HOTLINE: Effective August 16, 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
6	3001495	Aggressive B-Cell Lymphoma Reflex Panel by FISH, Tissue							x	x				
50	2007994	Allergen, Food, Alpha-Gal (galactose-alpha-1,3-galactose) IgE												x
50	2014011	Allergen, Food, Alpha-Gal (galactose-alpha-1,3-galactose) Panel												x
7	3003923	Allergen, Food, Alpha-Gal (galactose-alpha-1,3-galatose) IgE											x	
8	3003924	Allergen, Food, Alpha-Gal (galactose-alpha-1,3-galatose) Panel											x	

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9	3002685	Alport Syndrome Panel, Sequencing and Deletion/Duplication											x	
50	2002398	Alport Syndrome, X-linked (COL4A5) Sequencing and Deletion/Duplication												x
9	0020471	Amylase, Urine									x			
10	3003745	ANCA-Associated Vasculitis Profile (ANCA/MPO/PR3)											x	
50	2006480	ANCA-Associated Vasculitis Profile (ANCA/MPO/PR3) with Reflex to ANCA Titer												x
11	2012232	Angelman Syndrome and Prader-Willi Syndrome by Methylation-Sensitive PCR, Fetal				x								
50	2002068	Anti-Neutrophil Cytoplasmic Antibody with Reflex to Titer and MPO/PR3 Antibodies												x
50	0050811	Anti-Neutrophil Cytoplasmic Antibody, IgG												x
11	3003747	Anti-Neutrophil Cytoplasmic Antibody, IgG by IFA											x	
12	3004090	Apixaban Level											x	
50	0055654	Apolipoprotein B (APOB) Mutation Detection												x
12	0050100	*Aspergillus* Antibody by CF			x									
50	3003058	Autoimmune Neurologic Disease Reflexive Panel, Serum												x
13	3004070	Autoimmune Neurologic Disease Reflexive Panel, Serum											x	
50	0060182	Bacterial Strain Characterization by Pulsed-Field Gel Electrophoresis												x
14	2012201	Barbiturates, Serum or Plasma, Quantitative		x			x	x			x			
15	2012213	Barbiturates, Urine, Quantitative		x			x	x			x			
15	0020063	Beta-hCG, Serum Qualitative				x								
15	0020229	Beta-hCG, Urine Qualitative				x								
16	3003824	Brachyury by Immunohistochemistry											x	
16	0080392	Cancer Antigen 27.29				x	x	x						
17	3003992	Carbamylated Protein (CarP) Antibody, IgG											x	
17	3002508	Clobazam and Metabolite, Quantitative, Serum or Plasma			x									
17	0050170	*Coccidioides* Antibody by CF			x									
18	3003648	COVID-19 IgG, Semi-Quantitative by CIA											x	
18	0050503	Coxsackie A9 Virus Antibodies by CF			x									
18	3000479	Criteria Systemic Sclerosis Panel			x									
18	2006267	Cytogenomic SNP Microarray Buccal Swab				x								

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19	3003917	Distal Arthrogryposis Panel, Sequencing											x	
20	3004092	Edoxaban Level											x	
21	3001839	Emery-Dreifuss Muscular Dystrophy Panel, Sequencing											x	
21	2002378	Eosinophilia Panel by FISH (Pricing Change)						x		x				
22	0082024	Fetal Fibronectin				x								
22	3004075	FGFR1 Gene Amplification by FISH											x	
50	2012678	Gastrointestinal Bacterial Panel by PCR												x
50	2013577	Gastrointestinal Viral Panel by PCR												x
23	0020476	Glucose, Urine									x			
23	0040085	Hemoglobin					x							
23	3001842	Hereditary Myeloid Neoplasms Panel, Sequencing				x								
24	3002682	Heterotaxy and Situs Inversus Panel, Sequencing											x	
24	0050625	*Histoplasma* Antibodies by CF			x									
50	2009256	HIV1 Genotype and Integrase Inhibitor Resistance by Sequencing												x
50	2004457	HIV-1 Integrase Inhibitor Resistance by Sequencing												x
50	2002805	HLA Antibody Detection												x
25	3000870	Human Immunodeficiency Virus 1 (HIV-1) by Quantitative NAAT with Reflex to HIV-1 Drug Resistance by Next Generation Sequencing	x	x	x		x		x	x		x		
26	3003853	Human Immunodeficiency Virus 1 Drug Resistance by Next Generation Sequencing											x	
50	0055670	Human Immunodeficiency Virus 1, Genotype by Sequencing												x
50	3001242	Human Immunodeficiency Virus Type 1 (HIV-1) GenoSure MG												x
50	3001238	Human Immunodeficiency Virus Type 1 (HIV-1) GenoSure PRIme												x
26	3002134	IDH1 R132H Point Mutation by Immunohistochemistry with Reflex to IDH1 and IDH2 Mutation Analysis, Exon 4									x			
27	3003748	Inflammatory Bowel Disease Differentiation Panel											x	
50	2013270	Inflammatory Bowel Disease Differentiation Panel												x
27	0070068	Insulin, 120 Minutes				x								
28	2013566	Insulin, 180 Minutes				x								
28	0070064	Insulin, 30 Minutes				x								
28	0070066	Insulin, 60 Minutes				x								

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28	0070067	Insulin, 90 Minutes				x								
28	0070063	Insulin, Fasting				x	x							
29	0070155	Insulin, Free and Total				x	x							
29	0070022	Insulin, Other				x		x						
29	0070107	Insulin, Random				x		x						
30	3004046	*JAK2* (V617F) Mutation by ddPCR, Qualitative											x	
31	3003800	*JAK2* (V617F) Mutation by ddPCR, Qualitative with Reflex to *CALR* (Calreticulin) Exon 9 Mutation Analysis by PCR with Reflex to *MPL* Mutation Detection											x	
32	3003801	*JAK2* (V617F) Mutation by ddPCR, Qualitative with Reflex to *JAK2* Exon 12 Mutation Analysis by PCR											x	
50	0051245	JAK2 Gene, V617F Mutation, Qualitative (Inactive as of 8/16/2021, refer to 3004046)												x
50	2012084	JAK2 Gene, V617F Mutation, Qualitative with Reflex to *CALR* (Calreticulin) Exon 9 Mutation Analysis by PCR with Reflex to *MPL* Mutation Detection (Inactive as of 8/16/2021, refer to 3003800)												x
50	2012085	JAK2 Gene, V617F Mutation, Qualitative with Reflex to *JAK2* Exon 12 Mutation Analysis by PCR												x
32	0055167	Kappa/Lambda Quantitative Free Light Chains with Ratio, Serum				x								
32	0020407	Lactose Tolerance				x								
50	2008347	Legius Syndrome (SPRED1) Sequencing and Deletion/Duplication												x
50	2002705	Loeys-Dietz Syndrome (TGFBR1 and TGFBR2) Sequencing												x
33	3003947	Loeys-Dietz Syndrome Core Panel, Sequencing											x	
34	0020765	Macroprolactin				x	x							
35	3002688	Malignant Hyperthermia Panel, Sequencing											x	
35	2003996	Melan A by Immunohistochemistry (DAB Detection)	x									x		
36	3003729	Melan A by Immunohistochemistry (Red Detection)											x	
36	2003935	Melanoma Antibody, HMB45 by Immunohistochemistry (DAB Detection)	x									x		
37	3003741	Melanoma Antibody, HMB45 by Immunohistochemistry (Red Detection)											x	
37	3003971	Multiple Myeloma, Daratumamab, Immunofixation											x	

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50	2012182	Myeloid Malignancies Somatic Mutation and Copy Number Analysis Panel												x
38	3003746	Myeloperoxidase (MPO) Antibody and Serine Proteinase 3 (PR3) Antibody with Reflex to Anti-Neutrophil Cytoplasmic Antibody, IgG by IFA											x	
50	2007159	Neurofibromatosis Type 1 (NF1) Sequencing												x
50	2007154	Neurofibromatosis Type 1 (NF1) Sequencing and Deletion/Duplication												x
39	3003927	Neurofibromatosis Type 1 Sequencing and Deletion/Duplication and Legius Syndrome Sequencing Panel											x	
40	0092356	Nicotine and Metabolites, Urine, Quantitative					x	x			x			
40	2011697	Oxalate, Plasma					x							
40	3001309	1p/19q Deletion by FISH									x			
40	3002135	1p19q Deletion by FISH and IDH1 R132H Point Mutation by Immunohistochemistry with Reflex to IDH1 and IDH2 Mutation Analysis, Exon 4									x			
41	2006247	Parainfluenza 1-4 by PCR				x								
41	0030235	Partial Thromboplastin Time				x								
41	0060043	Parvovirus B19 by Qualitative PCR				x								
41	2007961	PCCA/ANNA by IFA with Reflex to Titer and Immunoblot	x											
41	2014041	Potassium, Total, RBC				x								
42	3001621	Primary Ciliary Dyskinesia Panel, Sequencing											x	
42	0070115	Prolactin				x	x		x					
43	0020724	Prolactin, Dilution Study				x	x		x					
43	2002930	Prostate Specific Antigen, Complexed					x	x						
43	0060764	Respiratory Virus Mini Panel by PCR				x								
44	3004055	Rheumatoid Arthritis Panel											x	
50	2003277	Rheumatoid Arthritis Panel												x
45	3004056	Rheumatoid Arthritis Panel with Reflex to Rheumatoid Factors, IgA, IgG, and IgM by ELISA											x	
50	2003278	Rheumatoid Arthritis Panel with Reflex to Rheumatoid Factors, IgA, IgG, and IgM by ELISA												x
46	3004094	Rivaroxaban Level											x	
46	2004127	S-100 Protein by Immunohistochemistry (DAB Detection)	x									x		
47	3003733	S-100 Protein by Immunohistochemistry (Red Detection)											x	

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47	0070103	Serum, C-Peptide	x			x	x					x		
47	3001562	SOX-10 By Immunohistochemistry (DAB Detection)	x									x		
48	3003737	SOX-10 by Immunohistochemistry (Red Detection)											x	
48	0090265	Theophylline				x								
48	2011172	Urogenital Ureaplasma and Mycoplasma Species by PCR			x	x								
49	3004071	von Willebrand Factor (VWF) GPIbM Activity											x	
49	0060132	Wound Culture and Gram Stain			x									

3001495 **Aggressive B-Cell Lymphoma Reflex Panel by FISH, Tissue** **DLBCL_RFLX**

Note: If Aggressive B-Cell Lymphoma Reflex Panel by FISH is positive, then *IGH-BCL2* Fusion, t(14;18) by FISH (ARUP test code 3001298) and *BCL6* (3q27) Gene Rearrangement by FISH (ARUP test code 3001311) will be added.
Additional charges apply.

CPT Code(s): 88366; if reflexed add 88366 x2

New Test **3003923** **Allergen, Food, Alpha-Gal (galactose-alpha-1,3-galatose) IgE** **ALPHAGAL**
Available Now
Click for Pricing

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat 12:00 am-11:59 pm, continuously
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided
Collect: Plain Serum separator tube. Multiple specimen tubes should be avoided
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 0.25 mL serum **plus** 0.1 mL for each additional allergen ordered to an ARUP Standard Transport Tube. (Min: 0.25 mL **plus** 0.04 mL for each allergen ordered)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed, icteric, or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval:

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

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

CPT Code(s): 86008

New York DOH Approved.

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

New Test **3003924** **Allergen, Food, Alpha-Gal (galactose-alpha-1,3-galatose) Panel** **ALPHAGALPN**
Available Now
Click for Pricing

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat: 12:00 am-11:59 pm continuously
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided
Collect: Plain Serum separator tube. Multiple specimen tubes should be avoided
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 0.25 mL serum **plus** 0.1 mL for each additional allergen ordered to an ARUP Standard Transport Tube. (Min: 0.25 mL **plus** 0.04 mL for each allergen ordered)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed, icteric, or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval:

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

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

CPT Code(s): 86008; 86003 x3

New York DOH Approved.

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

New Test **3002685** **Alport Syndrome Panel, Sequencing and Deletion/Duplication** **ALPORT NGS**
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Patient History for Alport 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: 2 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: Genes tested: *COL4A3***, *COL4A4***, *COL4A5*, *MYH9***
**Deletion/duplication detection is not performed for this gene.

CPT Code(s): 81407; 81408; 81479

New York DOH approval pending. Call for status update.

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

0020471 **Amylase, Urine** **UAMY**

HOTLINE NOTE: There is a component change associated with this test.
Add component 3004185, Urine Creatinine - mg per dL
Add component 3004186, Urine Creatinine - per 24 hour
Add component 3004187, Urine Total Volume
Add component 3004188, Collected Hours
Remove component 0020207, Creatinine, Urine - per volume
Remove component 0020208, Creatinine, Urine - per 24h
Remove component 0097110, Total Volume
Remove component 0097111, Hours Collected

New Test **3003745** **ANCA-Associated Vasculitis Profile (ANCA/MPO/PR3)** **ANCA-PRO**

Click for Pricing

Additional Technical Information

Methodology: Semi-Quantitative Indirect Fluorescent Antibody/Semi-Quantitative Multiplex Bead Assay
Performed: Sun-Sat
Reported: 2-5 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: CSF, plasma, urine, or other body fluids. Contaminated, hemolyzed, or severely lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval	
	ANCA IFA Titer	Less than 1:20	
	ANCA IFA Pattern	None Detected	
0050526	Myeloperoxidase (MPO) Ab, IgG		
		Negative	19 AU/mL or less
		Equivocal	20-25 AU/mL
		Positive	26 AU/mL or greater
0050527	Serine Proteinase 3 (PR3) Ab, IgG		
		Negative	19 AU/mL or less
		Equivocal	20-25 AU/mL
		Positive	26 AU/mL or greater

Interpretive Data:
Refer to report.

Note: Specimens are screened for ANCA, MPO and PR3. ANCA IFA is simultaneously tested on ethanol- and formalin-fixed slides to allow differentiation of C- and P-ANCA patterns.

CPT Code(s): 83516 x2; 86255

New York DOH Approved.

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

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

Specimen Required: Collect: **Fetal Specimen**: Two (2) T-25 flasks at 80 percent confluency of cultured amniocytes. **If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787**. Or amniotic fluid.
AND Maternal Specimen: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: **Cultured Amniocytes**: Fill flasks with culture media. Transport two (2) T-25 flasks at 80 percent confluency of cultured amniocytes. Backup cultures must be retained at the client's institution until testing is complete.
OR Amniotic Fluid: Transport 20 mL unspun fluid. (Min: 10 mL)
AND Maternal Specimen: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: **Cultured Amniocytes**: **CRITICAL ROOM TEMPERATURE**. Must be received within 48 hours of shipment due to liability of cells.
Amniotic Fluid: Room temperature.
Maternal Specimen: Room temperature.
Remarks: **Maternal specimen is recommended for proper test interpretation. Order Maternal Cell Contamination, Maternal Specimen. This can be arranged by contacting ARUP genetic counselors at (800) 242-2787 ext. 2141. Patient History Form is available on the ARUP Web site or by contacting ARUP Client Services.**
Stability (collection to initiation of testing): **Fetal Specimen**: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Maternal Specimen: Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

New Test 3003747 Anti-Neutrophil Cytoplasmic Antibody, IgG by IFA — ANCA-IFA

Click for Pricing

Methodology: Semi-Quantitative Indirect Fluorescent Antibody
Performed: Sun-Sat
Reported: 1-3 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: 0.15 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, urine, or other body fluids. Contaminated, hemolyzed, or severely lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval
	ANCA IFA Titer	Less than 1:20
	ANCA IFA Pattern	None Detected

Interpretive Data:
Neutrophil Cytoplasmic Antibodies (C-ANCA = granular cytoplasmic staining, P-ANCA = perinuclear staining) are found in the serum of over 90 percent of patients with certain necrotizing systemic vasculitides, and usually in less than 5 percent of patients with collagen vascular disease or arthritis.

Note: ANCA IFA is simultaneously tested on ethanol- and formalin-fixed slides to allow differentiation of C- and P-ANCA patterns.

CPT Code(s): 86255

New York DOH Approved.

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

New Test **3004090** **Apixaban Level** **APIX**

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Methodology: Chromogenic Assay
Performed: Tuesday
Reported: 1-8 days

Specimen Required: Collect: Lt. blue (sodium citrate). Refer to Specimen Handling at aruplab.com for hemostasis/thrombosis specimen handling guidelines.
Specimen Preparation: Transport 2 mL platelet-poor plasma. (Min: 1 mL)
Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when additional tests are ordered.
Remarks: This test cannot be used to quantitate anticoagulants other than Apixaban. This includes but is not limited to Unfractionated Heparin, Low Molecular Weight Heparin, Rivaroxaban (Xarelto), Edoxaban (Savaysa), and Fondaparinux (Arixtra).
Unacceptable Conditions: Serum. EDTA, oxalate, heparin, or plasma separator tubes, hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 4 hours; Refrigerated: Unacceptable; Frozen: 1 month

Reference Interval: Not established

Interpretive Data:

When 5 mg apixaban was administered twice daily for treatment of DVT and PE, apixaban steady state levels were as follows:
Peak: 59-302 ng/mL
Trough: 22-177 ng/mL
The lower limit of detection for this assay is 23 ng/mL.
For additional information, please refer to www.arupconsult.com

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): 80299

New York DOH approval pending. Call for status update.

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

0050100 ***Aspergillus* Antibody by CF** **ASPER**

Performed: Sun-Sat
Reported: 2-5 days

New Test **3004070** **Autoimmune Neurologic Disease Reflexive Panel, Serum** **NEURO R3**

Click for Pricing

Methodology: Semi-Quantitative Indirect Fluorescent Antibody/Qualitative Immunoblot/Quantitative Radioimmunoassay/Semi-Quantitative Enzyme-Linked Immunosorbent Assay
Performed: Tue
Reported: 3-10 days

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: 1 month (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	Paraneoplastic Antibodies (PCCA/ANNA) by IFA with Reflex to Titer and Immunoblot		
		Test Number / **Components** / **Reference Interval**	
		Purkinje Cell/Neuronal Nuclear IgG Scrn	None Detected
		Neuronal Nuclear Antibody (ANNA) IFA Titer, IgG	Less than 1:10
		Purkinje Cell Antibody, Titer	Less than 1:10
		3002917 / Neuronal Nuclear Antibodies (Hu, Ri, Yo, Tr/DNER) IgG by Immunoblot, Serum	**Components** / **Reference Interval**
			Refer to report
			Refer to report
			Refer to report
			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	

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: 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. 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.

CPT Code(s): 83519 x2; 84182 x2; 86255 x9; 86341; if reflexed, additional CPT codes may apply: 86256; 84182 x4

New York DOH Approved.

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

2012201 Barbiturates, Serum or Plasma, Quantitative BARBS SP

Methodology: Quantitative Gas Chromatography-Mass Spectrometry/Quantitative Liquid Chromatography-Tandem Mass Spectrometry

Reference Interval:
Effective August 16, 2021

Drugs Covered	Cutoff Concentrations
Butalbital	50 ng/mL
Pentobarbital	50 ng/mL
Phenobarbital	50 ng/mL

Interpretive Data:
Methodology: Quantitative Gas Chromatography-Mass Spectrometry/Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Positive cutoff: 50 ng/mL

For medical purposes only; not valid for forensic use.

The absence of expected drug(s) and/or drug metabolite(s) may indicate non-compliance, inappropriate timing of specimen collection relative to drug administration, poor drug absorption, or limitations of testing. The concentration value must be greater than or equal to the cutoff to be reported as positive. Interpretive questions should be directed to the laboratory.

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.

HOTLINE NOTE: There is a component change associated with this test.
Remove component 2012205, Amobarbital, S/P, Quant
Remove component 2012206, Secobarbital, S/P, Quant

2012213 Barbiturates, Urine, Quantitative BARB UR

Methodology: Quantitative Gas Chromatography-Mass Spectrometry/Quantitative Liquid Chromatography-Tandem Mass Spectrometry

Reference Interval:
Effective August 16, 2021

Drugs Covered	Cutoff Concentrations
Butalbital	50 ng/mL
Pentobarbital	50 ng/mL
Phenobarbital	50 ng/mL

Interpretive Data:
Methodology: Quantitative Gas Chromatography-Mass Spectrometry/Quantitative Liquid Chromatography-Tandem Mass Spectrometry.

Positive cutoff: 50 ng/mL

For medical purposes only; not valid for forensic use.

The absence of expected drug(s) and/or drug metabolite(s) may indicate non-compliance, inappropriate timing of specimen collection relative to drug administration, poor drug absorption, diluted/adulterated urine, or limitations of testing. The concentration value must be greater than or equal to the cutoff to be reported as positive. Interpretive questions should be directed to the laboratory.

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.

HOTLINE NOTE: There is a component change associated with this test.
Remove component 2012217, Amobarbital, Urn, Quant
Remove component 2012218, Secobarbital, Urn, Quant

0020063 Beta-hCG, Serum Qualitative BHCG-S

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Plasma. Specimens exposed to repeated freeze/thaw cycles.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 72 hours; Frozen: 2 months

0020229 Beta-hCG, Urine Qualitative BHCG-U

Specimen Required: Collect: Urine in a plastic container. First-morning urine is the preferred specimen as it usually contains the highest concentration of beta-hCG; however, any specimen is suitable for testing.
Specimen Preparation: Transfer 1 mL aliquot of urine to an ARUP Standard Transport Tube. If frozen, mix after thawing. Do not refreeze.
Storage/Transport Temperature: Frozen.
Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: 72 hours; Frozen: 6 months (one freeze/thaw cycle is acceptable)

New Test **3003824** **Brachyury by Immunohistochemistry** **BRACHY 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 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.

0080392 **Cancer Antigen 27.29** **CA27.29**

Specimen Required: Collect: Plain red or serum separator tube or EDTA plasma.
Specimen Preparation: Allow specimen to clot completely at room temperature. 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: Frozen.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 7 days; Frozen: 3 months

Reference Interval:
Effective August 16, 2021
Less than or equal to 39 U/mL

Interpretive Data:
Test Information: The CA 27.29 assay is intended for use in monitoring: 1) disease progression and/or response to therapy in patients with metastatic disease, and 2) disease recurrence in patients treated previously for stages II or III breast carcinoma who are clinically free of the disease. Serial testing in patients who are clinically free of disease should be used in conjunction with other clinical methods for early detection of cancer recurrence.

Limitations: Patients with confirmed breast carcinoma frequently have CA 27.29 assay values in the same range as healthy individuals. Elevations may also be observed in patients with non-malignant disease. Results of this test must always be interpreted in the context of morphologic and other relevant data and should not be used alone for a diagnosis of malignancy.

Methodology: Siemens Atellica IM BR 27.29 (BR) chemiluminescent immunoassay was used. Results obtained with different assay methods or kits cannot be used interchangeably.

New Test **3003992** **Carbamylated Protein (CarP) Antibody, IgG** **CARP IGG**

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Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay
Performed: Sun, Tue, Thu
Reported: 1-4 days

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: 0.3 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Contaminated, heat-inactivated, hemolyzed, icteric, or lipemic 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
	Carbamylated Protein Antibody, IgG	0-19 Units

Interpretive Data:
Anti-carbamylated protein (anti-CarP) IgG antibodies are present in about 34-53 percent of patients with RA, have specificities of greater than 90 percent and can occur in RA patients seronegative for both rheumatoid factor and anti-CCP. These autoantibodies may be present in the preclinical phase of disease, are associated with future RA development, and may predict radiographic joint destruction. Patients with weak positive results should be monitored and testing repeated.

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): 83516

New York DOH approval pending. Call for status update.

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

3002508 **Clobazam and Metabolite, Quantitative, Serum or Plasma** **CLOBAZAM**

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

0050170 ***Coccidioides* Antibody by CF** **COCCI**

Performed: Sun-Sat
Reported: 2-5 days

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3003648 COVID-19 IgG, Semi-Quantitative by CIA — COV19G SQ

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

Specimen Required: Collect: Serum separator tube (SST). Also acceptable: EDTA or lithium heparin.
Specimen Preparation: Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Specimens containing particulate material or otherwise obviously contaminated. Severely hemolyzed, heat-inactivated, or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month (avoid repeated freeze/thaw cycles)

Reference Interval:

Less than 1.00 Index Value	Negative
Greater than or equal to 1.00 Index Value	Positive

Interpretive Data:
This test is for in vitro diagnostic use under the FDA Emergency Use Authorization (EUA). In compliance with this authorization, please visit https://www.aruplab.com/infectious-disease/coronavirus/testing for more information and to access the applicable fact sheets.

CPT Code(s): 86769

New York DOH Approved.

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

0050503 Coxsackie A9 Virus Antibodies by CF — COX A9

Performed: Sun-Sat
Reported: 2-5 days

3000479 Criteria Systemic Sclerosis Panel — SSC PANEL

Performed: Sun, Tue, Thu
Reported: 1-4 days

2006267 Cytogenomic SNP Microarray Buccal Swab — CMA BUCCAL

Specimen Required: Collect: One buccal swab using the Oracollect collection kit ensuring the sponge tip does not come into contact with any surface prior to collection. Donor should not eat, drink, smoke or chew gum for 30 minutes before collecting oral sample.
Specimen Preparation: Transport Buccal swab in ORAcollect Collection kit (ARUP supply #49295). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Room temperature.
Unacceptable Conditions: Specimen exposed to extreme temperatures. Specimens collected in or by any specimen device other than indicated.
Stability (collection to initiation of testing): Ambient: 7 days; Refrigerated: Unacceptable; Frozen: Unacceptable

New Test **3003917** **Distal Arthrogryposis Panel, Sequencing** **DARTHR NGS**
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Additional Technical Information

Patient History for Distal Arthrogryposis Testing

Methodology: Massively Parallel Sequencing
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: 1.5 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: Genes tested: ECEL1, FBN2, MYBPC1, MYH3, MYH8*, NALCN*, PIEZO2*, TNNI2, TNNT3, TPM2
*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 **3004092** **Edoxaban Level** **EDOX**

Click for Pricing

Methodology: Chromogenic Assay
Performed: Tuesday
Reported: 1-8 days

Specimen Required: Collect: Lt. blue (sodium citrate). Refer to Specimen Handling at aruplab.com for hemostasis/thrombosis specimen handling guidelines.
Specimen Preparation: Transport 2 mL platelet-poor plasma. (Min: 1 mL)
Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when additional tests are ordered.
Remarks: This test cannot be used to quantitate anticoagulants other than Edoxaban. This includes but is not limited to Unfractionated Heparin, Low Molecular Weight Heparin, Apixaban (Eliquis), Rivaroxaban (Xarelto), and Fondaparinux (Arixtra).
Unacceptable Conditions: Serum. EDTA, oxalate, heparin, or plasma separator tubes, hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 4 hours; Refrigerated: Unacceptable; Frozen: 1 month

Reference Interval: Not established

Interpretive Data:

When 60 mg edoxaban was administered daily for treatment of DVT and PE, edoxaban steady state levels were as follows:
Peak: 149-317 ng/mL
Trough: 10-39 ng/mL
The lower limit of detection for this assay is 20 ng/mL.
For additional information, please refer to www.arupconsult.com

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): 80299

New York DOH approval pending. Call for status update.

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

New Test **3001839** **Emery-Dreifuss Muscular Dystrophy Panel, Sequencing** **EDMD NGS**

Click for Pricing

Additional Technical Information

Patient History for Emery-Dreifuss Muscular Dystrophy (EDMD) Testing

Methodology: Massively Parallel Sequencing
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: 1 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: Genes Tested: *EMD*, *FHL1*, *LMNA*

CPT Code(s): 81479; 81404; 81406

New York DOH approval pending. Call for status update.

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

2002378 **Eosinophilia Panel by FISH** **FISH EOS P**

Interpretive Data:
Probes included: PDGFR-alpha, PDGFR-beta, and FGFR1.

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): 88271 x3; 88275 x3

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

0082024 **Fetal Fibronectin** **FFN**

Specimen Required: Patient Prep: Collect specimen prior to any activities or procedures that might disrupt the cervix, eg, coitus, digital cervical examination, vaginal ultrasound, collection of culture specimens, or pap smear.
Testing should not be performed if the patient has had sexual intercourse within 24 hours prior to the sampling time because semen present may increase the possibility of a false-positive result. Contamination with lubricants, soaps, or disinfectants may cause invalid test results.
Collect: Insert the polyester-tipped swab provided in the specimen collection kit into the vagina and lightly rotate across the posterior fornix for approximately 10 seconds to absorb cervicovaginal secretions. Carefully remove the swab and place into the tube of buffer provided in the kit. Use only one specimen collection device per patient.
Specimen Preparation: Specimens that are not tested within eight hours of collection must be stored, refrigerated, and tested within 72 hours of collection. Avoid extreme temperatures. Transport swab in Fetal Fibronectin Specimen Collection Kit (ARUP supply #32748). Available online through eSupply using ARUP Connect™ or contact Client Services at (800) 522-2787. **Required Information:** Specimen must be labeled with gestational age and list patient condition as either "symptomatic" or "asymptomatic."
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Specimens collected in or by any specimen device other than Fetal Fibronectin Specimen Collection Kit, visible evidence of moderate or gross vaginal bleeding. Specimens from symptomatic patients who are less than 24 weeks or greater than or equal to 35 weeks gestation. Specimens from asymptomatic patients who are less than 22 weeks or greater than or equal to 35 weeks gestation.
Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: 3 days; Frozen: 2 weeks Only one freeze/thaw cycle acceptable.

New Test **3004075** **FGFR1 Gene Amplification by FISH** **FGFR1_FISH**
Click for Pricing

Methodology: Fluorescence in situ Hybridization (FISH)
Performed: Varies
Reported: 3-7 days

Specimen Required: Collect: Tumor tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed tumor tissue. Transport tissue block or 4 unstained, consecutively cut, 5-micron thick sections, mounted on positively charged glass slides. (Min: 4 slides) Protect paraffin block and/or slides from excessive heat.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated.
Remarks: Include surgical pathology report with reason for referral. The laboratory will not reject specimens that arrive without a pathology report but will hold the specimen until this information is received.
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 (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). No tumor in tissue. Decalcified specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

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.

CPT Code(s): 88366

New York DOH approval pending. Call for status update.

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

0020476 Glucose, Urine UGLU

HOTLINE NOTE: There is a component change associated with this test.
Add component 3004185, Urine Creatinine - mg per dL
Add component 3004186, Urine Creatinine - per 24 hour
Add component 3004187, Urine Total Volume
Add component 3004188, Collected Hours
Remove component 0020207, Creatinine, Urine - per volume
Remove component 0020208, Creatinine, Urine - per 24h
Remove component 0097110, Total Volume
Remove component 0097111, Hours Collected

0040085 Hemoglobin HGB

Reference Interval: Effective August 16, 2021

Age	0 days	1-6 days	7-13 days	14-29 days	30-60 days	61-90 days	91-180 days	6 - 23 months	2-5 years	6-11 years	12-17 years	18 years and older
Male (g/dL)	13.5-19.5	14.5-21.9	13.5-20.9	12.5-20.5	10.0-18.0	9.0-14.0	9.5-13.5	10.5-13.5	11.5-13.5	11.5-15.5	13.0-16.0	14.8-17.8
Female (g/dL)	13.5-19.5	14.5-21.9	13.5-20.9	12.5-20.5	10.0-18.0	9.0-14.0	9.5-13.5	10.5-13.5	11.5-13.5	11.5-15.5	12.0-16.0	12.6-15.9

3001842 Hereditary Myeloid Neoplasms Panel, Sequencing HMYE NGS

Specimen Required: Collect: Cultured skin fibroblasts (preferred) or
Whole blood: Lavender (EDTA) or yellow (ACD Solution A or B). or
Skin punch biopsy**:** Thaw media prior to tissue inoculation. Place skin punch biopsy in a sterile, screw-top container filled with tissue culture transport medium (ARUP Supply #32788). Available online through eSupply using ARUP Connect. If cytogenetics tissue media is not available, collect in plain RPMI, Hanks solution, sterile saline, or ringers. **New York State Clients: Collect Monday-Thursday only.**
Specimen Preparation: Cultured skin fibroblasts: 2 T-25 flasks at 80 percent confluency, Fill flasks with culture media. Backup cultures must be maintained at the client's institution until testing is complete.
Skin punch biopsy DO NOT FREEZE. Do not place in formalin. Transport a 4 mm skin biopsy in a sterile, screw-top container filled with tissue transport medium.
Whole blood: Transport 3 mL whole blood. (Min: 1.5 mL)
New York State Clients: Cultured skin fibroblasts: 2 T-25 flasks at 80 percent confluency. Whole blood: Transport 5 mL whole blood (min. 3 mL). **Do not send cultured fibroblasts to ARUP Laboratories**. Specimens must be received at performing laboratory within 48 hours of collection. For specimen requirements and direct submission instructions please contact ARUP Referral Testing at (800) 242-2787, ext. 5145.
Storage/Transport Temperature: Cultured skin fibroblasts: Critical room temperature. Must be received within 48 hours of shipment due to lability of cells
Skin punch biopsy: Room temperature
Whole Blood: Refrigerated.
Remarks: Cultured skin fibroblast backup cultures must be retained at the client's institution until testing is complete. Skin punch biopsies can be cultured at ARUP at an additional charge.
Unacceptable Conditions: Grossly hemolyzed or frozen specimens; formalin fixed tissue, FFPE
Stability (collection to initiation of testing): Cultured skin fibroblasts: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable,
Skin punch biopsy: Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Unacceptable
Whole blood: Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable
New York State Clients: Cultured skin fibroblasts: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable,
Whole blood: Ambient: 48 hours; Refrigerated: 1 week; Frozen: Unacceptable

New Test Available Now Click for Pricing **3002682** **Heterotaxy and Situs Inversus Panel, Sequencing** **HTX NGS**

Methodology: Massively Parallel Sequencing
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: 1.5 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: Genes tested: ANKS6*, ARL2BP, ARMC4*, CCDC103*, CCDC114*, CCDC151, CCDC39, CCDC40*, CFAP298*, CFAP53, CRELD1, DNAAF1, DNAAF2, DNAAF3, DNAAF4, DNAAF5*, DNAH1, DNAH11, DNAH5, DNAI1, DNAI2*, DNAL1, FOXH1, GATA4, GATA6*, INVS, LRRC6, MMP21, NKX2-5, NME8, NODAL, PIH1D3, PKD1L1*, SPAG1*, ZIC3, ZMYND10* 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.

0050625 ***Histoplasma* Antibodies by CF** **HISTO**

Performed: Sun-Sat
Reported: 2-5 days

3000870 Human Immunodeficiency Virus 1 (HIV-1) by Quantitative NAAT with Reflex to HIV-1 Drug Resistance by Next Generation Sequencing — HIV QT GR

Methodology: Quantitative Transcription-Mediated Amplification/Massively Parallel Sequencing
Performed: Sun-Sat
Reported: 2-14 days

Reference Interval:

Effective August 16, 2021

Test Number	Components	Reference Interval
3000867	Human Immunodeficiency Virus 1 (HIV-1) by Quantitative NAAT, Plasma	Not detected.
3003853	Human Immunodeficiency Virus 1, Drug Resistance by Next Generation Sequencing	By report

Note: If Human Immunodeficiency Virus 1 by Quantitative NAAT result is greater than or equal to 2.70 log copies/mL, then HIV- Drug Resistance by Next Generation Sequencing will be added. Additional charges apply.

CPT Code(s): 87536; if reflexed add 87900; 87901; 87906

HOTLINE NOTE: There is a reflexive pattern change associated with this test.
Add reflex to 3003853, Human Immunodeficiency Virus 1, Drug Resistance by Next Generation Sequencing
Remove reflex from 0055670, Human Immunodeficiency Virus 1, Genotype by Sequencing

New Test **3003853** **Human Immunodeficiency Virus 1 Drug Resistance by Next Generation Sequencing** **HIV1 NGS**

Click for Pricing

Methodology: Massively Parallel Sequencing
Performed: Sunday-Saturday
Reported: 4-10 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA) or plasma preparation tube.
Specimen Preparation: Separate plasma from cells within 24 hours. Transfer 2.5 mL plasma to an ARUP Standard Transport Tube. (Min: 1.5 mL)
Storage/Transport Temperature: Frozen.
Remarks: Please submit most recent viral load and test date, if available.
Unacceptable Conditions: Serum. Heparinized specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 72 hours; Frozen: 3 months

Reference Interval: By report

Interpretive Data:

This assay predicts HIV-1 resistance to protease inhibitors, nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors and integrase inhibitors. The protease gene, integrase gene and the reverse transcriptase gene of the viral genome are sequenced using Next Generation Sequencing. Drug resistance is assigned using the Stanford hivdb database.

This test should be used in conjunction with clinical presentation and other laboratory markers. A patient's response to therapy depends on multiple factors, including patient adherence, percentage of resistant virus population, dosing, and drug pharmacology issues.

This test detects populations down to 10 percent of the total population which may account for resistance interpretation differences between methods. Some insertions or deletions may be difficult to detect using this software.

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 may be unsuccessful if the plasma HIV-1 RNA viral load is less than 500 copies per mL of plasma.

CPT Code(s): 87900; 87901; 87906

New York DOH approval pending. Call for status update.

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

3002134 **IDH1 R132H Point Mutation by Immunohistochemistry with Reflex to IDH1 and IDH2 Mutation Analysis, Exon 4** **IDH1 RFLX**

HOTLINE NOTE: There is a component change associated with this test.
Add component 2007358, IDH1 R132H Mutation Reference Number
Remove component 2002148, Block ID

New Test **3003748** **Inflammatory Bowel Disease Differentiation Panel** **IBD-PAN**
Click for Pricing

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Semi-Quantitative Indirect Fluorescent Antibody
Performed: Sat-Sun
Reported: 1-4 days

Specimen Required: Patient Prep: N/A
Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1.5 mL serum to an ARUP Standard Transport Tube. (Min: 0.6 mL)
Storage/Transport Temperature: Refrigerated.
Remarks: N/A
Unacceptable Conditions: Contaminated, heat-inactivated, hemolyzed, or severely lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval	
	Saccharomyces cerevisiae Antibody, IgG		
		20.0 Units or less	Negative
		20.1-24.9 Units	Equivocal
		25.0 Units or greater	Positive
	Saccharomyces cerevisiae Antibody, IgA		
		20.0 Units or less	Negative
		20.1-24.9 Units	Equivocal
		25.0 Units or greater	Positive
	ANCA IFA Titer	Less than 1:20	
	ANCA IFA Pattern	None Detected	

Interpretive Data:
Refer to report.

Note: This test may be a useful tool for distinguishing ulcerative colitis (UC) from Crohn disease (CD) in patients with suspected inflammatory bowel disease. ANCA IFA is simultaneously tested on ethanol- and formalin-fixed slides to allow differentiation of C- and P-ANCA patterns.

CPT Code(s): 86671 x2; 86255

New York DOH Approved.

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

0070068 **Insulin, 120 Minutes** **INSULIN120**

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.4 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Heparinized plasma. I.V. fluid. Vitreous fluid. Gray (sodium fluoride/potassium oxalate). Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 1 month

2013566 **Insulin, 180 Minutes** **INSULIN180**

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. Transport 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.4 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Heparinized plasma, I.V. fluid, or Vitreous fluid. Gray (sodium fluoride/potassium oxalate). Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 1 month

0070064 **Insulin, 30 Minutes** **INSULIN 30**

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.4 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Heparinized plasma. Vitreous or I.V. fluids. Gray (sodium fluoride/potassium oxalate). Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 1 month

0070066 **Insulin, 60 Minutes** **INSULIN 60**

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.4 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Heparinized plasma. I.V. fluid. Vitreous fluid. Gray (sodium fluoride/potassium oxalate). Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 1 month

0070067 **Insulin, 90 Minutes** **INSULIN 90**

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.4 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Heparinized plasma. I.V. fluid. Vitreous fluid. Gray (sodium fluoride/potassium oxalate). Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 1 month.

0070063 **Insulin, Fasting** **INSULIN FT**

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min 0.4 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Heparinized plasma. Vitreous or I.V. fluids. Specimens collected in gray (sodium fluoride/potassium oxalate). Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 1 month

Reference Interval:
Effective August 16, 2021
3-25 µIU/mL

0070155 Insulin, Free and Total — INS F&T

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1.1 mL)
Storage/Transport Temperature: Frozen. **Separate specimens must be submitted when multiple tests are ordered.**
Unacceptable Conditions: Heparinized specimens. Sodium fluoride/potassium oxalate plasma. Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 1 month

Reference Interval:
Effective August 16, 2021

Test Number	Components	Reference Interval
	Insulin, Free	3-25 µIU/mL
	Insulin, Total	3-25 µIU/mL

0070022 Insulin, Other — INSULINOTH

Specimen Required: Collect: Serum Separator Tube(SST).
Specimen Preparation: Allow sample to clot completely at room temperature. Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.4 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Vitreous fluid. Gray (sodium fluoride/potassium oxalate) or heparinized plasma. Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 1 month

Interpretive Data:
This test reacts on a nearly equimolar basis with the analogs insulin aspart, insulin glargine, and insulin lispro. Insulin detemir exhibits approximately 50 percent cross-reactivity. Test reactivity with insulin glulisine is negligible (< 3 percent). To convert to pmol/L, multiply µIU/mL by 6.0. The reference interval for fasting insulin is 3-25 µIU/mL

0070107 Insulin, Random — INSULIN R

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.4 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Heparinized plasma. I.V. fluid. Vitreous fluid. Gray (potassium oxalate/sodium fluoride). Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 1 month.

Interpretive Data:
This test reacts on a nearly equimolar basis with the analogs insulin aspart, insulin glargine, and insulin lispro. Insulin detemir exhibits approximately 50 percent cross-reactivity. Test reactivity with insulin glulisine is negligible (< 3 percent). To convert to pmol/L, multiply µIU/mL by 6.0. The reference interval for a fasting insulin is 3-25 µIU/mL.

New Test **3004046** ***JAK2* (V617F) Mutation by ddPCR, Qualitative** **JAK2 QUAL**

Click for Pricing

Additional Technical Information

Methodology: Droplet Digital PCR (ddPCR)
Performed: DNA Isolation: Sun-Sat
Assay: Varies
Reported: 2-7 days

Specimen Required: Collect: Whole blood or bone marrow: Lavender (EDTA), preferred. Also acceptable: Green (sodium heparin)
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 fresh or frozen tissue, DNA extracted by a non-CLIA certified lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Refrigerated: 7 days; 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): 81270

New York DOH Approved.

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

New Test	**3003800**	***JAK2* (V617F) Mutation by ddPCR, Qualitative with Reflex to *CALR* (Calreticulin) Exon 9 Mutation Analysis by PCR with Reflex to *MPL* Mutation Detection**	**ETPMF RFX**

Click for Pricing

Additional Technical Information

Methodology: Droplet Digital Polymerase Chain Reaction/Capillary Electrophoresis
Performed: DNA Isolation: Sun-Sat
Assay: Varies
Reported: 3-15 days

Specimen Required: Collect: Whole blood or bone marrow: Lavender (EDTA), preferred. Also acceptable: Green (sodium heparin)
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 fresh 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): Refrigerated: 7 days; 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: If *JAK2* QUAL is reported as "Not Detected" then *CALR* Exon 9 Mutation Analysis by PCR will be added. If *CALR* is reported as "Not Detected," then *MPL* Mutation Detection will be added. Additional charges apply.

CPT Code(s): 81270; if reflexed add 81219; if reflexed again add 81338

New York DOH Approved.

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

New Test **3003801** ***JAK2* (V617F) Mutation by ddPCR, Qualitative with Reflex to *JAK2* Exon 12 Mutation Analysis by PCR** **PV RFX**

Click for Pricing

Additional Technical Information

Methodology: Droplet Digital Polymerase Chain Reaction/Polymerase Chain Reaction
Performed: DNA Isolation: Sun-Sat
Assay: Varies
Reported: 3-12 days

Specimen Required: Collect: Whole blood or bone marrow: Lavender (EDTA), preferred. Also acceptable: Green (sodium heparin).
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 fresh or frozen tissue, DNA extracted by a non-CLIA certified lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Refrigerated: 7 days; 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: If *JAK2* QUAL is reported as "Not Detected" then *JAK2* Exon 12 Mutation Analysis will be added. Additional charges apply.

CPT Code(s): 81270; if reflexed, add 81279

New York DOH Approved.

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

0055167 **Kappa/Lambda Quantitative Free Light Chains with Ratio, Serum** **KAP/LAM F**

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma. Grossly Hemolyzed and Lipemic Samples
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 3 weeks; Frozen: 6 months

0020407 **Lactose Tolerance** **LACTOL**

Specimen Required: Patient Prep: Recommend drawing specimens for baseline (fasting), 30 minutes, 60 minutes, 120 minutes, and 180 minutes after lactose load (lactose may be obtained from a hospital pharmacy). Fasting patient should be given 50 g lactose in 200-300 mL water consumed in 5 to 10 minutes. Note: If severe lactase deficiency is suspected, the dose should be lowered.
Collect: Gray (sodium fluoride/potassium oxalate). Collect separate tube for each timed point.
Specimen Preparation: Separate plasma from cells ASAP or within 2 hours of collection. Transfer 1 mL plasma **for each time point** to individual ARUP Standard Transport Tubes. (Min: 0.5 mL per timed determination)
Storage/Transport Temperature: Frozen.
Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 72 hours; Frozen: 1 year

New Test **3003947** **Loeys-Dietz Syndrome Core Panel, Sequencing** **LDS NGS**
Available Now
Click for Pricing

Patient History for Aortopathies Testing

Additional Technical Information

Methodology: Massively Parallel Sequencing
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: 1.5 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: Genes tested: *TGFBR1*, *TGFBR2*
CPT Code(s): 81405

New York DOH approval pending. Call for status update.

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

0020765 Macroprolactin MACROPRO

Specimen Required: Collect: Serum separator tube or plasma separator tube. Also acceptable: Lithium heparin or EDTA plasma.
Specimen Preparation: Allow specimen to clot completely at room temperature. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Frozen.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 7 days; Frozen: 1 month

Reference Interval:
Effective August 16, 2021

Test Number	Components	Reference Interval		
0070115	Prolactin	**Prolactin**		
			Male	**Female**
		1-9 years	2.1-17.7 ng/mL	2.1-17.7 ng/mL
		10 years and older		2.8-29.2 ng/mL
	Monomeric Prolactin			
		Age	**Male**	**Female**
		1-9 years	2.1-13.3 ng/mL	2.1-13.3 ng/mL
		10 years and older	2.1-13.3 ng/mL	2.8-19.5 ng/mL
	Monomeric Prolactin Percent	Greater than 50%		

HOTLINE NOTE: Remove information found in the Unacceptable Conditions field.

New Test **3002688** **Malignant Hyperthermia Panel, Sequencing** **MH NGS**
Click for Pricing

Additional Technical Information

Patient History for Malignant Hyperthermia Testing

Methodology: Massively Parallel Sequencing
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: 1.5 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: Genes tested: CACNA1S, RYR1*
*One or more exons are not covered by sequencing for the indicated gene; see Additional Technical Information.

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.

2003996 **Melan A by Immunohistochemistry (DAB Detection)** **MELANA IHC**

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 2003997, Melan A by IHC from Melan A by IHC to Melan A by IHC DAB Detection.
Change the charting name for component 2003998, Melan A Reference Number from Melan A Reference Number to Melan A DAB Detection Reference Number.

New Test **3003729** **Melan A by Immunohistochemistry (Red Detection)** **MELA R IHC**

Available Now

Click for Pricing

Immunohistochemistry Stain Form
Recommended (ARUP form #32978)

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

Specimen Required: Collect: Tissue or cells.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (ARUP supply #47808). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 2 slides). If sending precut slides, do not oven bake.
Storage/Transport Temperature: Room temperature or refrigerated. Ship in cooled container during summer months.
Remarks: **IMMUNOHISTOCHEMISTRY ORDERING AND SUBMISSION DETAILS:** Submit electronic request. If you do not have electronic ordering capability, use an ARUP Immunohistochemistry Stain Form (#32978) with an ARUP client number. For additional technical details, contact ARUP Client Services at (800) 522-2787.
Unacceptable Conditions: Specimens submitted with non-representative tissue type. Depleted specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

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.

2003935 **Melanoma Antibody, HMB45 by Immunohistochemistry (DAB Detection)** **HMB 45 IHC**

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 2003936, Melanoma Antibody, HMB45 by IHC from Melanoma Antibody, HMB45 by IHC to HMB45 by IHC DAB Detection.
Change the charting name for component 2003937, Melanoma Antibody, HMB45 Ref Num from HMB45 Ref Num to HMB45 DAB Detection Reference Number.

New Test **3003741** **Melanoma Antibody, HMB45 by Immunohistochemistry (Red Detection)** **HMB45R IHC**

Available Now
Click for Pricing

Immunohistochemistry Stain Form Recommended (ARUP form #32978)

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

Specimen Required: Collect: Tissue or cells.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (ARUP supply #47808). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 2 slides). If sending precut slides, do not oven bake.
Storage/Transport Temperature: Room temperature or refrigerated. Ship in cooled container during summer months.
Remarks: **IMMUNOHISTOCHEMISTRY ORDERING AND SUBMISSION DETAILS:** Submit electronic request. If you do not have electronic ordering capability, use an ARUP Immunohistochemistry Stain Form (#32978) with an ARUP client number. For additional technical details, contact ARUP Client Services at (800) 522-2787.
Unacceptable Conditions: Specimens submitted with non-representative tissue type. Depleted specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

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.

New Test **3003971** **Multiple Myeloma, Daratumamab, Immunofixation** **MM DARA**

Click for Pricing

Methodology: Qualitative Immunofixation Electrophoresis
Performed: Varies
Reported: 4-9 days

Specimen Required: Patient Prep: Fasting specimen preferred.
Collect: Plain Red.
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 1 mL)
Test is not performed at ARUP; separate specimens must be submitted when multiple tests are ordered.
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Stability (collection to initiation of testing): Ambient: 5 days; Refrigerated: 6 days; Frozen: 6 months

Reference Interval: By report

CPT Code(s): 86334

New York DOH Approved.

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

New Test **3003746** **Myeloperoxidase (MPO) Antibody and Serine Proteinase 3 (PR3) Antibody with Reflex to Anti-Neutrophil Cytoplasmic Antibody, IgG by IFA** **ANCA-PN**

Click for Pricing

Methodology: Semi-Quantitative Indirect Fluorescent Antibody/Semi-Quantitative Multiplex Bead Assay
Performed: Sun-Sat
Reported: 2-5 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: CSF, plasma, urine, or other body fluids. Contaminated, hemolyzed, or severely lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval	
3003747	Anti-Neutrophil Cytoplasmic Antibody IgG	Less than 1:20	
		None Detected	
0050526	Myeloperoxidase (MPO) Ab, IgG		
		Negative	19 AU/mL or less
		Equivocal	20-25 AU/mL
		Positive	26 AU/mL or greater
0050527	Serine Proteinase 3 (PR3) Ab, IgG		
		Negative	19 AU/mL or less
		Equivocal	20-25 AU/mL
		Positive	26 AU/mL or greater

Interpretive Data:
Refer to report.

Note: If MPO and/or PR3 results are equivocal or positive, then ANCA by IFA will be added. Additional changes apply. Specimens are screened by IFA on ethanol-fixed neutrophils, formalin-fixed neutrophils, and HEp-2 slides that allow differentiation of C- and P-ANCA patterns.

CPT Code(s): 83516 x 2; if reflexed, add 86255

New York DOH Approved.

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

New Test **3003927** **Neurofibromatosis Type 1 Sequencing and Deletion/Duplication and Legius Syndrome Sequencing Panel** **NF1 NGS**

Click for Pricing

Patient History for Neurofibromatosis Type 1 and Legius Syndrome

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: 2 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: Genes tested: *NF1*, *SPRED1***
** -Deletion/duplication detection is not available for this gene.

CPT Code(s): 81405, 81408, 81479

New York DOH approval pending. Call for status update.

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

0092356 Nicotine and Metabolites, Urine, Quantitative — NICOTINEUR

Reference Interval: Effective August 16, 2021

Drugs Covered	Cutoff Concentrations
Nicotine	15 ng/mL
Cotinine (metabolite)	15 ng/mL
3-OH-Cotinine (metabolite)	50 ng/mL
Anabasine (tobacco biomarker)	5 ng/mL

Interpretive Data:
Methodology: Quantitative Liquid Chromatography-Tandem Mass Spectrometry

Positive cutoff:
Nicotine 15 ng/mL
Cotinine 15 ng/mL
3-OH-Cotinine 50 ng/mL
Anabasine 5 ng/mL

For medical purposes only; not valid for forensic use.

This test is designed to evaluate recent use of nicotine-containing products. Passive and active exposure cannot be discriminated definitively, although a cutoff of 100 ng/mL cotinine is frequently used for surgery qualification purposes. For smoking cessation programs or compliance testing, the absence of expected drug(s) and/or drug metabolite(s) may indicate non-compliance, inappropriate timing of specimen collection relative to drug administration, poor drug absorption, diluted/adulterated urine, or limitations of testing. The concentration value must be greater than or equal to the cutoff to be reported as positive. Anabasine is included as a biomarker of tobacco use, versus nicotine replacement. Interpretive questions should be directed to the laboratory.

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.

HOTLINE NOTE: There is a component change associated with this test.
Remove component 0092360, Nornicotine, Urine

2011697 Oxalate, Plasma — POXAL

Reference Interval:
Effective August 16, 2021
Less than or equal to 2.0 umol/L

3001309 1p/19q Deletion by FISH — 1P19Q_FISH

HOTLINE NOTE: There is a component change associated with this test.
Add component 3003802, 1P Percent Deleted
Add component 3003803, 19Q Percent Deleted

3002135 1p19q Deletion by FISH and IDH1 R132H Point Mutation by Immunohistochemistry with Reflex to IDH1 and IDH2 Mutation Analysis, Exon 4 — OLIGO PAN

HOTLINE NOTE: There is a component change associated with this test.
Add component 2007358, IDH1 R132H Mutation Reference Number
Remove component 2002148, Block ID

2006247 **Parainfluenza 1-4 by PCR** **PARAFLUPCR**

Specimen Required: Collect: Bronchoalveolar lavage (BAL), nasal wash, nasopharyngeal swab or sputum.
Specimen Preparation: **Fluid:** Transfer 2 mL respiratory specimen to a sterile container. (Min: 0.5 mL) Also acceptable: Transfer to viral transport media (ARUP supply #12884). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. **Swabs**: Place in viral transport media.
Storage/Transport Temperature: Frozen.
Remarks: Specimen source required.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 4 days; Frozen: 1 month

0030235 **Partial Thromboplastin Time** **PTT**

Specimen Required: Collect: Lt. blue (sodium citrate).
Specimen Preparation: Separate plasma from cells ASAP or within 2 hours of collection and freeze. Transfer 1 mL platelet-poor plasma to an ARUP Standard Transport Tube.
Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Unacceptable Conditions: Serum. EDTA plasma, clotted or hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 4 hours; Refrigerated: Unacceptable; Frozen: 2 weeks
NOTE: Specimens from patients on heparin must be centrifuged within 1 hour of collection and ambient stability is reduced to 2 hours.

0060043 **Parvovirus B19 by Qualitative PCR** **PARVPCR**

Specimen Required: Collect: Lavender (EDTA), Pink (K2EDTA), or Serum Separator Tube (SST). Also acceptable: Amniotic fluid, CSF, tissue, paraffin embedded tissue, or synovial fluid.
Specimen Preparation: Separate serum or plasma from cells. Transfer 1 mL serum, plasma, bone marrow, amniotic fluid, CSF, or synovial fluid to a sterile container. (Min: 0.5 mL)
Fresh Tissue: Transfer fresh tissue to a sterile container and freeze immediately.
Paraffin Embedded Tissue: Transport 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: Frozen.
Bone Marrow: Refrigerated.
Paraffin Embedded Tissue: Room temperature.
Remarks: **Specimen source required.**
Unacceptable Conditions: Heparinized specimens, tissues in optimal cutting temperature compound.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: 6 months
Bone Marrow: Ambient: 1 week; Refrigerated: 1 week; Frozen: 1 week
Fresh Tissue: Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 6 months
Paraffin Embedded Tissue: Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

2007961 **PCCA/ANNA by IFA with Reflex to Titer and Immunoblot** **PCCA/ANNA**

HOTLINE NOTE: Name change only.

2014041 **Potassium, Total, RBC** **K RBC**

Specimen Required: Collect: Green (Lithium Heparin).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Leave RBCs in the original container and replace stopper. Transport 2 mL RBCs in the original collection tube. (Min: 0.7 mL)
Test is not performed at ARUP; separate specimens must be submitted when multiple tests are ordered.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Tubes containing potassium-based preservatives/anticoagulants. Light green (lithium heparin).
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 1 month; Frozen: Unacceptable

New Test **3001621** **Primary Ciliary Dyskinesia Panel, Sequencing** **PCD NGS**
Available Now
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Methodology: Massively Parallel Sequencing
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: 1.5 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: Genes tested: ARMC4*, CCDC103*, CCDC114*, CCDC151, CCDC39, CCDC40*, CCDC65, CCNO, CFAP298*, DNAAF1, DNAAF2, DNAAF3, DNAAF4, DNAAF5*, DNAH1, DNAH11, DNAH5, DNAI1, DNAI2*, DNAL1, DRC1, GAS8, LRRC6, MCIDAS, NME8, PIH1D3, RSPH1, RSPH3, RSPH4A, RSPH9, SPAG1*, ZMYND10
*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.

0070115 **Prolactin** **PROLAC**

Specimen Required: Collect: Serum separator tube or plasma separator tube. Also acceptable: Lithium heparin or EDTA plasma.
Specimen Preparation: Allow specimen to clot completely at room temperature. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Frozen.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 7 days; Frozen: 1 months.

Reference Interval:
Effective August 16, 2021

Prolactin		
Age	**Male**	**Female, nonpregnant**
1-9 years	2.1-17.7 ng/mL	2.1-17.7 ng/mL
10 years and older		2.8-29.2 ng/mL

Note: Pregnancy, lactation, and the administration of oral contraceptives can increase prolactin concentrations.

HOTLINE NOTE: Remove information found in the Unacceptable Conditions field.

0020724 Prolactin, Dilution Study — PROLAC MAC

Specimen Required: Collect: Serum separator tube or plasma separator tube. Also acceptable: Lithium heparin or EDTA plasma).
Specimen Preparation: Allow specimen to clot completely at room temperature. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube.
Storage/Transport Temperature: Frozen.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 7 days; Frozen: 1 month

Reference Interval:
Effective August 16, 2021

Prolactin		
Age	**Male**	**Female, nonpregnant**
1-9 years	2.1-17.7 ng/mL	2.1-17.7 ng/mL
10 years and older		2.8-29.2 ng/mL

Note: This test is intended for patients with prolactin-secreting macroadenomas, where a high-dose hook effect is a consideration. Pregnancy, lactation, and the administration of oral contraceptives can increase prolactin concentrations.

HOTLINE NOTE: Remove information found in the Unacceptable Conditions field.

2002930 Prostate Specific Antigen, Complexed — PSA COMP

Reference Interval:
Effective August 16, 2021
Less than or equal to 3.6 ng/mL

Interpretive Data:
This test uses the Siemens' Atellica® IM cPSA methodology, which is FDA approved for use as an aid in the detection of prostate cancer in men age 50 and older when used in conjunction with a digital rectal exam. This methodology is also approved as an aid in the management/monitoring of prostate cancer patients. Results obtained with different assay methods or kits cannot be used interchangeably. Prostatic biopsy is required for the diagnosis of cancer. cPSA is generally not elevated in healthy men or with non-prostatic carcinoma. cPSA concentrations may be elevated in benign prostatic hyperplasia or inflammatory conditions of the prostate. Prostate cancer patients under treatment with antiandrogens and LHRH agonists and antagonists may exhibit markedly reduced levels of cPSA. Care should be taken when interpreting values from these individuals.

0060764 Respiratory Virus Mini Panel by PCR — RESPMINI

Specimen Required: Collect: Respiratory specimen: Bronchoalveolar lavage (BAL), nasal wash, nasopharyngeal swab, or pleural fluid.
Specimen Preparation: **Fluid:** Transfer 1 mL respiratory specimen to a sterile container. (Min: 0.5 mL) Also acceptable: Transfer to viral transport media (ARUP Supply #12884). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. **Swabs**: Place in viral transport media. Place each specimen in an individually sealed bag.
Storage/Transport Temperature: Refrigerated.
Remarks: Specimen source required.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 4 days; Frozen: 1 month

New Test **3004055** **Rheumatoid Arthritis Panel** **RA PANEL**

Click for Pricing

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Quantitative Immunoturbidimetry
Performed: Sun-Sat
Reported: 1-4 days

Specimen Required: Patient Prep: Fasting specimen preferred.
Collect: Serum separator tube.
Specimen Preparation: Allow serum to clot completely at room temperature before centrifuging. Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 1 mL) Serum is the only acceptable specimen type for this assay without a disclaimer.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Contaminated, heat-inactivated, hemolyzed, icteric, or severely lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 1 month (should not be thawed more than once)

Reference Interval:

Available Separately	Components	Reference Interval	
0055256	Cyclic Citrullinated Peptide (CCP) Antibody, IgG		
		19 Units or less	Negative
		20-39 Units	Weak positive
		40-59 Units	Moderate positive
		60 Units or greater	Strong positive
0050465	Rheumatoid Factor	0-14 IU/mL	
3003992	Carbamylated Protein (CarP) Antibody, IgG	0-19 Units	

Interpretive Data:
Anticyclic citrullinated peptide (anti-CCP) IgG antibodies are present in about 69-83 percent of patients with rheumatoid arthritis (RA) and have specificities of 93-95 percent. Anticarbamylated protein (anti-CarP) IgG antibodies are present in about 34-53 percent of patients with RA, have specificities of greater than 90 percent and can occur in RA patients seronegative for both rheumatoid factor and anti-CCP. Anti-CCP and anti-CarP autoantibodies may be present in the preclinical phase of disease, are associated with future RA development, and may predict radiographic joint destruction. Patients with weak positive results should be monitored and testing repeated.

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): 86200; 86431; 83516

New York DOH approval pending. Call for status update.

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

New Test **3004056** **Rheumatoid Arthritis Panel with Reflex to Rheumatoid Factors, IgA, IgG, and IgM by ELISA** **RA PANEL R**

Click for Pricing

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Quantitative Immunoturbidimetry
Performed: Sun-Sat
Reported: 1-4 days

Specimen Required: Patient Prep: Fasting specimen preferred.
Collect: Serum separator tube (SST).
Specimen Preparation: Allow serum to clot completely at room temperature before centrifuging. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.8 mL) **Serum is the only acceptable specimen type for this test without a disclaimer.**
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Contaminated, heat-inactivated, hemolyzed, icteric, or severely lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 1 month (should not be thawed more than once)

Reference Interval:

<table>
<tr><th>Test Number</th><th>Components</th><th>Reference Interval</th></tr>
<tr><td>0055256</td><td>Cyclic Citrullinated Peptide (CCP) Antibody, IgG</td><td>
<table>
<tr><td>19 Units or less</td><td>Negative</td></tr>
<tr><td>20-39 Units</td><td>Weak positive</td></tr>
<tr><td>40-59 Units</td><td>Moderate positive</td></tr>
<tr><td>60 Units or greater</td><td>Strong positive</td></tr>
</table>
</td></tr>
<tr><td>0050465</td><td>Rheumatoid Factor</td><td>0-14 IU/mL</td></tr>
<tr><td>0051298</td><td>Rheumatoid Factors, IgA, IgG, and IgM by ELISA</td><td>
<table>
<tr><th>Test Number</th><th>Components</th><th>Reference Interval</th></tr>
<tr><td></td><td>Rheumatoid Factor, IgG by ELISA</td><td>Refer to report</td></tr>
<tr><td></td><td>Rheumatoid Factor, IgM by ELISA</td><td>Refer to report</td></tr>
<tr><td></td><td>Rheumatoid Factor, IgA by ELISA</td><td>Refer to report</td></tr>
</table>
</td></tr>
<tr><td>3003992</td><td>Carbamylated Protein (CarP) Antibody, IgG</td><td>0-19 Units</td></tr>
</table>

Interpretive Data:
Anticyclic citrullinated peptide (anti-CCP) IgG antibodies are present in about 69-83 percent of patients with rheumatoid arthritis (RA) and have specificities of 93-95 percent. Anticarbamylated protein (anti-CarP) IgG antibodies are present in about 34-53 percent of patients with RA, have specificities of greater than 90 percent and can occur in RA patients seronegative for both rheumatoid factor and anti-CCP. Anti-CCP and anti-CarP autoantibodies may be present in the preclinical phase of disease, are associated with future RA development, and may predict radiographic joint destruction. Patients with weak positive results should be monitored and testing repeated.

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 CCP IgG is 20 units or greater and/or rheumatoid factor is 15 IU/mL or greater, then Rheumatoid Factor, IgG/IgM/IgA by EIA will be performed. Additional charges apply.

CPT Code(s): 86200; 86431; 83516 if reflexed, add 83516 x3

New York DOH approval pending. Call for status update.

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

New Test **3004094** **Rivaroxaban Level** **RIVAROX**

Click for Pricing

Methodology: Chromogenic Assay
Performed: Tuesday
Reported: 1-8 days

Specimen Required: Collect: Lt. blue (sodium citrate). Refer to Specimen Handling at aruplab.com for hemostasis/thrombosis specimen handling guidelines.
Specimen Preparation: Transport 2 mL platelet-poor plasma. (Min: 1 mL)
Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when additional tests are ordered.
Remarks: This test cannot be used to quantitate anticoagulants other than Rivaroxaban. This includes but is not limited to Unfractionated Heparin, Low Molecular Weight Heparin, Apixaban (Eliquis), Edoxaban (Savaysa), and Fondaparinux (Arixtra).
Unacceptable Conditions: Serum. EDTA, oxalate, heparin, or plasma separator tubes, hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 4 hours; Refrigerated: Unacceptable; Frozen: 1 month

Reference Interval: Not established

Interpretive Data:
When 20 mg rivaroxaban was administered daily for treatment of DVT and PE, rivaroxaban steady state levels were as follows:
Peak: 189-419 ng/mL
Trough: 6-87 ng/mL
The lower limit of detection for this assay is 25 ng/mL.
For additional information, please refer to www.arupconsult.com

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): 80299

New York DOH approval pending. Call for status update.

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

2004127 **S-100 Protein by Immunohistochemistry (DAB Detection)** **S100 IHC**

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 2004128, S-100 Protein by IHC from S-100 Protein by IHC to S-100 Protein by IHC DAB Detection.
Change the charting name for component 2004129, S-100 Protein Reference Number from S-100 Protein Reference Number to S-100 Protein DAB Detection Ref Number.

New Test **3003733** **S-100 Protein by Immunohistochemistry (Red Detection)** **S100 R IHC**

Available Now

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Immunohistochemistry Stain Form Recommended (ARUP form #32978)

Methodology: Immunohistochemistry
Performed: Mon-Fri
Reported: 1-5 days

Specimen Required: Collect: Tissue or cells.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin is preferred) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin from excessive heat. Transport tissue block or 5 unstained (3-5 micron thick sections), on positively charged slides (Min: 2 slides). If sending precut slides, do not oven bake.
Storage/Transport Temperature: Room temperature or refrigerated. Ship in cooled container during summer months.
Remarks: **IMMUNOHISTOCHEMISTRY ORDERING AND SUBMISSION DETAILS:** Submit electronic request. If you do not have electronic ordering capability, use an ARUP Immunohistochemistry Stain Form (form #32978) with an ARUP client number. For additional technical details, please contact ARUP Client Services.
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.

0070103 **Serum, C-Peptide** **C PEP**

Specimen Required: Patient Prep: Fasting specimen preferred.
Collect: Serum separator tube
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate serum from cells ASAP. Submit specimen in an ARUP Standard Transport Tube.
Storage/Transport Temperature: Transport 1 mL serum, frozen. (Min: 0.5 mL)
Unacceptable Conditions: Grossly hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 7 days; Frozen: 1 month

Reference Interval:
Effective August 16, 2021
0.5-3.3 ng/mL

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 0070103, C-Peptide, Serum or Plasma from C-Peptide, Serum or Plasma to Serum, C-Peptide.

3001562 **SOX-10 By Immunohistochemistry (DAB Detection)** **SOX10 IHC**

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 3001563, SOX-10 Reference Number from SOX-10 Reference Number to SOX-10 DAB Detection Reference Number.
Change the charting name for component 3001564, SOX-10 By Immunohistochemistry from SOX-10 By Immunohistochemistry to SOX-10 By IHC DAB Detection.

New Test **3003737** **SOX-10 by Immunohistochemistry (Red Detection)** **SOX10R IHC**
Available Now
Click for Pricing

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.

0090265 **Theophylline** **THEO**

Specimen Required: Collect: Plain red. Also acceptable: Green (sodium heparin).
Specimen Preparation: 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.
Remarks: Lipemic specimens may cause an underestimation of Theophylline level
Unacceptable Conditions: Lipemic specimens. Gel separator tubes are not acceptable, regardless of the tube additive
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 8 days; Frozen: 3 months

2011172 **Urogenital Ureaplasma and Mycoplasma Species by PCR** **UR MYCOPCR**

Performed: Mon, Wed, Fri
Reported: 2-5 days

Specimen Required: Collect: Genital swab, rectal swab, or urine. Also acceptable: upper respiratory swabs, bronchoalveolar lavage, sputum, and tracheal aspirates.
Specimen Preparation: Transfer genital swab, rectal swab, respiratory swab, or 1 mL urine to viral transport media (ARUP supply #12884) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
BAL, sputum, or tracheal aspirate: Transfer 1 mL to an empty sterile container. (Min: 0.5 mL)
Storage/Transport Temperature: Frozen
Remarks: Specimen source required.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 10 days; Frozen: 14 days

New Test **3004071** **von Willebrand Factor (VWF) GPIbM Activity** **VWF GPIBM**

Click for Pricing

Methodology: Quantitative Enzyme-Linked Immunosorbent Assay
Performed: Varies
Reported: 7-10 days

Specimen Required: Collect: Light blue (sodium citrate).
Specimen Preparation: Transfer 0.5 mL plasma to an ARUP Standard Transport Tube. (Min: 0.3 mL)
Test is not performed at ARUP; separate specimens must be submitted when multiple tests are ordered.
Storage/Transport Temperature: **CRITICAL FROZEN**.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 2 weeks

Reference Interval: By Report

CPT Code(s): 85397

New York DOH Approved.

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

0060132 **Wound Culture and Gram Stain** **MC W**

Performed: Sun-Sat
Reported: Negative at 6 days
Positives as soon as detected

HOTLINE: Effective August 16, 2021

The following will be discontinued from ARUP's test menu on August 16, 2021.
Replacement test options are supplied if applicable.

Test Number	Test Name	Refer To Replacement
2007994	Allergen, Food, Alpha-Gal (galactose-alpha-1,3-galactose) IgE	Allergen, Food, Alpha-Gal (galactose-alpha-1,3-galatose) IgE (3003923)
2014011	Allergen, Food, Alpha-Gal (galactose-alpha-1,3-galactose) Panel	Allergen, Food, Alpha-Gal (galactose-alpha-1,3-galatose) Panel (3003924)
2002398	Alport Syndrome, X-linked (COL4A5) Sequencing and Deletion/Duplication	Alport Syndrome Panel, Sequencing and Deletion/Duplication (3002685)
2006480	ANCA-Associated Vasculitis Profile (ANCA/MPO/PR3) with Reflex to ANCA Titer	ANCA Vasculitis Profile (3003745)
2002068	Anti-Neutrophil Cytoplasmic Antibody with Reflex to Titer and MPO/PR3 Antibodies	MPO and PR3 with Reflex to ANCA (3003746)
0050811	Anti-Neutrophil Cytoplasmic Antibody, IgG	ANCA Vasculitis Profile (3003745)
0055654	Apolipoprotein B (APOB) Mutation Detection	
3003058	Autoimmune Neurologic Disease Reflexive Panel, Serum	Autoimmune Neurologic Disease Reflexive Panel, Serum (3004070)
0060182	Bacterial Strain Characterization by Pulsed-Field Gel Electrophoresis	Bacterial Strain Typing by Next Generation Sequencing (3002528)
2012678	Gastrointestinal Bacterial Panel by PCR	Gastrointestinal Pathogens Panel by PCR (3003279)
2013577	Gastrointestinal Viral Panel by PCR	Gastrointestinal Pathogens Panel by PCR (3003279)
2009256	HIV1 Genotype and Integrase Inhibitor Resistance by Sequencing	Human Immunodeficiency Virus 1 Drug Resistance by Next Generation Sequencing (3003853)
2004457	HIV-1 Integrase Inhibitor Resistance by Sequencing	Human Immunodeficiency Virus 1 Drug Resistance by Next Generation Sequencing (3003853)
2002805	HLA Antibody Detection	HLA Antibody Screen, Class I and Class II (3002850)
0055670	Human Immunodeficiency Virus 1, Genotype by Sequencing	Human Immunodeficiency Virus 1 Drug Resistance by Next Generation Sequencing (3003853)
3001242	Human Immunodeficiency Virus Type 1 (HIV-1) GenoSure MG	Human Immunodeficiency Virus 1 Drug Resistance by Next Generation Sequencing (3003853)
3001238	Human Immunodeficiency Virus Type 1 (HIV-1) GenoSure PRIme	Human Immunodeficiency Virus 1 Drug Resistance by Next Generation Sequencing (3003853)
2013270	Inflammatory Bowel Disease Differentiation Panel	IBD Differentiation (3003748)
0051245	JAK2 Gene, V617F Mutation, Qualitative (Inactive as of 8/16/2021, refer to 3004046)	JAK2 V617F Mutation by ddPCR Qualitative (3004046)
2012084	JAK2 Gene, V617F Mutation, Qualitative with Reflex to *CALR* (Calreticulin) Exon 9 Mutation Analysis by PCR with Reflex to *MPL* Mutation Detection (Inactive as of 8/16/2021, refer to 3003800)	JAK2 (V617F) Mutation by ddPCR, Qualitative with Reflex to *CALR* (Calreticulin) Exon 9 Mutation Analysis by PCR with Reflex to *MPL* Mutation Detection (3003800)
2012085	JAK2 Gene, V617F Mutation, Qualitative with Reflex to *JAK2* Exon 12 Mutation Analysis by PCR	JAK2 (V617F) Mutation by ddPCR, Qualitative with Reflex to *JAK2* Exon 12 Mutation Analysis by PCR (3003801)
2008347	Legius Syndrome (SPRED1) Sequencing and Deletion/Duplication	Neurofibromatosis Type 1 Sequencing and Deletion/Duplication and Legius Syndrome Sequencing Panel (3003927)
2002705	Loeys-Dietz Syndrome (TGFBR1 and TGFBR2) Sequencing	Loeys-Dietz Syndrome Core Panel, Sequencing (3003947)
2012182	Myeloid Malignancies Somatic Mutation and Copy Number Analysis Panel	Myeloid Malignancies Mutation Panel by Next Generation Sequencing (2011117)
2007159	Neurofibromatosis Type 1 (NF1) Sequencing	Neurofibromatosis Type 1 Sequencing and Deletion/Duplication and Legius Syndrome Sequencing Panel (3003927)
2007154	Neurofibromatosis Type 1 (NF1) Sequencing and Deletion/Duplication	Neurofibromatosis Type 1 Sequencing and Deletion/Duplication and Legius Syndrome Sequencing Panel (3003927)
2003277	Rheumatoid Arthritis Panel	Rheumatoid Arthritis Panel (3004055)
2003278	Rheumatoid Arthritis Panel with Reflex to Rheumatoid Factors, IgA, IgG, and IgM by ELISA	Rheumatoid Arthritis Panel with Reflex to Rheumatoid Factors, IgA, IgG, and IgM by ELISA (3004056)