Quarterly HOTLINE: Effective February 20, 2018

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
51	0091322	Acetophenazine, Serum or Plasma												x
6	3000182	ADAMTS13 Antibody											x	
7	3000228	ADAMTS13 Inhibitor											x	
8	3000239	ADAMTS13 Reflex Panel											x	
51	0080427	Alpha Fetoprotein (Amniotic Fluid) with Reflex to Acetylcholinesterase and Fetal Hemoglobin												x
9	3000142	Alpha Fetoprotein (Amniotic Fluid) with Reflex to Acetylcholinesterase and Fetal Hemoglobin											x	
9	2014513	Alpha/Beta Double-Negative T-Cells for Autoimmune Lymphoproliferative Syndrome								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
51	0090978	Amobarbital, Serum or Plasma												x
9	0098771	Angiotensin II, Plasma		x		x								
51	0090601	Antidepressant Panel Quantitative, Serum or Plasma												x
10	0060203	Antimicrobial Susceptibility - MBC	x						x					
10	3000265	*Aspergillus Species* by PCR											x	
51	0091317	Atenolol Quantitative, Serum or Plasma												x
10	2002464	Bence Jones Protein, Quantitation and Characterization, with Reflex to Kappa/Lambda Free Light Chains with Ratio, Urine				x								
51	0050626	Blastomyces Antibodies by CF and ID												x
51	0050130	Blastomyces Antibody by CF												x
11	3000231	*Blastomyces dermatitidis* Antibodies by EIA with Reflex to Immunodiffusion, CSF											x	
12	3000236	*Blastomyces dermatitidis* Antibodies by EIA with Reflex to Immunodiffusion, Serum											x	
12	0049003	Blood Smear - with Interpretation				x								
13	2001774	*Bordetella pertussis* Antibodies, IgA and IgG by ELISA with Reflex to Immunoblot					x		x			x		
14	2001775	*Bordetella pertussis* Antibodies, IgA, IgG, and IgM by ELISA with Reflex to Immunoblot					x		x			x		
15	2001784	*Bordetella pertussis* Antibodies, IgG and IgM by ELISA with Reflex to Immunoblot					x		x			x		
15	2005268	*Bordetella pertussis* Antibody, IgG by ELISA					x	x				x		
16	2001768	*Bordetella pertussis* Antibody, IgG by ELISA with Reflex to Immunoblot					x	x	x			x		
16	2001769	*Bordetella pertussis* Antibody, IgM by ELISA with Reflex to Immunoblot					x		x			x		
51	0090045	Butalbital												x
16	0090260	Carbamazepine, Total					x							
17	2011164	*Chlamydia trachomatis* and *Neisseria gonorrhoeae* (CTNG) by Transcription-Mediated Amplification (TMA) with Reflex to CT/NG Confirmation (Pricing Change)	x		x			x	x	x		x		
17	0098457	Chylomicron Screen, Body Fluid				x								
51	0091337	Cimetidine, Serum or Plasma												x
17	0095229	Cystatin C, Serum with Reflex to Estimated Glomerular Filtration Rate (eGFR)	x				x		x			x		
18	2013661	Cystic Fibrosis (*CFTR*) 165 Pathogenic Variants						x	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
18	2013663	Cystic Fibrosis (*CFTR*) 165 Pathogenic Variants with Reflex to Sequencing						x	x					
19	2013664	Cystic Fibrosis (*CFTR*) 165 Pathogenic Variants with Reflex to Sequencing and Reflex to Deletion/Duplication						x	x					
20	2013662	Cystic Fibrosis (*CFTR*) 165 Pathogenic Variants, Fetal				x		x	x					
20	2000624	Cytology, Pap Smear									x			
20	2000134	Cytology, SurePath Liquid-Based Pap Test									x			
21	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			
21	2000135	Cytology, SurePath Liquid-Based Pap Test with Reflex to Human Papillomavirus (HPV), High Risk by PCR, SurePath									x			
21	2000137	Cytology, ThinPrep Pap Test									x			
21	2000136	Cytology, ThinPrep Pap Test and Human Papillomavirus (HPV), High Risk by Transcription-Mediated Amplification (TMA) (for routine co-testing in women over 30)									x			
21	2000138	Cytology, ThinPrep Pap Test with Reflex to Human Papillomavirus (HPV), High Risk, E6/E7 mRNA by Transcription-Mediated Amplification (TMA)									x			
22	2006621	Drug Detection Panel, Umbilical Cord Tissue, Qualitative		x		x		x	x		x			
22	0090499	Drug Screen (Nonforensic), Serum			x			x	x					
22	0090500	Drug Screen (Nonforensic), Urine, Qualitative			x			x						
23	0090120	Ethanol, Serum or Plasma - Medical		x		x								
51	2011501	Ethotoin, Serum or Plasma												x
23	2007909	Ethyl Glucuronide and Ethyl Sulfate, Urine, Quantitative			x									
23	2001743	Fetal Hemoglobin Determination for Fetomaternal Hemorrhage						x			x			
51	2003887	Friend Leukemia Integration-1 (Fli-1) by Immunohistochemistry												x
51	0050750	Fungal Antibodies by CF, CSF												x
51	0050605	Fungal Antibodies by CF, Serum												x
24	3000235	Fungal Antibodies with Reflex to *Blastomyces dermatitidis* Antibodies by Immunodiffusion											x	
25	3000230	Fungal Antibodies with Reflex to *Blastomyces dermatitidis* Antibodies by Immunodiffusion, CSF											x	

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25	2012227	Gabapentin, Urine						x						
25	2004998	Ganglioside (GM1, GD1b, and GQ1b) Antibodies, IgG and IgM			x									
26	3000101	Herpes Simplex Virus (HSV) Types I/II by Immunohistochemistry											x	
26	0051654	HNPCC/Lynch Syndrome (*MSH2)* Sequencing and Deletion/Duplication					x	x						
27	2008863	Holoprosencephaly Panel, Nonsyndromic, Sequencing and Deletion/Duplication, 11 Genes, Fetal											x	
28	3000202	5-Hydroxyindoleacetic acid (5-HIAA), Plasma											x	
51	2004593	India Ink Stain												x
28	0050618	Kappa and Lambda Free Light Chains (Bence Jones Protein), Quantitative, Urine				x								
28	0050689	Kappa Free Light Chains (Bence Jones Protein), Quantitative, Urine				x								
28	0050682	Lambda Free Light Chains (Bence Jones Protein), Quantitative, Urine				x								
29	2013716	LipoFit by NMR				x								
29	2013715	LipoFit by NMR, Particle Count Only				x								
29	0020038	Lithium, Serum or Plasma					x							
30	0095862	Lymphocyte Subset Panel 6 - Total Lymphocyte Enumeration with CD45RA and CD45RO					x							
31	0095899	Lymphocyte Subset Panel 7 - Congenital Immunodeficiencies					x							
32	0095949	Lymphocyte Transplantation CD3				x	x			x	x			
51	0095798	Lymphocyte Transplantation Profile												x
51	0090662	Maprotiline Quantitative, Serum or Plasma												x
33	3000256	Marijuana Metabolite, Umbilical Cord Tissue, Qualitative											x	
51	0081293	Maternal Screening, Sequential, Specimen #1												x
34	3000146	Maternal Screening, Sequential, Specimen #1, hCG, PAPP-A, NT											x	
51	0081294	Maternal Screening, Sequential, Specimen #2												x
35	3000148	Maternal Screening, Sequential, Specimen #2, Alpha Fetoprotein, hCG, Estriol, and Inhibin A											x	
36	3000144	Maternal Serum Screen, Alpha Fetoprotein											x	
51	0080434	Maternal Serum Screen, Alpha Fetoprotein (Only)												x
51	0080269	Maternal Serum Screen, Alpha Fetoprotein, hCG, Estriol, and Inhibin A												x

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37	3000143	Maternal Serum Screen, Alpha Fetoprotein, hCG, Estriol, and Inhibin A (Quad)											x	
51	0081150	Maternal Serum Screen, First Trimester												x
38	3000145	Maternal Serum Screen, First Trimester, hCG, PAPP-A, NT											x	
51	0081062	Maternal Serum Screening, Integrated, Specimen #1												x
39	3000147	Maternal Serum Screening, Integrated, Specimen #1, PAPP-A, NT											x	
51	0081064	Maternal Serum Screening, Integrated, Specimen #2												x
40	3000149	Maternal Serum Screening, Integrated, Specimen #2, Alpha Fetoprotein, hCG, Estriol, and Inhibin A											x	
40	3000248	Meperidine and Metabolite Quantitative, Urine											x	
51	2002756	Meperidine and Metabolite, Serum or Plasma, Quantitative												x
51	2002760	Meperidine and Metabolite, Urine, Quantitative												x
41	2012288	Meperidine, Urine Screen with Reflex to Quantitation		x					x			x		
51	0091248	Mercury, Nails												x
51	2011531	Methsuximide and Normethsuximide, Serum or Plasma												x
41	3000251	Methsuximide Metabolite, Serum or Plasma											x	
41	3000253	Methylphenidate and Metabolite Quantitative, Serum or Plasma											x	
51	2003114	Methylphenidate and Metabolite, Serum or Plasma, Quantitative												x
42	2012420	Muscle-Specific Kinase (MuSK) Antibody by RIA	x		x	x								
42	3000221	Neurokinin A (Substance K), Plasma											x	
43	2010769	Noonan Spectrum Disorders Panel, Sequencing, 15 Genes, Fetal											x	
51	0091387	Oxazepam Quantitative, Serum or Plasma												x
43	2012312	Pain Management Panel, Screen with Reflex to Quantitation							x			x		
44	3000003	Parathyroid Hormone (PTH) Antibody											x	
44	2013284	PD-L1 22C3 IHC for NSCLC with Interpretation, pembrolizumab (KEYTRUDA)	x			x								
51	0091522	Pentazocine Quantitation, Serum or Plasma												x
51	0091456	Phenazopyridine, Urine												x
51	0091491	Piroxicam (Feldene), Serum or Plasma												x
44	2012229	Pregabalin, Urine						x						

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51	2010248	Prosigna Breast Cancer Prognostic Gene Signature												x
45	3000219	Prostaglandin D2 (PG D2), Serum or Plasma											x	
45	3000240	Prostaglandin D2 (PG D2), Urine											x	
45	0091539	Silicon Quantitative, Serum or Plasma			x	x								
51	0099528	ssDNA Antibody, IgG												x
46	0092066	Thiopurine Methyltransferase, RBC			x									
47	2006385	Thrombotic Risk Reflexive Panel											x	
49	3000005	*Trichinella* Antibody, IgG											x	
51	0091107	Trimipramine and Metabolite Quantitative, Serum or Plasma												x
49	0051076	*Trypanosoma cruzi* Antibody, IgG					x					x		
51	2005766	WT1 Mutation Detection by Sequencing												x
50	2006352	X-Chromosome Inactivation Analysis						x						

New Test Available Now **3000182** **ADAMTS13 Antibody** **ADAMTS AB**

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

Specimen Required: Patient Prep: Draw specimen prior to plasma exchange therapy.
Collect: Light Blue (Sodium Citrate). Refer to Specimen Handling at aruplab.com for hemostasis/thrombosis specimen handling guidelines.
Specimen Preparation: Transfer 1 mL platelet-poor plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**
Unacceptable Conditions: Serum or EDTA plasma. Clotted or hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 2 hours; Refrigerated: Unacceptable; Frozen: 2 weeks (No freeze/thaw cycles.)

Reference Interval:
Negative: Less than 12 U/mL
Borderline: 12-15 U/mL
Positive: Greater than 15 U/mL

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

CPT Code(s): 83520
New York DOH approval pending. Call for status update.

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

New Test Available Now | **3000228** | **ADAMTS13 Inhibitor** | **ADAMTS IN**

Methodology: Quantitative Enzyme-Linked Immunosorbent Assay
Performed: Sun-Sat
Reported: 1-3 days

Specimen Required: Collect: Light Blue (Sodium Citrate). Refer to Specimen Handling at aruplab.com for hemostasis/thrombosis specimen handling guidelines.
Specimen Preparation: Transfer 1 mL platelet-poor plasma to an ARUP Standard Transport Tube. (Min: 1 mL)
Storage/Transport Temperature: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**
Unacceptable Conditions: Serum or EDTA plasma. Clotted or hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 2 hours; Refrigerated: Unacceptable; Frozen: 2 weeks (No freeze/thaw cycles.)

Reference Interval:
0.4 BU (Bethesda Units) or less

Interpretive Data: The majority of cases of idiopathic thrombotic thrombocytopenic purpura (TTP) are caused by ADAMTS13 autoantibodies. Autoantibodies that neutralize ADAMTS13 function are found in approximately two-thirds of idiopathic cases and can be identified and titered by the ADAMTS13 inhibitor test. Non-neutralizing autoantibodies that result in increased ADAMTS13 clearance, but do not inhibit function, are found in approximately one-third of idiopathic TTP cases. Non-neutralizing antibodies are not detected in the inhibitor test but can be detected by ELISA (ADAMTS13 antibody test). ADAMTS13 autoantibodies are not present in congenital TTP (Upshaw-Schulman syndrome). Correlation with clinical information, ADAMTS13 activity, and other relevant laboratory testing is suggested.

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

CPT Code(s): 85335

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 **3000239** **ADAMTS13 Reflex Panel** **ADAMTS PAN**

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

Specimen Required: Collect Light Blue (Sodium Citrate). Refer to Specimen Handling at aruplab.com for hemostasis/thrombosis specimen handling guidelines.
Specimen Preparation: Transfer 3 mL platelet-poor plasma to an ARUP Standard Transport Tube. (Min: 2 mL)
Storage/Transport Temperature: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**
Unacceptable Conditions: Serum, or EDTA plasma. Clotted or hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 2 hours; Refrigerated: Unacceptable; Frozen: 2 weeks (No freeze/thaw cycles.)

Reference Interval:

Test Number	Components	Reference Interval
0030056	ADAMTS 13	Greater than 60 percent

Interpretive Data: Refer to report.

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

Note: If ADAMTS13 Activity is less than or equal to 30 percent, then ADAMTS13 Inhibitor will be added. If ADAMTS13 Inhibitor is less than 0.7 BU, then ADAMTS13 Antibody will be added. Additional charges apply.

CPT Code(s): 85397, if reflexed, add, 85335, if reflexed, add 83520

New York DOH approval pending. Call for status update.

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

New Test **3000142** **Alpha Fetoprotein (Amniotic Fluid) with Reflex to Acetylcholinesterase and Fetal Hemoglobin** **AF AFP**

Patient History for Prenatal Cytogenetics

Methodology: Quantitative Chemiluminescent Immunoassay/Electrophoresis
Performed: Sun-Sat
Reported: 3-4 days
Reflex: 3-11 days

Specimen Required: Patient Prep: Amniocentesis. Specimen must be drawn between 13 weeks, 0 days and 36 weeks, 6 days gestation.
Collect: Amniotic fluid.
Specimen Preparation: Transport 2.5 mL amniotic fluid. (Min: 1.5 mL)
Storage/Transport Temperature: Room temperature.
Remarks: **Submit with Order:** Gestational age at time of collection or estimated due date.
Unacceptable Conditions: Specimens contaminated with fetal blood.
Stability (collection to initiation of testing): Ambient: 1 month; Refrigerated: 3 months; Frozen: 3 months

Reference Interval:

Test Number	Components	Reference Interval
	AFP, Amniotic Fluid	By report Ranges are based upon the weeks of gestation.
2006848	Acetylcholinesterase and Fetal Hemoglobin, Amniotic Fluid	Acetylcholinesterase: Negative Fetal Hemoglobin: Negative
	Multiple of Median	1.99 or less

Interpretive Data: Refer to report.

Note: Information must include weeks of gestation. If the AFP (amniotic fluid) is elevated, then Acetylcholinesterase will be added. Additional charges apply. Acetylcholinesterase testing requires an additional 3-11 days to be reported.

CPT Code(s): 82106; if reflexed, add 82013 and 83033

New York DOH Approved.

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

2014513 **Alpha/Beta Double-Negative T-Cells for Autoimmune Lymphoproliferative Syndrome** **ALPS ABDNT**

CPT Code(s): 86356 x2

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

Methodology: Quantitative Radioimmunoassay

Specimen Required: Collect: Lavender (EDTA).
Specimen Preparation: Transfer 1 mL plasma to an ARUP Standard Transport Tube. (Min: 0.3 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 12 hours; Refrigerated: 24 hours; Frozen: 28 days

0060203 Antimicrobial Susceptibility - MBC — MA MBC

Note: The MBC is defined as the lowest concentration of an antimicrobial agent needed to kill 99.9 percent of the initial organism inoculum. Presently, specific guidelines for interpretation are not available; therefore, a clinician knowledgeable in both bactericidal testing and infectious diseases should be consulted to interpret the results.

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

For serious infections with coagulase-negative staphylococci, testing for oxacillin resistance will be performed in order to interpret the results for beta-lactam agents.

This test must be ordered for each antimicrobial agent tested.

The minimum turnaround time is 48 hours for nonfastidious, rapidly growing organisms and greater than or equal to 96 hours for fastidious, slow growing organisms.

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

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

New Test 3000265 *Aspergillus Species* by PCR — ASPERPCR

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

Specimen Required: Collect: Bronchoalveolar lavage (BAL), bronchial wash, sputum, or tissue.
Specimen Preparation: Transfer 1 mL bronchoalveolar lavage (BAL), bronchial wash, sputum to a sterile container. (Min: 0.9 mL)
Tissue: Transfer tissue to a sterile container and freeze immediately.
Storage/Transport Temperature: Frozen.
Remarks: Specimen source required.
Stability (collection to initiation of testing): **Tissue:** Ambient: Unacceptable; Refrigerated: 2 weeks; Frozen: 2 weeks
All Others: Ambient: 2 weeks; Refrigerated: 2 weeks; Frozen: 2 weeks

Interpretive Data: This test uses two probes to detect the most-common *Aspergillus* spp. and to differentiate *A. fumigatus*.

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

CPT Code(s): 87798

New York DOH approval pending. Call for status update.

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

2002464 Bence Jones Protein, Quantitation and Characterization, with Reflex to Kappa/Lambda Free Light Chains with Ratio, Urine — BJP-U REFLEX

Specimen Required: Collect: 24-hour urine. Refrigerate during collection. Also acceptable: Random urine specimens and urine supernate.
Specimen Preparation: Transfer two 4 mL aliquots from well-mixed 24 hour collection to individual ARUP Standard Transport Tubes. (Min: 4 mL)
Storage/Transport Temperature: Refrigerated.
Remarks: **Record total volume and collection time interval on transport tube and test request form.**
Unacceptable Conditions: Non-refrigerated specimens.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 1 month

New Test **3000231** ***Blastomyces dermatitidis* Antibodies by EIA with Reflex to Immunodiffusion, CSF** **BLST R CSF**

Available Now

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Qualitative Immunodiffusion
Performed: Sun-Sat
Reported: 2-5 days

Specimen Required: Collect: CSF.
Specimen Preparation: Transfer 1 mL CSF to an ARUP Standard Transport Tube. (Min: 0.15 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Other body fluids. Contaminated, hemolyzed, xanthochromic, or severely lipemic specimens.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval
3000230	Fungal Antibodies with Reflex to Blastomyces dermatitidis Antibodies by Immunodiffusion, CSF	0.9 IV or less: Negative 1.0-1.4 IV: Equivocal 1.5 IV or greater: Positive
	Blastomyces Ab by Immunodiffusion, CSF	None Detected

Interpretive Data: **Refer to Report**

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

Note: Negative fungal serology does not rule out the possibility of current infection. If *Blastomyces* antibodies are equivocal or positive by EIA then *Blastomyces* Immunodiffusion will be added. Additional charges apply.

CPT Code(s): 86612; if reflexed, add 86612

New York DOH approval pending. Call for status update.

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

New Test **3000236** ***Blastomyces dermatitidis* Antibodies by EIA with Reflex to Immunodiffusion, Serum** **BLST R SER**

Available Now

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Qualitative Immunodiffusion
Performed: Sun-Sat
Reported: 2-5 days

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.25 mL) Parallel testing is preferred and convalescent specimens **must** be received within 30 days from receipt of the acute specimens.
Storage/Transport Temperature: Refrigerated.
Remarks: **Mark specimens plainly as acute or convalescent.**
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
3000235	Fungal Antibodies with Reflex to Blastomyces dermatitidis Antibodies by Immunodiffusion	0.9 IV or less: Negative 1.0-1.4 IV: Equivocal 1.5 IV or greater: Positive
0050172	*Blastomyces* dermatitidis Abs Immunodifsn	None Detected

Interpretive Data: Refer to report.

Note: Negative fungal serology does not rule out the possibility of current infection. If *Blastomyces* antibodies are equivocal or positive by EIA then *Blastomyces* Immunodiffusion will be added. Additional charges apply.

CPT Code(s): 86612; if reflexed, add 86612

New York DOH Approved.

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

0049003 **Blood Smear - with Interpretation** **SMR INTERP**

Specimen Required: Collect: Lavender (EDTA) or Green (Sodium or Lithium Heparin). Immediately invert tube several times following procurement of whole blood.
Specimen Preparation: Transport 5 mL whole blood and 6 unfixed push smears. (Min: 0.1 mL whole blood and 2 unfixed push smears)
Storage/Transport Temperature: Room temperature.
Remarks: **Most recent CBC report, patient history, clinical indications and physician's name and telephone number are required.**
An instructional video with more information on how to make an adequate slide can be found at:
<https://www.youtube.com/watch?v=ca3NwrlpS40&feature=youtu.be>
Unacceptable Conditions: Serum or Plasma
Stability (collection to initiation of testing): **Whole Blood:** Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Unacceptable
Unfixed Push Smears: Ambient: 5 days; Refrigerated: 5 days; Frozen: Unacceptable

2001774 ***Bordetella pertussis* Antibodies, IgA and IgG by ELISA with Reflex to Immunoblot** **BORDPAN2**

Reference Interval:

Test Number	Components	Reference Interval			
	Bordetella pertussis Antibody, IgA by ELISA with Reflex to Immunoblot	**Test Number**	**Components**	**Reference Interval**	
			Bordetella pertussis Antibody, IgA by ELISA	Effective February 20, 2018	
				0.9 IV or less	Negative - No significant level of detectable *B. pertussis* IgA antibody.
				1.0-1.1 IV	Equivocal - Repeat testing in 10-14 days may be helpful.
				1.2 IV or greater:	Positive - IgA antibody to *B. pertussis* detected, which may indicate a current or past exposure/immunization to *B. pertussis.*
		2004316	*Bordetella pertussis* Antibody, IgA by Immunoblot	Negative	
2001768	*Bordetella pertussis* Antibody, IgG by ELISA with Reflex to Immunoblot	**Test Number**	**Components**	**Reference Interval**	
			Bordetella pertussis Antibody IgG by ELISA	Effective February 20, 2018	
				0.94 IV or less	Negative – No significant level of detectable *B. pertussis* IgG antibody.
				0.95-1.04 IV	Equivocal – Repeat testing in 10-14 days may be helpful.
				1.05 IV or greater	Positive – IgG antibody to *B. pertussis* detected, which may indicate a current or recent exposure/immunization to *B. pertussis*.
		2004327	*Bordetella pertussis* Antibody, IgG by Immunoblot	Refer to report	

Note: If *Bordetella pertussis* Antibody, IgA by ELISA is 1.2 IV or greater, then *Bordetella pertussis* IgA Immunoblot testing will be added; if *Bordetella pertussis* Antibody, IgG by ELISA is 1.05 IV or greater, then *Bordetella pertussis* IgG Immunoblot testing will be added. Additional charges apply.

HOTLINE NOTE: There is a unit of measure and a numeric map change associated with this test.
Change the unit of measure for component 2001770, B. pertussis Ab, IgA by ELISA from U/mL to IV.
Change the unit of measure for component 2001782, B. pertussis Ab, IgG by ELISA from U/mL to IV.
Change the numeric map for component 2001782, B. pertussis Ab, IgG by ELISA from X.X to X.XX.

2001775 ***Bordetella pertussis*** **Antibodies, IgA, IgG, and IgM by ELISA with Reflex to Immunoblot** **BORDPAN3**

Reference Interval:

Test Number	Components	Reference Interval			
	Bordetella pertussis Antibody, IgA by ELISA with Reflex to Immunoblot	**Test Number**	**Components**	**Reference Interval**	
			Bordetella pertussis Antibody, IgA by ELISA	Effective February 20, 2018	
				0.9 IV or less	Negative - No significant level of detectable *B. pertussis* IgA antibody.
				1.0-1.1 IV	Equivocal - Repeat testing in 10-14 days may be helpful.
				1.2 IV or greater:	Positive - IgA antibody to *B. pertussis* detected, which may indicate a current or past exposure/immunization to *B. pertussis*.
		2004316	*Bordetella pertussis* Antibody, IgA by Immunoblot	Negative	
2001768	*Bordetella pertussis* Antibody, IgG by ELISA with Reflex to Immunoblot	**Test Number**	**Components**	**Reference Interval**	
			Bordetella pertussis Antibody IgG by ELISA	Effective February 20, 2018	
				0.94 IV or less	Negative – No significant level of detectable *B. pertussis* IgG antibody.
				0.95-1.04 IV	Equivocal – Repeat testing in 10-14 days may be helpful.
				1.05 IV or greater	Positive – IgG antibody to *B. pertussis* detected, which may indicate a current or recent exposure/immunization to *B. pertussis*.
		2004327	*Bordetella pertussis* Antibody, IgG by Immunoblot	Refer to report	
2001769	*Bordetella pertussis* Antibody, IgM by ELISA with Reflex to Immunoblot	**Test Number**	**Components**	**Reference Interval**	
			Bordetella pertussis Antibody, IgM by ELISA	Effective February 20, 2018	
				0.9 IV or less	Negative - No significant level of detectable *B. pertussis* IgM antibody.
				1.0-1.1 IV	Equivocal - Repeat testing in 10-14 days may be helpful.
				1.2 IV or greater	Positive - IgM antibody to *B. pertussis* detected, which may indicate a current or recent exposure/immunization to *B. pertussis*.
		2004326	*Bordetella pertussis* Antibody, IgM by Immunoblot	Refer to report	

Note: If *Bordetella pertussis* Antibody, IgA by ELISA is 1.2 IV or greater, then *Bordetella pertussis* IgA Immunoblot testing will be added; if *Bordetella pertussis* Antibody, IgG by ELISA is 1.05 IV or greater, then *Bordetella pertussis* IgG Immunoblot testing will be added; If *Bordetella pertussis* Antibody, IgM by ELISA is 1.2 IV or greater, then *Bordetella pertussis* IgM Immunoblot testing will be added. Additional charges apply.

HOTLINE NOTE: There is a unit of measure and a numeric map change associated with this test.
Change the unit of measure for component 2001770, B. pertussis Ab, IgA by ELISA from U/mL to IV.
Change the unit of measure for component 2001782, B. pertussis Ab, IgG by ELISA from U/mL to IV.
Change the unit of measure for component 2001783, B. pertussis Ab, IgM by ELISA from U/mL to IV.
Change the numeric map for component 2001782, B. pertussis Ab, IgG by ELISA from X.X to X.XX.

2001784 *Bordetella pertussis* Antibodies, IgG and IgM by ELISA with Reflex to Immunoblot BORDPAN

Reference Interval:

Test Number	Components	Reference Interval
2001768	*Bordetella pertussis* Antibody, IgG by ELISA with Reflex to Immunoblot	

Test Number	Components	Reference Interval	
	Bordetella pertussis Antibody IgG by ELISA	Effective February 20, 2018	
		0.94 IV or less	Negative – No significant level of detectable *B. pertussis* IgG antibody.
		0.95-1.04 IV	Equivocal – Repeat testing in 10-14 days may be helpful.
		1.05 IV or greater	Positive – IgG antibody to *B. pertussis* detected, which may indicate a current or recent exposure/immunization to *B. pertussis*.
2004327	*Bordetella pertussis* Antibody, IgG by Immunoblot	Refer to report	

2001769	*Bordetella pertussis* Antibody, IgM by ELISA with Reflex to Immunoblot			
		Test Number	Components	Reference Interval
			Bordetella pertussis Antibody, IgM by ELISA	Effective February 20, 2018
				0.9 IV or less: Negative - No significant level of detectable *B. pertussis* IgM antibody.
				1.0-1.1 IV: Equivocal - Repeat testing in 10-14 days may be helpful.
				1.2 IV or greater: Positive - IgM antibody to *B. pertussis* detected, which may indicate a current or recent exposure/immunization to *B. pertussis*.
		2004326	*Bordetella pertussis* Antibody, IgM by Immunoblot	Refer to report

Note: If *Bordetella pertussis* Antibody, IgG by ELISA is 1.05 IV or greater, then *Bordetella pertussis* IgG Immunoblot testing will be added; if *Bordetella pertussis* Antibody, IgM by ELISA is 1.2 IV or greater, then *Bordetella pertussis* IgM Immunoblot testing will be added. Additional charges apply.

HOTLINE NOTE: There is a unit of measure and a numeric map change associated with this test.
Change the unit of measure for component 2001782, B. pertussis Ab, IgG by ELISA from U/mL to IV.
Change the unit of measure for component 2001783, B. pertussis Ab, IgM by ELISA from U/mL to IV.
Change the numeric map for component 2001782, B. pertussis Ab, IgG by ELISA from X.X to X.XX.

2005268 *Bordetella pertussis* Antibody, IgG by ELISA BORDIGG

Reference Interval:
Effective February 20, 2018

0.94 IV or less	Negative – No significant level of detectable *B. pertussis* IgG antibody.
0.95-1.04 IV	Equivocal – Repeat testing in 10-14 days may be helpful.
1.05 IV or greater	Positive – IgG antibody to *B. pertussis* detected, which may indicate a current or recent exposure/immunization to *B. pertussis*.

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

HOTLINE NOTE: There is a unit of measure and a numeric map change associated with this test.
Change the unit of measure for component 2001782, B. pertussis Ab, IgG by ELISA from U/mL to IV.
Change the numeric map for component 2001782, B. pertussis Ab, IgG by ELISA from X.X to X.XX.

2001768 *Bordetella pertussis* Antibody, IgG by ELISA with Reflex to Immunoblot BORDG

Reference Interval:

Test Number	Components	Reference Interval	
	Bordetella pertussis Antibody IgG by ELISA	Effective February 20, 2018	
		0.94 IV or less	Negative – No significant level of detectable *B. pertussis* IgG antibody.
		0.95-1.04 IV	Equivocal – Repeat testing in 10-14 days may be helpful.
		1.05 IV or greater	Positive – IgG antibody to *B. pertussis* detected, which may indicate a current or recent exposure/immunization to *B. pertussis*.
2004327	*Bordetella pertussis* Antibody, IgG by Immunoblot	Effective February 19, 2013	
		Components	**Reference Interval**
		Bordetella pertussis Ab, IgG by Immunoblot Interp	Negative
		B. pertussis, IgG Immunoblot PT100	Negative
		B. pertussis, IgG Immunoblot PT	Negative
		B. pertussis, IgG Immunoblot FHA	Negative

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

Note: If *Bordetella pertussis* Antibody, IgG by ELISA is 1.05 IV or greater, then *Bordetella pertussis* IgG Immunoblot testing will be added. Additional charges apply.

HOTLINE NOTE: There is a unit of measure and numeric map change associated with this test.
Change the unit of measure for component 2001782, B. pertussis Ab, IgG by ELISA from U/mL to IV.
Change the numeric map for component 2001782, B. pertussis Ab, IgG by ELISA from X.X to X.XX.

2001769 *Bordetella pertussis* Antibody, IgM by ELISA with Reflex to Immunoblot BORDM

Reference Interval:

Test Number	Components	Reference Interval	
	Bordetella pertussis Antibody, IgM by ELISA	Effective February 20, 2018	
		0.9 IV or less	Negative - No significant level of detectable *B. pertussis* IgM antibody.
		1.0-1.1 IV	Equivocal - Repeat testing in 10-14 days may be helpful.
		1.2 IV or greater	Positive - IgM antibody to *B. pertussis* detected, which may indicate a current or recent exposure/immunization to *B. pertussis*.
2004326	*Bordetella pertussis* Antibody, IgM by Immunoblot	Effective February 19, 2013	
		Components	**Reference Interval**
		Bordetella pertussis Ab, IgM by Immunoblot Interp	Negative
		B. pertussis, IgM Immunoblot PT	Negative
		B. pertussis, IgM Immunoblot FHA	Negative

Note: If *Bordetella pertussis* Antibody, IgM by ELISA is 1.2 IV or greater, then *Bordetella pertussis* IgM Immunoblot testing will be added. Additional charges apply.

HOTLINE NOTE: There is a unit of measure change associated with this test.
Change the unit of measure for component 2001783, B. pertussis Ab, IgM by ELISA from U/mL to IV.

0090260 Carbamazepine, Total TEG

Reference Interval: Therapeutic range: 4.0-12.0 µg/mL
Toxic: greater than 15.0 µg/mL

2011164 *Chlamydia trachomatis* and *Neisseria gonorrhoeae* (CTNG) by Transcription-Mediated Amplification (TMA) with Reflex to CT/NG Confirmation — CTNG CONF

Performed: Sun-Sat
Reported: 1-10 days

Interpretive Data:
This test is intended for medical purposes only. It is not intended for the evaluation of suspected sexual abuse or for other medicolegal indications. Refer to the most recent CDC recommendations for patients in whom a false positive result may have adverse psychosocial impact.
Positive results will be confirmed with alternative nucleic acid target assay.

Note: If *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae* by TMA is positive, then Chlamydia and/or Gonorrhea alternate target TMA will be added for confirmation. Additional charges apply.

CPT Code(s): 87491; 87591. If reflexed add 87491 or 87591

HOTLINE NOTE: There is a reflexive pattern change and a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.
Add reflex to 3000300, Chlamydia trachomatis Confirm by TMA.
Add reflex to 3000302, Neisseria gonorrhoeae Confirm by TMA.

0098457 Chylomicron Screen, Body Fluid — CHYLO FL

Specimen Required: Collect: Body fluid.
Specimen Preparation: Do not freeze. Transport 1 mL body fluid. (Min: 0.2 mL)
Storage/Transport Temperature: Refrigerated.
Remarks: Specify type of body fluid.
Unacceptable Conditions: CSF, plasma, serum, or whole blood.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 3 weeks; Frozen: Unacceptable

0095229 Cystatin C, Serum with Reflex to Estimated Glomerular Filtration Rate (eGFR) — CYSTAT C

Reference Interval:
Effective February 20, 2018

Test Number	Components	Reference Interval			
	Cystatin C	**Age**	**Reference Interval**		
		0-3 months	0.8-2.3 mg/L		
		4-11 months	0.7-1.5 mg/L		
		1-3 years	0.5-1.3 mg/L		
		4-8 years	0.5-1.3 mg/L		
		9-17 years	0.5-1.3 mg/L		
		18 years and older	0.5-1.0 mg/L		
	Cystatin C Reflex	**Age**	**Reference Interval**		
		17 years and less	Calculation not reported		
		18 years and greater	**Stage**	**Description**	**eGFR Range (mL/min/BSA)**
			1	Normal or increased eGFR	90 or greater
			2	Mildly decreased eGFR	60 - 89
			3	Moderately decreased eGFR	30 - 59
			4	Severely decreased eGFR	15 - 29
			5	Kidney Failure	Less than 15

Note: If the patient's age is either unknown or is 18 years or greater, then Cystatin C Reflex will be added at no extra charge.

HOTLINE NOTE: There is a reflexive pattern change associated with this test.
For patients 18 years of age or greater, add reflex to 3000246 Cystatin C Reflex.

2013661 Cystic Fibrosis (*CFTR*) 165 Pathogenic Variants CF VAR

Interpretive Data:
Background information for Cystic Fibrosis (*CFTR*), 165 Pathogenic Variants:
Characteristics of Classic Cystic Fibrosis (CF): Chronic sino-pulmonary disease, gastrointestinal malabsorption/pancreatic insufficiency, and obstructive azoospermia. Symptoms of a *CFTR*-related disorder are often limited to a single organ system such as isolated pancreatitis, bilateral absence of the vas deferens, nasal polyposis, or bronchiectasis.
Incidence: 1 in 2,300 Ashkenazi Jewish, 1 in 2,500 Caucasians, 1 in 13,500 Hispanics, 1 in 15,100 African Americans, 1 in 35,100 Asians.
Inheritance: Autosomal recessive.
Penetrance: High for severe pathogenic variants, variable for moderate and mild pathogenic variants.
Cause of Classic CF: Two severe, or one severe and one moderate, pathogenic *CFTR* variants on opposite chromosomes.
Cause of *CFTR*-Related Disorders: Two pathogenic *CFTR* variants on opposite chromosomes in any of the following combinations: two mild, one mild and one severe or one mild and one moderate.
Pathogenic Variants Tested: See the "Additional Technical Information" document.
Clinical Sensitivity: Ashkenazi Jewish 96 percent; Caucasian 92 percent; Hispanic 80 percent; African American 78 percent; Asian American 55 percent.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity & Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Only the 165 pathogenic *CFTR* variants and 5T variant will be interrogated.

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

Note: The CF 165Variants assay includes the 23 pathogenic CF variants recommended by the American College of Medical Genetics for population carrier screening.

2013663 Cystic Fibrosis (*CFTR*) 165 Pathogenic Variants with Reflex to Sequencing CF VAR SEQ

Interpretive Data:
Background information for Cystic Fibrosis (*CFTR*), 165 Pathogenic Variants with Reflex to Sequencing:
Characteristics of Classic Cystic Fibrosis (CF): Chronic sino-pulmonary disease, gastrointestinal malabsorption/pancreatic insufficiency, and obstructive azoospermia. Symptoms of a *CFTR*-related disorder are often limited to a single organ system such as isolated pancreatitis, bilateral absence of the vas deferens, nasal polyposis, or bronchiectasis.
Incidence: 1 in 2,300 Ashkenazi Jewish, 1 in 2,500 Caucasians, 1 in 13,500 Hispanics, 1 in 15,100 African Americans, 1 in 35,100 Asians.
Inheritance: Autosomal recessive.
Penetrance: High for severe pathogenic variants, variable for moderate and mild pathogenic variants.
Cause of Classic CF: Two severe, or one severe and one moderate, pathogenic *CFTR* variants on opposite chromosomes.
Cause of *CFTR*-Related Disorders: Two pathogenic *CFTR* variants on opposite chromosomes in any of the following combinations; two mild, one mild and one severe or one mild and one moderate.
Pathogenic Variants Tested: Refer to "Additional Technical Information" document.
Clinical Sensitivity of CF 165-Variants Test: Ashkenazi Jewish 96 percent; Caucasian 92 percent; Hispanic 80 percent; African American 78 percent; Asian American 55 percent.
Clinical Sensitivity for Sequencing: 97 percent.
Methodology for 165-Variants Test: Polymerase Chain Reaction (PCR) and fluorescence monitoring.
Methodology for Sequencing: Bidirectional sequencing of the *CFTR* coding region and intron-exon boundaries.
Analytical Sensitivity & Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. *CFTR* promoter and regulatory region variants and large gene deletions/duplications and inversions will not be detected.

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

Note: If less than two pathogenic variants are identified by the CF 165 Variants assay, then *CFTR* gene sequencing will be performed. Additional charges apply for each tier performed.

2013664	**Cystic Fibrosis (*CFTR*) 165 Pathogenic Variants with Reflex to Sequencing and Reflex to Deletion/Duplication**	**CFVAR COMP**

Interpretive Data:
Background information for Cystic Fibrosis (*CFTR*), 165 Pathogenic Variants with Reflex to Sequencing and Reflex to Deletion/Duplication:
Characteristics of Classic Cystic Fibrosis (CF): Chronic sino-pulmonary disease, gastrointestinal malabsorption/pancreatic insufficiency, and obstructive azoospermia. Symptoms of a *CFTR*-related disorder are often limited to a single organ system such as isolated pancreatitis, bilateral absence of the vas deferens, nasal polyposis, or bronchiectasis.
Incidence: 1 in 2,300 Ashkenazi Jewish, 1 in 2,500 Caucasians, 1 in 13,500 Hispanics, 1 in 15,100 African Americans, 1 in 35,100 Asians.
Inheritance: Autosomal recessive.
Penetrance: High for severe pathogenic variants, variable for moderate and mild pathogenic variants.
Cause of Classic CF: Two severe, or one severe and one moderate, pathogenic *CFTR* variants on opposite chromosomes.
Cause of *CFTR*-Related Disorders: Two pathogenic *CFTR* variants on opposite chromosomes in any of the following combinations: two mild, one mild and one severe or one mild and one moderate.
Pathogenic Variants Tested: Refer to "Additional Technical Information" document.
Clinical Sensitivity for CF 165-Variants Test: Ashkenazi Jewish 96 percent; Caucasian 92 percent; Hispanic 80 percent; African American 78 percent; Asian American 55 percent.
Clinical Sensitivity for Sequencing and Deletion/Duplication Tests: 97 and 2 percent, respectively.
Methodology for 165-Variants Test: Polymerase chain reaction (PCR) and fluorescence monitoring.
Methodology for Sequencing: Bidirectional sequencing of the *CFTR* coding region and intron-exon boundaries.
Methodology for Deletion/Duplication: Multiplex ligation-dependent probe amplification (MLPA) to detect large *CFTR* coding region deletions/duplications.
Analytical Sensitivity and Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. The breakpoints of large deletions/duplications will not be determined. Large *CFTR* inversions and regulatory region and intronic variants will not be detected.

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

Note: If less than two pathogenic variants are identified by the CF 165 Variants assay, then *CFTR* gene sequencing will be performed. Following sequencing, if less than two pathogenic variants are identified, then *CFTR* deletion/duplication analysis will be performed. Additional charges will apply for each tier performed .

2013662 Cystic Fibrosis (*CFTR*) 165 Pathogenic Variants, Fetal — CF VAR FE

Specimen Required: Collect: **Fetal Specimen:** Two T-25 flasks of cultured amniocytes at 80 percent confluency. ***If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787.**
Maternal Specimen: Lavender (EDTA), Pink (K_2EDTA), or Yellow (ACD Solution).
Specimen Preparation: **Cultured Amniocytes**: Fill flasks with culture media. Backup cultures must be retained at the client's institution until testing is complete.
Maternal Specimen: Transport 3 mL whole blood. (Min. 1 mL)
Storage/Transport Temperature: **Cultured Amniocytes**: **CRITICAL ROOM TEMPERATURE.** Must be received within 48 hours of shipment due to lability of cells.
Maternal Specimen: Refrigerated.
Remarks: **Maternal sample is recommended for proper test interpretation; order Maternal Cell Contamination, Maternal Specimen.** Patient History Form is available on the ARUP Web site or by contacting ARUP Client Services.
Unacceptable Conditions: **Maternal Specimen**: Plasma or serum. Specimens collected in sodium heparin or lithium heparin tubes.
Stability (collection to initiation of testing): **Fetal Specimen:** Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Maternal Specimen: Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Interpretive Data:

Background information for Cystic Fibrosis (*CFTR*), 165 Pathogenic Variants, Fetal
Characteristics of Classic Cystic Fibrosis (CF): Chronic sino-pulmonary disease, gastrointestinal malabsorption/pancreatic insufficiency, and obstructive azoospermia. Symptoms of a *CFTR*- related disorder are often limited to a single organ system such as isolated pancreatitis, bilateral absence of the vas deferens, nasal polyposis, or bronchiectasis.
Incidence: 1 in 2,300 Ashkenazi Jewish, 1 in 2,500 Caucasians, 1 in 13,500 Hispanics, 1 in 15,100 African Americans, 1 in 35,100 Asians.
Inheritance: Autosomal recessive.
Penetrance: High for severe and moderately severe pathogenic variants, variable for mild pathogenic variants.
Cause of Classic CF: Two severe, or one severe and one moderate, pathogenic *CFTR* variants on opposite chromosomes.
Cause of *CFTR*-Related Disorders: Two pathogenic *CFTR* variants on opposite chromosomes in any of the following combinations; two mild, one mild and one severe or one mild and one moderate.
Pathogenic Variants Tested: Refer to "Additional Technical Information" document.
Clinical Sensitivity: Ashkenazi Jewish 96 percent; Caucasian 92 percent; Hispanic 80 percent; African American 78 percent; Asian American 55 percent.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity & Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Only the 165 pathogenic *CFTR* variants and 5T variant will be interrogated.

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

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

Note: The CF 165-Variants assay includes the 23 pathogenic CF variants recommended by the American College of Medical Genetics for population carrier screening.

2000624 Cytology, Pap Smear — GG REQUEST

HOTLINE NOTE: There is a component change associated with this test.
Add reflex component 3000285, Pap Test Pathologist Review.
Optional reflex component added to provide a trigger for client interfaces to indicate when review by a pathologist has occurred.

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

HOTLINE NOTE: There is a component change associated with this test.
Add reflex component 3000285, Pap Test Pathologist Review.
Optional reflex component added to provide a trigger for client interfaces to indicate when review by a pathologist has occurred.

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**

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

HOTLINE NOTE: There is a component change associated with this test.
Add reflex component 3000285, Pap Test Pathologist Review.
Optional reflex component added to provide a trigger for client interfaces to indicate when review by a pathologist has occurred.

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

HOTLINE NOTE: There is a component change associated with this test.
Add reflex component 3000285, Pap Test Pathologist Review.
Optional reflex component added to provide a trigger for client interfaces to indicate when review by a pathologist has occurred.

2000137	**Cytology, ThinPrep Pap Test**	**GT REQUEST**

HOTLINE NOTE: There is a component change associated with this test.
Add reflex component 3000285, Pap Test Pathologist Review.
Optional reflex component added to provide a trigger for client interfaces to indicate when review by a pathologist has occurred.

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

HOTLINE NOTE: There is a component change associated with this test.
Add reflex component 3000285, Pap Test Pathologist Review.
Optional reflex component added to provide a trigger for client interfaces to indicate when review by a pathologist has occurred.

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

HOTLINE NOTE: There is a component change associated with this test.
Add reflex component 3000285, Pap Test Pathologist Review.
Optional reflex component added to provide a trigger for client interfaces to indicate when review by a pathologist has occurred.

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

Methodology: Qualitative Liquid Chromatography/Tandem Mass Spectrometry

Specimen Required: Collect: Umbilical Cord (At least 6 inches, approximately the length of an adult hand.)
Specimen Preparation: Drain and discard any blood. Rinse the exterior of the cord segment with normal saline or sterile water. Pat the cord dry and transport at least 6 inches of umbilical cord in a routine urine collection cup or Security Kit for Meconium/Umbilical Drug Detection (ARUP supply #51548) available online through eSupply using ARUP Connect™ or by contacting ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Cords soaking in blood or other fluid. Formalin fixed. Tissue that is obviously decomposed.
Stability (collection to initiation of testing): Ambient, 1 week; Refrigerated, 3 weeks; Frozen, 1 year

Interpretive Data:
Methodology: Qualitative Liquid Chromatography/Tandem Mass Spectrometry

Detection of drugs in umbilical cord tissue is intended to reflect maternal drug use during pregnancy. The pattern and frequency of drug(s) used by the mother cannot be determined by this test. A negative result does not exclude the possibility that a mother used drugs during pregnancy. Detection of drugs in umbilical cord tissue depends on extent of maternal drug use, as well as drug stability, unique characteristics of drug deposition in umbilical cord tissue, and the performance of the analytical method. Drugs administered during labor and delivery may be detected. Detection of drugs in umbilical cord tissue does not insinuate impairment and may not affect outcomes for the infant. Interpretive questions should be directed to the laboratory. Glucuronide metabolites are indicated as -G.

For medical purposes only; not valid for forensic use unless testing was performed within Chain of Custody process.
See Compliance Statement B: www.aruplab.com/CS

Note: Absolute Minimum: 6 inches. For marijuana metabolite, order Marijuana Metabolite, Umbilical Cord Tissue, Qualitative (ARUP test code 3000256).

HOTLINE NOTE: There is a component change associated with this test.
Remove component 2008360 Marijuana Metabolite, Cord, Screen.

0090499 Drug Screen (Nonforensic), Serum — BLD SCREEN

Performed: Sun-Sat
Reported: 1-6 days

Interpretive Data:
The following drugs or drug classes may be detected: acetaminophen, barbiturates, benzodiazepines, carbamazepine, carisoprodol, disopyramide, meprobamate, phenytoin, primidone, salicylate, theophylline, tricyclic and other antidepressants.

Note: This test is not optimized for most drugs of abuse (amphet/methamphet, barbiturates, benzodiazepines, cocaine, methadone, opiates, propoxyphene, PCP, THC); instead, refer to Drug Screen 9 Panel, Serum or Plasma - Immunoassay Screen with Reflex to Mass Spectrometry Confirmation/Quantitation (ARUP test code 0092420).

0090500 Drug Screen (Nonforensic), Urine, Qualitative — URN SCREEN

Performed: Sun-Sat
Reported: 1-6 days

Interpretive Data:
The following drugs or drug classes may be detected:

Acetaminophen, barbiturates, benzodiazepines, carbamazepine, carisoprodol, chlorpheniramine, cocaine and metabolites, diphenhydramine, ethchlorvynol, ibuprofen, lidocaine, meprobamate, narcotics and synthetics, phencyclidine, phenothiazines, phenytoin, primidone and metabolites, pyrilamine, salicylate, sympathomimetic amines, theophylline, tricyclic and other antidepressants.

0090120 Ethanol, Serum or Plasma - Medical — ETOH

Methodology: Quantitative Gas Chromatography

Specimen Required: Patient Prep: For medical purposes only. Timing of specimen collection: Dependent on time of exposure, test upon presentation to hospital.
Collect: Plain Red. Also acceptable: Lavender (EDTA), Pink (K_2EDTA), or Gray (Potassium Oxalate/Sodium Fluoride).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL) **Cap tube tightly to minimize alcohol loss.**
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Whole blood. Plasma Separator Tubes (PST), Serum Separator Tubes (SST).
Stability (collection to initiation of testing): After separation from cells: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 1 month

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

Performed: Mon, Wed, Sat
Reported: 1-6 days

2001743 Fetal Hemoglobin Determination for Fetomaternal Hemorrhage — FHGB

Reference Interval: By report

Interpretive Data: The performance characteristics of this test were determined by ARUP Laboratories, Inc.

Result	Interpretation
% Fetal RBCs	The fetal RBC percentage is directly measured by flow cytometry and gives the percentage of fetal RBCs in the maternal circulation resulting from recent fetal-maternal hemorrhage. Post-partum, some fetal cells are expected (0.04% plus or minus 0.024%, mean plus or minus SD). For accurate calculation of RhIG dosage that includes maternal height and weight, please refer to the CAP RhIG calculator (http://capatholo.gy/RHIG) or to the most recent AABB Technical Manual.

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

HOTLINE NOTE: There is a component change associated with this test.
Remove component 2001744, Fetal Hgb - Fetal Blood Volume.
Remove component 2001745, Fetal Hgb - RhIg Vials Required.
Remove component 2001746, Fetal Hgb - RhIg Required.

New Test **3000235** **Fungal Antibodies with Reflex to *Blastomyces dermatitidis* Antibodies by Immunodiffusion** **FUNG R SER**

Available Now

Methodology: Semi-Quantitative Complement Fixation/Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Qualitative Immunodiffusion
Performed: Sun-Sat
Reported: 2-6 days

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.4 mL) Parallel testing is preferred and convalescent specimens **must** be received within 30 days from receipt of the acute specimens.
Storage/Transport Temperature: Refrigerated.
Remarks: **Mark specimens plainly as acute or convalescent.**
Unacceptable Conditions: Contaminated 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
0050100	*Aspergillus* Antibody by CF	Less than 1:8
0050170	*Coccidioides* Antibody by CF	Less than 1:2
0050625	*Histoplasma* Antibodies by CF	
	Components	Reference Interval
	Histo M	Less than 1:8
	Histo Y	Less than 1:8
3000236	*Blastomyces dermatitidis* Antibodies by EIA with Reflex to Immunodiffusion, Serum	0.9 IV or less: Negative 1.0-1.4 IV: Equivocal 1.5 IV or greater: Positive
0050172	*Blastomyces dermatitidis* Abs, Precipitin	None Detected

Interpretive Data: Refer to report.

Note: Negative fungal serology does not rule out the possibility of current infection. If *Blastomyces* antibodies are equivocal or positive by EIA then *Blastomyces* Immunodiffusion will be added. Additional charges apply.

CPT Code(s): 86606; 86612; 86635; 86698 x2; if reflexed, add 86612

New York DOH Approved.

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

New Test **3000230** **Fungal Antibodies with Reflex to *Blastomyces dermatitidis* Antibodies by Immunodiffusion, CSF** **FUNG R CSF**

Available Now

Methodology: Semi-Quantitative Complement Fixation/Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Qualitative Immunodiffusion
Performed: Sun-Sat
Reported: 2-6 days

Specimen Required: Collect: CSF.
Specimen Preparation: Transfer 1 mL CSF to an ARUP Standard Transport Tube. (Min: 0.35 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Other body fluids. Contaminated, hemolyzed, xanthochromic, or severely lipemic specimens.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval
	Aspergillus Antibodies, CSF by CF	Less than 1:2
3000231	*Blastomyces* Antibody by ELISA, CSF	0.9 IV or less: Negative 1.0-1.4 IV: Equivocal 1.5 IV or greater: Positive
3000059	*Coccidioides* Antibody by CF, CSF	Less than 1:2
	Histoplasma Mycelia by CF	Less than 1:2
	Histoplasma Yeast by CF	Less than 1:2
	Blastomyces Ab by Immunodiffusion, CSF	None Detected

Interpretive Data: Refer to report.

Note: Negative fungal serology does not rule out the possibility of current infection. If *Blastomyces* antibodies are equivocal or positive by EIA then *Blastomyces* Immunodiffusion will be added. Additional charges apply.

CPT Code(s): 86606; 86612; 86635; 86698 x2; if reflexed, add 86612

New York DOH approval pending. Call for status update.

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

2012227 **Gabapentin, Urine** **GABAP U**

Interpretive Data: Positive cutoff: 5.0 µg/mL

For medical purposes only; not valid for forensic use.

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

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

2004998 **Ganglioside (GM1, GD1b, and GQ1b) Antibodies, IgG and IgM** **GM1 LIGHT**

Performed: Thu
Reported: 1-8 days

New Test Available Now **3000101** **Herpes Simplex Virus (HSV) Types I/II by Immunohistochemistry** **HSV IHC**

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

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

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

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

CPT Code(s): 88342

New York DOH Approved.

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

0051654 **HNPCC/Lynch Syndrome (*MSH2*) Sequencing and Deletion/Duplication** **MSH2 FGA**

Reference Interval:

Test Number	Components	Reference Interval
	MSH2 Full Gene Sequencing	By report
	MSH2 Deletion/Duplication/ Inversion	By report

Interpretive Data:
Background Information for HNPCC/Lynch syndrome (*MSH2*) Sequencing and Deletion/Duplication:
Characteristics of Lynch syndrome: Increased risk of colorectal and extra-colonic cancers including endometrial, renal, pelvis, ureter, ovary, stomach, small intestine, and hepatobiliary tract.
Incidence: 1-2 percent of colorectal cancer is due to pathogenic mismatch repair gene variants.
Inheritance: Autosomal dominant.
Penetrance: 80 percent lifetime risk of colorectal cancer; 20-60 percent risk for endometrial cancer.
Cause: Pathogenic germline *MLH1*, *MSH2*, *MSH6*, and *PMS2* gene variants.
Gene tested: *MSH2*
Clinical Sensitivity: 40 percent of Lynch syndrome is due to pathogenic *MSH2* variants.
Methodology: Bidirectional sequencing of *MSH2* coding regions and intron-exon boundaries; multiplex ligation-dependent probe amplification (MLPA) to detect large exonic deletions and duplications of *MSH2*, *EPCAM* (*TACSTD1*) exon 9 and the 10Mb *MSH2* exons1-7 inversion.
Analytical Sensitivity & Specificity: 99 percent.
Test Limitations: Diagnostic errors can occur due to rare sequence variations. The breakpoints of large deletions/duplications/inversions will not be determined. Deep intronic and regulatory region variants will not be detected. Variants in genes other than *MSH2* and *TACSTD1*, as described above, will not be detected.

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

New Test **2008863** **Holoprosencephaly Panel, Nonsyndromic, Sequencing and Deletion/Duplication, 11 Genes, Fetal** **HPE PAN FE**

Available Now

Patient History for Fetal Molecular Testing

Additional Technical Information

Supplemental Resources

Methodology: Massively Parallel Sequencing/Exonic Oligonucleotide-based CGH Microarray
Performed: Varies
Reported: 6-8 weeks

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

Reference Interval: By report

Interpretive Data: Refer to report.

Patient History forms are available online at www.aruplab.com.

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

CPT Code(s): 81479; 81265 Fetal Cell Contamination (FCC)

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 | **3000202** | **5-Hydroxyindoleacetic acid (5-HIAA), Plasma** | **5 HIAA PLA**

Methodology: Quantitative Gas Chromatography/Mass Spectrometry (GC/MS)
Performed: Varies
Reported: Within 1 month

Specimen Required: Patient Prep: Fast overnight prior to collection.
Collect: Z plasma preservative tube (ARUP supply #40874) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Specimen Preparation: Separate from cells within 10 minutes. Transfer 4 mL plasma to an ARUP Standard Transport Tube and freeze immediately. (Min: 1 mL)
Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Unacceptable Conditions: Specimens not collected in a Z plasma preservative tube. Thawed specimens.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 6 months

CPT Code(s): 82542

New York DOH Approved.

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

0050618 | **Kappa and Lambda Free Light Chains (Bence Jones Protein), Quantitative, Urine** | **BJ QUANT**

Specimen Required: Collect: 24-hour urine. Refrigerate during collection. Also acceptable: Random urine specimens and urine supernate.
Specimen Preparation: Transfer two 4 mL aliquots from a well-mixed 24-hour collection to individual ARUP Standard Transport Tubes. (Min: 4 mL)
Storage/Transport Temperature: Refrigerated.
Remarks: **Record total volume and collection time interval on transport tube and test request form.**
Stability (collection to initiation of testing): Ambient: 2 hours; Refrigerated: 1 week; Frozen: Unacceptable

0050689 | **Kappa Free Light Chains (Bence Jones Protein), Quantitative, Urine** | **BJQNTKAPP**

Specimen Required: Collect: 24-hour urine. Refrigerate during collection. Also acceptable: Urine supernate.
Specimen Preparation: Transfer two 4 mL aliquots from a well-mixed 24-hour urine collection to individual ARUP Standard Transport Tubes. (Min: 4 mL)
Storage/Transport Temperature: Refrigerated.
Remarks: **Record total volume and collection time interval on transport tube and test request form.**
Stability (collection to initiation of testing): Ambient: 2 hours; Refrigerated: 1 week; Frozen: Unacceptable

0050682 | **Lambda Free Light Chains (Bence Jones Protein), Quantitative, Urine** | **BJQNTLAMB**

Specimen Required: Collect: 24-hour urine. Refrigerate during collection. Also acceptable: Urine supernate.
Specimen Preparation: Transfer two 4 mL aliquots from a well-mixed 24-hour urine collection to individual ARUP Standard Transport Tubes. (Min: 4 mL)
Storage/Transport Temperature: Refrigerated.
Remarks: **Record total volume and collection time interval on transport tube and test request form.**
Stability (collection to initiation of testing): Ambient: 2 hours; Refrigerated: 1 week; Frozen: Unacceptable

2013716 **LipoFit by NMR** **NMRLIPFIT**

Specimen Required: Patient Prep: Fasting specimen required.
Collect: Greiner Bio-One Clot Activator Tube (ARUP supply #53483) available online through eSupply using ARUP Connect ™ or by contacting ARUP Client Services at (800) 522-2787. Also acceptable: Plain Red.
Specimen Preparation: Gently invert tube to mix contents; allow to clot at room temperature. Separate from cells within 8 hours. Transfer 4 mL serum to an ARUP Standard Transport Tube. (Min: 2 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma. Serum separator tubes other than Greiner Bio-One. Non-fasting or lipemic specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 1 week; Frozen: Unacceptable

2013715 **LipoFit by NMR, Particle Count Only** **NMRLIPFITP**

Specimen Required: Patient Prep: Fasting specimen required.
Collect: Greiner Bio-One Clot Activator Tube (ARUP supply #53483). Available online through eSupply using ARUP Connect ™ or by contacting ARUP Client Services at (800) 522-2787. Also acceptable: Plain red.
Specimen Preparation: Gently invert tube to mix contents and allow to clot at room temperature. Separate serum from cells within 8 hours. Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma. Serum separator tubes other than Greiner Bio-One. Non-fasting or lipemic specimens.
Stability (collection to initiation of testing): Ambient: 2 days; Refrigerated: 1 month; Frozen: Unacceptable

0020038 **Lithium, Serum or Plasma** **LI**

Reference Interval: Therapeutic: 0.5-1.2 mmol/L
Toxic: 1.6 or greater mmol/L

0095862 Lymphocyte Subset Panel 6 - Total Lymphocyte Enumeration with CD45RA and CD45RO TEXTENDED

Reference Interval: Effective February 20, 2018

Reports include age appropriate reference intervals and interpretation.

Pediatric reference values (0 - 6 days up to 10 - 15 years) taken from Scandinavian Journal of Immunology 2012; 75, 436-444.
Adult and Geriatric (16 - 64 and 65 plus years) ranges were developed in-lab.

Test Number	Components	0-6 days	1 week-1 month	2-4 months	5-8 months	9-14 months	15-23 months	2-4 years	5-9 years	10-15 years	16-64 years	65 years or older
	% CD3	38-88%	55-90 %	49-97 %	49-95%	56-87%	36-92%	52-92%	55-97%	52-90%	62-87%	62-89%
	Absolute CD3	1400-6800 cells/µL	1900-8400 cells/µL	2200-9200 cells/µL	1400-11500 cells/µL	2400-8300 cells/µL	700-8800 cells/µL	850-4300 cells/µL	770-4000 cells/µL	850-3200 cells/µL	570-2400 cells/µL	660-2200 cells/µL
	% CD4	26-62 %	39-69 %	37-69 %	27-81%	25-86%	16-91%	25-66%	26-61%	20-65%	32-64%	35-68%
	Absolute CD4	1000-4800 cells/µL	1500-6000 cells/µL	1600-6500 cells/µL	1000-7200 cells/µL	1300-7100 cells/µL	400-7200 cells/µL	500-2700 cells/µL	400-2500 cells/µL	400-2100 cells/µL	430-1800 cells/µL	490-1600 cells/µL
	% CD45RA	60-100%	63-100%	66-100%	68-99%	68-98%	57-100%	53-96%	47-97%	39-93%	28-71%	19-62%
	Absolute CD45RA	900-4500 cells/µL	1100-5200 cells/µL	1200-5300 cells/µL	800-5900 cells/µL	900-5200 cells/µL	400-5600 cells/µL	380-2500 cells/µL	250-2000 cells/µL	230-1400 cells/µL	150-870 cells/µL	260-1000 cells/µL
	% CD45RO	2-44%	2-36%	1-42%	1-46%	4-29%	5-39%	11-50%	8-76%	18-68%	28-72%	38-81%
	Absolute CD45RO	98-1300 cells/µL	110-1200 cells/µL	90-1400 cells/µL	100-950 cells/µL	160-710 cells/µL	68-630 cells/µL	150-640 cells/µL	100-510 cells/µL	160-700 cells/µL	190-1050 cells/µL	490-1200 cells/µL
	% CD8	5-37%	7-35%	6-41%	10-35%	7-58%	7-40%	9-49%	13-47%	14-40%	15-46%	10-46%
	Absolute CD8	200-2700 cells/µL	300-2700 cells/µL	300-3400 cells/µL	200-5400 cells/µL	400-4100 cells/µL	200-2800 cells/µL	200-1800 cells/µL	200-1700 cells/µL	300-1300 cells/µL	210-1200 cells/µL	150-1050 cells/µL
	CD4:CD8 Ratio	1.00-2.60	1.30-6.30	1.70-3.90	1.60-3.80	1.30-3.90	0.90-3.70	0.90-2.90	0.90-2.60	0.90-3.40	0.80-3.90	0.80-6.17
	% CD19	3-30%	3-60%	8-33%	4-54%	3-77%	8-45%	8-39%	4-33%	7-24%	6-23%	5-21%
	Absolute CD19	140-2000 cells/µL	180-3500 cells/µL	520-2300 cells/µL	130-6300 cells/µL	110-7700 cells/µL	160-3700 cells/µL	180-1300 cells/µL	100-800 cells/µL	120-740 cells/µL	91-610 cells/µL	74-510 cells/µL
	% NK-cells	8-62%	3-23%	2-20%	2-36%	1-64%	1-96%	2-25%	2-31%	4-51%	4-26%	5-28%
	Absolute NK-cells	500-3100 cells/µL	140-1900 cells/µL	97-2000 cells/µL	68-3900 cells/µL	71-3500 cells/µL	55-4000 cells/µL	61-510 cells/µL	70-590 cells/µL	92-1200 cells/µL	78-470 cells/µL	74-620 cells/µL

0095899 Lymphocyte Subset Panel 7 - Congenital Immunodeficiencies PIP

Reference Interval: Effective February 20, 2018

Reports include age appropriate reference intervals and interpretation.

Reference Interval Notes:
Pediatric reference values (0 - 6 days up to 10 - 15 years) taken from Scandinavian Journal of Immunology 2012; 75, 436-444.
Adult and Geriatric (16 - 64 and 65 plus years) ranges were developed in-lab.
Publications did not address HLA-DR; CD19 ranges were used for all HLA-DR pediatric ranges (0 - 6 days up to 10 - 15 years).

Test Number	Components	0-6 days	1 week-1 month	2-4 months	5-8 months	9-14 months	15-23 months	2-4 years	5-9 years	10-15 years	16-64 years	65 years or older
	% CD2	46-97%	58-97%	51-98%	51-98%	57-97%	37-92%	54-92%	57-97%	56-93%	73-91%	78-92%
	Absolute CD2	1900-8300 cells/µL	2000-9200 cells/µL	2300-10200 cells/µL	1500-13500 cells/µL	2500-10000 cells/µL	750-10800 cells/µL	900-4500 cells/µL	840-4300 cells/µL	950-3800 cells/µL	700-2600 cells/µL	680-2400 cells/µL
	% CD3	38-88%	55-90 %	49-97 %	49-95%	56-87%	36-92%	52-92%	55-97%	52-90%	62-87%	62-89%
	Absolute CD3	1400-6800 cells/µL	1900-8400 cells/µL	2200-9200 cells/µL	1400-11500 cells/µL	2400-8300 cells/µL	700-8800 cells/µL	850-4300 cells/µL	770-4000 cells/µL	850-3200 cells/µL	570-2400 cells/µL	660-2200 cells/µL
	% HLA-DR	3-30%	3-60%	8-33%	4-54%	3-77%	8-45%	8-39%	4-33%	7-24%	8-24%	7-20%
	Absolute HLA-DR	140-2000 cells/µL	180-3500 cells/µL	520-2300 cells/µL	130-6300 cells/µL	110-7700 cells/µL	160-3700 cells/µL	180-1300 cells/µL	100-800 cells/µL	120-740 cells/µL	100-640 cells/µL	98-430 cells/µL
	% CD4	26-62 %	39-69 %	37-69 %	27-81%	25-86%	16-91%	25-66%	26-61%	20-65%	32-64%	35-68%
	Absolute CD4	1000-4800 cells/µL	1500-6000 cells/µL	1600-6500 cells/µL	1000-7200 cells/µL	1300-7100 cells/µL	400-7200 cells/µL	500-2700 cells/µL	400-2500 cells/µL	400-2100 cells/µL	430-1800 cells/µL	490-1600 cells/µL
	% CD45RA	60-100%	63-100%	66-100%	68-99%	68-98%	57-100%	53-96%	47-97%	39-93%	28-71%	19-62%
	Absolute CD45RA	900-4500 cells/µL	1100-5200 cells/µL	1200-5300 cells/µL	800-5900 cells/µL	900-5200 cells/µL	400-5600 cells/µL	380-2500 cells/µL	250-2000 cells/µL	230-1400 cells/µL	150-870 cells/µL	260-1000 cells/µL
	% CD45RO	2-44%	2-36%	1-42%	1-46%	4-29%	5-39%	11-50%	8-76%	18-68%	28-72%	38-81%
	Absolute CD45RO	98-1300 cells/µL	110-1200 cells/µL	90-1400 cells/µL	100-950 cells/µL	160-710 cells/µL	68-630 cells/µL	150-640 cells/µL	100-510 cells/µL	160-700 cells/µL	190-1050 cells/µL	490-1200 cells/µL
	% CD8	5-37%	7-35%	6-41%	10-35%	7-58%	7-40%	9-49%	13-47%	14-40%	15-46%	10-46%
	Absolute CD8	200-2700 cells/µL	300-2700 cells/µL	300-3400 cells/µL	200-5400 cells/µL	400-4100 cells/µL	200-2800 cells/µL	200-1800 cells/µL	200-1700 cells/µL	300-1300 cells/µL	210-1200 cells/µL	150-1050 cells/µL
	CD4:CD8 Ratio	1.00-2.60	1.30-6.30	1.70-3.90	1.60-3.80	1.30-3.90	0.90-3.70	0.90-2.90	0.90-2.60	0.90-3.40	0.80-3.90	0.80-6.17
	% CD19	3-30%	3-60%	8-33%	4-54%	3-77%	8-45%	8-39%	4-33%	7-24%	6-23%	5-21%
	Absolute CD19	140-2000 cells/µL	180-3500 cells/µL	520-2300 cells/µL	130-6300 cells/µL	110-7700 cells/µL	160-3700 cells/µL	180-1300 cells/µL	100-800 cells/µL	120-740 cells/µL	91-610 cells/µL	74-510 cells/µL
	% NK-cells	8-62%	3-23%	2-20%	2-36%	1-64%	1-96%	2-25%	2-31%	4-51%	4-26%	5-28%
	Absolute NK-cells	500-3100 cells/µL	140-1900 cells/µL	97-2000 cells/µL	68-3900 cells/µL	71-3500 cells/µL	55-4000 cells/µL	61-510 cells/µL	70-590 cells/µL	92-1200 cells/µL	78-470 cells/µL	74-620 cells/µL

0095949 Lymphocyte Transplantation CD3 CD3

Specimen Required: Patient Prep: Draw specimen before administering immunosuppressive medications.
Collect: Green (Sodium or Lithium Heparin), Lavender (EDTA), or Pink (K_2EDTA).
Specimen Preparation: Transport 5 mL whole blood. (Min: 0.5 mL)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated.
Remarks: Specimens must be analyzed within 72 hours of collection.
New York State Clients: EDTA specimens must be analyzed within 30 hours of collection. Heparin specimens must be analyzed within 48 hours of collection.
Unacceptable Conditions: Clotted or hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 72 hours; Frozen: Unacceptable
New York State Clients: EDTA: Ambient: 30 hours; Refrigerated: 30 hours; Frozen: Unacceptable
Heparin: Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Unacceptable

Reference Interval: Effective February 20, 2018

Components	17 years and older
%CD3	56-85 %
Abs CD3	633-2532 cells/µL

CPT Code(s): 86356

HOTLINE NOTE: There is a component change associated with this test.
Remove component 0095883, Absolute Lymph.
Remove component 0097135, White Blood Cell Count.
Remove component 0097140, % Lymph.

New Test **3000256** **Marijuana Metabolite, Umbilical Cord Tissue, Qualitative** **THC QQQ CD**

Drug Test Table Meconium and Umbilical Cord

Additional Technical Information

Supplemental Resources

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

Specimen Required: Collect: Umbilical Cord (At least 6 inches, approximately the length of an adult hand.)
Specimen Preparation: Drain and discard any blood. Rinse the exterior of the cord segment with normal saline or sterile water. Pat the cord dry and transport at least 6 inches of umbilical cord in a routine urine collection cup or Security Kit for Meconium/Umbilical Drug Detection (ARUP supply #51548) available online through eSupply using ARUP Connect™ or by contacting ARUP Client Services at (800) 522-2787. (Min: 6 inches)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Cords soaking in saline or other solutions.
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval:

Drugs/Drug Classes	Cutoff Concentrations (ng/g)
THC-COOH	0.2

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

This test is designed to detect and document exposure that occurred during approximately the last trimester of a full term birth, to a common cannabis (marijuana) metabolite. Alternative testing is available to detect other drug exposures. The pattern and frequency of drug(s) used by the mother cannot be determined by this test. A negative result does not exclude the possibility that a mother used drugs during pregnancy. Detection of drugs in umbilical cord tissue depends on extent of maternal drug use, as well as drug stability, unique characteristics of drug deposition in umbilical cord tissue, and the performance of the analytical method. Drugs administered during labor and delivery may be detected. Detection of drugs in umbilical cord tissue does not insinuate impairment and may not affect outcomes for the infant. Interpretive questions should be directed to the laboratory.

For medical purposes only; not valid for forensic use unless testing was performed within Chain of Custody process.
See Compliance Statement B: www.aruplab.com/CS

Note: Absolute Minimum: 6 inches.

CPT Code(s): 80349 (Alt code: G0480)

New York DOH approval pending. Call for status update.

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

New Test **3000146** **Maternal Screening, Sequential, Specimen #1, hCG, PAPP-A, NT** **MS SEQ1**

Patient History For Maternal Serum Testing

Additional Technical Information

Supplemental Resources

Methodology: Quantitative Chemiluminescent Immunoassay
Performed: Sun-Sat
Reported: 2-4 days

Specimen Required: Patient Prep: Specimen must be drawn between 11 weeks, 0 days and 13 weeks, 6 days. (Crown-Rump length (CRL) must be between 43-83.9 mm at time of specimen collection.)
Collect: Serum Separator Tube (SST) or Plain Red.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 3 mL serum to an ARUP Standard Transport Tube. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Remarks: **Submit with Order:** Patient's date of birth, current weight, number of fetuses present, patient's race, if the patient was diabetic at the time of conception, if there is a known family history of neural tube defects, if the patient has had a previous pregnancy with a trisomy, if the patient is currently smoking, if the patient is taking valproic acid or carbamazepine (Tegretol), if this is a repeat sample, and the age of the egg donor if in vitro fertilization.

In addition to the above: the date of ultrasound, the CRL measurement, the nuchal translucency (NT) measurement and the name and certification number of the sonographer is required.

NT must be measured when the CRL is between 38-83.9 mm.

The NT measurement must also be performed by an ultrasonographer that is certified by one of the following agencies: Fetal Medicine Foundation (FMF) or Nuchal Translucency Quality Review (NTQR). To avoid possible test delays for an ultrasonographer that is new to our database, please contact the genetic counselor at (800) 242-2787 extension 2141 prior to sending specimen.

If an NT is unobtainable, order Maternal Serum Screening, Integrated (ARUP test codes 3000147 (collect in first trimester) and 3000149 (collect in second trimester)), which can be interpreted without an NT value.
Unacceptable Conditions: Plasma. Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 3 months (Avoid repeated freeze/thaw cycles.)

Reference Interval: By report

Interpretive Data: Refer to report.

Note: The first specimen of a Sequential Maternal Serum Screening is used to measure PAPP-A and hCG. This test is used to screen for fetal risk of Down syndrome (trisomy 21) and trisomy 18. Final interpretative report, which also includes fetal risk for Open Neural Tube Defect (ONTD), will be available when the second specimen test results are complete.

CPT Code(s): 81508

New York DOH Approved.

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

New Test **3000148** **Maternal Screening, Sequential, Specimen #2, Alpha Fetoprotein, hCG, Estriol, and Inhibin A** **MS SEQ2**

Additional Technical Information

Supplemental Resources

Methodology: Quantitative Chemiluminescent Immunoassay
Performed: Sun-Sat
Reported: 2-4 days

Specimen Required: Patient Prep: Specimen must be drawn between 14 weeks, 0 days and 24 weeks, 6 days gestation. The recommended time for maternal serum screening is 16 to 18 weeks gestation.
Collect: Serum Separator Tube (SST) or Plain Red.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 3 mL serum to an ARUP Standard Transport Tube. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Remarks: **Requires that a previous first trimester specimen, Maternal Screening, Sequential, Specimen #1, hCG, PAPP-A, NT (ARUP test code 3000146), has been performed.**
Unacceptable Conditions: Plasma. Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 year (Avoid repeated freeze/thaw cycles.)

Reference Interval: By report

Interpretive Data: Refer to report.

Note: This test is used to screen for fetal risk of Down syndrome (trisomy 21), trisomy 18, and Open Neural Tube Defect (ONTD, spina bifida).

The patient information provided with the Sequential, Specimen #1 will be used to calculate the risks for this report.

CPT Code(s): 81511

New York DOH Approved.

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

New Test **3000144** **Maternal Serum Screen, Alpha Fetoprotein** **MS AFP**

Patient History For Maternal Serum Testing

Supplemental Resources

Methodology: Quantitative Chemiluminescent Immunoassay
Performed: Sun-Sat
Reported: 2-3 days

Specimen Required: Patient Prep: Specimen must be drawn between 14 weeks, 0 days and 24 weeks, 6 days gestation.
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: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Remarks: **Submit with Order:** Patient's date of birth, current weight, due date, dating method (US, LMP), number of fetuses present, patient's race, if the patient was diabetic at the time of conception, if there is a known family history of neural tube defects, if the patient is currently smoking, if the patient is taking valproic acid or carbamazepine (Tegretol), and if this is a repeat sample.
Unacceptable Conditions: Plasma. Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 year (Avoid repeated freeze/thaw cycles.)

Reference Interval: By report

Interpretive Data: Refer to report.

Note: This test is used to screen for fetal risk of Open Neural Tube Defect (i.e., spina bifida).

CPT Code(s): 82105

New York DOH Approved.

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

New Test **3000143** **Maternal Serum Screen, Alpha Fetoprotein, hCG, Estriol, and Inhibin A (Quad)** **MS QUAD**

Patient History For Maternal Serum Testing

Additional Technical Information

Supplemental Resources

Methodology: Quantitative Chemiluminescent Immunoassay
Performed: Sun-Sat
Reported: 2-3 days

Specimen Required: Patient Prep: Specimen must be drawn between 14 weeks, 0 days and 24 weeks, 6 days gestation. The recommended time for maternal serum screening is 16 to 18 weeks gestation.
Collect: Serum Separator Tube (SST) or Plain Red.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 3 mL serum to an ARUP Standard Transport Tube. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Remarks: **Submit with Order:** Patient's date of birth, current weight, due date, dating method (US, LMP), number of fetuses present, patient's race, if the patient was diabetic at the time of conception, if there is a known family history of neural tube defects, if the patient has had a previous pregnancy with a trisomy, if the patient is currently smoking, if the patient is taking valproic acid or carbamazepine (Tegretol), if this is a repeat sample, and the age of the egg donor if in vitro fertilization.
Unacceptable Conditions: Plasma. Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 year (Avoid repeated freeze/thaw cycles.)

Reference Interval: By report

Interpretive Data: Refer to report.

Note: This test is used to screen for fetal risk of Down syndrome (trisomy 21), trisomy 18, and Open Neural Tube Defect (ONTD, spina bifida).

CPT Code(s): 81511

New York DOH Approved.

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

New Test **3000145** **Maternal Serum Screen, First Trimester, hCG, PAPP-A, NT** **MS FTS**

Patient History For Maternal Serum Testing

Additional Technical Information

Supplemental Resources

Methodology: Quantitative Chemiluminescent Immunoassay
Performed: Sun-Sat
Reported: 2-4 days

Specimen Required: Patient Prep: Specimen must be drawn between 11 weeks, 0 days and 13 weeks, 6 days. (Crown-Rump length (CRL) must be between 43-83.9 mm at time of specimen collection.)
Collect: Serum Separator Tube (SST) or Plain Red.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 3 mL serum to an ARUP Standard Transport Tube. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Remarks: **Submit with Order:** Patient's date of birth, current weight, number of fetuses present, patient's race, if the patient has had a previous pregnancy with a trisomy, if the patient is currently smoking, if this is a repeat sample, and the age of the egg donor if in vitro fertilization.

In addition to the above: the date of ultrasound, the CRL measurement, the nuchal translucency (NT) measurement and the name and certification number of the sonographer is required.

NT must be measured when the CRL is between 38-83.9 mm.

The NT measurement must also be performed by an ultrasonographer that is certified by one of the following agencies: Fetal Medicine Foundation (FMF) or Nuchal Translucency Quality Review (NTQR). To avoid possible test delays for an ultrasonographer that is new to our database, please contact the genetic counselor at (800) 242-2787 extension 2141 prior to sending specimen.

If an NT is unobtainable, order Maternal Serum Screening, Integrated (ARUP test codes 3000147 (collect in first trimester) and 3000149 (collect in second trimester)), which can be interpreted without an NT value.
Unacceptable Conditions: Plasma. Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 3 months (Avoid repeated freeze/thaw cycles.)

Reference Interval: By report

Interpretive Data: Refer to report.

Note: This test does not screen for Open Neural Tube Defect (ONTD). This test is used to screen for fetal risk of Down syndrome (trisomy 21) and trisomy 18.

CPT Code(s): 81508

New York DOH Approved.

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

New Test **3000147** **Maternal Serum Screening, Integrated, Specimen #1, PAPP-A, NT** **MS INT1**

Patient History For Maternal Serum Testing

Additional Technical Information

Supplemental Resources

Methodology: Quantitative Chemiluminescent Immunoassay
Performed: Sun-Sat
Reported: 2-4 days

Specimen Required: Patient Prep: Specimen must be drawn between 10 weeks, 0 days and 13 weeks, 6 days. (If gestational age is based on Crown-Rump length (CRL), the specimen must be collected when the CRL is between 32.4-83.9 mm.)
Collect: Serum Separator Tube (SST) or Plain Red.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 0.5 mL serum to an ARUP Standard Transport Tube. (Min: 0.3 mL)
Storage/Transport Temperature: Refrigerated.
Remarks: **Submit with Order:** Patient's date of birth, current weight, number of fetuses present, patient's race, if the patient was diabetic at the time of conception, if there is a known family history of neural tube defects, if the patient has had a previous pregnancy with a trisomy, if the patient is currently smoking, if the patient is taking valproic acid or carbamazepine (Tegretol), if this is a repeat sample, and the age of the egg donor if in vitro fertilization.

In addition to the above:

If a NT measurement is performed: the date of ultrasound, the CRL measurement, the nuchal translucency (NT) measurement and the name and certification number of the sonographer is required. NT must be measured when the CRL is between 38-83.9 mm.
or
If no NT measurement is performed: a due date *or* CRL measurement with the date of ultrasound is required.

The NT measurement must also be performed by an ultrasonographer that is certified by one of the following agencies: Fetal Medicine Foundation (FMF) or Nuchal Translucency Quality Review (NTQR). To avoid possible test delays for an ultrasonographer that is new to our database, please contact the genetic counselor at (800) 242-2787 extension 2141 prior to sending specimen.
Unacceptable Conditions: Plasma. Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 3 months (Avoid repeated freeze/thaw cycles.)

Reference Interval: By report

Interpretive Data: Refer to report.

Note: The first specimen of an Integrated Maternal Serum Screening is used to measure PAPP-A. Final interpretative report will be available when the second specimen test results are complete.

CPT Code(s): 84163

New York DOH Approved.

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

New Test **3000149** **Maternal Serum Screening, Integrated, Specimen #2, Alpha Fetoprotein, hCG, Estriol, and Inhibin A** **MS INT2**

Additional Technical Information

Supplemental Resources

Methodology: Quantitative Chemiluminescent Immunoassay
Performed: Sun-Sat
Reported: 2-4 days

Specimen Required: Patient Prep: Specimen must be drawn between 14 weeks, 0 days and 24 weeks, 6 days gestation. The recommended time for maternal serum screening is 16 to 18 weeks gestation.
Collect: Serum Separator Tube (SST) or Plain Red.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 3 mL serum to an ARUP Standard Transport Tube. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Remarks: **Requires that a previous first trimester specimen, Maternal Serum Screening, Integrated, Specimen #1, PAPP-A, NT (ARUP test code 3000147), has been performed.**
Unacceptable Conditions: Plasma. Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 year (Avoid repeated freeze/thaw cycles.)

Reference Interval: By report

Interpretive Data: Refer to report.

Note: This test is used to screen for fetal risk of Down syndrome (trisomy 21), trisomy 18, and Open Neural Tube Defect (ONTD, spina bifida).

The patient information provided with the Integrated, Spcm1 will be used to calculate the risks for this report.

CPT Code(s): 81511

New York DOH Approved.

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

New Test **3000248** **Meperidine and Metabolite Quantitative, Urine** **MEPERI U**

Methodology: Quantitative Gas Chromatography/Gas Chromatography-Mass Spectrometry
Performed: Varies
Reported: 3-10 days

Specimen Required: Collect: Random urine.
Specimen Preparation: Transport 2 mL urine in an ARUP Standard Transport Tube. (Min: 0.7 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 2 weeks

Reference Interval: By report

CPT Code(s): 80362 (Alt code: G0480)

New York DOH Approved.

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

2012288 Meperidine, Urine Screen with Reflex to Quantitation MEP RFX U

Methodology: Qualitative Enzyme Immunoassay/ Quantitative Gas Chromatography-Mass Spectrometry

Note: If the specimen screens positive, then Confirmation/Quantitation by GC-MS will be added to confirm result. See Meperidine and Metabolite Quantitative, Urine (3000248). Additional charges apply.

HOTLINE NOTE: There is a reflexive pattern change associated with this test.
Remove reflex to 2002760 Meperidine and Metabolite, Urine, Quantitative and add reflex to 3000248 Meperidine and Metabolite Quantitative, Urine

New Test 3000251 Methsuximide Metabolite, Serum or Plasma METHSU SP

Methodology: Quantitative High Performance Liquid Chromatography
Performed: Varies
Reported: 3-10 days

Specimen Required: Collect: Plain Red, Lavender (KEDTA), or Pink (K_2EDTA)
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.7 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Unacceptable Conditions: Separator tubes
Stability (collection to initiation of testing): Ambient: 2 weeks; Refrigerated: 2 weeks; Frozen: 2 weeks

CPT Code(s): 80339 (Alt code: G0480)

New York DOH Approved.

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

New Test 3000253 Methylphenidate and Metabolite Quantitative, Serum or Plasma METHYL SP

Methodology: Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry
Performed: Varies
Reported: 3-10 days

Specimen Required: Patient Prep: Collect specimen 1-6 hours post dose.
Collect: Plain Red, Lavender (EDTA), or Pink (K_2EDTA).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.7 mL)
Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Unacceptable Conditions: Separator tubes.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 5 months

Reference Interval: By report

CPT Code(s): 80360 (Alt code: G0480)

New York DOH Approved.

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

2012420 **Muscle-Specific Kinase (MuSK) Antibody by RIA** **MUSK**

Performed: Varies
Reported: 3-10 days

Specimen Required: Collect: Plain Red. Also acceptable: 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.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 month; Frozen: 1 month

New Test
Available Now

3000221 **Neurokinin A (Substance K), Plasma** **NEURO A**

Methodology: Quantitative Radioimmunoassay
Performed: Varies
Reported: 5-9 days

Specimen Required: Patient Prep: Pain medication, medications that affect hypertension or intestinal motility should be discontinued, if possible, at least 48 hours prior to collection.
Collect: Z plasma preservative tube (ARUP supply #40874) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Specimen Preparation: Separate from cells within 10 minutes. Transfer 4 mL plasma to an ARUP Standard Transport Tube and freeze immediately. (Min: 1 mL)
Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Unacceptable Conditions: Specimens not collected in a Z plasma preservative tube. Thawed specimens.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 6 months

Reference Interval: By Report

CPT Code(s): 83519

New York DOH Approved.

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

New Test Available Now | **2010769** | **Noonan Spectrum Disorders Panel, Sequencing, 15 Genes, Fetal** | **NOONAN FE**

Patient History for Fetal Molecular Testing

Additional Technical Information

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

Methodology: Massively Parallel Sequencing
Performed: Varies
Reported: 6-8 weeks

Specimen Required: Collect: **Fetal Specimen:** Four T-25 flasks at 80 percent confluent of cultured amniocytes or cultured CVS. If the client is unable to culture, this can be arranged by contacting ARUP Client Services at (800) 522-2787.
AND **Maternal Cell Contamination Specimen:** Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: **Cultured Amniocytes or Cultured CVS:** Fill flasks with culture media. Transport four T-25 flasks at 80 percent confluent of cultured cells filled with culture media. Backup
cultures must be retained at the client's institution until testing is complete.
AND **Maternal Cell Contamination Specimen:** Transport 3 mL whole blood (Min: 1 mL)
Storage/Transport Temperature: **Culture Amniocytes or Cultured CVS:** CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of shipment due to lability of cells.
Maternal Cell Contamination Specimen: Ambient.
Stability (collection to initiation of testing): **Fetal Specimen:** Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Maternal: Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data: Refer to report.

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

Note: Reported times are based on receiving the four T-25 flasks at 80 percent confluent. Cell culture time is independent of testing turn-around time. Maternal specimen is recommended for proper test interpretation. Order Maternal Cell Contamination.

CPT Code(s): 81442; 81265 Fetal Cell Contamination

New York DOH approval pending. Call for status update.

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

2012312 | **Pain Management Panel, Screen with Reflex to Quantitation** | **PAIN RFX U**

Note: If the specimen screens positive, then Confirmation/Quantitation by GC/MS and/or LC-MS/MS will be added to confirm result. Additional charges apply.

HOTLINE NOTE: There is a reflexive pattern change associated with this test.
Remove reflex to 2002760 Meperidine and Metabolite, Urine, Quantitative and add reflex to 3000248 Meperidine and Metabolite Quantitative, Urine

New Test Available Now **3000003** **Parathyroid Hormone (PTH) Antibody** **PTH-AB**

Methodology: Qualitative Radiobinding Assay
Performed: Varies
Reported: 4-15 days

Specimen Required: Collect: Plain Red. Also acceptable: Serum Separator Tube (SST).
Specimen Preparation: Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated or frozen.
Stability (collection to initiation of testing): Ambient: 2 weeks; Refrigerated: 2 weeks; Frozen: 28 days

Reference Interval: By report

CPT Code(s): 83519

New York DOH Approved.

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

2013284 **PD-L1 22C3 IHC for NSCLC with Interpretation, pembrolizumab (KEYTRUDA)** **22C3 IP**

Specimen Required: Collect: Tumor tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen. Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (ARUP supply #47808 recommended but not required), available online through eSupply using ARUP Connector contact ARUP Client Services at (800) 522-2787. (Min: 3 slides) If sending precut slides, do not oven bake.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks: Include surgical pathology report and indicate tissue site with the test order. For additional technical details, please contact ARUP Client Services at (800) 522-2787.
Unacceptable Conditions: Gastric/GEJ specimens. Paraffin block with no tumor tissue remaining. Specimens fixed in any fixative other than 10 percent neutral buffered formalin. Decalcified specimens. Specimens with fewer than 100 viable tumor cells.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

2012229 **Pregabalin, Urine** **PREGABA U**

Interpretive Data: Positive cutoff: 5.0 µg/mL

For medical purposes only; not valid for forensic use.

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

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

New Test **3000219** **Prostaglandin D2 (PG D2), Serum or Plasma** **PROSTAG D2**
Available Now

Methodology: Quantitative Radioimmunoassay
Performed: Varies
Reported: 5-10 days

Specimen Required: Patient Prep: Aspirin, indomethacin, or anti-inflammatory medications should be discontinued, if possible, at least 48 hours prior to collection.
Collect: Plain Red or Lavender (EDTA).
Specimen Preparation: Separate from cells within 10 minutes of collection. Transfer 3 mL serum or plasma to an ARUP Standard Transport Tube and freeze immediately. (Min: 1 mL)
Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 6 months

CPT Code(s): 84150

New York DOH approval pending. Call for status update.

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

New Test **3000240** **Prostaglandin D2 (PG D2), Urine** **PROST D2U**

Methodology: Quantitative Radioimmunoassay
Performed: Varies
Reported: 5-10 days

Specimen Required: Patient Prep: Aspirin, indomethacin, or anti-inflammatory medications should be discontinued, if possible, at least 48 hours prior to collection.
Collect: 24-hour urine. Refrigerate during collection.
Specimen Preparation: Transfer 10 mL urine from a well-mixed 24-hour collection to ARUP Standard Transport Tubes and freeze immediately. (Min: 5 mL)
Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Remarks: Record total volume and duration on transport tube and test request form.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 6 months

CPT Code(s): 84150

New York DOH approval pending. Call for status update.

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

0091539 **Silicon Quantitative, Serum or Plasma** **SILICON SP**

Performed: Varies
Reported: 1-2 weeks

Specimen Required: Collect: Royal blue (trace metal-free; EDTA) or royal blue (trace metal-free; no additive).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP Trace Element-Free Transport Tube (ARUP supply #43116) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 0.7 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Unacceptable Conditions: Separator tubes.
Stability (collection to initiation of testing): Ambient: 2 weeks; Refrigerated: 3 weeks; Frozen: 2 weeks

0092066	**Thiopurine Methyltransferase, RBC**	**TPMT RBC**

Performed: Mon, Wed, Fri
Reported: 3-5 days

New Test Available Now | **2006385** | **Thrombotic Risk Reflexive Panel** | **THROMRISKR**

Methodology: Chromogenic Assay/Electromagnetic Mechanical Clot Detection/Quantitative Enzymatic/Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Polymerase Chain Reaction/Fluorescence Monitoring/Microlatex Particle Mediated Immunoassay

Performed: Varies
Reported: 2-7 days

Specimen Required: Patient Prep: Fasting preferred. Refer to Specimen Handling at aruplab.com for hemostasis/thrombosis specimen handling guidelines.
Collect: Four light blue (sodium citrate) **AND** two lavender (EDTA) **AND** two serum separator tubes (SST). Also acceptable in place of one of the serum separator tubes: Green (sodium or lithium heparin).
Specimen Preparation: One serum separator tube or green (sodium or lithium heparin) must be centrifuged and serum or plasma separated within 1 hour of collection. Transfer 1 mL centrifuged serum or plasma to ARUP Standard Transport Tube and label centrifuged tube for homocysteine testing. (Min: 0.5 mL) **AND** Transfer 2 mL serum into 2 ARUP Standard Transport Tubes, label as serum (Min: 0.5 mL/tube**) AND** Transfer 7.5 mL light blue (sodium citrate) to 5 ARUP Standard Transport Tubes, label as sodium citrate. (Min: 1 mL/tube) **AND** Transfer 3 mL lavender whole blood to 2 ARUP Standard Transport Tubes. (Min: 1 mL/tube
Storage/Transport Temperature: **Light blue (sodium citrate):** CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered. **Lavender whole blood and Serum or Green (sodium or lithium heparin):** Refrigerated.
Unacceptable Conditions: Specimens collected in any tube type not listed above.
Stability (collection to initiation of testing): **Light blue (sodium citrate**): Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 2 weeks. **Lavender whole blood:** Ambient: 2 hours; Refrigerated: 1 week; Frozen: Unacceptable **Serum:** Ambient: 2 hours; Refrigerated: 1 week; Frozen: 2 weeks **Green (sodium or lithium heparin):** Ambient: 1 hour; Refrigerated: 1 week; Frozen: 3 months

Reference Interval:

Test Number	Components	Reference Interval
	Prothrombin Time	12.0-15.5 seconds
	Partial Thromboplastin Time	32-48 seconds
	Dilute Russell Viper Venom Time (dRVVT)	33-44 seconds
	Thrombin Time	14.7-19.5 seconds
	Reptilase Time	Less than 22.0 seconds
	PTT Heparin Neutralized	32-48 seconds
	Partial Thromboplastin Time 1:1 Mix (performed if PTT > 48 seconds)	32-48 seconds
	Platelet Neutralization Procedure (performed if PTT 1:1 Mix > 48 seconds)	Negative
	Dilute Russell Viper Venom (dRVVT) 1:1 Mix (performed if dRVVT > 44 seconds)	33-44 seconds
	Dilute Russell Viper Venom Time (dRVVT) Confirmation Test (performed if dRVVT 1:1 Mix > 44 seconds)	Negative
	Hexagonal Phospholipid Neutralization	Negative
0050901	Cardiolipin Antibody, IgG	Effective August 18, 2014 0-14 GPL: Negative 15-19 GPL: Indeterminate 20-80 GPL: Low to Moderately Positive 81 GPL or above: High Positive
0050902	Cardiolipin Antibody, IgM	Effective August 18, 2014 0-12 MPL: Negative 13-19 MPL: Indeterminate 20-80 MPL: Low to Moderately Positive 81 MPL or above: High Positive
	Beta-2 Glycoprotein 1 Antibody, IgG	Effective August 18, 2014 0-20 SGU
	Beta-2 Glycoprotein 1 Antibody, IgM	Effective August 18, 2014 0-20 SMU
0098894	Protein S Free, Antigen	**Age** / **Male** / **Female** 1-89 days: 15-55% / 15-55% 90-179 days: 35-92% / 35-92% 180-364 days: 45-115% / 45-115% 1-5 years: 62-120% / 62-120% 6-9 years: 62-130% / 62-130% 10-17 years: 60-140% / 60-140% 18 years and older: 74-147% / 55-123%
0099869	Homocysteine, Total	Less than 11 µmol/L, for both male and female
0030010	Antithrombin, Enzymatic (Activity)	**Age** / **Reference Interval** 1-4 days: 39-87% 5-29 days: 41-93% 30-89 days: 48-108% 90-179 days: 73-121% 180-364 days: 84-124% 1-5 years: 82-139% 6 years: 90-131% 7-9 years: 90-135% 10-11 years: 90-134% 12-13 years: 90-132% 14-15 years: 90-131% 16-17 years: 87-131% 18 years and older: 76-128%
0030113	Protein C, Functional	Effective November 17, 2014 **Age** / **Reference Interval** 1-4 days: 17-53% 5-29 days: 20-64% 30-89 days: 21-65% 90-179 days: 28-80% 180-364 days: 37-81% 1-6 years: 40-92% 7-9 years: 70-142% 10-11 years: 68-143% 12-13 years: 66-162% 14-15 years: 69-170% 16-17 years: 70-171% 18 years and older: 83-168%
	APC Resistance Profile	Effective February 21, 2011 2.00 or greater **Test Number** / **Components** / **Reference Interval**

		0030127	APC Resistance Profile	Refer to report
		0097720	Factor V Leiden (*F5*) R506Q Mutation	Refer to report
	Factor V Leiden by PCR & Fluorescence Monitoring	Negative: The sample is negative for factor V Leiden, R506Q mutation.		
0056060	Prothrombin (*F2*) c.*97G>A (G20210A) Pathogenic Variant			

Interpretive Data: Refer to individual components.

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

CPT Code(s): 86147 x2; 86146 x2; 85306; 83090; 85300; 85303; 85307; 85610; 81240; 85730; 85613. If PTT is abnormal, add 85670. If Thrombin time is abnormal, add 85635, 85730 and 85525. If PTT Heparin Neutralization is abnormal, add 85732. If PTT 1:1 Mix is abnormal, add 85597. If dRVVT is abnormal, add 85613. If dRVVT 1:1 mix is abnormal, add 85613. If PNP and dRVVT confirmation are normal, add 85598. If APC resistance is low, add 81241.

New York DOH Approved.

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

New Test Available Now **3000005** ***Trichinella* Antibody, IgG** **TRICHIN AB**

Methodology: Qualitative Enzyme-Linked Immunosorbent Assay
Performed: Varies
Reported: 3-10 days

Specimen Required: Collect: Plain Red. Also acceptable: Serum Separator Tube (SST).
Specimen Preparation: Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.1 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 1 month

Reference Interval: By report

CPT Code(s): 86784

New York DOH Approved.

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

0051076 ***Trypanosoma cruzi* Antibody, IgG** **CHAGAS G**

Reference Interval:
Effective November 9, 2017

1.0 IV or less	Negative - No significant level of *Trypanosoma cruzi* IgG antibody detected.
1.1 IV	Equivocal - Questionable presence of *Trypanosoma cruzi* IgG antibody detected. Repeat testing in 10-14 days may be helpful.
1.2 IV or greater	Positive - IgG antibodies to *Trypanosoma cruzi* detected, which may suggest current or past infection.

HOTLINE NOTE: There is a numeric map change associated with this test.
Change the numeric map for component 0051076, Trypanosoma cruzi Antibody, IgG from XX.XX to XXX.X.

2006352 **X-Chromosome Inactivation Analysis** **XCI**

Interpretive Data:
Characteristics: Females usually have two copies of the X-chromosome, one of which becomes randomly inactivated early in embryonic development in a process known as lyonization. If either the paternally or maternally derived X-chromosome is preferentially inactivated, this results in a non-random or "skewed" pattern of X-chromosome inactivation (XCI). The pattern of XCI may vary among tissue types. XCI ratios of 50:50 to 79:21 may suggest random XCI, ratios of 80:20 to 100:0 suggest non-random XCI.
Cause: Non-random XCI may result by chance or from secondary cell selection in females who are heterozygous for X-chromosome rearrangements, carriers of pathogenic variants in X-linked genes, or affected with neoplastic disease.
Gene Tested: The androgen receptor (*AR*) gene on the X chromosome.
Clinical Sensitivity: Approximately 90 percent. An estimated 10-15 percent of females have skewed X-inactivation by chance. However, skewed XCI may be seen more frequently with increasing age.
Methodology: Methylation-sensitive restriction digest followed by PCR and fragment analysis.
Limitations: Testing is limited to XX females only. This assay will be uninformative in up to 20 percent of females due to homozygosity for the polymorphic *AR* gene locus analyzed. XCI patterns may differ among tissues; therefore, the XCI ratio reported is for the tissue type tested with a standard deviation 0.09 in random XCI; 0.06 in non-random XCI. Although this test will detect the methylation status of the X-chromosomes, it will not determine if the X inactivation pattern is associated with rearrangements of the X chromosome, pathogenic variants in X-linked genes or neoplastic disease. If a non-random XCI pattern is present, the parent of origin of the active X cannot be determined without testing parental samples. XCI ratios should not be used to predict prognosis for female carriers of X-linked disorders as variable expressivity may result due to other genetic or environmental modifiers. Because the level of XCI may differ in prenatal specimens and whole blood, this test is not recommended for prenatal diagnosis. Diagnostic errors can occur due to rare sequence variations.

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

The following will be discontinued from ARUP's test menu on February 20, 2018.
Replacement test options are supplied if applicable.

Test Number	Test Name	Refer To Replacement
0091322	Acetophenazine, Serum or Plasma	
0080427	Alpha Fetoprotein (Amniotic Fluid) with Reflex to Acetylcholinesterase and Fetal Hemoglobin	Alpha Fetoprotein (Amniotic Fluid) with Reflex to Acetylcholinesterase and Fetal Hemoglobin (3000142)
0090978	Amobarbital, Serum or Plasma	
0090601	Antidepressant Panel Quantitative, Serum or Plasma	
0091317	Atenolol Quantitative, Serum or Plasma	
0050626	Blastomyces Antibodies by CF and ID	*Blastomyces dermatitidis* Antibodies by EIA with Reflex to Immunodiffusion, Serum (3000236)
0050130	Blastomyces Antibody by CF	*Blastomyces dermatitidis* Antibodies by EIA with Reflex to Immunodiffusion, Serum (3000236)
0090045	Butalbital	
0091337	Cimetidine, Serum or Plasma	
2011501	Ethotoin, Serum or Plasma	
2003887	Friend Leukemia Integration-1 (Fli-1) by Immunohistochemistry	
0050750	Fungal Antibodies by CF, CSF	Fungal Antibodies with Reflex to *Blastomyces dermatitidis* Antibodies by Immunodiffusion, CSF (3000230)
0050605	Fungal Antibodies by CF, Serum	Fungal Antibodies with Reflex to *Blastomyces dermatitidis* Antibodies by Immunodiffusion (3000235)
2004593	India Ink Stain	*Cryptococcus* Antigen, CSF (0050195)
0095798	Lymphocyte Transplantation Profile	Lymphocyte Transplantation CD3 (0095949)
0090662	Maprotiline Quantitative, Serum or Plasma	
0081293	Maternal Screening, Sequential, Specimen #1	Maternal Screening, Sequential, Specimen #1, hCG, PAPP-A, NT (3000146)
0081294	Maternal Screening, Sequential, Specimen #2	Maternal Screening, Sequential, Specimen #2, Alpha Fetoprotein, hCG, Estriol, and Inhibin A (3000148)
0080434	Maternal Serum Screen, Alpha Fetoprotein (Only)	Maternal Serum Screen, Alpha Fetoprotein (3000144)
0080269	Maternal Serum Screen, Alpha Fetoprotein, hCG, Estriol, and Inhibin A	Maternal Serum Screen, Alpha Fetoprotein, hCG, Estriol, and Inhibin A (Quad) (3000143)
0081150	Maternal Serum Screen, First Trimester	Maternal Serum Screen, First Trimester, hCG, PAPP-A, NT (3000145)
0081062	Maternal Serum Screening, Integrated, Specimen #1	Maternal Serum Screening, Integrated, Specimen #1, PAPP-A, NT (3000147)
0081064	Maternal Serum Screening, Integrated, Specimen #2	Maternal Serum Screening, Integrated, Specimen #2, Alpha Fetoprotein, hCG, Estriol, and Inhibin A (3000149)
2002756	Meperidine and Metabolite, Serum or Plasma, Quantitative	
2002760	Meperidine and Metabolite, Urine, Quantitative	Meperidine and Metabolite Quantitative, Urine (3000248)
0091248	Mercury, Nails	
2011531	Methsuximide and Normethsuximide, Serum or Plasma	Methsuximide Metabolite, Serum or Plasma (3000251)
2003114	Methylphenidate and Metabolite, Serum or Plasma, Quantitative	Methylphenidate and Metabolite Quantitative, Serum or Plasma (3000253)
0091387	Oxazepam Quantitative, Serum or Plasma	
0091522	Pentazocine Quantitation, Serum or Plasma	
0091456	Phenazopyridine, Urine	
0091491	Piroxicam (Feldene), Serum or Plasma	
2010248	Prosigna Breast Cancer Prognostic Gene Signature	
0099528	ssDNA Antibody, IgG	
0091107	Trimipramine and Metabolite Quantitative, Serum or Plasma	
2005766	WT1 Mutation Detection by Sequencing	Myeloid Malignancies Mutation Panel by Next Generation Sequencing (2011117)