HOTLINE: Effective May 20, 2019

MEDICARE COVERAGE OF LABORATORY TESTING

Please remember when ordering laboratory tests that are billed to Medicare/Medicaid or other federally funded programs, the following requirements apply:

1. Only tests that are medically necessary for the diagnosis or treatment of the patient should be ordered. Medicare does not pay for screening tests except for certain specifically approved procedures and may not pay for non-FDA approved tests or those tests considered experimental.
2. If there is reason to believe that Medicare will not pay for a test, the patient should be informed. The patient should then sign an Advance Beneficiary Notice (ABN) to indicate that he or she is responsible for the cost of the test if Medicare denies payment.
3. The ordering physician must provide an ICD-10 diagnosis code or narrative description, if required by the fiscal intermediary or carrier.
4. Organ- or disease-related panels should be billed only when all components of the panel are medically necessary.
5. Both ARUP- and client-customized panels should be billed to Medicare only when every component of the customized panel is medically necessary.
6. Medicare National Limitation Amounts for CPT codes are available through the Centers for Medicare & Medicaid Services (CMS) or its intermediaries. Medicaid reimbursement will be equal to or less than the amount of Medicare reimbursement.

The CPT Code(s) for test(s) profiled in this bulletin are for informational purposes only. The codes reflect our interpretation of CPT coding requirements, based upon AMA guidelines published annually. CPT codes are provided only as guidance to assist you in billing. ARUP strongly recommends that clients reconfirm CPT code information with their local intermediary or carrier. CPT coding is the sole responsibility of the billing party.

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

Hotline Page #	Test Number	Summary of Changes by Test Name	Name Change	Methodology	Performed/Reported Schedule	Specimen Requirements	Reference Interval	Interpretive Data	Note	CPT Code	Component Change	Other Interface Change	New Test	Inactive
50	2012710	Aggressive B-Cell Lymphoma FISH Reflex, Tissue												x
7	3001495	Aggressive B-Cell Lymphoma Reflex Panel by FISH, Tissue											x	
50	2014007	Allergen, Food, Milk (Boiled) IgE												x
50	2010738	Allergen, Food, Safflower IgE												x
50	2009210	Antimicrobial Level - Rifampin by HPLC, Serum or Plasma												x
7	0020734	Arsenic, Fractionated, Urine			x									
50	0091570	Aspirin and Oxycodone Quantitative, Serum or Plasma												x

Hotline Page #	Test Number	Summary of Changes by Test Name	Name Change	Methodology	Performed/Reported Schedule	Specimen Requirements	Reference Interval	Interpretive Data	Note	CPT Code	Component Change	Other Interface Change	New Test	Inactive
7	2005017	*BCR-ABL1*, Major (p210), Quantitative									x			
7	2005010	*BCR-ABL1*, Qualitative with Reflex to *BCR-ABL1* Quantitative										x		
8	3001635	Beckwith-Wiedemann Syndrome (BWS) and Russell-Silver Syndrome (RSS) by Methlyation-Specific MLPA											x	
8	2011479	Cadmium, Random Urine			x									
8	0025040	Cadmium, Urine			x									
9	2011603	Caffeine, Serum or Plasma				x					x			
9	0058002	*Campylobacter* Antigen		x	x	x				x				
9	2011763	Carbamazepine, Free and Total, Serum or Plasma			x	x					x			
50	2003827	Carcinoembryonic Antigen, Polyclonal (CEA P) by Immunohistochemistry												x
9	0025068	Chromium, Urine			x									
10	0099231	Cobalt, Blood				x		x	x					
10	0025037	Cobalt, Serum or Plasma				x		x	x					
11	0025032	Cobalt, Urine				x			x					
11	0050170	*Coccidioides* Antibody by CF			x									
11	3000059	*Coccidioides* Antibody by CF, CSF			x									
50	2013386	Congenital Adrenal Hyperplasia (CAH) (21-Hydroxylase Deficiency) Common Mutations												x
11	2011480	Copper, Random Urine			x	x			x					
12	0020096	Copper, Serum or Plasma			x	x	x	x	x			x		
12	0020461	Copper, Urine			x	x			x					
13	3001508	*CYP2C19*											x	
14	3001501	*CYP2C8* and *CYP2C9*											x	
15	3001513	*CYP2D6*											x	
16	3001518	*CYP3A4* and *CYP3A5*											x	
17	0095229	Cystatin C, Serum with Reflex to Estimated Glomerular Filtration Rate (eGFR)				x	x		x					
50	2012769	Cytochrome P450 2C19, *CYP2C19* - 9 Variants												x
50	2012766	Cytochrome P450 2C9, *CYP2C9* - 2 Variants												x
50	2014547	Cytochrome P450 2D6 (*CYP2D6*) 15 Variants and Gene Duplication												x
50	2012740	Cytochrome P450 3A5 Genotyping, *CYP3A5*, 2 Variants												x
50	2013098	Cytochrome P450 Genotype Panel												x

Hotline Page #	Test Number	Summary of Changes by Test Name	Name Change	Methodology	Performed/Reported Schedule	Specimen Requirements	Reference Interval	Interpretive Data	Note	CPT Code	Component Change	Other Interface Change	New Test	Inactive
18	3001524	Cytochrome P450 Genotyping Panel											x	
19	2011632	Disopyramide, Serum or Plasma				x					x			
50	2007763	Diuretic Survey Quantitative, Serum or Plasma												x
20	2006621	Drug Detection Panel, Umbilical Cord Tissue, Qualitative				x	x	x	x		x			
20	0049178	*ERBB2* (*HER2/neu*) (HercepTest) by Immunohistochemistry, Tissue with Reflex to FISH if 2+									x			
21	0049174	*ERBB2* (*HER2/neu*) (HercepTest) with Interpretation by Immunohistochemistry, Tissue									x			
21	2008603	ERBB2 (HER2/neu) Gene Amplification by FISH with Reflex, Tissue										x		
21	2010358	Ethosuximide, Serum or Plasma				x					x			
21	3000443	Ethyl Glucuronide, Umbilical Cord Tissue, Qualitative				x		x						
22	3001457	Exome Reanalysis (Originally Tested at ARUP – No Specimen Required)											x	
50	0060315	Fat, Body Fluid												x
50	0020240	Fat, Urine Qualitative												x
50	2007228	5-Fluorouracil (5-FU) Toxicity and Chemotherapeutic Response, 5 Mutations												x
50	2002662	Freeman-Sheldon Syndrome (*MYH3*) Sequencing Exon 17												x
23	3001416	Fumarate Hydratase by Immunohistochemistry											x	
23	0051033	Ganglioside (Asialo-GM1, GM1, GM2, GD1a, GD1b, and GQ1b) Antibodies								x				
23	2002674	Gastrointestinal Stromal Tumor Mutation		x	x	x			x					
50	0051476	Glaucoma (Primary Congenital), *CYP1B1* Sequencing												x
50	2002862	Glutamic Acid Decarboxylase Antibody (GAD65) and Insulin Antibodies with Reflex to IA-2 Antibody												x
24	0060101	Gram Stain				x								
50	2002044	Hearing Loss, Nonsyndromic, Mitochondrial DNA 2 Mutations												x
24	2011304	Heavy Metals Panel 3, Random Urine with Reflex to Arsenic Fractionated			x									
24	0099475	Heavy Metals Panel 3, Urine with Reflex to Arsenic Fractionated			x									
24	0020572	Heavy Metals Panel 4, Urine with Reflex to Arsenic Fractionated			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
24	0025055	Heavy Metals Panel 6, Urine with Reflex to Arsenic Fractionated			x	x			x					
50	0099414	HemoQuant, Fecal												x
25	0070036	Histamine, Plasma				x								
25	0070038	Histamine, Urine				x								
25	0070037	Histamine, Whole Blood				x								
25	2003020	Human Epididymis Protein 4 (HE4)		x	x	x	x	x						
50	0093061	Human Immunodeficiency Virus 1 (HIV-1) by Qualitative PCR												x
26	3001474	Human Immunodeficiency Virus 1 (HIV-1) Qualitative by NAAT, Whole Blood											x	
26	2007582	18-Hydroxycorticosterone by Mass Spectrometry			x	x								
27	3001560	Hypersensitivity Pneumonitis 2											x	
28	3001561	Hypersensitivity Pneumonitis Extended Panel (Farmer's Lung Panel)											x	
50	0050157	Hypersensitivity Pneumonitis Extended Panel (Farmer's Lung Panel)												x
50	0055226	Hypersensitivity Pneumonitis II												x
28	3000477	Hypersensitivity Pneumonitis Panel					x		x	x	x			
50	0050202	IA-2 Antibody												x
29	0050571	Immunoglobulin G Subclass 1				x								
29	0050572	Immunoglobulin G Subclass 2				x								
29	0050573	Immunoglobulin G Subclass 3				x								
29	0050576	Immunoglobulin G Subclass 4				x								
29	0050577	Immunoglobulin G Subclasses (1, 2, 3, 4)				x								
29	0020420	Iron and Iron Binding Capacity				x								
30	3001499	Islet Antigen-2 (IA-2) Autoantibody, Serum											x	
30	2002695	*KIT* Mutations, Melanoma		x	x	x			x					
30	0020745	Lead, Blood (Capillary)			x									
31	0020098	Lead, Blood (Venous)			x									
31	2011482	Lead, Random Urine			x									
31	0025060	Lead, Urine			x									
31	3001379	Liver Fibrosis - FibroMeter Vibration Controlled Transient Elastography (FibroMeter plus FibroScan VCTE)											x	
32	3001320	Lymphocyte Proliferation, Antigen Induced, by Flow Cytometry (24-Hr Critical Room Temp)											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
33	3001319	Lymphocyte Proliferation, Antigen-Mitogen Panel by Flow Cytometry (24-Hr Critical Room Temp)											x	
34	3001321	Lymphocyte Proliferation, Mitogen Induced, by Flow Cytometry Panel (48-Hr Critical Room Temp)											x	
35	3001337	Lymphocyte Proliferation, Anti-CD3, Anti-CD28 and IL-2 Induced, by Flow Cytometry (24-Hr Critical Room Temp)											x	
35	0092079	Magnesium, RBC			x									
35	0025070	Manganese, Urine			x									
36	3000256	Marijuana Metabolite, Umbilical Cord Tissue, Qualitative				x		x						
36	2014699	Maternal T Cell Engraftment in SCID				x		x	x					
36	2011481	Mercury, Random Urine			x									
36	0025050	Mercury, Urine			x									
37	2007967	Motor and Sensory Neuropathy Evaluation with Immunofixation Electrophoresis and Reflex to Titer and Neuronal Immunoblot								x				
37	2007966	Motor and Sensory Neuropathy Evaluation with Reflex to Titer and Neuronal Immunoblot								x				
37	0051225	Motor Neuropathy Panel								x				
37	3001576	Muscle-Specific Kinase (MuSK) Antibody, IgG											x	
50	2004911	*MUTYH*-Associated Polyposis (*MUTYH*) 2 Mutations												x
50	2006307	*MUTYH*-Associated Polyposis (*MUTYH*) 2 Mutations with Reflex to Sequencing												x
37	2011117	Myeloid Malignancies Mutation Panel by Next Generation Sequencing				x								
38	2012182	Myeloid Malignancies Somatic Mutation and Copy Number Analysis Panel				x								
38	0090141	Phenytoin, Free and Total				x					x			
39	3001053	Red Blood Cell Antigen Genotyping											x	
40	3001479	Respiratory Viral Panel by PCR											x	
50	2007805	Respiratory Virus Panel by PCR												x
40	3001496	Rifampin and Metabolite, Serum or Plasma											x	
41	2012618	Risk of Ovarian Malignancy Algorithm		x	x	x		x				x		
41	0025023	Selenium, Serum or Plasma			x									
50	2012125	SHOX Mutation Detection												x
42	3001395	*SHOX*-Related Disorders, Deletion/Duplication											x	

Hotline Page #	Test Number	Summary of Changes by Test Name	Name Change	Methodology	Performed/Reported Schedule	Specimen Requirements	Reference Interval	Interpretive Data	Note	CPT Code	Component Change	Other Interface Change	New Test	Inactive
43	3001401	*SHOX*-Related Disorders, Deletion/Duplication with Reflex to Sequencing											x	
44	3001399	*SHOX*-Related Disorders, Sequencing											x	
44	2007991	Solid Tumor Mutation Panel by Next Generation Sequencing				x	x							
45	3001562	SOX-10 By Immunohistochemistry											x	
45	0070111	Testosterone Free, Adult Male								x				
45	0081059	Testosterone Free, Females or Children								x				
45	0025019	Thallium, Urine			x									
50	2012233	Thiopurine Methyltransferase (*TPMT*) Genotyping, 4 Variants												x
50	2014109	Total Inhibin, Serum												x
46	3001535	*TPMT* and *NUDT15*											x	
50	0093067	Treponema pallidum Antibody Panel (FTA-ABS) IgG and IgM												x
50	0099590	Tryptophan, Plasma												x
47	3001541	Warfarin Sensitivity (*CYP2C8, CYP2C9, CYP4F2, VKORC1*) Genotyping											x	
50	2012772	Warfarin Sensitivity, *CYP2C9* and *VKORC1*, 3 Variants												x
48	0020598	Wilson Disease Screening Panel, Serum				x	x	x	x			x		
49	0020097	Zinc, Serum or Plasma			x	x	x	x	x			x		
49	0020462	Zinc, Urine			x	x			x					

New Test **3001495** **Aggressive B-Cell Lymphoma Reflex Panel by FISH, Tissue** **DLBCL_RFLX**
Click for Pricing

Additional Technical Information

Methodology: Fluorescence in situ Hybridization
Performed: Varies
Reported: 3-7 days, if reflexed, add 3 days for each reflex

Specimen Required: Collect: Tumor tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin-embed tissue. Transport tissue block or 8 unstained 3-micron slides. (Min: 4 slides) Protect paraffin block from excessive heat. Transport block(s) and/or slide(s) in a tissue transport kit (ARUP supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks: Include surgical pathology report.
Unacceptable Conditions: Specimens fixed or processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). No tumor in tissue. Decalcified specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

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

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

CPT Code(s): 88366, if reflexed add 88366; if further reflexed add 88366

New York DOH Approved.

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

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

Performed: Sun, Tue, Thu, Sat
Reported: 1-10 days

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

HOTLINE NOTE: There is a component change associated with this test.
Remove component 2005013, BCR-ABL1/ABL1, Major (p210) Quant Ratio

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

HOTLINE NOTE: There is a reflexive pattern change associated with this test.
Remove component 2005013, BCR-ABL1/ABL1, Major (p210) Quant Ratio from reflexive orderable 2005011

New Test **3001635** **Beckwith-Wiedemann Syndrome (BWS) and Russell-Silver Syndrome (RSS) by Methlyation-Specific MLPA** **BWS-RSS DD**

Click for Pricing

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

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

Reference Interval: By Report

Interpretive Data:
Characteristics of Beckwith-Wiedemann syndrome (BWS) and Russell-Silver syndrome (RSS): BWS is a phenotypically variable overgrowth syndrome associated with an increased risk for embryonal tumor development, neonatal hypoglycemia, macroglossia, macrosomia, hemihyperplasia, omphalocele, renal abnormalities, and ear creases or pits. RSS is characterized by pre- and postnatal growth deficiency, proportionate short stature, developmental delay, learning disabilities, limb-length asymmetry and distinctive faces.
Prevalence: BWS occurs 1 in 10,000-13,700 newborns; RSS 1 in 100,000 newborns.
Inheritance: BWS – 85 percent of cases are sporadic and 15 percent autosomal dominant; RSS – 60 percent of cases are sporadic, 40 percent unknown, rarely autosomal dominant or recessive.
Penetrance: RSS – complete; BWS – incomplete; individuals with a pathogenic CDKN1C variant will be asymptomatic if the variant is on the allele normally silenced due to imprinting.
Cause: BWS – 50 percent by loss of maternal methylation at imprinting center (IC)2, 20 percent by paternal uniparental disomy (UPD) of chromosome 11p15; 5 to 10 percent by pathogenic CDKN1C sequence variants, 5 percent by maternal methylation of IC1, 1 percent by chromosome rearrangements or duplications. RSS – 35 to 50 percent by paternal hypomethylation of IC1, 10 percent by maternal UPD of chromosome 7
Clinical Sensitivity: 75 percent for BWS; 35-50 percent for RSS
Methodology: Methylation-specific multiplex ligation probe amplification (MLPA).
Analytical Sensitivity and Specificity: 99 percent.
Limitations: This assay determines methylation patterns of IC1 and IC2 for chromosome 11p15. Disease mechanisms causing BWS and RSS that do not alter methylation patterns, such as sequence variants in *CDKN1C*, maternal UPD of chromosome 7 or chromosomal translocations, and inversions or duplications, will not be assessed. Diagnostic errors can occur due to rare sequence variations.

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

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

CPT Code(s): 81401

New York DOH approval pending. Call for status update.

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

2011479 **Cadmium, Random Urine** **U CAD RAND**

Performed: Sun-Sat
Reported: 1-5 days

0025040 **Cadmium, Urine** **CADMIUM U**

Performed: Sun-Sat
Reported: 1-5 days

2011603 Caffeine, Serum or Plasma — CAFFEINE S

Specimen Required: Collect: Serum Random or Plasma Random in Plain Red, Lavender (K_2EDTA), Lavender (K_3EDTA), or Pink (K_2EDTA).
Specimen Preparation: Separate from cells ASAP or within 6 hours of collection. Transfer 0.5 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.2 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Citrated Plasma, Serum separator tube (SST)
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 week; Frozen: 2 months

HOTLINE NOTE: Remove information found in the Specimen Require Remarks field. There is also a component change associated with this test.
Remove component 2011604, Caffeine Dose
Remove component 2011605, Caffeine Dose Frequency
Remove component 2011606, Caffeine Route
Remove component 2011607, Caffeine Type of Draw

0058002 *Campylobacter* Antigen — CAMPY

Methodology: Qualitative Enzyme Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Collect: Stool.
Specimen Preparation: Transport 5 g stool to an unpreserved stool transport vial (ARUP supply #40910) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 1 g)
Also acceptable: Transfer 5 g stool within one hour of collection to enteric transport media (Cary-Blair) (ARUP supply #29799) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 1 g)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Specimens in any transport media other than indicated above.
Stability (collection to initiation of testing): **Unpreserved Stool:** Ambient: Unacceptable; Refrigerated: 4 days; Frozen: 1 week
Cary-Blair/C&S Media: Ambient: 4 days; Refrigerated: 4 days; Frozen: Unacceptable

CPT Code(s): 87449

2011763 Carbamazepine, Free and Total, Serum or Plasma — CARB FT

Performed: Mon, Thu
Reported: 1-5 days

Specimen Required: Collect: Serum Pre-dose (Trough) Draw - At a Steady State Concentration in Plain Red.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Whole Blood, Citrated Plasma. Tubes that contain liquid anticoagulant.or Serum separator tube (SST).
Stability (collection to initiation of testing): Ambient: 5 days; Refrigerated: 5 days; Frozen: 3 months

HOTLINE NOTE: Remove information found in the Specimen Required Remarks field. There is also a component change associated with this test.
Remove component 2011764, Carbamazepine Dose
Remove component 2011765, Carbamazepine Dose Frequency
Remove component 2011766, Carbamazepine Route
Remove component 2011767, Carbamazepine Type of Draw

0025068 Chromium, Urine — CR-U

Performed: Sun-Sat
Reported: 1-5 days

0099231 Cobalt, Blood — COBALT B

Specimen Required: Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician).
Collect: Royal Blue (K_2EDTA) or Royal Blue (Na_2EDTA).
Specimen Preparation: Transport 6 mL whole blood in the original collection tube. (Min: 0.5 mL)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated.
Unacceptable Conditions: Specimens collected in containers other than specified. Specimens transported in containers other than specified. Clotted specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Interpretive Data: Elevated results may be due to skin or collection-related contamination, including the use of a noncertified metal-free collection/transport tube. If contamination concerns exist due to elevated levels of blood cobalt, confirmation with a second specimen collected in a certified metal-free tube is recommended.

Blood cobalt levels can be used in the assessment of occupational exposure or toxic ingestion. Symptoms associated with cobalt toxicity vary based on route of exposure and may include cardiomyopathy, allergic dermatitis, pulmonary fibrosis, cough and dyspnea. Blood is the preferred specimen type for evaluating metal ion release from metal-on-metal joint arthroplasty.

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

HOTLINE NOTE: Remove information found in the Note field.

0025037 Cobalt, Serum or Plasma — COBALT S

Specimen Required: Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician).
Collect: Royal Blue (No Additive) or Royal Blue (K_2 EDTA), or Royal Blue (Na_2 EDTA).
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: 0.5 mL)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated or frozen.
Unacceptable Conditions: Specimens collected in containers other than specified. Specimens transported in containers other than specified.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Indefinitely

Interpretive Data: Elevated results may be due to skin or collection-related contamination, including the use of a noncertified metal-free collection/transport tube. If contamination concerns exist due to elevated levels of serum/plasma cobalt, confirmation with a second specimen collected in a certified metal-free tube is recommended.

Serum cobalt levels can be used in the assessment of occupational exposure or toxic ingestion. Symptoms associated with cobalt toxicity vary based on route of exposure, and may include cardiomyopathy, allergic dermatitis, pulmonary fibrosis, cough and dyspnea.

Whole blood is the preferred specimen type for evaluating metal ion release from metal-on-metal joint arthroplasty. Serum cobalt levels may be increased in asymptomatic patients with metal-on-metal prosthetics and should be considered in the context of the overall clinical scenario.

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

HOTLINE NOTE: Remove information found in the Note field.

0025032 Cobalt, Urine — COBALT U

Specimen Required: Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician). Collection from patients receiving iodinated or gadolinium-based contrast media must be avoided for a minimum of 72 hours post-exposure. Collection from patients with impaired kidney function should be avoided for a minimum of 14 days post contrast media exposure.
Collect: 24 Hour Urine. Refrigerate during collection. Specimen must be collected in a plastic container. Also acceptable: Random Urine.
Specimen Preparation: Transfer an 8 mL aliquot from a well-mixed collection to ARUP Trace Element-Free Transport Tubes (ARUP supply #43116) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Remarks: Record total volume and collection time interval on transport tube and on test request form.
Unacceptable Conditions: Specimens collected within 72 hours after administration of iodinated or gadolinium-based contrast media. Acid preserved urine. Specimens transported in containers other than specified. Specimens contaminated with blood or fecal material.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 1 year

Note: High concentrations of iodine may interfere with elemental testing.

0050170 *Coccidioides* Antibody by CF — COCCI

Performed: Sun-Sat
Reported: 2-4 days

3000059 *Coccidioides* Antibody by CF, CSF — COCCICFCSF

Performed: Sun-Sat
Reported: 2-4 days

2011480 Copper, Random Urine — U COP RAND

Performed: Sun-Sat
Reported: 1-5 days

Specimen Required: Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician). Collection from patients receiving iodinated or gadolinium-based contrast media must be avoided for a minimum of 72 hours post-exposure. Collection from patients with impaired kidney function should be avoided for a minimum of 14 days post contrast media exposure.
Collect: Random urine.
Specimen Preparation: Transfer an 8 mL aliquot from a well-mixed collection to ARUP Trace Element-Free Transport Tubes (ARUP supply #43116), available online through eSupply using ARUP Connector contact ARUP Client Services at (800) 522-2787. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Unacceptable Conditions: Specimens collected within 72 hours after administration of iodinated or gadolinium-based contrast media. Acid preserved urine. Specimens transported in containers other than specified. Specimens contaminated with blood or fecal material.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 1 year

Note: Refer to Copper-Ceruloplasmin Index (Copper Free) (ARUP test code 0025079) for Wilson disease screening test. High concentrations of iodine or gadolinium may interfere with elemental testing.

0020096 Copper, Serum or Plasma — COPPER

Performed: Sun-Sat
Reported: 1-3 days

Specimen Required: Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician).
Collect: Royal Blue (No Additive), Royal Blue (K_2 EDTA), or Royal Blue (Na_2 EDTA).
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: 0.5 mL)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated or frozen.
Unacceptable Conditions: Specimens collected in containers other than specified. Specimens transported in containers other than specified.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Indefinitely

Reference Interval:
Effective May 20, 2019

Age	Male	Female
0-10 years	75.0-153.0 µg/dL	75.0-153.0 µg/dL
11 years-12 years	64.0-132.0 µg/dL	64.0-132.0 µg/dL
13 years-18 years	57.0-129.0 µg/dL	57.0-129.0 µg/dL
19 years and older	70.0-140.0 µg/dL	80.0-155.0 µg/dL

Interpretive Data: Elevated results may be due to skin or collection-related contamination, including the use of a noncertified metal-free collection/transport tube. If contamination concerns exist due to elevated levels of serum/plasma copper, confirmation with a second specimen collected in a certified metal-free tube is recommended.

Serum copper may be elevated with infection, inflammation, stress, and copper supplementation. In females, elevated copper may also be caused by oral contraceptives and pregnancy (concentrations may be elevated up to 3 times normal during the third trimester). Serum copper may be reduced by use of corticosteroids and zinc and by malnutrition or malabsorption.

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

HOTLINE NOTE: Remove information found in the Note field. There is also a numeric map change associated with this test.
Change the numeric map for component 0020096, Copper, Serum/Plasma from XXXX to XXX.X.

0020461 Copper, Urine — COPPER U

Performed: Sun-Sat
Reported: 1- 5 days

Specimen Required: Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician). Collection from patients receiving iodinated or gadolinium-based contrast media must be avoided for a minimum of 72 hours post-exposure. Collection from patients with impaired kidney function should be avoided for a minimum of 14 days post contrast media exposure.
Collect: 24 Hour Urine. Refrigerate during collection. Specimen must be collected in a plastic container. Also acceptable: Random Urine.
Specimen Preparation: Transfer an 8 mL aliquot from a well-mixed collection to ARUP Trace Element-Free Transport Tubes (ARUP supply #43116) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Remarks: Record total volume and collection time interval on transport tube and on test request form.
Unacceptable Conditions: Specimens collected within 72 hours after administration of iodinated or gadolinium-based contrast media. Acid preserved urine. Specimens transported in containers other than specified. Specimens contaminated with blood or fecal material.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 1 year

Note: Refer to Copper-Ceruloplasmin Index (Copper Free) (0025079) for Wilson disease screening test. High concentrations of iodine or gadolinium may interfere with elemental testing.

New Test **3001508** ***CYP2C19*** **2C19GENO**
Click for Pricing

Additional Technical Information

Out of Pocket Estimator

Supplemental Resources

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

Specimen Required: Collect: **Whole Blood:** Lavender (EDTA), Pink (K_2EDTA), or Yellow (ACD Solution A or B).
Saliva: Collection Device by DNA Genotek (OCD-100, ARUP Supply #49295) available online through eSupply using ARUP Connect™ or by contacting ARUP Client Services at (800) 522-2787.
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL) OR Transport the Saliva Collection Device.
Storage/Transport Temperature: **Whole Blood:** Refrigerated.
Saliva: Room temperature.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin.
Stability (collection to initiation of testing): **Whole Blood:** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Saliva: Ambient: 2 weeks; Refrigerated: Unacceptable; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:
Background Information for *CYP2C19*:
Characteristics: The cytochrome P450 (CYP) isozyme 2C19 is involved in the metabolism of many drugs. Variants in the gene that codes for CYP2C19 will influence pharmacokinetics of CYP2C19 substrates, and may predict or explain non-standard dose requirements, therapeutic failure or adverse reactions.
Inheritance: Autosomal co-dominant.
Cause: *CYP2C19* gene variants affect enzyme expression or activity.
Variants Tested: See the "Additional Technical Information" document.
Clinical Sensitivity: Drug-dependent.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Only the targeted *CYP2C19* variants will be detected by this panel, and assumptions about phase and content are made to assign alleles. Publically available sources such as the www.pharmvar.org or www.pharmgkb.org provide guidance on phenotype predictions and allele frequencies. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with CYP2C19 substrates may be affected by genetic and non-genetic factors that are not detected by this test. This result does not replace the need for therapeutic drug or clinical monitoring.

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

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

CPT Code(s): 81225

New York DOH approval pending. Call for status update.

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

New Test **3001501** ***CYP2C8* and *CYP2C9*** **2C8/2C9**

Click for Pricing

Additional Technical Information

Out of Pocket Estimator

Supplemental Resources

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

Specimen Required: Collect: **Whole Blood:** Lavender (EDTA), Pink (K_2EDTA), or Yellow (ACD Solution A or B).
Saliva: Collection Device by DNA Genotek (OCD-100, ARUP Supply #49295) available online through eSupply using ARUP Connect™ or by contacting ARUP Client Services at (800) 522-2787.
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL) OR Transport the Saliva Collection Device.
Storage/Transport Temperature: **Whole Blood:** Refrigerated.
Saliva: Room temperature.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin.
Stability (collection to initiation of testing): **Whole Blood:** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Saliva: Ambient: 2 weeks; Refrigerated: Unacceptable; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:
Background Information for *CYP2C8* and *CYP2C9*:
Characteristics: The cytochrome P450 (CYP) isozymes 2C8 and 2C9 are involved in the metabolism of many drugs. Variants in the genes that code for CYP2C8 and CYP2C9 may influence pharmacokinetics of substrates, and may predict or explain non-standard dose requirements, therapeutic failure or adverse reactions.
Inheritance: Autosomal co-dominant.
Cause: *CYP2C8* and *CYP2C9* gene variants affect enzyme expression or activity.
Variants Tested: See the "Additional Technical Information" document.
Clinical Sensitivity: Drug-dependent.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Only the targeted *CYP2C8* and *CYP2C9* variants will be detected by this panel, and assumptions about phase and content are made to assign alleles. Publically available sources such as the www.pharmvar.org or www.pharmgkb.org provide guidance on phenotype predictions and allele frequencies. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with CYP2C8 or CYP2C9 substrates may be affected by genetic and non-genetic factors that are not detected by this test. This result does not replace the need for therapeutic drug or clinical monitoring.

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

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

CPT Code(s): 81227, 81479

New York DOH approval pending. Call for status update.

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

New Test **3001513** ***CYP2D6*** **2D6GENO**
Click for Pricing

Additional Technical Information

Out of Pocket Estimator

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

Specimen Required: Collect: **Whole Blood:** Lavender (EDTA), Pink (K_2EDTA), or Yellow (ACD Solution A or B).
Saliva: Collection Device by DNA Genotek (OCD-100, ARUP Supply #49295) available online through eSupply using ARUP Connect™ or by contacting ARUP Client Services at (800) 522-2787.
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL) OR Transport the Saliva Collection Device.
Storage/Transport Temperature: **Whole Blood:** Refrigerated.
Saliva: Room temperature.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin.
Stability (collection to initiation of testing): **Whole Blood:** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Saliva: Ambient: 2 weeks; Refrigerated: Unacceptable; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:
Background Information for *CYP2D6*:
Characteristics: The cytochrome P450 (CYP) isozyme 2D6 is involved in the metabolism of many drugs. Variants in the gene that codes for CYP2D6 may influence pharmacokinetics of CYP2D6 substrates, and may predict or explain non-standard dose requirement, therapeutic failure or adverse reactions.
Inheritance: Autosomal co-dominant.
Cause: *CYP2D6* gene variants and copy number affect enzyme expression or activity.
Variants Tested: See the "Additional Technical Information" document.
Clinical Sensitivity: Drug-dependent.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Only the targeted *CYP2D6* variants will be detected by this panel, and assumptions about phase and content are made to assign alleles. Publically available sources such as the www.pharmvar.org or www.pharmgkb.org provide guidance on phenotype predictions and allele frequencies. A combination of the *5 (gene deletion) and a gene duplication cannot be specifically identified. This combination is not expected to adversely affect the phenotype prediction. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with CYP2D6 substrates may be affected by genetic and non-genetic factors that are not detected by this test. This result does not replace the need for therapeutic drug or clinical monitoring.

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

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

CPT Code(s): 81226

New York DOH approval pending. Call for status update.

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

New Test **3001518** ***CYP3A4* and *CYP3A5*** **3A4/3A5**

Click for Pricing

Additional Technical Information

Supplemental Resources

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

Specimen Required: Collect: **Whole Blood:** Lavender (EDTA), Pink (K_2EDTA), or Yellow (ACD Solution A or B).
Saliva: Collection Device by DNA Genotek (OCD-100, ARUP Supply #49295) available online through eSupply using ARUP Connect™ or by contacting ARUP Client Services at (800) 522-2787.
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL) OR Transport the Saliva Collection Device.
Storage/Transport Temperature: **Whole Blood:** Refrigerated.
Saliva: Room temperature.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin.
Stability (collection to initiation of testing): **Whole Blood:** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Saliva: Ambient: 2 weeks; Refrigerated: Unacceptable; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:
Background Information for *CYP3A4* and *CYP3A5*:
Characteristics: The cytochrome P450 (CYP) 3A subfamily of enzymes is involved in metabolism of many drugs. Variants in the genes that code for CYP3A4 and CYP3A5 may influence pharmacokinetics of CYP3A substrates, and may predict or explain non-standard dose requirements, therapeutic failure or adverse reactions.
Inheritance: Autosomal co-dominant.
Cause: *CYP3A4 or CYP3A5* gene variants affect enzyme expression or activity.
Variants Tested: See the "Additional Technical Information" document.
Clinical Sensitivity: Drug-dependent.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Only the targeted *CYP3A4* and *CYP3A5* variants will be detected by this panel, and assumptions about phase and content are made to assign alleles. Publically available sources such as the www.pharmvar.org or www.pharmgkb.org provide guidance on phenotype predictions and allele frequencies. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with CYP3A substrates may be affected by genetic and non-genetic factors that are not detected by this test. This result does not replace the need for therapeutic drug or clinical monitoring.

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

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

CPT Code(s): 81230; 81231

New York DOH approval pending. Call for status update.

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

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

Specimen Required: Collect: Serum Separator Tube (SST), Plasma Separator Tube (PST), or Green (Lithium or Sodium Heparin).
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.4 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Grossly hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 3 months

Reference Interval:
Effective May 20, 2019

Test Number	Components	Reference Interval			
	CYSTATIN C	0.5 - 1.2 mg/L			
	eGFR by Cystatin C	**Age**	**Reference Interval**		
		17 years or 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 additional charge.

New Test **3001524** **Cytochrome P450 Genotyping Panel** **CYP PANEL**
Click for Pricing

Supplemental Resources

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Mon, Thu
Reported: 5-10 days

Specimen Required: Collect: **Whole Blood:** Lavender (EDTA), Pink (K_2EDTA), or Yellow (ACD Solution A or B).
Saliva: Collection Device by DNA Genotek (OCD-100, ARUP Supply #49295) available online through eSupply using ARUP Connect™ or by contacting ARUP Client Services at (800) 522-2787.
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL) OR Transport the Saliva Collection Device.
Storage/Transport Temperature: **Whole Blood:** Refrigerated.
Saliva: Room temperature.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin.
Stability (collection to initiation of testing): **Whole Blood:** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Saliva: Ambient: 2 weeks; Refrigerated: Unacceptable; Frozen: Unacceptable

Reference Interval: By report

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

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

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

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

New York DOH approval pending. Call for status update.

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

2011632 **Disopyramide, Serum or Plasma** **DISOP**

Specimen Required: Collect: Serum Pre-dose (Trough) Draw - At a Steady State Concentration Serum or Plasma Pre-dose (Trough) Draw - At a Steady State Concentration in Plain Red, Lavender (K_2EDTA), Lavender (K_3EDTA), or Pink (K_2EDTA).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Whole blood. Gel Separator Tubes, Light Blue (Sodium Citrate), or Yellow (SPS or ACD Solution).
Stability (collection to initiation of testing): Ambient: 4 days; Refrigerated: 1 week; Frozen: 2 months

HOTLINE NOTE: Remove information found in the Specimen Required Remarks field. There is a component change associated with this test.
Remove component 2011633, Disopyramide Dose
Remove component 2011634, Disopyramide Dose Frequency
Remove component 2011635, Disopyramide Route
Remove component 2011636, Disopyramide Type of Draw

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

Specimen Required: Collect: Umbilical Cord (At least 8 inches, approximately the width of a sheet of paper.)
Specimen Preparation: Drain and discard any blood. Rinse the exterior of the cord segment with normal saline or water. Pat the cord dry and transport at least 8 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

Reference Interval:
Effective May 20, 2019

Drugs covered and range of cutoff concentrations.

Drugs/Drug Classes	Cutoff Concentrations (ng/g)	Drugs/Drug Classes	Cutoff Concentrations (ng/g)
Buprenorphine	1	Amphetamine	5
Norbuprenorphine	0.5	Benzoylecgonine	0.5
Drug removed		m-OH-Benzoylecgonine	1
Codeine	0.5	Cocaethylene	1
Dihydrocodeine	1	Cocaine	0.5
Fentanyl	0.5	MDMA (Ecstasy)	5
Hydrocodone	0.5	Methamphetamine	5
Norhydrocodone	1	Phentermine	8
Hydromorphone	0.5	Alprazolam	0.5
Meperidine	2	Alpha-OH-Alprazolam	0.5
Methadone	2	Butalbital	25
Methadone metabolite	1	Clonazepam	1
6-Acetylmorphine	1	7-Aminoclonazepam	1
Morphine	0.5	Diazepam	1
Naloxone	1	Lorazepam	5
Oxycodone	0.5	Midazolam	1
Noroxycodone	1	Alpha-OH-Midazolam	2
Oxymorphone	0.5	Nordiazepam	1
Noroxymorphone	0.5	Oxazepam	2
Propoxyphene	1	Phenobarbital	75
Tapentadol	2	Temazepam	1
Tramadol	2	Zolpidem	0.5
N-desmethyltramadol	2	Phencyclidine (PCP)	1
O-desmethyltramadol	2	Gabapentin	10

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

Detection of drugs in umbilical cord tissue is intended to reflect maternal drug use during approximately the last trimester of a full-term 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.

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). For alcohol metabolite, order Ethyl Glucuronide, Umbilical Cord Tissue, Qualitative (ARUP test code 3000443).

HOTLINE NOTE: There is a component change associated with this test.
Remove component 2006627, Buprenorphine G, Cord, Qual
Add component 3001452, Gabapentin, Cord, Qual

0049178 *ERBB2* (*HER2*/*neu*) (HercepTest) by Immunohistochemistry, Tissue with Reflex to FISH if 2+ HERCEP2IP

HOTLINE NOTE: There is a component change associated with this test.
Remove component 0049181, Hercep Comments

0049174 ***ERBB2* (*HER2/neu*) (HercepTest) with Interpretation by Immunohistochemistry, Tissue** **HERCEPIP**

HOTLINE NOTE: There is a component change associated with this test.
Remove component 0049181, Hercep Comments

2008603 **ERBB2 (HER2/neu) Gene Amplification by FISH with Reflex, Tissue** **ERBB2 FISH**

HOTLINE NOTE: There is a reflexive pattern change associated with this test.
Remove component 0049181, Hercep Comments from reflexive orderable 0049174

2010358 **Ethosuximide, Serum or Plasma** **ETHOSUX**

Specimen Required: Patient Prep: Timing of specimen collection: Pre-dose (trough) draw - At steady state concentration.
Collect: Plain Red. Also acceptable: Lavender (K_2 or K_3EDTA) or Pink (K_2EDTA).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Whole blood. Gel separator tubes, light blue (citrate), or yellow (SPS or ACD solution).
Stability (collection to initiation of testing): After separation from cells: Ambient: 5 days; Refrigerated: 1 week; Frozen: 2 months

HOTLINE NOTE: Remove information found in the Specimen Required Remarks field. There is also a component change associated with this test.
Remove component 2011497, Ethosuximide Dose
Remove component 2011498, Ethosuximide Dose Frequency
Remove component 2011499, Ethosuximide Route
Remove component 2011500, Ethosuximide Type of Draw

3000443 **Ethyl Glucuronide, Umbilical Cord Tissue, Qualitative** **ETG QQQ CD**

Specimen Required: Collect: Umbilical Cord (At least 8 inches, approximately the width of a sheet of paper.) Caution must be used when collecting specimen, to ensure no ethanol-containing personal care products (i.e., hand sanitizers, wipes, mouthwash) are used directly on the specimen or nearby during collection.
Specimen Preparation: Drain and discard any blood. Rinse the exterior of the cord segment with normal saline or water. Pat the cord dry and transport at least 8 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: 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

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

Caution must be used when collecting specimen, to ensure no ethanol-containing personal care products (i.e., hand sanitizers, wipes, mouthwash) are used directly on the specimen or nearby during collection.

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

New Test **3001457** **Exome Reanalysis (Originally Tested at ARUP – No Specimen Required)** **EX REANLYZ**

Available Now
Click for Pricing

Patient History for Exome Reanalysis (REQUIRED)

Methodology: Bioinformatic Processing and Variant Analysis
Performed: Varies
Reported: 3-6 weeks

Specimen Required Collect: **No new specimen is required to process this test.**
Remarks: **Patient History Form for Exome Reanalysis (REQUIRED); Fax to Genetics Processing at 801-584-5249.**

Reference Interval: By report.

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

Note: Orderable only if previous exome sequencing (test code 2006336 or 20063320) was performed at ARUP within the past 5 years. Reanalysis cannot be performed if initial exome sequencing occurred more than 5 years ago; in such cases exome sequencing should be reordered with a new sample.

CPT Code(s): 81417

New York DOH approval pending. Call for status update.

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

New Test **3001416** **Fumarate Hydratase by Immunohistochemistry** **FUMHYD IHC**
Available Now
Click for Pricing

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

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

Interpretive Data: 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 approval pending. Call for status update.

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

0051033 **Ganglioside (Asialo-GM1, GM1, GM2, GD1a, GD1b, and GQ1b) Antibodies** **GM1 COMBI**

CPT Code(s): 83516 x6

2002674 **Gastrointestinal Stromal Tumor Mutation** **GIST MUT**

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

Specimen Required: Collect: Tumor tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Diff-Quik and Papanicolaou stained cytology smears are also acceptable. Number of slides needed is dependent on the tumor cellularity of the smear. Slide(s) will be destroyed during testing process and will not be returned to client. Protect from excessive heat. Transport block and/or slides in a tissue transport kit (ARUP supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Resections: Transport 8 unstained 5-micron slides. (Min: 5 slides)
Small Biopsies: Transport 15 unstained 5-micron slides. (Min: 10 slides)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks: Include surgical pathology report.
Unacceptable Conditions: Less than 10 percent tumor. Specimens fixed/processed in heavy metal fixatives. Decalcified specimens. FNA smears with less than 50 tumor cells.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

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

0060101 **Gram Stain** **MS GRAM**

Time Sensitive

Specimen Required: Collect: Any site or fluid.
Specimen Preparation: Transport labeled slide or specimen in Eswab transport media (ARUP Supply #45877) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Room temperature.
Remarks: Specimen source required.
Unacceptable Conditions: Blood, bone marrow, stool, vaginal specimens, or body fluid inoculated in culture bottles.
Stability (collection to initiation of testing): Ambient: 48 Hours; Refrigerated: 48 Hours; Frozen: Unacceptable

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

Performed: Sun-Sat
Reported: 1-5 days

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

Performed: Sun-Sat
Reported: 1-5 days

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

Performed: Sun-Sat
Reported: 1-5 days

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

Performed: Sun-Sat
Reported: 1-5 days

Specimen Required: Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, non-essential over-the-counter medications (upon the advice of their physician), and avoid shellfish and seafood for 48 to 72 hours. Collection from patients receiving iodinated or gadolinium-based contrast media must be avoided for a minimum of 72 hours post-exposure. Collection from patients with impaired kidney function should be avoided for a minimum of 14 days post-contrast media exposure.
Collect: 24 Hour Urine. Refrigerate during collection. Specimen must be collected in a plastic container. Also acceptable: Random Urine.
Specimen Preparation: Transfer 8 mL aliquot from a well-mixed collection to ARUP Trace Element-Free Transport Tubes (ARUP supply #43116). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 2 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Remarks: Trace Elements requisition form may be required (ARUP form #32990-Barcode; #32991-No Barcode). Record total volume and collection time interval on transport tube and on test request form.
Unacceptable Conditions: Specimens collected within 72 hours after administration of iodinated or gadolinium-based contrast media. Acid preserved urine. Specimens transported in containers other than specified. Specimens contaminated with blood or fecal material.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 1 year

Note: High concentrations of iodine or gadolinium may interfere with elemental testing. If total arsenic concentration is between 35-2000 ug/L, then Arsenic, Fractionated, will be added to determine the proportion of organic, inorganic, and methylated forms. Additional charges apply.

0070036 Histamine, Plasma HIST-P

Specimen Required: Collect: Lavender (EDTA) or Pink (K_2EDTA). Collect in a pre-chilled tube and on ice.
Specimen Preparation: Centrifuge refrigerated and separate upper two-thirds of plasma within 20 minutes. Transfer 1 mL plasma to an ARUP Standard Transport Tube and freeze immediately. (Min: 0.5 mL)
Storage/Transport Temperature: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**
Unacceptable Conditions: Lipemic or hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 6 hours; Frozen: 6 months

0070038 Histamine, Urine HIST-U

Specimen Required: Collect: Random or 24-hour urine in a plastic container. Refrigerate during collection.
Specimen Preparation: Transfer a 4 mL aliquot from a well-mixed random or 24-hour collection to an ARUP Standard Transport Tube and freeze immediately. (Min: 1 mL) Record total volume and collection time interval on transport tube and test request form.
Storage/Transport Temperature: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 6 hours; Frozen: 6 months

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

0070037 Histamine, Whole Blood HIST-WB

Specimen Required: Collect: Green (sodium or lithium heparin).
Specimen Preparation: Transfer 1 mL well-mixed whole blood to an ARUP Standard Transport Tube and freeze. (Min: 0.5 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

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

2003020 Human Epididymis Protein 4 (HE4) HE4

Methodology: Quantitative Electrochemiluminescent Immunoassay (ECLIA)
Performed: Sun-Sat
Reported: Within 24 hours

Specimen Required: Collect: Serum Separator Tube (SST). Also acceptable: Green (Lithium Heparin), Lavender (K_2 EDTA), or Lavender (K_3 EDTA).
Specimen Preparation: Allow specimen to clot completely at room temperature. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 5 hours; Refrigerated: 48 hours; Frozen: 4 months

Reference Interval:
Effective May 20, 2019
0-140 pmol/L

Interpretive Data: Human Epididymis Protein 4 (HE4) is used as an aid in monitoring recurrence or progressive disease in patients with epithelial ovarian cancer. Serial testing for patient HE4 assay values should be used in conjunction with other clinical findings for monitoring ovarian cancer. ARUP uses the Roche Cobas e602 electrochemiluminescent assay. Values obtained with different assay methods should not be used interchangeably.

New Test **3001474** **Human Immunodeficiency Virus 1 (HIV-1) Qualitative by NAAT, Whole Blood** **HIV QUAL**

Click for Pricing

Methodology: Qualitative Transcription Mediated Amplification
Performed: Tue-Sat
Reported: 2-5 days

Specimen Required: Collect: Lavender (EDTA) or Pink (K_2EDTA).
Specimen Preparation: Transport 1 mL whole blood. (Min: 0.4 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Heparinized specimens.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 1 week

Reference Interval: Not detected

Interpretive Data: This test detects human immunodeficiency virus type 1 (HIV-1) RNA from Group M, N and O subtypes. A result of "Not Detected" does not rule out HIV-1 RNA concentrations below the limit of detection of the assay or the presence of inhibitors in the patient specimen. This assay may not detect HIV infection in infants during the first months of life. The diagnosis of HIV-1 infection should be made based on clinical presentation and results from additional diagnostic tests. Diagnosis should not be made based solely on a single HIV-1 test. Improper specimen handling can cause false negatives or contamination.

This assay should not be used for blood donor screening, associated re-entry protocols, or for screening Human Cell, Tissues and Cellular Tissue-Based Products (HCT/P).

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

Note: Assay detects HIV-1 virus RNA. Proviral DNA will not be detected.

CPT Code(s): 87535

New York DOH Approved.

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

2007582 **18-Hydroxycorticosterone by Mass Spectrometry** **18 HYDRO**

Performed: Varies
Reported: 3-16 days

Specimen Required: Collect: Plain Red or Serum Separator Tube (SST). Also acceptable: Lavender (EDTA) or Green (Sodium Heparin).
Specimen Preparation: Separate from cells within 1 hour 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: 24 hours; Refrigerated: 24 hours; Frozen: 3 months

New Test **3001560** **Hypersensitivity Pneumonitis 2** **HYPER 2**
Click for Pricing

Methodology: Qualitative Immunodiffusion
Performed: Mon-Fri
Reported: 3-5 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: 0.15 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma.
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
	A. flavus Ab, Precipitin	None detected
	A. fumigatus #2 Ab, Precipitin	None detected
	A. fumigatus #3 Ab, Precipitin	None detected
	S. viridis Ab, Precipitin	None detected
	T. candidus Ab, Precipitin	None detected

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

Note: Testing includes antibodies directed at *Aspergillus flavus*, *A. fumigatus* #2, *A. fumigatus* #3, *Saccharomonospora viridis*, and *Thermoactinomyces candidus.*

CPT Code(s): 86331 x2; 86606 x3

New York DOH Approved.

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

New Test **3001561** **Hypersensitivity Pneumonitis Extended Panel (Farmer's Lung Panel)** **HYPEREXT**

Click for Pricing

Methodology: Qualitative Immunodiffusion/Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat
Reported: 3-7 days

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer two 2.5 mL aliquots of serum to individual ARUP Standard Transport Tubes. (Min: 1 mL Per aliquot)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma. Contaminated, hemolyzed, or severely lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

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

Note: Testing includes antibodies directed at *Aspergillus fumigatus* #1, *A. fumigatus* #2, *A. fumigatus* #3, *A. fumigatus* #6, *A. flavus*, *Aureobasidium pullulans*, *Pigeon Serum*, *Micropolyspora faeni*, *Thermoactinomyces vulgaris* #1, *T. candidus*, and *Saccharomonospora viridis.*

CPT Code(s): 86003 x3; 86005; 86331 x6; 86606 x5

New York DOH Approved.

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

3000477 **Hypersensitivity Pneumonitis Panel** **HYPER PAN**

Reference Interval:

Test Number	Components	Reference Interval
	A. fumigatus #1 Ab, Precipitin	None detected
	A. fumigatus #6 Ab, Precipitin	None detected
	A. pullulans Ab, Precipitin	None detected
	Pigeon Serum, Ab, Precipitin	None detected
	M. faeni Ab, Precipitin	None detected
	T. vulgaris #1 Ab Precipitin	None detected
	A. flavus Ab, Precipitin	None detected
	A. fumigatus #2 Ab, Precipitin	None detected
	A. fumigatus #3 Ab, Precipitin	None detected
	S. viridis Ab, Precipitin	None detected
	T. candidus Ab, Precipitin	None detected

Note: Testing includes antibodies directed at *Aspergillus fumigatus* #1, *Aspergillus fumigatus* #6, *Aureobasidium pullulans*, *Pigeon Serum*, *Micropolyspora faeni*, *Thermoactinomyces vulgaris* #1, *Aspergillus flavus*, *Aspergillus fumigatus* #2, *Aspergillus fumigatus* #3, *Saccharomonospora viridis*, and *Thermoactinomyces candidus.*

CPT Code(s): 86331 x6; 86606 x5

HOTLINE NOTE: There is a component change associated with this test.
Remove component 0055225, T. sacchari Ab, Precipitin

0050571 **Immunoglobulin G Subclass 1** **IGG1**

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.45 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): After separation from cells: Ambient: 2 hours; Refrigerated: 8 days; Frozen: 6 month

0050572 **Immunoglobulin G Subclass 2** **IGG2**

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.45 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): After separation from cells: Ambient: 2 hours; Refrigerated: 8 days; Frozen: 6 months

0050573 **Immunoglobulin G Subclass 3** **IGG3**

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.45 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): After separation from cells: Ambient: 2 hours; Refrigerated: 8 days; Frozen: 6 months

0050576 **Immunoglobulin G Subclass 4** **IGG4**

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.45 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): After separation from cells: Ambient: 2 hours; Refrigerated: 8 days; Frozen: 6 months

0050577 **Immunoglobulin G Subclasses (1, 2, 3, 4)** **IGG SUB**

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.45 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): After separation from cells: Ambient: 2 hours; Refrigerated: 8 days; Frozen: 6 months

0020420 **Iron and Iron Binding Capacity** **FEIBC**

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL) Avoid hemolysis. Also acceptable: Heparinized plasma.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Grossly hemolyzed specimens. EDTA plasma.
Stability (collection to initiation of testing): After separation from cells: Ambient: 4 days; Refrigerated: 1 week; Frozen: 3 months

New Test **3001499** **Islet Antigen-2 (IA-2) Autoantibody, Serum** **IA-2 AB**

Click for Pricing

Additional Technical Information

Methodology: Quantitative Enzyme-Linked Immunosorbent Assay
Performed: Mon, Wed, Fri
Reported: 2-10 days

Specimen Required: Collect: Plain Red or Serum Separator Tube (SST).
Specimen Preparation: Transfer 0.5 mL serum to an ARUP Standard Transport Tube. (Min: 0.35 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma. Specimens submitted in frozen Serum Separator Tubes (SST). Grossly hemolyzed, icteric, or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 1 month

Reference Interval: 0.0-7.4 Units/mL

Interpretive Data: A value greater than or equal to 7.5 Units/mL is considered positive for IA-2 autoantibody.

This assay is intended for the quantitative determination of autoantibodies to Islet Antigen-2 (IA-2) in human serum. Results should be interpreted within the context of clinical symptoms.

CPT Code(s): 86341

New York DOH Approved.

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

2002695 ***KIT* Mutations, Melanoma** **KIT MELAN**

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

Specimen Required: Collect: Tumor tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Diff-Quik and Papanicolaou stained cytology smears are also acceptable. Number of slides needed is dependent on the tumor cellularity of the smear. Slide(s) will be destroyed during testing process and will not be returned to client. Protect from excessive heat. Transport block and/or slides in a tissue transport kit (ARUP supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Resections: Transport 8 unstained 5-micron slides. (Min: 5 slides)
Small Biopsies: Transport 15 unstained 5-micron slides. (Min: 10 slides)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks: Include surgical pathology report.
Unacceptable Conditions: Less than 10 percent tumor. Specimens fixed/processed in heavy metal fixatives. Decalcified specimens. FNA smears with less than 50 tumor cells.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

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

0020745 **Lead, Blood (Capillary)** **LEAD CAP**

Performed: Sun-Sat
Reported: 1-3 days

0020098 **Lead, Blood (Venous)** **LEAD-WB**

Performed: Sun-Sat
Reported: 1-3 days

2011482 **Lead, Random Urine** **U LEADRAND**

Performed: Sun-Sat
Reported: 1-5 days

0025060 **Lead, Urine** **LEAD U**

Performed: Sun-Sat
Reported: 1-5 days

New Test **3001379** **Liver Fibrosis - FibroMeter Vibration Controlled Transient Elastography (FibroMeter plus FibroScan VCTE)** **FIBRO VCTE**

Click for Pricing

Supplemental Resources

Methodology: Quantitative Nephelometry/Quantitative Enzymatic/Quantitative Spectrophotometry/Automated Cell Count/Electromagnetic Mechanical Clot Detection/Vibration Controlled Transient Elastography
Performed: Tue, Thu
Reported: 1-5 days

Specimen Required: Patient Prep: Patient must be 18 years of age or older. Platelet count should be performed on the EDTA whole blood sample at the client site within 3 days of submission for testing.
Collect: Lavender (EDTA) or Pink (K_2EDTA) AND Serum Separator Tube (SST) AND Light Blue (Sodium Citrate).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transport 3 mL serum in an ARUP Standard Transport Tube. (Min: 1.2 mL) AND Transport 1 mL platelet-poor citrated plasma in an ARUP Standard Transport Tube. (Min: 0.5 mL) **Do not send the EDTA whole blood to ARUP.**
Storage/Transport Temperature: **Serum:** Frozen.
Plasma (citrated): CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Remarks: **Include an automated platelet count.** The Liver Stiffness result (in kPa) from the Fibroscan VCTE must be submitted with the samples. The performance date of the VCTE must also be submitted. VCTE performance date greater than 6 months from the specimen draw date and time are not acceptable.
Unacceptable Conditions: All required specimens not received. No platelet count received. Hemolyzed specimens.
Stability (collection to initiation of testing): **Serum:** Ambient: 8 hours; Refrigerated: Unacceptable; Frozen: 2 weeks
Plasma: Ambient: 24 hours; Refrigerated: Unacceptable; Frozen: 2 weeks

Reference Interval: By report

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

Note: Delays in test performance may result if the VCTE result and date of performance is not included with the requisition.

CPT Code(s): 83883; 84450; 82977 (Alt code: 81599)

New York DOH approval pending. Call for status update.

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

New Test **3001320** **Lymphocyte Proliferation, Antigen Induced, by Flow Cytometry (24-Hr Critical Room Temp)** **LPA FLOW**

Available Now
Click for Pricing

Time Sensitive

Methodology: Cell Culture/Flow Cytometry
Performed: Thu, Fri
Reported: 9-10 days

Specimen Required: Patient Prep: Collect control specimen from a healthy individual unrelated to patient.
Patient and control specimens must be collected ONLY on Wednesdays or Thursdays AND shipped directly to ARUP the same calendar day to meet the strict 24-hour stability requirement.
Collect: Green (sodium heparin) (patient) **AND** green (sodium heparin) (control) only on Wednesdays or Thursdays.
Specimen Preparation: Transport 10 mL whole blood (patient) **AND** 10 mL whole blood (control) in original collection tubes. (Min: 7 mL (patient) **AND** 7 mL (control)). Infant Minimum: 3 mL (patient) **AND** 7 mL (control).
Do not refrigerate or freeze. LIVE LYMPHOCYTES REQUIRED.
Storage/Transport Temperature: **CRITICAL ROOM TEMPERATURE.**
Must be collected and shipped directly to ARUP the same calendar day.
Remarks: **Do not collect or ship on, or the day before, holidays.**
Unacceptable Conditions: Refrigerated or frozen specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

Reference Interval:

	Tetanus	Candida
CD45 Pos Cells	2.9% or greater	9.6% or greater
CD3 Pos Cells	3.0% or greater	2.8% or greater

Interpretive Data: This test measures T lymphocyte proliferation in response to stimulation with recall antigens tetanus toxoid and *Candida*, determined by flow cytometry. Proliferating cells are detected by fluorescent labeling. Results are reported as percent proliferating cells of total specific cell populations.

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

CPT Code(s): 86353 x2

New York DOH approval pending. Call for status update.

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

New Test **3001319** **Lymphocyte Proliferation, Antigen-Mitogen Panel by Flow Cytometry (24-Hr Critical Room Temp)** **LAMP FLOW**

Available Now
Click for Pricing

Time Sensitive

Methodology: Cell Culture/Flow Cytometry
Performed: Thu, Fri
Reported: 9-10 days

Specimen Required: Patient Prep: Collect control specimen from a healthy individual unrelated to patient.
Patient and control specimens must be collected ONLY on Wednesdays or Thursdays AND shipped directly to ARUP the same calendar day to meet the strict 24-hour stability requirement.
Collect: Green (sodium heparin) (patient) AND green (sodium heparin) (control) only on Wednesdays or Thursdays.
Specimen Preparation: Transport 10 mL whole blood (patient) **AND** 10 mL whole blood (control) in original collection tubes. (Min: 7 mL (patient) **AND** 7 mL (control)). Infant Minimum: 3 mL (patient) **AND** 7 mL (control).
Do not refrigerate or freeze. LIVE LYMPHOCYTES REQUIRED.
Storage/Transport Temperature: **CRITICAL ROOM TEMPERATURE.**
Must be collected and shipped directly to ARUP the same calendar day.
Remarks: **Do not collect or ship on, or the day before, holidays.**
Unacceptable Conditions: Refrigerated or frozen specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

Reference Interval:

	PHA	**Con A**	**PWM**
CD45 Pos Cells	39.7% or greater	15.5% or greater	10.0% or greater
CD3 Pos Cells	42.5% or greater	17.4% or greater	8.0% or greater
CD19 Pos Cells	51.9% or greater	N/A	6.3% or greater
	Tetanus	**Candida**	
CD45 Pos Cells	2.9% or greater	9.6% or greater	
CD3 Pos Cells	3.0% or greater	2.8% or greater	

Interpretive Data: This test measures lymphocyte proliferation in response to stimulation with nonspecific mitogens phytohemagglutinin (PHA), concanavalin A (Con A), and pokeweed mitogen (PWM); and T lymphocyte proliferation in response to stimulation with recall antigens tetanus toxoid and *Candida*, determined by flow cytometry. Proliferating cells are detected by fluorescent labeling. Results are reported as percent proliferating cells of total specific cell populations.

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

CPT Code(s): 86353 x5

New York DOH approval pending. Call for status update.

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

New Test **3001321** **Lymphocyte Proliferation, Mitogen Induced, by Flow Cytometry Panel (48-Hr Critical Room Temp)** **LPM FLOW**

Available Now
Click for Pricing

Time Sensitive

Methodology: Cell Culture/Flow Cytometry
Performed: Thu, Fri
Reported: 9-10 days

Specimen Required: Patient Prep: Collect control specimen from a healthy individual unrelated to patient.
Patient and control specimens must be collected ONLY on Wednesdays or Thursdays AND shipped directly to ARUP the same calendar day to meet the strict 48-hour stability requirement.
Collect: Green (sodium heparin) (patient) **AND** green (sodium heparin) (control) only on Wednesdays or Thursdays.
Specimen Preparation: Transport 10 mL whole blood (patient) **AND** 10 mL whole blood (control) in original collection tubes. (Min: 7 mL (patient) **AND** 7 mL (control)). Infant Minimum: 3 mL (patient) **AND** 7 mL (control).
Do not refrigerate or freeze. LIVE LYMPHOCYTES REQUIRED.
Storage/Transport Temperature: **CRITICAL ROOM TEMPERATURE.**
Must be collected and shipped directly to ARUP the same calendar day.
Remarks: **Do not collect or ship on, or the day before, holidays.**
Unacceptable Conditions: Refrigerated or frozen specimens.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

Reference Interval:

	PHA	Con A	PWM
CD45 Pos Cells	39.7% or greater	15.5% or greater	10.0% or greater
CD3 Pos Cells	42.5% or greater	17.4% or greater	8.0% or greater
CD19 Pos Cells	51.9% or greater	N/A	6.3% or greater

Interpretive Data: This test measures lymphocyte proliferation in response to stimulation with nonspecific mitogens phytohemagglutinin (PHA), concanavalin A (Con A), and pokeweed mitogen (PWM), determined by flow cytometry. Proliferating cells are detected by fluorescent labeling. Results are reported as percent proliferating cells of total specific cell populations.

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

CPT Code(s): 86353 x3

New York DOH approval pending. Call for status update.

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

New Test **3001337** **Lymphocyte Proliferation, Anti-CD3, Anti-CD28 and IL-2 Induced, by Flow Cytometry (24-Hr Critical Room Temp)** **LPCD3 FLOW**

Available Now
Click for Pricing

Time Sensitive

Methodology: Cell Culture/Flow Cytometry
Performed: Thu, Fri
Reported: 9-10 days

Specimen Required: Patient Prep: Collect control specimen from a healthy individual unrelated to patient.
Patient and control specimens must be collected ONLY on Wednesdays or Thursdays AND shipped directly to ARUP the same calendar day to meet the strict 24-hour stability requirement.
Collect: Green (sodium heparin) (patient) **AND** green (sodium heparin) (control) only on Wednesdays or Thursdays.
Specimen Preparation: Transport 10 mL whole blood (patient) **AND** 10 mL whole blood (control) in original collection tubes. (Min: 7 mL (patient) **AND** 7 mL (control)). Infant Minimum: 3 mL (patient) **AND** 7 mL (control).
Do not refrigerate or freeze. LIVE LYMPHOCYTES REQUIRED.
Storage/Transport Temperature: **CRITICAL ROOM TEMPERATURE.**
Must be collected and shipped directly to ARUP the same calendar day.
Remarks: **Do not collect or ship on, or the day before, holidays.**
Unacceptable Conditions: Refrigerated or frozen specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

Reference Interval:

	Anti-CD3	Anti-CD3/Anti-CD28	Anti-CD3/IL-2
CD45 Pos Cells	10.2% or greater	29.0% or greater	33.1% or greater
CD3 Pos Cells	13.5% or greater	24.3% or greater	36.1% or greater

Interpretive Data: This test measures T lymphocyte proliferation in response to stimulation with anti-CD3, anti-CD3/anti-CD28, and anti-CD3/Interleukin-2, determined by flow cytometry. Proliferating cells are detected by fluorescent labeling. Results are reported as percent proliferating cells of the total specific cell populations. This is a second-level test to be performed after Lymphocyte Proliferation to Mitogens (PHA, Con A, and PWM) by Flow Cytometry has been assessed.

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

CPT Code(s): 86353 x3

New York DOH approval pending. Call for status update.

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

0092079 **Magnesium, RBC** **MG RBC**

Performed: Sun-Sat
Reported: 1-4 days

0025070 **Manganese, Urine** **MANG U**

Performed: Sun-Sat
Reported: 1-5 days

3000256 Marijuana Metabolite, Umbilical Cord Tissue, Qualitative — THC QQQ CD

Specimen Required: Collect: Umbilical Cord (At least 8 inches, approximately the width of a sheet of paper.)
Specimen Preparation: Drain and discard any blood. Rinse the exterior of the cord segment with normal saline or water. Pat the cord dry and transport at least 8 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: 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

This test is designed to detect and document exposure that occurred during approximately the last trimester of a full term pregnancy, 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.

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

2014699 Maternal T Cell Engraftment in SCID — STR-SCID

Specimen Required: Collect: Lavender (EDTA), Pink (K_2EDTA), or Yellow (ACD Solution A).
Specimen Preparation: Transport 3 mL whole blood. (Min: 3 mL) Increase the amount of blood submitted for patients with low cell counts.
Storage/Transport Temperature: Room temperature. Ship overnight. Specimens should be received within 24 hours of collection for **optimal** isolation of T cells.
Remarks: Please provide the results and date of the patient's most recent WBC and differential counts.
Unacceptable Conditions: Clotted or hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Unacceptable

Interpretive Data:
Background Information for Maternal T Cell Engraftment in SCID:
Indication: Severe combined immunodeficiency (SCID) patients lack T cells and cannot recognize and reject maternal T cells from maternal-fetal transfusion. Maternal T cell can proliferate in the absence of host T cells, leading to difficulty in determining the host T cell numbers required for the diagnosis of SCID and/or can cause graft-versus-host disease-line (GVHD) presentation.
Methodology: PCR followed by capillary electrophoresis. Specimens are analyzed using 15 autosomal markers (D8S1179, D21S11, D7S820, CSF1PO, D3S1358, THO1, D13S317, D16S539, D2S1338, D19S433, vWa, TPOX, D18S51, D5S818, and FGA) and one gender marker (amelogenin).
Kit Used: AmpFLSTR Identifiler PCR Amplification Kit, Applied Biosystems.
Limit of Detection: 2 percent of minor cell population.
See Compliance Statement B: www.aruplab.com/CS

Note: To complete Maternal T Cell Engraftment in SCID testing, samples should be collected to perform the following three tests: (1) A buccal swab or brush collected from the patient for Maternal T Cell Engraftment in SCID, Pre-Engraftment Specimen (ARUP test code 2014694), used as a genetic baseline for the patient. (2) A peripheral blood sample from the biological mother for Maternal T Cell Engraftment in SCID, Maternal Specimen (ARUP test code 2014704), used as a genetic baseline for the mother. (3) A peripheral blood sample collected from the patient for Maternal T Cell Engraftment in SCID, (ARUP test code 2014699). T cells isolated from the blood sample will be genotyped for comparison to the patient and biological mother baseline genotypes. If T cell sorting is not completed on the blood sample before submission, BMT Cell Isolation (ARUP test code 2005498) will be added. Additional charges apply.

2011481 Mercury, Random Urine — U MERCRAND

Performed: Sun-Sat
Reported: 1-5 days

0025050 Mercury, Urine — MERCURY U

Performed: Sun-Sat
Reported: 1-5 days

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

CPT Code(s): 83516 x7; 84160; 82784 x3; 84165; 86334; 86255; if reflexed add 83516 and/or 86256

2007966	**Motor and Sensory Neuropathy Evaluation with Reflex to Titer and Neuronal Immunoblot**	**MSNER**

CPT Code(s): 83516 x7; 86255; if reflexed add 83516 and/or 86256

0051225	**Motor Neuropathy Panel**	**MSN PAN**

CPT Code(s): 83516 x7; 84160; 82784 x3; 84165; 86334

New Test 3001576 **Muscle-Specific Kinase (MuSK) Antibody, IgG** **MSK AB**

Click for Pricing

Methodology: Quantitative Radioimmunoassay
Performed: Mon, Thu
Reported: 2-8 days

Specimen Required: Patient Prep: None
Collect: One 4 mL Plain Red or Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL of serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Grossly lipemic, icteric, or hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 month (avoid multiple freeze/thaw cycles)

Reference Interval:

Negative	0.00-0.03 nmol/L
Positive	0.04 nmol/L or greater

Interpretive Data: Muscle-specific kinase (MuSK) antibody is found in a subset of patients with myasthenia gravis, primarily those seronegative for muscle acetylcholine receptor (AChR) antibody. Decreasing antibody levels may be associated with therapeutic response; therefore, clinical correlation must be strongly considered. A negative test result does not rule out a diagnosis of myasthenia gravis.

See Compliance statement A: www.aruplab.com/CS

CPT Code(s): 83519

New York DOH approval pending. Call for status update.

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

2011117	**Myeloid Malignancies Mutation Panel by Next Generation Sequencing**	**MYE NGS**

Specimen Required: Collect: Lavender (EDTA) **OR** Bone Marrow (EDTA).
Specimen Preparation: Do not freeze. Transport 5 mL whole blood. (Min: 1 mL) **OR** Transport 3 mL bone marrow. (Min: 1 mL).
Separate specimens must be submitted when multiple tests are ordered.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Serum, plasma or tissue. Specimens collected in anticoagulants other than EDTA. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable

2012182 **Myeloid Malignancies Somatic Mutation and Copy Number Analysis Panel** **MYE CMANGS**

Specimen Required: Collect: Lavender (EDTA) **OR** Bone Marrow (EDTA).
Specimen Preparation: Do not freeze. Transport 5 mL whole blood. (Min: 1 mL) **OR** Transport 3 mL bone marrow. (Min: 1 mL).
Separate specimens must be submitted when multiple tests are ordered.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Serum, plasma or tissue. Specimens collected in anticoagulants other than EDTA. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable

0090141 **Phenytoin, Free and Total** **FDIL**

Specimen Required: Patient Prep: Timing of specimen collection: Pre-dose (trough) draw - At steady state concentration.
Collect: Plain Red.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Whole blood. Citrated plasma. Serum separator tubes (SST). Tubes that contain liquid anticoagulant.
Stability (collection to initiation of testing): After separation from cells: Ambient: 4 days; Refrigerated: 4 days; Frozen: 1 month

HOTLINE NOTE: Remove information found in the Specimen Required Remarks field. There is also a component change associated with this test.
Remove component 2011597, Phenytoin Dose
Remove component 2011598, Phenytoin Dose Frequency
Remove component 2011599, Phenytoin Route
Remove component 2011600, Phenytoin Type of Draw

New Test **3001053** **Red Blood Cell Antigen Genotyping** **RBC GENO**
Available Now
Click for Pricing

Additional Technical Information

Methodology: Polymerase chain reaction followed by fluorescent probe ligation and detection
Performed: Sun-Sat
Reported: 7-14 days

Specimen Required: Collect: Lavender (EDTA)
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum; collection of specimen in sodium heparin tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:
Background Information for Red Blood Cell Antigen Genotyping:
Characteristics: Erythrocyte alloimmunization may result in hemolytic transfusion reactions or hemolytic disease of the fetus and newborn (HDFN). Clinical presentation is variable and dependent upon the specific antibody and recipient factors.
Incidence: Erythrocyte alloimmunization occurs in up to 58% of sickle cell patients, up to 35% in other transfusion-dependent patients, and in approximately 0.8% of all pregnant women.
Inheritance: Typically co-dominant for red blood cell (RBC) antigens, autosomal recessive for hemoglobin S (HbS).
Cause: Antigen-antibody mediated red-cell hemolysis between donor/recipient or transferred maternal antibodies.
Variants Tested: See the "Additional Technical Information" document.
Clinical Sensitivity: >99% for c (RH4), C (RH2), e (RH5), E (RH3), k (KEL2), K (KEL1), Jka (JK1), Jkb (JK2), Fya (FY1), Fyb (FY2), M (MNS1), N (MNS2), S (MNS3), s (MNS4). Unknown for Kpa (KEL3), Kpb (KEL4), Jsa (KEL6), Jsb (KEL7), Lua (LU1), Lub (LU2), Dia (DI1), Dib (DI2), Coa (CO1), Cob (CO2), Doa (DO1), Dob (DO2), Joa (DO5), Hy (DO4), LWa (LW5), LWb (LW7), Sc1 (SC1), Sc2 (SC2), U (MNS5), V (RH10), VS (RH20), Hemoglobin S (HbS).
Methodology: Immucor PreciseType™ HEA Molecular BeadChip which is FDA-approved for clinical testing. Predicted phenotypes are reported for each antigen and HbS based on the variants tested.
Analytical Sensitivity and Specificity: >99% for c (RH4), C (RH2), e (RH5), E (RH3), k (KEL2), K (KEL1), Jka (JK1), Jkb (JK2), Fya (FY1), Fyb (FY2), M (MNS1), N (MNS2), S (MNS3), s (MNS4). Unknown for Kpa (KEL3), Kpb (KEL4), Jsa (KEL6), Jsb (KEL7), Lua (LU1), Lub (LU2), Dia (DI1), Dib (DI2), Coa (CO1), Cob (CO2), Doa (DO1), Dob (DO2), Joa (DO5), Hy (DO4), LWa (LW5), LWb (LW7), Sc1 (SC1), Sc2 (SC2), U (MNS5), V (RH10), VS (RH20), Hemoglobin S (HbS).
Limitations: Only the targeted variants will be interrogated. Rare nucleotide changes leading to altered or partial antigen expression and null phenotypes may not be detected by this assay. This assay does not assess for RhD nor is it designed to diagnose sickle cell disease. Patients who have had hematopoietic stem cell transplants may have inconclusive results on this test. Abnormal signal intensities may result in indeterminate genotyping results for all tested antigens/HbS.

CPT Code(s): 0001U

New York DOH approval pending. Call for status update.

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

New Test **3001479** **Respiratory Viral Panel by PCR** **RVPPCR**
Click for Pricing

Methodology: Qualitative Polymerase Chain Reaction
Performed: Sun-Sat
Reported: 1-3 days

Specimen Required: Collect: Nasopharyngeal Swab.
Specimen Preparation: Place in viral transport media (ARUP Supply #12884). Available online through eSupply using ARUP Connect™or contact ARUP Client Services at (800) 522-2787. Place each specimen in an individually sealed bag.
Storage/Transport Temperature: Frozen
Unacceptable Conditions: Specimens not in viral transport media.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 4 days; Frozen: 1 month

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

Note: This test detects influenza A, influenza B, RSV, human metapneumovirus, human rhinovirus, and adenovirus. Detects and differentiates parainfluenza 1, 2, 3, and 4.

CPT Code(s): 87632

New York DOH Approved.

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

New Test **3001496** **Rifampin and Metabolite, Serum or Plasma** **RIFAMP SP**
Click for Pricing

Methodology: Quantitative High Performance Liquid Chromatography/Tandem Mass Spectrometry
Performed: Varies
Reported: 8-11 days

Specimen Required: Collect: Plain Red, Lavender (EDTA), or Pink (K_2EDTA).
Specimen Preparation: Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.4 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen.
Unacceptable Conditions: Specimens transported in separator tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 month; Frozen: 1 month

Reference Interval: By report

CPT Code(s): 80375 (Alt code: G0480)

New York DOH Approved.

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

2012618 Risk of Ovarian Malignancy Algorithm ROMA

Methodology: Quantitative Electrochemiluminescent Immunoassay (ECLIA)
Performed: Sun-Sat
Reported: Within 24 hours

Specimen Required: Collect: Serum Separator Tube (SST). Also acceptable: Green (Sodium or Lithium Heparin), Lavender (EDTA), or Pink (K2EDTA).
Specimen Preparation: Allow specimen to clot completely at room temperature. Transfer 1.5 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 5 hours; Refrigerated: 48 hours; Frozen: 4 months

Interpretive Data: The Risk of Ovarian Malignancy Algorithm (ROMA) combines the results of HE4, CA125, and menopausal status into a numerical score. If the patient is premenopausal, then a ROMA score of less than 1.14 is consistent with a low likelihood of finding a malignancy on surgery. If the patient is postmenopausal, then a ROMA score of less than 2.99 is consistent with a low likelihood of finding a malignancy on surgery.

ROMA is intended as an aid in assessing whether a premenopausal or postmenopausal woman who presenting with an ovarian adnexal mass is at high or low likelihood of having malignancy on surgery. ROMA is indicated for women who meet the following criteria: over age 18; ovarian adnexal mass present for which surgery is planned, and who has not yet referred to an oncologist. ROMA must be interpreted in conjunction with an independent clinical and radiological assessment. ROMA is not intended as a screening or stand-alone or tumor-monitoring assay. Tumor monitoring using HE4 and/or CA125 should be ordered separately.

Testing for HE4 and CA125 was performed using Roche Cobas e602 electrochemiluminescent methods. Analyte results obtained with different test methods or kits cannot be used interchangeably.

HOTLINE NOTE: There is a numeric map change associated with this test.
Change the numeric map for component 2012621, ROMA Cancer Antigen 125 from XXXXX to XXXXXX.
Change the numeric map for component 2012622, ROMA Human Epididymis Protein 4 from XXXXX to XXXXXX.
There is also a unit of measure change associated with this test.
Change the unit of measure for component 2012622, ROMA Human Epididymis Protein 4 from pM to pmol/L.

0025023 Selenium, Serum or Plasma SE S

Performed: Sun-Sat
Reported: 1-3 days

New Test **3001395** ***SHOX*-Related Disorders, Deletion/Duplication** **SHOX DD**

Click for Pricing

Patient History for *SHOX*-Related Disorders

Additional Technical Information

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

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

Reference Interval: By Report

Interpretive Data:
Background Information for *SHOX-Related Disorders*, Deletion/Duplication:
Characteristics of *SHOX*-related disorders (*SHOX* deficiency): Short stature, mesomelia, and abnormal alignment of the radius, ulna, and carpal bones at wrist (Madelung deformity). Variable expressivity results in some affected individuals with syndromic short stature and additional findings (eg, Leri-Weill dyschondrosteosis (LWD) or Langer mesomelic dysplasia (LMD)), while others have isolated short stature (ISS).
Prevalence of *SHOX* deficiency: 1 in 1,000
Inheritance: *SHOX* is located in pseudoautosomal region 1 (PAR1) on the X and Y chromosomes and escapes X inactivation. Thus, inheritance is pseudoautosomal dominant for ISS and LWD, and pseudoautosomal recessive for LMD.
Penetrance: High, with variability in expression.
Cause: One pathogenic variant (haploinsufficiency) of the *SHOX* gene causes ISS and LWD. Two pathogenic variants in *SHOX* (complete loss of *SHOX*) causes LMD.
Clinical Sensitivity: Approximately 80-90 percent of disease-causing *SHOX* variants are deletions.
Methodology: Multiplex Ligation-dependent Probe Amplification (MLPA) to detect large deletions/duplications in the *SHOX* gene and surrounding *SHOX* region, which includes upstream and downstream enhancer elements in the pseudoautosomal 1 region (PAR1).
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Deletion/duplication breakpoints are not determined. Contiguous gene syndromes, complex rearrangements, chromosome translocations, inversions or aneuploidy affecting the sex chromosomes are not detected by this assay; additional testing may be required in such cases. *SHOX* sequence variants, and deep intronic and promoter variants are not detected.

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

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

CPT Code(s): 81479

New York DOH approval pending. Call for status update.

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

New Test **3001401** ***SHOX*-Related Disorders, Deletion/Duplication with Reflex to Sequencing** **SHOXREFLEX**

Click for Pricing

Patient History for *SHOX*-Related Disorders

Additional Technical Information

Methodology: Multiplex Ligation-dependent Probe Amplification/Polymerase Chain Reaction/Sequencing
Performed: Varies
Reported: 14-28 days

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

Reference Interval: By Report

Interpretive Data:

Background information for *SHOX*-Related Disorders, Deletion/Duplication with Reflex to Sequencing:
Characteristics of *SHOX*-related disorders (*SHOX* deficiency): Short stature, mesomelia, and abnormal alignment of the radius, ulna and carpal bones at wrist (Madelung deformity). Variable expressivity results in some affected individuals with syndromic short stature and additional findings (eg, Leri-Weill dyschondrosteosis (LWD) or Langer mesomelic dysplasia (LMD)), while others have isolated short stature (ISS).
Prevalence of *SHOX* deficiency: 1 in 1,000
Inheritance: *SHOX* is located in pseudoautosomal region 1 (PAR1) on the X and Y chromosomes and escapes X-inactivation. Thus, inheritance is pseudoautosomal dominant for ISS and LWD, and pseudoautosomal recessive for LMD.
Penetrance: High, with variability in expression.
Cause: One pathogenic variant (haploinsufficiency) of the *SHOX* gene causes ISS and LWD. Two pathogenic variants in *SHOX* (complete loss of *SHOX*) cause LMD.
Clinical Sensitivity: Approximately 80-90 percent of disease-causing *SHOX* variants are deletions and 10-20 percent are sequence variants.
Methodology for deletion/duplication analysis: Multiplex Ligation-dependent Probe Amplification (MLPA) to detect large deletions/duplications in the *SHOX* gene and surrounding *SHOX* region, which includes upstream and downstream enhancer elements in the pseudoautosomal 1 region (PAR1).
Methodology for sequencing: Bidirectional Sanger sequencing of the *SHOX* coding regions, including exons 6a and 6b, and intron-exon boundaries.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Deletion/duplication breakpoints are not determined. Contiguous gene syndromes, complex rearrangements, chromosome translocations, inversions or aneuploidy affecting the sex chromosomes are not detected by this assay; additional testing may be required in such cases. Repeat element insertions, deep intronic variants and some regulatory region variants are not detected.

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

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

Note: Deletion/Duplication analysis is performed on all samples. If no large deletions or duplications are detected and/or results do not explain the clinical scenario, then sequencing of the *SHOX* gene will be added. Additional charges apply. If reflexed, an additional 14 days is required to complete testing.

CPT Code(s): 81479; if reflexed, add 81405

New York DOH approval pending. Call for status update.

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

New Test **3001399** ***SHOX*-Related Disorders, Sequencing** **SHOX FGS**
Click for Pricing

Additional Technical Information

Patient History for *SHOX*-Related Disorders

Methodology: Polymerase Chain Reaction/Sequencing
Performed: Sun-Sat
Reported: 12-14 days

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

Interpretive Data:
Background Information for *SHOX*-Related Disorders, Sequencing:
Characteristics of *SHOX*-related disorders (*SHOX* deficiency): Short stature, mesomelia, and abnormal alignment of the radius, ulna and carpal bones at wrist (Madelung deformity). Variable expressivity results in some affected individuals with syndromic short stature and additional findings (eg, Leri-Weill dyschondrosteosis (LWD) or Langer mesomelic dysplasia (LMD)), while others have isolated short stature (ISS).
Prevalence of *SHOX* deficiency: 1 in 1,000
Inheritance: *SHOX* is located in pseudoautosomal region 1 (PAR1) on the X and Y chromosomes and escapes X-inactivation. Thus, inheritance is pseudoautosomal dominant for ISS and LWD, and pseudoautosomal recessive for LMD.
Penetrance: High, with variability in expression.
Cause: One pathogenic variant (haploinsufficiency) of the *SHOX* gene causes ISS and LWD. Two pathogenic variants in *SHOX* (complete loss of *SHOX*) cause LMD.
Clinical Sensitivity: Approximately 10-20 percent of disease-causing variants in *SHOX* are sequence variants.
Methodology: Bidirectional Sanger sequencing of the *SHOX* coding regions, including exon 6a and 6b, and intron-exon boundaries.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Large deletions/duplications, repeat element insertions, deep intronic variants, and some regulatory region variants are not detected.

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

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

CPT Code(s): 81405

New York DOH approval pending. Call for status update.

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

2007991 **Solid Tumor Mutation Panel by Next Generation Sequencing** **SOLID NGS**

Specimen Required: Collect: Tumor tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Diff-Quik and Papanicolaou stained cytology smears are also acceptable. Number of slides needed is dependent on the tumor cellularity of the smear. Slide(s) will be destroyed during testing process and will not be returned to client. Protect from excessive heat. Transport block and/or slides in a tissue transport kit (ARUP supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Resections: Transport 8 unstained 5-micron slides. (Min: 5 slides)
Small Biopsies: Transport 15 unstained 5-micron slides. (Min: 10 slides)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks: Include surgical pathology report.
Unacceptable Conditions: Less than 10 percent tumor. Specimens fixed/processed in heavy metal fixatives. Decalcified specimens. FNA smears with less than 50 tumor cells.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Reference Interval: By report

New Test Available Now Click for Pricing

3001562 **SOX-10 By Immunohistochemistry** **SOX10 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 approval pending. Call for status update.

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

0070111 **Testosterone Free, Adult Male** **FREE T2**

CPT Code(s): 84403

0081059 **Testosterone Free, Females or Children** **TESTOS FR**

CPT Code(s): 84403

0025019 **Thallium, Urine** **THALU**

Performed: Sun-Sat
Reported: 1-5 days

New Test **3001535** ***TPMT* and *NUDT15*** **TPMT2**

Click for Pricing

Additional Technical Information

Supplemental Resources

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

Specimen Required: Collect: **Whole Blood:** Lavender (EDTA), Pink (K_2EDTA), or Yellow (ACD Solution A or B).
Saliva: Collection Device by DNA Genotek (OCD-100, ARUP Supply #49295) available online through eSupply using ARUP Connect™ or by contacting ARUP Client Services at (800) 522-2787.
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL) OR Transport the Saliva Collection Device.
Storage/Transport Temperature: **Whole Blood:** Refrigerated.
Saliva: Room temperature.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin.
Stability (collection to initiation of testing): **Whole Blood:** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Saliva: Ambient: 2 weeks; Refrigerated: Unacceptable; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:
Background Information for *TPMT* and *NUDT15*:
Characteristics: Thiopurine drug therapy is used for autoimmune diseases, inflammatory bowel disease, acute lymphoblastic leukemia, and to prevent rejection after solid organ transplant. The inactivation of thiopurine drugs is catalyzed in part by thiopurine methyltrasferase (TPMT) and nudix hydrolase 15 (NUDT15). Variants in the *TPMT* and/or *NUDT15* genes are associated with an accumulation of cytotoxic metabolites leading to increased risk of drug-related toxicity with standard doses of thiopurine drugs. These effects on thiopurine catabolism can be additive.
Inheritance: Autosomal co-dominant.
Cause: *TPMT* and *NUDT15* variants affect enzyme expression or activity.
Variants Tested: See the "Additional Technical Information" document.
Clinical Sensitivity: 95 percent.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: 99 percent.
Limitations: Only the targeted *TPMT* and *NUDT15* variants will be detected by this test. Because the complex TPMT*3A allele contains the variants found in the *3B and *3C alleles, this test cannot distinguish the 3A/Negative genotype (intermediate enzyme activity) from the rare *3B/*3C genotype (no or low enzyme activity). Genotyping may reflect donor status in patients who have received allogenic stem cell or bone marrow transplants within 2 weeks of specimen collection. Actual enzyme activity and expression and risk for adverse reactions to thiopurines may be affected by additional genetic and non-genetic factors not evaluated by this test. Diagnostic errors can occur due to rare sequence variations. Genotyping does not replace the need for therapeutic drug monitoring and clinical observation.

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

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

CPT Code(s): 81335; 81306

New York DOH approval pending. Call for status update.

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

New Test **3001541** **Warfarin Sensitivity (*CYP2C8, CYP2C9, CYP4F2, VKORC1*) Genotyping** **WARF PAN**

Click for Pricing

Additional Technical Information

Out of Pocket Estimator

Supplemental Resources

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

Specimen Required: Collect: **Whole Blood:** Lavender (EDTA), Pink (K_2EDTA), or Yellow (ACD Solution A or B).
Saliva: Collection Device by DNA Genotek (OCD-100, ARUP Supply #49295) available online through eSupply using ARUP Connect™ or by contacting ARUP Client Services at (800) 522-2787.
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL) OR Transport the Saliva Collection Device.
Storage/Transport Temperature: **Whole Blood:** Refrigerated.
Saliva: Room temperature.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin.
Stability (collection to initiation of testing): **Whole Blood:** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Saliva: Ambient: 2 weeks; Refrigerated: Unacceptable; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:
Background Information for Warfarin Sensitivity (CYP2C8, CYP2C9, CYP4F2, VKORC1) Genotyping:
Characteristics: Warfarin sensitivity can lead to a life-threatening overdose event such as excessive bleeding. Genetic variation is recognized to explain a large proportion of variability in warfarin dose requirements. This test may predict individual warfarin sensitivity and non-standard dose requirements. The cytochrome P450 (CYP) isozymes 2C8 and 2C9 are involved in the metabolism of many drugs. Variants in the genes that code for CYP2C8 and CYP2C9 may influence pharmacokinetics of substrates such as warfarin, and may predict or explain non-standard dose requirements, therapeutic failure or adverse reactions. Variants in the *VKORC1* and *CYP4F2* genes may predict sensitivity to warfarin. Genetic information and non-genetic factors can be used in combination with warfarin dose calculators, such as through www.WarfarinDosing.org.
Inheritance: Autosomal co-dominant.
Cause: *CYP2C8*, *CYP2C9* and *CYP4F2* gene variants affect enzyme expression or activity. The *VKORC1*2* allele is associated with reduced expression of the warfarin target, vitamin K epoxide reductase (VKOR), and a reduced dose requirement.
Variants Tested: See the "Additional Technical Information" document.
Clinical Sensitivity: Genetic factors and known non-genetic factors account for ~50% of the variability in warfarin dose.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Only the targeted *CYP2C8, CYP2C9, CYP4F2* and *VKORC1* variants will be detected by this panel, and assumptions about phase and content are made to assign alleles. Publically available sources such as the www.pharmvar.org or www.pharmgkb.org provide guidance on phenotype predictions and allele frequencies. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with CYP2C8 or CYP2C9 substrates may be affected by genetic and non-genetic factors that are not detected by this test. This result does not replace the need for therapeutic drug or clinical monitoring.

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

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

CPT Code(s): 81227; 81355

New York DOH approval pending. Call for status update.

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

0020598 Wilson Disease Screening Panel, Serum WILSON D

Specimen Required: Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances. Patient should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician).
Collect: Royal Blue (No Additive).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 4 mL serum 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: 2.5 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Specimens collected in containers other than specified. Specimens transported in containers other than specified.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 72 hours; Frozen: 1 month

Reference Interval:

Test Number	Components	Reference Interval		
0020096	Copper, Serum or Plasma	Effective May 20, 2019		
		Age	**Male**	**Female**
		0-10 years	75.0-153.0 µg/dL	75.0-153.0 µg/dL
		11 years-12 years	64.0-132.0 µg/dL	64.0-132.0 µg/dL
		13 years-18 years	57.0-129.0 µg/dL	57.0-129.0 µg/dL
		19 years and older	70.0-140.0 µg/dL	80.0-155.0 µg/dL
0050160	Ceruloplasmin	6 months-6 years	18-37 mg/dL	
		7-17 years	20-43 mg/dL	
		18 years and older	17-54 mg/dL	
0020596	Copper, Serum Free (Direct)	0.0-10.0 µg/dL		

Interpretive Data: Elevated results may be due to skin or collection-related contamination, including the use of a noncertified metal-free collection/transport tube. If contamination concerns exist due to elevated levels of serum copper, confirmation with a second specimen collected in a certified metal-free tube is recommended.

Free copper (direct) is determined with serum ultrafiltrate. In Wilson disease or other conditions of copper overload, serum ceruloplasmin is usually low and free copper (direct) is usually high. Other tests used to diagnosis Wilson disease include 24-hour urine copper, and hepatic copper. Slit lamp examination for Kayser-Fleischer rings and genetic testing may also be helpful.

HOTLINE NOTE: Remove information found in the Note field. There is also a numeric map change associated with this test.
Change the numeric map for component 0020096, Copper, Serum/Plasma from XXXX to XXX.X.

0020097 Zinc, Serum or Plasma ZINC

Performed: Sun-Sat
Reported: 1-3 days

Specimen Required: Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances. Upon the advice of their physician, patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and nonessential over-the-counter medications for one week prior to sample draw.
Collect: Royal Blue (No Additives), Royal Blue (K_2 EDTA), or Royal Blue (Na_2 EDTA).
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: 0.5 mL)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated or frozen.
Unacceptable Conditions: Specimens collected in containers other than specified. Specimens transported in containers other than specified. Hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Indefinitely

Reference Interval:
Effective May 20, 2019
60.0-120.0 µg/dL

Interpretive Data: Elevated results may be due to skin or collection-related contamination, including the use of a noncertified metal-free collection/transport tube. If contamination concerns exist due to elevated levels of serum/plasma zinc, confirmation with a second specimen collected in a certified metal-free tube is recommended.

Circulating zinc concentrations are dependent on albumin status and are depressed with malnutrition. Zinc may also be lowered with infection, inflammation, stress, oral contraceptives, and pregnancy. Zinc may be elevated with zinc supplementation or fasting. Elevated zinc concentrations may interfere with copper absorption.

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

HOTLINE NOTE: Remove information found in the Note field. There is also a numeric map change associated with this test.
Change the numeric map for component 0020097, Zinc, Serum/Plasma from XXXX to XXX.X.

0020462 Zinc, Urine ZINC U

Performed: Sun-Sat
Reported: 1- 5 days

Specimen Required: Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician). Collection from patients receiving iodinated or gadolinium-based contrast media must be avoided for a minimum of 72 hours post-exposure. Collection from patients with impaired kidney function should be avoided for a minimum of 14 days post contrast media exposure.
Collect: 24 Hour Urine. Refrigerate during collection. Specimen must be collected in a plastic container. Also acceptable: Random Urine.
Specimen Preparation: Transfer an 8 mL aliquot from a well-mixed collection to ARUP Trace Element-Free Transport Tubes (ARUP supply #43116) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Remarks: Record total volume and collection time interval on transport tube and on test request form.
Unacceptable Conditions: Specimens collected within 72 hours after administration of iodinated or gadolinium-based contrast media. Acid preserved urine. Specimens transported in containers other than specified. Specimen contaminated with blood or fecal material.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 1 year

Note: High concentrations of iodine or gadolinium may interfere with elemental testing.

ARUP LABORATORIES

HOTLINE: Effective May 20, 2019

The following will be discontinued from ARUP's test menu on May 20, 2019.
Replacement test options are supplied if applicable.

Test Number	Test Name	Refer To Replacement
2012710	Aggressive B-Cell Lymphoma FISH Reflex, Tissue	Aggressive B-Cell Lymphoma Reflex Panel by FISH, Tissue (3001495)
2014007	Allergen, Food, Milk (Boiled) IgE	
2010738	Allergen, Food, Safflower IgE	
2009210	Antimicrobial Level - Rifampin by HPLC, Serum or Plasma	Rifampin and Metabolite, Serum or Plasma (3001496)
0091570	Aspirin and Oxycodone Quantitative, Serum or Plasma	
2003827	Carcinoembryonic Antigen, Polyclonal (CEA P) by Immunohistochemistry	
2013386	Congenital Adrenal Hyperplasia (CAH) (21-Hydroxylase Deficiency) Common Mutations	
2012769	Cytochrome P450 2C19, *CYP2C19* - 9 Variants	*CYP2C19* (3001508)
2012766	Cytochrome P450 2C9, *CYP2C9* - 2 Variants	*CYP2C8* and *CYP2C9* (3001501)
2014547	Cytochrome P450 2D6 (*CYP2D6*) 15 Variants and Gene Duplication	*CYP2D6* (3001513)
2012740	Cytochrome P450 3A5 Genotyping, *CYP3A5*, 2 Variants	*CYP3A4* and *CYP3A5* (3001518)
2013098	Cytochrome P450 Genotype Panel	Cytochrome P450 Genotyping Panel (3001524)
2007763	Diuretic Survey Quantitative, Serum or Plasma	
0060315	Fat, Body Fluid	Triglycerides, Fluid (0020713) or Chylomicron Screen, Body Fluid (0098457)
0020240	Fat, Urine Qualitative	Chylomicron Screen, Body Fluid (0098457)
2007228	5-Fluorouracil (5-FU) Toxicity and Chemotherapeutic Response, 5 Mutations	Dihydropyrimidine Dehydrogenase (*DPYD*), 3 Variants (2012166)
2002662	Freeman-Sheldon Syndrome (*MYH3*) Sequencing Exon 17	
0051476	Glaucoma (Primary Congenital), *CYP1B1* Sequencing	
2002862	Glutamic Acid Decarboxylase Antibody (GAD65) and Insulin Antibodies with Reflex to IA-2 Antibody	
2002044	Hearing Loss, Nonsyndromic, Mitochondrial DNA 2 Mutations	Hearing Loss, Nonsyndromic Panel (*GJB2*) Sequencing, (*GJB6*) 2 Deletions and Mitochondrial DNA 2 Mutations (2001992)
0099414	HemoQuant, Fecal	
0093061	Human Immunodeficiency Virus 1 (HIV-1) by Qualitative PCR	Human Immunodeficiency Virus 1 (HIV-1) Qualitative by NAAT, Whole Blood (3001474)
0050157	Hypersensitivity Pneumonitis Extended Panel (Farmer's Lung Panel)	Hypersensitivity Pneumonitis Extended Panel (Farmer's Lung Panel) (3001561)
0055226	Hypersensitivity Pneumonitis II	Hypersensitivity Pneumonitis 2 (3001560)
0050202	IA-2 Antibody	Islet Antigen-2 (IA-2) Autoantibody, Serum (3001499)
2004911	*MUTYH*-Associated Polyposis (*MUTYH*) 2 Mutations	*MUTYH*-Associated Polyposis (*MUTYH*) Sequencing (2006191)
2006307	*MUTYH*-Associated Polyposis (*MUTYH*) 2 Mutations with Reflex to Sequencing	*MUTYH*-Associated Polyposis (*MUTYH*) Sequencing (2006191)
2007805	Respiratory Virus Panel by PCR	Respiratory Viral Panel by PCR (3001479)
2012125	*SHOX* Mutation Detection	*SHOX*-Related Disorders, Deletion/Duplication with Reflex to Sequencing (3001401)
2012233	Thiopurine Methyltransferase (*TPMT*) Genotyping, 4 Variants	*TPMT* and *NUDT15* (3001535)
2014109	Total Inhibin, Serum	
0093067	Treponema pallidum Antibody Panel (FTA-ABS) IgG and IgM	
0099590	Tryptophan, Plasma	
2012772	Warfarin Sensitivity, *CYP2C9* and *VKORC1*, 3 Variants	Warfarin Sensitivity (*CYP2C8*, *CYP2C9*, *CYP4F2*, *VKORC1*) Genotyping (3001541)