Quarterly HOT LINE: Effective August 15, 2016

MEDICARE COVERAGE OF LABORATORY TESTING

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

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

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

Hot Line Page #	Test Number	Summary of Changes by Test Name	Name Change	Methodology	Performed/Reported Schedule	Specimen Requirements	Reference Interval	Interpretive Data	Note	CPT Code	Component Change	Other Interface Change	New Test	Inactive
5	0083001	Adenosine Deaminase, RBC						x						
5	2003204	Alpha-Galactosidase, Serum				x					x			
5	0080001	Angiotensin Converting Enzyme, Serum				x								
5	0098771	Angiotensin II, Plasma			x	x								
6	0060201	Antimicrobial Susceptibility - MIC, Individual			x			x	x					
6	2003036	Aquaporin-4 Receptor Antibody (Pricing Change Only)												
6	2013327	Aquaporin-4 Receptor Antibody by ELISA with Reflex to Aquaporin-4 Receptor Antibody, IgG by IFA (Pricing Change Only)												
7	2013601	Autoimmune Encephalitis Reflexive Panel											x	
8	2005640	Autoimmune Neuromuscular Junction Reflexive Panel	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
9	2011411	Bath Salts Panel, Serum or Plasma				x								
9	0092303	Calprotectin, Fecal			x		x							
9	2002918	Carbohydrate Deficient Transferrin for Congenital Disorders of Glycosylation (CDG)	x											
23	2003496	Caspase-3 by Immunohistochemistry												x
23	2003583	CD45RO by Immunohistochemistry												x
23	0098930	Clozapine												x
23	2006476	Clozapine and Metabolite Quantitative, Serum or Plasma												x
9	2013433	Clozapine and Metabolites, Serum or Plasma, Quantitative											x	
10	2013258	Consultation, Hematopathology											x	
10	0081117	Cortisol, Saliva									x			
10	0020509	Creatinine, Body Fluid				x		x						
10	0020025	Creatinine, Serum or Plasma							x					
11	0051232	Cytochrome P450 2D6 (*CYP2D6*) 14 Variants and Gene Duplication				x		x			x			
11	2000135	Cytology, SurePath Liquid-Based Pap Test with Reflex to Human Papillomavirus (HPV), High Risk by PCR, SurePath	x	x	x				x			x		
12	2000133	Cytology, SurePath Liquid-Based Pap Test and Human Papillomavirus (HPV), High Risk by PCR, SurePath (for routine co-testing in women over 30)	x	x	x				x	x		x		
12	2006621	Drug Detection Panel, Umbilical Cord Tissue, Qualitative								x				
12	0092420	Drug Screen 9 Panel, Serum or Plasma - Immunoassay Screen with Reflex to Mass Spectrometry Confirmation/Quantitation					x			x	x			
12	2012868	*EGFR* T790M Mutation Detection in Circulating Tumor DNA by Digital Droplet PCR	x											
12	2008916	Encephalitis Panel with Reflex to Herpes Simplex Virus Types 1 and 2 Glycoprotein G-Specific Antibodies, IgG, CSF										x		
12	2008915	Encephalitis Panel with Reflex to Herpes Simplex Virus Types 1 and 2 Glycoprotein G-Specific Antibodies, IgG, Serum										x		
13	2010921	Eosinophil Granule Major Basic Protein, Tissue				x								
13	2002902	Epstein-Barr Virus (EBV) by in situ Hybridization, Paraffin				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
13	2013592	Epstein-Barr Virus (EBV) by In Situ Hybridization, Stain Only											x	
13	2012695	Ethyl Glucuronide Screen Only, Urine										x		
13	2007912	Ethyl Glucuronide Screen with Reflex to Confirmation, Urine					x							
23	2003881	Factor VIII by Immunohistochemistry												x
23	0095302	Fatty Acids Profile, Essential (C12-C22)												x
14	2013518	Fatty Acids Profile, Essential Serum or Plasma											x	
14	0080120	Fatty Acids, Free				x								
14	2012636	Gastrin, 1 Minute								x				
14	2012734	Gastrin, 10 Minute								x				
14	2012638	Gastrin, 2 Minute								x				
14	2012736	Gastrin, 30 Minute								x				
14	2012732	Gastrin, 5 Minute								x				
23	2010198	Gastrointestinal Hereditary Cancer Panel, Sequencing and Deletion/Duplication, 15 Genes												x
15	2013577	Gastrointestinal Viral Panel by PCR											x	
23	0097338	Heat Shock Protein 70 (68 kDa), IgG by Western Blot												x
15	2013590	Heat Shock Protein 70, IgG by Immunoblot											x	
16	2013399	Hemoglobin S, Sickle Solubility											x	
16	2010793	Hepatitis C Virus (HCV) by Quantitative PCR with Reflex to HCV High-Resolution Genotype by Sequencing							x					
16	2009255	Hepatitis C Virus (HCV) Genotype with Reflex to HCV High-Resolution Genotype by Sequencing							x					
16	2006898	Hepatitis C Virus High-Resolution Genotype by Sequencing							x					
23	0093900	Hist/Hpath Tracking Test												x
23	0060744	Human Papillomavirus (HPV), High Risk by Hybrid Capture, SurePath												x
17	2013599	Insulin-Like Growth Factor 2											x	
23	2007565	Insulin-Like Growth Factor 2 (IGF-2)												x
17	2013595	Kappa/Lambda Light Chain Panel by In Situ Hybridization, Stain Only											x	
18	0080650	17-Ketosteroids, Urine				x								
18	2007254	Manganese, RBC				x								
18	0040005	Manual Differential									x			

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18	2006878	Mitochondrial Disorders (121 Nuclear Genes by Sequencing, 119 Nuclear Genes by Deletion/Duplication)								x				
18	2006061	Mitochondrial Disorders (mtDNA and 119 Nuclear Genes) Deletion/Duplication								x				
18	2006054	Mitochondrial Disorders Panel (mtDNA by Sequencing and Deletion/Duplication, 121 Nuclear Genes by Sequencing, 119 Nuclear Genes by Deletion/Duplication)								x				
18	0051281	Norovirus Group 1 and 2 by PCR	x		x			x						
19	2011375	Occupation Screen - MMR/VZV Antibody Assessment Panel, IgG								x		x		
23	2007394	Ovarian Antibody, IgG Screen with Reflex to Titer by IFA												x
19	0020482	Oxalate, Urine				x								
19	0095611	Parathyroid Hormone, CAP				x								
19	2012007	Skeletal Dysplasia Panel, Deletion/Duplication, 36 Genes	x						x					
19	2012015	Skeletal Dysplasia Panel, Sequencing (39 Genes) and Deletion/Duplication (36 Genes)	x						x					
19	2012010	Skeletal Dysplasia Panel, Sequencing (39 Genes) and Deletion/Duplication (36 Genes), Fetal	x						x					
19	2011704	Smith-Lemli-Opitz Syndrome (*DHCR7*) Sequencing, Fetal	x			x								
23	2008789	Spinal Muscular Atrophy (SMA) Carrier Screening												x
20	2013436	Spinal Muscular Atrophy (SMA) Copy Number Analysis											x	
21	2013444	Spinal Muscular Atrophy (SMA) Copy Number Analysis, Fetal											x	
22	0050642	*Streptococcus pyogenes*, Group A Antibody (Streptozyme) with Reflex to Titer									x			
22	2006685	Thyroglobulin, Serum or Plasma with Reflex to LC-MS/MS or CIA				x								
22	0020183	Urea Nitrogen, Fluid				x		x						
23	2012086	Urine Cotinine Rapid												x
22	0050162	Varicella-Zoster Virus Antibodies, IgG and IgM										x		
22	0050167	Varicella-Zoster Virus Antibody, IgG										x		
22	0054444	Varicella-Zoster Virus Antibody, IgG, CSF										x		
23	2004178	Villin by Immunohistochemistry												x
23	0049176	Wright's Stain												x

0083001 **Adenosine Deaminase, RBC** **ADA**

Interpretive Data: Adenosine Deaminase (ADA) deficiency is an autosomal recessive disorder of purine metabolism primarily affecting lymphocyte development, viability, and function. Affected individuals have less than 1 percent of normal ADA catalytic activity in red cell hemolysates. ADA deficiency is the cause of 20-30 percent of SCID cases. If the patient has been recently transfused, ADA deficiency may be masked; interpret results with caution. Heterozygotes cannot be identified by this test. If clinical suspicion remains, consider testing to determine the ADA genotype: Severe Combined Immunodeficiency (SCID) Panel, Sequencing and Deletion/Duplication, 19 Genes (ARUP test code 2010219).

2003204 **Alpha-Galactosidase, Serum** **A GALACTO**

Specimen Required: Unacceptable Conditions: Thawed specimens.

HOT LINE NOTE: There is a component change associated with this test.
Remove component 2003205, Alpha-Galactosidase, Amendment
Remove component 2003207, Alpha-Galactosidase, Method
Remove component 2003208, Alpha-Galactosidase, Order Date
Remove component 2003209, Alpha-Galactosidase, Reason
Remove component 2003210, Alpha-Galactosidase, Release Date
Remove component 2003213, Alpha-Galactosidase, Source
Remove component 2003214, Alpha-Galactosidase, Specimen
Remove component 2003215, Alpha-Galactosidase, Specimen ID

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

Specimen Required: Unacceptable Conditions: EDTA, heparin plasma, or CSF (refer to Angiotensin Converting Enzyme, CSF test code 0098974) Hemolyzed specimens.

0098771 **Angiotensin II, Plasma** **ANGIO II**

Performed: Varies
Reported: 4-18 days

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

0060201 Antimicrobial Susceptibility - MIC, Individual — MA MIC

Performed: Sun-Sat
Reported: 2-4 days

Interpretive Data: **Susceptibility testing is performed by broth microdilution using custom-made MIC panels and is interpreted according to CLSI guidelines.**

Note: The MIC is defined as the lowest concentration of an antibiotic which will inhibit the in vitro growth of an infectious organism. Results are reported in micrograms per mL. The interpretation of in vitro data is based on achievable serum concentrations, which may vary depending on dose, route of administration, degree of protein binding, site of infection, age and weight of the patient, state of health of the patient, and other factors.

Reporting of MICs can provide the physician with precise information regarding the infectious organism's degree of susceptibility. When this information is coupled with the physician's knowledge of the site and severity of the infection, as well as the pharmacology of antibiotics, a rational choice of the most appropriate antibiotic can be made to suit the individual patient. With the quantitative MIC: (1) susceptibility can be determined for dosages and routes of administration other than those usually prescribed and (2) susceptibility can more accurately be related to the achievable antibiotic concentration in urine, bile, CSF, and other body fluids which may vary widely from the achievable concentration in serum.

This test will bill per antibiotic tested. Susceptibility panels are available for certain organisms. Refer to Antimicrobial Susceptibility by organism type. For organisms where panels are not available, specific agent(s) to be tested must be indicated.

For staphylococcal species, oxacillin resistance testing is performed in order to interpret the results for β-lactam agents.

Daptomycin MIC is available for testing MRSA or VRE.

An additional processing fee will be billed for all organisms not submitted in pure culture, as indicated in the specimen requirements.

If species identification is not provided, identification will be performed at ARUP. Additional charges apply.

2003036 Aquaporin-4 Receptor Antibody — AQP4

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

2013327 Aquaporin-4 Receptor Antibody by ELISA with Reflex to Aquaporin-4 Receptor Antibody, IgG by IFA — AQP4 R

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

New Test **2013601** **Autoimmune Encephalitis Reflexive Panel** **AUTOENCEPH**
Available August 15, 2016

Methodology: Semi-Quantitative Indirect Fluorescent Antibody/Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Quantitative Radioimmunoassay
Performed: Tue
Reported: 1-8 days

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer three 3 mL aliquots of serum to individual ARUP Standard Transport Tubes. (Min: 0.75 mL/aliquot)
Storage/Transport Temperature: Frozen.
Remarks: N/A
Unacceptable Conditions: Amniotic fluid, ocular fluid, peritoneal fluid, synovial fluid, CSF, or plasma. Contaminated, hemolyzed, icteric, or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 1 month (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Component	Reference Range
2004221	N-methyl-D-Aspartate Receptor Antibody, IgG with Reflex to Titer	Less than 1:10
2001771	Glutamic Acid Decarboxylase Antibody	0.0-5.0 IU/mL
2004890	Voltage-Gated Potassium Channel (VGKC) Antibody	Negative: 31 pmol/L or less Indeterminate: 32-87 pmol/L Positive: 88 pmol/L or greater
2003036	Aquaporin-4 Receptor Antibody	Negative: 4 U/mL or less Indeterminate: 5 U/mL Positive: 6 U/mL or greater
2013320	Aquaporin-4 Receptor Antibody, IgG by IFA with Reflex to Titer, Serum	Less than 1:10
2009456	Leucine-Rich, Glioma-Inactivated Protein 1 Antibody, IgG with Reflex to Titer	Less than 1:10
2009452	Contactin-Associated Protein-2 Antibody, IgG with Reflex to Titer	Less than 1:10

Interpretive Data: By report

Note: **AQP4:** If AQP4 antibody IgG by ELISA is positive, then AQP4 antibody IgG by IFA will be added. If AQP4 antibody IgG by IFA is positive, then an AQP4 antibody IgG titer will be added. Additional charges apply.
VGKC: If VGKC is Indeterminate or Positive, LGI1 Antibody IgG and CASPR2 Antibody IgG will be added. If LGI1 antibody IgG is positive, then LGI1 antibody IgG titer will be added. If CASPR2 antibody IgG is positive, then CASPR2 antibody IgG titer will be added. Additional charges apply.
NMDA: If NMDA antibody IgG is positive, then an NMDA antibody IgG titer is reported. Additional charges apply.

CPT Code(s): 83519; if reflexed add 86255 x2, if further reflexed add 86256 per titer; 83516; 86255, if reflexed add 86256; 83516, if reflexed add 86255, if further reflexed add 86256

New York DOH approval pending. Call for status update.

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

2005640 Autoimmune Neuromuscular Junction Reflexive Panel MUWA R PAN

Reference Interval: Effective August 15, 2016

Test Number	Components	Reference Interval	
0080009	Acetylcholine Receptor Binding Antibody	Negative: 0.0-0.4 nmol/L Positive: 0.5 nmol/L or greater	
0099580	Acetylcholine Receptor Blocking Antibody	Effective November 18, 2013	
		Negative:	0-26% blocking
		Indeterminate:	27-41% blocking
		Positive:	42% or greater blocking
0099521	Acetylcholine Receptor Modulating Antibody	Negative: 0-45% modulating Positive: 46% or greater modulating Effective August 20, 2012	
0092628	Voltage-Gated Calcium Channel (VGCC) Antibody	Effective November 14, 2011	
		Negative	0.0 to 24.5 pmol/L
		Indeterminate	24.6 to 45.6 pmol/L
		Positive	45.7 pmol/L or greater
2004890	Voltage-Gated Potassium Channel (VGKC) Antibody	Effective April 18, 2011	
		Negative	31 pmol/L or less
		Indeterminate	32-87 pmol/L
		Positive	88 pmol/L or greater
2005636	Titin Antibody	Effective January 17, 2012 **Titin Antibody**	
		Negative	0.00-0.45 IV
		Indeterminate	0.46-0.71 IV
		Positive	0.72 IV or greater
0050746	Striated Muscle Antibodies, IgG with Reflex to Titer	Less than 1:40	
2009460	LGI1 and CASPR2 Abs IgG w/Rflx to Titers	LGI1: Less than 1:10 CASPR2: Less than 1:10	

Note: If Acetylcholine Receptor Binding Antibody result is greater than 0.4 nmol/L or Acetylcholine Receptor Blocking Antibody result is greater than 26 percent, then Acetylcholine Receptor Modulating Antibody will be added. If Striated Muscle Ab is detected, then a titer will be added. If VGKC is Indeterminate or Positive, LGI1 Antibody IgG and CASPR2 Antibody IgG will be added. If LGI1 antibody IgG is positive, then LGI1 antibody IgG titer will be added. If CASPR2 antibody IgG is positive, then CASPR2 antibody IgG titer will be added. Additional charges apply.

CPT Code(s): 83519 x3; 83516 x2; 86255; if reflexed, add 83516 and/or 86256 and/or 86255 x2, if further reflexed add 86256 per titer

2011411 **Bath Salts Panel, Serum or Plasma** **BATHSLT SP**

Specimen Required: Collect: Plain Red, Lavender (EDTA), or Pink (K_2EDTA). Also acceptable: Light Blue (Sodium Citrate).

0092303 **Calprotectin, Fecal** **CALPRO**

Performed: Sun-Sat
Reported: 1-3 days

Reference Interval: Effective August 15, 2016

50 µg/g or less: Normal
51-120 µg/g: Borderline elevated, test should be re-evaluated in 4-6 weeks.
121 µg/g or greater: Abnormal

2002918 **Carbohydrate Deficient Transferrin for Congenital Disorders of Glycosylation (CDG)** **CARBOH-CDG**

New Test **2013433** **Clozapine and Metabolites, Serum or Plasma, Quantitative** **CLOZAP SP**
Available July 18, 2016

Methodology: Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed: Sun-Sat
Reported: 1-3 days

Specimen Required: Patient Prep: Timing of specimen collection: Pre-dose (trough) draw - At steady state concentration.
Collect: Plain Red. Also acceptable: Lavender (K_2 or K_3EDTA) or Pink (K_2EDTA).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Whole blood. Gel separator tubes, light blue (citrate), or yellow (SPS or ACD solution).
Stability (collection to initiation of testing): After separation from cells: Ambient: 5 weeks; Refrigerated: 2 months; Frozen: 2 months

Reference Interval:

Total Clozapine and Metabolites	Therapeutic: Not well established. Toxic: Greater than or equal to 1500 ng/mL

Interpretive Data: Therapeutic ranges are not well established. Clozapine is metabolized to norclozapine and clozapine-N-oxide. Clozapine concentrations between 100 and 700 ng/mL may correlate more with clinical response; however, non-responsiveness may also occur within this range. For refractory schizophrenia, clozapine concentrations greater than 350 ng/mL are suggested to achieve a therapeutic response.

Toxicity: Toxic ranges are not well established. Serum/plasma concentrations greater than or equal to 1500 ng/mL (clozapine, norclozapine and clozapine-N-oxide combined) may cause drug-induced agranulocytosis, Stevens-Johnson syndrome, seizures, hypotension, cardiovascular abnormalities, drowsiness, and death.

Therapeutic and toxic ranges are not well established in children.

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

CPT Code(s): 80159

New York DOH Approved.

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

New Test **2013258** **Consultation, Hematopathology** **HP CONSULT**
Available July 18, 2016

Methodology: Microscopy
Performed: Mon-Fri
Reported: Varies

Specimen Required: Collect: Tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin is preferred) and paraffin embed specimen. Protect paraffin block and/or slides from excessive heat. Transport all case material to include stained slides, paraffin blocks and surgical pathology report.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks: Submit electronic request. If you do not have electronic ordering capability, use an ARUP Anatomic Pathology Form (#32960) with an ARUP client number. For additional technical details, contact ARUP Client Services at (800) 522-2787.
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: Refer to report.

Note: Appropriate stains and other ancillary testing may be performed and charged separately. Tests requested by the referring physician (eg., immunostains, molecular studies, etc.) may not be performed if they are deemed to be unnecessary by the reviewing ARUP pathologist. For all pathology consultations, ancillary testing is ordered at the discretion of the ARUP pathologist.

CPT Code(s): 88321 or 88323 or 88325, if ancillary testing is performed, additional CPT codes and charges may apply

New York DOH approval pending. Call for status update.

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

0081117 **Cortisol, Saliva** **CORT SAL**

HOT LINE NOTE: There is a component change associated with this test that affects interface clients only.
Remove component 0092538, Saliva Collection Time

0020509 **Creatinine, Body Fluid** **CRT-FL**

Specimen Required: Collect: Peritoneal fluid.
Unacceptable Conditions: Specimens other that those listed.

Interpretive Data: Reference ranges for this assay have not been established for body fluid testing. Results should be interpreted in comparison to the concentration in blood and in conjunction with clinical context.

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

0020025 **Creatinine, Serum or Plasma** **CRT**

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

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

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

Interpretive Data:
Background Information for Cytochrome P450 2D6 (*CYP2D6*) 14 Variants and Gene Duplication:
Characteristics: Impaired drug metabolism causing adverse drug reactions or lack of drug response. Drugs metabolized by *CYP2D6* include antiestrogens (tamoxifen), alpha-blockers, analgesics, anticonvulsives, antidepressants, antidiabetics, antihypertensives, antipsychotics, antitussives, beta blockers, cardioactives, norepinephrine reuptake inhibitors, and stimulants. Additionally, many drugs inhibit *CYP2D6* activity, and may affect drug response.
Inheritance: Autosomal co-dominant.
Cause: *CYP2D6* gene variants.
Variants Tested: (Variants are numbered according to M33388 sequence.)
Functional: *2 (2850C>T), *2A (-1584C>G; 2850C>T).
Decreased function: *9 (2613-5delAGA), *10 (100C>T), *17 (1023C>T), *29 (1659G>A) *41 (2988G>A).
Non-functional: *3 (2549delA), *4 (1846G>A), *5 (gene deletion),*6 (1707delT), *7 (2935A>C), *8 (1758G>T), *12 (124G>A), *14 (1758G>A).
Increased function: Duplicated functional alleles.
Negative: No mutations detected is predictive of *1 functional alleles.
Incidence of Poor Metabolizer Phenotype: Caucasians and Hispanics - 10 percent; African Americans - 2 percent; Asians - 1 percent..
Clinical Sensitivity: Drug dependent.
Methodology: Multiplex polymerase chain reaction and detection primer extension.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Only the targeted *CYP2D6* variants will be detected by this panel. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with CYP2D6 substrates may be affected by genetic and non-genetic factors that are not detected by this test. This result does not replace the need for therapeutic drug or clinical monitoring.

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

HOT LINE NOTE: There is a component change associated with this test.
Remove component 0051512, CYP2D6 Predicted Phenotype
Remove component 0051513, CYP2D6 Variant
Remove component 0051514, CYP2D6 Variant
Remove component 0051515, CYP2D6 Variant
Remove component 0051516, CYP2D6 Variant
Add component 2008925, CYP2D6 Genotype
Add component 2008926, CYP2D6 Phenotype

2000135 Cytology, SurePath Liquid-Based Pap Test with Reflex to Human Papillomavirus (HPV), High Risk by PCR, SurePath — GR REQUEST

Methodology: Microscopy/ Qualitative Polymerase Chain Reaction
Performed: Sun-Sat
Reported: 1-14 days

Note: If the SurePath Liquid-Based Pap Test is interpreted as atypical squamous cells of undetermined significance (ASC-US), then Human Papillomavirus (HPV) High Risk by PCR, SurePath will be added. Additional charges apply.

HOT LINE NOTE: There is a reflexive pattern change associated with this test.
Remove reflex to 0065141 Human Papillomavirus (HPV), High Risk by Hybrid Capture and add reflex to 2011942 Human Papillomavirus (HPV), High Risk by PCR, SurePath

2000133 **Cytology, SurePath Liquid-Based Pap Test and Human Papillomavirus (HPV), High Risk by PCR, SurePath (for routine co-testing in women over 30)** **GH REQUEST**

Methodology: Microscopy/Qualitative Polymerase Chain Reaction
Performed: Sun-Sat
Reported: 1-14 days

Note: If the SurePath Liquid-Based Pap Test is interpreted as atypical squamous cells of undetermined significance (ASC-US), then Human Papillomavirus (HPV) High Risk by PCR, SurePath will be added. Additional charges apply. Unsatisfactory SurePath Liquid-Based Pap test specimens will not be tested for HPV.

CPT Code(s): 88142 or 88143, if reviewed by pathologist add 88141; if reflexed to HPV, add 87624

HOT LINE NOTE: There is a reflexive pattern change associated with this test.
Remove reflex to 0060744 Human Papillomavirus (HPV), High Risk by Hybrid Capture, SurePath and add reflex to 2011942 Human Papillomavirus (HPV), High Risk by PCR, SurePath

2006621 **Drug Detection Panel, Umbilical Cord Tissue, Qualitative** **TOF SCR CD**

CPT Code(s): 80304; 80301 (Alt codes: G0479; G0482)

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

Reference Interval:

Drugs Covered and Cutoff Concentrations

Drugs/Drug Classes	Screen
Amphetamines	30 ng/mL
Methamphetamine	30 ng/mL
Barbiturates	75 ng/mL
Benzodiazepines	75 ng/mL
Buprenorphine	Effective Aug 15, 2016 1 ng/mL
Cannabinoids	30 ng/mL
Cocaine	30 ng/mL
Methadone	40 ng/mL
Opiates	30 ng/mL
Oxycodone	30 ng/mL
Phencyclidine	15 ng/mL

CPT Code(s): 80301; if positive, add appropriate CPT code(s): 80324; 80359; 80345; 80347; 80349; 80353; 80358; 80361; 80365; 80348; 83992 (Alt code: G0479; if positive, add appropriate CPT code(s): G0480)

HOT LINE NOTE: There is a component change associated with this test.
Remove component 0092429, Propoxyphene, S/P, Screen
Add component 2013568, Buprenorphine, S/P, Screen

2012868 ***EGFR* T790M Mutation Detection in Circulating Tumor DNA by Digital Droplet PCR** **EGFR T790M**

2008916 **Encephalitis Panel with Reflex to Herpes Simplex Virus Types 1 and 2 Glycoprotein G-Specific Antibodies, IgG, CSF** **ENCEPHCSF**

HOT LINE NOTE: There is a numeric map change associated with this test that affects interface clients only.
Change the numeric map for component 0054444, VZV Antibody IgG CSF from XXXX.X to XXXXX

2008915 **Encephalitis Panel with Reflex to Herpes Simplex Virus Types 1 and 2 Glycoprotein G-Specific Antibodies, IgG, Serum** **ENCEPH**

HOT LINE NOTE: There is a numeric map change associated with this test that affects interface clients only.
Change the numeric map for component 0050167, Varicella-Zoster Virus Ab, IgG from XXXX.X to XXXXX

2010921 **Eosinophil Granule Major Basic Protein, Tissue** **EGMBP TIS**

Specimen Required: Specimen Preparation: Transport tissue in Michel's media (ARUP supply #45462) available online through eSupply using ARUP Connect or call ARUP Client Services at (800) 522-2787. Also acceptable: Zeus tissue fixative.
Unacceptable Conditions:
Stability (collection to initiation of testing): Ambient: 10 days; Refrigerated: 10 days; Frozen: Unacceptable

HOT LINE NOTE: Remove information found in the Unacceptable Conditions field.

2002902 **Epstein-Barr Virus (EBV) by in situ Hybridization, Paraffin** **EBV ISH**

Specimen Required: Specimen Preparation: Formalin fix (10% neutral buffered formalin) and paraffin-embed tissue. Transport tissue block or 5 unstained 5 micron slides. (Min: 4 slides) Protect paraffin block and/or slides from excessive heat.

New Test **2013592** **Epstein-Barr Virus (EBV) by In Situ Hybridization, Stain Only** **SO EBV ISH**
Available July 18, 2016

Immunohistochemistry Stain Form Recommended (ARUP form #32978)

Additional Technical Information

Methodology: In situ Hybridization
Performed: Mon-Fri
Reported: 2-5 days

Specimen Required: Collect: Tissue or cells.
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 6 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (ARUP supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 3 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: **IMMUNOHISTOCHEMISTRY ORDERING AND SUBMISSION DETAILS:** Submit electronic request. If you do not have electronic ordering capability, use an ARUP Immunohistochemistry Stain Form (#32978) with an ARUP client number. For additional technical details, contact ARUP Client Services at (800) 522-2787.
Unacceptable Conditions: Specimens submitted with non-representative tissue type. Depleted specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Reference Interval: Negative

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

CPT Code(s): 88365

New York DOH Approved.

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

2012695 **Ethyl Glucuronide Screen Only, Urine** **ETG SCR UR**

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HOT LINE NOTE: There is a unit of measure change associated with this test that affects interface clients only.
Add unit of measure for component 2012696, Ethyl Glucuronide, Urn, Screen as ng/mL

2007912 **Ethyl Glucuronide Screen with Reflex to Confirmation, Urine** **ETG SCR**

Reference Interval: Screen cutoff concentration: 500 ng/mL

New Test **2013518** **Fatty Acids Profile, Essential Serum or Plasma** **FA PRO SP**
Available August 15, 2016

Patient History For Biochemical Genetics

Methodology: Quantitative Gas Chromatography/Mass Spectrometry/Stable Isotope Dilution
Performed: Varies
Reported: 4-10 days

Specimen Required: Patient Prep: Patient must fast overnight for 12-14 hours. Patient must not consume any alcohol for 24 hours prior to collection.
Collect: **Plasma:** Green (sodium or lithium heparin) or Lavender (EDTA).
Serum: Plain Red or Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 45 minutes of draw. Transfer 0.5 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.15 mL) Freeze immediately.
Storage/Transport Temperature: Frozen.
Remarks: Patient age is required on the test request form. Include information regarding treatment, family history, and tentative diagnosis.
Unacceptable Conditions: Grossly hemolyzed, icteric, lipemic, or non-fasting specimens.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 1 week; Frozen: 3 months

Reference Interval: By Report

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

CPT Code(s): 82542

New York DOH approval pending. Call for status update.

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

0080120 **Fatty Acids, Free** **FFA**

Specimen Required: Collect: Serum Separator Tube (SST). Collect on ice.

2012636 **Gastrin, 1 Minute** **GAST 1**

CPT Code(s): 82938

2012734 **Gastrin, 10 Minute** **GAST 10**

CPT Code(s): 82938

2012638 **Gastrin, 2 Minute** **GAST 2**

CPT Code(s): 82938

2012736 **Gastrin, 30 Minute** **GAST 30**

CPT Code(s): 82938

2012732 **Gastrin, 5 Minute** **GAST 5**

CPT Code(s): 82938

New Test **2013577** **Gastrointestinal Viral Panel by PCR** **GIVIRALPCR**
Available August 15, 2016

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

Specimen Required: Collect: Stool.
Specimen Preparation: Transfer 1 mL stool to an unpreserved stool transport vial (ARUP Supply #40910) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 0.5 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Formalin-fixed stool.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 2 weeks; Frozen: 2 weeks

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

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

Note: This assay detects Astrovirus, Sapovirus, Rotavirus, Adenovirus Type 40/41, and differentiates Norovirus Group 1 and Group 2.

CPT Code(s): 87506

New York DOH approval pending. Call for status update.

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

New Test **2013590** **Heat Shock Protein 70, IgG by Immunoblot** **HSP**
Available October 3, 2016

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

Specimen Required: Collect: Serum Separator Tube (SST) or Plain Red.
Specimen Preparation: Transfer 0.5 mL serum to an ARUP Standard Transport Tube. (Min: 0.1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Urine or plasma. Heat inactivated and contaminated specimens.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval: Negative

Interpretive Data: The presence of HSP70 IgG antibodies may be useful in predicting corticosteroid responsiveness in a subset of patients with autoimmune inner ear disease (AIED) characterized by idiopathic rapidly progressive sensorineural hearing loss (SNHL). HSP70 IgG antibodies are also associated with a number of autoimmune diseases and have also been reported in apparently healthy individuals. A negative result does not rule out response to treatment or to a diagnosis of AIED.

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

CPT Code(s): 83516

New York DOH approval pending. Call for status update.

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

New Test **2013399** **Hemoglobin S, Sickle Solubility** **SICKLE**
Available August 15, 2016

Additional Technical Information
(Required: Initial Hemoglobin S results)

Methodology: RBC Solubility
Performed: Sun-Sat
Reported: 1-3 days

Specimen Required: Collect: Lavender (EDTA) or Pink (K_2EDTA).
Specimen Preparation: Transport 5 mL whole blood. (Min: 0.2 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data: Refer to report.

CPT Code(s): 85660

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

2010793 **Hepatitis C Virus (HCV) by Quantitative PCR with Reflex to HCV High-Resolution Genotype by Sequencing** **HCV QT HGR**

Note: The limit of quantification for the Hepatitis C Virus by Quantitative PCR assay is 1.2 log IU/mL (15 IU/mL). If the assay DID NOT DETECT the virus, the test result will be reported as "<1.2 log IU/mL (<15 IU/mL)." If the assay DETECTED the presence of the virus but was not able to accurately quantify the number of copies the test result will be reported as "Not Quantified."

If Hepatitis C Virus by Quantitative PCR result is greater than or equal to 5.0 log IU/mL, then Hepatitis C Virus High-Resolution Genotype by Sequencing will be added. Additional charges apply.

2009255 **Hepatitis C Virus (HCV) Genotype with Reflex to HCV High-Resolution Genotype by Sequencing** **HCV REFLEX**

Note: This test may be unsuccessful if HCV RNA viral load is less than log 5.0 or 100,000 IU/mL. If initial result is 1a or 1b, or a mixed genotype containing Type 1, or Type 6, then Hepatitis C High Resolution Genotyping will be added. Additional charges apply.

2006898 **Hepatitis C Virus High-Resolution Genotype by Sequencing** **HCV CORE**

Note: This test may be unsuccessful if the HCV RNA viral load is less than log 5.0 or 100,000 IU/mL.

New Test **2013599** **Insulin-Like Growth Factor 2** **IGF-2**
Available August 15, 2016

Methodology: Quantitative Enzyme-Linked Immunosorbent Assay
Performed: Tuesday
Reported: 1-8 days

Specimen Required: Collect: Plain Red or Serum Separator Tube (SST).
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transfer 0.5 mL serum to an ARUP Standard Transport Tube. (Min: 0.2 mL) Freeze immediately.
Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Unacceptable Conditions: Hemolyzed, lipemic, or icteric.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 2 days; Frozen: 2 months

Reference Interval:

Prepubertal (0-11 years old)	127 to 473 ng/mL
Post-pubertal (12 years and older)	180 to 580 ng/mL

Interpretive Data: Refer to report.

CPT Code(s): 83520

New York DOH approval pending. Call for status update.

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

New Test **2013595** **Kappa/Lambda Light Chain Panel by In Situ Hybridization, Stain Only** **SO K/L ISH**
Available July 18, 2016

Immunohistochemistry Stain Form Recommended (ARUP form #32978)

Additional Technical Information

Methodology: In situ Hybridization
Performed: Mon-Fri
Reported: 2-5 days

Specimen Required: Collect: Tissue or cells.
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 8 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (ARUP supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 4 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: **IMMUNOHISTOCHEMISTRY ORDERING AND SUBMISSION DETAILS:** Submit electronic request. If you do not have electronic ordering capability, use an ARUP Immunohistochemistry Stain Form (#32978) with an ARUP client number. For additional technical details, contact ARUP Client Services at (800) 522-2787.
Unacceptable Conditions: Specimens submitted with non-representative tissue type. Depleted specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Reference Interval: Negative

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

CPT Code(s): 88368; 88369

New York DOH Approved.

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

0080650 **17-Ketosteroids, Urine** **17 KETO**

Specimen Required: Specimen Preparation: Transfer two 4 mL aliquots from a well-mixed 24-hour urine collection into 2 ARUP Standard Transport Tubes or 2 ARUP Standard Transport Tubes containing 20 mg Sulfamic Acid (ARUP supply #48098) available online through eSupply using ARUP Connect™ or by contacting ARUP Client Services at (800) 522-2787. (Min: 3 mL/aliquot) Adequate refrigeration is the most important aspect of specimen preservation.
Remarks: Record total volume and collection time interval on transport tube and test request form.

2007254 **Manganese, RBC** **MANG RBC**

Specimen Required: Specimen Preparation: Separate cells ASAP or within 2 hours of collection. Transport 1 mL RBCs in the original collection tube. (Min: 0.4 mL)

0040005 **Manual Differential** **DIFF**

HOT LINE NOTE: There is a component change associated with this test.
Add component 2013603, Artifact
Add component 2013604, Atypical/Reactive Lymphocyte
Add component 2013634, Auer Rods
Add component 2013611, Echinocytes
Add component 2013618, Elliptocytes
Add component 2013619, Hairy Cell
Add component 2013620, Helmet Cells
Add component 2013621, Immature Basophil
Add component 2013622, Immature Eosinophil
Add component 2013623, Large Gran Lymphocyte
Add component 2013624, Megakaryocyte
Add component 2013625, Parasites
Add component 2013626, Plasmacyte
Add component 2013627, Prolymphocyte
Add component 2013628, Promonocyte
Add component 2013629, Sezary Cell
Add component 2013630, Stomatocytes

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

CPT Code(s): 81440

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

CPT Code(s): 81440, 81465

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

CPT Code(s): 81440, 81460, 81465

0051281 **Norovirus Group 1 and 2 by PCR** **NORO PCR**

Performed: Mon, Wed, Fri
Reported: 1-5 days

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

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

2011375 **Occupation Screen - MMR/VZV Antibody Assessment Panel, IgG** **MMRV PAN**

CPT Code(s): 86765; 86735; 86762; 86787

HOT LINE NOTE: There is a numeric map change associated with this test that affects interface clients only.
Change the numeric map for component 2011399, Varicella-zoster Virus Ab IgG from XXXX.X to XXXXX

0020482 **Oxalate, Urine** **UOXAL**

Specimen Required: Specimen Preparation: Thoroughly mix entire collection (24-hour) in one container. Freeze specimens immediately after aliquoting. Do not exceed 4 mL in tubes.
Preserved: Transfer 4 mL aliquot to an ARUP Transport Tube with 20 mg Sulfamic Acid (ARUP supply #48098). Available online through eSupply using ARUP Connector contact ARUP Client Services at (800) 522-2787. Mix well. (Min: 1.5 mL)
Unpreserved: If the collection tube with Sulfamic Acid is not available, transport a 4 mL unadjusted aliquot of urine. (Min: 1.5 mL)

0095611 **Parathyroid Hormone, CAP** **CAP**

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

2012007 **Skeletal Dysplasia Panel, Deletion/Duplication, 36 Genes** **SKEL DD**

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

2012015 **Skeletal Dysplasia Panel, Sequencing (39 Genes) and Deletion/Duplication (36 Genes)** **SKEL PANEL**

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, FLNA, FLNB, GNPAT, IFT80, LBR, LEPRE1, LIFR, NEK1, PEX7, POR, PPIB, RUNX2, SERPINH1, SLC26A2, SCL35D1, SOX9, TRIP11, TTC21B, WDR19, WDR35*

2012010 **Skeletal Dysplasia Panel, Sequencing (39 Genes) and Deletion/Duplication (36 Genes), Fetal** **SKEL FE**

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, FLNA, FLNB, GNPAT, IFT80, LBR, LEPRE1, LIFR, NEK1, PEX7, POR, PPIB, RUNX2, SERPINH1, SLC26A2, SCL35D1, SOX9, TRIP11, TTC21B, WDR19, WDR35*

2011704 **Smith-Lemli-Opitz Syndrome (*DHCR7*) Sequencing, Fetal** **DHCR7 FE**

Specimen Required: Collect: **Fetal Specimen:** Two T-25 flasks at 80 percent confluent culture of amniocytes. **If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787.**
Maternal Whole Blood: Lavender (K_2EDTA), Lavender (K_3EDTA), Pink (K_2EDTA), or Yellow (ACD Solution A or B).
Specimen Preparation: **Cultured Amniocytes**: Fill flask with culture media. Transport two T-25 flasks at 80 percent confluent of culture amniocytes filled with culture media.
Maternal Whole Blood: Transport 3 mL whole blood (Min: 1mL)
Storage/Transport Temperature: **Cultured Amniocytes: CRITICAL ROOM TEMPERATURE.** Must be received within 48 hours of shipment due to liability of cells.
Maternal Whole Blood: Room temperature.

New Test **2013436** **Spinal Muscular Atrophy (SMA) Copy Number Analysis** **SMA DD**
Available July 18, 2016

Patient History for Spinal Muscular Atrophy (SMA) Testing

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: 2 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:
Background information for Spinal Muscular Atrophy (SMA) Copy Number Analysis
Characteristics: Spinal muscular atrophy (SMA) is the most common lethal genetic disease in children, and is characterized by progressive muscle weakness due to degeneration of the lower motor neurons. Onset ranges from before birth to adulthood and severity is highly variable. Individuals with SMA have no (zero) functioning copies of the *SMN1* gene that produces survival motor neuron protein; most (95 percent) have homozygous loss of *SMN1* due to deletion or gene conversion, while some (5 percent) have a sequence variant in one remaining copy of *SMN1*. The *SMN2* gene, adjacent and highly homologous to *SMN1*, produces lower levels of survival motor neuron protein compared to *SMN1*. Disease severity has been shown to be modified by *SMN2* gene copy number in some cases, but phenotype cannot be predicted with certainty. *SMN2* copy number will be reported for individuals with zero copies of *SMN1* or symptomatic individuals with one copy of *SMN1*. Two variants that are part of a haplotype associated with *SMN1* duplication in silent carriers (2 copies of *SMN1* on one chromosome with zero copies on the other) will be reported if detected with 2 or more copies of *SMN1* in the context of carrier screening. The presence of these variants, particularly in Ashkenazi Jews and Asians, increases the likelihood that 2 copies of *SMN1* are on the same chromosome but this is not definitive.
Inheritance: Autosomal recessive
Cause: Pathogenic mutations in the *SMN1* gene.
Variants Tested: For copy number: *SMN1* (NM_000344.3) exon 7 c.840C and exon 8 c.*239G, and *SMN2* (NM_017411.3) exon 7 c.840T. For haplotype associated with *SMN1* duplication (silent carriers): *SMN1* c.*3+80T>G (rs143838139) and c.*211_*212del (rs200800214).
Clinical sensitivity: 95-98 percent in individuals affected with SMA. Detection rate for carrier screening is 95 percent in Caucasians, 94 percent in Ashkenazi Jewish, 93 percent in Asians, 71 percent in African Americans, and 91 percent in Hispanics.
Methodology: Multiplex probe ligation-dependent amplification (MLPA)
Analytical sensitivity and specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Single base pair substitutions, small deletions/duplications, regulatory region mutations, and deep intronic mutations will not be detected. This test is unable to determine chromosomal phase of *SMN1* or *SMN2* copies. Even if the variants associated with *SMN1* duplication are detected, the test cannot definitively differentiate individuals with one or more copies of *SMN1* on each chromosome from individuals with two or more copies of *SMN1* on one chromosome and zero on the other (silent carriers).

Counseling and informed consent are recommended for genetic testing. Consent forms are available online at www.aruplab.com.

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

CPT Code(s): 81401

New York DOH approval pending. Call for status update.

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

New Test 2013444 **Spinal Muscular Atrophy (SMA) Copy Number Analysis, Fetal** **SMA DD FE**
Available July 18, 2016

Patient History for Fetal Molecular Testing

Time Sensitive

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

Methodology: Multiplex Ligation-dependent Probe Amplification
Performed: Varies
Reported: 7-10 days

Specimen Required: Collect: **Fetal Specimen**: Two T-25 flasks at 80 percent confluency of cultured amniocytes**. If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787.**
AND Maternal Cell Contamination Specimen: Lavender (EDTA), Pink (K_2EDTA), or Yellow (ACD Solution A or B).
Specimen Preparation: **Cultured Amniocytes:** Fill flasks with culture media. Transport two T-25 flasks at 80 percent confluency of cultured amniocytes. Backup cultures must be retained at the client's institution until testing is complete.
Maternal Cell Contamination Specimen: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: **Amniotic Fluid:** Room temperature.
Cultured Amniocytes: CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of shipment due to viability of cells.
Maternal Cell Contamination Specimen: Room temperature.
Remarks: **Maternal specimen is recommended for proper test interpretation. Order Maternal Cell Contamination. Patient History Form is available on the ARUP Web site or by contacting ARUP Client Services at (800) 522-2787.**
Stability (collection to initiation of testing): **Fetal Specimen:** Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Maternal Cell Contamination Specimen: Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:
Background information for Spinal Muscular Atrophy (SMA) Copy Number Analysis, Fetal
Characteristics: Spinal muscular atrophy (SMA) is the most common lethal genetic disease in children, and is characterized by progressive muscle weakness due to degeneration of the lower motor neurons. Onset ranges from before birth to adulthood and severity is highly variable. Individuals with SMA have no (zero) functioning copies of the *SMN1* gene that produces survival motor neuron protein; most (95 percent) have homozygous loss of *SMN1* due to deletion or gene conversion, while some (5 percent) have a sequence variant in one remaining copy of *SMN1*. The *SMN2* gene, adjacent and highly homologous to *SMN1*, produces lower levels of survival motor neuron protein compared to *SMN1*. Disease severity has been shown to be modified by *SMN2* gene copy number in some cases, but phenotype cannot be predicted with certainty. *SMN2* copy number will be reported for individuals with zero copies of *SMN1* or symptomatic individuals with one copy of *SMN1*.
Inheritance: Autosomal recessive
Cause: Pathogenic mutations in the *SMN1* gene.
Variants Tested: For copy number: *SMN1* (NM_000344.3) exon 7 c.840C and exon 8 c.*239G, and *SMN2* (NM_017411.3) exon 7 c.840T.
Clinical sensitivity: 95-98 percent in individuals affected with SMA.
Methodology: Multiplex probe ligation-dependent amplification (MLPA)
Analytical sensitivity and specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Single base pair substitutions, small deletions/duplications, regulatory region mutations, and deep intronic mutations will not be detected. This test is unable to determine chromosomal phase of *SMN1* or *SMN2* copies.
For quality assurance purposes, ARUP Laboratories will confirm the above result at no charge following delivery. Order Confirmation of Fetal Testing and include a copy of the original fetal report (or the mother's name and date of birth) with the test submission. Please contact an ARUP genetic counselor at (800) 242-2787 extension 2141 prior to specimen submission.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online at www.aruplab.com.

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

CPT Code(s): 81401; 81265

New York DOH approval pending. Call for status update.

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

0050642 ***Streptococcus pyogenes*, Group A Antibody (Streptozyme) with Reflex to Titer** **STZ R**

HOT LINE NOTE: There is a component change associated with this test.
Remove component 0050644, Streptozyme Titer

2006685 **Thyroglobulin, Serum or Plasma with Reflex to LC-MS/MS or CIA** **THYROGRFX**

Specimen Required: Storage/Transport Temperature: Frozen.

0020183 **Urea Nitrogen, Fluid** **FL UN**

Specimen Required: Collect: Peritoneal fluid.
Unacceptable Conditions: Specimen types other than those listed.

Interpretive Data: Reference ranges for this assay have not been established for body fluid. Results should be interpreted in comparison to the concentration in blood and in conjunction with clinical context.

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

0050162 **Varicella-Zoster Virus Antibodies, IgG and IgM** **VZV PAN**

HOT LINE NOTE: There is a numeric map change associated with this test that affects interface clients only.
Change the numeric map for component 0050167, Varicella-Zoster Virus Ab, IgG from XXXX.X to XXXXX

0050167 **Varicella-Zoster Virus Antibody, IgG** **VZE**

HOT LINE NOTE: There is a numeric map change associated with this test that affects interface clients only.
Change the numeric map for component 0050167, Varicella-Zoster Virus Ab, IgG from XXXX.X to XXXXX

0054444 **Varicella-Zoster Virus Antibody, IgG, CSF** **VZECSF**

HOT LINE NOTE: There is a numeric map change associated with this test.
Change the numeric map for component 0054444, VZV Antibody IgG CSF from XXXX.X to XXXXX

The following will be discontinued from ARUP's test menu on October 3, 2016.
Replacement test options are supplied if applicable.

Test Number	Test Name	Refer To Replacement
2003496	Caspase-3 by Immunohistochemistry	
2003583	CD45RO by Immunohistochemistry	
0098930	Clozapine	Clozapine and Metabolites, Serum or Plasma, Quantitative (2013433)
2006476	Clozapine and Metabolite Quantitative, Serum or Plasma	Clozapine and Metabolites, Serum or Plasma, Quantitative (2013433)
2003881	Factor VIII by Immunohistochemistry	
0095302	Fatty Acids Profile, Essential (C12-C22)	Fatty Acids Profile, Essential Serum or Plasma (2013518)
2010198	Gastrointestinal Hereditary Cancer Panel, Sequencing and Deletion/Duplication, 15 Genes	Gastrointestinal Hereditary Cancer Panel, Sequencing and Deletion/Duplication, 16 Genes (2013449)
0097338	Heat Shock Protein 70 (68 kDa), IgG by Western Blot	Heat Shock Protein 70, IgG by Immunoblot (2013590)
0093900	Hist/Hpath Tracking Test	
0060744	Human Papillomavirus (HPV), High Risk by Hybrid Capture, SurePath	Human Papillomavirus (HPV), High Risk by PCR, SurePath (2011942)
2007565	Insulin-Like Growth Factor 2 (IGF-2)	Insulin-Like Growth Factor 2 (2013599)
2007394	Ovarian Antibody, IgG Screen with Reflex to Titer by IFA	
2008789	Spinal Muscular Atrophy (SMA) Carrier Screening	Spinal Muscular Atrophy (SMA) Copy Number Analysis (2013436)
2012086	Urine Cotinine Rapid	
2004178	Villin by Immunohistochemistry	
0049176	Wright's Stain	