Quarterly HOT LINE: Effective November 16, 2015

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-9 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.

Hot Line Page #	Test Number	Summary of Changes by Test Name	Name Change	Methodology	Performed/Reported Schedule	Specimen Requirements	Reference Interval	Interpretive Data	Note	CPT Code	Component Change	Other Interface Change	New Test	Inactive
9	2005639	Acetylcholine Receptor Antibodies and Striated Muscle Antibodies Reflexive Panels, and Titin Antibody									x			
10	2012710	Aggressive B-Cell Lymphoma FISH Reflex, Tissue Available Date 10/19/2015											x	
62	0080700	Albumin, Glycated												x
10	2011043	Alpha-1-Antitrypsin Clearance, Quantitative by ELISA, Timed Stool									x			
10	0090010	Alprazolam			x	x								
62	0099409	Antimony, Urine												x
62	2007609	Antiphospholipid Antibodies Extended Panel												x
11	0020734	Arsenic, Fractionated, Urine				x								

Hot Line 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
11	0025000	Arsenic, Urine with Reflex to Fractionated				x								
62	2011958	Ashkenazi Jewish (*BRCA1* and *BRCA2*) 3 Mutations												x
11	2002464	Bence Jones Protein, Quantitation and Characterization, with Reflex to Kappa/Lambda Free Light Chains with Ratio, Urine									x			
11	2010445	Benzodiazepines, Serum or Plasma, Quantitative					x	x			x			
62	0099410	Bismuth, Urine												x
62	2002742	Buprenorphine and Metabolites - Confirmation/Quantitation - Serum/Plasma												x
12	2012647	Buprenorphine and Metabolites, Serum or Plasma, Quantitative Available Date 01/04/2016											x	
12	2011603	Caffeine, Serum or Plasma				x	x							
13	2011763	Carbamazepine, Free and Total, Serum or Plasma				x	x							
62	0051600	Cardiolipin and Non-Criteria Anti-Phospholipid Syndrome (APS) Antibody Panel												x
62	0080512	Carnitine Transport, Fibroblasts												x
13	2002026	Celiac Disease Dual Antigen Screen with Reflex					x			x		x		
14	2008114	Celiac Disease Reflexive Cascade					x			x		x		
62	2006222	CHARGE Syndrome (*CHD7*) Sequencing												x
15	2012717	CHARGE Syndrome (*CHD7*) Sequencing, Fetal Available Date 10/19/2015											x	
16	2012609	CHARGE Syndrome, *CHD7* Sequencing Available Date 10/19/2015											x	
17	2010161	Chronic Enteric Hypersensitivity Reflexive Profile					x					x		
19	0093399	Circulating Tumor Cell Count								x				
19	0090055	Clonazepam				x								
20	0090196	Clorazepate (Assayed as Nordiazepam)				x	x					x		
62	2008097	Complement Component 1q, Functional												x
20	2003250	Cortisol by LC-MS/MS, Serum or Plasma				x								
62	0098391	Cortisol, Free												x
20	2012697	Cortisol, Free by Equilibrium Dialysis/LC-MS/MS Available Date 10/19/2015											x	
20	2003252	Cortisone by LC-MS/MS, Serum or Plasma				x								
21	2007081	Cotinine Screen, Urine				x								
62	2003102	*Coxiella burnetii* (Q-Fever) Antibodies, IgG & IgM by IFA with Reflex to Titer												x

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21	2012634	*Coxiella burnetii* (Q-Fever) Antibodies, IgG and IgM, Phase I and II with Reflex to Titer Available Date 01/04/2016											x	
62	0050462	*Coxiella burnetii* (Q-Fever) Antibody IgG, Phase I & II by IFA												x
22	2012625	*Coxiella burnetii* (Q-Fever) Antibody IgG, Phase I and II with Reflex to Titer Available Date 01/04/2016											x	
62	0050463	Coxiella burnetii (Q-Fever) Antibody IgG, Phase I by IFA												x
62	0050464	Coxiella burnetii (Q-Fever) Antibody IgG, Phase II by IFA												x
62	2001875	Creatine Transport, Fibroblasts												x
22	2002403	Cryoglobulin, Qualitative with Reflex to IFE Typing and Quantitative IgA, IgG, and IgM					x				x			
22	0055285	Cysticercosis Antibody, IgG by ELISA, CSF	x		x									
23	0055284	Cysticercosis Antibody, IgG by ELISA, Serum	x		x									
62	0051104	Cytochrome P450 2C19 (*CYP2C19*) 9 Variants												x
23	2012769	Cytochrome P450 2C19, *CYP2C19* - 9 Variants Available Date 01/04/2016											x	
62	0051103	Cytochrome P450 2C9 (*CYP2C9*) 2 Variants												x
24	2012766	Cytochrome P450 2C9, *CYP2C9* - 2 Variants Available Date 01/04/2016											x	
25	2012740	Cytochrome P450 3A5 Genotyping, *CYP3A5*, 2 Variants Available Date 10/19/2015											x	
25	2008920	Cytochrome P450 Pain Management Panel, *CYP2D6*, *CYP2C9*, *CYP2C19* - Common Variants (Pricing Change)	x	x						x	x			
25	2003248	Dexamethasone, Serum or Plasma by LC-MS/MS				x								
26	0090076	Diazepam and Nordiazepam				x	x					x		
26	0090085	Digitoxin					x							
26	2011632	Disopyramide, Serum or Plasma				x	x							
26	2006621	Drug Detection Panel, Umbilical Cord Tissue, Qualitative	x				x					x		
27	2012555	ERG by Immunohistochemistry Available Date 10/19/2015											x	
27	0090518	Ethanol, Urine, Qualitative - Medical				x								
27	2010358	Ethosuximide, Serum or Plasma				x								

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27	2012695	Ethyl Glucuronide Screen Only, Urine Available Date 11/16/2015											x	
28	0090110	Ethylene Glycol				x								
28	2008701	Expanded Carrier Screening Next Generation Sequencing, 100-Plus Disorders with Fragile X								x	x			
28	2007543	Expanded Carrier Screening Panel Targeted Mutation, 100-Plus Disorders								x				
28	2007531	Expanded Carrier Screening Panel Targeted Mutation, 100-Plus Disorders with Fragile X								x				
28	2012460	Febrile Seizures Panel, Females Available Date 10/19/2015											x	
28	2006069	Febrile Seizures Panel, Males	x							x		x		
62	0090180	Flurazepam												x
28	2007138	Galectin-3, Serum					x							
29	2012636	Gastrin, 1 Minute Available Date 10/19/2015											x	
29	2012734	Gastrin, 10 Minute Available Date 10/19/2015											x	
29	2012638	Gastrin, 2 Minute Available Date 10/19/2015											x	
30	2012736	Gastrin, 30 Minute Available Date 10/19/2015											x	
30	2012732	Gastrin, 5 Minute Available Date 10/19/2015											x	
31	2012738	Gastrin, Baseline Available Date 10/19/2015											x	
31	2012678	Gastrointestinal Bacterial Panel by PCR Available Date 10/19/2015											x	
32	2012558	GATA3 by Immunohistochemistry Available Date 10/19/2015											x	
32	0020058	Hemoglobin, Plasma					x							
32	0020057	Hemoglobin, Serum					x							
32	0051067	HLA DRB 3*,4*,5*		x										
32	2012482	HLA-A by Next Generation Sequencing Available Date 10/19/2015											x	
62	2003085	HLA-A Sequencing												x
33	2012486	HLA-B by Next Generation Sequencing Available Date 10/19/2015											x	
62	2002784	HLA-B Sequence												x
33	2002429	HLA-B*57:01 for Abacavir Sensitivity	x	x							x			

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33	2012490	HLA-C by Next Generation Sequencing Available Date 10/19/2015											x	
62	2002814	HLA-C Sequencing												x
34	2012502	HLA-DPB1 by Next Generation Sequencing Available Date 10/19/2015											x	
34	2012498	HLA-DQB1 by Next Generation Sequencing Available Date 10/19/2015											x	
35	2012494	HLA-DRB1 by Next Generation Sequencing Available Date 10/19/2015											x	
62	2002779	HLA-DRB1 Sequencing												x
35	0080422	Homovanillic Acid (HVA), Urine		x										
36	2012674	Human Immunodeficiency Virus (HIV) Combo Antigen/Antibody (HIV-1/O/2) by ELISA, Reflexive Panel Available Date 11/16/2015											x	
62	2007980	Human Immunodeficiency Virus (HIV) Combo Antigen/Antibody (HIV-1/O/2) by ELISA, with Reflex to HIV-1/HIV-2 Antibody Differentiation by Multispot												x
37	0020698	Human Immunodeficiency Virus Type 1 (HIV-1) Antibody, Confirmation by Western Blot, with Reflex to HIV-2 Antibody										x		
37	0051250	Human Immunodeficiency Virus Type 2 (HIV-2) Antibody by ELISA with Reflex to HIV-2 Supplemental									x			
38	2012669	Human Immunodeficiency Virus Types 1 and 2 (HIV-1/2) Antibody Differentiation, Supplemental, with Reflex to HIV-1 Quantitative PCR Available Date 11/16/2015											x	
62	2009464	Human Immunodeficiency Virus Types 1 and 2 (HIV-1/HIV-2) Antibody Differentiation by Multispot (Supplemental Use Only)												x
38	0091128	Hydrocarbon and Oxygenated Volatiles Quantitative Panel, Urine				x								
38	0080420	5-Hydroxyindoleacetic Acid (HIAA), Urine		x										
62	0050272	Immunofixation Electrophoresis Gel												x
39	0050049	Immunofixation Electrophoresis, Immunoglobulin D and Immunoglobulin E, Serum									x			
39	2012572	Immunofixation Electrophoresis, Qualitative, Gel Available Date 11/16/2015											x	
39	2007535	Infantile Epilepsy Panel, Sequence Analysis and Exon-Level Deletion/Duplication, 53 Genes	x									x		

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39	2004680	Interleukin 28B-Associated Variants, *IL28B*, 2 SNPs	x	x						x	x			
40	0090148	Librium and Nordiazepam				x	x					x		
40	2005661	Liver Fibrosis, Chronic Viral Hepatitis (Echosens FibroMeter)								x				
40	0090181	Lorazepam				x								
40	2008894	Lung Cancer Panel									x			
40	2008895	Lung Cancer Panel with KRAS									x			
41	0095854	Lymphocyte Subset Panel 1 - CD4 Absolute Count Only				x	x							
41	0095885	Lymphocyte Subset Panel 2 - CD4 Percent and Absolute				x	x				x			
42	0095853	Lymphocyte Subset Panel 3 - T-Cell Subsets (CD4 and CD8), Absolute Counts Only				x	x							
43	0095950	Lymphocyte Subset Panel 4 - T-Cell Subsets Percent and Absolute, Whole Blood				x	x				x			
44	0095892	Lymphocyte Subset Panel 5 - Total Lymphocyte Enumeration				x	x				x			
45	0095862	Lymphocyte Subset Panel 6 - Total Lymphocyte Enumeration with CD45RA and CD45RO				x	x				x			
46	0095899	Lymphocyte Subset Panel 7 - Congenital Immunodeficiencies				x	x				x			
62	2011515	Mephobarbital, Serum or Plasma												x
62	2011006	Mercaptopurine and Metabolites Quantitative, Blood												x
62	2002301	Microarray Family Study by FISH												x
47	0060050	Microsporidia Stain by Modified Trichrome			x									
47	0050615	Monoclonal Protein Detection Quantitation and Characterization, SPEP, IFE, IgA, IgG, IgM, Serum									x			
47	2002715	Monoclonal Protein Detection, Quantitation, Characterization, SPEP, IFE, IgA, IgG, IgM, FLC									x			
47	2007967	Motor and Sensory Neuropathy Evaluation with Immunofixation Electrophoresis and Reflex to Titer and Neuronal Immunoblot									x			
47	0051225	Motor Neuropathy Panel									x			
47	2005640	Muscle Weakness Autoimmune Reflexive Panel						x			x			
47	2012420	Muscle-Specific Receptor Tyrosine Kinase (MuSK) Antibody by RIA Available Date 10/19/2015											x	
48	0092404	Natural Killer Cells Enumeration				x	x							
48	2012535	Nerve Fiber Density Analysis, Intraepidermal Available Date 10/19/2015											x	

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49	2012730	Non-Criteria Antiphospholipid Syndrome (APS) (aPa, aPc, aPe, aPg, aPi) Antibodies Extended Panel Available Date 01/04/2016											x	
50	2012729	Non-Criteria Antiphospholipid Syndrome (APS) (aPs, aPt, aPs/aPt) Antibodies Panel Available Date 01/04/2016											x	
62	2005386	Non-Criteria Antiphospholipid Syndrome (APS) Antibody Panel												x
50	2009077	Non-Invasive Prenatal Testing for RhD Genotyping, Fetal (Pricing Change Only)												
50	2008767	Opioid Receptor, Mu 1, *OPRM1* Genotype, 1 Variant	x											
50	2007479	Pain Management Drug Panel by High-Resolution Time-of-Flight Mass Spectrometry and Enzyme Immunoassay, Urine									x			
51	2009288	Pain Management Drug Screen with Interpretation by High-Resolution Time-of-Flight Mass Spectrometry and Enzyme Immunoassay, Urine				x					x			
51	2012312	Pain Management Panel, Screen with Reflex Quantitation								x				
51	2010677	Parathyroid Hormone-Related Peptide (PTHrP) by LC-MS/MS, Plasma							x					
51	2004366	Paroxysmal Nocturnal Hemoglobinuria, High Sensitivity, RBC										x		
51	2005003	Paroxysmal Nocturnal Hemoglobinuria, High Sensitivity, WBC										x		
51	2005006	Paroxysmal Nocturnal Hemoglobinuria (PNH), High Sensitivity, RBC and WBC	x			x						x		
52	2012603	*PAX8-PPARG* Translocations Detection by PCR Available Date 10/19/2015											x	
52	0091551	Phenobarbital, Total/Free/Bound, Serum or Plasma	x											
52	0090141	Phenytoin, Free and Total					x							
52	0051050	Platelet Antibodies, Indirect				x								
53	0051718	Platelet Antibodies, Indirect with Reflex to Identification				x								
53	0051051	Platelet Antibody Identification - Refer to Platelet Antibodies Indirect (0051050). Platelet antibody detection must be performed first.				x								
53	0090800	Polychlorinated Biphenyls Quantitative, Serum or Plasma			x									
53	0090672	Prazepam (Assayed as Nordiazepam)				x	x					x		

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53	2008704	Prenatal Carrier Screening Next Generation Sequencing, 85 Disorders with Fragile X								x				
53	2007539	Prenatal Carrier Screening Targeted Mutation Panel, 85 Disorders								x				
53	2007541	Prenatal Carrier Screening Targeted Mutation Panel, 85 Disorders with Fragile X								x				
53	0020724	Prolactin, Dilution Study	x									x		
54	2002109	Protein Electrophoresis with Reflex to Immunofixation Electrophoresis Monoclonal Protein Detection, Quantitation and Characterization IgA, IgG, IgM - Serum	x								x			
54	0050640	Protein Electrophoresis, Serum									x			
54	2009345	Pulmonary Arterial Hypertension (PAH) Panel, Sequencing and Deletion/Duplication, Multigene	x									x		
54	2009350	Pulmonary Arterial Hypertension (PAH) Sequencing, Multigene	x									x		
54	2012654	*RET* Gene Rearrangements by FISH Available Date 10/19/2015											x	
55	2012605	*RET-CCDC6* and *RET-NCOA4* (*RET-PTC1* and *RET-PTC3*) Translocations Detection by PCR Available Date 10/19/2015											x	
55	2006462	Scleroderma Antibodies Panel				x				x				
56	2012561	SOX11 by Immunohistochemistry Available Date 10/19/2015											x	
56	2008426	Statin Sensitivity *SLCO1B1*, 1 Variant	x	x	x	x								
56	0050746	Striated Muscle Antibodies, IgG with Reflex to Titer									x			
62	0025009	Tellurium, Urine												x
56	2012233	Thiopurine Methyltransferase (TPMT) Genotyping, 4 Variants			x									
56	0092066	Thiopurine Methyltransferase, RBC				x								
57	2012755	Thyroid Translocation and Mutation Panel Available Date 10/19/2015											x	
57	0097709	Tissue Transglutaminase (tTG) Antibody, IgA					x	x				x		
58	0050734	Tissue Transglutaminase (tTG) Antibody, IgA with Reflex to Endomysial Antibody, IgA by IFA					x	x	x			x		
58	0056009	Tissue Transglutaminase Antibody, IgG					x					x		
58	0050206	*Treponema pallidum* (VDRL), Cerebrospinal Fluid with Reflex to Titer					x		x		x			
59	0093093	*Treponema pallidum* (VDRL), Serum with Reflex to Titer									x			

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59	0050787	*Trichinella* Antibody by ELISA			x									
59	0099310	Valproic Acid, Free and Total				x								
59	0080470	Vanillylmandelic Acid (VMA) and Homovanillic Acid (HVA), Urine		x										
59	0080421	Vanillylmandelic Acid (VMA), Urine		x										
62	2004358	Warfarin Genotyping Plus												x
62	0051370	Warfarin Sensitivity (*CYP2C9* and *VKORC1*) 3 Mutations												x
60	2012772	Warfarin Sensitivity, *CYP2C9* and *VKORC1*, 3 Variants Available Date 01/04/2016											x	
62	0091232	Zolpidem Quantitative, Serum or Plasma												x
61	2012652	Zolpidem, Serum or Plasma, Quantitative Available Date 10/19/2015											x	
61	0097908	Zonisamide				x								

2005639 **Acetylcholine Receptor Antibodies and Striated Muscle Antibodies Reflexive Panels, and Titin Antibody** **MGT R PAN**

HOT LINE NOTE: There is a component change associated with this test.
Remove component 0050748 Striated Muscle Antibodies, IgG Titer
Add reflex orderable 2012516 Striated Muscle Abs, IgG Titer

New Test **2012710** **Aggressive B-Cell Lymphoma FISH Reflex, Tissue** **DLBCL FISH**
Available October 19, 2015

Additional Technical Information

Methodology: Fluorescence in situ Hybridization
Performed: Varies
Reported: 7-10 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 *MYC* (8q24) Gene Rearrangement by FISH is positive then *IGH-BCL2* Fusion, t(14;18) by FISH will be added. If *IGH-BCL2* Fusion, t(14;18) by FISH is negative then *BCL6* (3q27) Gene Rearrangement by FISH will be added. Additional charges apply.

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

New York DOH Approved.

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

2011043 **Alpha-1-Antitrypsin Clearance, Quantitative by ELISA, Timed Stool** **A1ACLR**

HOT LINE NOTE: There is a component change associated with this test.
Change component 2011044 Alpha-1-Antitrypsin Stool, Elisa – Time, from a Resultable test to a Prompt test.

0090010 **Alprazolam** **ALPR**

Performed: Tue, Fri
Reported: 1-5 days

Specimen Required: Collect: Gray (Potassium Oxalate/Sodium Fluoride). Also acceptable: Plain Red, Green (Sodium Heparin), Lavender (K_2 or K_3EDTA) or pink (K_2EDTA).
Specimen Preparation: Separate serum or plasma from cells within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1 mL)
Unacceptable Conditions: Gel separator tubes. Plasma or whole blood collected in light blue (sodium citrate).
Stability (collection to initiation of testing): After separation from cells: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 3 years (Avoid repeated freeze/thaw cycles)

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

Specimen Required: Remarks: Record total volume and collection time interval on transport tube and on test request form.
Unacceptable Conditions: Urine collected within 48 hours after administration of a gadolinium (Gd) containing contrast media (may occur with MRI studies). Acid preserved urine. Specimens contaminated with blood or fecal material. Specimens transported in non-trace element-free transport tube (with the exception of the original device).

0025000 **Arsenic, Urine with Reflex to Fractionated** **ARS U**

Specimen Required: Unacceptable Conditions: Urine collected within 48 hours after administration of a gadolinium (Gd) containing contrast media (may occur with MRI studies). Acid preserved urine. Specimens contaminated with blood or fecal material. Specimens transported in non-trace element transport tube (with the exception of the original device).

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

HOT LINE NOTE: There is a component change associated with this test.
Add component 2012456, EER BJProtein Qnt w/Rflx k/l FLC w/Ratio.

2010445 **Benzodiazepines, Serum or Plasma, Quantitative** **BENZO SP**

Reference Interval: Effective November 16, 2015

Drugs Covered	Cutoff Concentrations
Alprazolam	5 ng/mL
Alpha-hydroxyalprazolam	5 ng/mL
Clonazepam	5 ng/mL
Chlordiazepoxide	20 ng/mL
7-aminoclonazepam	5 ng/mL
Diazepam	5 ng/mL
Lorazepam	20 ng/mL
Midazolam	20 ng/mL
Alpha-hydroxymidazolam	20 ng/mL
Nordiazepam	20 ng/mL
Oxazepam	20 ng/mL
Temazepam	20 ng/mL

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

Positive cutoff: 20 ng/mL unless specified below:

Diazepam	5 ng/mL
Alprazolam	5 ng/mL
Alpha-hydroxyalprazolam	5 ng/mL
Clonazepam	5 ng/mL
7-aminoclonazepam	5 ng/mL

For medical purposes only; not valid for forensic use.

Identification of specific drug(s) taken by specimen donor is problematic due to common metabolites, some of which are prescription drugs themselves. The absence of expected drug(s) and/or drug metabolite(s) may indicate non-compliance, inappropriate timing of specimen collection relative to drug administration, poor drug absorption, or limitations of testing. The concentration value must be greater than or equal to the cutoff to be reported as positive. Interpretive questions should be directed to the laboratory.

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

HOT LINE NOTE: There is a component change associated with this test.
Add component 2012676, Chlordiazepoxide, S/P, Quant
Add component 2012677, Alpha-hydoxymidazolam, S/P, Quant

New Test **2012647** **Buprenorphine and Metabolites, Serum or Plasma, Quantitative** **BUPRSP**
Available January 4, 2016

Methodology: Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed: Tue, Fri
Reported: 1-4 days

Specimen Required: Collect: Gray (sodium fluoride/potassium oxalate). Also acceptable: Plain red, green (sodium heparin), lavender (EDTA), or pink (K_2EDTA).
Specimen Preparation: Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Separator tubes. Plasma or whole blood collected in lt. blue (sodium citrate). Specimens exposed to repeated freeze/thaw cycles.
Stability (collection to initiation of testing): After separation from cells: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 3 years

Reference Interval:

Drugs Covered	Cutoff Concentrations
Buprenorphine	2 ng/mL
Norpbuprenorphine	2 ng/mL

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

Positive cutoff: 1 ng/mL

For medical purposes only; not valid for forensic use.

The presence of metabolite(s) without parent drug may indicate use of parent drug during the prior week. The absence of expected drug(s) and/or drug metabolite(s) may indicate non-compliance, inappropriate timing of specimen collection relative to drug administration, poor drug absorption, or limitations of testing. The concentration value must be greater than or equal to the cutoff to be reported as positive. Interpretive questions should be directed to the laboratory.

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

CPT Code(s): 80348; (Alt code: G6056)

New York DOH Approved.

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

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)
Unacceptable Conditions: Citrated Plasma, Serum separator tube (SST)
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 week; Frozen: 2 months

Reference Interval: Effective November 16, 2015

Therapeutic Range:	8-20 µg/mL (neonates)
Toxic:	Greater than 20 µg/mL

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

Specimen Required: Collect: Serum Pre-dose (Trough) Draw - At a Steady State Concentration in Plain Red.
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

Reference Interval:

Test Number	Components	Reference Interval
	Total Carbamazepine	Effective November 16, 2015 Therapeutic Range: 4.0-12.0 µg/mL Toxic Range: Greater than 15 µg/mL
	Free Carbamazepine	Therapeutic Range: 1.0-3.0 µg/mL Toxic Range: Greater than 3.8 µg/mL
	Percent Free Carbamazepine	8.0-35.0%

2002026 Celiac Disease Dual Antigen Screen with Reflex — CELIAC SCRN

Reference Interval:

Test Number	Components	Reference Interval
0051689	Celiac Disease Dual Antigen Screen	19 Units or less: Negative - No significant level of detectable IgA or IgG antibodies against human tissue transglutaminase or gliadin peptide. 20 Units or greater: Positive - Presence of IgA and/or IgG antibodies against human tissue transglutaminase and/or gliadin peptide; suggests possibility of certain gluten sensitive enteropathies such as celiac disease and dermatitis herpetiformis.
0097709	Tissue Transglutaminase (tTG) Antibody, IgA	Effective November 16, 2015 3 U/mL or less: Negative 4-10 U/mL: Weak Positive 11 U/mL or greater: Positive
0056009	Tissue Transglutaminase Antibody, IgG	Effective November 16, 2015 5 U/mL or less: Negative 6-9 U/mL: Weak Positive 10 U/mL or greater: Positive
0051357	Deamidated Gliadin Peptide (DGP) Antibody, IgA	19 Units or less: Negative 20-30 Units: Weak Positive 31 Units or greater: Positive
0051359	Deamidated Gliadin Peptide (DGP) Antibody, IgG	19 Units or less: Negative 20-30 Units: Weak Positive 31 Units or greater: Positive

CPT Code(s): 83516; if reflexed, add 83516 x2; if further reflexed, add 83516 x2

HOT LINE NOTE: There is a unit of measure change associated with this test.
Change Unit of measure for component 0097709, Tissue Transglutaminase (tTG) Ab, IgA from Units to U/mL
Change Unit of measure for component 0056009, Tissue Transglutaminase (tTG) Ab, IgG from EU to U/mL

2008114 Celiac Disease Reflexive Cascade CELIAC REF

Reference Interval:

Test Number	Components	Reference Interval
0050340	Immunoglobulin A	0-30 days: 1-7 mg/dL 1 month: 1-53 mg/dL 2 months: 3-47 mg/dL 3 months: 5-46 mg/dL 4 months: 4-72 mg/dL 5 months: 8-83 mg/dL 6 months: 8-67 mg/dL 7-8 months: 11-89 mg/dL 9-11 months: 16-83 mg/dL 1 year: 14-105 mg/dL 2 years: 14-122 mg/dL 3 years: 22-157 mg/dL 4 years: 25-152 mg/dL 5-7 years: 33-200 mg/dL 8-9 years: 45-234 mg/dL 10 years and older: 68-378 mg/dL
0051689	Celiac Disease Dual Antigen Screen	19 Units or less: Negative - No significant level of detectable IgA or IgG antibodies against human tissue transglutaminase or gliadin peptide. 20 Units or greater: Positive - Presence of IgA and/or IgG antibodies against human tissue transglutaminase and/or gliadin peptide; suggests possibility of certain gluten sensitive enteropathies such as celiac disease and dermatitis herpetiformis.
0051357	Deamidated Gliadin Peptide (DGP) Antibody, IgA	19 Units or less: Negative 20-30 Units: Weak Positive 31 Units or greater: Positive
0051359	Deamidated Gliadin Peptide (DGP) Antibody, IgG	19 Units or less: Negative 20-30 Units: Weak Positive 31 Units or greater: Positive
0097709	Tissue Transglutaminase (tTG) Antibody, IgA	Effective November 16, 2015 3 U/mL or less: Negative 4-10 U/mL: Weak Positive 11 U/mL or greater: Positive
0050736	Endomysial Antibody, IgA by IFA	Less than 1:10
0056009	Tissue Transglutaminase Antibody, IgG	Effective November 16, 2015 5 U/mL or less: Negative 6-9 U/mL: Weak Positive 10 U/mL or greater: Positive

CPT Code(s): 82784; if reflexed additional CPT codes may apply: 83516, 83516 x2 and/or 86256.

HOT LINE NOTE: There is a unit of measure change associated with this test.
Change Unit of measure for component 0097709, Tissue Transglutaminase (tTG) Ab, IgA from Units to U/mL
Change Unit of measure for component 0056009, Tissue Transglutaminase (tTG) Ab, IgG from EU to U/mL

New Test 2012717 **CHARGE Syndrome (*CHD7*) Sequencing, Fetal** **CHD7 FE**
Available October 19, 2015

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

Specimen Required: Collect: Two T-25 flasks at 80 percent confluent cultured amniocytes. **If the client is unable to culture amniocytes, this can be arranged by contacting Client Services at (800) 522-2787**. Or amniotic fluid **AND Maternal Whole Blood** in Lavender (K_2EDTA), Lavender (K_3EDTA), Pink (K_2EDTA) or yellow (ACD Solution A or B).
Specimen Preparation: **Cultured Amniocytes:** Fill flask with culture media. Transport two T-25 flasks at 80 percent confluent of culture amniocytes filled with culture media.
Or Amniotic Fluid: Transport 10 mL unspun fluid (Min: 5 mL)
AND Maternal Whole Blood: Transport 3 mL whole blood (Min: 1 mL)
Storage/Transport Temperature: **Cultured Amniocytes: CRITICAL ROOM TEMPERATURE**. Must be received within 48 hours of shipment due to liability of cells.
Amniotic Fluid: Room temperature.
Maternal Whole Blood: Room temperature.
Unacceptable Conditions: Plasma or serum.
Stability (collection to initiation of testing): **Fetal Specimen**: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Maternal Whole Blood: Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:
Background Information for Charge Syndrome (*CHD7*) Sequencing, Fetal:
Characteristics: CHARGE is an acronym for the major features of the condition, which are Coloboma, Heart defects, choanal Atresia, Restricted growth and delayed development, Genital abnormalities, Ear anomalies. This condition has a highly variable presentation.
Incidence: About 1 in 10,000.
Inheritance: Autosomal dominant.
Cause: Pathogenic *CHD7* gene mutations.
Clinical Sensitivity: Approximately 90 percent for fetuses fulfilling clinical criteria for CHARGE.
Methodology: Bidirectional sequencing of all coding regions and intron-exon boundaries of the *CHD7* gene.
Analytical Sensitivity and Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Regulatory region mutations, deep intronic mutations, and large deletions/duplications in *CHD7* will not be detected.

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

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

Note: Maternal sample is recommended for proper test interpretation.

CPT Code(s): 81407, 81265

New York DOH approval pending. Call for status update.

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

New Test **2012609** **CHARGE Syndrome, *CHD7* Sequencing** **CHD7 FGS**
Available October 19, 2015

Methodology: Polymerase Chain Reaction/Sequencing
Performed: Sun-Sat
Reported: 28-35 days

Specimen: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions:
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:
Background Information for CHARGE Syndrome (*CHD7*) Sequencing:
Characteristics: CHARGE is an acronym for the major features of the condition, which are Coloboma, Heart defects, choanal Atresia, Restricted growth and delayed development, Genital abnormalities and Ear anomalies. This condition has a highly variable presentation.
Incidence: About 1 in 10,000.
Inheritance: Autosomal dominant.
Cause: Pathogenic *CHD7* gene mutations.
Clinical Sensitivity: Approximately 90 percent for individuals fulfilling clinical criteria for CHARGE.
Methodology: Bidirectional sequencing of all coding regions and intron-exon boundaries of the *CHD7* gene.
Analytical Sensitivity and Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Regulatory region mutations, deep intronic mutations and large deletions/duplications in *CHD7* will not be detected.

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

CPT Code(s): 81407

New York DOH approval pending. Call for status update.

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

2010161 Chronic Enteric Hypersensitivity Reflexive Profile CEHP R

Reference Interval:

Test Number	Components	Reference Interval
2002026	Celiac Disease Dual Antigen Screen with Reflex	Effective November 16, 2015

Test Number	Components	Reference Interval
0051689	Celiac Disease Dual Antigen Screen	19 Units or less: Negative - No significant level of detectable IgA or IgG antibodies against human tissue transglutaminase or gliadin peptide 20 Units or greater: Positive - Presence of IgA and/or IgG antibodies against human tissue transglutaminase and/or gliadin peptide; suggests possibility of certain gluten sensitive enteropathies such as celiac disease and dermatitis herpetiformis.
0097709	Tissue Transglutaminase (tTG) Antibody, IgA	3 U/mL or less: Negative 4-10 U/mL: Weak Positive 11 U/mL or greater: Positive
0056009	Tissue Transglutaminase Antibody, IgG	5 U/mL or less: Negative 6-9 U/mL: Weak Positive 10 U/mL or greater: Positive
0051357	Deamidated Gliadin Peptide (DGP) Antibody, IgA	19 Units or less: Negative 20-30 Units: Weak Positive 31 Units or greater: Positive
0051359	Deamidated Gliadin Peptide (DGP) Antibody, IgG	19 Units or less: Negative 20-30 Units: Weak Positive 31 Units or greater: Positive

Test Number	Components	Reference Interval
0055036	Allergen, Food, Codfish IgE	**Effective 02/18/2014**

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

Test Number	Components	Reference Interval
0055013	Allergen, Food, Egg White	**Effective 02/18/2014**

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

Test Number	Components	Reference Interval
0099569	Allergen, Food, Gluten	**Effective 02/18/2014**

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

Test Number	Components	Reference Interval
0098617	Allergen, Food, Hazelnut (Filbert)	**Effective 02/18/2014**

		Reporting Range (reported in kU/L)	**Probability of IgE Mediated Clinical Reaction**	**Class Scoring**
		Less than 0.10	No significant level detected	0
		0.10 - 0.34	Clinical relevance undetermined	0/1
		0.35 - 0.70	Low	1
		0.71 - 3.50	Moderate	2
		3.51 - 17.50	High	3
		17.51 - 50.00	Very high	4
		50.01 - 100.00	Very high	5
		Greater than 100.00	Very high	6
0055020	Allergen, Food, Milk (Cow's)	**Effective 02/18/2014**		
		Reporting Range (reported in kU/L)	**Probability of IgE Mediated Clinical Reaction**	**Class Scoring**
		Less than 0.10	No significant level detected	0
		0.10 - 0.34	Clinical relevance undetermined	0/1
		0.35 - 0.70	Low	1
		0.71 - 3.50	Moderate	2
		3.51 - 17.50	High	3
		17.51 - 50.00	Very high	4
		50.01 - 100.00	Very high	5
		Greater than 100.00	Very high	6
0055024	Allergen, Food, Peanut	**Effective 02/18/2014**		
		Reporting Range (reported in kU/L)	**Probability of IgE Mediated Clinical Reaction**	**Class Scoring**
		Less than 0.10	No significant level detected	0
		0.10 - 0.34	Clinical relevance undetermined	0/1
		0.35 - 0.70	Low	1
		0.71 - 3.50	Moderate	2
		3.51 - 17.50	High	3
		17.51 - 50.00	Very high	4
		50.01 - 100.00	Very high	5
		Greater than 100.00	Very high	6
0099495	Allergen, Food, Scallop	**Effective 02/18/2014**		
		Reporting Range (reported in kU/L)	**Probability of IgE Mediated Clinical Reaction**	**Class Scoring**
		Less than 0.10	No significant level detected	0
		0.10 - 0.34	Clinical relevance undetermined	0/1
		0.35 - 0.70	Low	1
		0.71 - 3.50	Moderate	2
		3.51 - 17.50	High	3
		17.51 - 50.00	Very high	4
		50.01 - 100.00	Very high	5
		Greater than 100.00	Very high	6
0099698	Allergen, Food, Sesame Seed	**Effective 02/18/2014**		
		Reporting Range (reported in kU/L)	**Probability of IgE Mediated Clinical Reaction**	**Class Scoring**
		Less than 0.10	No significant level detected	0
		0.10 - 0.34	Clinical relevance undetermined	0/1
		0.35 - 0.70	Low	1
		0.71 - 3.50	Moderate	2
		3.51 - 17.50	High	3
		17.51 - 50.00	Very high	4
		50.01 - 100.00	Very high	5
		Greater than 100.00	Very high	6
0055030	Allergen, Food, Shrimp	**Effective 02/18/2014**		
		Reporting Range (reported in kU/L)	**Probability of IgE Mediated Clinical Reaction**	**Class Scoring**
		Less than 0.10	No significant level detected	0
		0.10 - 0.34	Clinical relevance undetermined	0/1

		0.35 - 0.70	Low	1
		0.71 - 3.50	Moderate	2
		3.51 - 17.50	High	3
		17.51 - 50.00	Very high	4
		50.01 - 100.00	Very high	5
		Greater than 100.00	Very high	6
0055031	Allergen, Food, Soybean	**Effective 02/18/2014**		
		Reporting Range (reported in kU/L)	**Probability of IgE Mediated Clinical Reaction**	**Class Scoring**
		Less than 0.10	No significant level detected	0
		0.10 - 0.34	Clinical relevance undetermined	0/1
		0.35 - 0.70	Low	1
		0.71 - 3.50	Moderate	2
		3.51 - 17.50	High	3
		17.51 - 50.00	Very high	4
		50.01 - 100.00	Very high	5
		Greater than 100.00	Very high	6
0055209	Allergen, Food, Walnut (*Juglans* spp.) IgE	**Effective 02/18/2014**		
		Reporting Range (reported in kU/L)	**Probability of IgE Mediated Clinical Reaction**	**Class Scoring**
		Less than 0.10	No significant level detected	0
		0.10 - 0.34	Clinical relevance undetermined	0/1
		0.35 - 0.70	Low	1
		0.71 - 3.50	Moderate	2
		3.51 - 17.50	High	3
		17.51 - 50.00	Very high	4
		50.01 - 100.00	Very high	5
		Greater than 100.00	Very high	6
0055034	Allergen, Food, Wheat	**Effective 02/18/2014**		
		Reporting Range (reported in kU/L)	**Probability of IgE Mediated Clinical Reaction**	**Class Scoring**
		Less than 0.10	No significant level detected	0
		0.10 - 0.34	Clinical relevance undetermined	0/1
		0.35 - 0.70	Low	1
		0.71 - 3.50	Moderate	2
		3.51 - 17.50	High	3
		17.51 - 50.00	Very high	4
		50.01 - 100.00	Very high	5
		Greater than 100.00	Very high	6

HOT LINE NOTE: There is a unit of measure change associated with this test.
Change Unit of measure for component 0097709, Tissue Transglutaminase (tTG) Ab, IgA from Units to U/mL
Change Unit of measure for component 0056009, Tissue Transglutaminase (tTG) Ab, IgG from EU to U/mL

0093399 Circulating Tumor Cell Count — CTC COUNT

CPT Code(s): 86152, 86153

0090055 Clonazepam — CLON

Specimen Required: Collect: Gray (Potassium Oxalate/Sodium Fluoride). Also acceptable: Plain Red, Green (Sodium Heparin), Lavender (K_2 or K_3EDTA) or pink (K_2EDTA).
Specimen Preparation: Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1 mL)
Unacceptable Conditions: Gel separator tubes. Plasma or whole blood collected in light blue (sodium citrate).
Stability (collection to initiation of testing): After separation from cells: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 3 years (Avoid repeated freeze/thaw cycles)

0090196 Clorazepate (Assayed as Nordiazepam) CLORAZ

Specimen Required: Collect: Gray (Potassium Oxalate/Sodium Fluoride). Also acceptable: Plain Red, Green (Sodium Heparin), Lavender (K_2 or K_3EDTA) or pink (K_2EDTA).
Specimen Preparation: Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1 mL)
Unacceptable Conditions: Gel separator tubes. Plasma or whole blood collected in light blue (sodium citrate).
Stability (collection to initiation of testing): After separation from cells: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 3 years (Avoid repeated freeze/thaw cycles)

Reference Interval: Effective: November 16, 2015

Dose-Related Range:	100–1500 ng/mL based on common dosage amounts
Toxic:	Greater than 2500 ng/mL

HOT LINE NOTE: There is a unit of measure change associated with this test.
Change Unit of measure for component 0090196, Clorazepate from ug/mL to ng/mL

2003250 Cortisol by LC-MS/MS, Serum or Plasma CORT TMS

Specimen Required: Patient Prep: Specimen should be collected between 8-10 a.m.

New Test 2012697 Cortisol, Free by Equilibrium Dialysis/LC-MS/MS FCORTS TMS

Available October 19, 2015

Methodology: Equilibrium Dialysis/Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry
Performed: Sun, Tue, Thu, Fri
Reported: 2-5 days

Specimen Required: Patient Prep: Recommended collection times are 8-10 a.m. or 4-6 p.m.
Collect: Plain red or serum separator tube, lavender (EDTA) or pink (K_2EDTA).
Specimen Preparation: Separate serum or plasma from cells within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.6 mL)
Storage/Transport Temperature: Frozen.
Remarks: Indicate time of draw on test request form **and** specimen tube.
Unacceptable Conditions: Grossly hemolyzed, icteric, lipemic or heparinized specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 6 months

Reference Interval:

Age	Time of Collection	Reference Range
0 – 17 years		Not established
18 years of age and older	8-10 a.m. collection	0.21 – 1.04 µg/dL
18 years of age and older	4-6 p.m. collection	0.10 – 0.63 µg/dL

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

Note: To convert to nmol/L, multiply µg/dL by 27.6.

CPT Code(s): 82530

New York DOH Approved.

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

2003252 Cortisone by LC-MS/MS, Serum or Plasma CONE TMS

Specimen Required: Patient Prep: Specimen should be collected between 8-10 a.m.

2007081 **Cotinine Screen, Urine** **COTININE**

Specimen Required: Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 week; Frozen: 3 months

New Test **2012634** ***Coxiella burnetii* (Q-Fever) Antibodies, IgG and IgM, Phase I and II with Reflex to Titer** **Q-F GM**

Available January 4, 2016

Methodology: Semi-Quantitative Indirect Fluorescent Antibody
Performed: Mon, Wed, Fri
Reported: 1-6 days

Specimen Required: Collect: Serum separator tube (SST).
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.15 mL) Parallel testing is preferred and convalescent specimens **must** be received within 30 days from receipt of the acute specimens. **Mark specimens plainly as "acute" and "convalescent."**
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Contaminated, hemolyzed, or severely lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval
	C. burnetii (Q-Fever) Ab, Phase I IgG	Negative
	C. burnetii (Q-Fever) Ab, Phase II IgG	Negative
	C. burnetii (Q-Fever) Ab, Phase I IgM	Negative
	C. burnetii (Q-Fever) Ab, Phase II IgM	Negative

Interpretive Data: Refer to report.

Note: For IgG or IgM testing, if any Phase I or Phase II screening result is Indeterminate or Positive, then titer(s) will be added. Additional charges apply.

CPT Code(s): 86638 x4; if reflexed add 86638 per titer
New York DOH Approved.

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

New Test 2012625 ***Coxiella burnetii* (Q-Fever) Antibody IgG, Phase I and II with Reflex to Titer** **QF G 1/2**

Available January 4, 2016

Methodology: Semi-Quantitative Indirect Fluorescent Antibody
Performed: Mon, Wed, Fri
Reported: 1-6 days

Specimen Required: Collect: Serum separator tube (SST).
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.1 mL) Parallel testing is preferred and convalescent specimens **must** be received within 30 days from receipt of the acute specimens. **Mark specimens plainly as "acute" and "convalescent."**
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Contaminated, hemolyzed, or severely lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Component	Reference Interval
	C. burnetii (Q-Fever) Ab, Phase I IgG	Negative
	C. burnetii (Q-Fever) Ab, Phase II IgG	Negative

Interpretive Data: Single phase II IgG titers of 1:256 and greater are considered evidence of *C. burnetii* infection at some time prior to the date of the serum specimen. Phase I antibody titers of 1:16 and greater are consistent with chronic infection or convalescent phase of Q-fever.

Note: If either *C. Burnetii* Abs IgG Phase I and/or Phase II result is indeterminate or positive, then titer(s) will be added. Additional charges apply.

CPT Code(s): 86638 x2; if reflexed add 86638 per titer

New York DOH Approved.

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

2002403 **Cryoglobulin, Qualitative with Reflex to IFE Typing and Quantitative IgA, IgG, and IgM** **CRYO TYPING**

Reference Interval: Effective November 16, 2015

Test Number	Components	Reference Interval
0050185	Cryoglobulin, Qualitative	Negative at 72 hours.
2012572	Immunofixation Electrophoresis, Qualitative, Gel	Normal IFE
	Immunoglobulin A, Cryoprecipitate	0 mg/dL
	Immunoglobulin G, Cryoprecipitate	0 mg/dL
	Immunoglobulin M, Cryoprecipitate	0 mg/dL

HOT LINE NOTE: There is a component change associated with this test.
Add reflex component 2012601, EER Immunofix Electrophoresis Gel.
Remove reflex component 0050272, Immunofixation Electrophoreses Gel

0055285 **Cysticercosis Antibody, IgG by ELISA, CSF** **CYST CSF**

Performed: Mon
Reported: 1-8 days

0055284 **Cysticercosis Antibody, IgG by ELISA, Serum** **CYST SER**

Performed: Mon
Reported: 1-8 days

New Test **2012769** **Cytochrome P450 2C19, *CYP2C19* - 9 Variants** **2C19 GENO**
Available January 4, 2016

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

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Heparinized specimens.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month.

Reference Interval: By report

Interpretive Data:
Background Information for Cytochrome P450 2C19, *CYP2C19* - 9 Variants:
Characteristics: The cytochrome P450 (CYP) isozyme 2C19 is involved in the metabolism of many drugs such as clopidogrel, phenytoin, diazepam, R-warfarin, tamoxifen, some antidepressants, proton pump inhibitors, and antimalarials. Variants of *CYP2C19* will influence pharmacokinetics of CYP2C19 substrates, and may predict non-standard dose requirements.
Inheritance: Autosomal co-dominant.
Cause: *CYP2C19* gene variants result in increased, decreased, or complete deficiency in enzyme activity.
Variants Tested: (Variants are numbered according to NM_000769 transcript).
Decreased function: *9 (rs17884712, c.431G>A); *10 (rs6413438, c.680C>T).
Non-functional: *2 (rs4244285, c.681G>A), *3 (rs4986893, c.636G>A), *4 (rs28399504, c.1A>G), *6 (rs72552267, c.395G>A), *7 (rs72558186, c.819+2T>A), *8 (rs41291556, c.358T>C).
Increased function: *17 (rs12248560, c.-806C>T).
Negative: No variants detected is predictive of *1 functional alleles and normal enzymatic activity.
Allele frequencies:
*CYP2C19**2: African American 18.3 percent, Caucasian 14.6 percent, Middle Eastern 13.2 percent, Oceanian 54.9 percent, South Asian 34.4 percent
*CYP2C19**3: African American 0.3 percent, Caucasian 0.6 percent, Middle Eastern 2.6 percent, Oceanian 13.9 percent, East Asian 8.5 percent
*CYP2C19**17: African American 19.4 percent, Caucasian 21.5 percent, Oceanian 2.5 percent, South Asian 16.5 percent
Other alleles are rare, with allele frequencies of less than 1 percent in all populations studied.
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. 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

CPT Code(s): 81225

New York DOH approval pending. Call for status update.

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

New Test **2012766** **Cytochrome P450 2C9, *CYP2C9* - 2 Variants** **2C9 GENO**
Available January 4, 2016

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

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Heparinized specimens.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Reference Interval: By report

Interpretive Data:
Background Information for Cytochrome P450 2C9, *CYP2C9* - 2 Variants:
Characteristics: The cytochrome P450 (CYP) isozyme 2C9 is involved in the metabolism of many drugs such as warfarin, phenytoin, tolbutamide, glipizide, ibuprofen, and phenobarbital. Variants of *CYP2C9* will influence pharmacokinetics of CYP2C9 substrates, and may predict non-standard dose requirements.
Inheritance: Autosomal co-dominant.
Cause: *CYP2C9* gene variants result in decreased or complete deficiency in enzyme activity.
Variants Tested:
(Variants are numbered according to NM_000771 transcript)
Decreased function: *2 (rs1799853, c.430C>T).
Non-functional: *3 (rs1057910, c.1075A>C).
Negative: No variants detected is predictive of *1 functional alleles and normal enzymatic activity.
Allele Frequencies:
CYP2C9 *2: Caucasians 13 percent, Asians Less than 1 percent, African Americans 3 percent.
CYP2C9 *3: Caucasians 7 percent, Asians 4 percent, African Americans 2 percent.
Clinical Sensitivity: Drug-dependent.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Only the targeted *CYP2C9* variants will be detected by this panel. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with 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

CPT Code(s): 81227

New York DOH approval pending. Call for status update.

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

New Test **2012740** **Cytochrome P450 3A5 Genotyping, *CYP3A5*, 2 Variants** **CYP3A5**
Available October 19, 2015

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

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Heparinized specimens.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Reference Interval: By report

Interpretive Data:
Background Information for Cytochrome P450 3A5 Genotyping, *CYP3A5*, 2 Variants:
Characteristics: The cytochrome P450 (CYP) 3A subfamily of enzymes is involved in metabolism of many drugs such as immunosuppressants, antibiotics, antivirals, benzodiazepines, and steroids. Nonfunctional variants of *CYP3A5* are common in some populations, preventing expression and function of the CYP3A5 enzyme, which will influence pharmacokinetics of CYP3A5 substrates, and may predict non-standard dose requirements.
Inheritance: Autosomal co-dominant.
Cause: *CYP3A5*gene variants result in enzyme deficiency.
Variants Tested: *CYP3A5* non-functional alleles: *3 (rs776746, c.6986A>G), *6 (rs10264272, c.14690G>A).
Negative: No variants detected is predictive of *1 functional alleles and normal CYP3A5 enzyme activity. **(**Variants are numbered according to NG_007938.1 transcript)
Allele Frequencies:
CYP3A5*3: African 29.8 percent, Asian 74.2 percent, Caucasian 92.1 percent, Latin American 76.5 percent, Middle Eastern 88.1 percent
CYP3A5*6: African 17.2 percent, Asian 0.1 percent, Caucasian 0.1 percent, Latin American 3.7 percent, Middle Eastern 1.9 percent
CYP3A5*7: African 7.7 percent, Asian 0 percent, Caucasian 0 percent, Latin American 2.5 percent, Middle Eastern 0.2 percent
Clinical Sensitivity: Drug-dependent.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Only the targeted *CYP3A5* variants will be detected by this panel. Diagnostic errors can occur due to rare sequence variations. Many CYP3A substrates are also metabolized by CYP3A4, for which clinically relevant genetic variation is not recognized to be common. Risk of therapeutic failure or adverse reactions with CYP3A5 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

CPT Code(s): 81401

New York DOH approval pending. Call for status update.

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

2008920 **Cytochrome P450 Pain Management Panel, *CYP2D6, CYP2C9, CYP2C19* - Common Variants** **PAIN PGX**

Methodology: Polymerase Chain Reaction/Primer Extension (*CYP2D6*)
Polymerase Chain Reaction/Fluorescence Monitoring (*CYP2C9, CYP2C19*)

CPT Code(s): 81226 (*CYP2D6*), 81225 (*CYP2C19*), 81227 (*CYP2C9*)

HOT LINE NOTE: There is a component change associated with this test.
There is a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.
Remove component 2008938, Pain Management Panel, Add'l Information

2003248 **Dexamethasone, Serum or Plasma by LC-MS/MS** **DEXA TMS**

Specimen Required: Patient Prep: Specimen should be collected between 8-10 a.m.

0090076 Diazepam and Nordiazepam DIAZ

Specimen Required: Collect: Gray (Potassium Oxalate/Sodium Fluoride). Also acceptable: Plain Red, Green (Sodium Heparin), Lavender (K_2 or K_3EDTA) or pink (K_2EDTA).
Specimen Preparation: Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1 mL)
Unacceptable Conditions: Gel separator tubes. Plasma or whole blood collected in light blue (sodium citrate).
Stability (collection to initiation of testing): After separation from cells: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 3 years (Avoid repeated freeze/thaw cycles)

Reference Interval: Effective November 16, 2015

Dose-Related Range:

Components	Dose-Related Range
Diazepam	200 – 1000 ng/mL - Based on normal dosage amounts
Nordiazepam	100 – 1500 ng/mL - Based on normal dosage amounts Toxic: Greater than 2500 ng/mL

HOT LINE NOTE: There is a unit of measure change associated with this test.
Change Unit of measure for component 0090075, Diazepam from ug/mL to ng/mL
Change Unit of measure for component 0090195, Nordiazepam from ug/mL to ng/mL

0090085 Digitoxin DIGT

Reference Interval: Effective November 16, 2015
Therapeutic Range: 10.0-30.0 ng/mL
Toxic: Greater than 45.0 ng/mL

2011632 Disopyramide, Serum or Plasma DISOP

Specimen Required: Stability (collection to initiation of testing): Ambient: 4 days; Refrigerated: 1 week; Frozen: 2 months

Reference Interval: Effective November 16, 2015

Therapeutic Range:	2.0-6.0 µg/mL
Toxic:	Greater than 6.0 µg/mL

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

Reference Interval: Effective November 16, 2015

Drugs covered and range of cutoff concentrations. Note that some drugs are identified based on the presence of unique drug metabolites not listed below.

Drugs/Drug Classes	Range of Cutoff Concentrations
Opioids: buprenorphine, codeine, fentanyl, heroin (6-acetylmorphine), dihydrocodeine, hydrocodone, hydromorphone, meperidine, methadone, morphine, naloxone, naltrexone, oxycodone, oxymorphone, propoxyphene, tapentadol, tramadol	1-10 ng/g
Stimulants: amphetamine, cocaine, methamphetamine, MDMA (Ecstasy), MDEA (Eve), MDA, phentermine	8 ng/g
Sedatives-hypnotics: alprazolam, butalbital, clonazepam, diazepam, flunitrazepam, flurazepam,lorazepam, midazolam, nitrazepam, nordiazepam, oxazepam, phenobarbital, secobarbital, temazepam, triazolam, zolpidem	5-75 ng/g
Cannabinoids (11-nor-9-carboxy-THC)	1 ng/g
Phencyclidine (PCP)	4 ng/g

HOT LINE NOTE: There is a unit of measure change associated with this test.
Change Unit of measure for component 2008360, Marajuana Metabolite from pg/g to ng/g

New Test **2012555** **ERG by Immunohistochemistry** **ERG IHC**
Available October 19, 2015

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

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

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

CPT Code(s): 88342

New York DOH approval pending. Call for status update.

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

0090518 **Ethanol, Urine, Qualitative - Medical** **ETOH URN**

Specimen Required: Stability (collection to initiation of testing): Ambient: 4 hours; Refrigerated: 1 week; Frozen: 3 months

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

Specimen Required: Stability (collection to initiation of testing): After separation from cells: Ambient: 5 days; Refrigerated: 1 week; Frozen: 2 months

New Test **2012695** **Ethyl Glucuronide Screen Only, Urine** **ETG SCR UR**
Available November 16, 2015

Methodology: Qualitative Enzyme Immuonassay
Performed: Sun-Sat
Reported: 1-4 days

Specimen Required: Collect: Random urine.
Specimen Preparation: Transfer 4 mL urine with no additives or preservatives to an ARUP Standard Transport Tube. (Min. 1 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): Ambient 20 days; Refrigerated: 20 days; Frozen: 20 days

Interpretive Data: **Screening results are obtained by immunoassay. Results obtained by immunoassay are not confirmed unless confirmation testing is specifically requested.**

Ethyl glucuronide is a direct metabolite of ethanol and can be detected in urine up to 80 hours after ethanol ingestion. This immunoassay cutoff for positive is set at 500 ng/mL.

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

CPT Code(s): 80302, (Alt code G0434)

New York DOH Approved.

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

0090110 **Ethylene Glycol** **ETG**

Specimen Required: Stability (collection to initiation of testing): After separation from cells: Ambient: 1 week; Refrigerated: 1 week; Frozen: 1 month

2008701 **Expanded Carrier Screening Next Generation Sequencing, 100-Plus Disorders with Fragile X** **ECS NGSFGX**

CPT Code(s): 81404, 81405, 81406, 81407, 81408, 81223, 81252, 81479, 81243, 81257

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

2007543 **Expanded Carrier Screening Panel Targeted Mutation, 100-Plus Disorders** **ECS PANEL**

CPT Code(s): 81200; 81205; 81209; 81220; 81242; 81250; 81251; 81255; 81260; 81290; 81330; 81332; 81400; 81401; 81479

2007531 **Expanded Carrier Screening Panel Targeted Mutation, 100-Plus Disorders with Fragile X** **ECS PANFGX**

CPT Code(s): 81200; 81205; 81209; 81220; 81242; 81250; 81251; 81255; 81260; 81290; 81330; 81332; 81400; 81401; 81479; 81243

New Test **2012460** **Febrile Seizures Panel, Females** **FEB PAN**
Available October 19, 2015

Methodology: High Performance Liquid Chromatography/Sequencing/Multiplex Ligation-dependent Probe Amplification/Polymerase Chain Reaction
Performed: Varies
Reported: 3-6 Weeks

Specimen Required: Collect: Lavender (EDTA).
Specimen Preparation: Transport 4 mL whole blood in the original tube. (Min: 4 mL)
Storage/Transport Temperature: Room temperature.
Stability (collection to initiation of testing): Ambient: 3 weeks; Refrigerated: 3 weeks; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data: Test detects the following genes: *SCN1A, SCN1A-DEL/DUP, SCN1B, SCN2A, SCN9A, GABRD, GABRG2, PCDH19.*

CPT Code(s): 81404, 81405 x2, 81407 (*SCN1A*), 81479 x2

New York DOH Approved.

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

2006069 **Febrile Seizures Panel, Males** **FEBRIL PAN**

CPT Code(s): 81404 (*SCN1B*), 81405 (*GABRG2*), 81407 (*SCN1A*), 81479 x2

HOT LINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name of component 2006070 from Febrile Seizures Panel to Febrile Seizures Panel, Males

2007138 **Galectin-3, Serum** **GALECTIN**

Reference Interval: Effective November 16, 2015
Less than or equal to 22.1 ng/mL

New Test **2012636** **Gastrin, 1 Minute** **GAST 1**
Available October 19, 2015

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

Specimen Required: Patient Prep: Patient fast for 12 hours prior to collection is recommended.
Collect: Serum separator tube (SST).
Specimen Preparation: Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, Tissue or Urine. Grossly hemolyzed or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 1 month

CPT Code(s): 82941

New York DOH Approved.

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

New Test **2012734** **Gastrin, 10 Minute** **GAST 10**
Available October 19, 2015

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

Specimen Required: Patient Prep: Patient fast for 12 hours prior to collection is recommended.
Collect: Serum separator tube (SST).
Specimen Preparation: Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, Tissue or Urine. Grossly hemolyzed or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 1 month

CPT Code(s): 82941

New York DOH Approved.

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

New Test **2012638** **Gastrin, 2 Minute** **GAST 2**
Available October 19, 2015

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

Specimen Required: Patient Prep: Patient fast for 12 hours prior to collection is recommended.
Collect: Serum separator tube (SST).
Specimen Preparation: Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, Tissue or Urine. Grossly hemolyzed or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 1 month

CPT Code(s): 82941

New York DOH Approved.

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

New Test **2012736** **Gastrin, 30 Minute** **GAST 30**
Available October 19, 2015

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

Specimen Required: Patient Prep: Patient fast for 12 hours prior to collection is recommended.
Collect: Serum separator tube (SST).
Specimen Preparation: Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, Tissue or Urine. Grossly hemolyzed or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 1 month

CPT Code(s): 82941

New York DOH Approved.

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

New Test **2012732** **Gastrin, 5 Minute** **GAST 5**
Available October 19, 2015

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

Specimen Required: Patient Prep: Patient fast for 12 hours prior to collection is recommended.
Collect: Serum separator tube (SST).
Specimen Preparation: Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, Tissue or Urine. Grossly hemolyzed or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 1 month

CPT Code(s): 82941

New York DOH Approved.

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

New Test **2012738** **Gastrin, Baseline** **GAST BASE**
Available October 19, 2015

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

Specimen Required: Patient Prep: Patient fast for 12 hours prior to collection is recommended.
Collect: Serum separator tube (SST).
Specimen Preparation: Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, Tissue or Urine. Grossly hemolyzed or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 1 month

Reference Interval: 0-100 pg/mL

CPT Code(s): 82941

New York DOH Approved.

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

New Test **2012678** **Gastrointestinal Bacterial Panel by PCR** **GI BACTPCR**
Available October 19, 2015

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

Specimen Required: Collect: Stool.
Specimen Preparation: Transfer 1 mL stool to an unpreserved stool transport vial (ARUP Supply #40910), OR place stool in 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: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Formalin-fixed stool.
Stability (collection to initiation of testing): Unpreserved stool: Ambient: Unacceptable; Refrigerated: 7 days; Frozen: 60 days
Stool in transport media: Ambient: 1 hr; Refrigerated: 3 days; Frozen: Unacceptable

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

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

Note: This assay detects *Shigella* spp., *Salmonella* spp., *Campylobacter jejuni/coli*, *Campylobacter upsaliensis*, Shiga-like toxin 1, and Shiga-like toxin 2.

CPT Code(s): 87506

New York DOH approval pending. Call for status update.

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

New Test **2012558** **GATA3 by Immunohistochemistry** **GATA3 IHC**
Available October 19, 2015

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

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

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

CPT Code(s): 88342

New York DOH approval pending. Call for status update.

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

0020058 **Hemoglobin, Plasma** **HGBP**

Reference Interval:
0.0-9.7 mg/dL

0020057 **Hemoglobin, Serum** **HGBS**

Reference Interval:
0.0-11.3 mg/dL

0051067 **HLA DRB 3*,4*,5*** **HLADRB345**

Methodology: Polymerase Chain Reaction/Sequence Specific Oligonucleotide Probe Hybridization

New Test **2012482** **HLA-A by Next Generation Sequencing** **HLA A NGS**
Available October 19, 2015

Methodology: Polymerase Chain Reaction/Massive Parallel Sequencing
Performed: Varies
Reported: 10-13 days

Specimen Required: Collect: Lavender (EDTA). Also acceptable: yellow (ACD Solution A).
Specimen Preparation: Transport 4 mL whole blood in the original container. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Yellow (ACD Solution B) specimens. Clotted, grossly hemolyzed, or heparinized specimens.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By Report

CPT Code(s): 81380

New York DOH approval pending. Call for status update.

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

New Test **2012486** **HLA-B by Next Generation Sequencing** **HLA B NGS**
Available October 19, 2015

Methodology: Polymerase Chain Reaction/Massive Parallel Sequencing
Performed: Varies
Reported: 10-13 days

Specimen Required: Collect: Lavender (EDTA). Also acceptable: yellow (ACD Solution A).
Specimen Preparation: Transport 4 mL whole blood in the original container. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Yellow (ACD Solution B) specimens. Clotted, grossly hemolyzed, or heparinized specimens.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By Report

CPT Code(s): 81380

New York DOH approval pending. Call for status update.

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

2002429 **HLA-B*57:01 for Abacavir Sensitivity** **HLA-B5701**

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring

HOT LINE NOTE: There is a clinically significant charting name change.
Change the charting name of component 2002431 from HLA-B*5701 Specimen to HLA-B*57:01 Specimen
Change the charting name of component 2002432 from HLA-B*5701 Genotyping to HLA-B*57:01 Allele

New Test **2012490** **HLA-C by Next Generation Sequencing** **HLA C NGS**
Available October 19, 2015

Methodology: Polymerase Chain Reaction/Massive Parallel Sequencing
Performed: Varies
Reported: 10-13 days

Specimen Required: Collect: Lavender (EDTA). Also acceptable: yellow (ACD Solution A).
Specimen Preparation: Transport 4 mL whole blood in the original container. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Yellow (ACD Solution B) specimens. Clotted, grossly hemolyzed, or heparinized specimens.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By Report

CPT Code(s): 81380

New York DOH approval pending. Call for status update.

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

New Test **2012502** **HLA-DPB1 by Next Generation Sequencing** **HLA DPB1**
Available October 19, 2015

Methodology: Polymerase Chain Reaction/Massive Parallel Sequencing
Performed: Varies
Reported: 10-13 days

Specimen Required: Collect: Lavender (EDTA). Also acceptable: yellow (ACD Solution A).
Specimen Preparation: Transport 4 mL whole blood in original container. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Yellow (ACD Solution B) specimens. Clotted, grossly hemolyzed, or heparinized specimens.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By Report

CPT Code(s): 81382

New York DOH approval pending. Call for status update.

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

New Test **2012498** **HLA-DQB1 by Next Generation Sequencing** **HLA DQB1**
Available October 19, 2015

Methodology: Polymerase Chain Reaction/Massive Parallel Sequencing
Performed: Varies
Reported: 10-13 days

Specimen Required: Collect: Lavender (EDTA). Also acceptable: yellow (ACD Solution A).
Specimen Preparation: Transport 4 mL whole blood in original container. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Yellow (ACD Solution B) specimens. Clotted, grossly hemolyzed, or heparinized specimens.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By Report

CPT Code(s): 81382

New York DOH approval pending. Call for status update.

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

New Test **2012494** **HLA-DRB1 by Next Generation Sequencing** **HLA DRB1**
Available October 19, 2015

Methodology: Polymerase Chain Reaction/Massive Parallel Sequencing
Performed: Varies
Reported: 10-13 days

Specimen Required: Collect: Lavender (EDTA). Also acceptable: yellow (ACD Solution A).
Specimen Preparation: Transport 4 mL whole blood in original container. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Yellow (ACD Solution B) specimens. Clotted, grossly hemolyzed, or heparinized specimens.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By Report

CPT Code(s): 81382

New York DOH approval pending. Call for status update.

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

0080422 **Homovanillic Acid (HVA), Urine** **HVA U**

Methodology: Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry

New Test 2012674 **Human Immunodeficiency Virus (HIV) Combo Antigen/Antibody (HIV-1/O/2) by ELISA, Reflexive Panel** **HIV PANEL**

Available November 16, 2015

Methodology: Qualitative Enzyme-Linked Immunosorbent Assay/Qualitative Immunoassay/Quantitative Polymerase Chain Reaction
Performed: Mon, Wed, Fri
Reported: 1-5 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA).
Specimen Preparation: Separate plasma from cells ASAP or within 2 hours of collection. Transfer 3 mL plasma into an ARUP Standard Transport Tube dedicated only for HIV testing. (Min: 2 mL) Remove particulate material.
Storage/Transport Temperature: Frozen.
Remarks: This test requires a dedicated tube of EDTA plasma submitted only for HIV testing.
Unacceptable Conditions: Serum. Heparinized or citrated plasma specimens. Specimens submitted in plasma preparation tube. Specimens containing particulate material. Severely hemolyzed or heat-inactivated specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 6 days; Frozen: 6 weeks (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval
	HIV 1,2 Combo Antigen/Antibody	Negative
	HIV-1 Antibody	Negative
	HIV-2 Antibody	Negative
0055598	Human Immunodeficiency Virus 1 by Quantitative PCR	Not detected

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

Note: The fourth-generation ELISA screen test is for the simultaneous qualitative detection of Human Immunodeficiency Virus Type 1 (HIV-1) p24 antigen and antibodies to HIV Type 1 (HIV-1 groups M and O) and HIV Type 2 (HIV-2). Results of the screen cannot be used to distinguish between the presence of HIV-1 p24 antigen, HIV-1 antibody, or HIV-2 antibody.

If the HIV-1,2 Combo Antigen/Antibody screen is repeatedly reactive, then the HIV-1/2 Ab Differentiation Immunoassay will be performed. Additional charges apply. The HIV-1/2 Ab Differentiation Immunoassay confirms and discriminates between HIV-1 and HIV-2 antibodies. Results for each type are reported.

If the HIV-1/2 Ab Differentiation Immunoassay is Negative or Indeterminate, then the Human Immunodeficiency Virus 1 by Quantitative PCR will be added. Additional charges apply.

This multi-test algorithm is recommended by the Centers for Disease Control and Prevention (CDC) and the Clinical Laboratory Standards Institute (CLSI) for the diagnosis of HIV (refer to http://www.arupconsult.com/Topics/HIV.html).

Refer to the following tests for additional information regarding Performed or Reported times, Interpretive Data and Notes for the reflex tests of this panel: Human Immunodeficiency Virus Types 1 and 2 (HIV-1/2) Antibody Differentiation, Supplemental with Reflex to HIV-1 Quantitative PCR (2012669); Human Immunodeficiency Virus 1 by Quantitative PCR (0055598)

CPT Code(s): 87389; if reflexed, add 86701 and 86702; if reflexed, add 87536

New York DOH Approved.

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

0020698	**Human Immunodeficiency Virus Type 1 (HIV-1) Antibody, Confirmation by Western Blot, with Reflex to HIV-2 Antibody**	**HIV1 WB R2**

HOT LINE NOTE: There is a component change associated with this test
Remove reflex component from 2008282, HIV-2 Antibody, Supplemental from component 0051250 (HIV-2) Antibody by ELISA with Reflex
Add component 2012688, HIV-2 Antibody, Supplemental to reflex component 0051250 (HIV-2) Antibody by ELISA with Reflex

0051250	**Human Immunodeficiency Virus Type 2 (HIV-2) Antibody by ELISA with Reflex to HIV-2 Supplemental**	**HIV-2 PAN**

HOT LINE NOTE: There is a component change associated with this test.
Remove component 008282, HIV-2 Antibody, Supplemental
Add component 2012688, HIV-2 Antibody, Supplemental

New Test **2012669** **Human Immunodeficiency Virus Types 1 and 2 (HIV-1/2) Antibody Differentiation, Supplemental, with Reflex to HIV-1 Quantitative PCR** **HIV AB DIF**

Available November 16, 2015

Methodology: Qualitative Immunoassay/Quantitative Polymerase Chain Reaction
Performed: Varies
Reported: 1-2 days

Specimen Required: Collect: Lavender (EDTA), or pink (K_2EDTA).
Specimen Preparation: Separate plasma from cells ASAP or within 2 hours of collection. Transfer 3 mL plasma into an ARUP Standard Transport Tube dedicated only for HIV testing. (Min: 1.5 mL) Remove particulate material.
Storage/Transport Temperature: Frozen.
Remarks: This test requires a dedicated tube of EDTA plasma submitted only for HIV testing.
Unacceptable Conditions: Serum. Heparinized or citrated plasma specimens. Specimens submitted in plasma preparation tube. Specimens containing particulate material. Severely hemolyzed or heat-inactivated specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 6 days; Frozen: 6 weeks (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval
	HIV-1 Antibody	Negative
	HIV-2 Antibody	Negative
0055598	Human Immunodeficiency Virus 1 by Quantitative PCR	Not detected

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

Note: For use only when patient has a repeatedly reactive third or fourth generation HIV screen test result. This test discriminates between HIV-1 and HIV-2 antibodies. Results for each type are reported. This test is for use as the antibody differentiation test in the specific multi-test algorithm. It is not to be ordered as a rapid screen test and cannot be used as a supplemental test if the initial screen test was a rapid test.

If the HIV-1/ 2 Antibody Differentiation Immunoassay is Negative or Indeterminate, then the Human Immunodeficiency Virus 1 by Quantitative PCR will be added. Additional charges apply. Refer to Human Immunodeficiency Virus 1 by Quantitative PCR (0055598) for additional information regarding Performed or Reported times, Interpretive Data and Notes for the reflex test.

The multi-test algorithm is recommended by the Centers for Disease Control and Prevention (CDC) and the Clinical Laboratory Standards Institute (CLSI) for the diagnosis of HIV (refer to http://www.arupconsult.com/Topics/HIV.html).

CPT Code(s): 86701; 86702; if reflexed, add 87536

New York DOH Approved.

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

0091128 **Hydrocarbon and Oxygenated Volatiles Quantitative Panel, Urine** **HYDR OX UR**

Specimen Required: Storage/Transport Temperature: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**

0080420 **5-Hydroxyindoleacetic Acid (HIAA), Urine** **HIAA**

Methodology: Quantitative High Performance Liquid Chromatography – Tandem Mass Spectrometry

0050049 **Immunofixation Electrophoresis, Immunoglobulin D and Immunoglobulin E, Serum** **IFE D/E**

HOT LINE NOTE: There is a component change associated with this test.
Add component 2012450, EER Immunofixation, IgD and IgE

New Test **2012572** **Immunofixation Electrophoresis, Qualitative, Gel** **IFE Q GEL**
Available November 16, 2015

Methodology: Qualitative Immunofixation Electrophoresis
Performed: Mon-Fri
Reported: 1-5 days

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.3 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 1 month

Reference Interval: Normal IFE

Interpretive Data: This information should be correlated with the results of serum protein electrophoresis, quantitative immunoglobulins, and other clinical and laboratory information.

Note: Immunofixation Electrophoresis Gel includes a qualitative interpretation of an IFE only.

CPT Code(s): 86334

New York DOH Approved.

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

2007535 **Infantile Epilepsy Panel, Sequence Analysis and Exon-Level Deletion/Duplication, 53 Genes** **INFAN EPIL**

HOT LINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name of component 2007536, Infantile Epilepsy Panel, 51 Genes to Infantile Epilepsy Panel, 53 Genes
Change the charting name of component 2010887, EER Infantile Epilepsy Panel, 51 Genes to EER Infantile Epilepsy Panel, 53 Genes

2004680 **Interleukin 28B-Associated Variants, *IL28B*, 2 SNPs** **IL28B**

Methodology: Polymerase Chain Reaction/Single Nucleotide Extension

CPT Code(s): 81400, 81479

HOT LINE NOTE: There is a component change associated with this test that affects interface clients only.
Remove component 2004684, IL28B-Assoc Variants, 2SNPs Interp
Add component 2012617, IL28B-Assoc Variants, 2 SNPs Interp

0090148 Librium and Nordiazepam LIB

Specimen Required: Patient Prep: Timing of specimen collection: Pre-dose (trough) draw - At steady state concentration.
Collect: Gray (Potassium Oxalate/Sodium Fluoride). Also acceptable: Plain Red, Green (Sodium Heparin), Lavender (K_2 or K_3EDTA) or pink (K_2EDTA).
Specimen Preparation: Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Gel separator tubes. Plasma or whole blood collected in light blue (sodium citrate).
Stability (collection to initiation of testing): After separation from cells: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 3 years (Avoid repeated freeze/thaw cycles)

Reference Interval: Effective: November 16, 2015

Components	Therapeutic Range
Librium	500 – 3000 ng/mL - Dose (Adult): 5-100 mg Toxic: Greater than 5000 ng/mL
Nordiazepam	100 – 1500 ng/mL - Based on normal dosages. Toxic: Greater than 2500 ng/mL

HOT LINE NOTE: There is a unit of measure change associated with this test.
Change the Unit of Measure for component 0090150, Librium from ug/mL to ng/mL
Change the Unit of Measure for component 0090195, Nordiazepam from ug/mL to ng/mL

2005661 Liver Fibrosis, Chronic Viral Hepatitis (Echosens FibroMeter) FIBRO V

CPT Code(s): (83883; 84450; 84460; 84520; 82977) or 81599*
*The 2015 AMA CPT manual contains the component CPT Codes and the new MAAA codes. Please direct any questions regarding CPT coding to the payer being billed.

0090181 Lorazepam LORAZ

Specimen Required: Patient Prep: Timing of specimen collection: Pre-dose (trough) draw - At steady state concentration.
Collect: Gray (Potassium Oxalate/Sodium Fluoride). Also acceptable: Plain Red, Green (Sodium Heparin), Lavender (K_2 or K_3EDTA) or pink (K_2EDTA).
Specimen Preparation: Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1 mL)
Unacceptable Conditions: Gel separator tubes. Plasma or whole blood collected in light blue (sodium citrate).
Stability (collection to initiation of testing): After separation from cells: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 3 years (Avoid repeated freeze/thaw cycles)

2008894 Lung Cancer Panel LUNG PANEL

HOT LINE NOTE: There is a component change associated with this test that affects interface clients only.
Remove component 2007326, ALK(D5F3) by IHC Pct of Tumor Staining

2008895 Lung Cancer Panel with KRAS LUNG PLUS

HOT LINE NOTE: There is a component change associated with this test that affects interface clients only.
Remove component 2007326, ALK(D5F3) by IHC Pct of Tumor Staining

0095854 Lymphocyte Subset Panel 1 - CD4 Absolute Count Only ABS4

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or green (sodium or lithium heparin). Hemogard tubes are preferred for laboratory automation and safety.
Remarks: Specimens must be analyzed within stability times provided. Some medications may affect immunophenotyping results and should be listed on the patient test request form.
This test is not approved for New York State Clients.
Stability (collection to initiation of testing): **EDTA:** Ambient: 72 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Heparin: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

Reference Interval: Effective November 16, 2015

Reports include age appropriate reference intervals and interpretation.

Test Number	Components	0-6 days	1 week-1 month	2-4 months	5-8 months	9-14 months	15-23 months	2-4 years	5-9 years	10-15 years	16-64 years	65 years or older
	Absolute CD4	1000-4800 cells/µL	1500-6000 cells/µL	1600-6500 cells/µL	1000-7200 cells/µL	1300-7100 cells/µL	400-7200 cells/µL	500-2700 cells/µL	400-2500 cells/µL	400-2100 cells/µL	430-1800 cells/µL	490-1600 cells/µL

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

0095885 Lymphocyte Subset Panel 2 - CD4 Percent and Absolute CD4

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or green (sodium or lithium heparin). Hemogard tubes are preferred for laboratory automation and safety.
Remarks: Specimens must be analyzed within stability times provided. Some medications may affect immunophenotyping results and should be listed on the patient test request form.
This test is not approved for New York State Clients.
Unacceptable Conditions: Clotted or hemolyzed
Stability (collection to initiation of testing): **EDTA:** Ambient: 72 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Heparin: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

Reference Interval: Effective November 16, 2015

Test Number	Components	0-6 days	1 week-1 month	2-4 months	5-8 months	9-14 months	15-23 months	2-4 years	5-9 years	10-15 years	16-64 years	65 years or older
	% CD4	26-62 %	39-69 %	37-69 %	27-81%	25-86%	16-91%	25-66%	26-61%	20-65%	32-64%	35-68%
	Absolute CD4	1000-4800 cells/µL	1500-6000 cells/µL	1600-6500 cells/µL	1000-7200 cells/µL	1300-7100 cells/µL	400-7200 cells/µL	500-2700 cells/µL	400-2500 cells/µL	400-2100 cells/µL	430-1800 cells/µL	490-1600 cells/µL

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

HOT LINE NOTE: There is a component change associated with this test.
Remove component 0095905 % CD4
Add component 2012587 % CD4

0095853 Lymphocyte Subset Panel 3 - T-Cell Subsets (CD4 and CD8), Absolute Counts Only — ABS

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or green (sodium or lithium heparin). Hemogard tubes are preferred for laboratory automation and safety.
Remarks: Specimens must be analyzed stability times provided. Some medications may affect immunophenotyping results and should be listed on the patient test request form. **This test is not approved for New York State clients.**
Unacceptable Conditions: Clotted or hemolyzed.
Stability (collection to initiation of testing): **EDTA:** Ambient: 72 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Heparin: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

Reference Interval: Effective November 16, 2015

Reports include age appropriate reference intervals and interpretation.

Test Number	Components	0-6 days	1 week-1 month	2-4 months	5-8 months	9-14 months	15-23 months	2-4 years	5-9 years	10-15 years	16-64 years	65 years or older
	Absolute CD3	1400-6800 cells/µL	1900-8400 cells/µL	2200-9200 cells/µL	1400-11500 cells/µL	2400-8300 cells/µL	700-8800 cells/µL	850-4300 cells/µL	770-4000 cells/µL	850-3200 cells/µL	570-2400 cells/µL	660-2200 cells/µL
	Absolute CD4	1000-4800 cells/µL	1500-6000 cells/µL	1600-6500 cells/µL	1000-7200 cells/µL	1300-7100 cells/µL	400-7200 cells/µL	500-2700 cells/µL	400-2500 cells/µL	400-2100 cells/µL	430-1800 cells/µL	490-1600 cells/µL
	Absolute CD8	200-2700 cells/µL	300-2700 cells/µL	300-3400 cells/µL	200-5400 cells/µL	400-4100 cells/µL	200-2800 cells/µL	200-1800 cells/µL	200-1700 cells/µL	300-1300 cells/µL	210-1200 cells/µL	150-1050 cells/µL
	Absolute CD4:CD8 Ratio	1.00-2.60	1.30-6.30	1.70-3.90	1.60-3.80	1.30-3.90	0.90-3.70	0.90-2.90	0.90-2.60	0.90-3.40	0.80-3.90	0.80-6.17

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

0095950 Lymphocyte Subset Panel 4 - T-Cell Subsets Percent and Absolute, Whole Blood TSHORT

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or green (sodium or lithium heparin). Hemogard tubes are preferred for laboratory automation and safety.
Remarks: Specimens must be analyzed within stability times provided. Some medication may affect immunophenotyping results and should be provided on the patient test request form.
Unacceptable Conditions: BAL specimens (refer to ARUP test code 0093420). Clotted or hemolyzed specimens.
Stability (collection to initiation of testing): **EDTA:** Ambient: 72 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Heparin: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
New York State Clients: EDTA: Ambient: 30 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Heparin: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

Reference Interval: Effective November 16, 2015

Reports include age appropriate reference intervals and interpretation.

Test Number	Components	0-6 days	1 week-1 month	2-4 months	5-8 months	9-14 months	15-23 months	2-4 years	5-9 years	10-15 years	16-64 years	65 years or older
	% CD3	38-88%	55-90 %	49-97 %	49-95%	56-87%	36-92%	52-92%	55-97%	52-90%	62-87%	62-89%
	Absolute CD3	1400-6800 cells/µL	1900-8400 cells/µL	2200-9200 cells/µL	1400-11500 cells/µL	2400-8300 cells/µL	700-8800 cells/µL	850-4300 cells/µL	770-4000 cells/µL	850-3200 cells/µL	570-2400 cells/µL	660-2200 cells/µL
	% CD4	26-62 %	39-69 %	37-69 %	27-81%	25-86%	16-91%	25-66%	26-61%	20-65%	32-64%	35-68%
	Absolute CD4	1000-4800 cells/µL	1500-6000 cells/µL	1600-6500 cells/µL	1000-7200 cells/µL	1300-7100 cells/µL	400-7200 cells/µL	500-2700 cells/µL	400-2500 cells/µL	400-2100 cells/µL	430-1800 cells/µL	490-1600 cells/µL
	% CD8	5-37%	7-35%	6-41%	10-35%	7-58%	7-40%	9-49%	13-47%	14-40%	15-46%	10-46%
	Absolute CD8	200-2700 cells/µL	300-2700 cells/µL	300-3400 cells/µL	200-5400 cells/µL	400-4100 cells/µL	200-2800 cells/µL	200-1800 cells/µL	200-1700 cells/µL	300-1300 cells/µL	210-1200 cells/µL	150-1050 cells/µL
	CD4:CD8 Ratio	1.00-2.60	1.30-6.30	1.70-3.90	1.60-3.80	1.30-3.90	0.90-3.70	0.90-2.90	0.90-2.60	0.90-3.40	0.80-3.90	0.80-6.17

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

HOT LINE NOTE: There is a component change associated with this test.

Remove component 0095905 % CD4
Remove component 0095910 % CD8
Remove component 0095920 CD4:CD8 Ratio

Add component 2012857 % CD4
Add component 2012858 % CD8
Add component 2012860 CD4:CD8 Ratio

0095892 Lymphocyte Subset Panel 5 - Total Lymphocyte Enumeration TIMMUNPAN

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or green (sodium or lithium heparin). Hemogard tubes are preferred for laboratory automation and safety.
Remarks: Specimens must be analyzed within stability times provided. Some medication may affect immunophenotyping results and should be provided on the patient test request form.
Unacceptable Conditions: Clotted or hemolyzed specimens.
Stability (collection to initiation of testing): **EDTA:** Ambient: 72 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Heparin: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
New York State Clients: EDTA: Ambient: 30 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Heparin: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

Reference Interval: Effective November 16, 2015

Reports include age appropriate reference intervals and interpretation.

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

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

HOT LINE NOTE: There is a component change associated with this test.

Remove component 0095905 % CD4
Remove component 0095910 % CD8
Remove component 0095920 CD4:CD8 Ratio
Remove component 0095914 % CD19

Add component 2012857 % CD4
Add component 2012858 % CD8
Add component 2012860 CD4:CD8 Ratio
Add component 2012859 % CD19

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

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or green (sodium or lithium heparin). Hemogard tubes are preferred for laboratory automation and safety.
Remarks: Specimens must be analyzed within stability times provided. Some medication may affect immunophenotyping results and should be provided on the patient test request form.
Unacceptable Conditions: Clotted or hemolyzed specimens.
Stability (collection to initiation of testing): **EDTA:** Ambient: 72 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Heparin: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
New York State Clients: EDTA: Ambient: 30 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Heparin: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

Reference Interval: Effective November 16, 2015

Reports include age appropriate reference intervals and interpretation.

Test Number	Components	0-6 days	1 week-1 month	2-4 months	5-8 months	9-14 months	15-23 months	2-4 years	5-9 years	10-15 years	16-64 years	65 years or older
	% CD3	38-88%	55-90 %	49-97 %	49-95%	56-87%	36-92%	52-92%	55-97%	52-90%	62-87%	62-89%
	Absolute CD3	1400-6800 cells/µL	1900-8400 cells/µL	2200-9200 cells/µL	1400-11500 cells/µL	2400-8300 cells/µL	700-8800 cells/µL	850-4300 cells/µL	770-4000 cells/µL	850-3200 cells/µL	570-2400 cells/µL	660-2200 cells/µL
	% CD4	26-62 %	39-69 %	37-69 %	27-81%	25-86%	16-91%	25-66%	26-61%	20-65%	32-64%	35-68%
	Absolute CD4	1000-4800 cells/µL	1500-6000 cells/µL	1600-6500 cells/µL	1000-7200 cells/µL	1300-7100 cells/µL	400-7200 cells/µL	500-2700 cells/µL	400-2500 cells/µL	400-2100 cells/µL	430-1800 cells/µL	490-1600 cells/µL
	% CD45RA	60-100%	63-100%	66-100%	68-99%	68-98%	57-100%	53-96%	47-97%	39-93%	28-71%	19-62%
	Absolute CD45RA	900-4500 cells/µL	1100-5200 cells/µL	1200-5300 cells/µL	800-5900 cells/µL	900-5200 cells/µL	400-5600 cells/µL	380-2500 cells/µL	250-2000 cells/µL	230-1400 cells/µL	350-1100 cells/µL	260-1000 cells/µL
	% CD45RO	2-44%	2-36%	1-42%	1-46%	4-29%	5-39%	11-50%	8-76%	18-68%	28-72%	38-81%
	Absolute CD45RO	98-1300 cells/µL	110-1200 cells/µL	90-1400 cells/µL	100-950 cells/µL	160-710 cells/µL	68-630 cells/µL	150-640 cells/µL	100-510 cells/µL	160-700 cells/µL	340-1150 cells/µL	490-1200 cells/µL
	% CD8	5-37%	7-35%	6-41%	10-35%	7-58%	7-40%	9-49%	13-47%	14-40%	15-46%	10-46%
	Absolute CD8	200-2700 cells/µL	300-2700 cells/µL	300-3400 cells/µL	200-5400 cells/µL	400-4100 cells/µL	200-2800 cells/µL	200-1800 cells/µL	200-1700 cells/µL	300-1300 cells/µL	210-1200 cells/µL	150-1050 cells/µL
	CD4:CD8 Ratio	1.00-2.60	1.30-6.30	1.70-3.90	1.60-3.80	1.30-3.90	0.90-3.70	0.90-2.90	0.90-2.60	0.90-3.40	0.80-3.90	0.80-6.17
	% CD19	3-30%	3-60%	8-33%	4-54%	3-77%	8-45%	8-39%	4-33%	7-24%	6-23%	5-21%
	Absolute CD19	140-2000 cells/µL	180-3500 cells/µL	520-2300 cells/µL	130-6300 cells/µL	110-7700 cells/µL	160-3700 cells/µL	180-1300 cells/µL	100-800 cells/µL	120-740 cells/µL	91-610 cells/µL	74-510 cells/µL
	% NK-cells	8-62%	3-23%	2-20%	2-36%	1-64%	1-96%	2-25%	2-31%	4-51%	4-26%	5-28%
	Absolute NK-cells	500-3100 cells/µL	140-1900 cells/µL	97-2000 cells/µL	68-3900 cells/µL	71-3500 cells/µL	55-4000 cells/µL	61-510 cells/µL	70-590 cells/µL	92-1200 cells/µL	78-470 cells/µL	74-620 cells/µL

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

HOT LINE NOTE: There is a component change associated with this test.

Remove component 0095905 % CD4	Add component 2012857 % CD4
Remove component 0095910 % CD8	Add component 2012858 % CD8
Remove component 0095920 CD4:CD8 Ratio	Add component 2012860 CD4:CD8 Ratio
Remove component 0095914 % CD19	Add component 2012859 % CD19

0095899 Lymphocyte Subset Panel 7 - Congenital Immunodeficiencies PIP

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or green (sodium or lithium heparin). Hemogard tubes are preferred for laboratory automation and safety.
Remarks: Specimens must be analyzed within stability times provided. Some medication may affect immunophenotyping results and should be provided on the patient test request form.
Unacceptable Conditions: Clotted or hemolyzed specimens.
Stability (collection to initiation of testing): **EDTA:** Ambient: 72 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Heparin: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
New York State Clients: EDTA: Ambient: 30 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Heparin: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

Reference Interval: Effective November 16, 2015

Reports include age appropriate reference intervals and interpretation.

Test Number	Components	0-6 days	1 week-1 month	2-4 months	5-8 months	9-14 months	15-23 months	2-4 years	5-9 years	10-15 years	16-64 years	65 years or older
	% CD2	46-97%	58-97%	51-98%	51-98%	57-97%	37-92%	54-92%	57-97%	56-93%	73-91%	78-92%
	Absolute CD2	1900-8300 cells/µL	2000-9200 cells/µL	2300-10200 cells/µL	1500-13500 cells/µL	2500-10000 cells/µL	750-10800 cells/µL	900-4500 cells/µL	840-4300 cells/µL	950-3800 cells/µL	700-2600 cells/µL	680-2400 cells/µL
	% CD3	38-88%	55-90 %	49-97 %	49-95%	56-87%	36-92%	52-92%	55-97%	52-90%	62-87%	62-89%
	Absolute CD3	1400-6800 cells/µL	1900-8400 cells/µL	2200-9200 cells/µL	1400-11500 cells/µL	2400-8300 cells/µL	700-8800 cells/µL	850-4300 cells/µL	770-4000 cells/µL	850-3200 cells/µL	570-2400 cells/µL	660-2200 cells/µL
	% HLA-DR	3-30%	3-60%	8-33%	4-54%	3-77%	8-45%	8-39%	4-33%	7-24%	8-24%	7-20%
	Absolute HLA-DR	140-2000 cells/µL	180-3500 cells/µL	520-2300 cells/µL	130-6300 cells/µL	110-7700 cells/µL	160-3700 cells/µL	180-1300 cells/µL	100-800 cells/µL	120-740 cells/µL	100-640 cells/µL	98-430 cells/µL
	% CD4	26-62 %	39-69 %	37-69 %	27-81%	25-86%	16-91%	25-66%	26-61%	20-65%	32-64%	35-68%
	Absolute CD4	1000-4800 cells/µL	1500-6000 cells/µL	1600-6500 cells/µL	1000-7200 cells/µL	1300-7100 cells/µL	400-7200 cells/µL	500-2700 cells/µL	400-2500 cells/µL	400-2100 cells/µL	430-1800 cells/µL	490-1600 cells/µL
	% CD45RA	60-100%	63-100%	66-100%	68-99%	68-98%	57-100%	53-96%	47-97%	39-93%	28-71%	19-62%
	Absolute CD45RA	900-4500 cells/µL	1100-5200 cells/µL	1200-5300 cells/µL	800-5900 cells/µL	900-5200 cells/µL	400-5600 cells/µL	380-2500 cells/µL	250-2000 cells/µL	230-1400 cells/µL	350-1100 cells/µL	260-1000 cells/µL
	% CD45RO	2-44%	2-36%	1-42%	1-46%	4-29%	5-39%	11-50%	8-76%	18-68%	28-72%	38-81%
	Absolute CD45RO	98-1300 cells/µL	110-1200 cells/µL	90-1400 cells/µL	100-950 cells/µL	160-710 cells/µL	68-630 cells/µL	150-640 cells/µL	100-510 cells/µL	160-700 cells/µL	340-1150 cells/µL	490-1200 cells/µL
	% CD8	5-37%	7-35%	6-41%	10-35%	7-58%	7-40%	9-49%	13-47%	14-40%	15-46%	10-46%
	Absolute CD8	200-2700 cells/µL	300-2700 cells/µL	300-3400 cells/µL	200-5400 cells/µL	400-4100 cells/µL	200-2800 cells/µL	200-1800 cells/µL	200-1700 cells/µL	300-1300 cells/µL	210-1200 cells/µL	150-1050 cells/µL
	CD4:CD8 Ratio	1.00-2.60	1.30-6.30	1.70-3.90	1.60-3.80	1.30-3.90	0.90-3.70	0.90-2.90	0.90-2.60	0.90-3.40	0.80-3.90	0.80-6.17
	% CD19	3-30%	3-60%	8-33%	4-54%	3-77%	8-45%	8-39%	4-33%	7-24%	6-23%	5-21%
	Absolute CD19	140-2000 cells/µL	180-3500 cells/µL	520-2300 cells/µL	130-6300 cells/µL	110-7700 cells/µL	160-3700 cells/µL	180-1300 cells/µL	100-800 cells/µL	120-740 cells/µL	91-610 cells/µL	74-510 cells/µL
	% NK-cells	8-62%	3-23%	2-20%	2-36%	1-64%	1-96%	2-25%	2-31%	4-51%	4-26%	5-28%
	Absolute NK-cells	500-3100 cells/µL	140-1900 cells/µL	97-2000 cells/µL	68-3900 cells/µL	71-3500 cells/µL	55-4000 cells/µL	61-510 cells/µL	70-590 cells/µL	92-1200 cells/µL	78-470 cells/µL	74-620 cells/µL

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

HOT LINE NOTE: There is a component change associated with this test.

Remove component 0095905 % CD4	Add component 2012857 % CD4
Remove component 0095910 % CD8	Add component 2012858 % CD8
Remove component 0095920 CD4:CD8 Ratio	Add component 2012860 CD4:CD8 Ratio
Remove component 0095914 % CD19	Add component 2012859 %CD19
Remove component 0095930 %CD2	Add component 2012861 %CD2
Remove component 0095931 Absolute CD2	Add component 2012862 Absolute CD2

0060050	**Microsporidia Stain by Modified Trichrome**	**MICROST**

Performed: Sun-Sat
Reported: 1-2 days

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

HOT LINE NOTE: There is a component change associated with this test.
Add component 2012452, EER Monoclonal Protein Detect Quant, Ser

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

HOT LINE NOTE: There is a component change associated with this test.
Add component 2012457, EER Monoclonal Protein and FLC, Serum

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

HOT LINE NOTE: There is a component change associated with this test.
Add component 2012458, EER Motor Sensory Neuropathy Comp

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

HOT LINE NOTE: There is a component change associated with this test.
Add component 2012454, EER Motor Neuropathy Panel

2005640	**Muscle Weakness Autoimmune Reflexive Panel**	**MUWA R PAN**

HOT LINE NOTE: There is a component change associated with this test.
Remove component 0050748 Striated Muscle Antibodies, IgG Titer
Add reflex orderable 2012516 Striated Muscle Abs, IgG Titer

New Test	2012420	**Muscle-Specific Receptor Tyrosine Kinase (MuSK) Antibody by RIA**	**MUSK**

Available October 19, 2015

Methodology: Quantitative Radioimmunoassay
Performed: Varies
Reported: 3-13 days

Specimen Required: Collect: Plain red.
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 month; Frozen: 1 month

Reference Interval: By report

CPT Code(s): 83519

New York DOH Approved.

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

0092404 **Natural Killer Cells Enumeration** **NK CELLS**

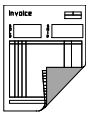
Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or green (sodium or lithium heparin). Hemogard tubes are preferred for laboratory automation and safety.
Remarks: Specimens must be analyzed within stability times provided. Some medication may affect immunophenotyping results and should be provided on the patient test request form.
Unacceptable Conditions: Clotted or hemolyzed specimens.
Stability (collection to initiation of testing): **EDTA:** Ambient: 72 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Heparin: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
New York State Clients: EDTA: Ambient: 30 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Heparin: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

Reference Interval: Effective November 16, 2015

Test Number	Components	0-6 days	1 week-1 month	2-4 months	5-8 months	9-14 months	15-23 months	2-4 years	5-9 years	10-15 years	16-64 years	65 years or older
	% NK-cells	8-62%	3-23%	2-20%	2-36%	1-64%	1-96%	2-25%	2-31%	4-51%	4-26%	5-28%
	Absolute NK-cells	500-3100 cells/µL	140-1900 cells/µL	97-2000 cells/µL	68-3900 cells/µL	71-3500 cells/µL	55-4000 cells/µL	61-510 cells/µL	70-590 cells/µL	92-1200 cells/µL	78-470 cells/µL	74-620 cells/µL

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

New Test **2012535** **Nerve Fiber Density Analysis, Intraepidermal** **INFDA IHC**
Available October 19, 2015



Anatomic Pathology Test Request Form
Recommended (ARUP form #32960)

Methodology: Microscopy/Immunohistochemistry
Performed: Mon-Fri
Reported: Within 2 weeks

Specimen Required: Collect: Obtain Nerve Fiber Fixative Collection Kit prior to collection procedure, (ARUP supply #44191) available online through eSupply using ARUP Connect™ or contact Client Services at (800) 522-2787. Special fixatives are required; collection instructions are provided with the kit.
Skin punch biopsies from lower extremity (one biopsy from the distal leg and one from the proximal thigh).
Specimen Preparation: Transport two 3 mm skin punch biopsies in the original collection kit. (Min: 3 mm)
Storage/Transport Temperature: Refrigerated.
Remarks: Submit clinical history.
Unacceptable Conditions: Specimens in inappropriate fixative. Specimens that are not collected according to the collection instructions provided in collection kit.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 2 weeks; Frozen: Unacceptable

Interpretive Data: Refer to report.

CPT Code(s): 88399 per specimen. Additional billing may apply if special studies are indicated.

New York DOH Approved.

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

New Test **2012730** **Non-Criteria Antiphospholipid Syndrome (APS) (aPa, aPc, aPe, aPg, aPi) Antibodies Extended Panel** **NCAPS EXT**

Available January 4, 2016

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

Specimen Required: Collect: Serum separator tube (SST).
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1.5 mL serum to an ARUP Standard Transport Tube. (Min: 0.9 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Heat-inactivated, grossly hemolyzed, icteric, or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval
2007610	Phosphatidic Acid Antibodies, IgG, IgM, and IgA	0-11 U/mL: Normal 12-18 U/mL: Equivocal. Suggest repeat testing in 4-6 weeks or consider antibody testing for cardiolipin IgG and IgM, beta-2 glycoprotein 1 IgG and IgM and lupus anticoagulant. 19 U/mL or greater: Positive
0051590	Phosphatidylcholine Antibodies, IgG, IgM and IgA	0-11 U/mL: Normal 12-18 U/mL: Equivocal. Suggest repeat testing in 4-6 weeks or consider antibody testing for cardiolipin IgG and IgM, beta-2 glycoprotein 1 IgG and IgM and lupus anticoagulant. 19 U/mL or greater: Positive
0051622	Phosphatidylethanolamine Antibodies, IgG, IgM and IgA	0-11 U/mL: Normal 12-18 U/mL: Equivocal. Suggest repeat testing in 4-6 weeks or consider antibody testing for cardiolipin IgG and IgM, beta-2 glycoprotein 1 IgG and IgM and lupus anticoagulant. 19 U/mL or greater: Positive
0051623	Phosphatidylglycerol Antibodies, IgG, IgM and IgA	0-11 U/mL: Normal 12-18 U/mL: Equivocal. Suggest repeat testing in 4-6 weeks or consider antibody testing for cardiolipin IgG and IgM, beta-2 glycoprotein 1 IgG and IgM and lupus anticoagulant. 19 U/mL or greater: Positive
0051624	Phosphatidylinositol Antibodies, IgG, IgM and IgA	0-11 U/mL: Normal 12-18 U/mL: Equivocal. Suggest repeat testing in 4-6 weeks or consider antibody testing for cardiolipin IgG and IgM, beta-2 glycoprotein 1 IgG and IgM and lupus anticoagulant. 19 U/mL or greater: Positive

Interpretive Data:

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

CPT Code(s): 83516 x15

New York DOH Approved.

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

New Test 2012729 **Non-Criteria Antiphospholipid Syndrome (APS) (aPs, aPt, aPs/aPt) Antibodies Panel** **NCAPS PAN**

Available January 4, 2016

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

Specimen Required: Collect: Serum separator tube (SST).
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1.5 mL serum to an ARUP Standard Transport Tube. (Min: 0.9 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Heat-inactivated, grossly hemolyzed, icteric, or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval
0050906	Phosphatidylserine Antibody, IgG	Less than 11 U/mL
0050907	Phosphatidylserine Antibody, IgM	Less than 25 U/mL
2009447	Phosphatidylserine and Prothrombin IgG	0-30 Units
2009449	Phosphatidylserine and Prothrombin IgM	0-30 Units
0051302	Prothrombin Antibody, IgG	Less than 20.0 Units
0051303	Prothrombin Antibody, IgM	Less than 20.0 Units

Interpretive Data: Refer to report.

CPT Code(s): 86148 x2; 83516 x2; 86849 x2

New York DOH Approved.

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

2009077 **Non-Invasive Prenatal Testing for RhD Genotyping, Fetal** **NIPT RHD**

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

2008767 **Opioid Receptor, Mu 1, *OPRM1* Genotype, 1 Variant** **OPRM1**

2007479 **Pain Management Drug Panel by High-Resolution Time-of-Flight Mass Spectrometry and Enzyme Immunoassay, Urine** **PAIN HYB U**

HOT LINE NOTE: There is a component change associated with this test.
Remove component 2007635, OPIATES, HIGH RES URINE
Remove component 2007639, OXYCODONE-LIKE, HIGHRES URINE
Remove component 2007648, OPIOIDS, OTHER, HIGH RES URINE
Remove component 2007657, OPIOIDS, OTHER, IMMUNOASSAY URINE
Remove component 2007661, AMPHETAMINE-LIKE, HIGH RES URINE
Remove component 2007669, COCAINE, IMMUNOASSAY URINE
Remove component 2007671, BENZODIAZEPINE-LIKE, HIGH RES URINE
Remove component 2007683, BARBITURATES, IMMUNOASSAY, URINE
Remove component 2007685, OTHERS, IMMUNOASSAY OR SPRECTRO URINE

2009288 **Pain Management Drug Screen with Interpretation by High-Resolution Time-of-Flight Mass Spectrometry and Enzyme Immunoassay, Urine** **PAIN HYB 2**

Specimen Required: Patient Prep: Information on the patient's current medications must be submitted with the order. Include trade name, generic name, dosing frequency and date of last dose, if known. Alternatively, please indicate if no prescription medications or drugs are being taken.

HOT LINE NOTE: There is a component change associated with this test.
Remove component 2007635, OPIATES, HIGH RES URINE
Remove component 2007639, OXYCODONE-LIKE, HIGHRES URINE
Remove component 2007648, OPIOIDS, OTHER, HIGH RES URINE
Remove component 2007657, OPIOIDS, OTHER, IMMUNOASSAY URINE
Remove component 2007661, AMPHETAMINE-LIKE, HIGH RES URINE
Remove component 2007669, COCAINE, IMMUNOASSAY URINE
Remove component 2007671, BENZODIAZEPINE-LIKE, HIGH RES URINE
Remove component 2007683, BARBITURATES, IMMUNOASSAY, URINE
Remove component 2007685, OTHERS, IMMUNOASSAY OR SPRECTRO URINE

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

CPT Code(s): 80301; 80302x7; if positive add appropriate CPT: 80324, 80359, 80345, 80347, 80348, 80369, 80353, 80321, 80354, 80362, 80358, 80349, 80361, 80365, 83992, 80367, 80368, 80372, 80373 (Alt code: G0431; if positive, add appropriate CPT code(s): G6042, G6043, G6031 x2, G6056 x4, G6052, 80299 x3, G6044, G6040, G6053, 82491 x2)

2010677 **Parathyroid Hormone-Related Peptide (PTHrP) by LC-MS/MS, Plasma** **PTHRP**

Note: Amino (N)- and carboxy (C)-terminus PTHrP fragments, such as those produced by some patients with renal insufficiency, do not interfere with this assay.

2004366 **Paroxysmal Nocturnal Hemoglobinuria, High Sensitivity, RBC** **PNH RBC**

HOT LINE NOTE: There is a numeric map change associated with this test that affects interface clients only.
Change the numeric map for component 2004367, % PHN RBC from XXX.XXX to XX.XXX

2005003 **Paroxysmal Nocturnal Hemoglobinuria, High Sensitivity, WBC** **PNH WBC**

HOT LINE NOTE: There is a numeric map change associated with this test that affects interface clients only.
Change the numeric map for component 2005004, % PNH Monocytes from XXX.X to XX.XXX

2005006 **Paroxysmal Nocturnal Hemoglobinuria (PNH), High Sensitivity, RBC and WBC** **PNH PAN**

Specimen Required: Specimen Preparation: Transport 4 mL whole blood. (Min: 4 mL)
Remarks: Specimens must be analyzed within stability times provided.
Unacceptable Conditions: Bone marrow. Clotted or hemolyzed specimens.

HOT LINE NOTE: There is a numeric map change associated with this test.
Change the numeric map for component 2005004, % PNH Monocytes from XXX.X to XX.XXX
Change the numeric map for component 2004367, % PHN RBC from XXX.XXX to XX.XXX

New Test **2012603** ***PAX8-PPARG* Translocations Detection by PCR** **PAX8-PPARG**
Available October 19, 2015

Additional Technical Information

Methodology: Polymerase Chain Reaction
Performed: **DNA isolation:** Sun-Sat
Assay: Mon, Thu
Reported: 10-12 days

Specimen Required: Collect: Tumor tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Transport tissue block or 5 unstained 5-micron slides. (Min: 3 slides) Tissue block will be returned after testing.
A Fine Needle Aspirate (FNA) smear may also be submitted. Prepare FNA smear with Diff-Quik or equivalent stain by standard methods (air-dried slides are preferred). Number of slides needed is dependent on the tumor cellularity of the smear. (Min: 1 slide) Slide(s) will be destroyed during testing process and will not be returned to client.
Transport of block and/or slide(s) in a tissue transport kit is preferred (ARUP supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Also acceptable: FNA specimens stored in saline, PreservCyt or CytoLyt.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Unacceptable Conditions: Less than 10 percent tumor. Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or 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
FNA cells in Saline: Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Indefinitely

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

CPT Code(s): 81401; add 88381 for FFPE

New York DOH approval pending. Call for status update.

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

0091551 **Phenobarbital, Total/Free/Bound, Serum or Plasma** **PHENOBAR**

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

Reference Interval: Effective November 16, 2015

Test Number	Components	Therapeutic Range
	Phenytoin - Total	Therapeutic: 10.0-20.0 µg/mL Toxic: Greater than 20.0 µg/mL
	Phenytoin - Free Level	Therapeutic: 1.0-2.0 µg/mL Toxic: Greater than 2.0 µg/mL
	Phenytoin - Percent Free	8.0-14.0%

0051050 **Platelet Antibodies, Indirect** **PLT ABSCRN**

Specimen Required: Collect: Serum separator tube (SST).
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube and freeze. (Min: 0.5 mL)

0051718 **Platelet Antibodies, Indirect with Reflex to Identification** **PLT R**

Specimen Required: Collect: Serum separator tube (SST).
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)

0051051 **Platelet Antibody Identification - Refer to Platelet Antibodies Indirect (0051050). Platelet antibody detection must be performed first.** **PLTABID**

Specimen Required: Patient Prep: **For newborns less than 30 days old, collect specimen from the mother.**
Collect: Serum separator tube (SST).
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube and freeze. (Min: 0.5 mL)
Storage/Transport Temperature: Frozen. Also acceptable: Refrigerated if maintained at temperature for 48 hours or less.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 48 hours; Frozen: 1 month

0090800 **Polychlorinated Biphenyls Quantitative, Serum or Plasma** **POLYCHL SP**

Performed: Varies
Reported: 5-12 days

0090672 **Prazepam (Assayed as Nordiazepam)** **PRAZE**

Specimen Required: Collect: Gray (Potassium Oxalate/Sodium Fluoride). Also acceptable: Plain Red, Green (Sodium Heparin), Lavender (K_2 or K_3EDTA) or pink (K_2EDTA).
Specimen Preparation: Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1 mL)
Unacceptable Conditions: Gel separator tubes. Plasma or whole blood collected in light blue (sodium citrate).
Stability (collection to initiation of testing): After separation from cells: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 3 years (Avoid repeated freeze/thaw cycles)

Reference Interval: Effective November 16, 2015

Dose-Related Range:	Prazepam (Dose: 20-60 mg/d) (Assayed as Nordiazepam)
Nordiazepam:	100–1500 ng/mL
Toxic:	Greater than 2500 ng/mL

HOT LINE NOTE: There is a unit of measure and numeric map change associated with this test
Change Unit of Measure for component 0090672 Prazepam (Assay As Nordiazepam) from ug/mL to ng/mL
Change the numeric map for component 0090672 Prazepam (Assay As Nordiazepam) from x.xx to xxxxx

2008704 **Prenatal Carrier Screening Next Generation Sequencing, 85 Disorders with Fragile X** **PCS NGSFGX**

CPT Code(s): 81404, 81405, 81406, 81407, 81408, 81223, 81252, 81479, 81243, 81257

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

2007539 **Prenatal Carrier Screening Targeted Mutation Panel, 85 Disorders** **PCS PANEL**

CPT Code(s): 81200; 81205; 81209; 81220; 81242; 81250; 81251; 81255; 81260; 81290; 81330; 81400; 81401; 81479

2007541 **Prenatal Carrier Screening Targeted Mutation Panel, 85 Disorders with Fragile X** **PCS PANFGX**

CPT Code(s): 81200; 81205; 81209; 81220; 81242; 81250; 81251; 81255; 81260; 81290; 81330; 81400; 81401; 81479; 81243

0020724 **Prolactin, Dilution Study** **PROLAC MAC**

HOT LINE NOTE: There is a clinically significant charting name change associated with this test.
Change charing name of component 0020724, Prolactin Macrodenoma to Prolactin, Dilution Study

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

HOT LINE NOTE: There is a component change associated with this test.
Add component 2012453, EER Serum Protein Electrophoresis Reflex

0050640	**Protein Electrophoresis, Serum**	**SPEP**

HOT LINE NOTE: There is a component change associated with this test.
Add component 2012453, EER Serum Protein Electrophoresis, Serum

2009345	**Pulmonary Arterial Hypertension (PAH) Panel, Sequencing and Deletion/Duplication, Multigene**	**PAH PANEL**

HOT LINE NOTE: There is a clinically significant charting name change associated with this test.
Change charting name of component 2009346, PAH Pan. Seq/DelDup, 5 Genes – Specimen to PAH Pan. Seq/DelDup, Specimen
Change charting name of component 2009349, PAH Pan. Seq/Dup, 5 Genes – Interp to PAH Pan. Seq/DelDup, Interp

2009350	**Pulmonary Arterial Hypertension (PAH) Sequencing, Multigene**	**PAH SEQ**

HOT LINE NOTE: There is a clinically significant charting name change associated with this test.
Change charting name of component 2009351, PAH Sequencing, 5 Genes – Specimen to PAH Sequencing Specimen
Change charting name of component 2009352, PAH Sequencing, 5 Genes – Interp to PAH Sequencing Interp

New Test 2012654 ***RET* Gene Rearrangements by FISH** **RET FISH**
Available October 19, 2015

Additional Technical Information

Methodology: Fluorescence in situ Hybridization
Performed: Varies
Reported: 7-10 days

Specimen Required: Collect: Tumor tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed tumor tissue. Transport tissue block or 4 unstained, consecutively cut, 5-micron thick sections, mounted on positively charged glass slides. (Min: 4 slides) Protect paraffin block and/or slides from excessive heat.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated.
Remarks: Include surgical pathology report with reason for referral. The laboratory will not reject specimens that arrive without a pathology report but will hold the specimen until this information is received.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Reference Interval: By report

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

CPT Code(s): 88366

New York DOH approval pending. Call for status update.

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

New Test **2012605** ***RET-CCDC6* and *RET-NCOA4* (*RET-PTC1* and *RET-PTC3*) Translocations Detection by PCR** **RET PTC**

Available October 19, 2015

Additional Technical Information

Methodology: Polymerase Chain Reaction
Performed: **DNA Isolation:** Sun-Sat
Assay: Mon, Thu
Reported: 10-12 days

Specimen Required: Collect: Tumor tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Transport tissue block or 5 unstained 5-micron slides. (Min: 3 slides) Tissue block will be returned after testing.
A Fine Needle Aspirate (FNA) smear may also be submitted. Prepare FNA smear with Diff-Quik or equivalent stain by standard methods (air-dried slides are preferred). Number of slides needed is dependent on the tumor cellularity of the smear. (Min: 1 slide). Slide(s) will be destroyed during testing process and will not be returned to client.
Transport of a block and/or slide(s) in a tissue transport kit is preferred (ARUP supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Also acceptable: FNA specimens stored in saline, PreservCyt or CytoLyt.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Unacceptable Conditions: Less than 10 percent tumor. Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or 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
FNA in Saline: Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Unacceptable

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

CPT Code(s): 81479; add 88381 for FFPE

New York DOH approval pending. Call for status update.

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

2006462 **Scleroderma Antibodies Panel** **SCLER PAN**

Specimen Required: Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 3 weeks; Frozen: 6 months

CPT Code(s): 86038; 86235 x4; 86256; 83516 x2

New Test 2012561 **SOX11 by Immunohistochemistry** **SOX11 IHC**
Available October 19, 2015

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

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

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

CPT Code(s): 88342

New York DOH approval pending. Call for status update.

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

2008426 **Statin Sensitivity *SLCO1B1*, 1 Variant** **SLCO1B1**

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

Specimen Required: Collect: Lavender (EDTA) or pink (K_2EDTA), or yellow (ACD Solution A or B).
Unacceptable Conditions: Plasma or serum. Heparinized specimens.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

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0050746 **Striated Muscle Antibodies, IgG with Reflex to Titer** **STM R**

HOT LINE NOTE: There is a component change associated with this test.
Remove component 0050748 Striated Muscle Antibodies, IgG Titer
Add reflex orderable 2012516 Striated Muscle Abs, IgG Titer

2012233 **Thiopurine Methyltransferase (TPMT) Genotyping, 4 Variants** **TPMT DNA**

Performed: Mon, Thu
Reported: 5-10 days

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

Specimen Required: Unacceptable Conditions: Gel separator tubes. Specimens collected in sodium fluoride/potassium oxalate (gray). Hemolyzed, frozen, or room temperature specimens.

New Test **2012755** **Thyroid Translocation and Mutation Panel** **THY PANEL**
Available October 19, 2015

Additional Technical Information

Methodology: Polymerase Chain Reaction/Pyrosequencing
Performed: **DNA isolation:** Sun-Sat
Assay: Mon, Thu
Reported: 12-14 days

Specimen Required: Collect: Tumor tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Transport tissue block or 5 unstained 5-micron slides. (Min: 3 slides) Tissue block will be returned after testing.
A Fine Needle Aspirate (FNA) smear may also be submitted. Prepare FNA smear with Diff-Quik or equivalent stain by standard methods (air-dried slides are preferred). Number of slides needed is dependent on the tumor cellularity of the smear. (Min: 2 slides) Slides will be destroyed during testing process and will not be returned to client.
Transport of a block and/or slide(s) in a tissue transport kit is preferred (ARUP supply #47808) available online through eSupply using ARUP Connect or contact ARUP Client Services at (800) 522-2787.
FNA specimens stored in saline, PreservCyt or CytoLyt are also acceptable.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Unacceptable Conditions: Less than 25 percent tumor. Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or 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
FNA in Saline: Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Acceptable

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

Note: This panel will detect and report mutations in *BRAF* codon 600, *KRAS* codons 12/13/61, *NRAS* codons 12/13/61, *HRAS* codons 12/13/61 and translocations *PAX8-PPARG*, *RET-CCDC6* and *RET-NCOA4*.

CPT Code(s): 81210; 81275; 81403; 81404; 81401; 81479; add 88381 for FFPE

New York DOH approval pending. Call for status update.

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

0097709 **Tissue Transglutaminase (tTG) Antibody, IgA** **TTG**

Reference Interval:
Effective November 16, 2015

3 U/mL or less: Negative
4-10 U/mL: Weak Positive
11 U/mL or greater: Positive

Interpretive Data: Presence of the tissue transglutaminase (tTG) IgA antibody is associated with gluten-sensitive enteropathies such as celiac disease and dermatitis herpetiformis. tTG IgA antibody concentrations greater than 10 U/mL usually correlate with results of duodenal biopsies consistent with a diagnosis of celiac disease. For antibody concentrations greater than 3 U/mL but less than 41 U/mL, additional testing for endomysial (EMA) IgA concentrations may improve the positive predictive value for disease.

HOT LINE NOTE: There is a unit of measure change associated with this test.
Change Unit of Measure for component 0097709, Tissue Transglutaminase (tTG) Ab, IgA from Units to U/mL

0050734 Tissue Transglutaminase (tTG) Antibody, IgA with Reflex to Endomysial Antibody, IgA by IFA — EMA R

Reference Interval:

Test Number	Components	Reference Interval
0097709	Tissue Transglutaminase (tTG) Antibody, IgA	Effective November 16, 2015 3 U/mL or less: Negative 4-10 U/mL: Weak Positive 11 U/mL or greater: Positive
0050736	Endomysial Antibody, IgA by IFA	Less than 1:10

Interpretive Data:
Tissue Transglutaminase Antibody, IgA: Presence of the tissue transglutaminase (tTG) IgA antibody is associated with gluten-sensitive enteropathies such as celiac disease and dermatitis herpetiformis. tTG IgA antibody concentrations greater than 10 U/mL usually correlate with results of duodenal biopsies consistent with a diagnosis of celiac disease. For antibody concentrations greater than 3 U/mL but less than 41 U/mL, additional testing for endomysial (EMA) IgA concentrations may improve the positive predictive value for disease.

Endomysial Antibody, IgA by IFA: The endomysial antigen has been identified as the protein cross-linking enzyme known as tissue transglutaminase.

Note: Testing for tTG IgA antibodies is recommended as an initial screen to identify patients at risk for celiac disease, and in whom duodenal biopsy should be performed to confirm disease.

Some patients may have positive tTG IgA but negative EMA IgA and/or deamidated gliadin peptide (DGP) IgA results, which may be associated with false positivity or may indicate early disease. Close clinical correlation with continued testing may be indicated in patients with a family history of or who are at increased risk for celiac disease. A positive serology but normal biopsy may also indicate a gluten-free diet (GFD) prior to testing, latent disease, or early enteropathy. Re-challenge with a gluten diet may be recommended if GFD had been initiated prior to subsequent testing. In the case of latent or early disease, HLA DQ2 and DQ8 testing may be necessary to determine risk for disease.

For patients with a high degree of suspicion for celiac disease and who test negative for tTG, EMA, and/or DGP IgA tests, selective IgA-deficiency should be considered and testing for tTG, EMA, and/or DGP IgG antibodies performed.

If serology is negative and suspicion of celiac disease is strong, intestinal biopsy may be warranted. Biopsy is particularly important for patients with diarrhea, steatorrhea, weight loss, failure to thrive, or with inherited genetic deficiencies such as Down or Turner syndromes.

Specimen is screened using tissue transglutaminase IgA by ELISA. If tTG IgA is 4 U/mL or greater, then EMA IgA by IFA testing will be added. Additional charges apply. All EMA IgA by IFA testing is titered to endpoint.

HOT LINE NOTE: There is a unit of measure change associated with this test.
Change Unit of Measure for component 0097709, Tissue Transglutaminase (tTG) Ab, IgA from Units to U/mL

0056009 Tissue Transglutaminase Antibody, IgG — TTG G

Reference Interval:
Effective November 16, 2015

5 U/mL or less: Negative
6-9 U/mL: Weak Positive
10 U/mL or greater: Positive

HOT LINE NOTE: There is a unit of measure change associated with this test.
Change Unit of Measure for component 0056009, Tissue Transglutaminase Antibody, IgG from EU to U/mL

0050206 *Treponema pallidum* (VDRL), Cerebrospinal Fluid with Reflex to Titer — VDRL CSF

HOT LINT NOTE: There is a component change associated with this test.
Remove component 0050208, Treponema pallidum (VDRL) Titer, CSF
Remove reflex orderable 0050339 VDRL Titer, CSF Bill
Add reflex orderable 2012513, VDRL Titer, CSF

0093093 ***Treponema pallidum* (VDRL), Serum with Reflex to Titer** **VDRL SERU**

HOT LINE NOTE: There is a component change associated with this test.
Remove component 0093094, Treponema pallidum (VDRL) Titer, Serum
Remove reflex orderable 0050348 VDRL Titer, Serum Bill
Add reflex orederable 2012299, VDRL Titer, Serum

0050787 ***Trichinella* Antibody by ELISA** **TRICH**

Performed: Mon
Reported: 1-8 days

0099310 **Valproic Acid, Free and Total** **VPA-F**

Specimen Required: Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 1 month

0080470 **Vanillylmandelic Acid (VMA) and Homovanillic Acid (HVA), Urine** **VH**

Methodology: Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry

0080421 **Vanillylmandelic Acid (VMA), Urine** **VMA U**

Methodology: Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry

New Test [2012772] **Warfarin Sensitivity, *CYP2C9* and *VKORC1*, 3 Variants** **WARFGENO**
Available January 4, 2016

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

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Heparinized specimens.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Reference Interval: By report

Interpretive Data:
Background Information for Cytochrome P450 2C9, *CYP2C9*, 2 Variants:
Characteristics: The cytochrome P450 (CYP) isozyme 2C9 is involved in the metabolism of many drugs such as warfarin, phenytoin, tolbutamide, glipizide, ibuprofen, and phenobarbital. Variants of *CYP2C9* will influence pharmacokinetics of *CYP2C9* substrates, and may predict non-standard dose requirements.
Inheritance: Autosomal co-dominant.
Cause: *CYP2C9* gene variants result in decreased or complete deficiency in enzyme activity.
Variants Tested:
(Variants are numbered according to NM_000771 transcript)
Decreased function: *2 (rs1799853, c.430C>T).
Non-functional: *3 (rs1057910, c.1075A>C).
Negative: No variants detected is predictive of *1 functional alleles and normal enzymatic activity.
Allele Frequencies:
CYP2C9 *2: Caucasians 13 percent, Asians <1 percent, African Americans 3 percent.
CYP2C9 *3: Caucasians 7 percent, Asians 4 percent, African Americans 2 percent.
Clinical Sensitivity: Drug-dependent.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Only the targeted *CYP2C9* variants will be detected by this panel. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with *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.

Background Information for Warfarin Sensitivity by *VKORC1*, 1 Variant:
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 *VKORC1* test should be performed in combination with the *CYP2C9* test for application to warfarin dose estimates, such as through www.WarfarinDosing.org .
Inheritance: Autosomal co-dominant.
Cause: The *VKORC1*2* allele is associated with reduced expression of the warfarin target, vitamin K epoxide reductase (VKOR), and a reduced dose requirement. *CYP2C9* gene variants result in decreased or complete deficiency in enzyme activity that will reduce metabolism and prolong the half-life of warfarin.
Variants Tested: *VKORC1*2* (rs9923231, c.-1639G>A).
(Note: Variant is numbered according to *VKORC1* transcript NM_024006.)
Negative: No variant detected is predictive of *1 functional allele and normal VKOR expression.
Allele Frequencies:
VKORC1*2: Caucasians 39 percent, Asians 91 percent, African Americans 11 percent.
Clinical Sensitivity: Approximately 90 percent of *CYP2C9* and *VKORC1* variants causing warfarin sensitivity in Caucasians are detected when both tests are performed. Less characterized in other populations.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Only the targeted *VKORC1* variant will be detected by this test. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with warfarin 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. This test does not identify patients at risk for warfarin resistance.

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

CPT Code(s): 81227, 81355

New York DOH approval pending. Call for status update.

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

New Test **2012652** **Zolpidem, Serum or Plasma, Quantitative** **ZOLPID SP**
Available October 19, 2015

Methodology: Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed: Tue, Fri
Reported: 1-5 days

Specimen Required: Collect: Gray (sodium fluoride/potassium oxalate). Also acceptable: Plain red, green (sodium heparin), lavender (EDTA), or pink (K_2EDTA).
Specimen Preparation: Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1 mL)
Storage/Transport Temperature: Room temperature.
Unacceptable Conditions: Gel Separator tubes. Plasma or whole blood collected in lt. blue (sodium citrate).
Stability (collection to initiation of testing): After separation from cells: Ambient: 1 week; Refrigerated: 1 month; Frozen: 3 years (Avoid repeated freeze/thaw cycles)

Interpretive Data:
Methodology: Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Drugs covered: zolpidem

Positive cutoff: 20 ng/mL

For medical purposes only; not valid for forensic use.

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

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

CPT Code(s): 80368; (Alt code: G6031)

New York DOH Approved.

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

0097908 **Zonisamide** **ZONI**

Specimen Required: Stability (collection to initiation of testing): After separation from cells: Ambient: 1 week; Refrigerated: 1 week; Frozen: 6 weeks

The following will be discontinued from ARUP's test menu on January, 4 2016.
Replacement test options are supplied if applicable.

Test Number	Test Name	Refer To Replacement
0080700	Albumin, Glycated	Fructosamine (0099012)
0099409	Antimony, Urine	
2007609	Antiphospholipid Antibodies Extended Panel	Non-Criteria Antiphospholipid Syndrome (APS) (aPs, aPt, aPs/aPt) Antibodies Panel (2012729) or Non-Criteria Antiphospholipid Syndrome (APS) (aPa, aPc, aPe, aPg, aPi) Antibodies Extended Panel (2012730)
2011958	Ashkenazi Jewish (*BRCA1* and *BRCA2*) 3 Mutations	
0099410	Bismuth, Urine	
2002742	Buprenorphine and Metabolites - Confirmation/Quantitation - Serum/Plasma	Buprenorphine and Metabolites, Serum or Plasma, Quantitative (2012647)
0051600	Cardiolipin and Non-Criteria Anti-Phospholipid Syndrome (APS) Antibody Panel	2 Non-Criteria Antiphospholipid Syndrome (APS) (aPs, aPt, aPs/aPt) Antibodies Panel (2012729) or Non-Criteria Antiphospholipid Syndrome (APS) (aPa, aPc, aPe, aPg, aPi) Antibodies Extended Panel (2012730)
0080512	Carnitine Transport, Fibroblasts	
2006222	CHARGE Syndrome (*CHD7*) Sequencing	CHARGE Syndrome (CHD7) Sequencing (2012609)
2008097	Complement Component 1q, Functional	
0098391	Cortisol, Free	Cortisol, Free by Equilibrium Dialysis/LC-MS/MS (2012697)
2003102	*Coxiella burnetii* (Q-Fever) Antibodies, IgG & IgM by IFA with Reflex to Titer	Coxiella burnetii (Q-Fever) Antibodies, IgG and IgM, Phase I and II with Reflex to Titer (2012634)
0050462	*Coxiella burnetii* (Q-Fever) Antibody IgG, Phase I & II by IFA	Coxiella burnetii (Q-Fever) Antibody IgG, Phase I and II (2012625)
0050463	Coxiella burnetii (Q-Fever) Antibody IgG, Phase I by IFA	
0050464	Coxiella burnetii (Q-Fever) Antibody IgG, Phase II by IFA	
2001875	Creatine Transport, Fibroblasts	
0051104	Cytochrome P450 2C19 (*CYP2C19*) 9 Variants	Cytochrome P450 2C19, *CYP2C19* - 9 Variants (2012769)
0051103	Cytochrome P450 2C9 (*CYP2C9*) 2 Variants	Cytochrome P450 2C9, *CYP2C9* - 2 Variants (2012766)
0090180	Flurazepam	
2003085	HLA-A Sequencing	HLA-A by Next Generation Sequencing (2012482)
2002784	HLA-B Sequence	HLA-B by Next Generation Sequencing (2012486)
2002814	HLA-C Sequencing	HLA-C by Next Generation Sequencing (2012490)
2002779	HLA-DRB1 Sequencing	HLA-DRB1 by Next Generation Sequencing (2012494)
2007980	Human Immunodeficiency Virus (HIV) Combo Antigen/Antibody (HIV-1/O/2) by ELISA, with Reflex to HIV-1/HIV-2 Antibody Differentiation by Multispot	Human Immunodeficiency Virus (HIV) Combo Antigen/Antibody (HIV-1/O/2) by ELISA, Reflexive Panel (2012674)
2009464	Human Immunodeficiency Virus Types 1 and 2 (HIV-1/HIV-2) Antibody Differentiation by Multispot (Supplemental Use Only)	Human Immunodeficiency Virus Types 1 and 2 (HIV-1/2) Antibody Differentiation, Supplemental, with Reflex to HIV-1 Quantitative PCR (2012669)
0050272	Immunofixation Electrophoresis Gel	Immunofixation Electrophoresis, Qualitative, Gel (2012572)
2011515	Mephobarbital, Serum or Plasma	
2011006	Mercaptopurine and Metabolites Quantitative, Blood	Thiopurine Drug Metabolites (2011134)
2002301	Microarray Family Study by FISH	
2005386	Non-Criteria Antiphospholipid Syndrome (APS) Antibody Panel	Non-Criteria Antiphospholipid Syndrome (APS) (aPs, aPt, aPs/aPt) Antibodies Panel (2012729) NCAPS PAN or Non-Criteria Antiphospholipid Syndrome (APS) (aPa, aPc, aPe, aPg, aPi) Antibodies Extended Panel (2012730)
0025009	Tellurium, Urine	
2004358	Warfarin Genotyping Plus	Warfarin Sensitivity, CYP2C9 and VKORC1, 3 Variants(2012772)
0051370	Warfarin Sensitivity (*CYP2C9* and *VKORC1*) 3 Mutations	Warfarin Sensitivity, CYP2C9 and VKORC1, 3 Variants (2012772)
0091232	Zolpidem Quantitative, Serum or Plasma	Zolpidem, Serum or Plasma, Quantitative (2012652)