Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA is detected, then Double-Stranded DNA (dsDNA) Antibody, IgG by IFA (using *Crithidia luciliae*) will be added. Additional charges apply.

CPT Code(s): 86038; if reflexed, add 86039; if reflexed, add 86235 x5 and 86225; if reflexed, add 86256

HOT LINE NOTE: There is a component change associated with this test:
Change the charting name of component 0050691 from SSA (Ro) (ENA) Antibody, IgG to SSA 52 (R0) (ENA) Antibody, IgG
Add component 2012055 SSA 60 (Ro) (ENA) Antibody, IgG

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

Reference Interval:
Effective May 18, 2015

Test Number	Components	Reference Interval
0050639	Nuclear Antibody (ANA) by IFA, IgG	Effective May 18, 2015 Less than 1:40
	Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA	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: Moderate 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
0050470	RNP (U1) (Ribonucleic Protein) (ENA) Antibody, IgG	Effective May 18, 2015 29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive
0050085	Smith (ENA) Antibody, IgG	Effective May 18, 2015 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	Effective May 18, 2015 29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive
0050599	Scleroderma (Scl-70) (ENA) Antibody, IgG	Effective May 18, 2015 29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive

Note: The Anti-Nuclear Antibody (ANA), IgG by IFA with Reflex by IFA Pattern begins with Nuclear Antibody (ANA) by IFA, IgG. Depending on findings, one or more reflexive tests may be required. Tests added may include Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA; Double-Stranded DNA (dsDNA) Antibody, IgG by IFA (using *Crithidiae luciliae*); Chromatin Antibody, IgG; RNP (U1) (Ribonucleic Protein) (ENA) Antibody, IgG; Smith (ENA) Antibody, IgG; SSA 52 (Ro) (ENA) Antibody, IgG; SSA 60 (Ro) (ENA) Antibody, IgG; SSB (La) (ENA) Antibody, IgG; Scleroderma (Scl-70) (ENA) Antibody, IgG; PM/Scl-100 Antibody, IgG, by Immunoblot; and/or RNA Polymerase III Antibody, IgG. Additional charges apply.

CPT Code(s): 86039; if homogenous pattern add 86225 and 83516; if reflexed add 86256; if speckled pattern add 86235 x6. If nucleolar pattern add 86235 x2 and 83516.

HOT LINE NOTE: There is a clinically significant charting name change and a component change associated with this test:
Change the charting name of component 0050691 from SSA (Ro) (ENA) Antibody, IgG to SSA 52 (R0) (ENA) Antibody, IgG
Remove reflex confirmation 0050653, Extractable Nuclear Antigen Antibodies (RNP, Smith, Scleroderma, SSA &SSB)
Depending on findings one of the following confirmation orders will be added:

Reflex component 0050470 RNP (UI) (Ribonucleic Protein) (ENA) Antibody, IgG
Reflex component 0050085 Smith (ENA) Antibody, IgG
Reflex component 0050692 SSB (La) (ENA) Antibody, IgG
Reflex component 0050599 Scleroderma (Scl-70) (ENA) Antibody, IgG
Reflex component 2012055 SSA 60 (Ro) (ENA) Antibody, IgG

New Test 2011890 Arginase 1 by Immunohistochemistry ARG1 IHC

Available April 20, 2015

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

Specimen Required: Collect: Tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (recommended but not required), (ARUP supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 2 slides) If sending precut slides, do not oven bake.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Unacceptable Conditions: Specimens submitted with non-representative tissue type. Depleted specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely, Refrigerated: Indefinitely, Frozen: Unacceptable

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

Note: This test code is handled as "Stain and Return." To request a consultation, submit the pathology report, all associated case materials (clinical history, blocks, slides, etc.) with an Anatomic Pathology requisition form (form #32960) in place of the Immunohistochemistry form.

CPT Code(s): 88342

New York DOH Approved.

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

0025000 Arsenic, Urine with Reflex to Fractionated ARS U

Reference Interval:

Test Number	Components	Reference Interval		
	Arsenic, Urine	0-35.0 µg/L (based on Biological Exposure Index)		
	Arsenic, Urine (24-hour)	0-50.0 µg/d		
	Arsenic per gram of creatinine	Effective May 18, 2015 Less than 30 ug/gCRT		
0020734	Arsenic, Fractionated, Urine	**Components**		**Reference Interval**
		As Organic		Refer to report
		Arsenic Total Inorganic		Refer to report
		Arsenic, Methylated		Refer to report
	Creatinine, Urine - per 24h	**Age**	**Male**	**Female**
		3-8 years	140-700 mg/d	140-700 mg/d
		9-12 years	300-1300 mg/d	300-1300 mg/d
		13-17 years	500-2300 mg/d	400-1600 mg/d
		18-50 years	1000-2500 mg/d	700-1600 mg/d
		51-80 years	800-2100 mg/d	500-1400 mg/d
		81 years and older	600-2000 mg/d	400-1300 mg/d

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 between 35-2000 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.

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

0020007 Aspartate Aminotransferase, Serum or Plasma AST

HOT LINE NOTE: There is a unit of measure change associated with this test.
For all clients except the University of Utah Hospital, there is a unit of measure change associated with this test.
Change Unit of measure for component 0020007, Aspartate Aminotransferase, from U/L to IU/L

Change Unit of measure for component 0020008, Alanine Aminotransferase, from U/L to IU/L

2011411 Bath Salts Panel, Serum or Plasma — BATHSLT SP

Note: Test includes: Mephedrone (1,3-dimethylamylamine; Methylhexaneamine); MDPV(1-(1,3-benzodioxol-5-yl)-2-pyrrolidin-1-ylpentan-1-one; MDPK; Methylenedioxypyrovalerone); Methylone (3,4-methylenedioxy-N-methylcathinone; bk-MDMA); Methoxetamine (2-MeO-Oxo-PC; MXE); Pentedrone ((RS)-1-phenyl-2-(methylamino)pentan-1-one); alpha-PVP ((RS)-1-phenyl-2-(1-pyrrolidinyl)-1-pentanone; alpha-Pyrrolidinovalerophenone)

0099410 Bismuth, Urine — BS U

Reference Interval:

Test Number	Components	Reference Interval		
	Bismuth, Urine - per volume	0.0-2.0 µg/L		
	Bismuth, Urine - per 24h	0.0-3.0 µg/d		
	Creatinine, Urine - per 24h	**Age**	**Male**	**Female**
		3-8 years	140-700 mg/d	140-700 mg/d
		9-12 years	300-1300 mg/d	300-1300 mg/d
		13-17 years	500-2300 mg/d	400-1600 mg/d
		18-50 years	1000-2500 mg/d	700-1600 mg/d
		51-80 years	800-2100 mg/d	500-1400 mg/d
		81 years and older	600-2000 mg/d	400-1300 mg/d
	Bismuth, Urine - ratio to CRT	No reference interval (µg/g crt)		

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

HOT LINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name of component 0025056, Bismuth, Urine ug/gCRT to Bismuth, Urine ratio to CRT
Change the charting name of component 0025078, Bismuth, Urine ug/g to Bismuth, Urine per 24 hr
Change the charting name of component 009982, Bismuth, Urine ug/L to Bismuth, Urine per volume

2002926 *Blastomyces dermatitidis* Antigen EIA — BLAST DERM

Specimen Required: Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 2 weeks; Frozen: Indefinitely

CPT Code(s): 87449

0060060 Blood Culture, Acid-Fast Bacillus (AFB) — MC BAFB

CPT Code(s): 87116. CPT codes vary based on method.

0060024 Blood Culture, AFB and Fungal — MC BLDAF

CPT Code(s): 87103; 87116. CPT codes vary based on method

0060070 Blood Culture, Fungal — MC BFUNG

CPT Code(s): 87103. CPT codes vary based on method.

New Test **0049003** **Blood Smear – with Interpretation** **SMR INTERP**

Methodology: Cytochemical Stain
Performed: Mon-Fri
Reported: 1-2 days

Specimen Required: Collect: Whole blood. Invert tube several times immediately following procurement of blood, at time of collection.
Specimen Preparation: Transport 5 mL whole blood (Min: 0.1 mL) and 6 unfixed push smears. (Min: 2 unfixed push smears)
Storage/Transport Temperature: Room temperature.
Remarks: **Most recent CBC report, patient history, clinical indications and physician's name and telephone number are required.**
Further information on how to make an adequate slide, in the form of an instructional video, can be found at:
<https://www.youtube.com/watch?v=ca3NwrlpS40&feature=youtu.be>
Stability (collection to initiation of testing): **Whole Blood:** Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Unacceptable **Unfixed Push Smears:** Ambient: 5 days; Refrigerated: 5 days; Frozen: Unacceptable

Interpretive Data: Refer to report.

CPT Code(s): 85060

New York DOH approval pending. Call for status update.

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

New Test **2012026** **Breast and Ovarian Hereditary Cancer Panel, Sequencing and Deletion/Duplication, 20 Genes** **BOCAPAN**

Available April 20, 2015

 Patient History for Hereditary Breast and Ovarian Cancer

 Additional Technical Information

Methodology: Massive Parallel Sequencing/Exonic Oligonucleotide-based CGH Microarray
Performed: Varies
Reported: 10-12 weeks

Specimen Required: Collect: Lavender (EDTA) or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 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

Interpretive Data: Refer to report.

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

Note: Genes tested by Sequencing: *ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2* common mutations, *MEN1,MLH1, MSH2, MSH6, MUTYH, NBN, PALB2, PTEN, RAD51C, RAD51D, STK11, TP53*

Genes tested by Deletion/Duplication: *ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2* common mutations, *EPCAM* deletions only, *MEN1,MLH1, MSH2, MSH6, MUTYH, NBN, PALB2, PTEN, RAD51C, RAD51D, STK11, TP53*

CPT Code(s): 81211, 81292, 81294, 81295, 81297, 81298, 81300, 81321, 81323, 81403 (*EPCAM*), 81404 x2 (*MEN1, STK11*), 81405 x3(*MEN1, STK11, TP53*), 81406 x3 (*CDH1, MUTYH, PALB2)*, 81408 (ATM), 81479 x2

New York DOH approval pending. Call for status update.

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

New Test 2012002 **Bruton Tyrosine Kinase (BTK) Protein Expression by Flow Cytometry** **BTK FLOW**

Available April 20, 2015

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

Specimen Required: Collect: Green (sodium or lithium heparin).
Specimen Preparation: Transport 4 mL whole blood. (Min: 0.5 mL)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated.
Remarks: Specimen must be analyzed within 72 hours of collection.
Unacceptable Conditions: Clotted or hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 72 hours; Frozen: Unacceptable

Reference Interval: Normal

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

CPT Code(s): 86356 x3

New York DOH approval pending. Call for status update.

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

2010757 **Cancer Panel, Hereditary, Deletion/Duplication, 46 Genes** **CANCER DD**

Note: Genes tested by Deletion/Duplication: *ALK, APC, ATM, BAP1, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN1B, CDKN2A, CHEK2* common mutations, *EPCAM* deletion only, *FH, FLCN, MAX, MEN1, MET, MLH1, MSH2, MSH6, MUTYH, NBN, NF2, PALB2, PHOX2B, PTEN, RAD51C, RAD51D, RB1, RET, SDHAF2, SDHB, SDHC, SDHD, SMAD4, SMARCB1,STK11, SUFU, TMEM127, TSC1, TSC2, TP53, VHL*

New Test **2012032** **Cancer Panel, Hereditary, Sequencing and Deletion/Duplication, 47 Genes** **CANCERPAN**

 Patient History For Hereditary Cancer

 Additional Technical Information

Methodology: Massive Parallel Sequencing/Exonic Oligonucleotide-based CGH Microarray
Performed: Varies
Reported: 10-12 weeks

Specimen Required: Collect: Lavender (EDTA) or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 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

Interpretive Data: Refer to report.
See Compliance Statement C: www.aruplab.com/CS

Note: Genes tested by Sequencing: *ALK, APC, ATM, BAP1, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN1B, CDKN2A, CHEK2* common mutations, *FH, FLCN, MAX, MEN1, MET, MLH1, MSH2, MSH6, MUTYH, NBN, NF2, PALB2, PHOX2B, PMS2, PTEN, RAD51C, RAD51D, RB1, RET, SDHAF2, SDHB, SDHC, SDHD, SMAD4, SMARCB1,STK11, SUFU, TMEM127, TSC1, TSC2, TP53, VHL*

Genes tested by Deletion/Duplication: *ALK, APC, ATM, BAP1, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN1B, CDKN2A, CHEK2* common mutations, *EPCAM* deletion only, *FH, FLCN, MAX, MEN1, MET, MLH1, MSH2, MSH6, MUTYH, NBN, NF2, PALB2, PHOX2B, PMS2, PTEN, RAD51C, RAD51D, RB1, RET, SDHAF2, SDHB, SDHC, SDHD, SMAD4, SMARCB1,STK11, SUFU, TMEM127, TSC1, TSC2, TP53, VHL*

CPT Code(s): 81201, 81203, 81211, 81292, 81294, 81295, 81297, 81298, 81300, 81317, 81319, 81321, 81323, 81403 x3 (*EPCAM, PHOX2B, VHL*), 81404 x7 (*CDKN2A, MEN1, PHOX2B, SDHC, SDHD, STK11, VHL*), 81405 x9 (*FH, MEN1, NF2, SDHB, SDHC, SMAD4, STK11, TP53, TSC1*), 81406 x8 (*CDH1, MUTYH, NF2, PALB2, RET, SMAD4, TSC1, TSC2)*, 81407 (*TSC2*), 81408 (*ATM*), 81479 x2

New York DOH approval pending. Call for status update.

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

0093399 **Circulating Tumor Cell Count** **CTC COUNT**

Performed: Sun-Sat
Reported: 1-5 days

Specimen Required: Remarks: REQUIRED ORDER INFORMATION: Source of metastatic cancer. This assay is FDA approved only for breast, colorectal, or prostate metastatic cancers; other types will not be tested.

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

Reference Interval: By report (reference interval may vary based on instrumentation).

HOT LINE NOTE: There is a unit of measure change associated with this test.
For all clients except the University of Utah Hospital, there is a unit of measure change associated with this test.
Change Unit of measure for component 0020007, Aspartate Aminotransferase, from U/L to IU/L
Change Unit of measure for component 0020008, Alanine Aminotransferase, from U/L to IU/L

0051668 Connective Tissue Diseases Profile CONN

Reference Interval:
Effective May 18, 2015

Test Number	Components	Reference Interval	
0050085	Smith (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	
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	
0099592	Jo-1 Antibody, IgG	29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive	
0099249	Ribosomal P Protein Antibody	29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive	
0050714	Centromere Antibody, IgG	29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: 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	

CPT Code(s): 86235 x7; 83516 x2

HOT LINE NOTE: There is a clinically significant charting name change and a component change associated with this test:
Change the charting name of component 0050691 from SSA (Ro) (ENA) Antibody, IgG to SSA 52 (R0) (ENA) Antibody, IgG
Add component 2012055 SSA 60 (Ro) (ENA) Antibody, IgG

0050195 *Cryptococcus* Antigen, CSF CRY CSF

Note: A titer is performed on all positive specimens. Titer results are reported to the client.
The College of American Pathologists (CAP) requires that Cryptococcal antigen detection testing performed on CSF specimens be confirmed by culture (CAP MIC.42005). When Cryptococcal antigen detection is ordered on CSF specimens by the University of Utah Hospital, Huntsman Cancer Hospital, or the VA Hospital of Salt Lake City, a CSF culture will be ordered automatically (see ARUP Test Code 0060106 for submission requirements). All other specimens will be processed with the assumption that a culture was performed before sending to ARUP unless a specific request for culture is included with the test order. Additional charges apply.

0060045 *Cryptosporidium* Antigen by EIA CRYSPOR

Specimen Required: Specimen Preparation: Transport 5 g stool in unpreserved stool transport vial (ARUP Supply #40910) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 1 g) Preserving in 10 percent formalin (within 1 hour of collection) is also acceptable.
Storage/Transport Temperature: Unpreserved: Frozen.
Preserved: Room temperature.
Stability (collection to initiation of testing): Unpreserved: Ambient: 2 hours; Refrigerated: 24 hours; Frozen: 1 week
Preserved: Ambient: 9 months; Refrigerated: 9 months; Frozen: Unacceptable

Note: This immunoassay is not a substitute for comprehensive testing. Refer to Ova & Parasite Exam, Fecal (Immunocompromised or Travel History) (ARUP test code 2002272).

0051813 Cytomegalovirus by Quantitative PCR — CMV QNT

Specimen Required: Collect: Lavender (EDTA) or pink (K_2EDTA), Bronchoalveolar lavage (BAL).
Specimen Preparation: Separate plasma from cells. Transfer 1 mL plasma or BAL to a sterile container (Min: 0.5 mL). Transport 1 mL whole blood (Min: 0.5 mL).
Storage/Transport Temperature: **Whole blood**: Refrigerated. **All others**: Frozen.
Stability (collection to initiation of testing): **Plasma:** Ambient: 24 hours; Refrigerated: 5 days; Frozen: 1 year
Whole blood: Ambient: 7 days; Refrigerated: 7 days; Frozen: Unacceptable
BAL: Ambient: 24 hours; Refrigerated: 5 days; Frozen: 3 months

HOT LINE NOTE: There is a component change associated with this test:
Add component 2012051, Cytomegalovirus Quant by PCR, Source
Change the charting name of component 2002316 from Cytomegalovirus, Quant. Cpy/mL to Cytomegalovirus Quant by PCR, Cpy/mL
Change the charting name of component 0051815 from Cytomegalovirus, Quant. Log cpy/mL to Cytomegalovirus Quant by PCR, Log Cpy/mL
Change the charting name of component 2006534 from Cytomegalovirus, Quant. IU/mL to Cytomegalovirus Quant by PCR, IU/mL
Change the charting name of component 2006535 from Cytomegalovirus, Quant. Log IU/mL to Cytomegalovirus Quant by PCR, Log IU/mL
Change the charting name of component 0051814 from Cytomegalovirus, Quant. Interp to Cytomegalovirus Quant by PCR, Interp

0070212 Deoxypyridinoline Crosslinks, Urine — DPD

Reference Interval:
Effective May 18, 2015

Test Number	Components	Reference Interval
	Deoxypyridinoline, Urine nM - ratio to CRT	Adult Male: 2.3-8.7 nmol/mmol Premenopausal Adult Female: 3.1-8.7 nmol/mmol
	Creatinine, Urine - per volume	No reference interval

HOT LINE NOTE: There is a unit of measure change and a clinically significant charting name change associated with this test
Change the charting name of component 0070224 from Deoxypyridinoline, Urine Calculation to Deoxypyridinoline, Urine – ratio to CRT
Change unit of measure for component 0070224, Deoxypyridinoline, Urine Calculation (Deoxypyridinoline, Urine – ratio to CRT), from nM/mM to nmol/mmol

New Test 0050757 DNA Extraction and Storage — DNA EXT

Available April 20, 2015

Methodology: Extraction
Performed: Sun-Sat
Reported: 1-7 days

Specimen Required: Collect: Lavender (EDTA) **OR** bone marrow (EDTA).
Specimen Preparation: Do not freeze. Transport 5 mL whole blood. (Min: 1 mL) **OR** Transport 3 mL bone marrow. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Remarks: DNA will be held for 2 months for possible add-on testing.
Stability (collection to initiation of testing): Ambient: 1 day; Refrigerated: 5 days; Frozen: Unacceptable

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.

0050220 DNase-B Antibody — DNSB

Performed: Sun, Wed, Fri
Reported: 1-4 days

0050652 Extractable Nuclear Antigen Antibodies (RNP, Smith, SSA 52, SSA 60, and SSB) ENA ABS4

Reference Interval:
Effective May 18, 2015

Test Number	Components	Reference Interval	
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	

CPT Code(s): 86235 x5

HOT LINE NOTE: There is a clinically significant charting name change and a component change associated with this test
Add component 2012055 SSA 60 (Ro) (ENA) Antibody, IgG
Change charting name of component 0050691 from SSA (Ro) (ENA) Antibody, IgG to SSA 52 (Ro) (ENA) Antibody IgG

0050791 Extractable Nuclear Antigen Antibodies (SSA 52, SSA 60, and SSB) SSA/SSB

Reference Interval:
Effective May 18, 2015

Test Number	Components	Reference Interval	
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	

CPT Code(s): 86235 x3

HOT LINE NOTE: There is a clinically significant charting name change and a component change associated with this test
Add component 2012055 SSA 60 (Ro) (ENA) Antibody, IgG
Change charting name of component 0050691 from SSA (Ro) (ENA) Antibody, IgG to SSA 52 (Ro) (ENA) Antibody IgG

0091341 Fluoride Quantitative, Serum or Plasma FLUORIDE

Methodology: Quantitative Ion Chromatography
Performed: Varies
Reported: 3-10 days

2005633 Genomic SNP Microarray, Products of Conception ARRAY POC

Performed: Sun-Sat
Reported: 2-3 weeks (Results requiring the completion of FISH testing may exceed the standard TAT)

0060048 ***Giardia* Antigen by EIA** **GLAM**

Specimen Required: Specimen Preparation: Transport 5 g stool in unpreserved stool transport vial (ARUP Supply #40910) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 1 g) Preserving in 10 percent formalin (within 1 hour of collection) is also acceptable.
Storage/Transport Temperature: Unpreserved: Frozen.
Preserved: Room temperature.
Stability (collection to initiation of testing): Unpreserved: Ambient: 2 hours; Refrigerated: 24 hours; Frozen: 1 week
Preserved: Ambient: 9 months; Refrigerated: 9 months; Frozen: Unacceptable

New Test **2011925** **Glypican 3 by Immunohistochemistry** **GLYP3 IHC**
Available April 20, 2015

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

Specimen Required: Collect: Tissue
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (recommended but not required), (ARUP supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 2 slides). If sending precut slides, do not oven bake.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Unacceptable Conditions: Specimens submitted with non-representative tissue type. Depleted specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely, Refrigerated: Indefinitely, Frozen: Unacceptable

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

Note: This test code is handled as "Stain and Return." To request a consultation, submit the pathology report, all associated case materials (clinical history, blocks, slides, etc.) with an Anatomic Pathology requisition form (form #32960) in place of the Immunohistochemistry form.

CPT Code(s): 88342

New York DOH Approved.

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

0099475 Heavy Metals Panel 3, Urine with Reflex to Arsenic Fractionated HY MET U

Reference Interval:
Effective May 18, 2015

Test Number	Components	Reference Interval		
	Arsenic, Urine	0-35.0 µg/L (based on Biological Exposure Index)		
	Arsenic, Urine (24-hour)	0-50.0 µg/d		
	Arsenic per gram of creatinine	Less than 30 ug/gCRT		
0020734	Arsenic, Fractionated, Urine	**Components**	**Reference Interval**	
		As Organic	Refer to report	
		Arsenic Total Inorganic	Refer to report	
		Arsenic, Methylated	Refer to report	
	Lead, Urine	0-23 µg/L		
	Lead, Urine (24-hour)	0-31 µg/d		
	Lead per gram of creatinine	Less than 5 ug/gCRT		
	Mercury, Urine - per 24h	0-15 µg/d		
	Mercury, Urine - per volume	0-10 µg/L		
	Mercury, Urine - ratio to CRT	Less than or equal to 35 µg/gCRT		
	Creatinine, 24-Hour Urine	**Age**	**Male**	**Female**
		3-8 years	140-700 mg/d	140-700 mg/d
		9-12 years	300-1300 mg/d	300-1300 mg/d
		13-17 years	500-2300 mg/d	400-1600 mg/d
		18-50 years	1000-2500 mg/d	700-1600 mg/d
		51-80 years	800-2100 mg/d	500-1400 mg/d
		81 years and older	600-2000 mg/d	400-1300 mg/d

0020572 Heavy Metals Panel 4, Urine with Reflex to Arsenic Fractionated HY MET U4

Reference Interval:
Effective May 18, 2015

Test Number	Components	Reference Interval		
	Arsenic, Urine	0-35.0 µg/L (based on Biological Exposure Index)		
	Arsenic, Urine (24-hour)	0-50.0 µg/d		
	Arsenic per gram of creatinine	Less than 30 ug/gCRT		
0020734	Arsenic, Fractionated, Urine	**Components**	**Reference Interval**	
		As Organic	Refer to report	
		Arsenic Total Inorganic	Refer to report	
		Arsenic, Methylated	Refer to report	
	Lead per gram of creatinine	Less than 5 ug/gCRT		
	Lead, Urine	0-23 µg/L		
	Lead, Urine (24-hour)	0-31 µg/d		
	Mercury, Urine - per 24h	0-15 µg/d		
	Mercury, Urine - per volume	0-10 µg/L		
	Mercury, Urine - ratio to CRT	Less than or equal to 35 µg/gCRT		
	Creatinine, Urine - per 24h	**Age**	**Male**	**Female**
		3-8 years	140-700 mg/d	140-700 mg/d
		9-12 years	300-1300 mg/d	300-1300 mg/d
		13-17 years	500-2300 mg/d	400-1600 mg/d
		18-50 years	1000-2500 mg/d	700-1600 mg/d
		51-80 years	800-2100 mg/d	500-1400 mg/d
		81 years and older	600-2000 mg/d	400-1300 mg/d
0025040	Cadmium, Urine	**Components**	**Reference Interval**	
		Cadmium, Urine - per volume	Refer to report	
		Cadmium, Urine - per 24h	Refer to report	
		Cadmium, Urine - ratio to CRT	Refer to report	
		Creatinine, Urine - per 24h	Refer to report	

0025055 Heavy Metals Panel 6, Urine with Reflex to Arsenic Fractionated — HYMET 6

Reference Interval:
Effective May 18, 2015

Test Number	Components	Reference Interval	
	Arsenic, Urine	0-35.0 µg/L (based on Biological Exposure Index)	
	Arsenic, Urine (24-hour)	0-50.0 µg/d	
	Arsenic per gram of creatinine	Less than 30 ug/gCRT	
0020734	Arsenic, Fractionated, Urine	**Components**	**Reference Interval**
		As Organic	Refer to report
		Arsenic Total Inorganic	Refer to report
		Arsenic, Methylated	Refer to report
	Cadmium, Urine - per volume	0.0-2.6 µg/L	
	Cadmium, Urine - per 24h	0.0-3.3 µg/d	
	Cadmium, Urine - ratio to CRT	0.0-3.0 µg/g crt	
	Copper, Urine	0.2-8.0 µg/dL	
	Copper, Urine (24-hour)	3-50 µg/d	
	Copper per gram of creatinine	No reference interval (µg/g crt)	
	Lead, Urine	0-23 µg/L	
	Lead, Urine (24-hour)	0-31 µg/d	
	Lead per gram of creatinine	Less than 5 ug/gCRT	
	Mercury, Urine - per 24h	0-15 µg/d	
	Mercury, Urine - per volume	0-10 µg/L	
	Mercury, Urine - ratio to CRT	Less than or equal to 35 µg/gCRT	
	Zinc, Urine	15-120 µg/dL	
	Zinc, Urine (24-hour)	150-1200 µg/d	
	Zinc per gram of creatinine	No reference interval (µg/g crt)	
	Creatinine, Urine - per volume	No reference interval	
	Creatinine, Urine - per 24h	**Age**	**Male** / **Female**
		3-8 years	140-700 mg/d / 140-700 mg/d
		9-12 years	300-1300 mg/d / 300-1300 mg/d
		13-17 years	500-2300 mg/d / 400-1600 mg/d
		18-50 years	1000-2500 mg/d / 700-1600 mg/d
		51-80 years	800-2100 mg/d / 500-1400 mg/d
		81 years and older	600-2000 mg/d / 400-1300 mg/d

0049020 Hemoglobin, Unstable — HGB UNSTAB

Performed: Mon-Fri
Reported: 1-5 days

0020416 Hepatic Function Panel — HEPATIC

Reference Interval: Reference intervals may vary based on instrumentation

Test Number	Components	Reference Interval
0020033	Bilirubin, Direct, Serum or Plasma	By report.
0020032	Bilirubin, Total, Serum or Plasma	By report.

HOT LINE NOTE: There is a unit of measure change associated with this test.
For all clients except the University of Utah Hospital, there is a unit of measure change associated with this test.
Change Unit of measure for component 0020007, Aspartate Aminotransferase, from U/L to IU/L
Change Unit of measure for component 0020008, Alanine Aminotransferase, from U/L to IU/L

New Test **2012023** **Hepatitis E Virus (HEV) Antibodies, IgG and IgM** **HEV PAN**
Available April 20, 2015

Methodology: Qualitative Enzyme-Linked Immunosorbent Assay
Performed: Tue, Sat
Reported: 1-8 days

Specimen Required: Collect: Serum separator tube (SST). Also acceptable: lavender (K_2 EDTA), lavender (K_3 EDTA), or pink (K_2EDTA).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 0.5 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.3 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Specimens containing particulate material.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 2 weeks; Frozen: Indefinitely (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Code	Component	Reference Interval
2010151	Hepatitis E Virus Antibody, IgG	Negative
2010156	Hepatitis E Virus Antibody, IgM	Negative

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

CPT Code(s): 86790 x2

New York DOH Approved.

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

New Test **2012052** **Hereditary Hemolytic Anemia Sequencing, 28 Genes** **HHA SEQ**
Available April 20, 2015

 Patient History For Hereditary Hemolytic Anemia  Additional Technical Information

Methodology: Massive Parallel Sequencing
Performed: Varies
Reported: 6-8 weeks

Specimen Required: Collect: Lavender (EDTA) or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 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

Interpretive Data: Refer to report.
See Compliance Statement C: www.aruplab.com/CS

Note: Genes tested: *ADA, AK1, ALDOA, ANK1, CYB5R3, EPB41, EPB42, G6PD, GCLC, GP1, GSR, GSS, HK1, NT5C3A, PFKL, PGK1,PFKM, PIEZO1, PKLR, SLC4A1, SLCO1B1, SLCO1B3, SPTA1, SPTB, TPI1, UGT1A1, UGT1A6, UGT1A7*

CPT Code(s): 81400 (*SLCO1B1*), 81479

New York DOH approval pending. Call for status update.

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

2007894 **Human Papillomavirus (HPV) Genotypes 16 and 18/45 by Transcription-Mediated Amplification (TMA), ThinPrep** **HPVGENOTMA**

HOT LINE NOTE: There is a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.

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

Specimen Required: Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Transport tissue block or 5 unstained positively charged, 5-micron slides in a tissue transport kit (recommended but not required) (ARUP supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 4 slides) Protect paraffin block and/or slides from excessive heat.

Interpretive Data: Refer to report.

2002899 **Human Papillomavirus (HPV), High Risk by in situ Hybridization, Paraffin** **HPVHI ISH**

Specimen Required: Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin-embed tissue. Transport tissue block or 5 unstained 5-micron slides in a tissue transport kit (recommended but not required) (ARUP supply #47808). Available online through eSupply using ARUP ConnectTM or contact ARUP Client Services at (800) 522-2787. (Min: 4 slides) Protect paraffin block and/or slides from excessive heat.

Interpretive Data: Refer to report

0020642 **Human T-Lymphotropic Virus Types I/II Antibodies, Western Blot** **HTLV WBLOT**

Specimen Required: Collect: Serum separator tube. Also acceptable: lavender (K_2 EDTA), lavender (K_3 EDTA), green (sodium heparin), green (lithium heparin), or light blue (sodium citrate).
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Specimens containing particulate material.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 1 week; Frozen: Indefinitely (avoid repeated freeze/thaw cycles)

0050157 **Hypersensitivity Pneumonitis Extended Panel (Farmer's Lung Panel)** **HYPER EXT**

Specimen Required: Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer two 2.5 mL aliquots of serum to individual ARUP Standard Transport Tubes. (Min: 1 mL each)

0050676 **Immunoglobulin G, CSF Index** **IGG SYN**

Specimen Required: Collect: CSF **AND** serum separator tube. Serum specimen should be drawn within 48 hours of CSF collection.

New Test **2012085** ***JAK2* Gene, V617F Mutation, Qualitative with Reflex to *JAK2* Exon 12 Mutation Analysis by PCR** **PV RFLX**

Available April 20, 2015

Methodology: Polymerase Chain Reaction
Performed: DNA Isolation: Sun-Sat
Assay: Mon, Wed, Fri
Reported: 7-10 days

Specimen Required: Collect: Lavender (EDTA) **OR** bone marrow (EDTA).
Specimen Preparation: Do not freeze. Transport 5 mL whole blood. (Min: 1 mL) **OR** Transport 3 mL bone marrow. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Serum. Specimens collected in anticoagulants other than EDTA. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable

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

Note: If *JAK2* V617F is reported as "Not Detected" then *JAK2* Exon 12 Mutation Analysis will be added. Additional charges apply.

CPT Code(s): 81270: if reflexed add 81403

New York DOH Approved.

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

New Test **2012084** ***JAK2* Gene, V617F Mutation, Qualitative with Reflex to *CALR* (Calreticulin) Exon 9 Mutation Analysis by PCR with Reflex to *MPL* codon 515 Mutation Detection by Pyrosequencing, Quantitative** **ET PMF RFLX**

Available April 20, 2015

Methodology: Polymerase Chain Reaction/Capillary Electrophoresis/Pyrosequencing
Performed: DNA Isolation: Sun-Sat
Assay: Mon, Wed, Fri
Reported: 12-14 days

Specimen Required: Collect: Lavender (EDTA) **OR** bone marrow (EDTA).
Specimen Preparation: Do not freeze. Transport 5 mL whole blood. (Min: 1 mL) **OR** Transport 3 mL bone marrow. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Serum. Specimens collected in anticoagulants other than EDTA. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable

Interpretive Data: Refer to report.

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

Note: If *JAK2* V617F is reported as "Not Detected" then *CALR* Exon 9 Mutation Analysis by PCR will be added. If *CALR* is reported as "Not Detected," then *MPL* codon 515 Mutation Detection by Pyrosequencing will be added. Additional charges apply.

CPT Code(s): 81270: if reflexed add 81479; if reflexed again add 81402

New York DOH Approved.

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

0020843 **Kidney Stone Risk Panel, Urine** **KID**

Specimen Required: Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 96 hours (after collection is complete); Frozen: 3 weeks

2007935	**Lactate to Pyruvate Ratio, Whole Blood**	**LP RATIO**

0025016	**Lead, Industrial Exposure Panel, Adults**	**LEAD-IND**

Interpretive Data: Elevated results may be due to skin or collection-related contamination, including use of a noncertified lead-free tube. Elevated levels of blood lead should be confirmed with a second specimen collected in a lead-free tube.

Reference interval and interpretive comments are based on the "Recommendations for Medical Management of Adult Lead Exposure, Environmental Health Perspectives, 2007." Thresholds and time intervals for retesting, medical evaluation, and response vary by state and regulatory body. Actions described by OSHA in 1978 and finalized in 1983 are shown below. Contact your State Department of Health and/or applicable regulatory agency for specific guidance on medical management recommendations.

"Occupational Safety and Health Standards: Lead (1983). 29 CFR Part 1910.1025 App C"
Action required for workers with Elevated Lead Values OSHA, Occupational Exposure to

No. of Tests	Lead	Action Required
1	Greater than or equal to 40.0 µg/dL	Notification of worker in writing; medical examination of worker and consultation.
3 (average)	Greater than or equal to 50.0 µg/dL	Removal of worker from job with potential lead exposure.
1	Greater than or equal to 60.0 µg/dL	Removal of worker from job with potential lead exposure.
2	Less than 40.0 µg/dL	Reinstatement of worker in job with potential lead exposure is based upon symptoms and medical evaluation.
OSHA requirements in effect since 1978 call for the measurement of whole blood lead and zinc protoporphyrins (ZPP) (NCCLS document C42-A, Nov. 1996) to evaluate the occupational exposure to lead. OSHA requires ZPP whole blood testing to be reported in units of µg/dL. For adults, conversion of ZPP units of µg/dL whole blood assumes a hematocrit of 45 percent. Conversion factor: umol/mol heme x 0.584= µg/dL.		

Information sources for reference intervals and interpretive comments provided below include the "CDC Response to the 2012 Advisory Committee on Childhood Lead Poisoning Prevention Report" and the "Recommendations for Medical Management of Adult Lead Exposure, Environmental Health Perspectives, 2007." Thresholds and time intervals for retesting, medical evaluation, and response vary by state and regulatory body. Contact your State Department of Health and/or applicable regulatory agency for specific guidance on medical management recommendations.

Age	Concentration	Comment
All ages	5-9.9 µg/dL	Adverse health effects are possible, particularly in pregnant women. Discuss health risks associated with continued lead exposure. For women who are or may become pregnant, reduce lead exposure.
All ages	10-19.9 µg/dL	Reduced lead exposure and increased biological monitoring are recommended.
All ages	20-69.9 µg/dL	Removal from lead exposure and prompt medical evaluation are recommended. Consider chelation therapy when concentrations exceed 50 µg/dL and symptoms of lead toxicity are present.
<19 years of age	Greater than 44.9 µg/dL	Critical. Immediate medical evaluation is recommended. Consider chelation therapy when symptoms of lead toxicity are present.
≥19 years of age	Greater than 69.9 µg/dL	Critical. Immediate medical evaluation is recommended. Consider chelation therapy when symptoms of lead toxicity are present.

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

0025060 Lead, Urine — LEAD U

Reference Interval:
Effective May, 18 2015

Test Number	Components	Reference Interval		
	Lead, Urine	0-23 µg/L		
	Lead, Urine (24-hour)	0-31 µg/d		
	Lead per gram of creatinine	Less than 5ug/gCRT		
	Creatinine, Urine - per 24h	**Age**	**Male**	**Female**
		3-8 years	140-700 mg/d	140-700 mg/d
		9-12 years	300-1300 mg/d	300-1300 mg/d
		13-17 years	500-2300 mg/d	400-1600 mg/d
		18-50 years	1000-2500 mg/d	700-1600 mg/d
		51-80 years	800-2100 mg/d	500-1400 mg/d
		81 years and older	600-2000 mg/d	400-1300 mg/d

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

0049000 Leukocyte Alkaline Phosphatase — LAP


Time Sensitive

Methodology: Cytochemical Stain
Performed: Mon-Fri
Reported: 1-5 days

Specimen Required: Remarks: Further information on how to make an adequate smear can be found in the following instructional video: https://www.youtube.com/watch?v=ca3NwrlpS40&feature=youtube

Interpretive Data: Refer to Report

2005661 Liver Fibrosis, Chronic Viral Hepatitis (Echosens FibroMeter) — FIBRO V

Specimen Required: Patient Prep: This test requires an automated platelet count, which should be performed on the EDTA whole blood sample at the client site.
Remarks: Include the platelet count with the patient test submission information.

HOT LINE NOTE: There is a unit of measure change associated with this test.
For all clients except the University of Utah Hospital, there is a unit of measure change associated with this test.
Change Unit of measure for component 2010929 Aspartate Aminotransferase, FibroMeter, from U/L to IU/L
Change Unit of measure for component 2010928 Alanine Aminotransferase, FibroMeter, from U/L to IU/L

0050119 Lupus Comprehensive Reflexive Panel — LUPUS COMP

Note: Initial testing includes RF, C3, C4, and ANA. Specimens are screened for ANA using ELISA. If antibodies are detected, then an IFA titer will be added. If confirmed by IFA, then specimen will be tested for Thyroid Peroxidase (TPO) Antibody, Anti-Scl-70 (ENA), EIA, RNP (U1) (Ribonucleic Protein) (ENA) Antibody, IgG, Smith (ENA) Antibody, IgG, SSA 52 and 60 (Ro) (ENA) Antibodies, IgG, SSB (La) (ENA) Antibody, IgG and Double-Stranded DNA (dsDNA) antibody, IgG by ELISA; if Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA result is Detected, then Double-Stranded DNA (dsDNA) Antibody, IgG by IFA (using *Crithidia luciliae*) is added. Additional charges apply.

CPT Code(s): 86431; 86160 x2; 86038; if reflexed, add 86039; if reflexed, add 86235 x6; 86376; 86225; if reflexed, add 86256

HOT LINE NOTE: There is a component change associated with this test
Add reflexive component 2012055 SSA 60 (Ro) (ENA) Antibody, IgG; if confirmend positive by IFA titer
Change the charting name of refelxive component 0050691 if confirmed positive by IFA from SSA (Ro) (ENA) Antibody, IgG to SSA 52 (R0) (ENA) Antibody, IgG

New Test **2012039** **Lysozyme, Serum** **LYSO SER**

Methodology: Quantitative Enzyme-Linked Immunosorbent Assay
Performed: Sun, Tue, Thu
Reported: 1-5 days

Specimen Required: Collect: Serum separator tube (SST).
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum an ARUP Standard Transport Tube. (Min: 0.4 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed, lipemic, icteric, or contaminated specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 3 months

Reference Interval: 0.00-2.75 µg/mL

Note: Serum lysozyme levels may be elevated in acute myelomonocytic leukemia (FAB-M4), chronic myelomonocytic leukemia (CMML), and chronic myelocytic leukemia (CML). Increased serum lysozyme activity is present in tuberculosis, sarcoidosis, megaloblastic anemias, acute bacterial infections, ulcerative colitis, regional enteritis, and Crohn disease. Elevated serum lysozyme occurs during severe renal insufficiency, renal transplant rejection, urinary tract infections, pyelonephritis, glomerulonephritis, and nephrosis.

CPT Code(s): 85549

New York DOH Approved.

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

0098819 **Melanocyte Stimulation Hormone, Alpha (a-MSH)** **MSH ALPHA**

Specimen Required: Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 24 hours; Frozen: 1 month

New Test **2011998** **MITF by Immunohistochemistry** **MITF IHC**
Available April 20, 2015

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

Specimen Required: Collect: Tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (recommended but not required), (ARUP supply #47808) available online through eSupply using ARUP Connect ™ or contact ARUP Client Services at (800) 522-2787. (Min: 2 slides). If sending precut slides, do not oven bake.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks:
Unacceptable Conditions: Specimens submitted with non-representative tissue type. Depleted specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely, Refrigerated: Indefinitely, Frozen: Unacceptable

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

Note: This test code is handled as "Stain and Return." To request a consultation, submit the pathology report, all associated case materials (clinical history, blocks, slides, etc.) with an Anatomic Pathology requisition form (form #32960) in place of the Immunohistochemistry form.

CPT Code(s): 88342

New York DOH Approved.

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

2006878 **Mitochondrial Disorders (121 Nuclear Genes by Sequencing, 119 Nuclear Genes by Deletion/Duplication)** **MT N SQDD**

Note: Genes tested by Sequencing: *ABCB7, ACAD9, ACADL, ACADM, ACADS, ACADVL, ACAT1, ADCK3, APTX, ASS1, ATPAF2, BCKDHA, BCKDHB, BCS1L, C10orf2, COQ2, COQ9, COX10, COX15, COX4I2, COX6B1, CPT1A, CPT2, CYCS, DARS2, DBT, DGUOK, DLAT, DLD, DNAJC19, DNM1L, ETFA, ETFB, ETFDH, ETHE1, FASTKD2, FH, FXN, GFER, GFM1, HADH, HADHA, HADHB, HMGCL, HMGCS2, HSPD1, ISCU, LARS2, LRPPRC, MCCC2, MFN2, MPV17, MRPS16, MRPS22, NDUFA1, NDUFA11, NDUFA2, NDUFAF1, NDUFAF2, NDUFAF3, NDUFAF4, NDUFAF5, NDUFS1, NDUFS2, NDUFS3, NDUFS4, NDUFS6, NDUFS7, NDUFS8, NDUFV1, NDUFV2, OPA1, OXCT1, PC, PCK2, PDHA1, PDHB, PDHX, PDP1, PDSS1, PDSS2, PINK1, POLG, POLG2, PPM1B, PREPL, PUS1, RARS2, RRM2B, SCO1, SCO2, SDHAF1, SDHB, SDHC, SDHD, SLC22A5, SLC25A13, SLC25A15, SLC25A19, SLC25A20, SLC25A22, SLC25A3, SLC25A4, SLC3A1, SPG7, SUCLA2, SUCLG1, SUOX, SURF1, TAZ, TIMM8A, TK2, TMEM70, TMPO, TRMU, TSFM, TUFM, TYMP, UQCRB, UQCRQ, WFS1*

Genes tested by Deletion/Duplication: *ABCB7, ACAD9, ACADL, ACADM, ACADS, ACADVL, ACAT1, ADCK3, APTX, ASS1, ATPAF2, BCKDHA, BCKDHB, BCS1L, C10orf2, COQ2, COQ9, COX10, COX15, COX4I2, COX6B1, CPT1A, CPT2, CYCS, DARS2, DBT, DGUOK, DLAT, DLD, DNAJC19, DNM1L, ETFA, ETFB, ETFDH, ETHE1, FASTKD2, FH, FXN, GFER, GFM1, HADH, HADHA, HADHB, HMGCL, HMGCS2, HSPD1, ISCU, LRPPRC, MCCC2, MFN2, MPV17, MRPS16, MRPS22, NDUFA1, NDUFA11, NDUFAF1, NDUFAF2, NDUFAF3, NDUFAF4, NDUFAF5, NDUFS1, NDUFS2, NDUFS3, NDUFS4, NDUFS6, NDUFS7, NDUFS8, NDUFV1, NDUFV2, OPA1, OXCT1, PC, PCK2, PDHA1, PDHB, PDHX, PDP1, PDSS1, PDSS2, PINK1, POLG, POLG2, PPM1B, PREPL, PUS1, RARS2, RRM2B, SCO1, SCO2, SDHAF1, SDHB, SDHC, SDHD, SLC22A5, SLC25A13, SLC25A15, SLC25A19, SLC25A20, SLC25A22, SLC25A3, SLC25A4, SLC3A1, SPG7, SUCLA2, SUCLG1, SUOX, SURF1, TAZ, TIMM8A, TK2, TMEM70, TMPO, TRMU, TSFM, TUFM, TYMP, UQCRB, UQCRQ, WFS1*

CPT Code(s): 81404 x3 (*MPV17, SDHC, SLC25A20*), 81405 x3 (*DBT, PDHA1, SPG7*), 81406 (*OPA1*), 81440, 81479

2006050 **Mitochondrial Disorders (121 Nuclear Genes) Sequencing** **MT N SQ**

Note: Genes tested by Sequencing: *ABCB7, ACAD9, ACADL, ACADM, ACADS, ACADVL, ACAT1, ADCK3, APTX, ASS1, ATPAF2, BCKDHA, BCKDHB, BCS1L, C10orf2, COQ2, COQ9, COX10, COX15, COX4I2, COX6B1, CPT1A, CPT2, CYCS, DARS2, DBT, DGUOK, DLAT, DLD, DNAJC19, DNM1L, ETFA, ETFB, ETFDH, ETHE1, FASTKD2, FH, FXN, GFER, GFM1, HADH, HADHA, HADHB, HMGCL, HMGCS2, HSPD1, ISCU, LARS2, LRPPRC, MCCC2, MFN2, MPV17, MRPS16, MRPS22, NDUFA1, NDUFA11, NDUFA2, NDUFAF1, NDUFAF2, NDUFAF3, NDUFAF4, NDUFAF5, NDUFS1, NDUFS2, NDUFS3, NDUFS4, NDUFS6, NDUFS7, NDUFS8, NDUFV1, NDUFV2, OPA1, OXCT1, PC, PCK2, PDHA1, PDHB, PDHX, PDP1, PDSS1, PDSS2, PINK1, POLG, POLG2, PPM1B, PREPL, PUS1, RARS2, RRM2B, SCO1, SCO2, SDHAF1, SDHB, SDHC, SDHD, SLC22A5, SLC25A13, SLC25A15, SLC25A19, SLC25A20, SLC25A22, SLC25A3, SLC25A4, SLC3A1, SPG7, SUCLA2, SUCLG1, SUOX, SURF1, TAZ, TIMM8A, TK2, TMEM70, TMPO, TRMU, TSFM, TUFM, TYMP, UQCRB, UQCRQ, WFS1*

CPT Code(s): 81440

HOT LINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name of component 2006051 from Mito Disorders (108 Nuc. Genes) Specimen to Mito Disorders (121 Nuc. Genes) Specimen
Change the charting name of component 2006052 from Mito Disorders (108 Nuc. Genes) Interp to Mito Disorders (121 Nuc. Genes) Interp

2006061 **Mitochondrial Disorders (mtDNA and 119 Nuclear Genes) Deletion/Duplication** **MT DD**

Note: Genes tested by Deletion/Duplication: *MT-ATP6, MT-ATP8, MT-CO1, MT-CO2, MT-CO3, MT-CYB, MT-ND1, MT-ND2, MT-ND3, MT-ND4, MT-ND4L, MT-ND5, MT-ND6, MT-RNR1, MT-RNR2, MT-TA, MT-TC, MT-TD, MT-TE, MT-TF, MT-TG, MT-TH, MT-TI, MT-TK, MT-TL1, MT-TL2, MT-TM, MT-TN, MT-TP, MT-TQ, MT-TR, MT-TS1, MT-TS2, MT-TT, MT-TV, MT-TW, MT-TY, ABCB7, ACAD9, ACADL, ACADM, ACADS, ACADVL, ACAT1, ADCK3, APTX, ASS1, ATPAF2, BCKDHA, BCKDHB, BCS1L, C10orf2, COQ2, COQ9, COX10, COX15, COX4I2, COX6B1, CPT1A, CPT2, CYCS, DARS2, DBT, DGUOK, DLAT, DLD, DNAJC19, DNM1L, ETFA, ETFB, ETFDH, ETHE1, FASTKD2, FH, FXN, GFER, GFM1, HADH, HADHA, HADHB, HMGCL, HMGCS2, HSPD1, ISCU, LRPPRC, MCCC2, MFN2, MPV17, MRPS16, MRPS22, NDUFA1, NDUFA11, NDUFAF1, NDUFAF2, NDUFAF3, NDUFAF4, NDUFAF5, NDUFS1, NDUFS2, NDUFS3, NDUFS4, NDUFS6, NDUFS7, NDUFS8, NDUFV1, NDUFV2, OPA1, OXCT1, PC, PCK2, PDHA1, PDHB, PDHX, PDP1, PDSS1, PDSS2, PINK1, POLG, POLG2, PPM1B, PREPL, PUS1, RARS2, RRM2B, SCO1, SCO2, SDHAF1, SDHB, SDHC, SDHD, SLC22A5, SLC25A13, SLC25A15, SLC25A19, SLC25A20, SLC25A22, SLC25A3, SLC25A4, SLC3A1, SPG7, SUCLA2, SUCLG1, SUOX, SURF1, TAZ, TIMM8A, TK2, TMEM70, TMPO, TRMU, TSFM, TUFM, TYMP, UQCRB, UQCRQ, WFS1*

CPT Code(s): 81404 x3 (*MPV17, SDHC, SLC25A20*), 81405 x3 (*DBT, PDHA1, SPG7*), 81406 (*OPA1*), 81465, 81479

HOT LINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name of component 2006062 from mtDNA Genome Del/Dup Specimen to Mito Disorders Del/Dup Specimen
Change the charting name of component 2006063 from Mitochondrial Genome Del/Dup Interp to Mito Disorders Del/Dup Interp

2006054 **Mitochondrial Disorders Panel (mtDNA by Sequencing and Deletion/Duplication, 121 Nuclear Genes by Sequencing, 119 Nuclear Genes by Deletion/Duplication)** **MT PANEL**

Note: Genes tested by Sequencing: *MT-ATP6, MT-ATP8, MT-CO1, MT-CO2, MT-CO3, MT-CYB, MT-ND1, MT-ND2, MT-ND3, MT-ND4, MT-ND4L, MT-ND5, MT-ND6, MT-RNR1, MT-RNR2, MT-TA, MT-TC, MT-TD, MT-TE, MT-TF, MT-TG, MT-TH, MT-TI, MT-TK, MT-TL1, MT-TL2, MT-TM, MT-TN, MT-TP, MT-TQ, MT-TR, MT-TS1, MT-TS2, MT-TT, MT-TV, MT-TW, MT-TY, ABCB7, ACAD9, ACADL, ACADM, ACADS, ACADVL, ACAT1, ADCK3, APTX, ASS1, ATPAF2, BCKDHA, BCKDHB, BCS1L, C10orf2, COQ2, COQ9, COX10, COX15, COX4I2, COX6B1, CPT1A, CPT2, CYCS, DARS2, DBT, DGUOK, DLAT, DLD, DNAJC19, DNM1L, ETFA, ETFB, ETFDH, ETHE1, FASTKD2, FH, FXN, GFER, GFM1, HADH, HADHA, HADHB, HMGCL, HMGCS2, HSPD1, ISCU, LARS2, LRPPRC, MCCC2, MFN2, MPV17, MRPS16, MRPS22, NDUFA1, NDUFA11, NDUFA2, NDUFAF1, NDUFAF2, NDUFAF3, NDUFAF4, NDUFAF5, NDUFS1, NDUFS2, NDUFS3, NDUFS4, NDUFS6, NDUFS7, NDUFS8, NDUFV1, NDUFV2, OPA1, OXCT1, PC, PCK2, PDHA1, PDHB, PDHX, PDP1, PDSS1, PDSS2, PINK1, POLG, POLG2, PPM1B, PREPL, PUS1, RARS2, RRM2B, SCO1, SCO2, SDHAF1, SDHB, SDHC, SDHD, SLC22A5, SLC25A13, SLC25A15, SLC25A19, SLC25A20, SLC25A22, SLC25A3, SLC25A4, SLC3A1, SPG7, SUCLA2, SUCLG1, SUOX, SURF1, TAZ, TIMM8A, TK2, TMEM70, TMPO, TRMU, TSFM, TUFM, TYMP, UQCRB, UQCRQ, WFS1*

Genes tested by Deletion/Duplication: *MT-ATP6, MT-ATP8, MT-CO1, MT-CO2, MT-CO3, MT-CYB, MT-ND1, MT-ND2, MT-ND3, MT-ND4, MT-ND4L, MT-ND5, MT-ND6, MT-RNR1, MT-RNR2, MT-TA, MT-TC, MT-TD, MT-TE, MT-TF, MT-TG, MT-TH, MT-TI, MT-TK, MT-TL1, MT-TL2, MT-TM, MT-TN, MT-TP, MT-TQ, MT-TR, MT-TS1, MT-TS2, MT-TT, MT-TV, MT-TW, MT-TY, ABCB7, ACAD9, ACADL, ACADM, ACADS, ACADVL, ACAT1, ADCK3, APTX, ASS1, ATPAF2, BCKDHA, BCKDHB, BCS1L, C10orf2, COQ2, COQ9, COX10, COX15, COX4I2, COX6B1, CPT1A, CPT2, CYCS, DARS2, DBT, DGUOK, DLAT, DLD, DNAJC19, DNM1L, ETFA, ETFB, ETFDH, ETHE1, FASTKD2, FH, FXN, GFER, GFM1, HADH, HADHA, HADHB, HMGCL, HMGCS2, HSPD1, ISCU, LRPPRC, MCCC2, MFN2, MPV17, MRPS16, MRPS22, NDUFA1, NDUFA11, NDUFAF1, NDUFAF2, NDUFAF3, NDUFAF4, NDUFAF5, NDUFS1, NDUFS2, NDUFS3, NDUFS4, NDUFS6, NDUFS7, NDUFS8, NDUFV1, NDUFV2, OPA1, OXCT1, PC, PCK2, PDHA1, PDHB, PDHX, PDP1, PDSS1, PDSS2, PINK1, POLG, POLG2, PPM1B, PREPL, PUS1, RARS2, RRM2B, SCO1, SCO2, SDHAF1, SDHB, SDHC, SDHD, SLC22A5, SLC25A13, SLC25A15, SLC25A19, SLC25A20, SLC25A22, SLC25A3, SLC25A4, SLC3A1, SPG7, SUCLA2, SUCLG1, SUOX, SURF1, TAZ, TIMM8A, TK2, TMEM70, TMPO, TRMU, TSFM, TUFM, TYMP, UQCRB, UQCRQ, WFS1*

CPT Code(s): 81404 x3 (*MPV17, SDHC, SLC25A20*), 81405 x3 (*DBT, PDHA1, SPG7*), 81406 (*OPA1*), 81440, 81460, 81465, 81479

2010851 **Myositis Antibody Comprehensive Panel** **MYOS COMP**

Reference Interval:
Effective May 18, 2015

Test Number	Components	Reference Interval	
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
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	
0099592	Jo-1 Antibody, IgG	29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive	
	Mi-2 (nuclear helicase protein) Antibody	Negative	
	PL-7 (threonyl-tRNA synthetase) Antibody	Negative	
	PL-12 (alanyl-tRNA synthetase) Antibody	Negative	
	P155/140 (TIF1-gamma) Antibody	Negative	
	EJ (glycyl - tRNA synthetase) Antibody	Negative	
	Ku Antibody	Negative	
	U2 sn (small nuclear) RNP Antibody	Negative	
	SRP (Signal Recognition Particle) Ab	Negative	
	OJ (isoleucyl-tRNA synthetase) Antibody	Negative	
	PM/Scl Complex Antibodies	Negative	

Note: Antibodies: Mi-2, PL-7, PL12, P155/140, EJ, Ku, OJ, PM/Scl, SRP, U2RNP, U1RNP, Ro52, Ro60, Jo-1

CPT Code(s): 83516 x10; 86235 x4

HOT LINE NOTE: There is a clinically significant charting name change and a component change associated with this test
Change the charting name of component 0050691 from SSA (Ro) (ENA) Antibody, IgG to SSA 52 (R0) (ENA) Antibody, IgG
Add component 2012055 SSA 60 (Ro) (ENA) Antibody, IgG

0020482 Oxalate, Urine UOXAL

Specimen Required: Specimen Preparation: Thoroughly mix entire collection (24-hour or random) in one container. Transfer 4 mL aliquot from the well-mixed 24-hour urine collection to an ARUP Transport Tube with 20 mg Sulfamic Acid (ARUP supply #48098) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. Mix well. (Min: 1.5 mL) **Record total volume and collection time interval on transport tube and test request form. This information is required for test interpretation.** If the collection tube with Sulfamic Acid is not available, transport a 4 mL unadjusted aliquot of urine. Freeze specimens immediately after aliquoting. Do not exceed 4 mL in tubes.
Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted with multiple tests are ordered.

Note: Vitamin C (ascorbic acid) quickly degrades to oxalate in non-acidified urine. Patients should discontinue use of vitamin C supplements at least 48 hours prior to the start of urine collection and abstain until collection is complete.

Preservation with Sulfamic Acid before transporting is highly recommended.

2007949 Paliperidone, Serum or Plasma PALIPERID

Interpretive Data: The therapeutic range is based on serum pre-dose (trough) draw at steady-state concentration. Adverse effects to paliperidone therapy may include headache, nausea, dizziness, tachycardia, orthostatic hypotension and dyskinesia.

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

New Test 2002528 Pancreatobiliary FISH PF REQUEST

Cytology Test Request Form

Methodology: Fluorescence in situ Hybridization/Computer Assisted Analysis/Microscopy
Performed: Weekly
Reported: 4-12 days

Specimen Required: Collect: Bile or pancreatic duct brushings, biliary stent, fine needle aspirates, or pancreatic juices.
Specimen Preparation: Place specimen in Cytolyt or PreservCyt fixative vial. If the specimen is a brushing, submit the brush in the fixative.
Storage/Transport Temperature: Refrigerated.
Remarks: Specimen source is required.
Unacceptable Conditions: Specimens not collected in Cytolyt or PreservCyt fixative.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 72 hours; Frozen: Unacceptable

Reference Interval:

Positive	≥ 5 cells with gains of two or more chromosomes are present
Equivocal Tetrasomy	Cells present with tetrasomic or near tetrasomic signal patterns
Equivocal Trisomy	≥ 10 cells with gains of a single chromosome, (Trisomy 7 or Trisomy 3)
Negative	< 5 abnormal cells are present

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

Note: The UroVysion Kit is designed to detect aneuploidy for chromosomes 3, 7 and 17via fluorescence in situ hybridization (FISH). Results of this test must be interpreted in conjunction with clinical evidence and other laboratory testing and should not be used alone,as a diagnosis of pancreatobiliary carcinoma.

CPT Code(s): 88366

New York DOH Approved.

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

New Test **2012043** **Parvovirus B19 by Quantitative PCR** **PARV QNT**
Available April 20, 2015

Methodology: Quantitative Polymerase Chain Reaction
Performed: Mon, Wed, Fri
Reported: 1-4 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or serum separator tube (SST).
Specimen Preparation: Separate serum or plasma from cells. Transfer 1 mL serum, plasma to a sterile container. (Min: 0.5 mL)
Storage/Transport Temperature: Frozen.
Remarks: Specimen source required.
Unacceptable Conditions: Heparinized specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: 6 months

Reference Interval: Not detected

Interpretive Data: The quantitative range of this test is 2.0- 8.0 log IU/mL (100 - 100,000,000 IU/mL).

A negative result (less than 2.0 log IU/mL or less than 100 IU/mL) does not rule out the presence of PCR inhibitors in the patient specimen or Parvovirus DNA 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 DNA test is 2.0 log IU/mL (100 IU/mL). If the test DID NOT DETECT the virus, the test result will be reported as "< 2.0 log IU/mL (< 100 IU/mL)." If the test DETECTED the presence of the virus but was not able to accurately quantify the number of international units, the test result will be reported as "Not Quantified."

CPT Code(s): 87799

New York DOH approval pending. Call for status update.

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

2009451 **Phosphatidylserine and Prothrombin Antibodies, IgG and IgM** **APS/PT PAN**

Specimen Required: Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

2010248 **Prosigna Breast Cancer Prognostic Gene Signature** **PROSIGNA**

Specimen Required: Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed excised tissue. Protect from excessive heat. Transport tissue block or 6 unstained 10-micron slides. (Min: 3 slides). Transport block(s) and/or slide(s) in a tissue transport kit (recommended but not required), (ARUP supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Unacceptable Conditions: Specimens fixed/processed in alternative fixatives (alcohol, Prefer). Decalcified specimens. Needle core biopsy. Less than 10 percent tumor.

0070213 **Pyridinium Crosslinks (Total), Urine** **PYD**

Reference Interval:
Effective May 18, 2015

Test Number	Components	Reference Interval
	Pyridinoline, Urine - ratio to CRT	Adult Male: 10.3-20.0 nmol/mmol Premenopausal Adult Female: 15.3-33.6 nmol/mmol
	Creatinine, Urine - per volume	No reference interval

HOT LINE NOTE: There is a unit of measure change and clinically significant charting name change associated with this test
Change charting name of component 0070221 from Pyridinoline, Urine Calculation to Pyridinoline, Urine – Ratio to Crt
Change unit of measure for component 0070221 from nM/mM to nmol/mmol

New Test **2008418** **ROS1 by FISH** **ROS1 FISH**
Available April 20, 2015

Methodology: Fluorescence in situ Hybridization
Performed: Varies
Reported: 3-8 days

Specimen Required: Collect: Tumor tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen. Transport tissue block or 5 unstained (3- to 5- micron thick sections), positively charged slides in a tissue transport kit (recommended but not required), (ARUP supply #47808), available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 2 slides) If sending precut slides, do not oven bake. Protect paraffin block and/or slides from excessive heat.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks: Include surgical pathology report.
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

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

CPT Code(s): 88366

New York DOH Approved.

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

New Test **2012007** **Skeletal Dysplasia Panel, Deletion/Duplication, 35 Genes** **SKEL DD**
Available April 20, 2015

 Patient History for Skeletal Dysplasia

 Additional Technical Information

Methodology: Exonic Oligonucleotide-based CGH Microarray
Performed: Varies
Reported: 3-4 weeks

Specimen Required: Collect: Lavender (EDTA) or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 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

Interpretive Data: Refer to report.
See Compliance Statement C: www.aruplab.com/CS

Note: Genes tested: *AGPS, ALPL, ARSE, COL1A1, COL1A2, COL2A1, CRTAP, DLL3, DYNC2H1, EBP, EVC, EVC2, FGFR1, FGFR2, FGFR3, FKBP10, FLNB, GNPAT, IFT80, LBR, LEPRE1, LIFR, NEK1, PEX7, POR, PPIB, RUNX2, SERPINH1, SLC26A2, SCL35D1, SOX9, TRIP11, TTC21B, WDR19, WDR35*

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 **2012015** **Skeletal Dysplasia Panel, Sequencing (39 Genes) and Deletion/Duplication (35 Genes)** **SKEL PANEL**

Available April 20, 2015

Patient History for Skeletal Dysplasia

Additional Technical Information

Methodology: Massive Parallel Sequencing/Exonic Oligonucleotide-based CGH Microarray
Performed: Varies
Reported: 10-12 weeks

Specimen Required: Collect: Lavender (EDTA) or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 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

Interpretive Data: Refer to report.

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

Note: Genes tested by sequencing: *AGPS, ALPL, ARSE, COL1A1, COL1A2, COL2A1, COMP, CRTAP, DLL3, DYNC2H1, EBP, EVC, EVC2, FGFR1, FGFR2, FGFR3, FKBP10, FLNA, FLNB, GNPAT, HSPG2, IFT80, LBR, LEPRE1, LIFR, NEK1, PEX7, POR, PPIB, RUNX2, SERPINH1, SLC26A2, SCL35D1, SOX9, TRIP11, TRPV4, TTC21B, WDR19, WDR35*

Genes tested by deletion/duplication: *AGPS, ALPL, ARSE, COL1A1, COL1A2, COL2A1, CRTAP, DLL3, DYNC2H1, EBP, EVC, EVC2, FGFR1, FGFR2, FGFR3, FKBP10, FLNB, GNPAT, IFT80, LBR, LEPRE1, LIFR, NEK1, PEX7, POR, PPIB, RUNX2, SERPINH1, SLC26A2, SCL35D1, SOX9, TRIP11, TTC21B, WDR19, WDR35*

CPT Code(s): 81404 x2 (*FGFR2, FGFR3*); 81405 (*FGFR1*); 81408 x2 (*COL1A1, COL1A2*); 81479 x2

New York DOH approval pending. Call for status update.

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

New Test **2012010** **Skeletal Dysplasia Panel, Sequencing (39 Genes) and Deletion/Duplication (35 Genes), Fetal** **SKEL FE**

Available April 20, 2015

 Patient History for Fetal Molecular Testing

 Additional Technical Information

Methodology: Massive Parallel Sequencing
Performed: Varies
Reported: 4-6 weeks

Specimen Required: Collect: **Fetal Specimen:** Four (4) T-25 flasks at 80 percent confluent of cultured amniocytes or cultured CVS. If the client is unable to culture, this can be arranged by contacting ARUP Client Services at (800) 522-2787.
AND **Maternal Cell Contamination Specimen:** Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: **Cultured Amniocytes or Cultured CVS:** Fill flasks with culture media. Transport four (4) T-25 flasks at 80 percent confluent of cultured cells filled with culture media. Backup cultures must be retained at the client's institution until testing is complete.
AND **Maternal Cell Contamination Specimen:** Transport 3 mL whole blood (Min: 1 mL)
Storage/Transport Temperature: **Culture Amniocytes or Cultured CVS:** CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of shipment due to lability of cells.
Maternal Cell Contamination Specimen: Room temperature.
Stability (collection to initiation of testing): **Fetal Specimen:** Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Maternal: Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data: Refer to report.

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

Note: Reported times are based on receiving the four T-25 flasks at 80 percent confluent. Cell culture time is independent of testing turn-around time. Maternal specimen is recommended for proper test interpretation. Order Maternal Cell Contamination.

Genes tested by sequencing: *AGPS, ALPL, ARSE, COL1A1, COL1A2, COL2A1, COMP, CRTAP, DLL3, DYNC2H1, EBP, EVC, EVC2, FGFR1, FGFR2, FGFR3, FKBP10, FLNA, FLNB, GNPAT, HSPG2, IFT80, LBR, LEPRE1, LIFR, NEK1, PEX7, POR, PPIB, RUNX2, SERPINH1, SLC26A2, SCL35D1, SOX9, TRIP11, TRPV4, TTC21B, WDR19, WDR35*

Genes tested by deletion/duplication: *AGPS, ALPL, ARSE, COL1A1, COL1A2, COL2A1, CRTAP, DLL3, DYNC2H1, EBP, EVC, EVC2, FGFR1, FGFR2, FGFR3, FKBP10, FLNB, GNPAT, IFT80, LBR, LEPRE1, LIFR, NEK1, PEX7, POR, PPIB, RUNX2, SERPINH1, SLC26A2, SCL35D1, SOX9, TRIP11, TTC21B, WDR19, WDR35*

CPT Code(s): 81404 x2 (*FGFR2, FGFR3*); 81405 (*FGFR1*); 81408 x2 (*COL1A1, COL1A2*); 81479 x2; 81265 Fetal Cell Contamination

New York DOH approval pending. Call for status update.

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

New Test **2012018** **Skeletal Dysplasia Panel, Sequencing, 39 Genes** **SKEL SEQ**
Available April 20, 2015

Patient History for Skeletal Dysplasia

Additional Technical Information

Methodology: Massive Parallel Sequencing
Performed: Varies
Reported: 10-12 weeks

Specimen Required: Collect: Lavender (EDTA) or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 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

Interpretive Data: Refer to report.

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

Note: Genes tested by sequencing: *AGPS, ALPL, ARSE, COL1A1, COL1A2, COL2A1, COMP, CRTAP, DLL3, DYNC2H1, EBP, EVC, EVC2, FGFR1, FGFR2, FGFR3, FKBP10, FLNA, FLNB, GNPAT, HSPG2, IFT80, LBR, LEPRE1, LIFR, NEK1, PEX7, POR, PPIB, RUNX2, SERPINH1, SLC26A2, SCL35D1, SOX9, TRIP11, TRPV4, TTC21B, WDR19, WDR35*

CPT Code(s): 81404 x2 (*FGFR2, FGFR3*); 81405 (*FGFR1*); 81408 x2 (*COL1A1, COL1A2*); 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 2012074 SSA 52 and 60 (Ro) (ENA) Antibodies, IgG SSA RO

Methodology: Semi-Quantitative Multiplex Bead Assay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Collect: Serum separator tube (SST).
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.2 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or other body fluids. 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 (avoid repeated freeze/thaw cycles)

Reference Interval:

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

Interpretive Data: SSA (Ro) antibody is seen in 70-75 percent of Sjögren syndrome cases, 30-40 percent of systemic lupus erythematosus (SLE), and 5-10 percent of progressive systemic sclerosis (PSS).

CPT Code(s): 86235 x2

New York DOH Approved.

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

0061162 *Streptococcus pneumoniae* Antigen, CSF SPN CSF

Note: Patients who have received the *S. pneumoniae* vaccines may test positive in the 48 hours following vaccination. Avoid antigen detection testing for at least 5 days after receiving vaccination.

The College of American Pathologists (CAP) requires that bacterial antigen detection testing performed on CSF specimens be confirmed by culture (CAP MIC.22550). When *S. pneumoniae* antigen detection on CSF specimens is ordered by the University of Utah Hospital, Huntsman Cancer Hospital, or the VA Hospital of Salt Lake City, a CSF culture will be added automatically (see 0060106 for submission requirements). All other CSF specimens will be processed with the assumption that a culture was performed before sending to ARUP unless a specific request for culture is included with the test order. Additional charges apply

New Test 2012057 Systemic Sclerosis Panel SSC PAN

Methodology: Semi-Quantitative Indirect Fluorescent Antibody/Semi-Quantitative Multiplex Bead Assay/Semi-Quantitative Enzyme-Linked Immunosorbent Assay
Performed: Sun, Tue, Thu
Reported: 1-4 days

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 3 mL serum to an ARUP Standard Transport Tube. (Min: 0.25 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Contaminated, hemolyzed, or severely lipemic specimens.
Stability (collection to initiation of testing): Ambient 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval
0050639	Nuclear Antibody (ANA) by IFA, IgG	Less than 1:40
0050599	Scleroderma (Scl-70) (ENA) Antibody, IgG	29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: 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

Interpretive Data: Refer to Individual Components.

CPT Code(s): 86039; 86235; 83516

New York DOH Approved.

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

0060132 Wound Culture and Gram Stain MC W

Specimen Required: Remarks: Refrigerated specimens are not recommended for recovery of some fastidious organisms such as *Neisseria* spp.
Stability (collection to initiation of testing): **Sterile Container:** Ambient: 24 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Eswab: Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Unacceptable

0020462 Zinc, Urine ZINC U

Interpretive Data: Zinc is predominantly eliminated in the feces. Elevated urine zinc may suggest excessive zinc supplementation but should be interpreted with a corresponding serum zinc concentration.

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

Quarterly HOT LINE: Effective May 18, 2015

The following will be discontinued from ARUP's test menu on May 18, 2015.
Replacement test options are supplied if applicable.

Test Number	Test Name	Refer To Replacement
2008710	BRAF V600E by Immunohistochemistry	BRAF Codon 600 Mutation Detection by Pyrosequencing (2002498)
0091520	Butorphanol, Urine - Screen with Reflex to Confirmation/Quantitation	
0091485	Cresols, Urine	
0091356	Dantrolene, Serum or Plasma	
2007785	ERBB2 (*HER2/neu*) (HercepTest) by Immunohistochemistry, Tissue with Reflex to Dual ISH if 2+	ERBB2 (HER2/neu) (HercepTest) by Immunohistochemistry, Tissue with Reflex to FISH if 2+ (0049178)
2007410	ERBB2 (HER2/neu) Gene Amplification by Dual in-situ Hybridization	ERBB2 (HER2/neu) Gene Amplification by FISH, Tissue (2008603)
0050653	Extractable Nuclear Antigen Antibodies (RNP, Smith, Scleroderma, SSA, & SSB)	Extractable Nuclear Antigen Antibodies (RNP, Smith, SSA 52, SSA 60 and SSB) (0050652) and Systemic Sclerosis Panel (2012057)
0091175	Hippuric Acid, Urine	
0091207	Hydroxyzine and Metabolite Quantitative, Serum or Plasma	
0050367	Lysozyme, Serum or Body Fluid	Lysozyme, Serum (2012039)
0050368	Lysozyme, Urine	
0091477	Methylhippuric Acid, Urine	
0091486	Nalbuphine, Urine - Screen with Reflex to Confirmation/Quantitation	
2002461	Pancreatobiliary FISH	Pancreatobiliary FISH (2002528)
2004103	*Pneumocystis jiroveci* by Immunohistochemistry	Special Stain, Grocott's Methenamine Silver (GMS) (2005945)
0050691	SSA (Ro) (ENA) Antibody, IgG	SSA 52 and 60 (Ro) (ENA) Antibodies, IgG (2012074)
0091534	Tolbutamide, Serum or Plasma	