Quarterly HOTLINE: Effective February 21, 2017

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
5	0021020	Alkaline Phosphatase Isoenzymes, Serum or Plasma				x								
5	2014007	Allergen, Food, Milk (Boiled) IgE											x	
5	2014003	Allergen, Fungi and Molds, *Aspergillus flavus* IgE											x	
6	2014005	Allergen, Fungi and Molds, *Fusarium solani* IgE											x	
6	2014009	Allergen, Weed, Wingscale (*Atriplex canescens*) IgE											x	
6	0099266	Aluminum, Serum			x									
6	0099408	Aluminum, Urine			x									
6	0099007	Antimony, Blood			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
7	2008467	Anti-Nuclear Antibody (ANA), IgG by IFA with Reflex by IFA Pattern		x			x		x	x	x			
8	0020734	Arsenic, Fractionated, Urine			x									
9	2013944	Autoimmune Neurologic Disease Reflexive Panel											x	
10	0099478	Bismuth, Blood			x									
11	2011603	Caffeine, Serum or Plasma					x							
11	2014027	Calcium, RBC											x	
12	2013901	*Candida FKS* Drug Resistance by Sequencing											x	
13	2013798	*Candida* Species by PCR											x	
14	2013784	*Candida* Species by PCR with Reflex to *FKS* Drug Resistance by Sequencing											x	
44	2005548	Chromium, Joint Fluid												x
14	0098830	Chromium, Serum			x									
14	0025068	Chromium, Urine			x									
44	2005549	Cobalt, Joint Fluid												x
15	2002063	Cryoglobulin, Qualitative, with Reflex to Quantitative IgA, IgG, and IgM										x		
15	2013956	CV2.1 Screen by IFA with Reflex to Titer											x	
15	2000624	Cytology, Pap Smear			x	x		x	x					
16	2000134	Cytology, SurePath Liquid-Based Pap Test			x	x		x	x					
16	2000133	Cytology, SurePath Liquid-Based Pap Test and Human Papillomavirus (HPV), High Risk by PCR, SurePath (for routine co-testing in women over 30)				x		x	x					
16	2000135	Cytology, SurePath Liquid-Based Pap Test with Reflex to Human Papillomavirus (HPV), High Risk by PCR, SurePath				x		x						
17	2000137	Cytology, ThinPrep Pap Test			x	x		x	x					
17	2000136	Cytology, ThinPrep Pap Test and Human Papillomavirus (HPV), High Risk, E6/E7 mRNA by Transcription-Mediated Amplification (TMA) (for routine co-testing in women over 30)			x	x		x	x					
18	2000138	Cytology, ThinPrep Pap Test with Reflex to Human Papillomavirus (HPV), High Risk, E6/E7 mRNA by Transcription-Mediated Amplification (TMA)			x	x		x	x					
19	2013991	Dermatomyositis Panel											x	
44	0091349	Disulfiram (Antabuse) and Metabolite Quantitation, Serum or Plasma												x
20	0095155	DNA Cell Cycle Analysis - Ploidy and S-Phase				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
20	2012868	*EGFR* T790M Mutation Detection in Circulating Tumor DNA by Digital Droplet PCR				x								
21	2014108	Enterovirus Antibodies Panel											x	
44	2003259	Enterovirus Antibody Panel												x
22	2014000	Expanded Carrier Screening Next Generation Sequencing											x	
22	2014035	Familial Transthyretin Amyloidosis (*TTR*) Sequencing											x	
23	2013929	Growth Hormone, 150 Minutes											x	
24	2013927	Growth Hormone, 180 Minutes											x	
24	0065147	*Helicobacter pylori* Antigen, Fecal by EIA			x									
44	2003917	Hepatitis B Surface Antigen by Immunohistochemistry												x
24	2004672	*HER2/neu* Quantitative by ELISA			x	x								
25	0092522	*Histoplasma* Antigen by EIA, Serum					x	x						
25	2014073	HLA-DP Genotyping											x	
26	2014079	HLA-DQ Genotyping											x	
44	2002810	HLA-DQB Genotyping												x
26	2011942	Human Papillomavirus (HPV), High Risk by PCR, SurePath				x		x						
27	2011933	Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by PCR, SurePath			x	x		x						
27	2011940	Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by PCR, ThinPrep				x		x						
27	2014056	IgA Deficiency (IgAD) Panel											x	
28	0080403	Indicans, Urine Qualitative			x									
28	2013566	Insulin, 180 Minutes											x	
28	2003390	Interferon Beta Neutralizing Antibody with Reflex to Titer			x									
29	2013993	Interstitial Lung Disease Panel											x	
44	0080570	Lipoprotein Electrophoresis with Qualitative Band Assessment												x
30	0099265	Manganese, Serum			x									
30	0099272	Manganese, Whole Blood			x									
44	0080108	Maternal Serum Screen, Alpha Fetoprotein, hCG, and Estriol												x
30	0054440	Measles (Rubeola) Antibody, IgG, CSF				x								
44	2005528	Metals, Joint Fluid												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
30	0054442	Mumps Virus Antibody IgG, CSF				x								
44	2010851	Myositis Antibody Comprehensive Panel												x
31	2013961	Myositis Extended Panel											x	
44	2010862	Myositis-Specific Antibody Panel												x
32	0099452	Nickel, Serum			x									
33	2013955	Paraneoplastic Reflexive Panel											x	
34	2014107	Poliovirus (Types 1, 3) Antibodies											x	
44	0060054	Poliovirus Antibodies												x
35	2013992	Polymyositis and Dermatomyositis Panel											x	
36	2013990	Polymyositis Panel											x	
37	2014041	Potassium, RBC											x	
44	0099132	Rabies Antibody, IgG (Vaccine Response)												x
37	0020373	Reducing Substances, Fecal			x									
37	2012155	Charcot-Marie-Tooth (CMT) and Related Hereditary Neuropathies, *PMP22* Deletion/Duplication with Reflex to Sequencing Panel			x				x					
44	2005933	Special Stain, Fibrin												x
44	2005951	Special Stain, Gridleys												x
44	2005969	Special Stain, Methyl Green Pyronin (MPG)												x
44	2005975	Special Stain, Nissl Substance												x
37	2009298	Tay-Sachs Disease (*HEXA*) Sequencing and 7.6kb Deletion		x										
38	0013410	Thermal Amplitude Test											x	
38	0051690	Transforming Growth Factor beta, Plasma			x									
38	0051694	Transforming Growth Factor beta, Serum			x									
38	0090307	Tricyclic Antidepressant Detection						x						
39	2014025	Trypsin											x	
39	2001181	UroVysion FISH				x								
39	0054444	Varicella-Zoster Virus Antibody, IgG, CSF				x								
39	0080388	Vitamin B_1 (Thiamine), Whole Blood				x								
40	2013701	Vulvovaginal *Candida* Species by PCR											x	
41	2014065	Zika Virus by PCR, Blood											x	
42	2014069	Zika Virus by PCR, Urine											x	
43	2013942	Zika Virus IgM Antibody Capture (MAC), by ELISA											x	

0021020 **Alkaline Phosphatase Isoenzymes, Serum or Plasma** **ALKP-ISO**

Specimen Required: Collect: Serum Separator Tube (SST) or Green (Sodium or Lithium Heparin).
Specimen Preparation: Allow serum specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube and refrigerate or freeze immediately. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Specimens collected in EDTA, sodium fluoride, sodium citrate, or potassium oxalate. Grossly hemolyzed or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 1 week; Refrigerated: 1 week; Frozen: 2 months

New Test **2014007** **Allergen, Food, Milk (Boiled) IgE** **MILK BOIL**

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Varies
Reported: 3-6 days

Specimen Required: Collect: Plain Red or Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 0.5 mL serum **plus** 0.1 mL for each additional allergen ordered to an ARUP Standard Transport Tube. (Min: 0.34 mL **plus** 0.04 mL for each allergen ordered)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated or frozen.
Unacceptable Conditions: Lipemic specimens
Stability (collection to initiation of testing): Ambient: 1 month; Refrigerated: 1 month; Frozen: 1 year

Reference Interval: By Report

CPT Code(s): 86003

New York DOH Approved.

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

New Test **2014003** **Allergen, Fungi and Molds, *Aspergillus flavus* IgE** **ASPER FLA**

Methodology: Quantitative Enzyme Immunoassay
Performed: Varies
Reported: 3-6 days

Specimen Required: Collect: Plain Red or Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 0.5 mL serum **plus** 0.1 mL for each additional allergen ordered to an ARUP Standard Transport Tube. (Min: 0.34 mL **plus** 0.04 mL for each allergen ordered)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated or frozen.
Unacceptable Conditions: Lipemic specimens.
Stability (collection to initiation of testing): Ambient: 1 month; Refrigerated: 1 month; Frozen 1 year

Reference Interval: By report

CPT Code(s): 86003

New York DOH Approved.

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

New Test **2014005** **Allergen, Fungi and Molds, *Fusarium solani* IgE** **FUSARIUM**

Methodology: Quantitative Enzyme Immunoassay
Performed: Varies
Reported: 3-5 days

Specimen Required: Collect: Plain Red or Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 0.5 mL serum **plus** 0.1 mL for each additional allergen ordered to an ARUP Standard Transport Tube. (Min: 0.34 mL **plus** 0.04 mL for each allergen ordered)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated or frozen.
Unacceptable Conditions: Lipemic specimens
Stability (collection to initiation of testing): Ambient: 1 month; Refrigerated: 1 month; Frozen: 1 year

Reference Interval: By report

CPT Code(s): 86003

New York DOH Approved.

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

New Test **2014009** **Allergen, Weed, Wingscale (*Atriplex canescens*) IgE** **WINGSCALE**

Methodology: Quantitative Enzyme Immunoassay
Performed: Varies
Reported: 3-6 days

Specimen Required: Collect: Plain Red or Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 0.5 mL serum **plus** 0.1 mL for each additional allergen ordered to an ARUP Standard Transport Tube. (Min: 0.34 mL **plus** 0.04 mL for each allergen ordered)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated or frozen.
Unacceptable Conditions: Lipemic specimens
Stability (collection to initiation of testing): Ambient: 1 month; Refrigerated: 1 month Frozen: 1 year

Reference Interval: By report

CPT Code(s): 86003

New York DOH Approved.

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

0099266 **Aluminum, Serum** **AL S**

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

0099408 **Aluminum, Urine** **AL U**

Performed: Tue, Thu, Sat
Reported: 1-5 days

0099007 **Antimony, Blood** **ANT B**

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

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

Methodology: Semi-Quantitative Indirect Fluorescent Antibody/Qualitative Enzyme-Linked Immunosorbent Assay/Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Semi-Quantitative Multiplex Bead Assay/Qualitative Immunoblot

Reference Interval: Effective February 21, 2017

Test Number	Components	Reference Interval	
	Anti-Nuclear Antibody (ANA), IgG by IFA with Reflex by IFA Pattern	Less than 1:40	
2003040	PM/SCL-100 Antibody, IgG by Immunoblot	Negative	
2012173	Fibrillarin (U3 RNP) Antibody, IgG	Negative	
0050215	Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA with Reflex to dsDNA Antibody, IgG by IFA	**Components**	**Reference Interval**
		Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA	None Detected.
		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	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	RNP (U1) (Ribonucleic Protein) (ENA) Antibody, IgG	29 AU/mL or less	Negative
		30-40 AU/mL	Equivocal
		41 AU/mL or greater	Positive
0050085	Smith (ENA) Antibody, IgG	29 AU/mL or less	Negative
		30-40 AU/mL	Equivocal
		41 AU/mL or greater	Positive
2012074	SSA 52 and 60 (Ro) (ENA) Antibodies, IgG	**Components**	**Reference Interval**
		SSA 52 (Ro) (ENA) Antibody, IgG	29 AU/mL or less: Negative
			30-40 AU/mL: Equivocal
			41 AU/mL or greater: Positive
		SSA 60 (Ro) (ENA) Antibody, IgG	29 AU/mL or less: Negative
			30-40 AU/mL: Equivocal
			41 AU/mL or greater: Positive
0050692	SSB (La) (ENA) Antibody, IgG	29 AU/mL or less	Negative
		30-40 AU/mL	Equivocal
		41 AU/mL or greater	Positive

Note: The Anti-Nuclear Antibody (ANA), IgG by IFA with Reflex by IFA Pattern begins with Nuclear Antibody (ANA) by IFA, IgG. Depending on findings, one or more reflexive tests may be required. Tests added may include Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA; Double-Stranded DNA (dsDNA) Antibody, IgG by IFA (using *Crithidiae luciliae*); Chromatin Antibody, IgG; RNP (U1) (Ribonucleic Protein) (ENA) Antibody, IgG; 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.

CPT Code(s): 86039; if homogenous pattern add 86225 and 83516; if reflexed add 86256; if speckled pattern add 86235 x6; If nucleolar pattern add 86235 x3 and 83516

HOTLINE NOTE: There is a reflexive pattern change associated with this test.
Add reflex to 2012173, Fibrillarin (U3 RNP) Antibody, IgG

0020734	**Arsenic, Fractionated, Urine**	**AS UF**

Performed: Sun, Tue, Thu, Sat
Reported: 1-5 days

New Test Available Now | 2013944 | **Autoimmune Neurologic Disease Reflexive Panel** | **NEURO R**

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

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer three 3 mL serum aliquots to ARUP Standard Transport Tubes. (Min: 1.50 mL/aliquot)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Amniotic fluid, ocular fluid, peritoneal fluid, synovial fluid, CSF, or plasma. Contaminated, hemolyzed, icteric, or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 1 month (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval
0050746	Striated Muscle Antibodies, IgG with Reflex to Titer	

Components	Reference Interval
Striated Muscle Antibodies, IgG Screen	Less than 1:40
Striated Muscle Antibodies, IgG Titer	Less than 1:40

2004221	N-methyl-D-Aspartate Receptor Antibody, IgG, Serum with Reflex to Titer
2001771	Glutamic Acid Decarboxylase Antibody
2013956	CV2.1 Screen by IFA with Reflex to Titer

Components	Reference Interval
CV2.1 Antibody IgG Screen by IFA	Less than 1:10
CV2.1 Antibody IgG Titer by IFA	Less than 1:10

0092628	Voltage-Gated Calcium Channel (VGCC) Antibody

Negative	0.0 to 24.5 pmol/L
Indeterminate	24.6 to 45.6 pmol/L
Positive	45.7 pmol/L or greater

2005636	Titin Antibody

Titin Antibody	
Negative	0.00-0.45 IV
Indeterminate	0.46-0.71 IV
Positive	0.72 IV or greater

2004890	Voltage-Gated Potassium Channel (VGKC) Antibody

Test Number	Components	Reference Interval
	Voltage-Gated Potassium Channel (VGKC) Antibody	Negative: 31 pmol/L or less Indeterminate: 32-87 pmol/L Positive: 88 pmol/L or greater
2009456	Leucine-Rich, Glioma-Inactivated Protein 1 Antibody, IgG with Reflex to Titer	Less than 1:10
2009452	Contactin-Associated Protein-2 Antibody, IgG with Reflex to Titer	Less than 1:10

2003036	Aquaporin-4 Receptor Antibody

		Test Number	**Components**	**Reference Interval**
			Aquaporin-4 Receptor Antibody	Negative: 2.9 U/mL or less Positive: 3.0 U/mL or greater
		2013320	Aquaporin-4 Receptor Antibody, IgG by IFA with Reflex to Titer, Serum	Less than 1:10
0080009	Acetylcholine Receptor Binding Antibody			
		Test Number	**Components**	**Reference Interval**
			Acetylcholine Receptor Binding Antibody	Negative: 0.0-0.4 nmol/L Positive: 0.5 nmol/L or greater
		0099521	Acetylcholine Receptor Modulating Antibody	Negative: 0-45% modulating Positive: 46% or greater modulating
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	None Detected
2008893	Amphiphysin Antibody, IgG	Negative		

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

Note:

- If Striated Muscle Ab is detected, then a titer will be added. Additional charges apply.
- If N-methyl-D-Aspartate Receptor Antibody is positive, then titer will be added. Additional charges apply.
- If CV2.1 Antibody IgG Screen by IFA is positive, then a titer will be added. Additional charges apply.
- If Aquaporin-4 Receptor Antibody IgG by ELISA is positive, then Aquaporin-4 Receptor Antibody, IgG by IFA will be added. If positive, then a titer will be added. Additional charges apply.
- If Voltage-Gated Calcium Channel (VGCC) Antibody is Indeterminate or Positive, then Leucine-Rich, Glioma-Inactivated Protein 1 Antibody IgG and Contactin-Associated Protein-2 Antibody IgG will be added. If LGI1 antibody IgG is positive, then LGI1 antibody IgG titer will be added. If CASPR2 antibody IgG is positive, then CASPR2 antibody IgG titer will be added. Additional charges apply.
- If Acetylcholine Receptor Binding Antibody result is greater than 0.4 nmol/L then Acetylcholine Receptor Modulating Antibody will be added. Additional charges apply.
- Purkinje Cell (PCCA) antibody and Neuronal Nuclear (ANNA) antibody IgG are screened by IFA. If the IFA screen is indeterminate, then a Neuronal Nuclear Antibodies (Hu, Ri, and Yo) IgG by Immunoblot will be added. If the IFA screen is positive at 1:10 or greater, then a PCCA/ANNA antibodies titer and Neuronal Nuclear Antibodies (Hu, Ri, and Yo) IgG by Immunoblot will be added. Additional charges apply.

CPT Code(s): 83519 x3; 83516 x4; 86255 x4; if reflexed add 86256; if reflexed add 86256; if reflexed add 86256; if reflexed add 86255 if further reflexed add 86256; if reflexed add 86255 x2 if further reflexed add 86256 per titer; if reflexed add 83516; if reflexed add 83516 and/or 86256

New York DOH approval pending. Call for status update.

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

0099478 **Bismuth, Blood** **BS B**

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

2011603 **Caffeine, Serum or Plasma** **CAFFEINE S**

Reference Interval: Effective February 21, 2017

Age	0-28 days	29 days and older
Therapeutic Range:	8-20 µg/mL	Less than or equal to 20 (not well established)
Toxic:	Greater than 20 µg/mL	Greater than 20 µg/mL

New Test
Available Now

2014027 **Calcium, RBC** **CA RBC**

Methodology: Quantitative Inductively Coupled Plasma-Optical Emission Spectrometry
Performed: Varies
Reported: 3-10 days

Specimen Required: Collect: Green (Sodium Heparin).
Specimen Preparation: Separate cells within 2 hours of collection. Transfer 2 mL RBCs to a trace metal-free or acid-washed plastic container. (Min: 0.7 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen.
Unacceptable Conditions: Lavender top (EDTA).
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 1 month; Frozen: 1 month

Reference Interval: By Report

CPT Code(s): 82310

New York DOH Approved.

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

New Test 2013901 ***Candida FKS* Drug Resistance by Sequencing** **FKS SEQ**

Methodology: Polymerase Chain Reaction/Sequencing
Performed: Sun, Mon, Wed
Reported: 3-5 days

Specimen Required: Collect: Body fluid, tissue, or pure isolate of *Candida* species on solid media.
Specimen Preparation: **Body Fluid:** Transfer 1 mL body fluid to a sterile container. (Min: 0.5 mL)
Tissue: Transfer to a sterile container and freeze immediately.
Isolate: Transport sealed container with pure isolate on solid media. Place each specimen in an individually sealed bag.
Storage/Transport Temperature: Frozen.
Remarks: Specimen source and organism identification required.
Unacceptable Conditions: Plasma, serum, or whole blood. Mixed cultures or isolates other than suspected *Candida* species. Isolates with no visible colonies.
Stability (collection to initiation of testing): **Body Fluid**: Ambient: 2 weeks; Refrigerated: 2 weeks; Frozen: 2 weeks
Tissue: Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 2 weeks
Isolate: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: Unacceptable

Interpretive Data: This assay detects known resistance mutations in *C. albicans*, *C. glabrata*, *C. krusei*, *C. parapsilosis*, and *C. tropicalis* by sequencing. The *FKS1* and *FKS2* genes are sequenced. Mutations associated with resistance to Echinocandins are reported. Mutations in sub-populations below 20 percent of total may not be detected.

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

Note: This test may be unsuccessful if the specimen or isolate does not contain *C. albicans*, *C. glabrata*, *C. krusei*, *C. parapsilosis*, *C. tropicalis*, or if multiple *Candida* species are present.

CPT Code(s): 87900

New York DOH approval pending. Call for status update.

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

New Test 2013798 ***Candida* Species by PCR** **CANDPCR**

Methodology: Qualitative Polymerase Chain Reaction
Performed: Mon, Thu
Reported: 2-5 days

Specimen Required: Collect: Body fluid, tissue, or pure isolate of *Candida* species on solid media.
Specimen Preparation: **Body Fluid:** Transfer 1 mL body fluid to a sterile container. (Min: 0.5 mL)
Tissue: Transfer to a sterile container and freeze immediately.
Isolate: Transport sealed container with pure isolate on solid media. Place each specimen in an individually sealed bag.
Storage/Transport Temperature: **Body Fluid and Tissue**: Frozen**.**
Isolate: Refrigerated.
Remarks: Specimen source required.
Unacceptable Conditions: Plasma, serum, or whole blood. Mixed cultures or isolates other than suspected *Candida* species. Isolates with no visible colonies.
Stability (collection to initiation of testing): **Body Fluid**: Ambient: 2 weeks; Refrigerated: 2 weeks; Frozen: 2 weeks
Tissue: Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 2 weeks
Isolate: Ambient: 1 week; Refrigerated; 2 weeks; Frozen: Unacceptable

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

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

Note: This test detects and differentiates *C. albicans*, *C. glabrata*, *C. parapsilosis* complex (*C. parapsilosis*, *C. orthopsilosis*, *C. metapsilosis)*, *C. tropicalis*, *C. krusei*, and *C. dubliniensis.*

CPT Code(s): 87481 x6

New York DOH approval pending. Call for status update.

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

New Test 2013784 ***Candida* Species by PCR with Reflex to *FKS* Drug Resistance by Sequencing** **CAND RFX**

Methodology: Qualitative Polymerase Chain Reaction/Sequencing
Performed: Mon, Thu
Reported: 7-10 days

Specimen Required: Collect: Body fluid, tissue, or pure isolate of *Candida* species on solid media.
Specimen Preparation: **Body Fluid:** Transfer 2 mL body fluid to a sterile container. (Min: 1.5 mL)
Tissue: Transfer to a sterile container and freeze immediately.
Isolate: Transport sealed container with pure isolate on solid media. Place each specimen in an individually sealed bag.
Storage/Transport Temperature: **Body Fluid and Tissue**: Frozen**.**
Isolate: Refrigerated.
Remarks: Specimen source required.
Unacceptable Conditions: Plasma, serum, or whole blood. Mixed cultures or isolates other than suspected *Candida* species. Isolates with no visible colonies.
Stability (collection to initiation of testing): **Body Fluid**: Ambient: 2 weeks; Refrigerated: 2 weeks; Frozen: 2 weeks
Tissue: Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 2 weeks
Isolate: Ambient: 1 week; Refrigerated; 2 weeks; Frozen: Unacceptable

Reference Interval:

Test Number	Components	Reference Interval
2013798	*Candida* Species by PCR	Not Detected
2013901	*Candida FKS* Drug Resistance by Sequencing	By report

Interpretive Data: Refer to report.

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

Note: The *Candida* Species by PCR detects and differentiates *C. albicans, C. glabrata, C. parapsilosis* complex (*C. parapsilosis, C. orthopsilosis, C. metapsilosis), C. tropicalis, C. krusei,* and *C. dubliniensis.* If *Candida* Species by PCR result is detected for a single *Candida* species (*C. albicans, C. glabrata, C. krusei, C. parapsilosis* complex, *C. tropicalis*) then *Candida FKS* Drug Resistance by Sequencing will be added. Additional charges apply. If *Candida* Species by PCR result is not detected, or detected for multiple *Candida* species, or detected for *C. dubliniensis* then *Candida FKS* Drug Resistance by Sequencing will be not be added.

CPT Code(s): 87481 x6; if reflexed, add 87900

New York DOH approval pending. Call for status update.

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

0098830 **Chromium, Serum** **CR S**

Performed: Mon, Wed-Sat
Reported: 1-4 days

0025068 **Chromium, Urine** **CR-U**

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

2002063 Cryoglobulin, Qualitative, with Reflex to Quantitative IgA, IgG, and IgM — CRYGB QNT

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name of component 0050188 from Cryoglobulin Quantitative Screen to Cryoglobulin Qualitative Screen

New Test 2013956 CV2.1 Screen by IFA with Reflex to Titer — CV2.1 SCRN

Available Now

Additional Technical Information

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

Specimen Required: Collect: Serum Separator Tube (SST) or Plain Red.
Specimen Preparation: Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.25 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed, contaminated, or severely lipemic specimens.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval: Less than 1:10

Interpretive Data:
CV2.1 antibodies aid in discriminating between chronic paraneoplastic neurological disorder (PND) and other inflammatory disorders of the nervous system. Anti-CV2.1 is associated with small-cell lung cancer and thymoma.

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

Note: If CV2.1 Antibody IgG Screen by IFA is positive, then CV2.1 Antibody IgG Titer by IFA will be added. Additional charges apply.

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

New York DOH approval pending. Call for status update.

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

2000624 Cytology, Pap Smear — GG REQUEST

Performed: Sun-Sat
Reported: 1-14 days

Specimen Required: Collect: Unstained cervical or endocervical slides. For specific instructions, refer to Specimen Collection and Handling.
Specimen Preparation: Label and transport slides in slide holders.
Storage/Transport Temperature: Room temperature.
Unacceptable Conditions: Unlabeled slide(s).
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Interpretive Data: Refer to report.

Note: A conventional pap smear is used as a screening test for evaluation of the lower female genital tract to detect the presence of inflammatory/infectious or benign proliferative conditions; detection of unsuspected or confirmation of suspected atypical, premalignant, or malignant changes; or follow-up of patients with known and/or treated premalignant or malignant lesions.

The Pap test is a screening test for cervical cancer and its precursors with an inherent false-negative rate.

HOTLINE NOTE: Remove information found in the Patient Preparation field.

2000134 Cytology, SurePath Liquid-Based Pap Test — GA REQUEST

Performed: Sun-Sat
Reported: 1-14 days

Specimen Required: Collect: Cervical specimen in a SurePath collection kit, Rovers Cervex-Brush Kit (ARUP Supply #22216), PAP Perfect Plastic Spatula and Cytobrush Plus GT Collection Kit (ARUP Supply #41126), or Rovers Cervex-Brush Combi Collection Kit (ARUP Supply #45031) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. For specific instructions refer to Specimen Collection and Handling.
Specimen Preparation: Transport cervical specimen in the original collection kit.
Storage/Transport Temperature: Room temperature.
Unacceptable Conditions: Specimens not collected in a SurePath collection kit. Expired preservative vials or vials received without the collection devices.
Stability (collection to initiation of testing): Ambient: 1 month; Refrigerated: 6 months; Frozen: Unacceptable

Interpretive Data: Refer to report.

Note: This test does not include HPV testing. The Pap test is a screening test for cervical cancer and its precursors with an inherent false-negative rate.

HOTLINE NOTE: Remove information found in the Patient Preparation field.

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

Specimen Required: Collect: Cervical specimen in a SurePath collection kit, Rovers Cervex-Brush Kit (ARUP Supply #22216), PAP Perfect Plastic Spatula and Cytobrush Plus GT Collection Kit (ARUP Supply #41126), or Rovers Cervex-Brush Combi Collection Kit (ARUP Supply #45031) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. For specific instructions refer to Specimen Collection and Handling.
Specimen Preparation: Transport cervical specimen in the original collection kit.
Storage/Transport Temperature: Room temperature.
Unacceptable Conditions: Specimens not collected in a SurePath collection kit. Expired preservative vials or vials received without the collection devices.
Stability (collection to initiation of testing): Ambient: 1 month; Refrigerated: 6 months; Frozen: Unacceptable

Interpretive Data: Refer to report.

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

The Pap test is a screening test for cervical cancer and its precursors with an inherent false-negative rate.

HOTLINE NOTE: Remove information found in the Patient Preparation field.

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

Specimen Required: Collect: Cervical specimen in a SurePath collection kit, Rovers Cervex-brush Kit (ARUP Supply #22216), PAP Perfect Plastic Spatula and Cytobrush Plus GT Collection Kit (ARUP Supply #41126), or Rovers Cervex-Brush Combi Collection Kit (ARUP Supply #45031) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. For specific instructions refer to Specimen Collection and Handling.
Specimen Preparation: Transport cervical specimen in the original collection kit.
Storage/Transport Temperature: Room temperature.
Unacceptable Conditions: Specimens not collected in a SurePath collection kit. Expired preservative vials or vials received without the collection devices.
Stability (collection to initiation of testing): Ambient: 1 month; Refrigerated: 6 months; Frozen: Unacceptable

Interpretive Data: Refer to report.

HOTLINE NOTE: Remove information found in the Patient Preparation field.

2000137 Cytology, ThinPrep Pap Test — GT REQUEST

Performed: Sun-Sat
Reported: 1-14 days

Specimen Required: Collect: Cervical specimen in a ThinPrep Pap Test collection kit, broom kit (ARUP Supply #12587) or brush/spatula kit (ARUP Supply #40624) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. For specific instructions refer to Specimen Collection and Handling.
Specimen Preparation: Transport cervical specimen in the original collection kit.
Storage/Transport Temperature: Room temperature.
Unacceptable Conditions: Specimens not collected in a ThinPrep Pap Test collection kit or specimens submitted in an expired collection kit.
Stability (collection to initiation of testing): Ambient: 3 weeks; Refrigerated; 3 weeks; Frozen; Unacceptable

Interpretive Data: Refer to report.

Note: The ThinPrep 2000 System is for use in screening for the presence of atypical cells, cervical cancer, or precursor lesions (LSIL, HSIL) as well as other cytologic categories as defined by the Bethesda System for Reporting Cervical Cytology, and is intended as a replacement for the conventional method of Pap smears.

The Pap test is a screening test for cervical cancer and its precursors with an inherent false-negative rate.

Store PreservCyt Solution without cytologic samples at 15°C to 30°C in the vials provided. Do not use solution beyond expiration date marked on the vial.

HOTLINE NOTE: Remove information found in the Patient Preparation field.

2000136 Cytology, ThinPrep Pap Test and Human Papillomavirus (HPV), High Risk, E6/E7 mRNA by Transcription-Mediated Amplification (TMA) (for routine co-testing in women over 30) — TH REQUEST

Performed: Sun-Sat
Reported: 1-14 days

Specimen Required: Collect: Cervical specimen in a ThinPrep Pap Test collection kit, broom kit (ARUP Supply #12587) or brush/spatula kit (ARUP Supply #40624) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Specimen Preparation: Transport cervical specimen in the original collection kit.
Storage/Transport Temperature: Room temperature.
Unacceptable Conditions: Specimens not collected in a ThinPrep Pap Test collection kit or specimens submitted in an expired collection kit.
Stability (collection to initiation of testing): Ambient: 3 weeks; Refrigerated; 3 weeks; Frozen; Unacceptable

Interpretive Data: Refer to report.

Note: Unsatisfactory ThinPrep Pap test speciens will not be tested for HPV.

The ThinPrep 2000 System is for use in screening for the presence of atypical cells, cervical cancer, or precursor lesions (LSIL, HSIL) as well as other cytologic categories as defined by the Bethesda System for Reporting Cervical Cytology, and is intended as a replacement for the conventional method of Pap smears.

The Pap test is a screening test for cervical cancer and its precursors with an inherent false-negative rate.

Store PreservCyt Solution without cytologic samples at 15°C to 30°C in the vials provided. Do not use solution beyond expiration date marked on the vial.

HOTLINE NOTE: Remove information found in the Patient Preparation field.

2000138 **Cytology, ThinPrep Pap Test with Reflex to Human Papillomavirus (HPV), High Risk, E6/E7 mRNA by Transcription-Mediated Amplification (TMA)** **TR REQUEST**

Performed: Sun-Sat
Reported: 1-14 days

Specimen Required: Collect: Cervical specimen in a ThinPrep Pap Test collection kit, broom kit (ARUP Supply #12587) or brush/spatula kit (ARUP Supply #40624) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Specimen Preparation: Transport cervical specimen in the original collection kit.
Storage/Transport Temperature: Room temperature.
Unacceptable Conditions: Specimens not collected in a ThinPrep Pap Test collection kit or specimens submitted in an expired collection kit.
Stability (collection to initiation of testing): Ambient: 3 weeks; Refrigerated; 3 weeks; Frozen; Unacceptable

Interpretive Data: Refer to report.

Note: If the ThinPrep Pap Test is interpreted as atypical squamous cells of undetermined significance (ASC-US), then Human Papillomavirus (HPV), High Risk, E6/E7 mRNA by Transcription-Mediated Amplification (TMA) will be added. Additional charges apply.

The Pap test is a screening test for cervical cancer and its precursors with an inherent false-negative rate.
The ThinPrep 2000 System is for use in screening for the presence of atypical cells, cervical cancer, or precursor lesions (LSIL, HSIL) as well as other cytologic categories as defined by the Bethesda System for Reporting Cervical Cytology, and is intended as a replacement for the conventional method of Pap smears.

Store PreservCyt Solution without cytologic samples at 15°C to 30°C in the vials provided. Do not use solution beyond expiration date marked on the vial.

HOT LINE NOTE: Remove information found in the Patient Preparation field.

New Test Available Now **2013991** **Dermatomyositis Panel** **DERM MYO**

Additional Technical Information

Methodology: Qualitative Immunoprecipitation/Qualitative Immunoblot
Performed: Mon, Tue, Thu, Fri
Reported: 7-15 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 (TIF1-gamma) Antibody	Negative
	SAE1 (SUMO activating enzyme) Antibody	Negative
	MDA5 (CADM-140) Antibody	Negative
	NXP-2 (Nuclear matrix protein-2) Ab	Negative
	TIF1-gamma Antibody	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 approval pending. Call for status update.

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

0095155 DNA Cell Cycle Analysis - Ploidy and S-Phase — DNA MISC

Specimen Required: Collect: Tumor tissue, body fluid, peripheral blood in Green (Sodium or Lithium Heparin), bone marrow in Green (Sodium or Lithium Heparin), **OR** urine/bladder washings.
Specimen Preparation: **Tissue:** Paraffin embed tissue block enriched with tumor.
OR Body Fluid: Transport: 100 mL body fluid. (Min: 10 mL)
OR Peripheral Blood: Transport 5 mL whole blood. (Min: 1 mL)
OR Bone Marrow: Transport 2 mL bone marrow. (Min: 1 mL) Specimens with low mononuclear cell counts may require more volume.
OR Urine/Bladder Washings: Centrifuge and remove supernatant. The cell pellet should then be re-suspended in a cell culture media such as Hank's Balanced Salt Solution or RPMI.
Storage/Transport Temperature: **Tissue (paraffin embedded), Peripheral Blood or Bone Marrow:** Refrigerated.
Body Fluid or Urine/Bladder Washings: Refrigerated.
Remarks: Provide the clinical information (pathology report) and specimen source.
Peripheral Blood, Bone Marrow, or Urine/Bladder Washings: Provide a Wright stained slide with specimens.
Unacceptable Conditions: Products of Conception. No tumor tissue remaining on block. Specimens fixed in Bouin's solution (picric acid), mercuric chloride containing fixatives (e.g., B5, Zenker solution) or ethanol-based fixatives containing ethylene glycol, acetic acid, or zinc chloride. Clotted or hemolyzed blood or bone marrow. Decalcified specimens.
Stability (collection to initiation of testing): **Tissue (paraffin embedded):** Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Body Fluid or Urine/Bladder Washings: Ambient: Unacceptable; Refrigerated: 24 hours; Frozen: Unacceptable
Peripheral Blood or Bone Marrow: Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Unacceptable

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

Specimen Required: Collect: Whole blood in two 10 mL Cell-Free DNA (cfDNA) BCT Tubes or CSF in one 10 mL Cell-Free DNA (cfDNA) BCT Tube. (ARUP Supply #52358) available online through eSupply or contacting ARUP Client Services at (800) 522-2787.
Specimen Preparation: **Whole Blood:** Transport 20 mL whole blood. (Min: 16 mL)
CSF: Transport 4 mL CSF. (Min: 4 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: FFPE tissue. Specimens collected in non-cfDNA BCT tubes.
Stability (collection to initiation of testing): **Whole Blood:** Ambient: 5 days; Refrigerated: 5 days; Frozen: Unacceptable
CSF: Ambient: Unacceptable; Refrigerated: 5 days; Frozen: Unacceptable

New Test **2014108** **Enterovirus Antibodies Panel** **ENT AB PAN**

Methodology: Serum Neutralization/Complement Fixation
Performed: Mon-Fri
Reported: 6-9 days

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.75 mL) Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Mark specimens plainly as "acute" or "convalescent."
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 year (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval
0050503	Coxsackie A9 Virus Antibodies by CF	< 1:8
0060055	Coxsackie B Virus Antibodies	Coxsackie B1: Less than 1:10 Coxsackie B2: Less than 1:10 Coxsackie B3: Less than 1:10 Coxsackie B4: Less than 1:10 Coxsackie B5: Less than 1:10 Coxsackie B6: Less than 1:10
0060053	Echovirus Antibodies	Echovirus 6: Less than 1:10 Echovirus 7: Less than 1:10 Echovirus 9: Less than 1:10 Echovirus 11: Less than 1:10 Echovirus 30: Less than 1:10
2014107	Poliovirus (Types 1,3) Antibodies	Less than 1:10: No detectable poliovirus antibodies. 1:10 or greater: Antibody to poliovirus detected, which may represent prior immunization or current or past infection.

Interpretive Data: Refer to report.

CPT Code(s): 86658 x14

New York DOH Approved.

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

New Test Available Now | 2014000 | **Expanded Carrier Screening Next Generation Sequencing** | **ECS NGS**

Patient History for Prenatal or Expanded Carrier Screening

Additional Technical Information

Methodology: Massively Parallel Sequencing/Polymerase Chain Reaction
Performed: Varies
Reported: Within 3 weeks

Specimen Required: Collect: Lavender (EDTA).
Specimen Preparation: Transport 4 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated.
Remarks: Patient History form required.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

CPT Code(s): 81404; 81405; 81406; 81407; 81408; 81223; 81252; 81479; 81257

New York DOH Approved.

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

New Test Available Now | **2014035** | **Familial Transthyretin Amyloidosis (*TTR*) Sequencing** | **TTR FGS**

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

Specimen Required: Collect: Lavender (EDTA), Pink (K_2 EDTA).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data: **Background Information for Familial Transthyretin Amyloidosis (*TTR*) Sequencing:**
Characteristics: Familial Transthyretin Amyloidosis is caused by pathogenic variants of the *TTR* gene resulting in abnormal amyloid accumulation in various tissues and is generally categorized into three phenotypes: 1) familial amyloid polyneuropathy, a slowly progressive sensorimotor and autonomic neuropathy; 2) familial amyloid cardiomyopathy, a restrictive cardiomyopathy with cardiomegaly, conduction block, angina, congestive heart failure and aortic dissection/dilatation; and 3) leptomeningeal amyloidosis, primarily affecting the CNS, causing dementia, visual impairment, seizures, ataxia, psychosis, hemorrhage, and hydrocephalus. *TTR* variants can also be associated with benign familial euthyroid hyperthyroxinemia.
Incidence: 1 in 568 individuals from Northern Portugal; 1 in 100,000 individuals of Northern European ancestry.
Inheritance: Autosomal dominant.
Penetrance: Incomplete.
Cause: Pathogenic *TTR* gene variants.
Clinical Sensitivity: 99 percent for Familial *TTR* Amyloidosis.
Methodology: Bidirectional sequencing of all coding regions and intron-exon boundaries of the *TTR* gene.
Analytical Sensitivity and Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Regulatory region variants, deep intronic variants and large deletions/duplications in *TTR* will not be detected.

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

CPT Code(s): 81404

New York DOH approval pending. Call for status update.

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

New Test Available Now | 2013929 | **Growth Hormone, 150 Minutes** | **GH 150**

Methodology: Quantitative Chemiluminescent Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Collect: Plasma Separator Tube (PST) or Serum Separator Tube (SST). Collect one tube per timed specimen. Also acceptable: Green (sodium or lithium heparin), Lavender (EDTA), or Pink (K_2EDTA).
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma per timed specimen to individual ARUP Standard Transport Tubes. (Min: 0.4 mL per timed specimen)
Storage/Transport Temperature: Frozen. Also acceptable: Refrigerated.
Unacceptable Conditions: Tissue or urine. Grossly hemolyzed or lipemic specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 1 week; Frozen: 2 months

Interpretive Data: Growth hormone stimulation tests should induce a peak of greater than 5 ng/mL in children and greater than 4 ng/mL in adults; lower values suggest growth hormone deficiency. For children, some experts consider values of 5-8 ng/mL equivocal and only peak values of greater than 8 ng/mL as truly normal.

For suppression testing, normal subjects have growth hormone concentrations of less than 0.8 ng/mL within 2 hours of ingestion of a 75 or 100 gram glucose dose. Patients with acromegaly fail to show normal suppression.

Note: This Growth Hormone assay is now standardized to the Recombinant Second International Standard (IS): 98/574. Growth hormone results read approximately 25 percent lower than with the previous standards (First IS: 80/505). Reference ranges have also been modified according to the assay manufacturer.

CPT Code(s): 83003

New York DOH Approved.

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

New Test Available Now | 2013927 | **Growth Hormone, 180 Minutes** | **GH 180**

Methodology: Quantitative Chemiluminescent Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Collect: Plasma Separator Tube (PST) or Serum Separator Tube (SST). Collect one tube per timed specimen. Also acceptable: Green (sodium or lithium heparin), Lavender (EDTA), or Pink (K_2EDTA).
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma per timed specimen to individual ARUP Standard Transport Tubes. (Min: 0.4 mL per timed specimen)
Storage/Transport Temperature: Frozen. Also acceptable: Refrigerated.
Unacceptable Conditions: Tissue or urine. Grossly hemolyzed or lipemic specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 1 week; Frozen: 2 months

Interpretive Data: Growth hormone stimulation tests should induce a peak of greater than 5 ng/mL in children and greater than 4 ng/mL in adults; lower values suggest growth hormone deficiency. For children, some experts consider values of 5-8 ng/mL equivocal and only peak values of greater than 8 ng/mL as truly normal.

For suppression testing, normal subjects have growth hormone concentrations of less than 0.8 ng/mL within 2 hours of ingestion of a 75 or 100 gram glucose dose. Patients with acromegaly fail to show normal suppression.

Note: This Growth Hormone assay is now standardized to the Recombinant Second International Standard (IS): 98/574. Growth hormone results read approximately 25 percent lower than with the previous standards (First IS: 80/505). Reference ranges have also been modified according to the assay manufacturer.

CPT Code(s): 83003

New York DOH Approved.

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

0065147 | ***Helicobacter pylori* Antigen, Fecal by EIA** | **PYLORI AG**

Performed: Sun-Sat
Reported: Within 48 hours

2004672 | ***HER2/neu* Quantitative by ELISA** | **HER2 QUANT**

Performed: Varies
Reported: 5-10 days

Specimen Required: Collect: Plain red or serum separator tube.
Specimen Preparation: Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.2 mL)
Storage/Transport Temperature: **CRITICAL FROZEN**. **Separate specimens must be submitted when multiple tests are ordered.**
Unacceptable Conditions: Hemolyzed or thawed specimens.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 1 month

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

Reference Interval: Negative - Less than 2.0 U/mL
Weak Positive - 2.0-4.0 U/mL
Positive - Greater than 4.0 U/mL

Interpretive Data: 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.

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

New Test
Available Now

2014073 **HLA-DP Genotyping** **HLA-DP DNA**

Methodology: Polymerase Chain Reaction/Sequence Specific Oligonucleotide Probe Hybridization
Performed: Mon-Fri
Reported: 3-7 days

Specimen Required: Collect: Lavender (EDTA), Pink (K_2EDTA), or Yellow (ACD Solution A or B).
Specimen Preparation: Transport 5 mL whole blood. (Min: 3 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Green (Sodium or Lithium Heparin) tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:
Background Information for HLA-DP Genotyping:
Purpose: For immunization/vaccination trials or to aid the clinical diagnosis of diseases strongly associated with the HLA-DP locus.
Methodology: PCR followed by Sequence Specific Oligonucleotide Probe Hybridization of HLA-DP locus.
Analytical Sensitivity & Specificity: Medium to high resolution of HLA-DP locus.
Limitations: The presence of a disease-associated HLA combination does not establish a diagnosis. If fewer than 2 alleles are reported for a locus, the patient is likely homozygous. Rare diagnostic errors can occur due to primer or probe site mutations. This test is not sufficient for comprehensive HLA evaluation for clinical hematopoietic stem cell transplantation; for pre-transplant allele matching, consider HLA Class I (ABC) by Next Generation Sequencing (ARUP test code 2011264) and/or HLA Class II (*DRB1* and *DQB1*) by Next Generation Sequencing (ARUP test code 2011272). Occasionally the specific allele cannot be determined; in this case, the most likely allele assignment is made followed by a sequence of letters indicating other possible allele assignments. Interpretation of allele codes can be found at https://bioinformatics.bethematchclinical.org/hla/alpha.v3.html.

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

Note: Order this test for single antigen HLA-DP identification.

CPT Code(s): 81382

New York DOH approval pending. Call for status update.

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

New Test Available Now | 2014079 | **HLA-DQ Genotyping** | **HLADQ DNA**

Methodology: Polymerase Chain Reaction/Sequence Specific Oligonucleotide Probe Hybridization
Performed: Mon-Fri
Reported: 3-7 days

Specimen Required: Collect: Lavender (EDTA), Pink (K_2EDTA), or Yellow (ACD Solution A or B).
Specimen Preparation: Transport 5 mL whole blood. (Min: 3 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Green (sodium or lithium heparin) tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:
Background Information for HLA-DQ Genotyping:
Purpose: For immunization/vaccination trials or to aid the clinical diagnosis of diseases strongly associated with the HLA-DQ locus.
Methodology: PCR followed by Sequence Specific Oligonucleotide Probe Hybridization of HLA-DQ locus.
Analytical Sensitivity & Specificity: Medium to high resolution of HLA-DQ locus.
Limitations: The presence of a disease-associated HLA combination does not establish a diagnosis. If fewer than 2 alleles are reported for a locus, the patient is likely homozygous. Rare diagnostic errors can occur due to primer or probe site mutations. This test is not sufficient for comprehensive HLA evaluation for clinical hematopoietic stem cell transplantation; for pre-transplant allele matching, consider HLA Class I (ABC) by Next Generation Sequencing (ARUP test code 2011264) and/or HLA Class II (*DRB1* and *DQB1*) by Next Generation Sequencing (ARUP test code 2011272). Occasionally the specific allele cannot be determined; in this case, the most likely allele assignment is made followed by a sequence of letters indicating other possible allele assignments. Interpretation of allele codes can be found at https://bioinformatics.bethematchclinical.org/hla/alpha.v3.html.

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

Note: Order this test for single antigen HLA-DQ identification.

CPT Code(s): 81382

New York DOH approval pending. Call for status update.

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

2011942 | **Human Papillomavirus (HPV), High Risk by PCR, SurePath** | **SP HPV PCR**

Specimen Required: Collect: Cervical, anal or vaginal specimens with SurePath collection kit and place in SurePath media.
Specimen Preparation: Mix well. Transfer 3 mL to an ARUP Standard Transport Tube. (Min 1.5 mL)
Storage/Transport Temperature: Refrigerated.
Remarks: Specimen source required.
Unacceptable Conditions: Bloody or dark brown specimens. Specimens in any media other than indicated above.
Stability (collection to initiation of testing): Ambient: 1 month; Refrigerated: 6 months; Frozen: Unacceptable

Interpretive Data: This test amplifies DNA of 14 high-risk HPV types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) associated with cervical cancer and its precursor lesions. Sensitivity may be affected by specimen collection methods, stage of infection, and the presence of interfering substances. Results should be interpreted in conjunction with other available laboratory and clinical data. A negative high-risk HPV result does not exclude the presence of other high-risk HPV types, the possibility of future cytologic abnormalities, underlying CIN2-3, or cancer.

This test is intended for medical purposes only and is not valid for the evaluation of suspected sexual abuse or for other forensic purposes. HPV testing should not be used for screening or management of atypical squamous cells of undetermined significance (ASCUS) in women under age 21.

2011933 Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by PCR, SurePath — SP HPV1618

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

Specimen Required: Collect: Cervical specimen with SurePath collection kit and place in SurePath media.
Specimen Preparation: Mix well. Transfer 3 mL to an ARUP Standard Transport Tube. (Min 1.5 mL)
Storage/Transport Temperature: Refrigerated.
Remarks: Specimen source required.
Unacceptable Conditions: Bloody or dark brown specimens. Specimens in any media other than indicated above.
Stability (collection to initiation of testing): Ambient: 1 month; Refrigerated: 6 months; Frozen: Unacceptable

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

This test is intended for medical purposes only and is not valid for the evaluation of suspected sexual abuse or for other forensic purposes. HPV testing should not be used for screening or management of atypical squamous cells of undetermined significance (ASCUS) in women under age 21.

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

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

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

This test is intended for medical purposes only and is not valid for the evaluation of suspected sexual abuse or for other forensic purposes. HPV testing should not be used for screening or management of atypical squamous cells of undetermined significance (ASCUS) in women under age 21.

New Test
Available Now

2014056 IgA Deficiency (IgAD) Panel — IGAD PAN

Methodology: Quantitative Enzyme-Linked Immunosorbent Assay/Radial Immunodiffusion
Performed: Varies
Reported: 8-16 days

Specimen Required: Collect: Plain Red or Serum Separator Tube (SST).
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen.
Unacceptable Conditions: Lipemic specimens.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 2 weeks

Reference Interval: By report

CPT Code(s): 82784, 83520

New York DOH Approved.

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

0080403 **Indicans, Urine Qualitative** **INDICANS**

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

New Test
Available Now

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

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

Specimen Required: Collect: Serum Separator Tube (SST). Also acceptable: Lavender (EDTA) or Pink (K_2EDTA).
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transport 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.4 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Heparinized plasma, I.V. fluid, or Vitreous fluid. Gray (sodium fluoride/potassium oxalate). Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 1 month

Reference Interval: 180 minutes: 4-62 µIU/mL

Interpretive Data: This test reacts on a nearly equimolar basis with the analogs insulin aspart, insulin glargine, and insulin lispro. Insulin detemir exhibits approximately 50 percent cross-reactivity. Test reactivity with insulin glulisine is negligible (< 3 percent). To convert to pmol/L, multiply by 6.0. The reference interval is based on a 75 g glucose challenge.

CPT Code(s): 83525

New York DOH Approved.

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

2003390 **Interferon Beta Neutralizing Antibody with Reflex to Titer** **IFNB NEU R**

Performed: Mon
Reported: 1-15 days

New Test Available Now **2013993** **Interstitial Lung Disease Panel** **ILD PAN**

Additional Technical Information

Methodology: Qualitative Immunoprecipitation/Semi-Quantitative Multiplex Bead Assay/Qualitative Immunoblot/Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Quantitative Immunoturbidimetry
Performed: Mon, Tue, Thu, Fri
Reported: 7-15 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	**Components** / **Reference Interval** SSA 52 (Ro) (ENA) Antibody, IgG: 29 AU/mL or less: Negative; 30-40 AU/mL: Equivocal; 41 AU/mL or greater: Positive SSA 60 (Ro) (ENA) Antibody, IgG: 29 AU/mL or less: Negative; 30-40 AU/mL: Equivocal; 41 AU/mL or greater: Positive
0050599	Scleroderma (Scl-70) (ENA) Antibody	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) Antibody	Negative
	NXP-2 (Nuclear matrix protein-2 Ab)	Negative
0050465	Rheumatoid Factor	Negative
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
0050639	Nuclear Antibody (ANA) by IFA, IgG	Less than 1:40

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

CPT Code(s): 83516 x8; 86235 x5; 86200; 86431; 86039

New York DOH approval pending. Call for status update.

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

0099265 **Manganese, Serum** **MANG**

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

0099272 **Manganese, Whole Blood** **MANG WB**

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

0054440 **Measles (Rubeola) Antibody, IgG, CSF** **MEASLGCSF**

Specimen Required: Collect: CSF.
Specimen Preparation: Transfer 0.5 mL CSF to an ARUP Standard Transport Tube. (Min: 0.3 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen.
Unacceptable Conditions: Specimens other than CSF. Contaminated, heat-inactivated or hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: 2 weeks; Frozen: 1 year

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0054442 **Mumps Virus Antibody IgG, CSF** **MUMPSCSF**

Specimen Required: Collect: CSF.
Specimen Preparation: Transfer 0.5 mL CSF to an ARUP Standard Transport Tube. (Min: 0.3 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen.
Unacceptable Conditions: Specimens other than CSF. Contaminated, heat-inactivated or hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: 2 weeks; Frozen 1 year

New Test Available Now **2013961** **Myositis Extended Panel** **MYOS PAN**

Additional Technical Information

Methodology: Qualitative Immunoprecipitation/Semi-Quantitative Multiplex Bead Assay/Qualitative Immunoblot
Performed: Mon, Tue, Thu, Fri
Reported: 7-15 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
2012074	SSA 52 and 60 (Ro) (ENA) Antibodies, IgG	**Components** / **Reference Interval** SSA 52 (Ro) (ENA) Antibody, IgG: 29 AU/mL or less: Negative; 30-40 AU/mL: Equivocal; 41 AU/mL or greater: Positive SSA 60 (Ro) (ENA) Antibody, IgG: 29 AU/mL or less: Negative; 30-40 AU/mL: Equivocal; 41 AU/mL or greater: Positive
0050470	RNP (U1) (Ribonucleic Protein) (ENA) Antibody, IgG	29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive
0099592	Jo-1 Antibody, IgG	29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive
	Mi-2 (nuclear helicase protein) Antibody	Negative
	PL-7 (threonyl-tRNA synthetase) Antibody	Negative
	PL-12 (alanyl-tRNA synthetase) Antibody	Negative
	P155/140 (TIF1-gamma) Antibody	Negative
	EJ (glycyl-tRNA synthetase) Antibody	Negative
	Ku Antibody	Negative
	U2 sn (small nuclear) RNP Antibody	Negative
	SRP (Signal Recognition Particle) Ab	Negative
	OJ (isoleucyl-tRNA synthetase) Antibody	Negative
	SAE1 (SUMO activating enzyme) Antibody	Negative
	MDA5 (CADM-140) Antibody	Negative
	NXP-2 (Nuclear matrix protein-2) Ab	Negative
	TIF1-gamma (TIF1-y) Antibody	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, U2RNP, U1RNP, Ro52, Ro60, Jo-1, U3 Fib, SAE1, NXP2, MDA5, TIF1-gamma

CPT Code(s): 83516 x13; 86235 x6

New York DOH approval pending. Call for status update.

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

0099452 **Nickel, Serum** **NICKEL**

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

New Test Available Now **2013955** **Paraneoplastic Reflexive Panel** **PNS PAN**

Methodology: Semi-Quantitative Indirect Fluorescent Antibody/Qualitative Immunoblot
Performed: Wed
Reported: 1-9 days

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 3 mL serum aliquot to an ARUP Standard Transport Tube. (Min: 1.0 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Contaminated, heat-inactivated, hemolyzed, or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval:

Test Number	Components	Reference Interval
2013956	CV2.1 Screen by IFA with Reflex to Titer	

Components	Reference Interval
CV2.1 Antibody IgG Screen by IFA	Less than 1:10
CV2.1 Antibody IgG Titer by IFA	Less than 1:10

Test Number	Components	Reference Interval
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	None Detected

2008893	Amphiphysin Antibody, IgG	Negative

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

Note: Purkinje Cell (PCCA) antibody and Neuronal Nuclear (ANNA) antibody IgG are screened by IFA. If the IFA screen is indeterminate, then a Neuronal Nuclear Antibodies (Hu, Ri, and Yo) IgG by Immunoblot will be added. If the IFA screen is positive at 1:10 or greater, then a PCCA/ANNA antibodies titer and Neuronal Nuclear Antibodies (Hu, Ri, and Yo) IgG by Immunoblot will be added. Additional charges apply. If CV2.1 Antibody IgG Screen by IFA is positive, then CV2.1 Antibody IgG Titer by IFA will be added. Additional charges apply.

CPT Code(s): 86255 x2; 83516; if reflexed add 86256 and/or 83516; if reflexed add 86256

New York DOH approval pending. Call for status update.

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

New Test **2014107** **Poliovirus (Types 1, 3) Antibodies** **POLIO AB**

Methodology: Semi-Quantitative Serum Neutralization
Performed: Mon-Fri
Reported: 6-9 days

Specimen Required: Collect: Serum Separator Tube (SST) or Plain Red.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.2 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma. Contaminated, hemolyzed, or severely lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval:

Less than 1:10	No detectable poliovirus antibodies.
1:10 or greater	Antibody to poliovirus detected, which may represent prior immunization or current or past infection.

Interpretive Data:
The presence of neutralizing antibodies against poliovirus implies immunity. The serum neutralization test is serotype specific. Antibodies against one type does not indicate immunity against the other type.

Reference interval applies to Poliovirus Antibodies Types 1 and 3.

CPT Code(s): 86658 x2

New York DOH Approved.

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

New Test Available Now **2013992** **Polymyositis and Dermatomyositis Panel** **COMBI MYO**

Additional Technical Information

Methodology: Qualitative Immunoprecipitation/Semi-Quantitative Multiplex Bead Assay/Qualitative Immunoblot
Performed: Mon, Tue, Thu, Fri
Reported: 7-15 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) Antibody	Negative
	MDA5 (CADM-140) Antibody	Negative
	NXP-2 (Nuclear matrix protein-2) Ab	Negative
	TIF1-gamma (TIF1-y) Antibody	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 approval pending. Call for status update.

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

New Test Available Now **2013990** **Polymyositis Panel** **POLY MYO**

Additional Technical Information

Methodology: Qualitative Immunoprecipitation/Semi-Quantitative Multiplex Bead Assay
Performed: Mon, Tue, Thu, Fri
Reported: 7-15 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

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

Note: Antibodies: PL-7, PL12, EJ, OJ, SRP, Jo-1

CPT Code(s): 83516 x5; 86235

New York DOH approval pending. Call for status update.

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

New Test Available Now **2014041** **Potassium, RBC** **K RBC**

Methodology: Quantitative Inductively Coupled Plasma-Optical Emission Spectrometry
Performed: Varies
Reported: 3-10 days

Specimen Required: Collect: Green (Lithium Heparin).
Specimen Preparation: Separate cells within 2 hours of collection. Transfer 2 mL RBCs to a trace metal-free or acid-washed plastic container. (Min: 0.7 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen.
Unacceptable Conditions: Light blue (sodium citrate), gray (potassium oxalate) or yellow (ACD Solution).
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 1 month; Frozen: 1 month

Reference Interval: By Report

CPT Code(s): 84132

New York DOH Approved.

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

0020373 **Reducing Substances, Fecal** **FECRED**

Performed: Sun-Sat
Reported: 1-2 days

2012155 **Charcot-Marie-Tooth (CMT) and Related Hereditary Neuropathies, *PMP22* Deletion/Duplication with Reflex to Sequencing Panel** **CMT REFLEX**

Performed: Varies
Reported: Within 2 weeks
If reflexed, add 56-70 days

Note: Deletion/Duplication analysis is performed on all samples. If no large deletions or duplications are detected and/or results do not explain the clinical scenario, then sequencing of the Charcot-Marie-Tooth and Related Hereditary Neuropathy gene will be added. Additional charges apply. If reflexed, an additional 8-10 weeks is required to complete testing.

78 Genes sequenced: *AARS, AIFM1, ARHGEF10, ATL1, ATP7A, BAG3, BICD2, BSCL2, CCT5, DCTN1, DHTKD1, DNAJB2, DNM2, DNMT1, DYNC1H1, EGR2, FAM134B, FBLN5, FGD4, FIG4, GAN, GARS, GDAP1, GJB1, GNB4, HARS, HEXA, HINT1, HK1, HOXD10, HSPB1, HSPB3, HSPB8, IGHMBP2, IKBKAP, INF2, KARS, KIF1A, KIF1B, KIF5A, LAS1L, LITAF, LMNA, LRSAM1, MARS, MED25, MFN2, MPZ, MTMR2, MYH14, NDRG1, NEFL, NGF, NTRK1, PDK3, PLEKHG5, PMP22, PRNP, PRPS1, PRX, RAB7A, REEP1, SBF1, SBF2, SCN9A, SETX, SH3TC2, SLC12A6, SLC5A7, SOX10, SPTLC1, SPTLC2, TDP1, TFG, TRIM2, TRPV4, WNK1, YARS.*

2009298 **Tay-Sachs Disease (*HEXA*) Sequencing and 7.6kb Deletion** **HEXA FGS**

Methodology: Polymerase Chain Reaction/Sequencing/Gel Electrophoresis

New Test Available Now | 0013410 | **Thermal Amplitude Test** | **IRL-THERM**

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

Specimen Required: Collect: Lavender (EDTA) or Pink (K_2 EDTA) **AND** Plain Red.
Specimen Preparation: Maintain at 37°C until separated from cells. Transport 7 mL red blood cells and 5 mL plasma or serum in ARUP Standard Transport Tubes. (Min: 7 mL red blood cells and 3 mL plasma or serum)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Separator or Gel Tubes.
Stability (collection to initiation of testing): Ambient: 72 hours, Refrigerated: 1 week, Frozen: Unacceptable

CPT Code(s): 86870

New York DOH Approved.

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

0051690 | **Transforming Growth Factor beta, Plasma** | **TGFB PLA**

Performed: Tue
Reported: 1-8 days

0051694 | **Transforming Growth Factor beta, Serum** | **TGFB SER**

Performed: Tue
Reported: 1-8 days

0090307 | **Tricyclic Antidepressant Detection** | **S TAD**

Interpretive Data: This test is positive when the total concentration of all detectable tricyclic antidepressants produces a response greater than the cutoff of 300 ng/mL nortriptyline. This is a screening test, results are unconfirmed. Unconfirmed results are to be used for medical (treatment) purposes only. Tricyclic antidepressants detectable with this assay include: amitriptyline, clomipramine, desipramine, doxepin, imipramine, nortriptyline, protriptyline, and trimipramine.

Levels of tricyclic antidepressants in the therapeutic range may not be detectable.

False-positive results may occur with the following drugs: Seroquel (quetiapine fumarate), Trileptal (oxcarbazepine), Benadryl (diphenhydramine) at toxic concentrations, Flexeril (cyclobenzaprine), Thioridazine, and Thorazine (chlorpromazine).

New Test 2014025 **Trypsin** **TRYPS**
Available Now

Methodology: Quantitative Radioimmunoassay
Performed: Tue, Fri
Reported: 1-5 days

Specimen Required: Collect: Serum Separator Tube (SST) or Plain Red.
Specimen Preparation: Allow specimen to clot for 15-20 minutes at room temperature. Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.3 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Plasma. Grossly hemolyzed or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 2 hours; Refrigerated: 24 hours; Frozen: 3 months

Reference Interval:

Age	Reference Interval
0 -17 years	Not established
18 years and older	180.5-885.3 ng/mL

Interpretive Data: Results should be correlated with clinical presentation and other diagnostic data for the diagnosis of pancreatitis. Individuals with acute pancreatitis have significantly elevated trypsin concentrations. Concentrations in those with chronic pancreatitis are variable and may be below, within, or above the reference interval. Trypsin concentrations are not diagnostic for carcinoma of the pancreas. Results obtained with different assay methods or kits cannot be used interchangeably.

CPT Code(s): 83519

New York DOH approval pending. Call for status update.

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

2001181 **UroVysion FISH** **UF REQUEST**

Specimen Required: Collect: Second-morning, clean-catch voided urine specimen in UroVysion FISH Collection Kit (ARUP Supply #41440) available online through eSupply using ARUP Connector contact Client Services at (800) 522-2787. For specific instructions refer to Specimen Collection & Handling.
Specimen Preparation: Transport the entire collection in the original collection kit. (Min: 35 mL)
Storage/Transport Temperature: Refrigerated.
Remarks: Submit source information with the specimen.
Unacceptable Conditions: Specimens in inappropriate fixative. Specimens submitted in expired reagents.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 72 hours; Frozen: Unacceptable

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

Specimen Required: Collect: CSF.
Specimen Preparation: Transfer 0.5 mL CSF to an ARUP Standard Transport Tube. (Min: 0.3 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen.
Unacceptable Conditions: Specimens other than CSF. Contaminated, heat-inactivated or hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: 2 weeks; Frozen: 1 year

0080388 **Vitamin B_1 (Thiamine), Whole Blood** **VIT B1 WB**

Specimen Required: Collect: Green (Sodium or Lithium Heparin), Lavender (EDTA), or Pink (K_2EDTA).
Specimen Preparation: Transfer 3 mL whole blood to an ARUP Standard Tube. (Min: 0.6 mL)
Storage/Transport Temperature: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**
Unacceptable Conditions: Any specimen other than whole blood. Plasma separator tubes. Glass tubes. Clotted or non-frozen specimens.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 4 hours; Frozen: 6 months

New Test 2013701 **Vulvovaginal *Candida* Species by PCR** **VCANPCR**

Methodology: Qualitative Polymerase Chain Reaction
Performed: Mon, Thu
Reported: 2-5 days

Specimen Required: Collect: Vaginal specimen with APTIMA Unisex Swab Specimen Collection kit (ARUP supply #28907). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Specimen Preparation: Place blue swab in Swab Specimen Transport Tube, break off shaft at scoreline then recap tube.
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Heparinized specimens.
Stability (collection to initiation of testing): Ambient: 2 months; Refrigerated: 2 months; Frozen: 2 months

Interpretive Data: Low positive results are reported as Equivocal. Low levels of *Candida* species can be found in asymptomatic women. A cutoff for low positive results for this test was determined in a study of asymptomatic women.

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

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

Note: This test detects and differentiates *C. albicans*, *C. glabrata*, *C. parapsilosis* complex (*C. parapsilosis*, *C. orthopsilosis*, *C. metapsilosis*), *C. tropicalis*, *C. krusei*, and *C. dubliniensis.*

CPT Code(s): 87481 x6

New York DOH approval pending. Call for status update.

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

New Test Available Now | 2014065 | **Zika Virus by PCR, Blood** | **ZIKAPCR B**

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

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells. Transfer 2 mL serum to a sterile container. (Min: 1 mL)
Storage/Transport Temperature: Frozen.
Remarks: Specimen source required.
Unacceptable Conditions: Urine (refer to Zika Virus by PCR, Urine, ARUP test code 2014069).
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 5 days; Frozen: 6 weeks

Interpretive Data:

Zika Virus by PCR is a real-time RT-PCR test intended for the qualitative detection of Zika virus RNA from individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated).

A positive RT-PCR result confirms Zika virus infection, and no additional testing is indicated. When test results are negative, the serum should be tested as outlined in the current CDC-issued algorithm (http://www.cdc.gov/zika/laboratories/lab-guidance.html).

If serologic testing is needed as a follow-up to PCR, contact ARUP client services to order Zika Virus IgM Antibody Capture (MAC), by ELISA (ARUP test code 2013942). Additional charges apply.

The Zika Virus by PCR test is for in vitro diagnostic use under the FDA Emergency Use Authorization (EUA). This test 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.

CPT Code(s): 87798

New York DOH Approved.

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

New Test Available Now | 2014069 | **Zika Virus by PCR, Urine** | **ZIKAPCR U**

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

Specimen Required: Collect: Urine and patient-matched Serum Separator Tube (SST).
Specimen Preparation: **Urine:** Transfer 1 mL urine to a sterile container. (Min: 0.5 mL)
Serum: Collect and retain 2 mL of patient-matched serum at the client site in the event that serological follow-up testing is needed. (Min: 1 mL)
Storage/Transport Temperature: Frozen.
Remarks: Specimen source required.
Unacceptable Conditions: Serum (refer to Zika Virus by PCR, Blood, ARUP test code 2014065).
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 5 days; Frozen: 6 weeks

Interpretive Data:

Zika Virus by PCR is a real-time RT-PCR test intended for the qualitative detection of Zika virus RNA from individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated).

Health care providers are strongly encouraged to collect serum specimens alongside other specimen types to provide additional opportunities for diagnosing Zika. A positive RT-PCR result confirms Zika virus infection, and no additional testing is indicated. When test results are negative for urine, the patient-matched serum should be tested as outlined in the current CDC-issued algorithm (http://www.cdc.gov/zika/laboratories/lab-guidance.html).

If serologic testing is needed on a patient-matched serum specimen, contact ARUP client services to order Zika Virus IgM Antibody Capture (MAC), by ELISA (ARUP test code 2013942). Additional charges apply.

The Zika Virus by PCR test is for in vitro diagnostic use under the FDA Emergency Use Authorization (EUA). This test 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.

CPT Code(s): 87798

New York DOH Approved.

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

New Test Available Now | 2013942 | **Zika Virus IgM Antibody Capture (MAC), by ELISA** | **ZIKA M**

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay
Performed: Mon, Wed, Fri
Reported: 1-6 days

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: 1.0 mL) Parallel testing is preferred and convalescent specimens **must** be received within 30 days from receipt of the acute specimens. **Mark specimen plainly as "acute or convalescent."**
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Contaminated, heat-inactivated, hemolyzed, or severely lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval: Negative

Interpretive Data: The ZIKV Detect IgM Capture ELISA assay is intended for in vitro diagnostic use under FDA Emergency Use Authorization (EUA). This test 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/.

CPT Code(s): 86790

New York DOH approval pending. Call for status update.

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

Quarterly HOTLINE: Effective February 21, 2017

The following will be discontinued from ARUP's test menu on February 21, 2017.
Replacement test options are supplied if applicable.

Test Number	Test Name	Refer To Replacement
2005548	Chromium, Joint Fluid	
2005549	Cobalt, Joint Fluid	
0091349	Disulfiram (Antabuse) and Metabolite Quantitation, Serum or Plasma	
2003259	Enterovirus Antibody Panel	Enterovirus Antibodies Panel (2014108)
2003917	Hepatitis B Surface Antigen by Immunohistochemistry	
2002810	HLA-DQB Genotyping	HLA-DQ Genotyping (2014079) and/or HLA-DP Genotyping (2014073)
0080570	Lipoprotein Electrophoresis with Qualitative Band Assessment	
0080108	Maternal Serum Screen, Alpha Fetoprotein, hCG, and Estriol	Maternal Serum Screen, Alpha Fetoprotein, hCG, Estriol, and Inhibin A (0080269)
2005528	Metals, Joint Fluid	
2010851	Myositis Antibody Comprehensive Panel	Myositis Extended Panel (2013961) or Polymyositis and Dermatomyositis Panel (2013992)
2010862	Myositis-Specific Antibody Panel	Polymyositis Panel (2013990), Dermatomyositis Panel (2013991), and Polymyositis and Dermatomyositis Panel (2013992)
0060054	Poliovirus Antibodies	Poliovirus (Types 1, 3) Antibodies (2014107)
0099132	Rabies Antibody, IgG (Vaccine Response)	
2005933	Special Stain, Fibrin	
2005951	Special Stain, Gridleys	
2005969	Special Stain, Methyl Green Pyronin (MPG)	
2005975	Special Stain, Nissl Substance	