HOTLINE: Effective November 15, 2021

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.

The regulations described above are only guidelines. Additional procedures may be required by your fiscal intermediary or carrier.

Hotline 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
49	2011906	Adrenoleukodystrophy, X-Linked (ABCD1) Sequencing and Deletion/Duplication												x
6	3004262	Ammonium, 24-Hour Urine											x	
49	2005564	Angelman Syndrome (UBE3A) Sequencing												x
7	2003222	Antiphospholipid Syndrome Reflexive Panel					x							
7	2011478	Arsenic, Random Urine with Reflex to Fractionated						x	x					
8	0025000	Arsenic, Urine with Reflex to Fractionated						x	x					
9	3001431	Autoimmune Encephalitis Extended Panel, Serum				x	x		x	x	x	x		
49	2013601	Autoimmune Encephalitis Reflexive Panel, Serum												x

Hotline 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
10	3004070	Autoimmune Neurologic Disease Reflexive Panel, Serum				x	x		x	x	x	x		
11	3004244	BAP1 by Immunohistochemistry											x	
12	0092099	B-Cell CD20 Expression								x				
12	0050321	Beta-2 Glycoprotein 1 Antibodies, IgG and IgM					x							
12	2002569	Beta-2 Glycoprotein 1 Antibodies, IgG, IgM and IgA					x							
12	0050324	Beta-2 Glycoprotein 1 Antibody, IgA					x							
12	0090067	BK Virus, Quantitative PCR				x								
12	2002304	BK Virus, Quantitative PCR, Blood				x								
12	0062224	*Blastomyces dermatitidis* Identification		x								x		
13	2002498	*BRAF* Codon 600 Mutation Detection by Pyrosequencing (Pricing Change)				x			x	x				
13	0051750	BRAF Codon 600 Mutation Detection with Reflex to MLH1 Promoter Methylation (Pricing Change)							x	x				
13	0050140	C1-Esterase Inhibitor		x	x	x	x					x		
14	0050139	C-1-Esterase Inhibitor Panel		x	x	x	x					x		
14	0099460	Calculi (Stone) Analysis									x			
14	2005231	Calculi (Stone) Analysis with Photo									x			
15	0099344	Cardiolipin Antibodies, IgG and IgM					x							
15	0051162	Cardiolipin Antibodies, IgG, IgM, and IgA					x							
15	0098358	Cardiolipin Antibody, IgA					x							
15	0050901	Cardiolipin Antibody, IgG					x							
16	0050902	Cardiolipin Antibody, IgM					x							
16	2004247	*CEBPA* Mutation Detection				x								
49	2012151	Charcot-Marie-Tooth (CMT) and Related Hereditary Neuropathies Panel, Sequencing												x
49	2007069	Citrullinemia, Type I (ASS1) Sequencing												x
16	0062225	*Coccidioides immitis* Identification		x								x		
16	3001524	Cytochrome P450 Genotyping Panel									x			
17	3004255	Cytochrome P450 Genotyping Panel, with GeneDose Access											x	
18	3004275	Cytogenomic Molecular Inversion Probe Array FFPE Tissue - Oncology											x	
19	3004273	Cytogenomic Molecular Inversion Probe Array FFPE Tissue - Products of Conception											x	
49	2010229	Cytogenomic Molecular Inversion Probe Array, FFPE Tissue - Oncology												x

Hotline 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
49	2010795	Cytogenomic Molecular Inversion Probe Array, FFPE Tissue - Products of Conception												x
49	2009353	Cytogenomic SNP Microarray with Five-Cell Chromosome Study, Constitutional Blood												x
20	3004359	Dipeptidyl Aminopeptidase-Like Protein 6 (DPPX) Antibody, IgG by IFA With Reflex to Titer, Serum											x	
21	2002440	*EGFR* Mutation Detection by Pyrosequencing (Pricing Change)				x			x	x				
21	2007914	*EPOR* Mutation Detection by Sequencing				x								
21	0051626	Epstein-Barr Virus Antibody to Viral Capsid Antigen, IgA				x	x					x		
22	0051627	Epstein-Barr Virus Antibody to Viral Capsid Antigen, IgG and IgA				x	x					x		
22	2007909	Ethyl Glucuronide and Ethyl Sulfate, Urine, Quantitative			x									
23	3001851	Fatty Acid Oxidation Disorders Panel, Sequencing											x	
23	0094030	Felbamate					x	x						
49	2002674	Gastrointestinal Stromal Tumor Mutation												x
24	3004279	Gastrointestinal Stromal Tumor Mutations											x	
25	3001627	Glycogen Storage Disorders Panel, Sequencing											x	
49	2011140	Guanidinoacetate Methyltransferase (GAMT) Deficiency Sequencing												x
49	2001992	Hearing Loss, Nonsyndromic Panel (GJB2) Sequencing, (*GJB6*) 2 Deletions and Mitochondrial DNA 2 Mutations												x
25	2011304	Heavy Metals Panel 3, Random Urine with Reflex to Arsenic Fractionated						x	x					
26	0099475	Heavy Metals Panel 3, Urine with Reflex to Arsenic Fractionated						x	x					
26	0020572	Heavy Metals Panel 4, Urine with Reflex to Arsenic Fractionated						x	x					
26	0025055	Heavy Metals Panel 6, Urine with Reflex to Arsenic Fractionated							x					
27	2001759	Hemophilia A (*F8*) 2 Inversions (Extended TAT as of 11/20/20-no referral available)						x						
28	3004232	Hemophilia A (*F8*) 2 Inversions with Reflex to Sequencing and Reflex to Deletion/Duplication											x	
49	2001614	Hemophilia A (F8) 2 Inversions with Reflex to Sequencing and Reflex to Deletion/Duplication												x
29	2001755	Hemophilia A (*F8*) 2 Inversions, Fetal						x						
30	3004241	Hemophilia A (F8) Sequencing											x	

Hotline 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
49	2001747	Hemophilia A (F8) Sequencing												x
49	2001578	Hemophilia B (F9) Sequencing												x
49	2010494	Hemophilia B (F9) Sequencing and Deletion/Duplication												x
31	3004201	HGAL by Immunohistochemistry											x	
31	0062226	*Histoplasma capsulatum* Identification		x								x		
49	0051650	HNPCC/Lynch Syndrome (MLH1) Sequencing and Deletion/Duplication												x
49	0051654	HNPCC/Lynch Syndrome (MSH2) Sequencing and Deletion/Duplication												x
49	0051656	HNPCC/Lynch Syndrome (MSH6) Sequencing and Deletion/Duplication												x
49	0051737	HNPCC/Lynch Syndrome (PMS2) Sequencing and Deletion/Duplication												x
32	2011940	Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by PCR, ThinPrep											x	
33	3004267	*IDH1* and *IDH2* Mutation Analysis Exon 4, Formalin-Fixed, Paraffin-Embedded (FFPE) Tissue											x	
33	2006444	*IDH1* and *IDH2* Mutation Analysis, exon 4				x								
49	2014188	IDH1 and IDH2 Mutation Analysis, Exon 4, Formalin-Fixed, Paraffin-Embedded (FFPE) Tissue												x
34	0040227	*IGHV* Mutation Analysis by Sequencing				x								
49	2006274	Inherited Insulin Resistance Syndromes (INSR) Sequencing												x
49	2004992	Juvenile Polyposis Syndrome (BMPR1A) Sequencing and Deletion/Duplication												x
34	2002437	*KIT* Mutations in AML by Fragment Analysis and Sequencing				x								
35	3004283	KIT Mutations Melanoma											x	
49	2002695	KIT Mutations, Melanoma												x
35	0040248	KRAS Mutation Detection (Pricing Change)							x	x				
49	2001932	KRAS Mutation Detection with Reflex to *BRAF* Codon 600 Mutation Detection												x
36	2003182	Lacosamide, Serum or Plasma					x	x						
36	2004359	Leukocyte Adhesion Deficiency Panel				x	x	x		x	x			
49	2009313	Li-Fraumeni (TP53) Sequencing and Deletion/Duplication												x
49	2004543	LMNA-Related Disorders (LMNA) Sequencing												x
49	2008894	Lung Cancer Panel												x

Hotline 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
49	2008895	Lung Cancer Panel with KRAS												x
49	2005584	Marfan Syndrome (FBN1) Sequencing and Deletion/Duplication												x
37	3004102	Marfan Syndrome (FBN1) Sequencing and Deletion/Duplication											x	
49	2005589	Marfan Syndrome, FBN1 Sequencing												x
49	0051758	Medium Chain Acyl-CoA Dehydrogenase Deficiency (*ACADM*) Sequencing												x
37	2009310	*MGMT* Promoter Methylation Detection (Pricing Change)				x			x	x				
38	3004277	Microsatellite Instability (MSI) HNPCC/Lynch Syndrome by PCR											x	
49	0051740	Microsatellite Instability (MSI), HNPCC/Lynch Syndrome, by PCR												x
38	2002327	Mismatch Repair by Immunohistochemistry with Reflex to *BRAF* Codon 600 Mutation and *MLH1* Promoter Methylation							x	x				
39	3004308	*MLH1* Promoter Methylation											x	
49	2002499	MLH1 Promoter Methylation, Paraffin												x
49	2005359	Multiple Endocrine Neoplasia Type 1 (*MEN1)* Sequencing												x
49	0098198	Neuron Specific Enolase												x
40	3004314	Neuron Specific Enolase, CSF											x	
49	0081226	Neuron Specific Enolase, CSF												x
40	3004312	Neuron Specific Enolase, Serum											x	
41	3004316	NKX2.2 by Immunohistochemistry											x	
49	0051805	Noonan Syndrome (PTPN11) Sequencing												x
41	2003123	*NRAS* Mutation Detection by Pyrosequencing (Pricing Change)				x			x	x				
42	0098833	Olanzapine	x		x	x	x	x						
49	2004896	Ornithine Transcarbamylase Deficiency (OTC) Sequencing and Deletion/Duplication												x
49	2010703	Pancreatitis (CTRC) Sequencing												x
43	3002700	Peroxisomal Disorder Panel, Sequencing											x	
49	2008398	Peutz-Jeghers Syndrome (STK11) Sequencing and Deletion/Duplication												x
49	2004203	Primary Carnitine Deficiency (SLC22A5) Sequencing and Deletion/Duplication												x
49	2002470	PTEN-Related Disorders (PTEN) Sequencing and Deletion/Duplication												x

Hotline 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
49	3002059	Pyruvate Kinase Deficiency (PKLR) Sequencing												x
49	0051614	Rett Syndrome (MECP2), Sequencing and Deletion/Duplication												x
49	2011457	Smith-Lemli-Opitz Syndrome (DHCR7) Sequencing												x
49	2007991	Solid Tumor Mutation Panel by Next Generation Sequencing												x
44	3004294	Solid Tumor Mutation Panel, Sequencing											x	
50	2010015	Telangiectasia Syndrome (BMP9/GDF2) Sequencing												x
45	2006385	Thrombotic Risk Reflexive Panel					x							
50	0065153	Vaginal Pathogen Panel by DNA Probe												x
50	2002970	von Hippel-Lindau (VHL) Sequencing												x
50	2002965	von Hippel-Lindau (VHL) Sequencing and Deletion/Duplication												x
50	2005476	von Willebrand Disease, Platelet Type (*GP1BA*) 4 Mutations												x

New Test **3004262** **Ammonium, 24-Hour Urine** **AMMO U**

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Methodology: Quantitative Enzymatic
Performed: Varies
Reported: 3-5 days

Specimen Required: Collect: 24-hour urine. Refrigerate during collection or add 5 mL of diazolidinyl urea (Germall) as preservative at start of collection.
Specimen Preparation: From a well-mixed 24-hour collection, transfer 4 mL urine to an ARUP Standard Transport Tube. (Min: 1 mL). Collection duration and urine volume must be provided for testing.
Test is not performed at ARUP; separate specimens must be submitted when multiple tests are ordered.
Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen.
Remarks: Specimens with pH >8 may indicate bacterial contamination and testing will be cancelled. Do not attempt to adjust pH as it will adversely affect results.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 2 weeks

Reference Interval: By Report

Note: Reference values have not been established for patients less than 18 years and greater than 77 years of age. The presence of sulfasalazine, sulfapyridine, or temozolomide may lead to false results.

CPT Code(s): 82140

New York DOH Approved.

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

2003222 Antiphospholipid Syndrome Reflexive Panel PHOS SYN

Reference Interval:
Effective November 15, 2021

Available Separately	Components	Reference Interval
No	Beta-2 Glycoprotein 1 Antibody, IgG	<=20 SGU
No	Beta-2 Glycoprotein 1 Antibody, IgM	<=20 SMU
Yes (0050901)	Cardiolipin Antibody, IgG	Effective November 15, 2021 <=14 GPL: Negative 15-19 GPL: Indeterminate 20-80 GPL: Low to Moderately Positive 81 GPL or above: High Positive
Yes (0050902)	Cardiolipin Antibody, IgM	Effective November 15, 2021 <=12 MPL: Negative 13-19 MPL: Indeterminate 20-80 MPL: Low to Moderately Positive 81 MPL or above: High Positive
Yes (0030215)	Prothrombin Time	Effective February 18, 2014 12.0-15.5 seconds
Yes (0030235)	Partial Thromboplastin Time	Effective February 18, 2014 32-48 seconds
No	Dilute Russell Viper Venom Time (dRVVT)	Effective February 18, 2014 33-44 seconds
No	Thrombin Time	Effective February 18, 2014 14.7-19.5 seconds
No	Reptilase Time	Effective February 18, 2014 Less than 22.0 seconds
No	PTT Heparin Neutralized	Effective February 18, 2014 32-48 seconds
No	Partial Thromboplastin Time 1:1 Mix (performed if PTT >48 seconds)	Effective February 18, 2014 32-48 seconds
No	Platelet Neutralization Procedure (performed if PTT 1:1 Mix >48 seconds)	Effective February 18, 2014 Negative
No	Dilute Russell Viper Venom (dRVVT) 1:1 Mix (performed if dRVVT >44 seconds)	Effective February 18, 2014 33-44 seconds
No	Dilute Russell Viper Venom Time (dRVVT) Confirmation Test (performed if dRVVT 1:1 Mix >44 seconds)	Effective February 18, 2014 Negative
No	Hexagonal Phospholipid Neutralization	Effective February 18, 2014 Negative

2011478 Arsenic, Random Urine with Reflex to Fractionated U ARS RAND

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 elevated total arsenic results, fractionation is automatically performed to determine the proportions of inorganic, methylated and organic species.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Note: If total arsenic concentration is found to be elevated based on reference intervals, then Arsenic, Fractionated, will be added to determine the proportion of organic, inorganic, and methylated forms. Additional charges apply.

0025000 **Arsenic, Urine with Reflex to Fractionated** **ARS U**

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 elevated total arsenic results, fractionation is automatically performed to determine the proportions of inorganic, methylated and organic species.

Per 24h calculations are provided to aid interpretation for collections with a duration of 24 hours and an average daily urine volume. For specimens with notable deviations in collection time or volume, ratios of analytes to a corresponding urine creatinine concentration may assist in result interpretation.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Note: If total arsenic concentration is found to be elevated based on reference intervals, then Arsenic, Fractionated, will be added to determine the proportion of organic, inorganic, and methylated forms. Additional charges apply.

3001431 Autoimmune Encephalitis Extended Panel, Serum ENCEPH EXT

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer three (3) 1 mL serum aliquots to ARUP Standard Transport Tubes. (Min: 0.5 mL/aliquot)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Contaminated specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 30 days (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval
2004221	N-methyl-D-Aspartate Receptor Antibody, IgG, Serum 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, Serum	Negative: 31 pmol/L or less Indeterminate: 32-87 pmol/L Positive: 88 pmol/L 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, Serum	Less than 1:10
2009452	Contactin-Associated Protein-2 Antibody, IgG with Reflex to Titer, Serum	Less than 1:10
3001260	Alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic Acid (AMPA) Receptor Antibody, IgG by IFA with Reflex to Titer, Serum	Less than 1:10
3001270	Gamma Aminobutyric Acid Receptor, Type B (GABA-BR) Antibody, IgG by IFA with Reflex to Titer, Serum	Less than 1:10
3001277	Myelin Oligodendrocyte Glycoprotein (MOG) Antibody, IgG by IFA with Reflex to Titer, Serum	Less than 1:10
3004359	Dipeptidyl aminopeptidase-like protein 6 (DPPX) antibody, IgG by IFA with reflex to Titer, Serum	Effective November 15, 2021 Less than 1:10

Note: If N-methyl-D-Aspartate Receptor Antibody is positive, then a titer will be added. Additional charges apply.
If Aquaporin-4 Receptor antibody IgG is positive, then a titer will be added. Additional charges apply.
If LGI1 antibody IgG is positive, then LGI1 antibody IgG titer will be added. Additional charges apply.
If CASPR2 antibody IgG is positive, then CASPR2 antibody IgG titer will be added. Additional charges apply.
If AMPAR Antibody IgG is positive, then a titer will be added. Additional charges apply.
If GABABR Antibody IgG is positive, then a titer will be added. Additional charges apply.
If MOG Antibody IgG is positive, then a titer will be added. Additional charges apply.
If DPPX Antibody IgG is positive, then a titer will be added. Additional charges apply.

CPT Code(s): 83519; 86341; 86255 x8, if reflexed add 86256 per titer

HOTLINE NOTE: There is a component change associated with this test.
Add component 2013322, Neuromyelitis Optica/AQP4-IgG, Serum
Add component 3004361, DPPX Ab IgG CBA IFA Screen, Serum
Remove component 2003121, Aquaporin 4 Receptor Antibody
There is a reflexive pattern change associated with this test.
Add reflex to 2013323, Aquaporin-4 Receptor Antibody, IgG by IFA, Serum Titer (Reflex for New Test AQP4 SER - Not Orderable by Clients)
Add reflex to 3004360, Dipeptidyl Aminopeptidase-Like Protein 6 (DPPX) Antibody Titer, IgG by IFA, Serum (Reflex for 3004359 DPPX SER Only - Not Orderable by Clients)
Remove reflex from 2013320, Aquaporin-4 Receptor Antibody, IgG by IFA with Reflex to Titer, Serum

3004070 Autoimmune Neurologic Disease Reflexive Panel, Serum NEURO R3

Specimen Required: Collect: Serum Separator Tube (SST)
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer three 1 mL serum aliquots to ARUP Standard Transport Tubes. (Min: 0.5 mL/aliquot)
Storage/Transport Temperature: Frozen
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: 30 days (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval
2004221	N-methyl-D-Aspartate Receptor Antibody, IgG, Serum with Reflex to Titer	Less than 1:10
2001771	Glutamic Acid Decarboxylase Antibody	0.0-5.0 IU/mL
2013956	CV2.1 Screen by IFA with Reflex to Titer	Less than 1:10
2004890	Voltage-Gated Potassium Channel (VGKC) Antibody, Serum	Negative: 31 pmol/L or less Indeterminate: 32-87 pmol/L Positive: 88 pmol/L or greater
2007961	PCCA/ANNA by IFA with Reflex to Titer and Immunoblot	Effective August 17, 2020 Purkinje Cell/Neuronal Nuclear IgG Scrn: None Detected Neuronal Nuclear Antibody (ANNA) IFA Titer, IgG: Less than 1:10 Purkinje Cell Antibody, Titer: Less than 1:10 3002917 Neuronal Nuclear Antibodies (Hu, Ri, Yo, Tr/DNER) IgG by Immunoblot, Serum: Refer to report
2008893	Amphiphysin Antibody, IgG	Negative
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, Serum	Less than 1:10
2009452	Contactin-Associated Protein-2 Antibody, IgG with Reflex to Titer, Serum	Less than 1:10
0080009	Acetylcholine Receptor Binding Antibody	Negative: 0.0-0.4 nmol/L Positive: 0.5 nmol/L or greater
3001260	Alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic Acid (AMPA) Receptor Antibody, IgG by IFA with Reflex to Titer, Serum	Less than 1:10
3001270	Gamma Aminobutyric Acid Receptor, Type B (GABA-BR) Antibody, IgG by IFA with Reflex to Titer, Serum	Less than 1:10
3001277	Myelin Oligodendrocyte Glycoprotein (MOG) Antibody, IgG by IFA with Reflex to Titer, Serum	Less than 1:10
3002885	SOX1 Antibody, IgG by Immunoblot, Serum	Negative
0092628	P/Q-Type 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
3003020	Ganglionic Acetylcholine Receptor Antibody	Negative: 0.0 - 8.4 pmol/L Indeterminate: 8.5 - 11.6 pmol/L Positive: 11.7 pmol/L or greater
3004359	Dipeptidyl aminopeptidase-like protein 6 (DPPX) antibody, IgG by IFA with reflex to Titer, Serum	Less than 1:10

Note: If N-methyl-D-Aspartate Receptor Antibody is positive, then titer will be performed. Additional charges apply.
If CV2.1 Antibody IgG Screen by IFA is positive, then titer will be performed and Acetylcholine Receptor Binding Antibody will be added. Additional charges apply.
If Aquaporin-4 Receptor Antibody, IgG by IFA with Reflex to Titer, Serum is positive, then titer will be performed. Additional charges apply.
Purkinje Cell (PCCA) antibody and Neuronal Nuclear (ANNA) antibody IgG are screened by IFA. If the IFA screen is indeterminate, then a Neuronal Nuclear Antibodies (Hu, Ri, Yo, and Tr/DNER) IgG by Immunoblot will be performed. If the IFA screen is positive at 1:10 or greater, then a PCCA/ANNA antibodies titer and Neuronal Nuclear Antibodies (Hu, Ri, Yo, Tr/DNER) IgG by Immunoblot will be performed. Additional charges apply.
If Leucine-Rich, Glioma-Inactivated Protein 1 Antibody, IgG with Reflex to Titer, Serum is positive, then Leucine-Rich, Glioma-Inactivated Protein 1 Antibody Titer, IgG by IFA, Serum will be performed. Additional charges apply.
If Contactin-Associated Protein-2 Antibody, IgG with Reflex to Titer, Serum is positive, then Contactin-Associated Protein-2 Antibody Titer, IgG by IFA, Serum will be performed. Additional charges apply.
If Alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic Acid (AMPA) Receptor Antibody, IgG by IFA with Reflex to Titer, Serum is positive, then an Alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic Acid (AMPA) Receptor Antibody Titer, IgG, Serum will be performed. Additional charges apply.
If Gamma Aminobutyric Acid Receptor, Type B (GABA-BR) Antibody, IgG by IFA with Reflex to Titer, Serum is positive, then a Gamma Aminobutyric Acid Receptor, Type B (GABA-BR) Antibody Titer, IgG, Serum will be performed. Additional charges apply.
If Myelin Oligodendrocyte Glycoprotein (MOG) Antibody, IgG by IFA with Reflex to Titer, Serum is positive, then a Myelin Oligodendrocyte Glycoprotein (MOG) Antibody Titer, IgG will be performed. Additional charges apply.
If Dipeptidyl aminopeptidase-like protein 6 (DPPX) antibody, IgG by IFA with reflex to Titer, Serum is positive, then a Dipeptidyl aminopeptidase-like protein 6 (DPPX) antibody Titer, IgG will be performed. Additional charges apply.

CPT Code(s): 83519 x3; 84182 x2; 86255 x10; 86341; if reflexed, additional CPT codes may apply: 86256; 83519; 84182 x4

HOTLINE NOTE: There is a component change associated with this test.
Add component 0092629, P/Q-Type Calcium Channel Antibody
Add component 3003019, Ganglionic Acetylcholine Receptor Ab
Add component 3004361, DPPX Ab IgG CBA IFA Screen, Serum
Remove component 080009, Acetylcholine Binding Antibody
There is a reflexive pattern change associated with this test.
Add reflex to 0080009, Acetylcholine Binding Antibody
Add reflex to 3004360, Dipeptidyl Aminopeptidase-Like Protein 6 (DPPX) Antibody Titer, IgG by IFA, Serum (Reflex for 3004359 DPPX SER Only - Not Orderable by Clients)

New Test Available Now Click for Pricing

3004244 **BAP1 by Immunohistochemistry** **BAP1 IHC**

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

Specimen Required: Collect: Tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (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:

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Note: This test is performed as a stain and return (technical) service only.

CPT Code(s): 88342

New York DOH Approved.

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

0092099 B-Cell CD20 Expression — CD20

CPT Code(s): 88184; 88185

0050321 Beta-2 Glycoprotein 1 Antibodies, IgG and IgM — B2GPI PAN

Reference Interval:
Effective November 15, 2021

Test Number	Components	Reference Interval
	Beta-2 Glycoprotein 1 Antibody, IgG	<=20 SGU
	Beta-2 Glycoprotein 1 Antibody, IgM	<=20 SMU

2002569 Beta-2 Glycoprotein 1 Antibodies, IgG, IgM and IgA — B2GPI PAN3

Reference Interval:
Effective November 15, 2021

Test Number	Components	Reference Interval
	Beta-2 Glycoprotein 1 Antibody, IgG	<=20 SGU
	Beta-2 Glycoprotein 1 Antibody, IgM	<=20 SMU
	Beta-2 Glycoprotein 1 Antibody, IgA	<=20 SAU

0050324 Beta-2 Glycoprotein 1 Antibody, IgA — B2GPI A

Reference Interval:
Effective November 15, 2021
<=20 SAU

0090067 BK Virus, Quantitative PCR — BK QNT

Specimen Required: Collect: Lavender (EDTA), pink (K2EDTA) or serum separator tube **OR** urine.
Specimen Preparation: Transport 1 mL whole blood, serum, plasma or urine in 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: 72 hours; Frozen: 1 month

2002304 BK Virus, Quantitative PCR, Blood — BK QNT BLD

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or serum separator tube
Specimen Preparation: Transport 1 mL whole blood, serum or plasma in a sterile container. (Min: 0.5 mL).
Storage/Transport Temperature: Frozen.
Remarks: Specimen source required.
Unacceptable Conditions: Urine (refer to BK Virus, Quantitative PCR, Urine, ARUP test code 2002310). Heparinized specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 72 hours; Frozen: 1 month

0062224 *Blastomyces dermatitidis* Identification — MC BP

Methodology: Matrix-Assisted Laser Desorption Ionization (MALDI)/Sequencing

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 0062224, Blastomyces dermatitidis DNA Probe from Blastomyces dermatitidis DNA Probe to Blastomyces dermatitidis Identification.

2002498 *BRAF* Codon 600 Mutation Detection by Pyrosequencing — BRAF PCR

Specimen Required: Collect: Tumor tissue.
Specimen Preparation: **Tumor Tissue:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or 5 unstained 5 micron slides. (Min: 3 slides). Transport block and/or slide(s) in a tissue transport kit (ARUP Supply # 47808) available online through eSupply using ARUP Connect™or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks: Include surgical pathology report.
If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.
Unacceptable Conditions: Less than 25 percent tumor. DNA extracted by a non-CLIA lab. DNA extracted without a corresponding circled H&E slide. Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). Decalcified specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Note: For billing requirements, *BRAF* Bill will be added separately. Additional charges apply.

CPT Code(s): 88381; add 81210

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

0051750 BRAF Codon 600 Mutation Detection with Reflex to MLH1 Promoter Methylation — BRAF RFLX

Note: If *BRAF* codon 600 Mutation Detection is negative, then *MLH1* Promoter Methylation will be added. Additional charges apply.
For billing requirements, *BRAF* Bill will be added separately. Additional charges apply.

CPT Code(s): 88381; add 81210; If reflexed, add 81288

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

0050140 C1-Esterase Inhibitor — C1ESTER

Methodology: Quantitative Turbidimetric
Performed: Sun-Sat
Reported: 1-4 days

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Ambient. Grossly hemolyzed and/or lipemic specimens
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 14 days; Frozen: 1 month.

Reference Interval:
Effective November 15, 2021
21-38 mg/dL

HOTLINE NOTE: There is a numeric map change associated with this test.
Change the numeric map for component 0050140, C-1-Esterase Inhibitor from XXXX to XX.

0050139 C-1-Esterase Inhibitor Panel — C1 INH PAN

Methodology: Immunoturbidimetry/Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Quantitative Turbidimetric
Performed: Wed, Fri, Sat
Reported: 1-4 days

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer **three** 1 mL aliquots of serum to individual ARUP Standard Transport Tubes and freeze immediately. (Min: 1.0 mL/tube)
Storage/Transport Temperature: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**
Unacceptable Conditions: Non-frozen specimens.
Stability (collection to initiation of testing): Refer to individual components.

Reference Interval:

Test Number	Components	Reference Interval	
0050140	C1-Esterase Inhibitor	Effective November 15, 2021 21-38 mg/dL	
0050141	C1-Esterase Inhibitor Functional	68% or greater: Normal 41-67%: Indeterminate 40% or less: Abnormal	
0050155	Complement Component 4		
		0-30 days: 8-30 mg/dL 1 month: 9-33 mg/dL 2 months: 9-37 mg/dL 3 months: 10-35 mg/dL 4 months: 10-49 mg/dL 5 months: 9-48 mg/dL 6 months: 12-55 mg/dL	7-8 months: 13-48 mg/dL 9-11 months: 16-51 mg/dL 1 year: 16-52 mg/dL 2-4 years: 12-47 mg/dL 5-11 years: 13-44 mg/dL 12-17 years: 14-41 mg/dL 18 years and older: 10-40 mg/dL

HOTLINE NOTE: There is a numeric map change associated with this test.
Change the numeric map for component 0050140, C-1-Esterase Inhibitor from XXXX to XX.

0099460 Calculi (Stone) Analysis — CALCULI

HOTLINE NOTE: There is a component change associated with this test.
Remove component 0093364, Calculi Number
Remove component 0093365, Calculi Size

2005231 Calculi (Stone) Analysis with Photo — CALCPHOTO

HOTLINE NOTE: There is a component change associated with this test.
Remove component 0093364, Calculi Number
Remove component 0093365, Calculi Size

0099344 Cardiolipin Antibodies, IgG and IgM — ANTI-CARD

Reference Interval:

Test Number	Components	Reference Interval
0050901	Cardiolipin Antibody, IgG	Effective November 15, 2021
		<=14 GPL: Negative
		15-19 GPL: Indeterminate
		20-80 GPL: Low to Moderately Positive
		81 GPL or above: High Positive
0050902	Cardiolipin Antibody, IgM	Effective November 15, 2021
		<=12 MPL: Negative
		13-19 MPL: Indeterminate
		20-80 MPL: Low to Moderately Positive
		81 MPL or above: High Positive

0051162 Cardiolipin Antibodies, IgG, IgM, and IgA — CARD PAN

Reference Interval:

Test Number	Components	Reference Interval
0050901	Cardiolipin Antibody, IgG	Effective November 15, 2021
		<=14 GPL: Negative
		15-19 GPL: Indeterminate
		20-80 GPL: Low to Moderately Positive
		81 GPL or above: High Positive
0050902	Cardiolipin Antibody, IgM	Effective November 15, 2021
		<=12 MPL: Negative
		13-19 MPL: Indeterminate
		20-80 MPL: Low to Moderately Positive
		81 MPL or above: High Positive
0098358	Cardiolipin Antibody, IgA	Effective November 15, 2021
		<=11 APL: Negative
		12-19 APL: Indeterminate
		20-80 APL: Low to Moderately Positive
		81 APL or above: High Positive

0098358 Cardiolipin Antibody, IgA — CARDIO IGA

Reference Interval:
Effective November 15, 2021

<=11 APL	Negative
12-19 APL	Indeterminate
20-80 APL	Low to Moderately Positive
81 APL or above	High Positive

0050901 Cardiolipin Antibody, IgG — AC-IGG

Reference Interval:
Effective November 15, 2021

<=14 GPL	Negative
15-19 GPL	Indeterminate
20-80 GPL	Low to Moderately Positive
81 GPL or above	High Positive

0050902 Cardiolipin Antibody, IgM — AC-IGM

Reference Interval:
Effective November 15, 2021

<=12 MPL	Negative
13-19 MPL	Indeterminate
20-80 MPL	Low to Moderately Positive
81 MPL or above	High Positive

2004247 *CEBPA* Mutation Detection — CEBPA MUT

Specimen Required: Collect: Lavender (EDTA) or bone marrow (EDTA).
Specimen Preparation: **Whole Blood:** Do not freeze. Transport 5 mL whole blood (Min: 1 mL)
Bone Marrow: Transport 3 mL bone marrow. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, serum, FFPE tissue blocks/slides, or frozen tissue, DNA extracted by a non-CLIA lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable

0062225 *Coccidioides immitis* Identification — MC CP

Methodology: Matrix-Assisted Laser Desorption Ionization (MALDI)/Sequencing

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 0062225, Coccidioides immitis DNA Probe from Coccidioides immitis DNA Probe to Coccidioides immitis identification.

3001524 Cytochrome P450 Genotyping Panel — CYP PANEL

HOTLINE NOTE: There is a component change associated with this test.
Remove component 3002511, CYP PANEL, GeneDose Link

New Test **3004255** **Cytochrome P450 Genotyping Panel, with GeneDose Access** **CYP GD**

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Additional Technical Information

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Varies
Reported: 5-10 days

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

Reference Interval: By report

Interpretive Data:
Background Information for Cytochrome P450 Genotyping Panel:
Characteristics: The cytochrome P450 (CYP) isozymes 2C19, 2C8, 2C9, 2D6 and the CYP3A subfamily are involved in the metabolism of many drugs. Variants in the genes that code for CYP2C19, CYP2C8, CYP2C9, CYP2D6, CYP3A4, and CYP3A5 will influence pharmacokinetics of respective substrates, and may predict or explain non-standard dose requirements, therapeutic failure, or adverse reactions.
Inheritance: Autosomal codominant.
Cause: Gene variants affect enzyme expression or activity.
Variants Tested: See the Additional Technical Information document.
Clinical Sensitivity: Drug-dependent.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Only the targeted variants will be detected by this panel, and assumptions about phase and content are made to assign alleles. Publically available sources such as the www.pharmvar.org or www.pharmgkb.org provide guidance on phenotype predictions and allele frequencies. A combination of the *CYP2D6**5 (gene deletion) and a *CYP2D6* gene duplication cannot be specifically identified; however, this combination is not expected to adversely affect the phenotype prediction. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with gene 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.

Please note the information contained in this report does not contain medication recommendations, and should not be interpreted as recommending any specific medications. Any dosage adjustments or other changes to medications should be evaluated in consultation with a medical provider.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Note: Whole blood is the preferred specimen. Saliva samples that yield inadequate DNA quality and/or quantity will be reported as inconclusive if test performance does not meet laboratory-determined criteria for reporting.

CPT Code(s): 81225; 81226; 81227; 81230; 81231; 81479

New York DOH Approved.

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

New Test **3004275** **Cytogenomic Molecular Inversion Probe Array FFPE Tissue - Oncology** **FFPEARRAY**

Click for Pricing

Additional Technical Information

Methodology: Molecular Inversion Probe Array
Performed: Sun-Sat
Reported: 2-3 weeks

Specimen Required: Collect: Tumor tissue
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Transport 10 slides, each with 5-micron unstained sections or four 20-micron scrolls or tissue block. Tissue block will be returned after testing. Transport tissue in a tissue transport kit (ARUP supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks: If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.
Unacceptable Conditions: Specimens fixed or processed in alternative fixatives or heavy metal fixatives (B-4 or B-5).
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Interpretive Data:
For detection of copy number alterations and loss of heterozygosity in FFPE specimens.
Refer to report.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Note: Samples must contain a region with at least 50 percent tumor.

CPT Code(s): 88381; 81277

New York DOH approval pending. Call for status update.

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

New Test **3004273** **Cytogenomic Molecular Inversion Probe Array FFPE Tissue - Products of Conception** **CMAPFFPE**

Click for Pricing

Cytogenetic Test Request Form Recommended (ARUP form #43098)

Additional Technical Information

Patient History for Prenatal Cytogenetics

Supplemental Resources

Methodology: Molecular Inversion Probe Array
Performed: Sun-Sat
Reported: 14-21 days

Specimen Required: Collect: Fetal autopsy or products of conception.
Specimen Preparation: **FFPE Fetal tissue:** Transport ten slides, each with 5 µm unstained sections or four 20 µm scrolls or tissue block.
OR FFPE villi: Transport one H&E stained slide and ten slides, each with 5 µm unstained sections or tissue block.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks: If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.
Unacceptable Conditions: Specimens fixed or processed in alternative fixatives or heavy metal fixatives (B-4 or B-5).
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Interpretive Data:
For detection of copy number alterations and loss of heterozygosity in FFPE specimens.
Refer to report.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Note: If sending placenta instead of fetal tissue, at least 80% villi for products of conception specimens.

This test must be ordered using Cytogenetic test request form #43098 or through your ARUP interface. Please submit the Patient History for Prenatal Cytogenetics form with the electronic packing list (http://ltd.aruplab.com/Tests/Pdf/65).

CPT Code(s): 88381; 81229

New York DOH approval pending. Call for status update.

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

New Test **3004359** **Dipeptidyl Aminopeptidase-Like Protein 6 (DPPX) Antibody, IgG by IFA With Reflex to Titer, Serum** **DPPX SER**

Click for Pricing

Additional Technical Information

Methodology: Semi-Quantitative Indirect Fluorescent Antibody
Performed: Wed
Reported: 1-8 days

Specimen Required: Patient Prep: Serum separator tube.
Collect: Separate serum from cells 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: CSF or plasma. Contaminated, hemolyzed, or severely lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 30 days (avoid repeated freeze/thaw cycles)

Reference Interval: Less than 1:10

Interpretive Data:
Anti-DPPX IgG antibody is found in a subset of patients with autoimmune encephalitis and may occur with or without associated tumor. Decreasing antibody levels may be associated with therapeutic response; therefore, clinical correlation must be strongly considered. A negative test result does not rule out a diagnosis of autoimmune limbic encephalitis.

This indirect fluorescent antibody cell-based assay (CBA) utilizes dipeptidyl aminopeptidase-like protein 6 (DPPX) transfected cells for the detection of the DPPX IgG antibody.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Note: If DPPX antibody IgG is positive, then DPPX antibody IgG titer will be added. Additional charges apply.

CPT Code(s): 86255; if reflexed, add 86256

New York DOH approval pending. Call for status update.

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

2002440 *EGFR* Mutation Detection by Pyrosequencing — EGFR PCR

Specimen Required: Patient Prep: For a general FNA collection and smear preparation refer to ARUP's Laboratory Test Directory: Cytology, Fine Needle Aspiration Collection at http://ltd.aruplab.com/tests/pdf/366
Collect: Tumor tissue.
Specimen Preparation: **Tumor Tissue:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or 5 unstained 5-micron slides. (Min: 3 slides)
Fine Needle Aspirate (FNA): Prepare FNA smear with Diff-Quik or equivalent stain by standard methods (air-dried slides are preferred). Number of slides needed is dependent on the tumor cellularity of the smear. (Min: 1 slide). Slide(s) will be destroyed during testing process and will not be returned to client. Transport block and/or slide(s) in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks: Include surgical pathology report.
If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.
Unacceptable Conditions: Less than 25 percent tumor. DNA extracted by a non-CLIA lab. DNA extracted without a corresponding circled H&E slide. Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). Decalcified specimens. FNA smears with less than 50 tumor cells.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Note: This test detects mutations in *EGFR* exons 18, 19, 20 and 21 (codons 719, 745-753, 768, 790, 858, and 861). For billing requirements, *EGFR* PCR Bill will be added separately. Additional charges apply.

CPT Code(s): 88381; add 81235

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

2007914 *EPOR* Mutation Detection by Sequencing — EPOR

Specimen Required: Collect: Lavender (EDTA).
Specimen Preparation: **Whole Blood:** Do not freeze. Transport 5 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, serum, FFPE tissue blocks/slides, or frozen tissue, DNA extracted by a non-CLIA lab, bone marrow. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable

0051626 Epstein-Barr Virus Antibody to Viral Capsid Antigen, IgA — EBV A

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 0.5 mL serum to an ARUP Standard Transport Tube. (Min: 0.1 mL) Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. **Mark specimen plainly as "acute" or "convalescent."**
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Contaminated or heat-inactivated specimens. Grossly hemolytic, icteric or, lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 month

Reference Interval:
Effective November 15, 2021

8 U or less	Not Detected
9-11 U	Indeterminate - Repeat testing in 10-14 days may be helpful.
12 U or greater	Detected

HOTLINE NOTE: There is a numeric map change associated with this test.
Change the numeric map for component 0051626, EBV Antibody To Viral Capsid Antigen IgA from XX.X to XX.
There is a unit of measure change associated with this test.
Change the unit of measure for component 0051626, EBV Antibody To Viral Capsid Antigen IgA from U/L to U.

0051627 Epstein-Barr Virus Antibody to Viral Capsid Antigen, IgG and IgA — EBV PAN 3

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL) Parallel testing is preferred and convalescent specimens **must** be received within 30 days from receipt of the acute specimens.
Storage/Transport Temperature: Refrigerated.
Remarks: **Label specimens plainly as acute or convalescent.**
Unacceptable Conditions: Contaminated, heat-inactivated, or grossly hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 month (Avoid repeated freeze/thaw cycles).

Reference Interval:

Test Number	Components	Reference Interval	
0050235	Epstein-Barr Virus Antibody to Viral Capsid Antigen, IgG	Effective February 19, 2013	
		17.9 U/mL or less	Not Detected
		18.0-21.9 U/mL	Indeterminate - Repeat testing in 10-14 days may be helpful.
		22.0 U/mL or greater	Detected
0051626	Epstein-Barr Virus Antibody to Viral Capsid Antigen, IgA	Effective November 15, 2021	
		8 U or less	Not Detected
		9-11 U	Indeterminate - Repeat testing in 10-14 days may be helpful.
		12 U or greater	Detected

HOTLINE NOTE: There is a numeric map change associated with this test.
Change the numeric map for component 0051626, EBV Antibody To Viral Capsid Antigen IgA from XX.X to XX.
There is a unit of measure change associated with this test.
Change the unit of measure for component 0051626, EBV Antibody To Viral Capsid Antigen IgA from U/L to U.

2007909 Ethyl Glucuronide and Ethyl Sulfate, Urine, Quantitative — CDCO ETG/S

Performed: Sun, Tues-Sat
Reported: 1-7 days

New Test **3001851** **Fatty Acid Oxidation Disorders Panel, Sequencing** **FAOD NGS**

Available Now

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Patient History for Fatty Acid Oxidaton Disorders Testing

Additional Technical Information

Methodology: Massively Parallel Sequencing
Performed: Varies
Reported: 3-6 weeks

Specimen Required: Collect: Lavender or Pink (EDTA) or Yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Pediatric minimum 1.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Serum or plasma; grossly hemolyzed or frozen specimens. Saliva. Buccal brush or swab. FFPE tissue.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:
Refer to report.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Note: Genes tested: *ACAD9*, *ACADM*, *ACADS*, *ACADVL*, *ACAT1*, *CPT1A*, *CPT2*, *ECHS1*, *ETFA*, *ETFB*, *ETFDH*, *FLAD1*, *HADH*, *HADHA*, *HADHB*, *HMGCL*, *HMGCS2*, *HSD17B10*, *LPIN1**, *MLYCD*, *SLC22A5*, *SLC25A20*, *SLC52A1*, *SLC52A2*, *SLC52A3*.
*One or more exons are not covered by sequencing for the indicated gene; see Additional Technical Information

CPT Code(s): 81404; 81405; 81406; 81479

New York DOH approval pending. Call for status update.

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

0094030 **Felbamate** **FELBAMA**

Reference Interval: Effective November 15, 2021

Therapeutic Range	30-60 µg/mL
Toxic Level	Greater than or equal to 100 µg/mL

Interpretive Data:
Felbamate is indicated for treatment of epilepsy. The therapeutic range is based on serum, predose (trough) draw collection at steady-state concentration. Patient pharmacokinetics may be variable due to age, comedications, and/or compromised renal function. Adverse effects may include nausea, vomiting, dizziness, blurred vision, and ataxia. Felbamate use may increase the incidence of liver failure and aplastic anemia.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

New Test **3004279** **Gastrointestinal Stromal Tumor Mutations** **GISTMUT**

Click for Pricing

Additional Technical Information

Methodology: Massively Parallel Sequencing
Performed: Varies
Reported: 10-12 days

Specimen Required: Collect: Tumor tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Diff-Quik and Papanicolaou stained cytology smears are also acceptable. Number of slides needed is dependent on the tumor cellularity of the smear. Slide(s) will be destroyed during testing process and will not be returned to client. Protect from excessive heat. Transport block and/or 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.
Resections: Transport 8 unstained 5-micron slides. (Min: 5 slides)
Small Biopsies: Transport 15 unstained 5-micron slides. (Min: 10 slides)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks: Include surgical pathology report.
If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.
Unacceptable Conditions: Less than 10 percent tumor. Specimens fixed/processed in heavy metal fixatives. Decalcified specimens. FNA smears with less than 50 tumor cells.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:
Refer to report

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Note: A full list of the targeted genes and regions is listed in the Additional Technical Information.

CPT Code(s): 88381; 81272; 81314

New York DOH Approved.

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

New Test **3001627** **Glycogen Storage Disorders Panel, Sequencing** **GSD NGS**
Available Now
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Patient History for Glycogen Storage Disorders Testing

Additional Technical Information

Methodology: Massively Parallel Sequencing
Performed: Varies
Reported: 3-6 weeks

Specimen Required: Collect: Lavender or Pink (EDTA) or Yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 3 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Serum or plasma; grossly hemolyzed or frozen specimens; saliva; buccal brush or swab; FFPE tissue.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:
Refer to report.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Note: Genes tested: *ACAT1, AGL, ALDOA, ALDOB, CPT2, ENO3,* FBP1, G6PC, GAA, GBE1, GYG1, GYS1, GYS2, LAMP2, LDHA, NHLRC1, OXCT1,* PFKM,* PGAM2, PGK1, PGM1, PHKA1, PHKA2, PHKB, PHKG2, PRKAG2, PYGL, PYGM, RBCK1, SLC16A1, SLC2A2, SLC37A4.*
*One or more exons are not covered by sequencing for the indicated gene; see Additional Technical Information.

CPT Code(s): 81403, 81404, 81405, 81406, 81407, 81479

New York DOH approval pending. Call for status update.

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

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

Interpretive Data:
Quantification of urine excretion rates before or after chelation therapy has been used as an indicator of lead exposure. Urinary excretion on >125 mg of lead per 24 hours is usually associated with related evidence of lead toxicity.

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

The ACGIH Biological Exposure Index (BEI) for arsenic in urine is 35 µg/L. The ACGIH BEI is based on the sum of inorganic and methylated species. For specimens with elevated total arsenic results, fractionation is automatically performed to determine the proportions of inorganic, methylated and organic species.

Note: If total arsenic concentration is found to be elevated based on reference intervals, then Arsenic, Fractionated, will be added to determine the proportion of organic, inorganic, and methylated forms. Additional charges apply.

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

Interpretive Data:
Quantification of urine excretion rates before or after chelation therapy has been used as an indicator of lead exposure. Urinary excretion of >125 mg of lead per 24 hours is usually associated with related evidence of lead toxicity.

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

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 elevated total arsenic results, fractionation is automatically performed to determine the proportions of inorganic, methylated and organic species.

Per 24h calculations are provided to aid interpretation for collections with a duration of 24 hours and an average daily urine volume. For specimens with notable deviations in collection time or volume, ratios of analytes to a corresponding urine creatinine concentration may assist in result interpretation.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Note: If total arsenic concentration is found to be elevated based on reference intervals, then Arsenic, Fractionated, will be added to determine the proportion of organic, inorganic, and methylated forms. Additional charges apply.

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

Interpretive Data:
Quantification of urine excretion rates before or after chelation therapy has been used as an indicator of lead exposure. Urinary excretion of >125 mg of lead per 24 hours is usually associated with related evidence of lead toxicity.

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

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

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 elevated total arsenic results, fractionation is automatically performed to determine the proportions of inorganic, methylated and organic species.

Per 24h calculations are provided to aid interpretation for collections with a duration of 24 hours and an average daily urine volume. For specimens with notable deviations in collection time or volume, ratios of analytes to a corresponding urine creatinine concentration may assist in result interpretation.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Note: If total arsenic concentration is found to be elevated based on reference intervals, then Arsenic, Fractionated, will be added to determine the proportion of organic, inorganic, and methylated forms. Additional charges apply.

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

Note: High concentrations of iodine or gadolinium may interfere with elemental testing. If total arsenic concentration is found to be elevated based on reference intervals, then Arsenic, Fractionated, will be added to determine the proportion of organic, inorganic, and methylated forms. Additional charges apply.

2001759	**Hemophilia A (*F8*) 2 Inversions (Extended TAT as of 11/20/20-no referral available)**	**F8 INV**

Interpretive Data:

Background Information for Hemophilia A (*F8*) 2 Inversions:

Characteristics: Hemophilia A is characterized by deficiency of factor VIII clotting activity. Less than 1 percent factor VIII activity results in severe deficiency associated with spontaneous joint or deep muscle bleeding. Moderate deficiency (1-5 percent activity) and mild deficiency (6-40 percent activity) are associated with prolonged bleeding after tooth extractions, surgery, or injuries, and recurrent or delayed wound healing. Female carriers of hemophilia A may have increased bleeding tendencies.

Epidemiology: 1 in 5,000 live male births worldwide

Cause: Pathogenic *F8* germline variants

Inheritance: X-linked recessive. In the estimated 30 percent of cases that appear to be de novo, the mother is found to be a carrier at least 80 percent of the time.

Penetrance: 100 percent in males. Approximately 30 percent of female carriers have factor VIII activity levels of less than 40 percent and are at risk for bleeding symptoms typically consistent with mild hemophilia A.

Clinical Sensitivity: 51 percent of variants causing severe hemophilia A are detected by *F8* inversion testing. This assay does not detect *F8* variants associated with mild or moderate hemophilia A in males.

Methodology: Intron 22-A and intron 1 inversions detected by inverse PCR and electrophoresis.

Analytical Sensitivity/Specificity: 99 percent

Limitations: A negative result does not exclude a diagnosis of or carrier status for hemophilia A. Diagnostic errors can occur due to rare sequence variations. *F8* variants, other than the *F8* type 1 or type 2 intron 22-A and intron 1 inversions, will not be detected. Rare *F8* intron 22-A and intron 1 inversions with different breakpoints may not be detected by this assay.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

New Test 3004232 **Hemophilia A (*F8*) 2 Inversions with Reflex to Sequencing and Reflex to Deletion/Duplication** **F8-COMP**

Click for Pricing

Patient History for Hemophilia A or B Gene Testing

Additional Technical Information

Methodology: Inverse Polymerase Chain Reaction/Massively Parallel Sequencing/Multiplex Ligation-dependent Probe Amplification
Performed: Varies
Reported: Within 2 weeks, if reflexed add 3-6 weeks

Specimen Required: Collect: Lavender or Pink (EDTA) or Yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 3 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Serum or plasma; grossly hemolyzed or frozen specimens. Saliva. Buccal brush or swab, FFPE tissue, DNA.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report.

Interpretive Data: Refer to report.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Note: *F8* inversion testing is performed on all specimens. If inversion testing does not explain the clinical scenario, then *F8* gene sequencing will be added. If sequencing does not explain the clinical scenario, then deletion/duplication testing will be added. Additional charges apply.

CPT Code(s): 81403; if reflexed to NGS, add 81407; if reflexed to Del/Dup, add 81406

New York DOH approval pending. Call for status update.

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

2001755 **Hemophilia A (*F8*) 2 Inversions, Fetal** **F8 INV FE**

Interpretive Data:
Background Information for Hemophilia A (*F8*) 2 Inversions:
Characteristics: Hemophilia A is characterized by deficiency of factor VIII clotting activity. Less than 1 percent factor VIII activity results in severe deficiency associated with spontaneous joint or deep muscle bleeding. Moderate deficiency (1-5 percent activity) and mild deficiency (6-40 percent activity) are associated with prolonged bleeding after tooth extractions, surgery, or injuries, and recurrent or delayed wound healing. Female carriers of hemophilia A may have increased bleeding tendencies.
Epidemiology: 1 in 5,000 live male births worldwide
Cause: Pathogenic *F8* germline variants
Inheritance: X-linked recessive. In the estimated 30 percent of cases that appear to be de novo, the mother is found to be a carrier at least 80 percent of the time.
Penetrance: 100 percent in males. Approximately 30 percent of female carriers have factor VIII activity levels of less than 40 percent and are at risk for bleeding symptoms typically consistent with mild hemophilia A.
Clinical Sensitivity: 51 percent of variants causing severe hemophilia A are detected by *F8* inversion testing. This assay does not detect *F8* variants associated with mild or moderate hemophilia A in males.
Methodology: Intron 22-A and intron 1 inversions detected by inverse PCR and electrophoresis.
Analytical Sensitivity/Specificity: 99 percent
Limitations: A negative result does not exclude a diagnosis of or carrier status for hemophilia A. Diagnostic errors can occur due to rare sequence variations. *F8* variants, other than the *F8* type 1 or type 2 intron 22-A and intron 1 inversions, will not be detected. Rare *F8* intron 22-A and intron 1 inversions with different breakpoints may not be detected by this assay.

For quality assurance purposes, ARUP Laboratories will provide a confirmation of the above result at no charge. Following delivery, please collect a cord blood sample from the infant in a lavender (EDTA) or yellow (ACD Solution A or B) top tube and transport 1mL cord blood at 2-8 °C. Please specify on the test request form that this is a confirmatory study to be performed at no charge. Please provide the mother's name for specimen identification purposes.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

New Test **3004241** **Hemophilia A (F8) Sequencing** **F8 NGS**

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Patient History for Hemophilia A Testing

Additional Technical Information

Methodology: Massively Parallel Sequencing
Performed: Varies
Reported: 3-6 weeks

Specimen Required: Collect: Lavender or Pink (EDTA) or Yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 3 mL)
Storage/Transport Temperature: Refrigerated
Unacceptable Conditions: Serum or plasma; grossly hemolyzed or frozen specimens; saliva; buccal brush or swab; FFPE tissue
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:
Refer to report

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Note: Gene tested: *F8*

CPT Code(s): 81407

New York DOH approval pending. Call for status update.

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

New Test **3004201** **HGAL by Immunohistochemistry** **HGAL IHC**
Available Now
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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 nonrepresentative tissue type. Depleted specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Interpretive Data:
This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Note: This test is performed as a stain and return (technical) service only.

CPT Code(s): 88342

New York DOH Approved.

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

0062226 ***Histoplasma capsulatum* Identification** **MC HP**

Methodology: Matrix-Assisted Laser Desorption Ionization (MALDI)/Sequencing

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 0062226, Histoplasma capsulatum DNA Probe from Histoplasma capsulatum DNA Probe to Histoplasma capsulatum identification.

New Test **2011940** **Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by PCR, ThinPrep** **TP HPV1618**

Click for Pricing

Methodology: Qualitative Polymerase Chain Reaction
Performed: Tuesday-Saturday
Reported: 1-5 days

Specimen Required: Collect: Cervical specimen with brush or spatula from ThinPrep kit and place in PreservCyt Media.
Specimen Preparation: Mix well. Transfer 3 mL to an ARUP Standard Transport Tube. (Min 1.5 mL). If test is being used for primary screening, submit specimen aliquot and retain the original specimen at the client site.
Storage/Transport Temperature: Refrigerated.
Remarks: Specimen source required.
Unacceptable Conditions: Bloody or dark brown specimens. Specimens in any media other than indicated above.
Stability (collection to initiation of testing): Ambient: 6 months; Refrigerated: 6 months; Frozen: Unacceptable

Reference Interval: Negative

Interpretive Data:
This test amplifies DNA of HPV16, HPV18 and 12 other high-risk HPV types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) associated with cervical cancer and its precursor lesions. Sensitivity may be affected by specimen collection methods, stage of infection, and the presence of interfering substances. Results should be interpreted in conjunction with other available laboratory and clinical data. A negative high-risk HPV result does not exclude the presence of other high-risk HPV types, the possibility of future cytologic abnormalities, underlying CIN2-3, or cancer.

HPV testing should not be used for screening or management of atypical squamous cells of undetermined significance (ASCUS) in women under age 21.

CPT Code(s): 87624

New York DOH Approved.

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

New Test **3004267** ***IDH1* and *IDH2* Mutation Analysis Exon 4, Formalin-Fixed, Paraffin-Embedded (FFPE) Tissue** **IDH12FFPE**

Click for Pricing

Additional Technical Information

Methodology: Polymerase Chain Reaction/Sequencing
Performed: DNA isolation: Sun-Sat
Assay: Varies
Reported: 8-14 days

Specimen Required: Collect: Tumor tissue.
Specimen Preparation: **Tumor Tissue:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or 4 unstained 5-micron slides. (Min: 3 slides) Transport block and/or slide(s) in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks: For FFPE specimens include surgical pathology report.
If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.
Unacceptable Conditions: Less than 25 percent tumor. DNA extracted by a non-CLIA lab. DNA extracted without a corresponding circled H&E slide. Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). Decalcified specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Interpretive Data:
Refer to report.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

CPT Code(s): 88381; 81120; 81121

New York DOH Approved.

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

2006444 ***IDH1* and *IDH2* Mutation Analysis, exon 4** **IDH1-2**

Specimen Required: Collect: Lavender (EDTA) or bone marrow (EDTA).
Specimen Preparation: **Whole Blood**: Do not freeze. Transport 5 mL whole blood. (Min: 1 mL)
Bone Marrow: Do not freeze. Transport 3 mL bone marrow. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, serum, FFPE tissue blocks/slides, or frozen tissue, DNA extracted by a non-CLIA lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable

0040227 ***IGHV* Mutation Analysis by Sequencing** **IGHV MUT**

Specimen Required: Collect: Lavender (EDTA) or bone marrow (EDTA).
Specimen Preparation: **Whole Blood:** Transport 5 mL whole blood. (Min: 1 mL)
Bone Marrow: Transport 3 mL bone marrow. (Min: 1 mL)
Specimens must be received within 48 hours of collection due to lability of RNA.
Storage/Transport Temperature: **Whole Blood or Bone Marrow**: CRITICAL REFRIGERATED. Separate specimens must be submitted when multiple tests are ordered.
Unacceptable Conditions: Serum, plasma, CSF, extracted DNA, RNA extracted by a non-CLIA lab, bone core, or FFPE tissue. Specimens collected in anticoagulants other than EDTA. Severely hemolyzed or clotted specimens.
Stability (collection to initiation of testing): Ambient: 1 hour; Refrigerated: 48 hours; Frozen: Unacceptable

2002437 ***KIT* Mutations in AML by Fragment Analysis and Sequencing** **KIT AML**

Specimen Required: Collect: Lavender (EDTA) or green (Sodium heparin) whole blood or bone marrow.
Specimen Preparation: **Whole Blood:** Do not freeze. Transport 5 mL whole blood. (Min: 1 mL)
Bone Marrow: Do not freeze. Transport 3 mL bone marrow (Min: 1 mL).
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, serum, FFPE tissue blocks/slides, or frozen tissue, DNA extracted by a non-CLIA lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable

New Test **3004283** **KIT Mutations Melanoma** **KITMELAN**

Click for Pricing

Additional Technical Information

Methodology: Massively Parallel Sequencing
Performed: Varies
Reported: 10-12 days

Specimen Required: Collect: Tumor tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Diff-Quik and Papanicolaou stained cytology smears are also acceptable. Number of slides needed is dependent on the tumor cellularity of the smear. Slide(s) will be destroyed during testing process and will not be returned to client. Protect from excessive heat. Transport block and/or 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.
Resections: Transport 8 unstained 5-micron slides. (Min: 5 slides)
Small Biopsies: Transport 15 unstained 5-micron slides. (Min: 10 slides)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks: Include surgical pathology report.
If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.
Unacceptable Conditions: Less than 10 percent tumor. Specimens fixed/processed in heavy metal fixatives. Decalcified specimens. FNA smears with less than 50 tumor cells.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:
Refer to report.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Note: A full list of the targeted genes and regions is listed in the Additional Technical Information.

CPT Code(s): 81272; 88381; 81314

New York DOH Approved.

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

0040248 **KRAS Mutation Detection** **KRAS**

Note: This assay detects mutations in codons 12, 13, and 61.
For billing requirements, *KRAS* Bill will be added separately. Additional charges apply.

CPT Code(s): 88381; add 81275; 81276

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

2003182 Lacosamide, Serum or Plasma — LACOSA SP

Reference Interval:
Effective November 15, 2021

Reference Interval:	
Therapeutic Range:	1.0-10.0 µg/mL
Toxic Level	Greater than or equal to 20 µg/mL

Interpretive Data:
Lacosamide is an anticonvulsant drug indicated for adjunctive therapy for partial-onset seizures. The therapeutic range is based on serum, predose (trough) draw collection at steady-state concentration. Adverse effects may include dizziness, fatigue, nausea, vomiting, blurred vision, and tremor.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

2004359 Leukocyte Adhesion Deficiency Panel — LAD PAN

Specimen Required: Collect: Green (Na-Heparin) or Purple (K-EDTA)..
Specimen Preparation: Transport 5 mL whole blood. (Min: 1 mL) Specimen must be analyzed within 48 hours of collection.
Storage/Transport Temperature: Room temperature or refrigerated.
Unacceptable Conditions: Clotted or hemolyzed specimens. Frozen specimens.
Stability (collection to initiation of testing): Room temperature and refrigerated: 48 hours

Reference Interval:
Effective November 15, 2021

Available Separately	Component	Reference Interval
No	% CD11a	97-100%
No	% CD11b	96-100%
No	% CD15	95-100%
No	% CD18	99-100%

Interpretive Data:
The Leukocyte Adhesion Deficiency Panel measures the receptors CD11a, CD11b, CD15, and CD18 normally found on neutrophils. The percentage of patient neutrophils bearing these receptors is reported. Decreased values outside of the reference interval may correlate with abnormal neutrophil function. For example, CD11 and CD18 are decreased or absent in Leukocyte Adhesion Deficiency (LAD) type I and CD15 is decreased or absent in LAD type II.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

CPT Code(s): 86356 x 4

HOTLINE NOTE: There is a component change associated with this test.
Add component 3004266, %CD11a

New Test **3004102** **Marfan Syndrome (FBN1) Sequencing and Deletion/Duplication** **FBN1 NGS**
Click for Pricing

Patient History for Marfan Syndrome Testing

Additional Technical Information

Methodology: Massively Parallel Sequencing/Multiplex Ligation-dependent Probe Amplification
Performed: Varies
Reported: 3-6 weeks

Specimen Required: Collect: Lavender (EDTA) or Yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 3 mL)
Storage/Transport Temperature: Refrigerated
Unacceptable Conditions: Serum or plasma; grossly hemolyzed or frozen specimens
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:
Refer to report

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Note: Gene Tested: FBN1

CPT Code(s): 81408, 81479

New York DOH approval pending. Call for status update.

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

2009310 ***MGMT* Promoter Methylation Detection** **MGMT**

Specimen Required: Collect: Tumor tissue.
Specimen Preparation: **Tumor Tissue:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or 5 unstained 5-micron slides. (Min: 3 slides) Transport block and/or slide(s) in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Room temperature. Ship in cooled container during summer months.
Remarks: Include surgical pathology report.
If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.
Unacceptable Conditions: Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). Decalcified specimens. Less than 25 percent tumor.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Note: For billing requirements, *MGMT* Bill will be added separately. Additional charges apply.

CPT Code(s): 88381; add 81287

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

New Test **3004277** **Microsatellite Instability (MSI) HNPCC/Lynch Syndrome by PCR** **MSIPCR**
Click for Pricing

Additional Technical Information

Methodology: Capillary Electrophoresis
Performed: **DNA isolation:** Sun-Sat
Assay: Varies
Reported: 10-20 days

Specimen Required: Collect: Tumor **AND** normal epithelial tissue.
Specimen Preparation: **Tissue:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Transport tissue block(s) or 10 unstained 5-micron slides (5 tumor and 5 normal epithelial). (Min: 3 tumor tissue and 3 normal epithelial tissue slides) Transport block(s) and/or slide(s) in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months
Extracted DNA: Refrigerated.
Remarks: Include surgical pathology report.
If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.
Unacceptable Conditions: Less than 25 percent tumor or less than 50 percent normal epithelial tissue. DNA extracted by a non-CLIA lab. DNA extracted without a corresponding circled H&E slide. Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). Decalcified specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerated: Indefinitely; Frozen: Indefinitely

Interpretive Data:
Refer to report.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

CPT Code(s): 88381; 81301

New York DOH Approved.

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

2002327 **Mismatch Repair by Immunohistochemistry with Reflex to *BRAF* Codon 600 Mutation and *MLH1* Promoter Methylation** **MSI REFLEX**

Note: If MLH1 is abnormal for Mismatch Repair by IHC, then *BRAF* codon 600 will be added. If *BRAF* codon 600 is negative, *MLH1* Promoter Methylation will be added. Additional charges apply.

For billing requirements, *BRAF* Bill will be added separately. Additional charges apply.

CPT Code(s): 88342; 88341 x3; if reflexed, add 88381; add 81210; if further reflexed, add 81288

New Test **3004308** ***MLH1* Promoter Methylation** **MLH1 PCR**

Click for Pricing

Additional Technical Information

Methodology: Real-Time Polymerase Chain Reaction/Fluorescence Resonance Energy Transfer
Performed: **DNA isolation:** Sun-Sat
Assay: Varies
Reported: 7-12 days

Specimen Required: Collect: Tumor tissue. Also acceptable: DNA extracted by CLIA certified lab with corresponding client-circled H&E slide.
Specimen Preparation: **Tumor Tissue:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Transport tissue block or 5 unstained 5-micron slides. (Min: 3 slides) Transport block and/or slide(s) in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Extracted DNA: Refrigerated.
Remarks: Include surgical pathology report.
If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.
Unacceptable Conditions: Less than 25 percent tumor. DNA extracted by a non-CLIA lab. DNA extracted without a corresponding circled H&E slide. Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). Decalcified specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerated: Indefinitely; Frozen: Indefinitely

Interpretive Data:
Refer to report.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

CPT Code(s): 88381; 81288

New York DOH Approved.

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

New Test **3004314** **Neuron Specific Enolase, CSF** **NSE C**

Click for Pricing

Methodology: Quantitative Immunoassay
Performed: Mon, Wed, Fri
Reported: 1-8 days

Specimen Required: Collect: CSF.
Specimen Preparation: Separate from cells within 1 hour of collection. Transfer 0.5 mL CSF to an ARUP Standard Transport Tube and freeze immediately. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated
Unacceptable Conditions: Hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval: Less than or equal to 27.3 ng/mL

Interpretive Data:
This test is performed using the BRAHMS NSE Kryptor Immunoassay. Results obtained with different methods or kits cannot be used interchangeably. Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

CPT Code(s): 86316

New York DOH approval pending. Call for status update.

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

New Test **3004312** **Neuron Specific Enolase, Serum** **NSE S**

Click for Pricing

Methodology: Quantitative Immunoassay
Performed: Mon, Wed, Fri
Reported: 1-4 days

Specimen Required: Collect: Serum Separator Tube (SST). Also acceptable: Plain Red.
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma. Hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval: Less than or equal to 12.7 ng/mL

Interpretive Data:
This assay is performed using the BRAHMS NSE Kryptor Immunoassay. Results obtained with different assay methods or kits cannot be used interchangeably. Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

CPT Code(s): 86316

New York DOH approval pending. Call for status update.

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

New Test Available Now Click for Pricing

3004316 **NKX2.2 by Immunohistochemistry** **NKX2.2 IHC**

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

Specimen Required: Collect: Tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (highly recommended), (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 nonrepresentative tissue type. Depleted specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Interpretive Data:
This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA-certified laboratory and is intended for clinical purposes.

Note: This test is performed as a stain and return (technical) service only.

CPT Code(s): 88342

New York DOH Approved.

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

2003123 ***NRAS* Mutation Detection by Pyrosequencing** **NRAS**

Specimen Required: Collect: Tumor tissue.
Specimen Preparation: **Tumor Tissue:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or 5 unstained 5 micron slides. (Min: 3 slides). Transport block and/or slide(s) in a tissue transport kit (ARUP Supply # 47808) available online through eSupply using ARUP Connect™or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks: Include surgical pathology report.
If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.
Unacceptable Conditions: Less than 25 percent tumor. DNA extracted by a non-CLIA lab. DNA extracted without a corresponding circled H&E slide. Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). Decalcified specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Note: This assay detects mutations in codons 12, 13, and 61. For billing requirements, *NRAS* Bill will be added separately. Additional charges apply.

CPT Code(s): 88381; add 81311

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

0098833 Olanzapine OLANZ

Performed: Tues, Fri
Reported: 1-7 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 serum or plasma from cells within 2 hours of collection. Transport 2 mL serum or plasma. (Min: 1 mL)
Storage/Transport Temperature: **CRITICAL FROZEN**. **Separate specimens must be submitted when multiple tests are ordered.**
Remarks: Olanzapine shows slight interference with high levels of hemolysis in the sample. Noroxycodone causes an analytical interference and impacts the quantitation of Olanzapine.
Unacceptable Conditions: Whole blood. Gel separator tubes, light blue (citrate), or yellow (SPS or ACD solution). Hemolyzed samples.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 1 month

Reference Interval:
Effective November 15, 2021

Therapeutic Range:	20-80 ng/mL
Toxic:	Greater than or equal to 100 ng/mL

Interpretive Data:
Olanzapine is an antipsychotic drug indicated for the treatment of depression and bipolar disorder. The therapeutic range is based on serum, predose (trough) draw collection at steady-state concentration. Adverse effects may include dizziness, akathisia, postural hypotension, delirium, somnolence, neuroleptic malignant syndrome, hyperglycemia, and agitation.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA-certified laboratory and is intended for clinical purposes.

New Test Available Now
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3002700 **Peroxisomal Disorder Panel, Sequencing** **PBD NGS**

Patient History for Peroxisomal Disorder Testing

Additional Technical Information

Methodology: Massively Parallel Sequencing
Performed: Varies
Reported: 3-6 weeks

Specimen Required: Collect: Lavender or Pink (EDTA) or Yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Serum or plasma; grossly hemolyzed or frozen specimens; saliva; buccal brush or swab; FFPE tissue.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:
Refer to report.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Note: Genes tested: *ABCD3*, *ACBD5*,* *ACOX1*, *AGPS*, *AGXT*, *AMACR*, *DNM1L*, *FAR1*, *GNPAT*, *HSD17B4*, *PEX1*, *PEX10*, *PEX11B*, *PEX12*, *PEX13*, *PEX14*, *PEX16*, *PEX19*, *PEX2*, *PEX26*, *PEX3*, *PEX5*, *PEX6*, *PEX7*, *PHYH*, *SCP2**
*One or more exons are not covered by sequencing for the indicated gene; see Additional Technical Information.

CPT Code(s): 81479

New York DOH approval pending. Call for status update.

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

New Test **3004294** **Solid Tumor Mutation Panel, Sequencing** **SOLIDNGS**

Click for Pricing

Additional Technical Information

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

Methodology: Massively Parallel Sequencing
Performed: Varies
Reported: 12-14 days

Specimen Required: Collect: Tumor tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Diff-Quik and Papanicolaou stained cytology smears are also acceptable. Number of slides needed is dependent on the tumor cellularity of the smear. Slide(s) will be destroyed during testing process and will not be returned to client. Protect from excessive heat. Transport block and/or 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.
Resections: Transport 8 unstained 5-micron slides. (Min: 5 slides)
Small Biopsies: Transport 15 unstained 5-micron slides. (Min: 10 slides)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks: Include surgical pathology report.
If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.
Unacceptable Conditions: Less than 10 percent tumor. Specimens fixed/processed in heavy metal fixatives. Decalcified specimens. FNA smears with less than 50 tumor cells.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Interpretive Data:
Refer to report.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Note: A full list of the targeted genes and regions is listed in the Additional Technical Information.

CPT Code(s): 81445; 88381

New York DOH approval pending. Call for status update.

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

2006385 **Thrombotic Risk Reflexive Panel** **THROMRISKR**

Reference Interval:
Effective November 15, 2021

Test Number	Components	Reference Interval
	Prothrombin Time	12.0-15.5 seconds
	Dilute Russell Viper Venom Time (dRVVT)	33-44 seconds
	Dilute Russell Viper Venom (dRVVT) 1:1 Mix **(performed if dRVVT > 44 seconds)**	33-44 seconds
	Dilute Russell Viper Venom Time (dRVVT) Confirmation Test **(performed if dRVVT 1:1 Mix > 44 seconds)**	Negative
	Partial Thromboplastin Time	32-48 seconds
	Thrombin Time	14.7-19.5 seconds
	Reptilase Time	Less than 22.0 seconds
	PTT Heparin Neutralized	32-48 seconds
	Partial Thromboplastin Time 1:1 Mix **(performed if PTT > 48 seconds)**	32-48 seconds
	Platelet Neutralization Procedure **(performed if PTT 1:1 Mix > 48 seconds)**	Negative
	Hexagonal Phospholipid Neutralization	Negative
0050901	Cardiolipin Antibody, IgG	Effective November 15, 2021 <=14 GPL: Negative 15-19 GPL: Indeterminate 20-80 GPL: Low to Moderately Positive 81 GPL or above: High Positive
0050902	Cardiolipin Antibody, IgM	Effective November 15, 2021 <=12 MPL: Negative 13-19 MPL: Indeterminate 20-80 MPL: Low to Moderately Positive 81 MPL or above: High Positive
	Beta-2 Glycoprotein 1 Antibody, IgG	<=20 SGU
	Beta-2 Glycoprotein 1 Antibody, IgM	<=20 SMU
0098894	Protein S Free, Antigen	**Age** / **Male** / **Female** 1-89 days: 15-55% / 15-55% 90-179 days: 35-92% / 35-92% 180-364 days: 45-115% / 45-115% 1-5 years: 62-120% / 62-120% 6-9 years: 62-130% / 62-130% 10-17 years: 60-140% / 60-140% 18 years and older: 74-147% / 55-123%
0099869	Homocysteine, Total	Effective January 4, 2021: 0-15 µmol/L, for both male and female
0030010	Antithrombin, Enzymatic (Activity)	**Age** / **Reference Interval** 1-4 days: 39-87% 5-29 days: 41-93% 30-89 days: 48-108% 90-179 days: 73-121% 180-364 days: 84-124% 1-5 years: 82-139% 6 years: 90-131% 7-9 years: 90-135% 10-11 years: 90-134% 12-13 years: 90-132% 14-15 years: 90-131% 16-17 years: 87-131% 18 years and older: 76-128%
0030113	Protein C, Functional	Effective November 17, 2014 **Age** / **Reference Interval** 1-4 days: 17-53% 5-29 days: 20-64% 30-89 days: 21-65% 90-179 days: 28-80% 180-364 days: 37-81% 1-6 years: 40-92% 7-9 years: 70-142% 10-11 years: 68-143% 12-13 years: 66-162%

		14-15 years: 69-170% 16-17 years: 70-171% 18 years and older: 83-168%
	APC Resistance Profile	Effective February 21, 2011 2.00 or greater **Test Number** / **Components** / **Reference Interval** 0030127 / APC Resistance Profile / Refer to report 0097720 / Factor V Leiden (*F5*) R506Q Mutation / Refer to report
	Factor V Leiden by PCR & Fluorescence Monitoring	Negative: The sample is negative for factor V Leiden, R506Q mutation.
0056060	Prothrombin (*F2*) c.*97G>A (G20210A) Pathogenic Variant	

HOTLINE: Effective November 15, 2021

The following will be discontinued from ARUP's test menu on November 15, 2021. Replacement test options are supplied if applicable.

Test Number	Test Name	Refer To Replacement
2011906	Adrenoleukodystrophy, X-Linked (ABCD1) Sequencing and Deletion/Duplication	
2005564	Angelman Syndrome (UBE3A) Sequencing	
2013601	Autoimmune Encephalitis Reflexive Panel, Serum	Autoimmune Encephalitis Extended Panel, Serum (3001431)
2012151	Charcot-Marie-Tooth (CMT) and Related Hereditary Neuropathies Panel, Sequencing	Charcot-Marie-Tooth (CMT) and Related Hereditary Neuropathies, PMP22 Deletion/Duplication with Reflex to Sequencing Panel (2012155)
2007069	Citrullinemia, Type I (ASS1) Sequencing	
2010229	Cytogenomic Molecular Inversion Probe Array, FFPE Tissue - Oncology	Cytogenomic Molecular Inversion Probe Array FFPE Tissue - Oncology (3004275)
2010795	Cytogenomic Molecular Inversion Probe Array, FFPE Tissue - Products of Conception	Cytogenomic Molecular Inversion Probe Array FFPE Tissue - Products of Conception (3004273)
2009353	Cytogenomic SNP Microarray with Five-Cell Chromosome Study, Constitutional Blood	
2002674	Gastrointestinal Stromal Tumor Mutation	Gastrointestinal Stromal Tumor Mutations (3004279)
2011140	Guanidinoacetate Methyltransferase (GAMT) Deficiency Sequencing	
2001992	Hearing Loss, Nonsyndromic Panel (GJB2) Sequencing, (*GJB6*) 2 Deletions and Mitochondrial DNA 2 Mutations	
2001614	Hemophilia A (F8) 2 Inversions with Reflex to Sequencing and Reflex to Deletion/Duplication	Hemophilia A (F8) 2 Inversions with Reflex to Sequencing and Reflex to Deletion/Duplication (3004232)
2001747	Hemophilia A (F8) Sequencing	Hemophilia A (F8) Sequencing (3004241)
2001578	Hemophilia B (F9) Sequencing	
2010494	Hemophilia B (F9) Sequencing and Deletion/Duplication	
0051650	HNPCC/Lynch Syndrome (MLH1) Sequencing and Deletion/Duplication	
0051654	HNPCC/Lynch Syndrome (MSH2) Sequencing and Deletion/Duplication	
0051656	HNPCC/Lynch Syndrome (MSH6) Sequencing and Deletion/Duplication	
0051737	HNPCC/Lynch Syndrome (PMS2) Sequencing and Deletion/Duplication	
2014188	IDH1 and IDH2 Mutation Analysis, Exon 4, Formalin-Fixed, Paraffin-Embedded (FFPE) Tissue	IDH1 and IDH2 Mutation Analysis Exon 4, Formalin-Fixed, Paraffin-Embedded (FFPE) Tissue (3004267)
2006274	Inherited Insulin Resistance Syndromes (INSR) Sequencing	
2004992	Juvenile Polyposis Syndrome (BMPR1A) Sequencing and Deletion/Duplication	
2002695	KIT Mutations, Melanoma	KIT Mutations Melanoma (3004283)
2001932	KRAS Mutation Detection with Reflex to *BRAF* Codon 600 Mutation Detection	KRAS Mutation Detection (0040248) and BRAF Codon 600 Mutation Detection by Pyrosequencing (2002498)
2009313	Li-Fraumeni (TP53) Sequencing and Deletion/Duplication	
2004543	LMNA-Related Disorders (LMNA) Sequencing	
2008894	Lung Cancer Panel	EGFR Mutation Detection by Pyrosequencing (2002440), ALK (D5F3) with Interpretation by Immunohistochemistry (2007324), and ROS1 with Interpretation by Immunohistochemistry with Reflex to FISH if Equivocal or Positive (2008414)
2008895	Lung Cancer Panel with KRAS	KRAS Mutation Detection (0040248), EGFR Mutation Detection by Pyrosequencing (2002440), ALK (D5F3) with Interpretation by Immunohistochemistry (2007324), and ROS1 with Interpretation by Immunohistochemistry with Reflex to FISH if Equivocal or Positive (2008414)
2005584	Marfan Syndrome (FBN1) Sequencing and Deletion/Duplication	Marfan Syndrome (FBN1) Sequencing and Deletion/Duplication (3004102)
2005589	Marfan Syndrome, FBN1 Sequencing	Marfan Syndrome (FBN1) Sequencing and Deletion/Duplication (3004102)
0051758	Medium Chain Acyl-CoA Dehydrogenase Deficiency (*ACADM*) Sequencing	Fatty Acid Oxidation Disorders Panel, Sequencing (3001851)
0051740	Microsatellite Instability (MSI), HNPCC/Lynch Syndrome, by PCR	Microsatellite Instability (MSI) HNPCC/Lynch Syndrome by PCR (3004277)
2002499	MLH1 Promoter Methylation, Paraffin	MLH1 Promoter Methylation (3004308)
2005359	Multiple Endocrine Neoplasia Type 1 (*MEN1)* Sequencing	Multiple Endocrine Neoplasia Type 1 (MEN1) Sequencing and Deletion/Duplication (2005360)
0098198	Neuron Specific Enolase	Neuron Specific Enolase, Serum (3004312)
0081226	Neuron Specific Enolase, CSF	Neuron Specific Enolase, CSF (3004314)
0051805	Noonan Syndrome (PTPN11) Sequencing	
2004896	Ornithine Transcarbamylase Deficiency (OTC) Sequencing and Deletion/Duplication	
2010703	Pancreatitis (CTRC) Sequencing	Pancreatitis, Panel (CFTR, CTRC, PRSS1, SPINK1) Sequencing (Temporary Referral as of 12/7/20) (2010876)
2008398	Peutz-Jeghers Syndrome (STK11) Sequencing and Deletion/Duplication	
2004203	Primary Carnitine Deficiency (SLC22A5) Sequencing and Deletion/Duplication	Fatty Acid Oxidation Disorders Panel, Sequencing (3001851)
2002470	PTEN-Related Disorders (PTEN) Sequencing and Deletion/Duplication	
3002059	Pyruvate Kinase Deficiency (PKLR) Sequencing	
0051614	Rett Syndrome (MECP2), Sequencing and Deletion/Duplication	
2011457	Smith-Lemli-Opitz Syndrome (DHCR7) Sequencing	
2007991	Solid Tumor Mutation Panel by Next Generation Sequencing	Solid Tumor Mutation Panel, Sequencing (3004294)

2010015	Telangiectasia Syndrome (BMP9/GDF2) Sequencing	
0065153	Vaginal Pathogen Panel by DNA Probe	Vaginitis Panel by TMA (3002581)
2002970	von Hippel-Lindau (VHL) Sequencing	
2002965	von Hippel-Lindau (VHL) Sequencing and Deletion/Duplication	
2005476	von Willebrand Disease, Platelet Type (*GP1BA*) 4 Mutations	