HOTLINE: Effective August 19, 2019

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
9	3001868	Acetylcholine Receptor Binding Antibody with reflex to Muscle-Specific Kinase (MuSK) Ab, IgG											x	
9	2005894	Allergen Panel, IgE by ImmunoCap ISAC				x				x				
10	0055422	Allergen, Drugs, Ampicillin											x	
81	0098422	Allergen, Occupational, Phthalic Anhydride IgE												x
11	3001720	Allergen, Region 10 Respiratory Panel IgE											x	
12	3001721	Allergen, Region 11 Respiratory Panel IgE											x	
13	3001722	Allergen, Region 12 Respiratory Panel IgE											x	
14	3001723	Allergen, Region 13 Respiratory Panel IgE											x	

Hotline Page #	Test Number	Summary of Changes by Test Name	Name Change	Methodology	Performed/Reported Schedule	Specimen Requirements	Reference Interval	Interpretive Data	Note	CPT Code	Component Change	Other Interface Change	New Test	Inactive
15	3001724	Allergen, Region 14 Respiratory Panel IgE											x	
16	3001725	Allergen, Region 15 Respiratory Panel IgE											x	
17	3001728	Allergen, Region 18 Respiratory Panel IgE											x	
18	3001729	Allergen, Region 19 Respiratory Panel IgE											x	
19	3001712	Allergen, Region 2 Respiratory Panel IgE											x	
20	3001730	Allergen, Region 20 Respiratory Panel IgE											x	
21	3001713	Allergen, Region 3 Respiratory Panel IgE											x	
22	3001714	Allergen, Region 4 Respiratory Panel IgE											x	
23	3001715	Allergen, Region 5 Respiratory Panel IgE											x	
24	3001716	Allergen, Region 6 Respiratory Panel IgE											x	
25	3001717	Allergen, Region 7 Respiratory Panel IgE											x	
26	3001718	Allergen, Region 8 Respiratory Panel IgE											x	
27	3001719	Allergen, Region 9 Respiratory Panel IgE											x	
28	3001726	Allergen, Region 16 Respiratory Panel IgE											x	
29	3001727	Allergen, Region 17 Respiratory Panel IgE											x	
29	0097933	Allergen, Tree, Oak Red IgE		x										
81	2006038	Allergens, Respiratory Panel, Region 10, Southwestern Grasslands (OK, TX) IgE												x
81	2006039	Allergens, Respiratory Panel, Region 11, Rocky Mountain (AZ, ID, NM, WY CO, MT, UT) IgE												x
81	2006040	Allergens, Respiratory Panel, Region 12, Arid Southwest (S. AZ, S.E. CA) IgE												x
81	2006041	Allergens, Respiratory Panel, Region 13, Southern Coastal (CA) IgE												x
81	2006042	Allergens, Respiratory Panel, Region 14, Central California (CA) IgE												x
81	2006043	Allergens, Respiratory Panel, Region 15, Intermountain West (NV, S. ID) IgE												x
81	2006044	Allergens, Respiratory Panel, Region 16, Inland Northwest (OR, Central and East WA) IgE												x
81	2006045	Allergens, Respiratory Panel, Region 17, Pacific Northwest (NW CA, W. OR, WA) IgE												x
81	2006046	Allergens, Respiratory Panel, Region 18, Alaska IgE												x
81	2006047	Allergens, Respiratory Panel, Region 19, Puerto Rico IgE												x
81	2005718	Allergens, Respiratory Panel, Region 2, Mid-Atlantic (DE, MD, VA, DC, NC) IgE												x
81	2006048	Allergens, Respiratory Panel, Region 20, Hawaii IgE												x

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81	2006025	Allergens, Respiratory Panel, Region 3, South Atlantic (GA, SC, N. FL) IgE												x
81	2006026	Allergens, Respiratory Panel, Region 4, Subtropic Florida (S. of Orlando) IgE												x
81	2006031	Allergens, Respiratory Panel, Region 5, Ohio Valley (IN, OH, TN, WV, KY) IgE												x
81	2006032	Allergens, Respiratory Panel, Region 6, South Central (AL, AR, LA, MS) IgE												x
81	2006033	Allergens, Respiratory Panel, Region 7, Northern Midwest (MI, WI, MN) IgE												x
81	2006034	Allergens, Respiratory Panel, Region 8, Central Midwest (IL, MO, IA) IgE												x
81	2006037	Allergens, Respiratory Panel, Region 9, Great Plains (KS, NE, ND, SD) IgE												x
30	0051495	Alpha Thalassemia (*HBA1* and *HBA2*) 7 Deletions			x	x								
81	0091195	Amantadine Quantitative, Serum or Plasma												x
30	2006480	ANCA-Associated Vasculitis Profile (ANCA/MPO/PR3) with Reflex to ANCA Titer	x				x	x	x			x		
30	0010004	Antibody Detection RBC with Reflex to ID	x			x			x	x				
31	0013003	Antibody ID Package (IRL)			x	x								
31	0013005	Antibody ID RBC Prenatal-Reflex to Titer	x			x			x					
31	0013006	Antibody Titer			x	x			x					
31	2002068	Anti-Neutrophil Cytoplasmic Antibody with Reflex to Titer and MPO/PR3 Antibodies	x				x	x	x					
32	0050317	Antinuclear Antibodies (ANA), IgG by ELISA with Reflex to ANA HEp-2 Substrate, IgG by IFA and ENA Confirmation					x	x	x					
33	0050080	Antinuclear Antibodies (ANA), IgG by ELISA with Reflex to ANA, HEp-2 Substrate, IgG by IFA						x						
33	3000601	Antinuclear Antibody (ANA) with HEp-2 Substrate, IgG by IFA with Reflex by Pattern					x		x					
34	0051415	Ashkenazi Jewish Diseases, 16 Genes									x			
34	2014314	Autism and Intellectual Disability Comprehensive Panel							x					
81	0091165	Barium Quantitative, Urine												x
34	3001410	Basement Membrane Zone Antibody Panel											x	
35	2006193	B-Cell Clonality Screening (IgH and IgK) by PCR				x								
35	2005017	*BCR-ABL1*, Major (p210), Quantitative				x								
35	2005016	*BCR-ABL1*, Minor (p190), Quantitative				x								

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36	2005010	*BCR-ABL1*, Qualitative with Reflex to *BCR-ABL1* Quantitative				x								
81	0051421	Beta Globin (*HBB*) HbS, HbC, and HbE Mutations												x
81	0051422	Beta Globin (*HBB*) HbS, HbC, and HbE Mutations, Fetal												x
36	3001798	*Blastomyces* Antigen Quantitative by EIA, Urine											x	
36	2002926	*Blastomyces dermatitidis* Antigen Quantitative by EIA				x			x					
37	0062224	*Blastomyces dermatitidis* Identification	x	x	x					x				
37	0060108	Body Fluid Culture and Gram Stain				x			x					
37	0070053	Bone Specific Alkaline Phosphatase				x								
37	2002498	*BRAF* Codon 600 Mutation Detection by Pyrosequencing				x								
38	0051750	*BRAF* Codon 600 Mutation Detection with Reflex to *MLH1* Promoter Methylation				x		x						
38	2007132	BRAF V600E Mutation Detection in Hairy Cell Leukemia by Real-Time PCR, Quantitative				x								
81	2014493	Bupivacaine Quantitative, Serum or Plasma												x
81	2014027	Calcium, RBC												x
38	2008708	Calculi Risk Assessment, Urine				x								
39	2010673	*CALR* (Calreticulin) Exon 9 Mutation Analysis by PCR				x								
39	2002918	Carbohydrate Deficient Transferrin for Congenital Disorders of Glycosylation (CDG)			x	x								
39	3001697	Carbonic Anhydrase IX by IHC											x	
40	0080407	Catecholamines Fractionated by LC-MS/MS, Urine Free					x							
41	2011114	*CBFB-MYH11* inv(16) Detection, Quantitative				x								
41	2004247	*CEBPA* Mutation Detection				x								
41	0080469	Chromogranin A					x							
41	2011075	*Coccidioides* Antigen Quantitative by EIA			x	x								
41	0062225	*Coccidioides immitis* Identification	x	x	x					x				
42	3000480	Comprehensive Systemic Sclerosis Panel					x		x			x		
42	0051668	Connective Tissue Diseases Profile					x					x		
43	2000133	Cytology, SurePath Liquid-Based Pap Test and Human Papillomavirus (HPV), High Risk by PCR, SurePath (for routine co-testing in women over 30)							x	x				
43	3001783	Dermatomyositis and Polymyositis Panel											x	

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44	3001782	Dermatomyositis Autoantibody Panel											x	
81	2013991	Dermatomyositis Panel												x
81	0091219	Diphenhydramine Quantitative, Urine												x
44	2002440	*EGFR* Mutation Detection by Pyrosequencing				x			x					
45	2007914	*EPOR* Mutation Detection by Sequencing				x								
81	0049050	Esterase Stain, Nonspecific												x
81	2014674	Expanded Carrier Screen, Genotyping												x
81	2014671	Expanded Carrier Screen, Genotyping with Fragile X												x
45	3001781	Extended Myositis Panel											x	
46	0050652	Extractable Nuclear Antigen Antibodies (Smith/RNP, Smith, SSA 52, SSA 60, and SSB)	x				x					x		
46	0094030	Felbamate					x	x						
46	3001161	*FLT3* ITD and TKD Mutation Detection				x								
47	2009033	Fragile X (*FMR1*) with Reflex to Methylation Analysis				x		x	x					
47	2009034	Fragile X (*FMR1*) with Reflex to Methylation Analysis, Fetal				x			x					
81	0091263	Furosemide Quantitative, Serum or Plasma												x
48	3001648	Gaucher Disease (*GBA*) Sequencing											x	
48	3000258	Genetic Carrier Screen, (CF, FXS, and SMA) with Reflex to Methylation							x					
48	0080135	Glucose-6-Phosphate Dehydrogenase				x								
49	2013590	Heat Shock Protein 70, IgG by Immunoblot			x									
49	2010476	*Helicobacter pylori* Breath Test, Adult				x								
49	2010925	*Helicobacter pylori* Breath Test, Pediatric				x								
49	2005792	Hemoglobin Evaluation Reflexive Cascade									x	x		
50	0092522	*Histoplasma* Antigen Quantitative by EIA, Serum	x	x	x	x	x	x	x			x		
50	0062226	*Histoplasma capsulatum* Identification	x	x	x					x				
81	0051067	HLA DRB 3*,4*,5*												x
51	3001791	HNF-1B by Immunohistochemistry											x	
51	2006444	*IDH1* and *IDH2* Mutation Analysis, exon 4				x								
51	2014188	*IDH1* and *IDH2* Mutation Analysis, Exon 4, Formalin-Fixed, Paraffin-Embedded (FFPE) Tissue				x								
52	0040227	*IGHV* Mutation Analysis by Sequencing				x								
52	3001409	Immunobullous Disease Panel, Epithelial Antibody Screening Panel											x	

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81	2008788	Influenza A Virus H1/H3 Subtype by PCR with Reflex to H1N1 (2009) Oseltamivir Resistance by Sequencing												x
81	0093148	Interferon-Alpha by ELISA, Serum												x
53	3001784	Interstitial Lung Disease Autoantibody Panel											x	
81	2013993	Interstitial Lung Disease Panel												x
54	3001568	*IRF4/DUSP22* (6p25) Gene Rearrangement by FISH											x	
54	2002357	*JAK2* Exon 12 Mutation Analysis by PCR				x								
55	0051245	*JAK2* Gene, V617F Mutation, Qualitative				x	x							
55	2012084	*JAK2* Gene, V617F Mutation, Qualitative with Reflex to *CALR* (Calreticulin) Exon 9 Mutation Analysis by PCR with Reflex to *MPL* Mutation Detection				x								
55	2012085	*JAK2* Gene, V617F Mutation, Qualitative with Reflex to *JAK2* Exon 12 Mutation Analysis by PCR				x								
55	0040168	*JAK2* Gene, V617F Mutation, Quantitative				x	x							
56	0020843	Kidney Stone Risk Panel, Urine				x								
56	3000440	*KIT* (D816V) Mutation by PCR				x								
56	2002437	*KIT* Mutations in AML by Fragment Analysis and Sequencing				x								
56	0040248	*KRAS* Mutation Detection				x								
57	2001932	*KRAS* Mutation Detection with Reflex to *BRAF* Codon 600 Mutation Detection				x								
57	3001866	Krebs von den Lungen-6											x	
81	2008003	Leukemia/Lymphoma Phenotyping by Flow Cytometry												x
58	3001780	Leukemia/Lymphoma Phenotyping Evaluation by Flow Cytometry											x	
59	0020421	Lipid Panel						x			x			
60	0020468	Lipid Panel, Extended						x			x			
81	0091200	LSD, Serum or Plasma - Screen with Reflex to Confirmation/Quantitation												x
60	0091224	LSD, Urine - Screen with Reflex to Confirmation/Quantitation			x	x								
60	0050119	Lupus Comprehensive Reflexive Panel							x					
81	0091272	Mercury, Hair												x
61	2009310	*MGMT* Promoter Methylation Detection				x								
61	0051740	Microsatellite Instability (MSI), HNPCC/Lynch Syndrome, by PCR				x								

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61	2002499	*MLH1* Promoter Methylation, Paraffin				x		x						
62	0050615	Monoclonal Protein Detection Quantitation and Characterization, SPEP, IFE, IgA, IgG, IgM, Serum		x		x	x			x		x		
63	2002715	Monoclonal Protein Detection, Quantitation, Characterization, SPEP, IFE, IgA, IgG, IgM, FLC		x		x	x			x		x		
64	2007967	Motor and Sensory Neuropathy Evaluation with Immunofixation Electrophoresis and Reflex to Titer and Neuronal Immunoblot		x		x	x			x		x		
65	0051225	Motor Neuropathy Panel		x		x	x			x		x		
66	2005545	*MPL* Mutation Detection by Capillary Electrophoresis				x								
66	0050707	MPO/PR3 (ANCA) Antibodies	x				x					x		
67	3000523	Mumps Virus by PCR				x								
67	3001869	Myasthenia Gravis Reflexive Panel											x	
68	2009318	*MYD88* L265P Mutation Detection by PCR, Quantitative				x								
68	0050526	Myeloperoxidase (MPO) Antibody	x											
68	0050742	Myocardial Antibody, IgG with Reflex to Titer			x									
81	2013961	Myositis Extended Panel												x
69	3001907	Myotonic Dystrophy Type 1 (*DMPK*) CTG Expansion											x	
69	0099465	Neuronal Cell Antibodies Quantitative, Serum			x									
70	0096657	Neutrophil Oxidative Burst Assay (DHR)				x								
81	0092140	Nitrogen, Total, Urine												x
70	3000066	*NPM1* Mutation Detection by RT-PCR, Quantitative				x								
70	2003123	*NRAS* Mutation Detection by Pyrosequencing				x								
71	3001760	Pancreatitis (*PRSS1*) Deletion/Duplication											x	
81	2002016	Pancreatitis (*PRSS1*) Sequencing												x
72	3001768	Pancreatitis (*PRSS1*) Sequencing and Deletion/Duplication											x	
73	3001764	Pancreatitis *(SPINK1)* Deletion/Duplication											x	
73	3000496	PanFungal Identification by Sequencing				x								
73	3001170	Platelet Antigen 1 Genotyping (HPA-1)			x									
74	3000193	Platelet Antigen Genotyping Panel			x									
74	2002871	*PML-RARA* Translocation, t(15;17) by RT-PCR, Quantitative				x			x					
74	2009226	*Pneumocystis jirovecii* DFA with Reflex to *Pneumocystis jirovecii* by PCR			x									

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81	2013992	Polymyositis and Dermatomyositis Panel												x
75	2002109	Protein Electrophoresis with Reflex to Immunofixation Electrophoresis Monoclonal Protein Detection, Quantitation & Characterization, IgA, IgG, and IgM, Serum	x	x		x	x			x		x		
76	0050640	Protein Electrophoresis, Serum		x		x	x			x		x		
76	3000010	Relapsing Fever *Borrelia* Species by PCR				x			x					
76	0051368	RhD Gene (*RHD*) Copy Number	x					x				x		
77	2003176	Rufinamide, Serum or Plasma					x							
77	2010138	*RUNX1-RUNX1T1* (*AML1-ETO*) t(8;21) Detection, Quantitative				x								
77	0050527	Serine Proteinase 3 (PR3) Antibody	x									x		
77	0050085	Smith (ENA) Antibody, IgG						x						
77	3000460	Smith and Smith/RNP (ENA) Antibodies, IgG	x				x					x		
77	0050470	Smith/RNP (ENA) Antibody, IgG	x					x	x			x		
78	0060137	Stool Culture, *Yersinia*				x								
78	0060705	*Streptococcus* Group B by PCR				x								
81	0091568	Sulfhemoglobin Quantitative, Whole Blood												x
78	2008771	Supersaturation Profile, Urine			x	x								
78	0093199	T-Cell Clonality by Flow Cytometry Analysis of TCR V-Beta				x								
79	0055567	T-Cell Clonality Screening by PCR				x								
79	2013484	TP53 Somatic Mutation, Prognostic			x									
79	3001704	Treponema Pallidum by IHC											x	
81	0098803	Troponin T												x
80	3001831	Troponin T (cTnT) 5th Generation											x	
80	0065031	*Ureaplasma* Species and *Mycoplasma hominis* Culture				x								
80	0020056	Viscosity, Serum					x							
80	2013942	Zika Virus IgM Antibody Capture (MAC) by ELISA						x	x			x		

New Test **3001868** **Acetylcholine Receptor Binding Antibody with reflex to Muscle-Specific Kinase (MuSK) Ab, IgG** **ACHR BIN R**

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Additional Technical Information

Methodology: Quantitative Radioimmunoassay
Performed: Sun-Sat
Reported: 2-8 days

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate 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: Plasma. Contaminated, hemolyzed, or severely lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 2 weeks; Frozen: 1 month (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval	
0080009	Acetylcholine Receptor Binding Antibody	Negative	0.0-0.4 nmol/L
		Positive	0.5 nmol/L or greater
3001576	Muscle-Specific Kinase (MuSK) Antibody, IgG	Negative	0.00-0.03 nmol/L
		Positive	0.04 nmol/L or greater

Interpretive Data: Approximately 85-90 percent of patients with myasthenia gravis (MG) express antibodies to the acetylcholine receptor (AChR), which can be divided into binding, blocking, and modulating antibodies. Binding antibody can activate complement and lead to loss of AChR. Blocking antibody may impair binding of acetylcholine to the receptor, leading to poor muscle contraction. Modulating antibody causes receptor endocytosis resulting in loss of AChR expression, which correlates most closely with clinical severity of disease. Approximately 10-15 percent of individuals with confirmed myasthenia gravis have no measurable binding, blocking, or modulating antibodies.

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

Note: If Acetylcholine Receptor Binding Antibody result is less than or equal to 0.4 nmol/L then Muscle-Specific Kinase (MuSK) Ab, IgG (ARUP test code 3001576) will be added. Additional charges apply.

CPT Code(s): 83519; if reflexed, add 83519

New York DOH Approved.

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

2005894 **Allergen Panel, IgE by ImmunoCap ISAC** **ISAC MICRO**

Specimen Required: Collect: Serum Separator Tube (SST). Also acceptable: Lavender (EDTA) or Green (Sodium or Lithium Heparin).
Specimen Preparation: Transfer 0.4 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.25 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 1 week; Frozen: 1 month

CPT Code(s): 86008 x112

New Test **0055422** **Allergen, Drugs, Ampicillin** **AMPICIL**
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Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided.
Collect: Serum Separator Tube (SST). Multiple specimen tubes should be avoided.
Specimen Preparation: Separate 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): 86003

New York DOH Approved.

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

New Test **3001720** **Allergen, Region 10 Respiratory Panel IgE** **REG10PANEL**
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Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided.
Collect: Serum Separator Tube (SST). Multiple specimen tubes should be avoided.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 4 mL serum to an ARUP Standard Transport Tube. (Min: 1.4 mL)
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:

Reference Intervals for all Components

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

Test Number	Components	Reference Interval	
0050345	Immunoglobulin E	Effective November 17, 2014	
		Age	**Reference Interval**
		0-5 months	13 kU/L or less
		6-12 months	34 kU/L or less
		1-2 years	97 kU/L or less
		3 years	199 kU/L or less
		4-6 years	307 kU/L or less
		7-8 years	403 kU/L or less
		9-12 years	696 kU/L or less
		13-15 years	629 kU/L or less
		16-17 years	537 kU/L or less
		18 years and older	214 kU/L or less

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.

Note: Allergens included in this panel: *Alternaria alternata (tenuis)*, *Aspergillus fumigatus*, Bermuda Grass, Birch Tree, Box Elder/Maple Tree, Cat Dander, Cockroach (German), Common Short Ragweed, Cottonwood Tree, *D. farinae* (mites), *D. Pteronyssinus* (mites), Dog Dander, Elm Tree, *Hormodendrum* (*Cladosporium*), Marsh Elder, Mouse Epithelium, Mountain Cedar (Juniper) Tree, *Mucor racemosus*, Nettle, Oak Tree, Pecan (White Hickory) Tree, *Penicillium notatum*, Pigweed, Sheep Sorrel (Dock), Timothy Grass, White Ash Tree, White Mulberry Tree, and IgE Serum Total.

CPT Code(s): 86003 x27; 82785

New York DOH Approved.

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

New Test **3001721** **Allergen, Region 11 Respiratory Panel IgE** **REG11PANEL**
Click for Pricing

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided.
Collect: Serum Separator Tube (SST). Multiple specimen tubes should be avoided.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 4 mL serum to an ARUP Standard Transport Tube. (Min: 1.3 mL)
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:

Reference Intervals for all Components

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

Test Number	Components	Reference Interval	
0050345	Immunoglobulin E	Effective November 17, 2014	
		Age	**Reference Interval**
		0-5 months	13 kU/L or less
		6-12 months	34 kU/L or less
		1-2 years	97 kU/L or less
		3 years	199 kU/L or less
		4-6 years	307 kU/L or less
		7-8 years	403 kU/L or less
		9-12 years	696 kU/L or less
		13-15 years	629 kU/L or less
		16-17 years	537 kU/L or less
		18 years and older	214 kU/L or less

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.

Note: Allergens included in this panel: Alder Tree, *Alternaria alternata (tenuis)*, *Aspergillus fumigatus*, Bermuda Grass, Box Elder/Maple Tree, Cat Dander, Cockroach (German), Common Short Ragweed, Cottonwood Tree, *D. farinae* (mites), *D. Pteronyssinus* (mites), Dog Dander, Elm Tree, *Hormodendrum* (*Cladosporium*), Mouse Epithelium, Mountain Cedar (Juniper) Tree, *Mucor racemosus*, Mugwort, Oak Tree, Olive Tree, *Penicillium notatum*, Pigweed, Russian Thistle, Sheep Sorrel (Dock), Timothy Grass, White Mulberry Tree, and IgE Serum Total.

CPT Code(s): 86003 x26; 82785

New York DOH Approved.

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

New Test **3001722** **Allergen, Region 12 Respiratory Panel IgE** **REG12PANEL**
Click for Pricing

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided.
Collect: Serum Separator Tube (SST). Multiple specimen tubes should be avoided.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 4 mL serum to an ARUP Standard Transport Tube. (Min: 1.3 mL)
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:

Reference Intervals for all Components

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

Test Number	Components	Reference Interval	
0050345	Immunoglobulin E	Effective November 17, 2014	
		Age	**Reference Interval**
		0-5 months	13 kU/L or less
		6-12 months	34 kU/L or less
		1-2 years	97 kU/L or less
		3 years	199 kU/L or less
		4-6 years	307 kU/L or less
		7-8 years	403 kU/L or less
		9-12 years	696 kU/L or less
		13-15 years	629 kU/L or less
		16-17 years	537 kU/L or less
		18 years and older	214 kU/L or less

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.

Note: Allergens included in this panel: Acacia Tree, *Alternaria alternata (tenuis)*, *Aspergillus fumigatus*, Bermuda Grass, Cat Dander, Cockroach (German), Common Short Ragweed, Cottonwood Tree, *D. farinae* (mites), *D. Pteronyssinus* (mites), Dog Dander, Elm Tree, *Hormodendrum (Cladosporium)*, Johnson Grass, Mouse Epithelium, Mountain Cedar (Juniper) Tree, *Mucor racemosus*, Mugwort, Oak Tree, Olive Tree, *Penicillium notatum*, Perennial Rye Grass, Pigweed, Russian Thistle and IgE Serum Total.

CPT Code(s): 86003 x24; 82785

New York DOH Approved.

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

New Test **3001723** **Allergen, Region 13 Respiratory Panel IgE** **REG13PANEL**

Click for Pricing

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided.
Collect: Serum Separator Tube (SST). Multiple specimen tubes should be avoided.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 4 mL serum to an ARUP Standard Transport Tube. (Min: 1.3 mL)
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:

Reference Intervals for all Components

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

Test Number	Components	Reference Interval	
0050345	Immunoglobulin E	Effective November 17, 2014	
		Age	**Reference Interval**
		0-5 months	13 kU/L or less
		6-12 months	34 kU/L or less
		1-2 years	97 kU/L or less
		3 years	199 kU/L or less
		4-6 years	307 kU/L or less
		7-8 years	403 kU/L or less
		9-12 years	696 kU/L or less
		13-15 years	629 kU/L or less
		16-17 years	537 kU/L or less
		18 years and older	214 kU/L or less

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**.**

Note: Allergens included in this panel: Alder Tree, *Alternaria alternata (tenuis)*, *Aspergillus fumigatus*, Bermuda Grass, Cat Dander, Cockroach (German), Common Short Ragweed, Cottonwood Tree, *D. farinae* (mites), *D. Pteronyssinus* (mites), Dog Dander, Elm Tree, *Hormodendrum (Cladosporium)*, Johnson Grass, Mouse Epithelium, Mountain Cedar (Juniper) Tree, *Mucor racemosus*, Mugwort, Oak Tree, Olive Tree, *Penicillium notatum*, Pigweed, Russian Thistle, Timothy Grass, Walnut Tree, White Mulberry Tree and IgE Serum Total.

CPT Code(s): 86003 x26; 82785

New York DOH Approved.

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

New Test **3001724** **Allergen, Region 14 Respiratory Panel IgE** **REG14PANEL**

Click for Pricing

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided.
Collect: Serum Separator Tube (SST). Multiple specimen tubes should be avoided.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 4 mL serum to an ARUP Standard Transport Tube. (Min: 1.3 mL)
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:

Reference Intervals for all Components

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

Test Number	Components	Reference Interval	
0050345	Immunoglobulin E	Effective November 17, 2014	
		Age	**Reference Interval**
		0-5 months	13 kU/L or less
		6-12 months	34 kU/L or less
		1-2 years	97 kU/L or less
		3 years	199 kU/L or less
		4-6 years	307 kU/L or less
		7-8 years	403 kU/L or less
		9-12 years	696 kU/L or less
		13-15 years	629 kU/L or less
		16-17 years	537 kU/L or less
		18 years and older	214 kU/L or less

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.

Note: Allergens included in this panel: Alder Tree, *Alternaria alternata (tenuis)*, *Aspergillus fumigatus*, Bermuda Grass, Birch Tree, Cat Dander, Cockroach (German), Common Short Ragweed, *D. farinae* (mites), *D. Pteronyssinus* (mites), Dog Dander, Elm Tree, *Hormodendrum (Cladosporium)*, Mouse Epithelium, Mountain Cedar (Juniper) Tree, *Mucor racemosus*, Mugwort, Oak Tree, Olive Tree, *Penicillium notatum*, Pigweed, Russian Thistle, Sycamore Tree, Timothy Grass, White Mulberry Tree, and IgE Serum Total

CPT Code(s): 86003 x25; 82785

New York DOH Approved.

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

New Test **3001725** **Allergen, Region 15 Respiratory Panel IgE** **REG15PANEL**
Click for Pricing

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided.
Collect: Serum Separator Tube (SST). Multiple specimen tubes should be avoided.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 4 mL serum to an ARUP Standard Transport Tube. (Min: 1.3 mL)
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:

Reference Intervals for all Components

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

Test Number	Components	Reference Interval	
0050345	Immunoglobulin E	Effective November 17, 2014	
		Age	**Reference Interval**
		0-5 months	13 kU/L or less
		6-12 months	34 kU/L or less
		1-2 years	97 kU/L or less
		3 years	199 kU/L or less
		4-6 years	307 kU/L or less
		7-8 years	403 kU/L or less
		9-12 years	696 kU/L or less
		13-15 years	629 kU/L or less
		16-17 years	537 kU/L or less
		18 years and older	214 kU/L or less

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.

Note: Allergens included in this panel: *Alternaria alternata (tenuis)*, *Aspergillus fumigatus*, Bermuda Grass, BoxElder/Maple Tree, Cat Dander, Cockroach (German), Common Short Ragweed, Cottonwood Tree, *D. farinae* (mites), *D. Pteronyssinus* (mites), Dog Dander, Elm Tree, *Hormodendrum (Cladosporium)*, Mouse Epithelium, Mountain Cedar (Juniper) Tree, *Mucor racemosus*, Mugwort, Oak Tree, Olive Tree, *Penicillium notatum*, Pigweed, Russian Thistle, Timothy Grass, White Mulberry Tree, and IgE Serum Total

CPT Code(s): 86003 x24; 82785

New York DOH Approved.

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

New Test **3001728** **Allergen, Region 18 Respiratory Panel IgE** **REG18PANEL**

Click for Pricing

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided.
Collect: Serum Separator Tube (SST). Multiple specimen tubes should be avoided.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 3 mL serum to an ARUP Standard Transport Tube. (Min: 1 mL)
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:

Reference Intervals for all Components

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

Test Number	Components	Reference Interval	
0050345	Immunoglobulin E	Effective November 17, 2014	
		Age	**Reference Interval**
		0-5 months	13 kU/L or less
		6-12 months	34 kU/L or less
		1-2 years	97 kU/L or less
		3 years	199 kU/L or less
		4-6 years	307 kU/L or less
		7-8 years	403 kU/L or less
		9-12 years	696 kU/L or less
		13-15 years	629 kU/L or less
		16-17 years	537 kU/L or less
		18 years and older	214 kU/L or less

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**.**

Note: Allergens included in this panel: Alder Tree, *Alternaria alternata (tenuis)*, *Aspergillus fumigatus*, Birch Tree, Cat Dander, Cockroach (German), Cottonwood Tree, *D. farinae* (mites), *D. Pteronyssinus* (mites), Dog Dander, *Hormodendrum (Cladosporium)*, Mouse Epithelium, *Mucor racemosus*, Mugwort, *Penicillium notatum*, Sheep Sorrel (Dock), Timothy Grass, and IgE Serum Total.

CPT Code(s): 86003 x17; 82785

New York DOH Approved.

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

New Test **3001729** **Allergen, Region 19 Respiratory Panel IgE** **REG19PANEL**

Click for Pricing

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided.
Collect: Serum Separator Tube (SST). Multiple specimen tubes should be avoided.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 4 mL serum to an ARUP Standard Transport Tube. (Min: 1.2 mL)
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:

Reference Intervals for all Components

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

Test Number	Components	Reference Interval	
0050345	Immunoglobulin E	Effective November 17, 2014	
		Age	**Reference Interval**
		0-5 months	13 kU/L or less
		6-12 months	34 kU/L or less
		1-2 years	97 kU/L or less
		3 years	199 kU/L or less
		4-6 years	307 kU/L or less
		7-8 years	403 kU/L or less
		9-12 years	696 kU/L or less
		13-15 years	629 kU/L or less
		16-17 years	537 kU/L or less
		18 years and older	214 kU/L or less

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**.**

Note: Allergens included in this panel: *Alternaria alternata (tenuis)*, *Aspergillus fumigatus*, *Aureobasidium*, Bent/Redtop, *B. tropicalis*, Bermuda Grass, Cat Dander, Cockroach (German), *D. pteronyssinus* (mites), *D. farinae* (mites), Dog Dander, Elm Tree, Eucalyptus Tree, *Hormodendrum* (*Cladosporium)*, Johnson Grass, Mouse Epithelium, *Mucor racemosus*, Oak Tree, *Penicillium notatum*, Pigweed, Pine/Australian Pine, Sheep Sorrel (Dock), Wall Pellitory, and IgE Serum Total.

CPT Code(s): 86003 x23; 82785

New York DOH Approved.

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

New Test [3001712] **Allergen, Region 2 Respiratory Panel IgE** **REG2PANEL**
Click for Pricing

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided.
Collect: Serum Separator Tube (SST). Multiple specimen tubes should be avoided.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 4 mL serum to an ARUP Standard Transport Tube. (Min: 1.3 mL)
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:

Allergens, Respiratory Panel, Region 2, Mid-Atlantic (DE, MD, VA, DC, NC) IgE
Reference Intervals for all Components

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

Test Number	Components	Reference Interval	
0050345	Immunoglobulin E	Effective November 17, 2014	
		Age	**Reference Interval**
		0-5 months	13 kU/L or less
		6-12 months	34 kU/L or less
		1-2 years	97 kU/L or less
		3 years	199 kU/L or less
		4-6 years	307 kU/L or less
		7-8 years	403 kU/L or less
		9-12 years	696 kU/L or less
		13-15 years	629 kU/L or less
		16-17 years	537 kU/L or less
		18 years and older	214 kU/L or less

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.

Note: Allergens included in this panel: *Alternaria alternata (tenuis)*, *Aspergillus fumigatus*, Bermuda Grass, Birch Tree, Box Elder/Maple Tree, Cat Dander, Cockroach (German), Common Short Ragweed, Cottonwood Tree, *D. pteronyssinus* (mites), *D. farinae* (mites), Dog Dander, Elm Tree, *Hormodendrum* (*Cladosporium)*, Johnson Grass, Mouse Epithelium, Mountain Cedar (Juniper) Tree, *Mucor racemosus*, Oak Tree, Pecan Tree, *Penicillium notatum*, Pigweed, Sheep Sorrel (Dock), Timothy Grass, White Mulberry Tree, and IgE Serum Total.

CPT Code(s): 86003 x25; 82785

New York DOH Approved.

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

New Test **3001730** **Allergen, Region 20 Respiratory Panel IgE** **REG20PANEL**

Click for Pricing

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided.
Collect: Serum Separator Tube (SST). Multiple specimen tubes should be avoided.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 4 mL serum to an ARUP Standard Transport Tube. (Min: 1.3 mL)
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:

Allergens, Respiratory Panel, Region 20, Hawaii IgE
Reference Intervals for all Components

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

Test Number	Components	Reference Interval	
0050345	Immunoglobulin E	Effective November 17, 2014	
		Age	**Reference Interval**
		0-5 months	13 kU/L or less
		6-12 months	34 kU/L or less
		1-2 years	97 kU/L or less
		3 years	199 kU/L or less
		4-6 years	307 kU/L or less
		7-8 years	403 kU/L or less
		9-12 years	696 kU/L or less
		13-15 years	629 kU/L or less
		16-17 years	537 kU/L or less
		18 years and older	214 kU/L or less

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**.**

Note: Allergens included in this panel: *Alternaria alternata (tenuis)*, *Aspergillus fumigatus*, Bahia Grass, Bayberry Tree, Bermuda Grass, Cat Dander, Cocklebur, Cockroach (German), Common Short Ragweed, *D. pteronyssinus* (mites), *D. farinae* (mites), Dog Dander, English Plantain, Eucalyptus Tree, *Hormodendrum* (*Cladosporium)*, Mesquite Tree, Mouse Epithelium, *Mucor racemosus*, Palm Tree, *Penicillium notatum*, Perennial Rye Grass, Pigweed, Pine/Australian Pine, Sagebrush/Wormwood, White Mulberry Tree, and IgE Serum Total.

CPT Code(s): 86003 x25; 82785

New York DOH Approved.

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

New Test **3001713** **Allergen, Region 3 Respiratory Panel IgE** **REG3PANEL**

Click for Pricing

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided.
Collect: Serum Separator Tube (SST). Multiple specimen tubes should be avoided.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 4 mL serum to an ARUP Standard Transport Tube. (Min: 1.3 mL)
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:

Reference Intervals for all Components

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

Test Number	Components	Reference Interval	
0050345	Immunoglobulin E	Effective November 17, 2014	
		Age	**Reference Interval**
		0-5 months	13 kU/L or less
		6-12 months	34 kU/L or less
		1-2 years	97 kU/L or less
		3 years	199 kU/L or less
		4-6 years	307 kU/L or less
		7-8 years	403 kU/L or less
		9-12 years	696 kU/L or less
		13-15 years	629 kU/L or less
		16-17 years	537 kU/L or less
		18 years and older	214 kU/L or less

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.

Note: Allergens included in this panel: *Alternaria alternata (tenuis)*, *Aspergillus fumigatus*, Bahia Grass, Bermuda Grass, Birch Tree, Box Elder/Maple Tree, Cat Dander, Cockroach (German), Common Short Ragweed, *D. pteronyssinus* (mites), *D. farinae* (mites), Dog Dander, Elm Tree, *Hormodendrum* (*Cladosporium)*, Mouse Epithelium, Mountain Cedar (Juniper) Tree, *Mucor racemosus*, Nettle, Oak Tree, Pecan (White Hickory) Tree, *Penicillium notatum*, Pigweed, Sheep Sorrel (Dock), Timothy Grass, and IgE Serum Total.

CPT Code(s): 86003 x24; 82785

New York DOH Approved.

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

New Test **3001714** **Allergen, Region 4 Respiratory Panel IgE** **REG4PANEL**
Click for Pricing

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided.
Collect: Serum Separator Tube (SST). Multiple specimen tubes should be avoided.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 4 mL serum to an ARUP Standard Transport Tube. (Min: 1.3 mL)
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:

Reference Intervals for all Components

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

Test Number	Components	Reference Interval	
0050345	Immunoglobulin E	Effective November 17, 2014	
		Age	**Reference Interval**
		0-5 months	13 kU/L or less
		6-12 months	34 kU/L or less
		1-2 years	97 kU/L or less
		3 years	199 kU/L or less
		4-6 years	307 kU/L or less
		7-8 years	403 kU/L or less
		9-12 years	696 kU/L or less
		13-15 years	629 kU/L or less
		16-17 years	537 kU/L or less
		18 years and older	214 kU/L or less

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**.**

Note: Allergens included in this panel: *Alternaria alternata (tenuis)*, *Aspergillus fumigatus*, *B. tropicalis*, Bahia Grass, Bermuda Grass, Box Elder/Maple Tree, Cat Dander, Cockroach (German), Common Short Ragweed, *D. pteronyssinus* (mites), *D. farinae* (mites), Dog Dander, Elm Tree, *Hormodendrum* (*Cladosporium)*, Mouse Epithelium, Mountain Cedar (Juniper) Tree, *Mucor racemosus*, Nettle, Oak Tree, *Penicillium notatum*, Pigweed, Pine/Australian Pine, Sheep Sorrel (Dock), Timothy Grass, and IgE Serum Total.

CPT Code(s): 86003 x24; 82785

New York DOH Approved.

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

New Test **3001715** **Allergen, Region 5 Respiratory Panel IgE** **REG5PANEL**
Click for Pricing

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided.
Collect: Serum Separator Tube (SST). Multiple specimen tubes should be avoided.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 4 mL serum to an ARUP Standard Transport Tube. (Min: 1.4 mL)
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:

Reference Intervals for all Components

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

Test Number	Components	Reference Interval	
0050345	Immunoglobulin E	Effective November 17, 2014	
		Age	**Reference Interval**
		0-5 months	13 kU/L or less
		6-12 months	34 kU/L or less
		1-2 years	97 kU/L or less
		3 years	199 kU/L or less
		4-6 years	307 kU/L or less
		7-8 years	403 kU/L or less
		9-12 years	696 kU/L or less
		13-15 years	629 kU/L or less
		16-17 years	537 kU/L or less
		18 years and older	214 kU/L or less

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.

Note: Allergens included in this panel: *Alternaria alternata (tenuis)*, *Aspergillus fumigatus*, Bermuda Grass, Birch Tree, Box Elder/Maple Tree, Cat Dander, Cockroach (German), Common Short Ragweed, Cottonwood Tree, *D. farinae* (mites), *D. Pteronyssinus* (mites), Dog Dander, Elm Tree, *Hormodendrum* (*Cladosporium*), Mouse Epithelium, Mountain Cedar (Juniper) Tree, *Mucor racemosus*, Oak Tree, Pecan (White Hickory) Tree, *Penicillium notatum*, Pigweed, Russian Thistle, Sheep Sorrel (Dock), Sycamore Tree, Timothy Grass, Walnut Tree, White Ash Tree, White Mulberry Tree, and IgE Serum Total.

CPT Code(s): 86003 x28; 82785

New York DOH Approved.

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

New Test **3001716** **Allergen, Region 6 Respiratory Panel IgE** **REG6PANEL**

Click for Pricing

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided.
Collect: Serum Separator Tube (SST). Multiple specimen tubes should be avoided.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 4 mL serum to an ARUP Standard Transport Tube. (Min: 1.3 mL)
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:

Reference Intervals for all Components

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

Test Number	Components	Reference Interval	
0050345	Immunoglobulin E	Effective November 17, 2014	
		Age	**Reference Interval**
		0-5 months	13 kU/L or less
		6-12 months	34 kU/L or less
		1-2 years	97 kU/L or less
		3 years	199 kU/L or less
		4-6 years	307 kU/L or less
		7-8 years	403 kU/L or less
		9-12 years	696 kU/L or less
		13-15 years	629 kU/L or less
		16-17 years	537 kU/L or less
		18 years and older	214 kU/L or less

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**.**

Note: Allergens included in this panel: *Alternaria alternata (tenuis)*, *Aspergillus fumigatus*, Bermuda Grass, Birch Tree, Box Elder/Maple Tree, Cat Dander, Cockroach (German), Common Short Ragweed, *D. farinae* (mites), *D. Pteronyssinus* (mites), Dog Dander, Elm Tree, *Hormodendrum* (*Cladosporium*), Marsh Elder, Mouse Epithelium, Mountain Cedar (Juniper) Tree, *Mucor racemosus*, Oak Tree, Pecan (White Hickory) Tree, *Penicillium notatum*, Pigweed, Timothy Grass, Walnut Tree, White Mulberry Tree, and IgE Serum Total.

CPT Code(s): 86003 x24; 82785

New York DOH Approved.

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

New Test **3001717** **Allergen, Region 7 Respiratory Panel IgE** **REG7PANEL**
Click for Pricing

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided.
Collect: Serum Separator Tube (SST). Multiple specimen tubes should be avoided.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 4 mL serum to an ARUP Standard Transport Tube. (Min: 1.3 mL)
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:

Reference Intervals for all Components

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

Test Number	Components	Reference Interval	
0050345	Immunoglobulin E	Effective November 17, 2014	
		Age	**Reference Interval**
		0-5 months	13 kU/L or less
		6-12 months	34 kU/L or less
		1-2 years	97 kU/L or less
		3 years	199 kU/L or less
		4-6 years	307 kU/L or less
		7-8 years	403 kU/L or less
		9-12 years	696 kU/L or less
		13-15 years	629 kU/L or less
		16-17 years	537 kU/L or less
		18 years and older	214 kU/L or less

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.

Note: Allergens included in this panel: *Alternaria alternata (tenuis)*, *Aspergillus fumigatus*, Bermuda Grass, Birch Tree, Box Elder/Maple Tree, Cat Dander, Cockroach (German), Common Short Ragweed, Cottonwood Tree, *D. farinae* (mites), *D. Pteronyssinus* (mites), Dog Dander, Elm Tree, *Hormodendrum* (*Cladosporium*), Marsh Elder, Mouse Epithelium, Mountain Cedar (Juniper) Tree, *Mucor racemosus*, Nettle, Oak Tree, *Penicillium notatum*, Russian Thistle, Timothy Grass, White Ash Tree, White Mulberry Tree, and IgE Serum Total.

CPT Code(s): 86003 x25; 82785

New York DOH Approved.

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

New Test **3001718** **Allergen, Region 8 Respiratory Panel IgE** **REG8PANEL**

Click for Pricing

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided
Collect: Serum Separator Tube (SST). Multiple specimen tubes should be avoided.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 4 mL serum to an ARUP Standard Transport Tube. (Min: 1.4 mL)
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:

Reference Intervals for all Components

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 100.01	Very high	6

Test Number	Components	Reference Interval	
0050345	Immunoglobulin E	Effective November 17, 2014	
		Age	**Reference Interval**
		0-5 months	13 kU/L or less
		6-12 months	34 kU/L or less
		1-2 years	97 kU/L or less
		3 years	199 kU/L or less
		4-6 years	307 kU/L or less
		7-8 years	403 kU/L or less
		9-12 years	696 kU/L or less
		13-15 years	629 kU/L or less
		16-17 years	537 kU/L or less
		18 years and older	214 kU/L or less

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.

Note: Allergens included in this panel: *Alternaria alternata (tenuis)*, *Aspergillus fumigatus*, Bermuda Grass, Box Elder/Maple Tree, Cat Dander, Cockroach (German), Common Short Ragweed, Cottonwood Tree, *D. farinae* (mites), *D. Pteronyssinus* (mites), Dog Dander, Elm Tree, *Hormodendrum* (*Cladosporium*), Marsh Elder, Mouse Epithelium, Mountain Cedar (Juniper) Tree, *Mucor racemosus*, Oak Tree, Pecan (White Hickory) Tree, *Penicillium notatum*, Pigweed, Russian Thistle, Sycamore Tree, Timothy Grass, Walnut Tree, White Ash Tree, White Mulberry Tree, and IgE Serum Total.

CPT Code(s): 86003 x27; 82785

New York DOH Approved.

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

New Test **3001719** **Allergen, Region 9 Respiratory Panel IgE** **REG9PANEL**
Click for Pricing

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided.
Collect: Serum Separator Tube (SST). Multiple specimen tubes should be avoided.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 4 mL serum to an ARUP Standard Transport Tube. (Min: 1.3 mL)
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:

Reference Intervals for all Components

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

Test Number	Components	Reference Interval	
0050345	Immunoglobulin E	Effective November 17, 2014	
		Age	**Reference Interval**
		0-5 months	13 kU/L or less
		6-12 months	34 kU/L or less
		1-2 years	97 kU/L or less
		3 years	199 kU/L or less
		4-6 years	307 kU/L or less
		7-8 years	403 kU/L or less
		9-12 years	696 kU/L or less
		13-15 years	629 kU/L or less
		16-17 years	537 kU/L or less
		18 years and older	214 kU/L or less

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.

Note: Allergens included in this panel: *Alternaria alternata (tenuis)*, *Aspergillus fumigatus*, Bermuda Grass, Box Elder/Maple Tree, Cat Dander, Cockroach (German), Common Short Ragweed, Cottonwood Tree, *D. farinae* (mites), *D. Pteronyssinus* (mites), Dog Dander, Elm Tree, *Hormodendrum* (*Cladosporium*), Mouse Epithelium, Mountain Cedar (Juniper) Tree, *Mucor racemosus*, Nettle, Oak Tree, *Penicillium notatum*, Russian Thistle, Sheep Sorrel (Dock), Timothy Grass, White Ash Tree, White Mulberry Tree, and IgE Serum Total.

CPT Code(s): 86003 x24; 82785

New York DOH Approved.

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

New Test **3001726** **Allergen, Region 16 Respiratory Panel IgE** **REG16PANEL**
Click for Pricing

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided.
Collect: Serum Separator Tube (SST). Multiple specimen tubes should be avoided.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 4 mL serum to an ARUP Standard Transport Tube. (Min: 1.2 mL)
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:

Reference Intervals for all Components

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

Test Number	Components	Reference Interval	
0050345	Immunoglobulin E	Effective November 17, 2014	
		Age	**Reference Interval**
		0-5 months	13 kU/L or less
		6-12 months	34 kU/L or less
		1-2 years	97 kU/L or less
		3 years	199 kU/L or less
		4-6 years	307 kU/L or less
		7-8 years	403 kU/L or less
		9-12 years	696 kU/L or less
		13-15 years	629 kU/L or less
		16-17 years	537 kU/L or less
		18 years and older	214 kU/L or less

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**.**

Note: Allergens included in this panel: Alder Tree, *Alternaria alternata (tenuis)*, *Aspergillus fumigatus*, Birch Tree, BoxElder/Maple Tree, Cat Dander, Cockroach (German), Cottonwood Tree, *D. farinae* (mites), *D. Pteronyssinus* (mites), Dog Dander, Elm Tree, *Hormodendrum (Cladosporium)*, Mouse Epithelium, Mountain Cedar (Juniper) Tree, *Mucor racemosus*, Mugwort, Oak Tree, *Penicillium notatum*, Pigweed, Russian Thistle, Sheep Sorrel (Dock), Timothy Grass, and IgE Serum Total.

CPT Code(s): 86003 x23; 82785

New York DOH Approved.

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

New Test **3001727** **Allergen, Region 17 Respiratory Panel IgE** **REG17PANEL**
Click for Pricing

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided.
Collect: Serum Separator Tube (SST). Multiple specimen tubes should be avoided.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 4 mL serum to an ARUP Standard Transport Tube. (Min: 1.3 mL)
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:

Reference Intervals for all Components

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

Test Number	Components	Reference Interval	
0050345	Immunoglobulin E	Effective November 17, 2014	
		Age	**Reference Interval**
		0-5 months	13 kU/L or less
		6-12 months	34 kU/L or less
		1-2 years	97 kU/L or less
		3 years	199 kU/L or less
		4-6 years	307 kU/L or less
		7-8 years	403 kU/L or less
		9-12 years	696 kU/L or less
		13-15 years	629 kU/L or less
		16-17 years	537 kU/L or less
		18 years and older	214 kU/L or less

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**.**

Note: Allergens included in this panel: Alder Tree, *Alternaria alternata (tenuis)*, *Aspergillus fumigatus*, Birch Tree, BoxElder/Maple Tree, Cat Dander, Cockroach (German), Common Short Ragweed, Cottonwood Tree, *D. farinae* (mites), *D. Pteronyssinus* (mites), Dog Dander, Elm Tree, *Hormodendrum (Cladosporium)*, Mouse Epithelium, Mountain Cedar (Juniper) Tree, *Mucor racemosus*, Nettle, Oak Tree, *Penicillium notatum*, Pigweed, Sheep Sorrel (Dock), Timothy Grass, Walnut Tree, White Ash Tree and IgE Serum Total.

CPT Code(s): 86003 x25; 82785

New York DOH Approved.

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

0097933 **Allergen, Tree, Oak Red IgE** **OAK RED**

Methodology: Quantitative Enzyme Immunoassay

0051495 Alpha Thalassemia (*HBA1* and *HBA2*) 7 Deletions — ALPHA THAL

Additional Technical Information

Out of Pocket Estimator

Performed: Varies
Reported: 7-10 days

Specimen Required: Collect: Lavender (EDTA), Pink (K_2EDTA), or Yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 month; Frozen: 6 months

2006480 ANCA-Associated Vasculitis Profile (ANCA/MPO/PR3) with Reflex to ANCA Titer — ANCA PRO

Reference Interval:

Test Number	Components	Reference Interval	
	Anti-Neutrophil Cytoplasmic Antibody, IgG	< 1:20: Not significant	
	Myeloperoxidase Antibody	Negative	19 AU/mL or less
		Equivocal	20-25 AU/mL
		Positive	26 AU/mL or greater
	Serine Proteinase 3 Antibody	Negative	19 AU/mL or less
		Equivocal	20-25 AU/mL
		Positive	26 AU/mL or greater

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. Approximately 90 percent of patients with a P-ANCA pattern by IFA have antibodies specific for MPO. Approximately 85 percent of patients with a C-ANCA pattern by IFA have antibodies specific for PR3.

Note: Specimens are screened for ANCA, MPO and PR3. If the ANCA screen detects antibodies at a 1:20 dilution or greater, then a titer to end point will be added. Additional charges apply.

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

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 0050527, Serine Protease 3, IgG to Serine Proteinase 3, IgG

0010004 Antibody Detection RBC with Reflex to ID — IRL-ABSC

Specimen Required: Collect: Plain Red **AND** Lavender (K_2EDTA) or Pink (K_2EDTA).
Specimen Preparation: **Do not freeze.**
Transport 10 mL whole blood (Plain Red) **AND** 5 mL whole blood (EDTA). (Min: 7 mL (Plain Red) and 3 mL (EDTA))
Pediatric: Transport 1 mL whole blood (Plain Red) **AND** 0.5 mL whole blood (EDTA). (Min: 1 mL (Plain Red) and 0.5 mL (EDTA))
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Separator tubes.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 1 week; Frozen: Unacceptable

Note: Panel identification will be performed on all positive specimens at an additional charge.
Positive screens are reflexed:
Female 15-45 years are reflexed to Antibody Identification, RBC (Prenatal Only) (ARUP test code 0013005)
All other Positive Screens are reflexed to Antibody ID Package (IRL) (ARUP test code 0013003)

CPT Code(s): 86850; additional CPT codes may apply

0013003 Antibody ID Package (IRL) — IRL-AB PKG

Performed: Mon-Fri
Reported: 2-5 days

Specimen Required: Collect: Lavender (K_2EDTA) or Pink (K_2EDTA) **AND** Plain Red.
Specimen Preparation: **Do not freeze.** Transport 10 mL whole blood (plain red) **AND** 20 mL whole blood (EDTA). (Min: 7 mL plain red **AND** 10 mL EDTA)
Storage/Transport Temperature: Refrigerated. Deliver to lab immediately.
Unacceptable Conditions: Separator tubes.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 1 week; Frozen: Unacceptable

0013005 Antibody ID RBC Prenatal-Reflex to Titer — IRL-ABID

Specimen Required: Collect: 3 (7mL) Lavender (K_2EDTA) or Pink (K_2EDTA) **AND** 1 (7mL) Plain Red.
Specimen Preparation: **Do not freeze.** Transport 3 (7 mL) whole blood EDTA **AND** 1 (7 mL) whole blood plain red. (Min: 10 mL EDTA and 3 mL Plain Red)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Separator tubes.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 1 week; Frozen: Unacceptable

Note: **This test is for prenatal patients only**. Includes: ABO/Rh Type, Rh Phenotype, Direct Coombs, RBC Antibody Identification by various methods. Titers will be performed, at an additional charge, on prenatal specimens for clinically significant antibodies.

0013006 Antibody Titer — IRL-ABTR1

Performed: Mon-Fri
Reported: 2-5 days

Specimen Required: Collect: Lavender (K_2EDTA) or Pink (K_2EDTA).
Specimen Preparation: **Do not freeze.** Transport 10 mL whole blood. (Min: 10 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Separator tubes.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 1 week; Frozen: Unacceptable

Note: Antibody identification must be performed prior to performing this test. Additional charges apply. Titer result is the inverse of the highest dilution that has a positive reaction. Example: if the highest dilution is 1:16 then the titer result is 16.

2002068 Anti-Neutrophil Cytoplasmic Antibody with Reflex to Titer and MPO/PR3 Antibodies — ANCA PN

Reference Interval:

Test Number	Components	Reference Interval	
	Anti-Neutrophil Cytoplasmic Antibody, IgG	< 1:20: Not significant	
0050526	Myeloperoxidase Antibody	Negative	19 AU/mL or less
		Equivocal	20-25 AU/mL
		Positive	26 AU/mL or greater
0050527	Serine Proteinase 3 Antibody	Negative	19 AU/mL or less
		Equivocal	20-25 AU/mL
		Positive	26 AU/mL or greater

Interpretive Data: Neutrophil cytoplasmic antibodies (C-ANCA = granular cytoplasmic staining, P-ANCA = perinuclear staining) are found in the serum of over 90% of patients with certain necrotizing systemic vasculitides, and usually in less than 5% of patients with collagen vascular disease or arthritis. Approximately 90% of patients with a P-ANCA pattern by IFA have antibodies specific for MPO. Approximately 85% of patients with a C-ANCA pattern by IFA have antibodies specific for PR3.

Note: 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.

If screen is positive, then titer and MPO/PR3 antibodies will be added to aid in antibody determination. Additional charges apply.

0050317 Antinuclear Antibodies (ANA), IgG by ELISA with Reflex to ANA HEp-2 Substrate, IgG by IFA and ENA Confirmation — ANA REF

Reference Interval:
Effective May 18, 2015

Test Number	Components	Reference Interval	
	Antinuclear Antibodies (ANA), IgG by ELISA	None Detected	
3000082	Antinuclear Antibody (ANA) with HEp-2 Substrate, IgG by IFA	Less than 1:80	
	Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA	None Detected	
2002693	Double-Stranded DNA (dsDNA) Antibody, IgG by IFA (using *Crithidia luciliae)*	Less than 1:10	
0050470	Smith/RNP (ENA) Antibody, IgG	29 AU/mL or less	Negative
		30-40 AU/mL	Equivocal
		41 AU/mL or greater	Positive
0050085	Smith (ENA) Antibody, IgG	29 AU/mL or less	Negative
		30-40 AU/mL	Equivocal
		41 AU/mL or greater	Positive
2012074	SSA 52 and 60 (Ro) (ENA) Antibodies, IgG	**Test Number**	**Components** / **Reference Interval**
			SSA-52 (Ro52) (ENA) Antibody, IgG: 29 AU/mL or Less — Negative; 30-40 AU/mL — Equivocal; 41 AU/mL or — Positive
			SSA-60 (Ro60) (ENA) Antibody, IgG: 29 AU/mL or Less — Negative; 30-40 AU/mL — Equivocal; 41 AU/mL or — Positive
0050692	SSB (La) (ENA) Antibody, IgG	29 AU/mL or less 30-40 AU/mL	Negative Equivocal
		41 AU/mL or greater	Positive
0099592	Jo-1 Antibody, IgG	29 AU/mL or less	Negative
		30-40 AU/mL	Equivocal
		41 AU/mL or greater	Positive
0050599	Scleroderma (Scl-70) (ENA) Antibody, IgG	29 AU/mL or less	Negative
		30-40 AU/mL	Equivocal
		41 AU/mL or greater	Positive

Interpretive Data: Antinuclear Antibodies (ANA), IgG by ELISA: ANA specimens are screened using enzyme-linked immunosorbent assay (ELISA) methodology. All ELISA results reported as detected are further tested by indirect fluorescent assay (IFA) using HEp-2 substrate with an IgG-specific conjugate. The ANA ELISA screen is designed to detect antibodies against dsDNA, histone, SS-A (Ro), SS-B (La), Smith, Smith/RNP, Scl-70, Jo-1, centromeric proteins, and other antigens extracted from the HEp-2 cell nucleus. ANA ELISA assays have been reported to have lower sensitivities than ANA IFA for systemic autoimmune rheumatic diseases (SARD).

Negative results do not necessarily rule out SARD.

Note: ANA lacks diagnostic specificity, and is associated with in variety diseases (cancers, autoimmune, infectious, and inflammatory conditions) and occurs in healthy individuals in varying prevalence. The lack of diagnostic specificity requires confirmation of positive ANA by more-specific serologic tests, which may be guided by the pattern(s) observed.

Specimens are screened for ANA using ELISA. If ANA IgG is detected by ELISA, then Antinuclear Antibody (ANA), HEp-2, IgG by IFA will be added. If ANA, IgG by IFA is confirmed positive with a titer of 1:80 or greater, then a titer and pattern will be reported. In addition, samples positive for ANA, IgG by IFA will reflex to Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA; Jo-1 Antibody, IgG; Smith/RNP (ENA) Antibody, IgG; Scleroderma (Scl-70) (ENA) Antibody, IgG; Smith (ENA) Antibody, IgG; SSA 52 and 60 (Ro) (ENA) Antibodies, IgG; and SSB (La) (ENA) Antibody, IgG. If Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA is detected, then Double-Stranded DNA (dsDNA) Antibody, IgG by IFA (using *Crithidia luciliae*) will be added. Additional charges apply.

ANA determined by indirect fluorescence assay (IFA) use HEp-2 substrate and IgG-specific conjugate at a screening dilution of 1:80. If positive, patterns reported include homogeneous, speckled, centromere, nucleolar, nuclear dots, or cytoplasmic. All positive results are reported with endpoint titers.

0050080 Antinuclear Antibodies (ANA), IgG by ELISA with Reflex to ANA, HEp-2 Substrate, IgG by IFA — ANA

Interpretive Data: Antinuclear Antibodies (ANA), IgG by ELISA: ANA specimens are screened using enzyme-linked immunosorbent assay (ELISA) methodology. All ELISA results reported as Detected are further tested by indirect fluorescent assay (IFA) using HEp-2 substrate with an IgG-specific conjugate. The ANA ELISA screen is designed to detect antibodies against dsDNA, histones, SS-A (Ro), SS-B (La), Smith, Smith/RNP, Scl-70, Jo-1, centromeric proteins, and other antigens extracted from the HEp-2 cell nucleus. ANA ELISA assays have been reported to have lower sensitivities than ANA IFA for systemic autoimmune rheumatic diseases (SARD).

Negative results do not necessarily rule out SARD.

3000601 Antinuclear Antibody (ANA) with HEp-2 Substrate, IgG by IFA with Reflex by Pattern — ANA AB PAT

Reference Interval:

Test Number	Components	Reference Interval
3000082	Antinuclear Antibody (ANA) with HEp-2 Substrate, IgG by IFA	Less than 1:80
2003040	PM/Scl-100 Antibody, IgG by Immunoblot	Negative
2012173	Fibrillarin (U3 RNP) Antibody, IgG (Temporary Delay as of 3/18/2019 - no referral available)	Negative
0050215	Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA with Reflex to dsDNA Antibody, IgG by IFA	Effective August 20, 2012
		Test Number / **Components** / **Reference Interval**
		(blank) / Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA / None Detected.
		2002693 / Double-Stranded DNA (dsDNA) Antibody, IgG by IFA (using Crithidia luciliae) / Less than 1:10
2002693	Double-Stranded DNA (dsDNA) Antibody, IgG by IFA (using *Crithidia luciliae)*	Less than 1:10
2005287	Chromatin Antibody, IgG	19 Units or less: Negative 20-60 Units: Moderate Positive 61 Units or greater: Strong Positive
2001601	RNA Polymerase III Antibody, IgG	19 Units or less: Negative 20-39 Units: Weak Positive 40-80 Units: Moderate Positive 81 Units or greater: Strong Positive
0050599	Scleroderma (Scl-70) (ENA) Antibody, IgG	29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive
0050470	Smith/RNP (ENA) Antibody, IgG	29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive
0050085	Smith (ENA) Antibody, IgG	29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive
2012074	SSA 52 and 60 (Ro) (ENA) Antibodies, IgG	**Test Number** / **Components** / **Reference Interval**
		(blank) / SSA-52 (Ro52) (ENA) Antibody, IgG / 29 AU/mL or Less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or: Positive
		(blank) / SSA-60 (Ro60) (ENA) Antibody, IgG / 29 AU/mL or Less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or: Positive
0050692	SSB (La) (ENA) Antibody, IgG	29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive

Note: The Antinuclear Antibody (ANA), IgG by IFA with Reflex by IFA Pattern begins with Nuclear Antibody (ANA) by IFA, IgG. Depending on findings, one or more reflexive tests may be required. Tests added may include Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA; Double-Stranded DNA (dsDNA) Antibody, IgG by IFA (using *Crithidiae luciliae*); Chromatin Antibody, IgG; Smith/RNP (ENA) Antibody, IgG; Fibrillarin (U3 RNP) Antibody, IgG; Smith (ENA) Antibody, IgG; SSA 52 (Ro) (ENA) Antibody, IgG; SSA 60 (Ro) (ENA) Antibody, IgG; SSB (La) (ENA) Antibody, IgG; Scleroderma (Scl-70) (ENA) Antibody, IgG; PM/Scl-100 Antibody, IgG, by Immunoblot; and/or RNA Polymerase III Antibody, IgG. Additional charges apply.

ANA determined by indirect fluorescence assay (IFA) use HEp-2 substrate and IgG-specific conjugate at a screening dilution of 1:80. If positive, patterns reported include homogeneous, speckled, centromere, nucleolar, nuclear dots, or cytoplasmic. All positive results are reported with endpoint titers.

0051415 **Ashkenazi Jewish Diseases, 16 Genes** **AJP**

HOTLINE NOTE: There is a component change associated with this test.
Remove component 0051417, Ashkenazi Jewish Diseases, Allele 1
Removed component 0051418, Ashkenazi Jewish Diseases, Allele 2
Add component 3001464, Ashkenazi Jewish Diseases, Gene 1
Add component 3001465, Ashkenazi Jewish Diseases, Gene 2
Add component 3001466, AJP Gene 1, Allele 1
Add component 3001467, AJP Gene 1, Allele 2
Add component 3001468, AJP Gene 2, Allele 1
Add component 3001469, AJP Gene 2, Allele 2
Add component 3001470, Ashkenazi Jewish Diseases Carrier Status
Add component 3001754, Ashkenazi Jewish Diseases, Panel Results

2014314 **Autism and Intellectual Disability Comprehensive Panel** **AID COMP**

Note: This panel includes Acylcarnitine Quantitative Profile, Plasma (ARUP test code 0040033); Mucopolysaccharides Screen - Electrophoresis and Quantitation, Urine (ARUP test code 0081352); Organic Acids, Urine (ARUP test code 0098389); Creatine Disorders Panel, Serum or Plasma (ARUP test code 2002328); Creatine Disorders Panel, Urine (ARUP test code 2002333); Amino Acids Quantitative by LC-MS/MS, Plasma (ARUP test code 2009389); Cytogenomic SNP Microarray (ARUP test code 2003414); Fragile X (FMR1) with Reflex to Methylation Analysis (ARUP test code 2009033). If Fragile X testing detects a CGG repeat of 100 or greater by PCR and capillary electrophoresis, methylation analysis will be added. Additional charges apply.

New Test **3001410** **Basement Membrane Zone Antibody Panel** **BMZ AB PAN**
Available Now
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Methodology: Indirect Fluorescent Antibody/Enzyme-Linked Immunosorbent Assay

Performed: Varies
Reported: 4-9 days

Specimen Required: Collect: Plain Red or Serum Separator Tube (SST).
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma. Hemolyzed or lipemic specimens.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: Indefinitely

Reference Interval: By report

Interpretive Data: Refer to report.

Note: For specimens less than 0.5 mL, call the Immunodermatology Laboratory at (866) 266-5699.

CPT Code(s): 88346, 88350 x3, 83516 x3

New York DOH approval pending. Call for status update.

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

2006193 B-Cell Clonality Screening (IgH and IgK) by PCR — BCELL SCRN

Specimen Required: Collect: Lavender (EDTA), bone marrow (EDTA), or tissue. Also acceptable: DNA extracted by CLIA certified lab.
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)
Fresh Tissue: Freeze immediately. Transport 100 mg or 0.5-2.0 cm^3 tissue.
FFPE Tumor Tissue: Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or four 10-micron shavings in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: **Whole Blood, Bone Marrow or Extracted DNA:** Refrigerated.
Fresh Tissue: Frozen on dry ice.
FFPE Tumor Tissue: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Unacceptable Conditions: Plasma, serum, frozen tissue, DNA extracted by a non-CLIA lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens. Specimens fixed/processed in alternative fixatives or heavy metal fixatives (B-4 or B-5) or tissue sections on slides. Decalcified specimens.
Stability (collection to initiation of testing): **Whole Blood or Bone Marrow:** Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable
Fresh Tissue: Ambient: Unacceptable; Refrigerated: 2 hours; Frozen: 1 year
FFPE Tumor Tissue: Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerate: Indefinitely; Frozen: Indefinitely

2005017 *BCR-ABL1*, Major (p210), Quantitative — BCR MAJ

Specimen Required: Collect: Lavender (EDTA) or bone marrow (EDTA). Also acceptable: RNA extracted by CLIA certified lab.
Specimen Preparation **Whole Blood:** Transport 5 mL whole blood. (Min: 1 mL)
Bone Marrow: Transport 3 mL bone marrow. (Min: 1 mL)
Specimens must be received within 48 hours of collection due to lability of RNA.
Extracted RNA: Transport 40 uL RNA with at least 40 ng/uL concentration. (Min: 40 uL) Transport RNA 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: **Whole Blood or Bone Marrow**: CRITICAL REFRIGERATED. Separate specimens must be submitted when multiple tests are ordered.
Extracted RNA: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Unacceptable Conditions: Serum, plasma, CSF, extracted DNA, RNA extracted by a non-CLIA lab, bone core, or FFPE tissue. Specimens collected in anticoagulants other than EDTA. Severely hemolyzed or clotted specimens.
Stability (collection to initiation of testing): Ambient: 1 hour; Refrigerated: 48 hours; Frozen: Unacceptable
Extracted RNA: Ambient: Unacceptable; Refrigerate: Unacceptable; Frozen: Indefinitely

2005016 *BCR-ABL1*, Minor (p190), Quantitative — BCR MIN

Specimen Required: Collect: Lavender (EDTA) or bone marrow (EDTA). Also acceptable: RNA extracted by CLIA certified lab.
Specimen Preparation: **Whole Blood:** Transport 5 mL whole blood. (Min: 1 mL)
Bone Marrow: Transport 3 mL bone marrow. (Min: 1 mL)
Specimens must be received within 48 hours of collection due to lability of RNA.
Extracted RNA: Transport 40 uL RNA with at least 40 ng/uL concentration. (Min: 40 uL) Transport RNA 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: **Whole Blood or Bone Marrow**: CRITICAL REFRIGERATED. Separate specimens must be submitted when multiple tests are ordered.
Extracted RNA: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Unacceptable Conditions: Serum, plasma, CSF, extracted DNA, RNA extracted by a non-CLIA lab, bone core, or FFPE tissue. Specimens collected in anticoagulants other than EDTA. Severely hemolyzed or clotted specimens.
Stability (collection to initiation of testing): Ambient: 1 hour; Refrigerated: 48 hours; Frozen: Unacceptable
Extracted RNA: Ambient: Unacceptable; Refrigerate: Unacceptable; Frozen: Indefinitely

2005010 *BCR-ABL1*, Qualitative with Reflex to *BCR-ABL1* Quantitative — BCR RFLX

Specimen Required: Collect: Lavender (EDTA) or bone marrow (EDTA). Also acceptable: RNA extracted by CLIA certified lab.
Specimen Preparation: **Whole Blood:** Transport 5 mL whole blood. (Min: 1 mL)
Bone Marrow: Transport 3 mL bone marrow. (Min: 1 mL)
Specimens must be received within 48 hours of collection due to lability of RNA.
Extracted RNA: Transport 40 uL RNA with at least 40 ng/uL concentration. (Min: 40 uL) Transport RNA 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: **Whole Blood or Bone Marrow**: CRITICAL REFRIGERATED. Separate specimens must be submitted when multiple tests are ordered.
Extracted RNA: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Unacceptable Conditions: Serum, plasma, CSF, extracted DNA, RNA extracted by a non-CLIA lab, bone core, or FFPE tissue. Specimens collected in anticoagulants other than EDTA. Severely hemolyzed or clotted specimens.
Stability (collection to initiation of testing): Ambient: 1 hour; Refrigerated: 48 hours; Frozen: Unacceptable
Extracted RNA: Ambient: Unacceptable; Refrigerate: Unacceptable; Frozen: Indefinitely

New Test 3001798 *Blastomyces* Antigen Quantitative by EIA, Urine — BLASTOAG U

Click for Pricing

Methodology: Quantitative Enzyme Immunoassay
Performed: Tue, Thu, Sat
Reported: 1-4 days

Specimen Required: Collect: Urine.
Specimen Preparation: Transfer 1 mL urine to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Specimens preserved in boric acid.
Stability (collection to initiation of testing): Ambient: 2 weeks; Refrigerated: 2 weeks; Frozen: Indefinitely

Reference Interval:

Less than 1.25 ng/ml	Not Detected
1.25-200 ng/mL	Detected
Greater than 200 ng/mL	Detected (above the limit of quantification)

Interpretive Data: The quantitative range of this assay is 1.25-200 ng/mL. Antigen concentrations between 200 ng/mL fall outside the linear range of the assay and cannot be accurately quantified.

This EIA test should be used in conjunction with other diagnostic procedures, including microbiological culture, histological examination of biopsy samples, and/or radiographic evidence, to aid in the diagnosis of blastomycosis.

Cross-reactivity with other endemic mycoses (*Histoplasma* and *Coccidioides*) may occur. Positive test results should be correlated with other clinical findings and relevant exposure history.

CPT Code(s): 87449

New York DOH approval pending. Call for status update.

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

2002926 *Blastomyces dermatitidis* Antigen Quantitative by EIA — BLAST DERM

Specimen Required: Collect: Plain Red, Serum Separator Tube (SST), Lavender (K_2 or K_3EDTA), Green (Sodium or Lithium Heparin), Light Blue (Sodium Citrate), CSF, or BAL.
Specimen Preparation: Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1.2 mL)
Transfer 1 mL CSF to an ARUP Standard Transport Tube. (Min: 0.8 mL)
Transfer 1 mL BAL to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Unacceptable Conditions: Urine.
Stability (collection to initiation of testing): Ambient: 2 weeks; Refrigerated: 2 weeks; Frozen: Indefinitely

Note: For urine specimens refer to *Blastomyces* Antigen Quantitative by EIA, Urine (ARUP test code 3001798).

0062224 *Blastomyces dermatitidis* Identification — MC BP

Methodology: Nucleic Acid Probe/MALDI (Matrix-Assisted Laser Desorption/Ionization)
Performed: Sun-Sat
Reported: 2-7 days

CPT Code(s): Varies based on identification methods.

0060108 Body Fluid Culture and Gram Stain — MC BF

Specimen Required: Collect: Aspirate of amniotic, culdocentesis, pericardial, peritoneal, synovial, thoracentesis or other normally sterile body fluid.
Specimen Preparation: Transfer 5 mL aspirate to a Sterile Container. (Min: 2 mL) Place each specimen in an individually sealed bag.
Storage/Transport Temperature: Room temperature.
Remarks: Specimen source required.
Unacceptable Conditions: CSF or blood. Syringes with needle attached.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

Note: Gram stain, identification, and susceptibility tests are billed separately from culture. Anaerobe culture is NOT included with this order. Anaerobe culture is recommended for body fluids, tissue, and deep wound/surgical cultures. If anaerobe culture is needed, please order Anaerobe Culture (ARUP test code 0060143) and use anaerobic collection device for transportation.

For CSF, order Cerebrospinal Fluid (CSF) Culture and Gram Stain (ARUP test code 0060106). For blood, order Blood Culture (ARUP test code 0060102) or Blood Culture, AFB and Fungal (ARUP test code 0060024).

0070053 Bone Specific Alkaline Phosphatase — BSAP

Specimen Required: Collect: Serum separator tube. Also acceptable: Green (sodium or lithium heparin).
Specimen Preparation: Transfer 0.5 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.3 mL)
Storage/Transport Temperature: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**
Unacceptable Conditions: Urine. Grossly hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 2 hours; Refrigerated: 48 hours; Frozen: 2 months

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

Specimen Required: Collect: Tumor tissue. Also acceptable: DNA extracted by CLIA certified lab with corresponding client-circled H&E slide.
Specimen Preparation: **Tumor Tissue:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or 5 unstained 5 micron slides. (Min: 3 slides). Transport block and/or slide(s) in a tissue transport kit (ARUP Supply # 47808) available online through eSupply using ARUP Connect™or contact ARUP Client Services at (800) 522-2787.
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Extracted DNA: Refrigerated.
Remarks: Include surgical pathology report.
Unacceptable Conditions: Less than 25 percent tumor. DNA extracted by a non-CLIA lab. DNA extracted without a corresponding circled H&E slide. Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). Decalcified specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerated: Indefinitely; Frozen: Indefinitely

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

Specimen Required: Collect: Tumor tissue. Also acceptable: DNA extracted by CLIA certified lab with corresponding client-circled H&E slide.
Specimen Preparation: **Tumor Tissue:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or 5 unstained 5 micron slides. (Min: 3 slides). Transport block and/or slide(s) in a tissue transport kit (ARUP Supply # 47808) available online through eSupply using ARUP Connect™or contact ARUP Client Services at (800) 522-2787.
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Extracted DNA: Refrigerated.
Remarks: Include surgical pathology report.
Unacceptable Conditions: Less than 25 percent tumor. DNA extracted by a non-CLIA lab. DNA extracted without a corresponding circled H&E slide. Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). Decalcified specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerated: Indefinitely; Frozen: Indefinitely

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

2007132 **BRAF V600E Mutation Detection in Hairy Cell Leukemia by Real-Time PCR, Quantitative** **BRAF HCL**

Specimen Required: Collect: Lavender (EDTA) or bone marrow (EDTA). Also acceptable: DNA extracted by CLIA certified lab.
Specimen Preparation: **Whole Blood:** Do not freeze. Transport 5 mL whole blood. (Min: 1 mL)
Bone Marrow: Transport 3 mL bone marrow. (Min: 1 mL)
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, serum, FFPE tissue blocks/slides, or frozen tissue, DNA extracted by a non-CLIA lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerate: Indefinitely; Frozen: Indefinitely

2008708 **Calculi Risk Assessment, Urine** **CRA**

Specimen Required: Collect: 24-hour urine. Refrigerate during collection.
Specimen Preparation: Thoroughly mix entire collection (24-hour) in one container. Transport four separate 4 mL aliquots of urine using Calculi Risk/Supersaturation Urine Collection Kit (ARUP supply# 46007). Available online through eSupply using ARUP Connect™ or contact Client Services at (800) 522-2787. **Do not exceed 4 mL in tubes.**
Aliquot according to the following specifications:
1st aliquot (pH 2): Transfer 4 mL urine into a Sulfamic Acid Tube. (Min: 4 mL) Mix well. Freeze immediately.
2nd aliquot (pH 2): Transfer 4 mL urine into a Sulfamic Acid Tube. (Min: 4 mL) Mix well. Freeze immediately.
3rd aliquot (pH 9): Transfer 4 mL urine into a Sodium Carbonate Tube. (Min: 4mL) Mix well. Freeze immediately.
4th aliquot: Transfer 4 mL urine into an Unpreserved Tube. (Min: 4 mL) Freeze immediately.
If collection kit is unavailable, transport four 4 mL unadjusted aliquots of urine.
Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered. Ship patient and control specimens together.
Remarks: Record total volume and collection time interval on transport tube and test request form.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 2 weeks

2010673 *CALR* (Calreticulin) Exon 9 Mutation Analysis by PCR — CALR

Specimen Required: Collect: Lavender (EDTA) or bone marrow (EDTA). Also acceptable: DNA extracted by CLIA certified lab.
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)
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, serum, FFPE tissue blocks/slides, or frozen tissue, DNA extracted by a non-CLIA lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerate: Indefinitely; Frozen: Indefinitely

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

Performed: Varies
Reported: 5-13 days

Specimen Required: Collect: Plain red or serum separator tube (SST).
Specimen Preparation: Transfer 0.1 mL serum to an ARUP Standard Transport Tube. (Min: 0.05 mL)
Storage/Transport Temperature: Frozen. Also acceptable: Room temperature or refrigerated.
Remarks: Patient age is required on the test request form. Provide reason (eg, diagnosis) for referral with each specimen.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 28 days; Frozen: 45 days

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3001697 Carbonic Anhydrase IX by IHC — CAIX IHC

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

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

Note: All stains will be handled as "Stain and Return" unless a consultation is requested. To request a consultation, submit the pathology report, all associated case materials (clinical history, blocks, slides, etc.), and the Anatomic Pathology requisition form (#32960) in place of the Immunohistochemistry Stain Form.

CPT Code(s): 88342

New York DOH Approved.

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

0080407 Catecholamines Fractionated by LC-MS/MS, Urine Free — CATE UF

Reference Interval:

Reference Intervals for 24-Hour Calculations (24-Hour Urine)

Test Number	Components	Reference Interval		
	Dopamine	Effective August 17, 2015		
		Age	**Dopamine**	
		0-3 years	Not Established	
		4-6 years	95-221 µg/d	
		7-12 years	76-371 µg/d	
		13-17 years	137-393 µg/d	
		18-69 years	77-324 µg/d	
		70 years and older	56-272 µg/d	
	Epinephrine	Effective August 19, 2019		
		Age	**Epinephrine**	
		0-3 years	Not Established	
		4-10 years	1-14 µg/d	
		11-17 years	1-18 µg/d	
		18 years and older	1-14 µg/d	
	Norepinephrine	Effective August 17, 2015		
		0-3 years	Not Established	
		4-12 years	6-45 µg/d	
		13-17 years	15-57 µg/d	
		18-69 years	16-71 µg/d	
		70 years and older	11-60 µg/d	
0020473	Creatinine, Urine - per 24h	**Age**	**Male**	**Female**
		3-8 years	140-700 mg/d	140-700 mg/d
		9-12 years	300-1300 mg/d	300-1300 mg/d
		13-17 years	500-2300 mg/d	400-1600 mg/d
		18-50 years	1000-2500 mg/d	700-1600 mg/d
		51-80 years	800-2100 mg/d	500-1400 mg/d
		81 years and older	600-2000 mg/d	400-1300 mg/d

Reference Intervals for Ratio-to-Creatinine (CRT) Calculations (Random Urine)

Test Number	Components	Reference Interval	
	Dopamine	**Age**	**Dopamine**
		0-11 months	240-1290 µg/g crt
		1-3 years	80-1220 µg/g crt
		4-10 years	220-720 µg/g crt
		11-17 years	120-450 µg/g crt
		18 years and older	0-250 µg/g crt
	Epinephrine	**Age**	**Epinephrine**
		0-11 months	0-380 µg/g crt
		1-3 years	0-82 µ/g crt
		4-10 years	5-93 µg/g crt
		11-17 years	3-58 µg/g crt
		18 years and older	0-20 µg/g crt
	Norepinephrine	**Age**	**Norepinephrine**
		0-11 months	25-310 µg/g crt
		1-3 years	25-290 µg/g crt
		4 -10 years	27-110 µg/g crt
		11-17 years	4-105 µg/g crt
		18 years and older	0-45 µg/g crt

2011114 *CBFB-MYH11* inv(16) Detection, Quantitative — INV 16 QNT

Specimen Required: Collect: Lavender (EDTA) or bone marrow (EDTA). Also acceptable: RNA extracted by CLIA certified lab.
Specimen Preparation: **Whole Blood:** Transport 5 mL whole blood. (Min: 1 mL)
Bone Marrow: Transport 3 mL bone marrow. (Min: 1 mL)
Specimens must be received within 48 hours of collection due to lability of RNA.
Extracted RNA: Transport 40 uL RNA with at least 40 ng/uL concentration. (Min: 40 uL) Transport RNA 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: **Whole Blood or Bone Marrow**: CRITICAL REFRIGERATED. Separate specimens must be submitted when multiple tests are ordered.
Extracted RNA: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Unacceptable Conditions: Serum, plasma, CSF, extracted DNA, RNA extracted by a non-CLIA lab, bone core, or FFPE tissues. Specimens collected in anticoagulants other than EDTA. Severely hemolyzed or clotted specimens.
Stability (collection to initiation of testing): Ambient: 1 hour; Refrigerated: 48 hours; Frozen: Unacceptable
Extracted RNA: Ambient: Unacceptable; Refrigerate: Unacceptable; Frozen: Indefinitely

2004247 *CEBPA* Mutation Detection — CEBPA MUT

Specimen Required: Collect: Lavender (EDTA) or bone marrow (EDTA). Also acceptable: DNA extracted by CLIA certified lab.
Specimen Preparation: **Whole Blood:** Do not freeze. Transport 5 mL whole blood (Min: 1 mL)
Bone Marrow: Transport 3 mL bone marrow. (Min: 1 mL)
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, serum, FFPE tissue blocks/slides, or frozen tissue, DNA extracted by a non-CLIA lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerate: Indefinitely; Frozen: Indefinitely

0080469 Chromogranin A — CGA SERUM

Reference Interval:
Effective August 19, 2019
0-160 ng/mL

2011075 *Coccidioides* Antigen Quantitative by EIA — COCCI AG

Performed: Varies
Reported: 3-4 days

Specimen Required: Collect: Plain Red, Serum Separator Tube (SST), Lavender (K_2 or K_3EDTA), Pink (K_2EDTA), Green (Sodium or Lithium Heparin), or Light Blue (CTAD). Also acceptable: Urine, CSF, or BAL.
Specimen Preparation: Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1.2 mL)
Transfer 1 mL urine or BAL to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Transfer 1 mL CSF to an ARUP Standard Transport Tube. (Min: 0.8 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Remarks: Specimen source required.
Stability (collection to initiation of testing): Ambient: 28 days; Refrigerated: 28 days; Frozen: Indefinitely

0062225 *Coccidioides immitis* Identification — MC CP

Methodology: Nucleic Acid Probe/MALDI (Matrix-Assisted Laser Desorption/Ionization)
Performed: Sun-Sat
Reported: 2-7 days

CPT Code(s): Varies based on identification methods.

3000480 Comprehensive Systemic Sclerosis Panel SCL COMPRE

Reference Interval:

Test Number	Components	Reference Interval	
0050599	Scleroderma (Scl-70) (ENA) Antibody, IgG	29 AU/mL or less	Negative
		30-40 AU/mL	Equivocal
		41 AU/mL or greater	Positive
0050470	Smith/RNP (ENA) Antibody, IgG	29 AU/mL or less	Negative
		30-40 AU/mL	Equivocal
		41 AU/mL or greater	Positive
3000082	Antinuclear Antibody (ANA) with HEp-2 Substrate, IgG by IFA	Less than 1:80	
2012173	Fibrillarin (U3 RNP) Antibody, IgG	Negative	
2003040	PM/Scl-100 Antibody, IgG by Immunoblot	Negative	
2001601	RNA Polymerase III Antibody, IgG	19 Units or less	Negative
		20-39 Units	Weak Positive
		40-80 Units	Moderate Positive
		81 Units or greater	Strong Positive

Note: Panel includes: Antinuclear Antibody (ANA) with HEp-2 Substrate, IgG by IFA, Scleroderma (Scl-70) (ENA) Antibody, IgG, RNA Polymerase III Antibody, IgG, Smith/RNP (ENA) Antibody, IgG, Fibrillarin (U3 RNP) Antibody, IgG, PM/Scl-100 Antibody, IgG by Immunoblot.

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 0050470 from Ribonucleic Protein (U1) (ENA) Ab, IgG to Smith/RNP (ENA) Ab, IgG.

0051668 Connective Tissue Diseases Profile CONN

Reference Interval:
Effective May 18, 2015

Test Number	Components	Reference Interval			
0050085	Smith (ENA) Antibody, IgG	29 AU/mL or less	Negative		
		30-40 AU/mL	Equivocal		
		41 AU/mL or greater	Positive		
0050470	Smith/RNP (ENA) Antibody, IgG	29 AU/mL or less	Negative		
		30-40 AU/mL	Equivocal		
		41 AU/mL or greater	Positive		
2012074	SSA 52 and 60 (Ro) (ENA) Antibodies, IgG	**Test Number**	**Components**	**Reference Interval**	
			SSA-52 (Ro52) (ENA) Antibody, IgG	29 AU/mL or Less	Negative
				30-40 AU/mL	Equivocal
				41 AU/mL or	Positive
			SSA-60 (Ro60) (ENA) Antibody, IgG	29 AU/mL or Less	Negative
				30-40 AU/mL	Equivocal
				41 AU/mL or	Positive
0050692	SSB (La) (ENA) Antibody, IgG	29 AU/mL or less	Negative		
		30-40 AU/mL	Equivocal		
		41 AU/mL or greater	Positive		
0099592	Jo-1 Antibody, IgG	29 AU/mL or less	Negative		
		30-40 AU/mL	Equivocal		
		41 AU/mL or greater	Positive		
0099249	Ribosomal P Protein Antibody	29 AU/mL or less	Negative		
		30-40 AU/mL	Equivocal		
		41 AU/mL or greater	Positive		
0050714	Centromere Antibody, IgG	29 AU/mL or less	Negative		
		30-40 AU/mL	Equivocal		
		41 AU/mL or greater	Positive		
0050599	Scleroderma (Scl-70) (ENA) Antibody, IgG	29 AU/mL or less	Negative		
		30-40 AU/mL	Equivocal		
		41 AU/mL or greater	Positive		

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 0050470 from Ribonucleic Protein (U1) (ENA) Ab, IgG to Smith/RNP (ENA) Ab, IgG.

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

Note: In addition to the SurePath Pap Test, Human Papillomavirus (HPV) High Risk by PCR will be performed and reported under a separate accession. The Pap test is a screening test for cervical cancer and its precursors with an inherent false-negative rate.

CPT Code(s): 87624; 88142, if reviewed by pathologist add 88141

New Test **3001783** **Dermatomyositis and Polymyositis Panel** **COMBI PAN**

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Additional Technical Information

Methodology: Qualitative Immunoprecipitation/Semi-Quantitative Multiplex Bead Assay/Qualitative Immunoblot
Performed: Sun-Sat
Reported: 7-18 days

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer two 1 mL serum aliquots to ARUP Standard Transport Tubes. (Min: 0.5 mL/aliquot)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed, hyperlipemic, icteric, heat-treated or contaminated specimens.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval:

Test Number	Components	Reference Interval	
0099592	Jo-1 Antibody, IgG	29 AU/mL or less	Negative
		30-40 AU/mL	Equivocal
		41 AU/mL or greater	Positive
	PL-7 (threonyl-tRNA synthetase) Antibody	Negative	
	PL-12 (alanyl-tRNA synthetase) Antibody	Negative	
	EJ (glycyl-tRNA synthetase) Antibody	Negative	
	SRP (Signal Recognition Particle) Ab	Negative	
	OJ (isoleucyl-tRNA synthetase) Antibody	Negative	
	Mi-2 (nuclear helicase protein) Antibody	Negative	
	P155/140 Antibody	Negative	
	SAE1 (SUMO activating enzyme) Ab	Negative	
	MDA5 (CADM-140) Ab	Negative	
	NXP2 (Nuclear matrix protein-2) Ab	Negative	
	TIF1-gamma Ab	Negative	

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

Note: Antibodies: PL-7, PL12, EJ, OJ, SRP, Jo-1, Mi-2, P155/140, SAE1, MDA5, NXP2, TIF1-gamma

CPT Code(s): 83516 x11; 86235

New York DOH Approved.

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

New Test [3001782](#) **Dermatomyositis Autoantibody Panel** **DERM PAN**

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Additional Technical Information

Methodology: Qualitative Immunoprecipitation/Qualitative Immunoblot
Performed: Sun-Sat
Reported: 7-18 days

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer one 1 mL serum aliquots to ARUP Standard Transport Tubes. (Min: 0.5 mL/aliquot)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed, hyperlipemic, icteric, heat-treated or contaminated specimens.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval:

Test Number	Components	Reference Interval
	Mi-2 (nuclear helicase protein) Antibody	Negative
	P155/140 Antibody	Negative
	SAE1 (SUMO activating enzyme) Ab	Negative
	MDA5 (CADM-140) Ab	Negative
	NXP2 (Nuclear matrix protein-2) Ab	Negative
	TIF1-gamma Ab	Negative

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

Note: Antibodies: Mi-2, P155/140, SAE1, MDA5, NXP2, TIF1-gamma

CPT Code(s): 83516 x6

New York DOH Approved.

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

[2002440](#) ***EGFR* Mutation Detection by Pyrosequencing** **EGFR PCR**

Specimen Required: Patient Prep: For a general FNA collection and smear preparation refer to ARUP's Laboratory Test Directory: Cytology, Fine Needle Aspiration Collection at http://ltd.aruplab.com/tests/pdf/366
Collect: Tumor tissue. Also acceptable: DNA extracted by CLIA certified lab with corresponding client-circled H&E slide.
Specimen Preparation: **Tumor Tissue:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or 5 unstained 5-micron slides. (Min: 3 slides)
Fine Needle Aspirate (FNA): Prepare FNA smear with Diff-Quik or equivalent stain by standard methods (air-dried slides are preferred). Number of slides needed is dependent on the tumor cellularity of the smear. (Min: 1 slide). Slide(s) will be destroyed during testing process and will not be returned to client. Transport block and/or slide(s) in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Extracted DNA: Refrigerated.
Unacceptable Conditions: Less than 25 percent tumor. DNA extracted by a non-CLIA lab. DNA extracted without a corresponding circled H&E slide. Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). Decalcified specimens. FNA smears with less than 50 tumor cells.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerated: Indefinitely; Frozen: Indefinitely

Note: This test detects mutations in *EGFR* exons 18, 19, 20 and 21 (codons 719, 745-753, 768, 790, 858, and 861).

2007914 ***EPOR* Mutation Detection by Sequencing** **EPOR**

Specimen Required: Collect: Lavender (EDTA). Also acceptable: DNA extracted by CLIA certified lab.
Specimen Preparation: **Whole Blood:** Do not freeze. Transport 5 mL whole blood. (Min: 1 mL)
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, serum, FFPE tissue blocks/slides, or frozen tissue, DNA extracted by a non-CLIA lab, bone marrow. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerate: Indefinitely; Frozen: Indefinitely

New Test **3001781** **Extended Myositis Panel** **MYOS EXT**
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Additional Technical Information

Methodology: Qualitative Immunoprecipitation/Semi-Quantitative Multiplex Bead Assay/Qualitative Immunoblot
Performed: Sun-Sat
Reported: 7-18 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: Refrigerated.
Unacceptable Conditions: Hemolyzed, hyperlipemic, icteric, heat-treated or contaminated specimens.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval:

Test Number	Components	Reference Interval		
		Test Number	**Components**	**Reference Interval**
2012074	SSA 52 and 60 (Ro) (ENA) Antibodies, IgG		SSA-52 (Ro52) (ENA) Antibody, IgG	29 AU/mL or Less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive
			SSA-60 (Ro60) (ENA) Antibody, IgG	29 AU/mL or Less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive
0050470	SM/RNP (ENA) Antibody, IgG	29 AU/mL or less	Negative	
		30-40 AU/mL	Equivocal	
		41 AU/mL or greater	Positive	
0099592	Jo-1 Antibody, IgG	29 AU/mL or less	Negative	
		30-40 AU/mL	Equivocal	
		41 AU/mL or greater	Positive	
	Mi-2 (nuclear helicase protein) Antibody	Negative		
	PL-7 (threonyl-tRNA synthetase) Antibody	Negative		
	PL-12 (alanyl-tRNA synthetase) Antibody	Negative		
	P155/140 Antibody	Negative		
	EJ (glycyl-tRNA synthetase) Antibody	Negative		
	Ku Antibody	Negative		
	SRP (Signal Recognition Particle) Ab	Negative		
	OJ (isoleucyl-tRNA synthetase) Antibody	Negative		
	SAE1 (SUMO activating enzyme) Ab	Negative		
	MDA5 (CADM-140) Ab	Negative		
	NXP2 (Nuclear matrix protein-2) Ab	Negative		
	TIF1-gamma Ab	Negative		
2012173	Fibrillarin (U3 RNP) Antibody, IgG	Negative		
2003040	PM/Scl-100 Antibody, IgG by Immunoblot	Negative		

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

Note: Antibodies: Mi-2, PL-7, PL12, P155/140, EJ, Ku, OJ, PM/Scl, SRP, SM/RNP, Ro52, Ro60, Jo-1, U3 Fib, SAE1, NXP2, MDA5, TIF1-gamma

CPT Code(s): 83516 x12; 86235 x6

New York DOH Approved.

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

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

Reference Interval:
Effective May 18, 2015

Test Number	Components	Reference Interval	
0050470	Smith/RNP (ENA) Antibody, IgG	29 AU/mL or less	Negative
		30-40 AU/mL	Equivocal
		41 AU/mL or greater	Positive
0050085	Smith (ENA) Antibody, IgG	29 AU/mL or less	Negative
		30-40 AU/mL	Equivocal
		41 AU/mL or greater	Positive
2012074	SSA 52 and 60 (Ro) (ENA) Antibodies, IgG	**Test Number**	**Components** / **Reference Interval**
			SSA-52 (Ro52) (ENA) Antibody, IgG: 29 AU/mL or Less – Negative; 30-40 AU/mL – Equivocal; 41 AU/mL or – Positive
			SSA-60 (Ro60) (ENA) Antibody, IgG: 29 AU/mL or Less – Negative; 30-40 AU/mL – Equivocal; 41 AU/mL or – Positive
0050692	SSB (La) (ENA) Antibody, IgG	29 AU/mL or less	Negative
		30-40 AU/mL	Equivocal
		41 AU/mL or greater	Positive

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 0050470 from Ribonucleic Protein (U1) (ENA) Ab, IgG to Smith/RNP (ENA) Ab, IgG.

0094030 Felbamate FELBAMA

Reference Interval:
Effective August 19, 2019

Therapeutic Range	30 – 60 µg/mL
Toxic Level	Greater than 120 µg/mL

Interpretive Data: Patient pharmacokinetics may be variable due to age, co-medications, and/or compromised renal function. Adverse effects may include nausea, vomiting, dizziness, blurred vision and ataxia. Felbamate use may increase the incidence of liver failure and aplastic anemia.

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

3001161 *FLT3* ITD and TKD Mutation Detection FLT3-PCR

Specimen Required: Collect: Lavender (EDTA) or bone marrow (EDTA). Also acceptable: DNA extracted by CLIA certified lab.
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)
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, serum, FFPE tissue blocks/slides, or frozen tissue, DNA extracted by a non-CLIA lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerate: Indefinitely; Frozen: Indefinitely

2009033 Fragile X (*FMR1*) with Reflex to Methylation Analysis FRAG X PCR

Specimen Required: Collect: Lavender (K_2EDTA), Pink (K_2EDTA), or Yellow (ACD Solution A or B).
Specimen Preparation: Transport 5 mL whole blood. (Min: 1.5 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 month; Frozen: 6 months

Interpretive Data:
Background Information for Fragile X (*FMR1*)
Characteristics: Fragile X syndrome, the most common heritable form of mental retardation, is characterized by moderate mental retardation in males and mild mental retardation in females, hyperactivity, perseverative speech, social anxiety, poor eye contact, hand flapping or biting, autism spectrum disorders behavioral phenotype, and connective tissue anomalies. Adult males may have physical findings including: macroorchidism, a long narrow face, prominent ears and jaw, and a single palmar crease.
Incidence: 1 in 4,000 Caucasian males and 1 in 8,000 Caucasian females; unknown in other ethnicities.
Inheritance: X-linked dominant.
Penetrance: Reduced in females.
Cause: Expansion of the *FMR1* gene CGG triplet repeat.
Full mutation: >200-230 CGG repeats (methylated)
Premutation: 55-200 CGG repeats (unmethylated)
Intermediate: 45-54 CGG repeats (unmethylated)
Normal: 5-44 CGG repeats (unmethylated)
Clinical Sensitivity: 99 percent.
Methodology: Triplet repeat-primed polymerase chain reaction (PCR) followed by size analysis using capillary electrophoresis. Methylation-specific PCR analysis is performed for CGG repeat lengths of 100 or greater. Methylation analysis is used to distinguish between premutation and full mutation alleles.
Analytic Sensitivity and Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations.

Phenotype	Number of CGG Repeats
Unaffected	<45
Intermediate	45-54
Premutation	55-200
Affected	>200

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

Note: If a CGG repeat of 100 or greater is detected by PCR and Capillary Electrophoresis, methylation analysis will be added. Additional charges apply.

2009034 Fragile X (*FMR1*) with Reflex to Methylation Analysis, Fetal FX PCR FE

Specimen Required: Collect: **Fetal Specimen**: Amniotic fluid or two T-25 flasks at 80 percent confluency of cultured amniocytes. If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787.
AND Maternal Specimen: Lavender (EDTA), pink (K2EDTA), or yellow (ACD Solution A or B).

Specimen Preparation: **Amniotic Fluid:** Transport 10 mL unspun fluid. (Min: 5 mL)
Cultured Amniocytes: Fill flasks with culture media. Transport two T-25 flasks at 80 percent confluency of cultured amniocytes. Backup cultures must be retained at the client's institution until testing is complete.
Maternal Specimen: Transport 3 mL whole blood. (Min: 1 mL)

Storage/Transport Temperature: **Amniotic Fluid:** Room temperature.
Cultured Amniocytes: CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of shipment due to viability of cells.
Maternal 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 at (800) 522-2787.

Stability (collection to initiation of testing): **Fetal Specimen:** Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Maternal Specimen: Ambient: 1 week; Refrigerated: 1 month; Frozen: 6 months

Note: If a CGG repeat of 100 or greater is detected by PCR and Capillary Electrophoresis; methylation analysis will be added. Additional charges apply.

New Test **3001648** **Gaucher Disease (*GBA*) Sequencing** **GBA FGS**

Click for Pricing

Patient History for Gaucher Disease Sequencing

Additional Technical Information

Out of Pocket Estimator

Methodology: Polymerase Chain Reaction/Sequencing
Performed: Sun-Sat
Reported: 2-3 weeks

Specimen Required: Collect: Lavender (K_2 or K_3 EDTA) or Pink (K_2 EDTA). Also acceptable: Yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 month; Frozen: 6 months

Reference Interval:
Background information for Gaucher Disease (*GBA*) Sequencing:
Characteristics: Gaucher disease (GD) is a lysosomal storage disorder with phenotypes ranging from perinatal lethality to lack of symptoms. There are three GD subtypes. Type 1 GD manifests with bone disease, hepatosplenomegaly, anemia, thrombocytopenia, and lung disease but no central nervous system (CNS) involvement. Type 2 GD exhibits CNS symptoms before age 2 and rapidly progresses resulting in death by age 4. Type 3 GD presents as early as age 2 with CNS symptoms that slowly progress resulting in death during the third or fourth decade.
Incidence: 1 in 900 Ashkenazi Jewish individuals; approximately 1 in 57,000 to 1 in 75,000 in general population.
Inheritance: Autosomal recessive.
Cause: Two pathogenic *GBA* variants on opposite chromosomes.
Clinical Sensitivity: 99 percent.
Methodology: Long range PCR followed by bidirectional sequencing of all coding regions and intron-exon boundaries of the *GBA* gene.
Analytical Sensitivity and Specificity: approximately 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Regulatory region variants, deep intronic variants, large deletions/duplications/insertions, gene conversion and complex gene events may not be detected.

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

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.

3000258 **Genetic Carrier Screen, (CF, FXS, and SMA) with Reflex to Methylation** **CF FX SMA**

Note: Cystic Fibrosis: The 165-variant test includes the 23 pathogenic CF variants recommended by the American College of Medical Genetics for population carrier screening.

Fragile X: If a CGG repeat of 100 or greater is detected by PCR and Capillary Electrophoresis; methylation analysis will be added. Additional charges apply.

0080135 **Glucose-6-Phosphate Dehydrogenase** **G6PD**

Specimen Required: Collect: Yellow (ACD Solution A). Also acceptable: Green (Sodium or Lithium Heparin), Lavender (K_2 EDTA or K_3 EDTA), or Pink (K_2EDTA). Enzyme most stable in acid citrate dextrose (ACD).
Specimen Preparation: **Do not freeze.** Transport 3 mL whole blood. (Min: 1.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Clotted or hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: 1 week; Frozen: Unacceptable

2013590 Heat Shock Protein 70, IgG by Immunoblot — HSP

Performed: Thu
Reported: 1-8 days

2010476 *Helicobacter pylori* Breath Test, Adult — UBIT

Specimen Required: Patient Prep: This test requires the adult patient (>17 years of age) to fast for 1 hour prior to test administration. The patient should not have taken antibiotics, proton pump inhibitors (e.g., Prilosec, Prevacid, Aciphex, Nexium), or bismuth preparations (e.g., Pepto-Bismol) within the previous 14 days. The effect of histamine 2-receptor antogonists (e.g., Axid, Pepcid, Tagamet, Zantac) may reduce urease activity on urea breath tests and should be discontinued for 24-48 hours before the sample is collected. When used to monitor treatment, the test should be performed four weeks after cessation of definitive therapy. The patient should be informed that the Pranactin-Citric drink that will be administered contains phenylalanine. Phenylketonurics restrict dietary phenylalanine.
Collect: BreathTek UBT Kit (ARUP Supply #51124) available online through eSupply using ARUP Connect™ or contact ARUPClient Services at (800) 522-2787.
Specimen Preparation: 1) Label breath collection bags with patient name, MRN, date and time of collection, and indicate Pre (blue) or Post (pink).
2) Collect the baseline (Pre) breath specimen according to the instructions in the BreathTek UBT kit.
3) After the allotted time, collect the Post breath specimen according to the instructions in the kit.
Storage/Transport Temperature: **CRITICAL ROOM TEMPERATURE. Do not freeze.**
Remarks: **For a valid result, the post breath specimen must be collected between 15 and 30 minutes after the patient drinks the Pranactin-Citric solution.**
Unacceptable Conditions: Underinflated bags. Pediatric specimens
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: Unacceptable; Frozen: Unacceptable

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

Specimen Required: Patient Prep: This test requires the pediatric patient (3-17 years old) to fast for 1 hour prior to test administration. The patient should not have taken antibiotics, proton pump inhibitors (e.g., Prilosec, Prevacid, Aciphex, Nexium), or bismuth preparations (e.g., Pepto-Bismol) within the previous 14 days. The effect of histamine 2-receptor antogonists (e.g., Axid, Pepcid, Tagamet, Zantac) may reduce urease activity on urea breath tests and should be discontinued for 24-48 hours before the sample is collected. When used to monitor treatment, the test should be performed four weeks after cessation of definitive therapy. The patient should be informed that the Pranactin-Citric drink that will be administered contains phenylalanine. Phenylketonurics restrict dietary phenylalanine.
Collect: BreathTek UBT Kit. (ARUP Supply #51124) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Specimen Preparation: 1) Label breath collection bags with patient name, MRN, date and time of collection, and indicate Pre (blue) or Post (pink).
2) Collect the baseline (Pre) breath specimen according to the instructions in the BreathTek UBT kit.
3) After the allotted time, collect the Post breath specimen according to the instructions in the kit.
Storage/Transport Temperature: **CRITICAL ROOM TEMPERATURE**. **Do not freeze.**
Remarks: **Submit with Order: Weight (in pounds), height (in inches), sex, and age.**
Unacceptable Conditions: Underinflated bags. Specimens from patients younger than 3 years.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: Unacceptable; Frozen: Unacceptable

2005792 Hemoglobin Evaluation Reflexive Cascade — HB CASCADE

HOTLINE NOTE: There is a component change associated with this test.
Remove component 2005799, Beta Gloibn (*HBB*) Mutations
Remove component 2005803 Hereditary Persistent Fetal Hemoglobin
There is also a reflexive pattern change associated with this test.
Remove reflex to 2005828, Beta Globin (*HBB*) Mutations Bill
Remove reflex to 2005836, Hereditary Persistent Fetal HGB Bill

0092522 *Histoplasma* Antigen Quantitative by EIA, Serum — HISTOAG S

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

Specimen Required: Collect: Plain Red or Serum Separator Tube (SST).
Specimen Preparation: Transfer 2 mL serum to a sterile ARUP Standard Transport Tube (ARUP Supply #43115). (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Specimen types other than those listed.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 2 weeks; Frozen: 1 month (avoid repeated freeze/thaw cycles)

Reference Interval:
Effective August 19, 2019

Less than 0.19 ng/ml	Not Detected
0.19-60.0 ng/mL	Detected
Greater than 60.0 ng/mL	Detected (above the limit of quantification).

Interpretive Data: The quantitative range of this assay is 0.19-60.0 ng/mL. Antigen concentrations greater than 60.0 ng/mL fall outside the linear range of the assay and cannot be accurately quantified.

This EIA test should be used in conjunction with other diagnostic procedures, including microbiological culture, histological examination of biopsy samples, and/or radiographic evidence, to aid in the diagnosis of histoplasmosis.

Crossreactivity with *Blastomyces dermatiditis*, *Coccidioides immitis*, and possibly *Talaromyces marneffei* have been observed with this EIA. Other clinically and geographically relevant endemic mycoses should be considered in the case of a positive test result.

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement B: aruplab.com/CS

Note: For urine, refer to test *Histoplasma Galactomannan* Antigen Quantitative by EIA, Urine (ARUP test code 2009418).

HOTLINE NOTE: There is a numeric map change associated with this test. There is a unit of measure change associated with this test.
Change the numeric map for component 0060749, Histoplasma Antigen, Serum from XXX.X to XX.XX.
Change the unit of measure for component 0060749, Histoplasma Antigen, Serum from U/mL to ng/mL.

0062226 *Histoplasma capsulatum* Identification — MC HP

Methodology: Nucleic Acid Probe/MALDI (Matrix-Assisted Laser Desorption/Ionization)
Performed: Sun-Sat
Reported: 2-7 days

CPT Code(s): Varies depending on identification methods.

New Test Available Now Click for Pricing | **3001791** | **HNF-1B by Immunohistochemistry** | **HNF1B IHC**

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

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

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

Note: All stains will be handled as "Stain and Return" unless a consultation is requested. To request a consultation, submit the pathology report, all associated case materials (clinical history, blocks, slides, etc.), and the Anatomic Pathology requisition form (#32960) in place of the Immunohistochemistry Stain Form.

CPT Code(s): 88342

New York DOH Approved.

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

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

Specimen Required: Collect: Lavender (EDTA) or bone marrow (EDTA). Also acceptable: DNA extracted by CLIA certified lab.
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)
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, serum, FFPE tissue blocks/slides, or frozen tissue, DNA extracted by a non-CLIA lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerate: Indefinitely; Frozen: Indefinitely

2014188 | ***IDH1* and *IDH2* Mutation Analysis, Exon 4, Formalin-Fixed, Paraffin-Embedded (FFPE) Tissue** | **IDH1-2FFPE**

Specimen Required: Collect: Tumor tissue. Also acceptable: DNA extracted by CLIA certified lab with corresponding client-circled H&E slide.
Specimen Preparation: **Tumor Tissue:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Tissue block will be returned after testing.Transport tissue block or 4 unstained 5-micron slides. (Min: 3 slides) Transport block and/or slide(s) in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™or contact ARUP Client Services at (800) 522-2787.
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Extracted DNA: Refrigerated.
Remarks: For FFPE specimens include surgical pathology report.
Unacceptable Conditions: Less than 25 percent tumor. DNA extracted by a non-CLIA lab. DNA extracted without a corresponding circled H&E slide. Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). Decalcified specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Extracted DNA Ambient: 1 month; Refrigerated: Indefinitely; Frozen: Indefinitely

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

Specimen Required: Collect: Lavender (EDTA) or bone marrow (EDTA). Also acceptable: RNA extracted by CLIA certified lab.
Specimen Preparation: **Whole Blood:** Transport 5 mL whole blood. (Min: 1 mL)
Bone Marrow: Transport 3 mL bone marrow. (Min: 1 mL)
Specimens must be received within 48 hours of collection due to lability of RNA.
Extracted RNA: Transport 40uL RNA with at least 40 ng/uL concentration (Min: 40uL). Transport RNA 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: **Whole Blood or Bone Marrow**: CRITICAL REFRIGERATED. Separate specimens must be submitted when multiple tests are ordered.
Extracted RNA: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Unacceptable Conditions: Serum, plasma, CSF, extracted DNA, RNA extracted by a non-CLIA lab, bone core, or FFPE tissue. Specimens collected in anticoagulants other than EDTA. Severely hemolyzed or clotted specimens.
Stability (collection to initiation of testing): Ambient: 1 hour; Refrigerated: 48 hours; Frozen: Unacceptable
Extracted RNA: Ambient: Unacceptable; Refrigerate: Unacceptable; Frozen: Indefinitely

New Test **3001409** **Immunobullous Disease Panel, Epithelial Antibody Screening Panel** **IMBULDZPAN**

Available Now
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Methodology: Indirect Fluorescent Antibody/Enzyme-Linked Immunosorbent Assay
Performed: Varies
Reported: 4-9 days

Specimen Required: Collect: Plain Red or Serum Separator Tube (SST).
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: Indefinitely

Reference Interval: By Report

Interpretive Data: Refer to report

Note: For specimens less than 0.5 mL, call the Immunodermatology Laboratory at (866) 266-5699.

CPT Code(s): 88346, 88350 x5, 83516 x5

New York DOH approval pending. Call for status update.

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

New Test [3001784] **Interstitial Lung Disease Autoantibody Panel** **ILD PANEL**
Click for Pricing

Additional Technical Information

Methodology: Qualitative Immunoprecipitation/Semi-Quantitative Multiplex Bead Assay/Qualitative Immunoblot/Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Quantitative Immunoturbidimetry
Performed: Sun-Sat
Reported: 7-18 days

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer five 1 mL serum aliquots to ARUP Standard Transport Tubes. (Min: 0.5 mL/aliquot)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed, hyperlipemic, icteric, heat-treated or contaminated specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 1 weeks; Frozen: 1 month

Reference Interval:

Test Number	Components	Reference Interval		
2012074	SSA 52 and 60 (Ro) (ENA) Antibodies, IgG	**Test Number**	**Components**	**Reference Interval**
			SSA-52 (Ro52) (ENA) Antibody, IgG	29 AU/mL or Less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive
			SSA-60 (Ro60) (ENA) Antibody, IgG	29 AU/mL or Less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive
0050599	Scleroderma (Scl-70) (ENA) Antibody, IgG	29 AU/mL or less	Negative	
		30-40 AU/mL	Equivocal	
		41 AU/mL or greater	Positive	
0099592	Jo-1 Antibody, IgG	29 AU/mL or less	Negative	
		30-40 AU/mL	Equivocal	
		41 AU/mL or greater	Positive	
	PL-7 (threonyl-tRNA synthetase) Antibody	Negative		
	PL-12 (alanyl-tRNA synthetase) Antibody	Negative		
	EJ (glycyl-tRNA synthetase) Antibody	Negative		
	Ku Antibody	Negative		
	SRP (Signal Recognition Particle) Ab	Negative		
	OJ (isoleucyl-tRNA synthetase) Antibody	Negative		
2003040	PM/Scl-100 Antibody, IgG by Immunoblot	Negative		
	MDA5 (CADM-140) Ab	Negative		
	NXP2 (Nuclear matrix protein-2) Ab	Negative		
0050465	Rheumatoid Factor	0-14 IU/mL		
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	
3000082	Antinuclear Antibody (ANA) with HEp-2 Substrate, IgG by IFA	Less than 1:80		
2001601	RNA Polymerase III Antibody, IgG	19 Units or less	Negative	
		20-39 Units	Weak Positive	
		40-80 Units	Moderate Positive	
		81 Units or greater	Strong Positive	

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

Note: Antibodies: Ro52, Ro60, Jo-1, PL-7, PL12, EJ, Ku, SRP, OJ, PM/Scl-100, MDA5, CCP, Scl-70, RA, ANA, NXP-2, RNA Polymerase III

CPT Code(s): 83516 x9; 86235 x5; 86200; 86431; 86039

New York DOH Approved.

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

New Test Available Now Click for Pricing

3001568 ***IRF4/DUSP22* (6p25) Gene Rearrangement by FISH** **IRF4 FISH**

Additional Technical Information

Methodology: Fluorescence in situ Hybridization
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.
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.
See Compliance Statement B: www.aruplab.com/CS

Note: The laboratory will not reject specimens that arrive without a pathology report but will hold the specimen until this information is received.

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.

2002357 ***JAK2* Exon 12 Mutation Analysis by PCR** **JAK2 EX12**

Specimen Required: Collect: Lavender (EDTA) **or** bone marrow (EDTA). Also acceptable: DNA extracted by CLIA certified lab.
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)
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, serum, FFPE tissue blocks/slides, or frozen tissue, DNA extracted by a non-CLIA lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerate: Indefinitely; Frozen: Indefinitely

0051245 ***JAK2* Gene, V617F Mutation, Qualitative** **JAK2**

Specimen Required: Collect: Lavender (EDTA) **OR** bone marrow (EDTA). Also acceptable: DNA extracted by CLIA certified lab.
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)
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, serum, FFPE tissue blocks/slides, or frozen tissue, DNA extracted by a non-CLIA lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerate: Indefinitely; Frozen: Indefinitely

HOTLINE NOTE: Remove information found in the Reference Interval field.

2012084 ***JAK2* Gene, V617F Mutation, Qualitative with Reflex to *CALR* (Calreticulin) Exon 9 Mutation Analysis by PCR with Reflex to *MPL* Mutation Detection** **ET PMF RFX**

Specimen Required: Collect: Lavender (EDTA) or bone marrow (EDTA). Also acceptable: DNA extracted by CLIA certified lab.
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)
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, serum, FFPE tissue blocks/slides, or frozen tissue, DNA extracted by a non-CLIA lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerate: Indefinitely; Frozen: Indefinitely

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

Specimen Required: Collect: Lavender (EDTA) or bone marrow (EDTA). Also acceptable: DNA extracted by CLIA certified lab.
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)
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, serum, FFPE tissue blocks/slides, or frozen tissue, DNA extracted by a non-CLIA lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerate: Indefinitely; Frozen: Indefinitely

0040168 ***JAK2* Gene, V617F Mutation, Quantitative** **JAK2 QNT**

Specimen Required: Collect: Lavender (EDTA). Also acceptable: DNA extracted by CLIA certified lab.
Specimen Preparation: **Whole Blood:** Do not freeze. Transport 5 mL whole blood. (Min: 1 mL).
Extracted DNA: Transport 40uL DNA with at least 50 ng/uL concentration (Min: 40uL). Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, serum, FFPE tissue blocks/slides, or frozen tissue, bone marrow, DNA extracted by a non-CLIA lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 48 hours; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerate: Indefinitely; Frozen: Indefinitely

HOTLINE NOTE: Remove information found in the Reference Interval field.

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

Specimen Required: Collect: 24-hour urine. Refrigerate during collection.
Specimen Preparation: Thoroughly mix entire collection (24-hour) in one container. Transport four separate 4 mL aliquots of urine using Calculi Risk/Supersaturation Urine Collection Kit (ARUP supply# 46007). Available online through eSupply using ARUP Connect™ or contact Client Services at (800) 522-2787. Do not exceed 4 mL in tubes.
Aliquot according to the following specifications:
1st aliquot (pH 2): Transfer 4 mL urine into a Sulfamic Acid Tube. (Min: 4 mL) Mix well. Freeze immediately.
2nd aliquot (pH 2): Transfer 4 mL urine into a Sulfamic Acid Tube. (Min: 4 mL) Mix well. Freeze immediately.
3rd aliquot (pH 9): Transfer 4 mL urine into a Sodium Carbonate Tube. (Min: 4 mL) Mix well. Freeze immediately.
4th aliquot: Transfer 4 mL urine into an Unpreserved Tube. (Min: 4 mL) Freeze immediately.
If collection kit is unavailable, transport four 4 mL unadjusted aliquots of urine.
Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered. Ship patient and control specimens together.
Remarks: Record total volume and collection time interval on transport tube and test request form.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 2 weeks

3000440 ***KIT* (D816V) Mutation by PCR** **KIT D816V**

Specimen Required: Collect: Lavender (EDTA) or bone marrow (EDTA). Also acceptable: DNA extracted by CLIA certified lab.
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)
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, serum, FFPE tissue blocks/slides, or frozen tissue, DNA extracted by a non-CLIA lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerate: Indefinitely; Frozen: Indefinitely

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

Specimen Required: Collect: Lavender (EDTA) or bone marrow (EDTA). Also acceptable: DNA extracted by CLIA certified lab.
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).
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, serum, FFPE tissue blocks/slides, or frozen tissue, DNA extracted by a non-CLIA lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerated: Indefinitely; Frozen: Indefinitely

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

Specimen Required: Collect: Tumor tissue. Also acceptable: DNA extracted by CLIA certified lab with corresponding client-circled H&E slide.
Specimen Preparation: **Tumor Tissue:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Transport tissue block or 5 unstained 5-micron slides. (Min: 3 slides) Transport block(s) and/or slide(s) in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Extracted DNA: Refrigerated.
Remarks: Include surgical pathology report.
Unacceptable Conditions: Less than 25 percent tumor. DNA extracted by a non-CLIA lab. DNA extracted without a corresponding circled H&E slide. Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). Decalcified specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerate: Indefinitely; Frozen: Indefinitely

2001932 ***KRAS* Mutation Detection with Reflex to *BRAF* Codon 600 Mutation Detection** **KRAS RFLX**

Specimen Required: Collect: Tumor tissue. Also acceptable: DNA extracted by CLIA certified lab with corresponding client-circled H&E slide.
Specimen Preparation: **Tumor Tissue:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect paraffin block from excessive heat. Tissue block will be returned after testing. Transport tissue block or 5 unstained 5-micron slides. (Min: 3 slides). Transport block and/or slide(s) in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Extracted DNA: Transport 40uL DNA with at least 50 ng/uL concentration. (Min: 40uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Extracted DNA: Refrigerated.
Remarks: Include surgical pathology report.
Unacceptable Conditions: Less than 25 percent tumor. DNA extracted by a non-CLIA lab. DNA extracted without a corresponding circled H&E slide. Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). Decalcified specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerated: Indefinitely; Frozen: Indefinitely

New Test **3001866** **Krebs von den Lungen-6** **KL 6**
Click for Pricing

Methodology: Quantitative Immunoturbidimetric
Performed: Tue
Reported: 1-8 days

Specimen Required: Collect: Plain Red.
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transfer 1.5 mL serum to ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed, hyperlipemic, icteric, heat-treated or contaminated.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 month

Reference Interval: 0-500 U/mL

Interpretive Data: Krebs von den Lungen-6 (KL-6) is an indicator of lung inflammation or damage. Elevated levels are associated with various types of interstitial lung diseases (ILD). Abnormal KL-6 results should be interpreted in the appropriate clinical context. A negative result does not rule out ILD.

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

Note: Samples with results greater than 10,000 U/mL will be diluted to the maximum reportable range (>40,000 U/mL).

CPT Code(s): 83520

New York DOH approval pending. Call for status update.

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

New Test **3001780** **Leukemia/Lymphoma Phenotyping Evaluation by Flow Cytometry** **LL PANEL**

Click for Pricing

Time Sensitive

Additional Technical Information

Methodology: Flow Cytometry
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Collect: Bone marrow. Whole blood: Green (Sodium Heparin), Lavender (K_2EDTA), or Pink (K_2EDTA). Tissue or fluid.
Specimen Preparation: **Bone Marrow:** Transport 1 mL heparinized bone marrow (Min: 0.5 mL*)
Whole Blood: Transport 5 mL whole blood. (Min: 1mL*)
Tissue: Transport 100 mg fresh tissue suspended in tissue culture media (e.g., RPMI 1640) (Min: 100 mg*)
Fluid: Transport 10-100 mL fresh fluid (Min: 3 mL*).
*Minimum volume is dependent on cellularity.
Storage/Transport Temperature: **Specimen should be received within 24 hours of collection for optimal cell viability**.
Bone Marrow or Whole Blood: Room temperature. Also acceptable: Refrigerated.
Tissue or Fluid: Refrigerated.
Remarks: A minimum of 10,000 viable cells is required for flow cytometry phenotyping of samples containing a very limited number of markers (may also be called antibodies or antigens). For low-count specimens, supplying clinical and diagnostic information is especially important to help ensure the most appropriate marker combinations are evaluated before the specimen is depleted of cells.
Bone Marrow or Whole Blood: Provide specimen source, CBC, Wright stained smear (if available), clinical history, differential diagnosis, and any relevant pathology reports.
Tissue or Fluid: Provide specimen source, clinical history, differential diagnosis, and any relevant pathology reports.
Follow up: If previous leukemia/lymphoma phenotyping was performed at another lab, the outside flow cytometry report and histograms (if possible) should accompany the specimen.
Unacceptable Conditions: Clotted or hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Unacceptable

Reference Interval: By Report

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

Note: Flow cytometric leukemia and lymphoma analysis may aid in identifying the tumor lineage for diagnostic and prognostic purposes. After review of the clinical history and morphology, a panel of markers is selected for each case by a board-certified hematopathologist. In most cases, the lineage can be identified as T-cell, B-cell, or myeloid and a diagnosis or differential diagnosis can be made.

Available Markers*:
T-cell: CD1, CD2, CD3, CD4, CD5, CD7, CD8, TCR alpha-beta, TCR gamma-delta, Cytoplasmic CD3
B-cell: CD10, CD19, CD20, CD22, CD23, CD103, surface Kappa, surface Lambda, FMC7, Cytoplasmic Kappa, Cytoplasmic Lambda
Myelo/Mono: CD11b, CD13, CD14 (Mo2), CD14 (MY4), CD15, CD33, CD64, CD117, myeloperoxidase
Misc: CD11c, CD16, CD25, CD30, CD34, CD38, CD41, CD42b, CD45, CD56, CD57, CD61, HLA-DR, glycophorin, TdT, bcl-2, ALK-1, CD123, CD138, CD200, CD26, CD45, CRLF-2.

***Not all markers will be reported in all cases.** Requests for specific markers to be run must be listed on manual requisition or by footnote for electronic orders. We do not offer individual marker identification separately outside of the markers in this panel.

The report will include a pathologist interpretation and a marker interpretation range corresponding to CPT codes of 2-8 markers, 9-15 markers, and 16+ markers interpreted. Charges apply per marker.

CPT Code(s): 88184, 88185 each additional marker; 88187 or 88188 or 88189.

New York DOH Approved.

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

0020421 **Lipid Panel** **CRISK**

Interpretive Data: An HDL cholesterol less than 40 mg/dL is low and constitutes a coronary heart disease risk factor. An HDL cholesterol greater than 60 mg/dL is a negative risk factor for coronary heart disease.

Non-HDL cholesterol is a secondary target of therapy in persons with high serum triglycerides (greater than 199 mg/dL). The goal for non-HDL cholesterol in persons with high triglycerides is 30 mg/dL higher than their LDL cholesterol goal.

CHD Risk Factors

+1 Age: Men, 45 years and older
Women, 55 years and older or premature menopause without estrogen therapy
+1 Family history of premature CHD
+1 Current smoking
+1 Hypertension
+1 Diabetes mellitus
+1 Low HDL cholesterol: 39 mg/dL or less
- 1 High HDL cholesterol: 60 mg/dL or greater

Adult Values	Desirable	Borderline	Higher Risk
Total Cholesterol	199 mg/dL or less	200-239 mg/dL	240 mg/dL or greater
Triglycerides	149 mg/dL or less	150-199 mg/dL	200-499 mg/dL
HDL Cholesterol	40 mg/dL or greater		39 mg/dL or less
LDL Cholesterol **(calculated)**	129 mg/dL or less (99 mg/dL or less if patient has CHD)	130-159 mg/dL	160 mg/dL or greater
removed			
VLDL Cholesterol (calculated)	30 mg/dL or less		

Children & Adolescents	Desirable	Borderline	Higher Risk
Total Cholesterol	169 mg/dL or less	170-199 mg/dL	200 mg/dL or greater
Triglycerides	149 mg/dL or less	150-199 mg/dL	200-499 mg/dL
HDL Cholesterol	40 mg/dL or greater		39 mg/dL or less
LDL-Cholesterol	109 mg/dL or less	110-129 mg/dL	130 mg/dL or greater
removed			
VLDL Cholesterol (calculated)	30 mg/dL or less		

HOTLINE NOTE: There is a component change associated with this test.
Remove component 0095038, Appearance Chemistry

0020468 Lipid Panel, Extended CRISK E

Interpretive Data: An HDL cholesterol less than 40 mg/dL is low and constitutes a coronary heart disease risk factor. An HDL cholesterol greater than 60 mg/dL is a negative risk factor for coronary heart disease.

Non-HDL cholesterol is a secondary target of therapy in persons with high serum triglycerides (greater than 199 mg/dL). The goal for non-HDL cholesterol in persons with high triglycerides is 30 mg/dL higher than their LDL cholesterol goal.

CHD Risk Factors

+1 Age: Men, 45 years and older
Women, 55 years and older or premature menopause without estrogen therapy
+1 Family history of premature CHD
+1 Current smoking
+1 Hypertension
+1 Diabetes mellitus
+1 Low HDL cholesterol: 39 mg/dL or less
- 1 High HDL cholesterol: 60 mg/dL or greater

20 years and older	Desirable	Borderline	Higher Risk
Total Cholesterol	199 mg/dL or less	200-239 mg/dL	240 mg/dL or greater
Triglycerides	149 mg/dL or less	150-199 mg/dL	200-499 mg/dL
HDL Cholesterol	40 mg/dL or greater		39 mg/dL or less
LDL Cholesterol	129 mg/dL or less (99 mg/dL or less if patient has CHD)	130-159 mg/dL	160 mg/dL or greater
removed			
VLDL Cholesterol **(calculated)**	30 mg/dL or less		

0-19 years	Desirable	Borderline	High Risk
Total Cholesterol	169 mg/dL or less	170-199 mg/dL	200 mg/dL or greater
Triglycerides	149 mg/dL or less	150-199 mg/dL	200-499 mg/dL
HDL Cholesterol	40 mg/dL or greater		39 mg/dL or less
LDL-Cholesterol (measured)	109 mg/dL or less	110-129 mg/dL	130 mg/dL or greater
removed			
VLDL Cholesterol (calculated)	30 mg/dL or less		

HOTLINE NOTE: There is a component change associated with this test.
Remove component 0095038, Appearance Chemistry

0091224 LSD, Urine - Screen with Reflex to Confirmation/Quantitation LSD URN

Performed: Varies
Reported: 8-18 days

Specimen Required: Collect: Random urine.
Specimen Preparation: Protect from light. Transfer 2 mL urine to an ARUP Amber Transport Tube. (Min: 0.9 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Unacceptable Conditions: Specimens not protected from light. Specimens submitted in glass containers.
Stability (collection to initiation of testing): Ambient: 1 month; Refrigerated: 1 month; Frozen: 24 months

0050119 Lupus Comprehensive Reflexive Panel LUPUS COMP

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

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

Specimen Required: Collect: Tumor tissue. Also acceptable: DNA extracted by CLIA certified lab with corresponding client-circiled H&E slide.
Specimen Preparation: **Tumor Tissue:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or 5 unstained 5-micron slides. (Min: 3 slides) Transport block and/or slide(s) in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Room temperature. Ship in cooled container during summer months.
Extracted DNA: Refrigerated.
Remarks: Include surgical pathology report.
Unacceptable Conditions: Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). Decalcified specimens. Less than 25 percent tumor.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerated: Indefinitely; Frozen: Indefinitely

0051740 **Microsatellite Instability (MSI), HNPCC/Lynch Syndrome, by PCR** **MSI PCR**

Specimen Required: Collect: Tumor **AND** normal epithelial tissue. Also acceptable: DNA extracted by CLIA certified lab.
Specimen Preparation: **Tissue:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block(s) or 10 unstained 5-micron slides (5 tumor and 5 normal epithelial). (Min: 3 tumor tissue and 3 normal epithelial tissue slides) Transport block(s) and/or slide(s) in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL)Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months
Extracted DNA: Refrigerated.
Remarks: Include surgical pathology report.
Unacceptable Conditions Less than 25 percent tumor or less than 50 percent normal epithelial tissue. DNA extracted by a non-CLIA lab. DNA extracted without a corresponding circled H&E slide. Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). Decalcified specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerated: Indefinitely; Frozen: Indefinitely

2002499 ***MLH1* Promoter Methylation, Paraffin** **MLH1PCR**

Specimen Required: Collect: Tumor tissue. Also acceptable: DNA extracted by CLIA certified lab with corresponding client-circled H&E slide.
Specimen Preparation: **Tumor Tissue:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or 5 unstained 5-micron slides. (Min: 3 slides) Transport block and/or slide(s) in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Extracted DNA: Refrigerated.
Remarks: Include surgical pathology report.
Unacceptable Conditions: Less than 25 percent tumor. DNA extracted by a non-CLIA lab. DNA extracted without a corresponding circled H&E slide. Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). Decalcified specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerated: Indefinitely; Frozen: Indefinitely

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

0050615 Monoclonal Protein Detection Quantitation and Characterization, SPEP, IFE, IgA, IgG, IgM, Serum — IFE

Methodology: Qualitative Immunofixation Electrophoresis/Quantitative Capillary Electrophoresis/Quantitative Nephelometry/Quantitative Spectrophotometry

Specimen Required: 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: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma.
Stability (collection to initiation of testing): After separation from cells: Ambient: 4 hours; Refrigerated: 1 week; Frozen: 1 month

Reference Interval:

Test Number	Components	Reference Interval
0050640	Protein Electrophoresis, Serum	Effective August 19, 2019

Test Number	Components	Reference Interval
	Total Protein, Serum	Refer to report
	Albumin	Refer to report
	Alpha-1 Globulins	Refer to report
	Alpha-2 Globulins	Refer to report
	Beta Globulins	Refer to report
	Gamma	Refer to report

0050340	Immunoglobulin A	Effective February 16, 2016	
		0-30 days: 1-7 mg/dL 1 month: 1-53 mg/dL 2 months: 3-47 mg/dL 3 months: 5-46 mg/dL 4 months: 4-72 mg/dL 5 months: 8-83 mg/dL 6 months: 8-67 mg/dL 7-8 months: 11-89 mg/dL	9-11 months: 16-83 mg/dL 1 year: 14-105 mg/dL 2 years: 14-122 mg/dL 3 years: 22-157 mg/dL 4 years: 25-152 mg/dL 5-7 years: 33-200 mg/dL 8-9 years: 45-234 mg/dL 10 years and older: 68-408 mg/dL
0050350	Immunoglobulin G	0- 30 days: 611-1542 mg/dL 1 month: 241-870 mg/dL 2 months: 198-577 mg/dL 3 months: 169-558 mg/dL 4 months: 188-536 mg/dL 5 months: 165-781 mg/dL 6 months: 206-676 mg/dL 7-8 months: 208-868 mg/dL	9-11 months: 282-1026 mg/dL 1 year: 331-1164 mg/dL 2 years: 407-1009 mg/dL 3 years: 423-1090 mg/dL 4 years: 444-1187 mg/dL 5-7 years: 608-1229 mg/dL 8-9 years: 584-1509 mg/dL 10 years and older: 768-1632 mg/dL
0050355	Immunoglobulin M	Effective February 16, 2016	
		0-30 days: 0-24 mg/dL 1 month: 19-83 mg/dL 2 months: 16-100 mg/dL 3 months: 23-85 mg/dL 4 months: 26-96 mg/dL 5 months: 31-103 mg/dL 6 months: 33-97 mg/dL 7-8 months: 32-120 mg/dL	9-11 months: 39-142 mg/dL 1 year: 41-164 mg/dL 2 years: 46-160 mg/dL 3 years: 45-190 mg/dL 4 years: 41-186 mg/dL 5-7 years: 46-197 mg/dL 8-9 years: 49-230 mg/dL 10 years and older: 35-263 mg/dL

CPT Code(s): 82784 x3; 84155; 84165; 86334

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 0050545 from Total Protein-Electrophoresis to Total Protein, Serum.

2002715 Monoclonal Protein Detection, Quantitation, Characterization, SPEP, IFE, IgA, IgG, IgM, FLC — IFE FLC

Methodology: Qualitative Immunofixation Electrophoresis/Quantitative Capillary Electrophoresis/Quantitative Nephelometry/Quantitative Spectrophotometry

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: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma. Room temperature specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 2 weeks

Reference Interval:

Test Number	Components	Reference Interval
0050640	Protein Electrophoresis, Serum	Effective August 19, 2019

Test Number	Components	Reference Interval
	Total Protein, Serum	Refer to report
	Albumin	Refer to report
	Alpha-1 Globulins	Refer to report
	Alpha-2 Globulins	Refer to report
	Beta Globulins	Refer to report
	Gamma	Refer to report

0050350	Immunoglobulin G	0- 30 days: 611-1542 mg/dL 1 month: 241-870 mg/dL 2 months: 198-577 mg/dL 3 months: 169-558 mg/dL 4 months: 188-536 mg/dL 5 months: 165-781 mg/dL 6 months: 206-676 mg/dL 7-8 months: 208-868 mg/dL	9-11 months: 282-1026 mg/dL 1 year: 331-1164 mg/dL 2 years: 407-1009 mg/dL 3 years: 423-1090 mg/dL 4 years: 444-1187 mg/dL 5-7 years: 608-1229 mg/dL 8-9 years: 584-1509 mg/dL 10 years and older: 768-1632 mg/dL
0050340	Immunoglobulin A	Effective February 16, 2016 0-30 days: 1-7 mg/dL 1 month: 1-53 mg/dL 2 months: 3-47 mg/dL 3 months: 5-46 mg/dL 4 months: 4-72 mg/dL 5 months: 8-83 mg/dL 6 months: 8-67 mg/dL 7-8 months: 11-89 mg/dL	9-11 months: 16-83 mg/dL 1 year: 14-105 mg/dL 2 years: 14-122 mg/dL 3 years: 22-157 mg/dL 4 years: 25-152 mg/dL 5-7 years: 33-200 mg/dL 8-9 years: 45-234 mg/dL 10 years and older: 68-408 mg/dL
0050355	Immunoglobulin M	Effective February 16, 2016 0-30 days: 0-24 mg/dL 1 month: 19-83 mg/dL 2 months: 16-100 mg/dL 3 months: 23-85 mg/dL 4 months: 26-96 mg/dL 5 months: 31-103 mg/dL 6 months: 33-97 mg/dL 7-8 months: 32-120 mg/dL	9-11 months: 39-142 mg/dL 1 year: 41-164 mg/dL 2 years: 46-160 mg/dL 3 years: 45-190 mg/dL 4 years: 41-186 mg/dL 5-7 years: 46-197 mg/dL 8-9 years: 49-230 mg/dL 10 years and older: 35-263 mg/dL
	Kappa Quantitative Free Light Chains, Serum	0.33 - 1.94 mg/dL	
	Lambda Quantitative Free Light Chains, Serum	0.57-2.63 mg/dL	
	Kappa/Lambda Free Light Chain Ratio, Serum	0.26-1.65	

CPT Code(s): 82784 x3; 84155; 84165; 86334; 83883 x2

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 0050545 from Total Protein-Electrophoresis to Total Protein, Serum.

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

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Semi-Quantitative Indirect Fluorescent Antibody/Qualitative Immunoblot/Quantitative Nephelometry/Quantitative Capillary Electrophoresis/Qualitative Immunofixation Electrophoresis/Quantitative Spectrophotometry

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 4 mL serum to an ARUP Standard Transport Tube. (Min: 2 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, CSF, or other body fluids. Contaminated, heat-inactivated, hemolyzed, severely icteric, or lipemic specimens.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 1 month

Reference Interval:

Test Number	Components	Reference Interval	
	Albumin	3.75-5.01 g/dL	
	Alpha-1 Globulins	0.19-0.46 g/dL	
	Alpha-2 Globulins	0.48-1.05 g/dL	
	Beta Globulins	0.48-1.10 g/dL	
	Gamma	0.62-1.51 g/dL	
0050340	Immunoglobulin A	Effective February 16, 2016	
		0-30 days: 1-7 mg/dL 1 month: 1-53 mg/dL 2 months: 3-47 mg/dL 3 months: 5-46 mg/dL 4 months: 4-72 mg/dL 5 months: 8-83 mg/dL 6 months: 8-67 mg/dL 7-8 months: 11-89 mg/dL	9-11 months: 16-83 mg/dL 1 year: 14-105 mg/dL 2 years: 14-122 mg/dL 3 years: 22-157 mg/dL 4 years: 25-152 mg/dL 5-7 years: 33-200 mg/dL 8-9 years: 45-234 mg/dL 10 years and older: 68-408 mg/dL
0050350	Immunoglobulin G	0- 30 days: 611-1542 mg/dL 1 month: 241-870 mg/dL 2 months: 198-577 mg/dL 3 months: 169-558 mg/dL 4 months: 188-536 mg/dL 5 months: 165-781 mg/dL 6 months: 206-676 mg/dL 7-8 months: 208-868 mg/dL	9-11 months: 282-1026 mg/dL 1 year: 331-1164 mg/dL 2 years: 407-1009 mg/dL 3 years: 423-1090 mg/dL 4 years: 444-1187 mg/dL 5-7 years: 608-1229 mg/dL 8-9 years: 584-1509 mg/dL 10 years and older: 768-1632 mg/dL
0050355	Immunoglobulin M	Effective February 16, 2016	
		0-30 days: 0-24 mg/dL 1 month: 19-83 mg/dL 2 months: 16-100 mg/dL 3 months: 23-85 mg/dL 4 months: 26-96 mg/dL 5 months: 31-103 mg/dL 6 months: 33-97 mg/dL 7-8 months: 32-120 mg/dL	9-11 months: 39-142 mg/dL 1 year: 41-164 mg/dL 2 years: 46-160 mg/dL 3 years: 45-190 mg/dL 4 years: 41-186 mg/dL 5-7 years: 46-197 mg/dL 8-9 years: 49-230 mg/dL 10 years and older: 35-263 mg/dL
	Total Protein, Serum	Effective August 19, 2019 Refer to Report	
	Asialo-GM1 Antibodies, IgG/IgM	29 IV or less	Negative
		30-50 IV	Equivocal
		51-100 IV	Positive
		101 IV or greater	Strong Positive
	GM1 Antibodies, IgG/IgM	29 IV or less	Negative
		30-50 IV	Equivocal
		51-100 IV	Positive
		101 IV or greater	Strong Positive
	GD1a Antibodies, IgG/IgM	29 IV or less	Negative
		30-50 IV	Equivocal
		51-100 IV	Positive
		101 IV or greater	Strong Positive
	GD1b Antibodies, IgG/IgM	29 IV or less	Negative
		30-50 IV	Equivocal
		51-100 IV	Positive
		101 IV or greater	Strong Positive
	GQ1b Antibodies, IgG/IgM	29 IV or less	Negative
		30-50 IV	Equivocal
		51-100 IV	Positive
		101 IV or greater	Strong Positive

0051284	Sulfate-3-Glucuronyl Paraglobоside (SGPG) Antibody, IgM	Less than 1.00 IV		
0051285	Myelin Associated Glycoprotein (MAG) Antibody, IgM	Less than 1000 TU		
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
		2007963	Neuronal Nuclear Antibodies (Hu, Ri, Yo) IgG by Immunoblot	Refer to report
2007963	Neuronal Nuclear Antibodies (Hu, Ri, Yo) IgG by Immunoblot	None Detected		

CPT Code(s): 83516 x7; 82784 x3; 84155; 84165; 86334; 86255 if reflexed add 83516 and/or 86256

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 0050545 from Total Protein-Electrophoresis to Total Protein, Serum.

0051225 Motor Neuropathy Panel MSN PAN

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Quantitative Nephelometry/Quantitative Capillary Electrophoresis/Qualitative Immunofixation Electrophoresis/Quantitative Spectrophotometry

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 4 mL serum to an ARUP Standard Transport Tube. (Min: 2 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, CSF, or other body fluids. Room temperature specimens. Contaminated, heat-inactivated, hemolyzed, severely icteric, or lipemic specimens.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 1 month

Reference Interval:

Test Number	Components	Reference Interval	
	Asialo-GM1 Antibodies, IgG/IgM	29 IV or less	Negative
		30-50 IV	Equivocal
		51-100 IV	Positive
		101 IV or greater	Strong Positive
	GM1 Antibodies, IgG/IgM	29 IV or less	Negative
		30-50 IV	Equivocal
		51-100 IV	Positive
		101 IV or greater	Strong Positive
	GD1a Antibodies, IgG/IgM	29 IV or less	Negative
		30-50 IV	Equivocal
		51-100 IV	Positive
		101 IV or greater	Strong Positive
	GD1b Antibodies, IgG/IgM	29 IV or less	Negative
		30-50 IV	Equivocal
		51-100 IV	Positive
		101 IV or greater	Strong Positive
	GQ1b Antibodies, IgG/IgM	29 IV or less	Negative
		30-50 IV	Equivocal
		51-100 IV	Positive
		101 IV or greater	Strong Positive
	Total Protein, Serum	Effective August 19, 2019 Refer to Report	
	Albumin	3.75-5.01 g/dL	
	Alpha-1 Globulins	0.19-0.46 g/dL	
	Alpha-2 Globulins	0.48-1.05 g/dL	
	Beta Globulins	0.48-1.10 g/dL	
	Gamma	0.62-1.51 g/dL	

0050340	Immunoglobulin A	Effective February 16, 2016	
		0-30 days: 1-7 mg/dL 1 month: 1-53 mg/dL 2 months: 3-47 mg/dL 3 months: 5-46 mg/dL 4 months: 4-72 mg/dL 5 months: 8-83 mg/dL 6 months: 8-67 mg/dL 7-8 months: 11-89 mg/dL	9-11 months: 16-83 mg/dL 1 year: 14-105 mg/dL 2 years: 14-122 mg/dL 3 years: 22-157 mg/dL 4 years: 25-152 mg/dL 5-7 years: 33-200 mg/dL 8-9 years: 45-234 mg/dL 10 years and older: 68-408 mg/dL
0050350	Immunoglobulin G	0- 30 days: 611-1542 mg/dL 1 month: 241-870 mg/dL 2 months: 198-577 mg/dL 3 months: 169-558 mg/dL 4 months: 188-536 mg/dL 5 months: 165-781 mg/dL 6 months: 206-676 mg/dL 7-8 months: 208-868 mg/dL	9-11 months: 282-1026 mg/dL 1 year: 331-1164 mg/dL 2 years: 407-1009 mg/dL 3 years: 423-1090 mg/dL 4 years: 444-1187 mg/dL 5-7 years: 608-1229 mg/dL 8-9 years: 584-1509 mg/dL 10 years and older: 768-1632 mg/dL
0050355	Immunoglobulin M	Effective February 16, 2016	
		0-30 days: 0-24 mg/dL 1 month: 19-83 mg/dL 2 months: 16-100 mg/dL 3 months: 23-85 mg/dL 4 months: 26-96 mg/dL 5 months: 31-103 mg/dL 6 months: 33-97 mg/dL 7-8 months: 32-120 mg/dL	9-11 months: 39-142 mg/dL 1 year: 41-164 mg/dL 2 years: 46-160 mg/dL 3 years: 45-190 mg/dL 4 years: 41-186 mg/dL 5-7 years: 46-197 mg/dL 8-9 years: 49-230 mg/dL 10 years and older: 35-263 mg/dL
0051285	Myelin Associated Glycoprotein (MAG) Antibody, IgM	Less than 1000 TU	
0051284	Sulfate-3-Glucuronyl Paragloboside (SGPG) Antibody, IgM	Less than 1.00 IV	

CPT Code(s): 83516 x7; 82784 x3; 84155; 84165; 86334

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 0050545 from Total Protein-Electrophoresis to Total Protein, Serum.

2005545 *MPL* Mutation Detection by Capillary Electrophoresis MPL

Specimen Required: Collect: Lavender (EDTA) or bone marrow (EDTA). Also acceptable: DNA extracted by CLIA certified lab.
Specimen Preparation: **Whole Blood:** Do not freeze. Transport 5 mL whole blood. (Min: 1 mL)
Bone Marrow: Transport 3 mL bone marrow. (Min: 1 mL)
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, serum, FFPE tissue blocks/slides, or frozen tissue, DNA extracted by a non-CLIA lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerate: Indefinitely; Frozen: Indefinitely

0050707 MPO/PR3 (ANCA) Antibodies MPO/PR3

Reference Interval:

Test Number	Components	Reference Interval	
0050526	Myeloperoxidase Antibody	Negative	19 AU/mL or less
		Equivocal	20-25 AU/mL
		Positive	26 AU/mL or greater
0050527	Serine Proteinase 3 Antibody	Negative	19 AU/mL or less
		Equivocal	20-25 AU/mL
		Positive	26 AU/mL or greater

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 0050527, Serine Protease 3, IgG to Serine Proteinase 3, IgG

3000523 **Mumps Virus by PCR** **MPSPCR**

Specimen Required: Patient Prep: Patient should not eat, drink, smoke or chew gum for 30 minutes before collecting oral sample.
Collect: Buccal swab.
Specimen Preparation: Transfer buccal swab to viral transport media (ARUP supply #12884) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 0.5 mL)
Storage/Transport Temperature: Frozen.
Remarks: Specimen source required.
Unacceptable Conditions: Urine. Nasopharyngeal swab.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 1 week; Frozen: 1 week

New Test **3001869** **Myasthenia Gravis Reflexive Panel** **MG R PAN**
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Additional Technical Information

Methodology: Quantitative Radioimmunoassay/Semi-Quantitative Flow Cytometry
Performed: Sun-Sat
Reported: 3-8 days

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Contaminated, hemolyzed, or severely lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 month (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval	
0080009	Acetylcholine Receptor Binding Antibody		
		Negative	0.0-0.4 nmol/L
		Positive	0.5 nmol/L or greater
0099580	Acetylcholine Receptor Blocking Antibody	Effective November 18, 2013	
		Negative:	0-26% blocking
		Indeterminate:	27-41% blocking
		Positive:	42% or greater blocking
0099521	Acetylcholine Receptor Modulating Antibody	Effective August 20, 2012	
		Negative	0-45% modulating
		Positive	46% or greater modulating
3001576	Muscle-Specific Kinase (MuSK) Antibody, IgG	Negative	0.00-0.03 nmol/L
		Positive	0.04 nmol/L or greater

Interpretive Data: Approximately 85-90 percent of patients with myasthenia gravis (MG) express antibodies to the acetylcholine receptor (AChR), which can be divided into binding, blocking, and modulating antibodies. Binding antibody can activate complement and lead to loss of AChR. Blocking antibody may impair binding of acetylcholine to the receptor, leading to poor muscle contraction. Modulating antibody causes receptor endocytosis resulting in loss of AChR expression, which correlates most closely with clinical severity of disease. Approximately 10-15 percent of individuals with confirmed myasthenia gravis have no measurable binding, blocking, or modulating antibodies.

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

Note: If Acetylcholine Receptor Binding Antibody result is greater than 0.4 nmol/L or Acetylcholine Receptor Blocking Antibody result is greater than 26 percent, then Acetylcholine Receptor Modulating Antibody (ARUP test code 0099521) will be added. If Acetylcholine Receptor Binding Antibody result is less than or equal to 0.4 nmol/L, then Muscle-Specific Kinase (MuSK) Ab, IgG (ARUP test code 3001576) will be added. Additional charges apply.

CPT Code(s): 83519; 83516; if reflexed, add 83516, 83519

New York DOH Approved.

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

2009318 ***MYD88* L265P Mutation Detection by PCR, Quantitative** **MYD88**

Specimen Required: Collect: Lavender (EDTA), bone marrow (EDTA), or tissue. Also acceptable: DNA extracted by CLIA certified lab.
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)
FFPE Tumor Tissue: Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Transport tissue in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: **Whole Blood, Bone Marrow or Extracted DNA:** Refrigerated.
FFPE Tumor Tissue: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Unacceptable Conditions: Plasma, serum, FFPE tissue slides, frozen tissue, DNA extracted by a non-CLIA lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
FFPE Tumor Tissue: Specimens fixed/processed in alternative fixatives or heavy metal fixatives (B-4 or B-5) or tissue sections on slides. Decalcified specimens.
Stability (collection to initiation of testing): **Whole Blood or Bone Marrow:** Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable
FFPE Tumor Tissue: Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerated: Indefinitely; Frozen: Indefinitely

0050526 **Myeloperoxidase (MPO) Antibody** **MPO-AB**

HOTLINE NOTE: Name change only.

0050742 **Myocardial Antibody, IgG with Reflex to Titer** **MYO R**

Performed: Thu
Reported: 1-8 days

New Test **3001907** **Myotonic Dystrophy Type 1 (*DMPK*) CTG Expansion** **DM1 PCR**
Available Now
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Methodology: Polymerase Chain Reaction/Capillary Electrophoresis
Performed: Varies
Reported: 7-10 days

Specimen Required: Collect: Lavender (K_2EDTA), Pink (K_2EDTA), or Yellow (ACD Solution A or B).
Specimen Preparation: Transport 5 mL whole blood. (Min: 3 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 month; Frozen: 6 months

Reference Interval: By report

Interpretive Data:
Background Information for Myotonic Dystrophy Type 1 (*DMPK*):
Characteristics: Myotonic dystrophy type 1 (DM1) is a multisystem disorder characterized by myotonic myopathy with involvement of the eye, heart, endocrine system and central nervous system. Clinical findings span a continuum from mild to severe, with overlap in the three recognized clinical subtypes of DM1: mild, classic and congenital. Mild DM1 is adult-onset and features include mild myotonia and premature cataracts or baldness. Onset of classic DM1 is typically between 10-30 years of age and findings include distal muscle weakness, myotonia, cataracts, GI disturbances, and cardiac conduction abnormalities. Congenital DM1 may present prenatally with polyhydramnios and reduced fetal movement, and postnatal features commonly include infantile hypotonia, respiratory insufficiency, facial diplegia, and intellectual disability.
Prevalence: 1:20,000.
Inheritance: Autosomal dominant.
Penetrance: Age-related, approaches 100 percent by age 50.
Cause: Expanded number of CTG repeats in the *DMPK* gene.
Normal: 5-34 CTG repeats, stably transmitted, not associated with DM1 manifestations.
Premutation: 35-49 CTG repeats, may be unstably transmitted, not associated with DM1 manifestations.
Full-penetrance disease allele: 50 or more CTG repeats, unstably transmitted, associated with DM1 manifestations.
Clinical Sensitivity: >99 percent for DM1.
Methodology: Triplet repeat-primed polymerase chain reaction (PCR) followed by size analysis using capillary electrophoresis to assess the CTG repeat in the *DMPK* 3' untranslated region. Specific allele sizing estimates cannot be determined for CTG repeats of >150. Repeat sizing precision is approximately +/- 2 repeats for alleles with 5-24 repeats and +/- 4 repeats for alleles with 77 to 150 repeats.
Analytical Sensitivity and Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. This assay will not detect myotonic dystrophy type 2.

Phenotype	Number of CTG Repeats
Normal allele	Less than or equal to 34
Premutation	35 - 49
Mild	50 – approx. 150
Classic	approx.100 - approx 1000
Congenital	>1000

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

CPT Code(s): 81234

New York DOH approval pending. Call for status update.

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

0099465 **Neuronal Cell Antibodies Quantitative, Serum** **NEURON-SER**

Performed: Varies
Reported: 3-8 days

0096657 Neutrophil Oxidative Burst Assay (DHR) — DHR

Specimen Required: Patient Prep: Collect control specimen from a healthy individual unrelated to patient at approximately the same time as and under similar conditions to the patient.
Collect: Green (Sodium or Lithium Heparin) (patient) **AND** Green (Sodium or Lithium Heparin) (control). **Patient and control specimens must be collected within 48 hours of test performance.**
Specimen Preparation: Transport 3 mL whole blood (patient) **AND** 3 mL whole blood (control) in original collection tubes. (Min: 1 mL (patient) **AND** 1 mL (control)) **Do not refrigerate or freeze. LIVE NEUTROPHILS REQUIRED.**
Storage/Transport Temperature: **CRITICAL ROOM TEMPERATURE.**
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
New York State Clients: Ambient 24 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

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

3000066 *NPM1* Mutation Detection by RT-PCR, Quantitative — NPM1 QNT

Specimen Required: Collect: Lavender (EDTA) or bone marrow (EDTA). Also acceptable: RNA extracted by CLIA certified lab.
Specimen Preparation: **Whole Blood:** Transport 5 mL whole blood. (Min: 1 mL)
Bone Marrow: Transport 3 mL bone marrow. (Min: 1 mL)
Specimens must be received within 48 hours of collection due to lability of RNA.
Extracted RNA: Transport 40 uL RNA with at least 40 ng/uL concentration. (Min: 40 uL) Transport RNA 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: **Whole Blood or Bone Marrow**: CRITICAL REFRIGERATED. Separate specimens must be submitted when multiple tests are ordered.
Extracted RNA: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Unacceptable Conditions: Serum, plasma, CSF, extracted DNA, RNA extracted by a non-CLIA lab, bone core, or FFPE tissue. Specimens collected in anticoagulants other than EDTA. Severely hemolyzed or clotted specimens.
Stability (collection to initiation of testing): Ambient: 1 hour; Refrigerated: 48 hours; Frozen: Unacceptable
Extracted RNA: Ambient: Unacceptable; Refrigerate: Unacceptable; Frozen: Indefinitely

2003123 *NRAS* Mutation Detection by Pyrosequencing — NRAS

Specimen Required: Collect: Tumor tissue. Also acceptable: DNA extracted by CLIA certified lab with corresponding client-circled H&E slide.
Specimen Preparation: **Tumor Tissue:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or 5 unstained 5 micron slides. (Min: 3 slides). Transport block and/or slide(s) in a tissue transport kit (ARUP Supply # 47808) available online through eSupply using ARUP Connect™or contact ARUP Client Services at (800) 522-2787.
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Room temperature. Ship in cooled container during summer months.
Extracted DNA: Refrigerated.
Remarks: Include surgical pathology report.
Unacceptable Conditions: Less than 25 percent tumor. DNA extracted by a non-CLIA lab. DNA extracted without a corresponding circled H&E slide. Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). Decalcified specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerated: Indefinitely; Frozen: Indefinitely

New Test **3001760** **Pancreatitis (*PRSS1*) Deletion/Duplication** **PRSS1 DD**

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Patient History for Pancreatitis (*PRSS1*) Del/Dup

Additional Technical Information

Methodology: Multiplex Ligation-dependent Probe Amplification
Performed: Varies
Reported: 12-14 days

Specimen Required: Collect: Lavender (K_2EDTA), Pink (K_2EDTA), or Yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 2 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 month; Frozen: 6 months

Reference Interval: By Report

Interpretive Data:
Background Information for *Pancreatitis (PRSS1)* Deletion/Duplication:
Characteristics: Hereditary pancreatitis typically presents in late childhood with recurrent episodes of pancreatic inflammation, abdominal pain, nausea, and vomiting. Ultimately, this evolves into chronic pancreatitis resulting in permanent pancreatic damage.
Epidemiology: Incidence of chronic pancreatitis is 5-12 in 100,000 per year and prevalence is approximately 50 in 100,000.
Inheritance of SPINK1-related pancreatitis: Autosomal recessive and possibly digenic.
Penetrance: Variable.
Cause: Pathogenic variants in *PRSS1*, *SPINK1*, *CFTR*, *CASR*, *CTRC*, *CPA1* and *CLDN2* genes are associated with pancreatitis.
Clinical Sensitivity: Unknown.
Methodology: Multiplex ligation-dependent probe amplification (MLPA) of the *PRSS1* gene.
Analytical Sensitivity and Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Single base pair substitutions, small deletions/duplications, regulatory region and deep intronic variants will not be detected. Deletion/duplication breakpoints will not be determined. Variants in genes other than *PRSS1* will not be detected.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online at www.aruplab.com
See Compliance Statement C: www.aruplab.com/CS

New York DOH approval pending. Call for status update.

CPT Code(s): 81479

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

New Test **3001768** **Pancreatitis (*PRSS1*) Sequencing and Deletion/Duplication** **PRSS1 FGA**

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Patient History for Pancreatitis Testing

Additional Technical Information

Out of Pocket Estimator

Methodology: Polymerase Chain Reaction/Sequencing and Multiplex Ligation Dependent Probe Amplification
Performed: Varies
Reported: 2-3 weeks

Specimen Required: Collect: Lavender (K_2EDTA), Pink (K_2EDTA), or Yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 2 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 month; Frozen: 6 months

Interpretive Data:
Background Information for Pancreatitis (*PRSS1*) Sequencing and Deletion/Duplication
Characteristics: Characteristics of *PRSS1*-related hereditary pancreatitis: Recurrent episodes of pancreatic inflammation that typically begin to present in late childhood, often with signs and symptoms including abdominal pain, nausea, and vomiting. Ultimately, these recurrent episodes of acute pancreatitis progress to permanent damage of the pancreas.
Epidemiology: Incidence of chronic pancreatitis: 5-12 in 100,000 per year
Prevalence of chronic pancreatitis: approximately 50 in 100,000
Inheritance: Autosomal dominant.
Penetrance: Varies geographically; estimated at 80 percent in the US.
Cause: Pathogenic variants in the cationic trypsinogen (*PRSS1*) gene.
Clinical Sensitivity: 15 percent of hereditary pancreatitis is caused by pathogenic *PRSS1* copy number variants or sequence variants.
Methodology: Bidirectional sequencing of *PRSS1* coding regions and intron/exon boundaries and multiplex ligation-dependent probe amplification (MLPA) of the *PRSS1* gene.
Analytical Sensitivity and Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Regulatory region variants and deep intronic variants will not be detected. The breakpoints of large deletions/duplications will not be determined. Variants in genes other than *PRSS1* are not evaluated.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online at www.aruplab.com
See Compliance Statement C: www.aruplab.com/CS

New York DOH approval pending. Call for status update.

CPT Code(s): 81404, 81479

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

New Test **3001764** **Pancreatitis *(SPINK1)* Deletion/Duplication** **SPINK1 DD**
Click for Pricing

Patient History for Pancreatitis (*SPINK1*) Del/Dup

Additional Technical Information

Methodology: Multiplex Ligation-dependent Probe Amplification
Performed: Varies
Reported: 12-14 days

Specimen Required: Collect: Lavender (K_2EDTA), Pink (K_2EDTA), or Yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 2 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 month; Frozen: 6 months

Reference Interval: By Report

Interpretive Data:
Background Information for *Pancreatitis (SPINK1)* Deletion/Duplication:
Characteristics: Hereditary pancreatitis typically presents with recurrent episodes of pancreatic inflammation, abdominal pain, nausea, and vomiting. Ultimately, this evolves into chronic pancreatitis resulting in permanent pancreatic damage.
Epidemiology: Incidence of chronic pancreatitis is 5-12 in 100,000 per year and prevalence is approximately 50 in 100,000.
Inheritance of SPINK1-related pancreatitis: Autosomal dominant.
Penetrance: Variable.
Cause: Pathogenic variants in *SPINK1*, *PRSS1*, *CFTR*, *CASR*, *CTRC*, *CPA1* and *CLDN2* genes are associated with pancreatitis.
Clinical Sensitivity: 6 percent of hereditary pancreatitis is caused by pathogenic *SPINK1* copy number variants.
Methodology: Multiplex ligation-dependent probe amplification (MLPA)
Analytical Sensitivity and Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Single base pair substitutions, small deletions/duplications, regulatory region and deep intronic variants will not be detected. Deletion/duplication breakpoints will not be determined. Variants in genes other than *SPINK1* will not be detected.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online at www.aruplab.com.
See Compliance Statement C: www.aruplab.com/CS

CPT Code(s): 81479

New York DOH approval pending. Call for status update.

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

3000496 **PanFungal Identification by Sequencing** **PANFUNGSEQ**

Specimen Required: Collect: Tissue.
Specimen Preparation: Transfer fresh tissue to a sterile container and freeze immediately. (Min: 25 mg) Also acceptable: Formalin-fixed paraffin-embedded (FFPE) tissue. (Min: 3 10-micron thick sections)
Storage/Transport Temperature: **Fresh Tissue:** Frozen.
FFPE: Room temperature.
Unacceptable Conditions: Finger nails, toe nails, or bone. Formalin-fixed paraffin-embedded tissue on slides.
Stability (collection to initiation of testing): **Fresh Tissue**: Ambient: 5 days; Refrigerated: 5 days; Frozen: 5 days
FFPE: Ambient: 1 month; Refrigerated: 1 month; Frozen: Unacceptable

3001170 **Platelet Antigen 1 Genotyping (HPA-1)** **HPA-1 GENO**

Performed: Mon, Thu
Reported: 7-14 days

3000193 **Platelet Antigen Genotyping Panel** **HPA GENO**

Performed: Varies
Reported: 7-14 days

2002871 ***PML-RARA* Translocation, t(15;17) by RT-PCR, Quantitative** **PML QNT**

Specimen Required: Collect: Lavender (EDTA) or bone marrow (EDTA). Also acceptable: RNA extracted by CLIA certified lab.
Specimen Preparation: **Whole Blood:** Transport 5 mL whole blood. (Min: 1 mL)
Bone Marrow: Transport 3 mL bone marrow. (Min: 1 mL)
Specimens must be received within 48 hours of collection due to lability of RNA.
Extracted RNA: Transport 40uL RNA with at least 40 ng/uL concentration (Min: 40uL). Transport RNA 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: **Whole Blood and Bone Marrow**: CRITICAL REFRIGERATED. Separate specimens must be submitted when multiple tests are ordered.
Extracted RNA: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Unacceptable Conditions: Serum, plasma, CSF, extracted DNA, RNA extracted by a non-CLIA lab, bone core, or FFPE tissue. Specimens collected in anticoagulants other than EDTA. Severely hemolyzed or clotted specimens.
Stability (collection to initiation of testing): Ambient: 1 hour; Refrigerated: 48 hours; Frozen: Unacceptable
Extracted RNA: Ambient: Unacceptable; Refrigerate: Unacceptable; Frozen: Indefinitely

HOTLINE NOTE: Remove information found in the Note field.

2009226 ***Pneumocystis jirovecii* DFA with Reflex to *Pneumocystis jirovecii* by PCR** **PNEUMST R**

Performed: Sun-Sat
Reported: 1-6 days

2002109 Protein Electrophoresis with Reflex to Immunofixation Electrophoresis Monoclonal Protein Detection, Quantitation & Characterization, IgA, IgG, and IgM, Serum — SPEP REFLEX

Methodology: Quantitative Capillary Electrophoresis/Qualitative Immunofixation Electrophoresis/Quantitative Nephelometry/Quantitative Spectrophotometry

Specimen Required: 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: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma.
Stability (collection to initiation of testing): After separation from cells: Ambient: 4 hours; Refrigerated: 1 week; Frozen: 1 month

Reference Interval:

Test Number	Components	Reference Interval
0050640	Protein Electrophoresis, Serum	Effective August 19, 2019

Test Number	Components	Reference Interval
	Total Protein, Serum	Refer to report
	Albumin	Refer to report
	Alpha-1 Globulins	Refer to report
	Alpha-2 Globulins	Refer to report
	Beta Globulins	Refer to report
	Gamma	Refer to report

0050350	Immunoglobulin G	0- 30 days: 611-1542 mg/dL 1 month: 241-870 mg/dL 2 months: 198-577 mg/dL 3 months: 169-558 mg/dL 4 months: 188-536 mg/dL 5 months: 165-781 mg/dL 6 months: 206-676 mg/dL 7-8 months: 208-868 mg/dL	9-11 months: 282-1026 mg/dL 1 year: 331-1164 mg/dL 2 years: 407-1009 mg/dL 3 years: 423-1090 mg/dL 4 years: 444-1187 mg/dL 5-7 years: 608-1229 mg/dL 8-9 years: 584-1509 mg/dL 10 years and older: 768-1632 mg/dL
0050340	Immunoglobulin A	Effective February 16, 2016	
		0-30 days: 1-7 mg/dL 1 month: 1-53 mg/dL 2 months: 3-47 mg/dL 3 months: 5-46 mg/dL 4 months: 4-72 mg/dL 5 months: 8-83 mg/dL 6 months: 8-67 mg/dL 7-8 months: 11-89 mg/dL	9-11 months: 16-83 mg/dL 1 year: 14-105 mg/dL 2 years: 14-122 mg/dL 3 years: 22-157 mg/dL 4 years: 25-152 mg/dL 5-7 years: 33-200 mg/dL 8-9 years: 45-234 mg/dL 10 years and older: 68-408 mg/dL
0050355	Immunoglobulin M	Effective February 16, 2016	
		0-30 days: 0-24 mg/dL 1 month: 19-83 mg/dL 2 months: 16-100 mg/dL 3 months: 23-85 mg/dL 4 months: 26-96 mg/dL 5 months: 31-103 mg/dL 6 months: 33-97 mg/dL 7-8 months: 32-120 mg/dL	9-11 months: 39-142 mg/dL 1 year: 41-164 mg/dL 2 years: 46-160 mg/dL 3 years: 45-190 mg/dL 4 years: 41-186 mg/dL 5-7 years: 46-197 mg/dL 8-9 years: 49-230 mg/dL 10 years and older: 35-263 mg/dL

CPT Code(s): 84155; 84165; if reflexed, add 82784 x3; 86334

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 0050545 from Total Protein-Electrophoresis to Total Protein, Serum.

0050640 Protein Electrophoresis, Serum SPEP

Methodology: Quantitative Capillary Electrophoresis/Quantitative Spectrophotometry

Specimen Required: 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: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma.
Stability (collection to initiation of testing): After separation from cells: Ambient: 4 hours; Refrigerated: 1 week; Frozen: 1 month

Reference Interval:
Effective August 19, 2019

Test Number	Components	Reference Interval
	Total Protein, Serum	Refer to Report
	Albumin	3.75-5.01 g/dL
	Alpha-1 Globulins	0.19-0.46 g/dL
	Alpha-2 Globulins	0.48-1.05 g/dL
	Beta Globulins	0.48-1.10 g/dL
	Gamma	0.62-1.51 g/dL

CPT Code(s): 84155; 84165

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 0050545 from Total Protein-Electrophoresis to Total Protein, Serum.

3000010 Relapsing Fever *Borrelia* Species by PCR RFBPCR

Specimen Required: Collect: Lavender (K_2EDTA) or Pink (K_2EDTA).
Specimen Preparation: Transport 1 mL whole blood. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Remarks: Specimen source required.
Unacceptable Conditions: Serum or plasma. Heparinized specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: 1 week

Note: This test is designed to detect but not differentiate the nucleic acid from *B. hermsii*, *B. miyamotoi*, *B. parkeri*, and *B. turicatae*. Additional less-frequently encountered relapsing fever *Borrelia* species may also be detected, including *B. recurrentis*, *B. coriaceae*, *B. theileri*, *B. lonestari*, and *B. anserina*. A result of "Detected" indicates the presence of nucleic acid from any one of these species in the specimen.

0051368 RhD Gene (*RHD*) Copy Number RHD

Interpretive Data:
Background Information for RhD Gene (*RHD*) Copy Number:
Characteristics: Fetal or neonatal erythroblastosis and hydrops.
Incidence of *RHD*-negative genotype: 15 percent Caucasians, 5 percent African Americans, less than 1 percent Asians
Inheritance: Autosomal recessive
Cause: Maternal-fetal Rh D antigen incompatibility
Methods: Determine the presence of the *RHD* exons 5, 7, and a 37 base pair insertion in the intron 3/exon 4 boundary by PCR and fluorescence monitoring. Allelic height ratios are used to determine the number of copies of *RHD* as compared to *RHCE*.
Limitations: Bloody amniotic fluid specimens may give false-negative results because of maternal cell contamination; specificity may be compromised by mutations in primer sites or those outside the *RHD* exons examined; fetuses predicted to be unaffected should continue to be monitored by noninvasive means. Diagnostic errors can occur due to rare sequence variations.
Analytic Sensitivity and Specificity: Greater than 99 percent
Clinical Sensitivity: Greater than 98 percent

For quality assurance purposes, ARUP Laboratories will confirm the above result at no charge following delivery. Order Confirmation of Fetal Testing and include a copy of the original fetal report (or the mother's name and date of birth) with the test submission. Please contact an ARUP genetic counselor at (800) 242-2787 extension 2141 prior to specimen submission.

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

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 0051369, RhD Antigen (RhD) Specimen to RhD Gene (RHD) Copy Number Specimen.
Change the charting name for component 0050422 RhD, Antigen (RhD) Genotyping to RhD Gene (RHD) Copy Number.

2003176 Rufinamide, Serum or Plasma — RUFIN SP

Reference Interval:
Effective August 19, 2019

Therapeutic Range	5-30 µg/mL
Dose-related range (values at dosages of 800-7200 mg/day)	3-30 µg/mL
Toxic	Not well established

2010138 *RUNX1-RUNX1T1* (*AML1-ETO*) t(8;21) Detection, Quantitative — AML1-ETO Q

Specimen Required: Collect: Lavender (EDTA) or bone marrow (EDTA). Also acceptable: RNA extracted by CLIA certified lab.
Specimen Preparation: **Whole Blood:** Transport 5 mL whole blood. (Min: 1 mL)
Bone Marrow: Transport 3 mL bone marrow. (Min: 1 mL)
Specimens must be received within 48 hours of collection due to lability of RNA.
Extracted RNA: Transport 40 uL RNA with at least 40 ng/uL concentration. (Min: 40 uL) Transport RNA 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: **Whole Blood or Bone Marrow**: CRITICAL REFRIGERATED. Separate specimens must be submitted when multiple tests are ordered.
Extracted RNA: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Unacceptable Conditions Serum, plasma, CSF, extracted DNA, RNA extracted by a non-CLIA lab, bone core, or FFPE tissue. Specimens collected in anticoagulants other than EDTA. Severely hemolyzed or clotted specimens.
Stability (collection to initiation of testing): Ambient: 1 hour; Refrigerated: 48 hours; Frozen: Unacceptable
Extracted RNA: Ambient: Unacceptable; Refrigerate: Unacceptable; Frozen: Indefinitely

0050527 Serine Proteinase 3 (PR3) Antibody — PR3

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 0050527, Serine Protease 3, IgG to Serine Proteinase 3, IgG.

0050085 Smith (ENA) Antibody, IgG — SMITH

Interpretive Data: Smith antibody is highly specific (greater than 90 percent) for systemic lupus erythematosus (SLE) but only occurs in 30-35 percent of SLE cases. The presence of antibodies to Smith has variable associations with SLE clinical manifestations.

3000460 Smith and Smith/RNP (ENA) Antibodies, IgG — SMITH_RNP

Reference Interval:

Test Number	Components	Reference Interval	
0050470	Smith/RNP (ENA) Antibody, IgG	29 AU/mL or less	Negative
		30-40 AU/mL	Equivocal
		41 AU/mL or greater	Positive
0050085	Smith (ENA) Antibody, IgG	29 AU/mL or less	Negative
		30-40 AU/mL	Equivocal
		41 AU/mL or greater	Positive

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 0050470 from Ribonucleic Protein (U1) (ENA) Ab, IgG to Smith/RNP (ENA) Ab, IgG.

0050470 Smith/RNP (ENA) Antibody, IgG — RNP

Interpretive Data: Smith/RNP antibodies are frequently seen in patients with mixed connective tissue disease (MCTD) and are also associated with other systemic autoimmune rheumatic diseases (SARDs) such as systemic lupus erythematosus (SLE), systemic sclerosis, and myositis. Antibodies targeting the Smith/RNP antigenic complex also recognize Smith antigens, therefore, the Smith antibody response must be considered when interpreting these results.

Note: Purified Smith/RNP antigen is used in this assay. U1RNP IgG antibodies detected using immunoassays that employ recombinant U1-70K, A, and C proteins may yield discrepant results.

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 0050470 from Ribonucleic Protein (U1) (ENA) Ab, IgG to Smith/RNP (ENA) Ab, IgG.

0060137 **Stool Culture, *Yersinia*** **MC YERS**

Specimen Required: Collect: Stool.
Specimen Preparation: Preserve 5 mL stool in enteric transport media (Cary-Blair) immediately (ARUP supply #29799) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Multiple specimens (more than one in 24 hours).Delayed transport without use of appropriate preservative.
Stability (collection to initiation of testing): **Unpreserved:** Ambient: 2 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Preserved: Ambient: 4 hours; Refrigerated: 72 hours; Frozen: Unacceptable

0060705 ***Streptococcus* Group B by PCR** **GBS PCR**

Specimen Required: Collect: Vaginal then rectal specimen with the same swab.
Specimen Preparation: Transfer swab to Amies media or Liquid Stuart media (ARUP supply #43875) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Refrigerated.
Remarks: Specimen source required.
Unacceptable Conditions: Specimens in any transport media other than indicated above.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 6 days; Frozen: Unacceptable

2008771 **Supersaturation Profile, Urine** **SUPERSAT**

Performed: Mon, Wed, Fri
Reported: 1-8 days

Specimen Required: Collect: 24-hour urine. Refrigerate during collection.
Specimen Preparation: Thoroughly mix entire collection (24-hour) in one container. Transport four separate 4 mL aliquots of urine using Calculi Risk/Supersaturation Urine Collection Kit (ARUP supply# 46007). Available online through eSupply using ARUP Connect™ or contact Client Services at (800) 522-2787. **Do not exceed 4 mL in tubes.**
Aliquot according to the following specifications:
1st aliquot (pH 2): Transfer 4 mL urine into a Sulfamic Acid Tube. (Min: 4 mL) Mix well. Freeze immediately.
2nd aliquot (pH 2): Transfer 4 mL urine into a Sulfamic Acid Tube. (Min: 4 mL) Mix well. Freeze immediately.
3rd aliquot (pH 9): Transfer 4 mL urine into a Sodium Carbonate Tube. (Min: 4 mL) Mix well. Freeze immediately.
4th aliquot: Transfer 4 mL urine into an Unpreserved Tube. (Min: 4 mL) Freeze immediately.
If collection kit is unavailable, transport four 4 mL unadjusted aliquots of urine.
Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered. Ship patient and control specimens together.
Remarks: Record total volume and collection time interval on tube and test request form.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 2 weeks

0093199 **T-Cell Clonality by Flow Cytometry Analysis of TCR V-Beta** **TCR V-BETA**

Specimen Required: Collect: Green (sodium heparin).
Specimen Preparation: Transport 5 mL whole blood.
Storage/Transport Temperature: Room temperature. Specimen should be received within 24 hours of collection for optimal viability.
Remarks: Previous leukemia/lymphoma phenotyping is required. If prior studies were not performed at ARUP, the outside flow cytometry report and histograms must accompany the specimen. If outside reports and histograms are not provided, a Leukemia/Lymphoma Phenotyping Evaluation by Flow Cytometry (ARUP test code 3001780) will be added, at an additional cost. In addition, please provide CBC, Wright's stained smear (if available), clinical history, differential diagnosis, and any relevant pathology reports.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Unacceptable

0055567 T-Cell Clonality Screening by PCR — T CELL-F

Specimen Required: Collect: Lavender (EDTA), bone marrow (EDTA), or tissue. Also acceptable: DNA extracted by CLIA certified lab.
Specimen Preparation: **Whole Blood:** Do not freeze. Transport 5 mL. (Min: 1 mL)
Bone marrow: Do not freeze. Transport 3 mL. (Min: 1 mL)
Fresh Tissue: Freeze immediately. Transport 100 mg or 0.5-2.0 cm3 tissue
FFPE Tumor Tissue: Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or four 10-micron shavings in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Extracted DNA: Transport 40uL DNA with at least 50 ng/uL concentration. Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: **Whole Blood, Bone Marrow or Extracted DNA:** Refrigerated.
Fresh Tissue: Frozen on dry ice.
FFPE Tumor Tissue: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Unacceptable Conditions: Plasma, serum, frozen tissue, DNA extracted by a non-CLIA lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens. Specimens fixed/processed in alternative fixatives or heavy metal fixatives (B-4 or B-5) or tissue sections on slides. Decalcified specimens.
Stability (collection to initiation of testing): **Whole Blood or Bone Marrow:** Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable
Fresh Tissue: Ambient: Unacceptable; Refrigerated: 2 hours; Frozen: 1 year
FFPE Tumor Tissue: Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerate: Indefinitely; Frozen: Indefinitely

2013484 TP53 Somatic Mutation, Prognostic — P53 MUTAT

Performed: Varies
Reported: 3-11 days

New Test
Available Now
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3001704 Treponema Pallidum by IHC — TPALL IHC

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

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

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

Note: All stains will be handled as "Stain and Return" unless a consultation is requested. To request a consultation, submit the pathology report, all associated case materials (clinical history, blocks, slides, etc.), and the Anatomic Pathology requisition form (#32960) in place of the Immunohistochemistry Stain Form.

CPT Code(s): 88342

New York DOH Approved.

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

New Test **3001831** **Troponin T (cTnT) 5th Generation** **CTNT**
Click for Pricing

Methodology: Quantitative Electrochemiluminescent Immunoassay (ECLIA)
Performed: Mon, Wed, Fri
Reported: 1-4 days

Specimen Required: Collect: Plasma Separator Tube (PST), or Green (Lithium Heparin).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**
Unacceptable Conditions: Specimens collected in potassium oxalate, sodium fluoride, or sodium citrate. Grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 24 hours; Frozen: 1 year

Reference Interval:

Female	Less than or equal to 10 ng/L
Male	Less than or equal to 15 ng/L

CPT Code(s): 84484

New York DOH Approved.

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

0065031 ***Ureaplasma* Species and *Mycoplasma hominis* Culture** **V UREA**

Specimen Required: Collect: Body fluid, CSF, semen, cervical or urethral swab, tissue, or urine. Also acceptable: Respiratory specimens from patients younger than 1 year of age.
Specimen Preparation: Place swab or 0.5 mL of fluid (Min: 0.3 mL). in *Mycoplasma/Ureaplasma* transport media (UTM) (ARUP supply #12884) immediately. Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. Also acceptable: Any transport media validated for *Mycoplasma/Ureaplasma* transport such as M4 (DO NOT USE M4 RT).
Storage/Transport Temperature: Frozen. Transport specimen on dry ice.
Remarks: Specimen source preferred.
Unacceptable Conditions: Non-patient specimens. Specimens not in *Mycoplasma/Ureaplasma* transport media. M4 RT or bacterial transport media. Dry swabs.
Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: 48 hours; Frozen at -20°C: Unacceptable; Frozen at -70°C: 1 month

0020056 **Viscosity, Serum** **VIS-S**

Reference Interval:
Effective August 19, 2019
1.10-1.80 cP

2013942 **Zika Virus IgM Antibody Capture (MAC) by ELISA** **ZIKA M**

Interpretive Data: This assay is intended for in vitro diagnostic use under FDA Emergency Use Authorization (EUA) and has not been FDA cleared or approved. In compliance with this authorization, please visit https://aruplab.com/zika for more information and to access the applicable information sheets.

The possibility of false-positive or false-negative results must be considered. RT-PCR testing on both a serum and urine specimen is recommended by the Centers for Disease Control and Prevention (CDC) to rule out false-negative IgM results in patients experiencing symptoms for less than 2 weeks. Specimens collected for IgM testing greater than or equal to 2 weeks after symptom onset do not require any additional testing. For more information, please review the current clinical guidelines for Zika virus testing at: www.cdc.gov/zika/.

Note: If the result is "Presumptive Zika," then Zika IgM Ab Capture (MAC) Confirmation (ARUP test code 3001904) will be added at no additional charge.

HOTLINE NOTE: There is a reflexive pattern change associated with this test.
Add reflex to 3001904, Zika IgM Ab Capture (MAC) Confirmation

HOTLINE: Effective August 19, 2019

The following will be discontinued from ARUP's test menu on August 19, 2019.
Replacement test options are supplied if applicable.

Test Number	Test Name	Refer To Replacement
0098422	Allergen, Occupational, Phthalic Anhydride IgE	
2006038	Allergens, Respiratory Panel, Region 10, Southwestern Grasslands (OK, TX) IgE	Allergen, Region 10 Respiratory Panel IgE (3001720)
2006039	Allergens, Respiratory Panel, Region 11, Rocky Mountain (AZ, ID, NM, WY CO, MT, UT) IgE	Allergen, Region 11 Respiratory Panel IgE (3001721)
2006040	Allergens, Respiratory Panel, Region 12, Arid Southwest (S. AZ, S.E. CA) IgE	Allergen, Region 12 Respiratory Panel IgE (3001722)
2006041	Allergens, Respiratory Panel, Region 13, Southern Coastal (CA) IgE	Allergen, Region 13 Respiratory Panel IgE (3001723)
2006042	Allergens, Respiratory Panel, Region 14, Central California (CA) IgE	Allergen, Region 14 Respiratory Panel IgE (3001724)
2006043	Allergens, Respiratory Panel, Region 15, Intermountain West (NV, S. ID) IgE	Allergen, Region 15 Respiratory Panel IgE (3001725)
2006044	Allergens, Respiratory Panel, Region 16, Inland Northwest (OR, Central and East WA) IgE	Allergen, Region16 Respiratory Panel IgE (3001726)
2006045	Allergens, Respiratory Panel, Region 17, Pacific Northwest (NW CA, W. OR, WA) IgE	Allergen, Region17 Respiratory Panel IgE (3001727)
2006046	Allergens, Respiratory Panel, Region 18, Alaska IgE	Allergen, Region 18 Respiratory Panel IgE (3001728)
2006047	Allergens, Respiratory Panel, Region 19, Puerto Rico IgE	Allergen, Region 19 Respiratory Panel IgE (3001729)
2005718	Allergens, Respiratory Panel, Region 2, Mid-Atlantic (DE, MD, VA, DC, NC) IgE	Allergen, Region 2 Respiratory Panel IgE (3001712)
2006048	Allergens, Respiratory Panel, Region 20, Hawaii IgE	Allergen, Region 20 Respiratory Panel IgE (3001730)
2006025	Allergens, Respiratory Panel, Region 3, South Atlantic (GA, SC, N. FL) IgE	Allergen, Region 3 Respiratory Panel IgE (3001713)
2006026	Allergens, Respiratory Panel, Region 4, Subtropic Florida (S. of Orlando) IgE	Allergen, Region 4 Respiratory Panel IgE (3001714)
2006031	Allergens, Respiratory Panel, Region 5, Ohio Valley (IN, OH, TN, WV, KY) IgE	Allergen, Region 5 Respiratory Panel IgE (3001715)
2006032	Allergens, Respiratory Panel, Region 6, South Central (AL, AR, LA, MS) IgE	Allergen, Region 6 Respiratory Panel IgE (3001716)
2006033	Allergens, Respiratory Panel, Region 7, Northern Midwest (MI, WI, MN) IgE	Allergen, Region 7 Respiratory Panel IgE (3001717)
2006034	Allergens, Respiratory Panel, Region 8, Central Midwest (IL, MO, IA) IgE	Allergen, Region 8 Respiratory Panel IgE (3001718)
2006037	Allergens, Respiratory Panel, Region 9, Great Plains (KS, NE, ND, SD) IgE	Allergen, Region 9 Respiratory Panel IgE (3001719)
0091195	Amantadine Quantitative, Serum or Plasma	
0091165	Barium Quantitative, Urine	
0051421	Beta Globin (*HBB*) HbS, HbC, and HbE Mutations	Beta Globin (*HBB*) Gene Sequencing (0050578)
0051422	Beta Globin (*HBB*) HbS, HbC, and HbE Mutations, Fetal	Beta Globin (*HBB*) Sequencing, Fetal (0050388)
2014493	Bupivacaine Quantitative, Serum or Plasma	
2014027	Calcium, RBC	
2013991	Dermatomyositis Panel	Dermatomyositis Autoantibody Panel (3001782)
0091219	Diphenhydramine Quantitative, Urine	
0049050	Esterase Stain, Nonspecific	
2014674	Expanded Carrier Screen, Genotyping	Expanded Carrier Screen by Next Generation Sequencing (2014680)
2014671	Expanded Carrier Screen, Genotyping with Fragile X	Expanded Carrier Screen by Next Generation Sequencing with Fragile X (2014677)
0091263	Furosemide Quantitative, Serum or Plasma	
0051067	HLA DRB 3*,4*,5*	
2008788	Influenza A Virus H1/H3 Subtype by PCR with Reflex to H1N1 (2009) Oseltamivir Resistance by Sequencing	
0093148	Interferon-Alpha by ELISA, Serum	
2013993	Interstitial Lung Disease Panel	Interstitial Lung Disease Autoantibody Panel (3001784)
2008003	Leukemia/Lymphoma Phenotyping by Flow Cytometry	Leukemia/Lymphoma Phenotyping Evaluation by Flow Cytometry (3001780)
0091200	LSD, Serum or Plasma - Screen with Reflex to Confirmation/Quantitation	
0091272	Mercury, Hair	
2013961	Myositis Extended Panel	Extended Myositis Panel (3001781)
0092140	Nitrogen, Total, Urine	
2002016	Pancreatitis (*PRSS1*) Sequencing	Pancreatitis (*PRSS1*) Deletion/Duplication (3001760), Pancreatitis (*SPINK1*) Deletion/Duplication (3001764), and Pancreatitis (*PRSS1*) Sequencing and Deletion/Duplication (3001768)
2013992	Polymyositis and Dermatomyositis Panel	Dermatomyositis and Polymyositis Panel (3001783)
0091568	Sulfhemoglobin Quantitative, Whole Blood	
0098803	Troponin T	Troponin T (cTnT) 5th Generation (3001831)