

HOT LINE Effective May 17, 2010

This Hot Line is published by ARUP Laboratories to notify clients of updates to our test menu. New tests, inactivated tests, and test changes will be included in the Hot Line, which is mailed at least 30 days prior to the effective date of changes, unless otherwise noted. Hot Lines and the up-to-date Laboratory Test Directory may also be viewed on our Web site at www.aruplab.com 45 days before the effective date. For additional information, contact ARUP Client Services at (800) 522-2787.

Please use the following information to update your 2008-2010 ARUP Laboratory Test Directory and databases. Changes are indicated by the red type. Note that only amended fields of an assay appear in this publication. All other fields remain the same. A red check mark (✓) indicates changes that also apply to other tests.

Hot Line Page #	LTD 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	New Test	Inactive
15	HL2/10	2002647	Acute Lymphocytic Leukemia (ALL) Panel by FISH, Adult			●								
15	HL2/10	2002719	Acute Lymphocytic Leukemia (ALL) Panel by FISH, Pediatric			●								
15	HL2/10	2002653	Acute Myelogenous Leukemia (AML) with Myelodysplastic Syndrome (MDS), or Therapy-Related AML, by FISH			●								
15	HL11/09	2002384	Acute Myelogenous Leukemia Panel by FISH			●								
67	48	0092330	Adrenal Steroid Quantitative Panel by LC-MS/MS, Serum or Plasma (<i>See 0092332 on pg 67</i>)					●						
16	49	0060115	Aerobic Organism Identification				●							
16	50	0065070	Aerobic Organism Identification with Reflex to Susceptibility				●							
16	54	0020030	Albumin, Serum or Plasma by Spectrophotometry				●							
16	HL2/10	2002582	Aldosterone & Renin, Direct with Ratio				●							
16	57	0020005	Alkaline Phosphatase, Serum or Plasma				●							
17	--	0051835	Allergens, Food, Shell Fish Profile										●	
17	67	0050001	Alpha-1-Antitrypsin				●							
18	67	0051256	Alpha-1-Antitrypsin (<i>SERPINA1</i>) Enzyme Concentration and 2 Mutations with Reflex to Alpha-1-Antitrypsin Phenotype	●			●				●			
18	65	0080427	Alpha Fetoprotein (Amniotic Fluid) with Reflex to Acetylcholinesterase and Fetal Hemoglobin	●		●	●			●	●			

HOT LINE Effective May 17, 2010

Hot Line Page #	LTD 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	New Test	Inactive
18	65	0080428	Alpha Fetoprotein, Serum (Tumor Marker)	●			●							
19	66	0051495	Alpha Thalassemia, (<i>HBA1</i> & <i>HBA2</i>) 7 Deletions	●			●	●			●			
19	68	0051710	Alport Syndrome, X-linked (<i>COL4A5</i>) 3 Mutations				●							
19	69	0099266	Aluminum, Serum				●							
19	74	0080276	Amniotic Bilirubin Scan				●							
20	75	0020506	Amylase, Body Fluid				●							
20	HL 11/09	0040208	Aneuploidy Panel by FISH			●								
20	79	0051113	Angelman Syndrome by Methylation	●			●	●			●			
20	79	0098974	Angiotensin Converting Enzyme, CSF			●								
21	388	0050392	Ankylosing Spondylitis (HLA-B27) Genotyping	●				●						
22	NEW	2002656	Anti-Mullerian Hormone Effective April 19, 2010										●	
22	82	0050811	Anti-Neutrophil Cytoplasmic Antibody, IgG							●				
22	101	0030192	APC Resistance Profile with Reflex to Factor V Leiden				●				●			
23	102	0055654	Apolipoprotein B (<i>APOB</i>) Mutation Detection	●			●	●			●			
24	103	0055566	Apolipoprotein E (<i>APOE</i>) 2 Mutations, Cardiovascular Risk				●	●			●			
24	105	0020734	Arsenic, Fractionated, Urine					●						
24	106	0090216	Arsenic, Tissue											●
25	--	0093013	Bacterial Antigen Detection											●
25	119	0055557	<i>bcl-1/JH</i> , t(11;14) Translocation by PCR, Fluid					●			●			
25	119	0055622	<i>bcl-1/JH</i> , t(11;14) Translocation by PCR, Paraffin				●	●			●			
25	120	0055564	<i>bcl-1/JH</i> , t(11;14) Translocation by PCR, Tissue								●			
25	121	0040138	<i>BCR-ABL1</i> Kinase Domain Mutation Analysis						●		●			

HOT LINE Effective May 17, 2010

Hot Line Page #	LTD 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	New Test	Inactive
25	--	2002464	Bence Jones Protein Detection, Quantitation & Characterization with Reflex to Quantitative Free Kappa & Lambda Light Chains, Urine. (Test Orderable by University of Utah Only)				●			●				
26	127	0051288	Beta-2-Adrenergic Receptor (<i>ADRB2</i>) Haplotyping	●			●		●		●			
27	--	2002569	Beta-2 Glycoprotein 1 Antibodies, IgG, IgM & IgA										●	
27	128	0080054	Beta-2 Microglobulin, CSF				●							
28	125	0051421	Beta Globin (<i>HBB</i>) HbS, HbC, & HbE Mutations	●			●		●		●			
28	130	0020730	Beta-hCG, Quantitative (Tumor Marker), CSF	●			●							
28	127	0070029	Beta-hCG, Quantitative (Tumor Marker)	●			●							
28	132	0020032	Bilirubin, Total, Serum or Plasma				●							
65	133	0051700	Biotinidase Deficiency (<i>BTD</i>) 5 Mutations (See 0051737 on pg 65)						●					
29	NEW	2002926	<i>Blastomyces dermatitidis</i> Antigen EIA Effective April 19, 2010										●	
29	136	0060102	Blood Culture		●		●							
30	138	0051433	Bloom (<i>BLM</i>) 2281del6/ins7 Mutation				●		●					
31	149	0050135	<i>Brucella</i> Total Antibody, Agglutination	●										
31	NEW	2002853	<i>Brucella</i> Antibodies, IgG & IgM by ELISA & Bacterial Agglutination										●	
32	150	0060159	<i>Brucella</i> Culture				●							
33	151	0030191	B-Type Natriuretic Peptide				●							
67 98	HL 11/09	2002282	CAH 11-Beta Hydroxylase Deficiency Panel (See 0092332 on pg 67 and 0081058 on pg 98)						●					
67	HL 11/09	2002283	CAH 21 Hydroxylase Deficiency Panel (See 0092332 on pg 67)						●					
33	156	0020472	Calcium, Urine						●					
33	HL 9/08	0092303	Calprotectin, Fecal									●		

HOT LINE Effective May 17, 2010

Hot Line Page #	LTD 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	New Test	Inactive
34	158	0058002	<i>Campylobacter</i> Antigen	●	●		●				●			
34	158	0051453	Canavan Disease (<i>ASPA</i>) 4 Mutations				●		●					
35	168	0080055	Carotene, Serum Total				●							
35	169	0021021	Carotenes, Fractionated, Plasma or Serum			●								
35	HL 7/08	0040203	Chorionic Villus, FISH			●								
35	183	0098830	Chromium, Serum				●							
35	HI 11/09	2002293	Chromosome Analysis, Amniotic Fluid			●								
35	HI 11/09	2002292	Chromosome Analysis, Bone Marrow			●								
35	HI 11/09	2002291	Chromosome Analysis, Chorionic Villus			●								
35	HI 11/09	2002290	Chromosome Analysis, Leukemic Blood			●								
35	HI 11/09	2002300	Chromosome Analysis, Lymph Node			●								
36	HI 11/09	2002289	Chromosome Analysis, Peripheral Blood			●								
36	HI 11/09	2002287	Chromosome Analysis, Rule Out Mosaicism			●								
36	HI 11/09	2002296	Chromosome Analysis, Solid Tumor			●								
36	HI 11/09	2002295	Chromosome FISH, CLL Panel			●								
36	HI 11/09	2002298	Chromosome FISH, Interphase			●								
36	HI 11/09	2002299	Chromosome FISH, Metaphase			●								
36	HI 11/09	2002297	Chromosome FISH, Prenatal			●								
36	HL 8/09	2002022	Chronic Urticaria Index™ Panel				●							
37	NEW	2002552	<i>Clostridium difficile</i> Cytotoxin Antibody Effective April 19, 2010										●	
37	NEW	2002838	<i>Clostridium difficile</i> toxin B gene (tcdB) by PCR Effective April 19, 2010										●	
37	195	0025037	Cobalt, Serum or Plasma				●							
38	200	0050155	Complement Component 4				●							

HOT LINE Effective May 17, 2010

Hot Line Page #	LTD 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	New Test	Inactive
67 98	HL8/09	2002029	Congenital Adrenal Hyperplasia Treatment Panel (<i>See 0092332 on pg 67, and 0081058 on pg 98</i>)					●						
38	205	0020096	Copper, Serum				●							
38	NEW	2002932	Coxsackie A Antibodies (A-2, 4, 7, 9, 10 & 16 Serotypes) Effective April 19, 2010										●	
39	210	0070103	C-Peptide, Serum or Plasma				●							
39	HL 8/09	2001613	Crohn Disease Prognostic Panel				●							
39	223	0050098	Cystic Fibrosis (<i>CFTR</i>) 3199del6 Mutation	●			●	●	●					
40	229	0051103	Cytochrome P450 2C9 (<i>CYP2C9</i>) 2 Mutations				●	●						
40	229	0051104	Cytochrome P450 2C19 (<i>CYP2C19</i>) 7 Mutations	●			●				●			
40	255	0050166	Cytomegalovirus Antibodies (Total)						●					
40	HL 11/09	2002349	5-a-Dihydrotestosterone by Tandem Mass Spectrometry, Serum				●							
41	275	0091372	Drugs of Abuse Confirmation/Quantitation - Amphetamine- Serum or Plasma				●	●						
41	275	0092310	Drugs of Abuse Confirmation/Quantitation - Amphetamines (Amphetamine & Methamphetamine) - Meconium					●						
41	275	0090439	Drugs of Abuse Confirmation/Quantitation - Amphetamines - Urine					●						
42	311	0051463	Dysautonomia, Familial (<i>IKBKAP</i>) 2 Mutations				●	●						
42	NEW	2002994	<i>Ehrlichia chaffeensis</i> DNA, Real-Time PCR Effective April 19, 2010										●	
42	HL 11/09	2002378	Eosinophilia Panel by FISH			●								
43	HL5/09	2001599	Epidermal Transglutaminase (TGe) Antibody, IgA				●							
43	300	0020610	Erythrocyte Porphyrin (EP), Whole Blood				●							

HOT LINE Effective May 17, 2010

Hot Line Page #	LTD 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	New Test	Inactive
43	302	0070051	Estriol, Serum				●							
43	303	0090120	Ethanol, Serum or Plasma - Medical Effective Immediately					●						
43	307	0051220	Ewing Sarcoma by RT-PCR								●			
43	307	0097720	Factor V Leiden (<i>F5</i>) R506Q Mutation				●							
44	311	0030120	Factor XIII, Qualitative											●
44	NEW	2002819	Factor XIII, Qualitative, with Reflex to Factor XIII 1:1 Mix										●	
45	312	0051468	Fanconi Anemia, Group C (<i>FANCC</i>) 2 Mutations				●		●					
45	312	0060315	Fat, Body Fluid				●							
46	HL 11/09	2002350	Fat, Fecal Quantitative				●							
46	HL 11/09	2002354	Fat, Fecal Quantitative 24-Hour Collection (Includes Homogenization)				●							
46	HL 11/09	2002355	Fat, Fecal Quantitative 48-Hour Collection (Includes Homogenization)				●							
46	HL 11/09	2002356	Fat, Fecal Quantitative 72-Hour Collection (Includes Homogenization)				●							
47	HL 9/08	0051752	FG Syndrome, FGS1 (<i>MED12</i>) R961W Mutation				●				●	●		
47	324	0040011	Fragile X (<i>FMRI</i>) Diagnostic				●							
47	325	0050543	Fragile X (<i>FMRI</i>) Diagnostic, Fetal				●							
47	681	0060756	Fungal Identification by ITS rDNA Sequencing	●			●							
47	332	0020009	Gamma Glutamyl Transferase, Serum or Plasma				●							
48	334	0051438	Gaucher (<i>GBA</i>) 8 Mutations				●		●					
48	HL 7/08	0040201	Genomic Microarray, UARRAY Chip			●								
48	339	0049190	Glomerular Basement Membrane Antibodies, IgA & IgG (IFA) Effective Immediately								●			

HOT LINE Effective May 17, 2010

Hot Line Page #	LTD 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	New Test	Inactive
48	340	0049191	Glomerular Basement Membrane Antibody, IgG (IFA) Effective Immediately								●			
48	340	0051001	Glomerular Basement Membrane Antibody Panel Effective Immediately								●			
49	341	0099165	Glucagon				●							
49	343	0051684	Glucose-6-Phosphate Dehydrogenase (<i>G6PD</i>) 2 Mutations	●			●				●			
49	NEW	2002862	Glutamic Acid Decarboxylase Antibody (<i>GAD65</i>) & Insulin Antibodies with Reflex to IA-2 Antibody Effective April 19, 2010										●	
50	349	0040116	Haptoglobin by (<i>HP</i>) Genotyping	●			●							
50	202	0051383	Hearing Loss, Nonsyndromic, Connexin 26 (<i>GJB2</i>) 35delG Mutation				●				●			
50	350	0099470	Heavy Metals Panel 3, Blood				●							
50	351	0020584	Heavy Metals Panel 4, Blood		●									
50	360	0020591	Hepatitis A Virus Antibodies (Total)		●	●	●							
50	360	0020093	Hepatitis A Virus Antibody, IgM		●	●	●							
51	360	0020597	Hepatitis A Virus Antibodies Panel	●	●	●	●				●			
51	374	0065005	Herpes Simplex Virus Culture				●							
51	374	0065065	Herpes Simplex Virus Culture with Reflex to HSV Typing				●							
52	NEW	2002829	Herpesvirus 6 Antibody, IgM Effective April 19, 2010										●	
52	NEW	2002996	Herpes Virus 8 DNA, Qualitative Real-Time PCR Effective April 19, 2010										●	
98	HI 5/09	2001763	Hirsutism Evaluation Panel (See 0081058 on pg 98)					●						
53	387	0095859	HLA Ab Detection Assay											●

HOT LINE Effective May 17, 2010

Hot Line Page #	LTD 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	New Test	Inactive
53	NEW	2002805	<i>HLA Antibody Detection</i>										●	
53	386	0056019	HLA-A Sequence-Based Typing											●
54	NEW	2003085	<i>HLA-A Sequencing</i>										●	
55	385	0096046	HLA A and B Oligotyping											●
55	NEW	2002801	<i>HLA-A & B Genotyping</i>										●	
56	386	0056018	HLA-ABC Sequence-Based Typing											●
56	NEW	2002788	<i>HLA-ABC Sequencing</i>										●	
57	387	0056020	HLA-B Sequence-Based Typing											●
57	NEW	2002784	<i>HLA-B Sequencing</i>										●	
58	388	0095844	HLA Bone Marrow Transplantation Evaluation											●
58	NEW	2002806	<i>HLA Bone Marrow Transplantation Evaluation</i>										●	
59	388	0095715	HLA-C Oligotyping											●
59	NEW	2002807	<i>HLA-C Genotyping</i>										●	
60	389	0056021	HLA-C Sequence-Based Typing											●
60	NEW	2002814	<i>HLA-C Sequencing</i>										●	
61	389	0095845	HLA-DQ Oligotyping											●
61	NEW	2002810	<i>HLA-DQB Genotyping</i>										●	
62	390	0055653	HLA-DRB1 Sequence-Based Typing											●
62	NEW	2002779	<i>HLA-DRB1 Sequencing</i>										●	
63	389	0098580	HLA DR Oligotyping											●
63	NEW	2002798	<i>HLA-DR Genotyping</i>										●	
64	494	0051650	HNPCC/Lynch Syndrome (<i>MLH1</i>) Sequencing and Deletion/Duplication	●				●	●					
65	497	0051656	HNPCC/Lynch Syndrome (<i>MSH6</i>) Sequencing and Deletion/Duplication	●				●	●					
65	HL 7/08	0051737	HNPCC/Lynch Syndrome (<i>PMS2</i>) Sequencing and Deletion/Duplication						●					
66	391	0099869	Homocysteine, Total							●				

HOT LINE Effective May 17, 2010

Hot Line Page #	LTD 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	New Test	Inactive
66	391	0080422	Homovanillic Acid (HVA), Urine									●		
66	NEW	2003020	Human Epididymis Protein 4 (HE4) Effective April 19, 2010										●	
66	391	0091177	Hydrocarbon & Oxygenated Volatiles, Serum or Plasma		●		●							
67	405	0092335	17-Hydroxypregnenolone Baseline Specimen					●						
67	407	0092332	17-Hydroxyprogesterone Quantitative by LC-MS/MS, Serum or Plasma					●						
68	HL 11/09	2002348	25-Hydroxyvitamin D2 and D3 by Tandem Mass Spectrometry, Serum	●				●						
68	409	0051367	Hypochondroplasia (<i>FGFR3</i>) 1 Mutation	●			●		●		●			
68	529	0098843	IGF Binding Protein-1				●							
68	HL 9/08	0040227	<i>IgVH</i> Mutation Analysis by Sequencing								●			
69	NEW	2002577	Infliximab Effective April 19, 2010										●	
69	NEW	2002579	Infliximab/HACA Measurement Effective April 19, 2010										●	
70	NEW	2002942	Influenza Virus A & B DFA (Includes Respiratory Mini Panel with H1N1 (2009) Typing by RT-PCR 2002559) Effective April 19, 2010										●	
70	424	0070413	Inhibin B Effective Immediately					●						
71	426	0070063	Insulin, Fasting				●							
71	426	0070240	Insulin, I.V. Fluid				●							
71	427	0070064	Insulin, 30 Minutes				●	●		●				
71	- -	0070690	Insulin, Veterinary				●							
71	432	0051393	Interleukin-1-Receptor-Associated Kinase-4 (IRAK-4) Deficiency Screen			●								
71	434	0091124	Iodide, Urine											●

HOT LINE Effective May 17, 2010

Hot Line Page #	LTD 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	New Test	Inactive
72	NEW	2002992	Iodine, Random, Urine Effective April 19, 2010										●	
72	434	0091180	Ipecac Use Markers Screen, Serum or Plasma				●				●			
72	HL11/09	2000271	Isohemagglutinin Titer, IgG							●				
72	HL11/09	2000280	Isohemagglutinin Titer, IgG & IgM							●				
72	HL11/09	2000270	Isohemagglutinin Titer, IgM							●				
73	439	0051644	Kell K/k Antigen (<i>KEL</i>) Genotyping	●			●				●			
73	445	0080940	Lamellar Body Counts				●							
74	448	0025016	Lead, Industrial Exposure Panel, Adults					●						
74	451	0060113	<i>Legionella</i> Species, Culture				●							
75	NEW	2002945	Legius Syndrome (<i>SPRED1</i>) Sequencing and (<i>NFI</i>) Sequencing Exon 22 (Exon 17) Effective Immediately										●	
75	HL2/10	2002650	Lymphoma (Aggressive) Panel by FISH			●								
75	473	0051674	Macular Degeneration, Age-Related, 2 DNA Markers	●			●				●			
76	475	0099265	Manganese, Serum				●							
76	477	0081293	Maternal Screening, Sequential, Specimen #1		●		●					●		
76	479	0080269	Maternal Serum Screen, Alpha Fetoprotein, hCG, Estriol, & Inhibin A									●		
77	480	0081150	Maternal Serum Screen, First Trimester		●		●							
77	481	0081062	Maternal Serum Screening, Integrated, Specimen #1									●		
78	487	0050184	Metanephrines, Plasma (Free)			●	●							
78	NEW	2002928	Metformin, Urine Effective April 19, 2010										●	
79	489	0051286	Methotrexate Sensitivity by MTHFR Genotyping				●				●			
79	490	0055655	Methylenetetrahydrofolate Reductase (MTHFR) 2 Mutations				●							

HOT LINE Effective May 17, 2010

Hot Line Page #	LTD 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	New Test	Inactive
79	497	0051448	Mucopolidosis, Type IV (<i>MCOLN1</i>) 2 Mutations				●		●					
80	498	0051492	Multiple Endocrine Neoplasia, Type 2B (<i>RET</i>) 2 Mutations	●			●		●		●			
80	HL 11/09	2002294	Multiple Myeloma Panel by FISH			●								
80	HL 11/09	2002360	Myeloproliferative Disorders Panel by FISH			●								
80	HL 8/09	2001930	Neuromyelitis Optica (NMO) Autoantibody, IgG				●							
80	512	0051088	Neuronal Nuclear Antibodies (ANNA) IgG, Immunoblot, Serum				●							
80	515	0099452	Nickel, Serum				●							
81	516	0051458	Niemann-Pick, Type A (<i>SMPD1</i>) 4 Mutations				●		●					
81	522	0060310	Occult Blood, Gastric					●			●	●		
81	527	0020728	Osteocalcin by Electrochemiluminescent Immunoassay			●								
82	NEW	2002984	Oxygen Dissociation (P50) by Hemoximetry Effective April 19, 2010										●	
82	534	0093014	Parathyroid Hormone-Related Peptide (PTHrP)				●							
83	547	0020478	Phosphorus, Urine					●						
83	550	0051309	Platelet Antigen 1 Genotyping (HPA-1)				●		●		●			
84	551	0051310	Platelet Antigen 2 Genotyping (HPA-2)				●		●		●			
85	551	0051311	Platelet Antigen 3 Genotyping (HPA-3)				●		●		●			
86	551	0051490	Platelet Antigen 4 Genotyping (HPA-4)				●		●		●			
87	551	0051312	Platelet Antigen 5 Genotyping (HPA-5)				●		●		●			
88	551	0051313	Platelet Antigen 6 Genotyping (HPA-6)				●		●		●			
89	552	0051314	Platelet Antigen 15 Genotyping (HPA-15)				●		●		●			
90	552	0051308	Platelet Antigen Genotyping Panel				●		●		●			
91	HL 11/09	2002363	PML/RAR α FISH			●								

HOT LINE Effective May 17, 2010

Hot Line Page #	LTD 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	New Test	Inactive
91	--	0056100	PML/RAR α , t(15;17) by RT-PCR											●
91	NEW	2002871	PML-RARα, t(15;17) Translocation by RT-PCR, Quantitative										●	
91	554	0060054	Poliovirus Antibodies					●						
91	555	0090800	Polychlorinated Biphenyls, Serum			●	●							
92	556	0099824	Porphyryns, Fecal						●					
92	556	0080429	Porphyryns, Serum Total				●							
92	558	0051116	Prader-Willi Syndrome by Methylation	●			●	●		●				
93	NEW	2002554	Pregabalin Effective April 19, 2010										●	
93	561	0070110	Progesterone				●							
93	561	0070256	Proinsulin/Insulin Ratio				●							
94	NEW	2002930	Prostate Specific Antigen, Complexed Effective April 19, 2010										●	
94	567	0020029	Protein, Total, Plasma or Serum				●							
94	567	0020479	Protein, Total, Urine					●						
95	568	0051302	Prothrombin Antibody, IgG				●							
95	568	0051303	Prothrombin Antibody, IgM				●							
95	HL 9/08	0051729	QuantiFERON®-TB Gold In Tube Effective Immediately				●							
95	HL 2/10	2002730	<i>RASAI</i> -Related Disorders (<i>RASAI</i>) Sequencing							●				
95	HL 2/10	2002565	Respiratory Viruses DFA with Reflex to Respiratory Virus Mini Panel by RT-PCR					●						
95	585	0050465	Rheumatoid Factor				●							
96	594	0025023	Selenium, Serum				●							
96	597	0099375	Sex Hormone Binding Globulin				●							
96	601	0070283	Soluble Transferrin Receptor				●							
96	603	0081054	Squamous Cell Carcinoma Antigen, Serum			●								

HOT LINE Effective May 17, 2010

Hot Line Page #	LTD 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	New Test	Inactive
97	609	0060705	<i>Streptococcus</i> Group B by PCR				●	●	●					
97	613	0090944	Sulfonylurea Hypoglycemics, Serum or Plasma		●		●				●			
97	613	0091100	Sulfonylurea Hypoglycemics, Urine		●		●				●			
97	614	0040114	SYT-SSX t(X;18) Translocations by RT-PCR				●							
97	617	0070135	T3 Uptake						●					
98	619	0051428	Tay-Sachs (<i>HEXA</i>) 7 Mutations				●		●					
98	621	0081057	Testosterone, Bioavailable & Sex Hormone Binding Globulin (Includes Total Testosterone), Females or Children <i>(See 0081058 on pg 98)</i>					●						
98	622	0081058	Testosterone, Females or Children					●						
99	623	0081059	Testosterone Free, Females or Children				●							
98	622	0081056	Testosterone, Free & Total (Includes Sex Hormone Binding Globulin), Females or Children <i>(See 0081058 on pg 98)</i>					●						
65	625	0051508	Thanatophoric Dysplasia, Types 1 & 2 (<i>FGFR3</i>) 13 Mutations, Fetal <i>(See 0051737 on pg 65)</i>						●					
99	NEW	2002575	Thiopurine Metabolites Effective April 19, 2010										●	
99	626	0092066	Thiopurine Methyltransferase, RBC				●							
99	628	0030133	Thrombotic Risk, Inherited Etiologies (Most Common) with Reflex to Factor V Leiden								●			
99	629	0070421	Thyroglobulin, Serum or Plasma						●					
	630	0070141	Thyroid Panel <i>(See 0070140 on pg ??)</i>						●					
100	631	0070145	Thyroid Stimulating Hormone					●						
100	632	0070225	Thyroid Stimulating Hormone 3rd Generation					●						
100	633	0098720	Thyrotropin Releasing Hormone (TRH) Effective Immediately			●		●						

HOT LINE Effective May 17, 2010

Hot Line Page #	LTD 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	New Test	Inactive
100	633	0070140	Thyroxine					●	●					
101	633	0093244	Thyroxine, Free by Equilibrium Dialysis/ HPLC-Tandem Mass Spectrometry				●							
101	634	0070138	Thyroxine, Free (Free T4)					●						
101	635	0099187	Tissue Plasminogen Activator, Antigen				●							
101	NEW	2002550	Total Inhibin Effective April 19, 2010										●	
102	NEW	2002573	TPMT Genotype Effective April 19, 2010										●	
102	648	0093243	Triiodothyronine, Free by Equilibrium Dialysis/HPLC-Tandem Mass Spectrometry				●							
102	648	0070474	Triiodothyronine, Total (Total T3)				●	●						
103	NEW	2002939	Tysabri® Antibodies Effective April 19, 2010										●	
103	654	0051332	UDP Glucuronosyltransferase 1A1 (<i>UGT1A1</i>) Genotyping						●					
104	655	0020480	Urea Nitrogen, Urine				●							
104	655	0065031	<i>Ureaplasma urealyticum</i> & <i>Mycoplasma hominis</i> Culture			●	●							
104	657	0060131	Urine Culture				●							
104	665	0099435	Vasoactive Intestinal Peptide				●							
98	HL 8/09	2002028	Virilization Panel 1 (<i>See 0081058 on pg 98</i>)					●						
67 98	HL 11/09	2002281	Virilization Panel 2 (<i>See 0092332 on pg 67, and 0081058 on pg 98,</i>)					●						
105	668	0080389	Vitamin B ₁ (Thiamine), Plasma				●							
105	669	0070150	Vitamin B ₁₂				●							
105	670	0080385	Vitamin D, 1, 25-Dihydroxy				●		●					

HOT LINE Effective May 17, 2010

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.

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

2002647	Acute Lymphocytic Leukemia (ALL) Panel by FISH, Adult	FISH A ALL
Performed:	Sun-Sat	
Reported:	1-3 days	
2002719	Acute Lymphocytic Leukemia (ALL) Panel by FISH, Pediatric	FISH P ALL
Performed:	Sun-Sat	
Reported:	3-10 days	
2002653	Acute Myelogenous Leukemia (AML) with Myelodysplastic Syndrome (MDS), or Therapy-Related AML, by FISH	F TAML MDS
Performed:	Sun-Sat	
Reported:	3-10 days	
2002384	Acute Myelogenous Leukemia Panel by FISH	FISH AML P
Performed:	Sun-Sat	
Reported:	3-10 days	

HOT LINE Effective May 17, 2010

0060115 Aerobic Organism Identification MC ORG

Specimen Required: Collect: Actively growing isolated organism, in pure culture, on agar slant or on a swab in bacterial transport media. Source of specimen is required.
Transport: Sealed container at 20-25°C. **Submit specimen according to Biological Substance, Category B, shipping guidelines.**
Remarks: Indicate source of organism and any other pertinent information, including a warning if organism is suspected to be a dangerous pathogen (*Salmonella*, *Shigella*, *Neisseria meningitidis*, etc.). For suspected agents of bioterrorism, notify your state department of health and refer isolates to your state laboratory for identification. Susceptibilities on agents of bioterrorism are not performed at ARUP. The selection and extent of tests used for identification vary according to the specimen source and the type of organism suspected. **For identification of *E. coli* 0157:H7 order test *E. coli* Shiga-like toxin by EIA (0060047). For identification AND susceptibility testing order Aerobic Organism Identification with Reflex to Susceptibility (0065070).**
Unacceptable Conditions: Nonviable organisms, mixed cultures, or leaking **containers**.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: Unacceptable; Frozen: Unacceptable

0065070 Aerobic Organism Identification with Reflex to Susceptibility MC ORG1S

Specimen Required: Collect: Actively growing organism, in pure culture, on agar slant or on a swab in bacterial transport media. Source of specimen is required.
Transport: Sealed container at 20-25°C. Submit specimen according to **Biological Substance, Category B**, shipping guidelines.
Remarks: Indicate source of organism and any other pertinent information, including a warning if organism is suspected to be a dangerous pathogen (*Salmonella*, *Shigella*, *Neisseria meningitidis*, etc.). For suspected agents of bioterrorism, notify your state department of health and refer isolates to your state laboratory for identification. Susceptibilities on agents of bioterrorism are not performed at ARUP. The selection and extent of tests used for identification vary according to the specimen source, and the type of organism suspected. The susceptibility method and antibiotic panel will be selected based on organism identification. (Refer to Antimicrobial Susceptibility) Susceptibility testing will not be performed if inappropriate for source and/or organism.
Unacceptable Conditions: Nonviable organisms, mixed cultures, or leaking **containers**.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: Unacceptable; Frozen: Unacceptable

0020030 Albumin, Serum or Plasma by Spectrophotometry ALB

Specimen Required: Collect: One 4 mL serum separator tube or plasma separator tube.
Transport: 1 mL serum or plasma at 2-8°C. (Min: 0.2 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Allow specimen to clot completely at room temperature. Separate serum or plasma from cells ASAP.
Stability (collection to initiation of testing): After separation from cells: Ambient: **1 week**; Refrigerated: **5 months**; Frozen: 6 months

2002582 Aldosterone & Renin, Direct with Ratio A/DR

Specimen Required: Collect: One 6 mL plastic serum separator tube **and** one 5 mL lavender (EDTA) or pink (K₂EDTA).
Transport: 1 mL serum **and** 2 mL plasma (EDTA), frozen. (Min: 0.5 mL serum and 1 mL plasma) Submit specimens in an ARUP Standard Transport Tube.
Remarks: **Renin Direct: EDTA plasma is a CRITICAL FROZEN. Do not refrigerate. Do not collect in refrigerated tubes. Separate plasma from cells ASAP and freeze.**
Aldosterone: Serum specimen needs to be collected in a plastic tube. **Both specimens** should be drawn between 7:00 - 10:00 a.m. The patient must not have taken any antihypertensive medication for 8 days and have been supine or upright for more than two hours before specimen collection.
Unacceptable Conditions: Refrigerated plasma specimens. Hemolyzed specimens. Specimens collected in glass tubes.
Stability (collection to initiation of testing): **Refer to individual components.**

0020005 Alkaline Phosphatase, Serum or Plasma ALKP

Specimen Required: Collect: One 4 mL plasma separator tube or serum separator tube.
Transport: 1 mL serum or plasma at 2-8°C. (Min: 0.2 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Allow specimen to clot completely at room temperature. Separate serum or plasma from cells ASAP.
Unacceptable Conditions: Grossly hemolyzed specimens. Specimens collected in EDTA or sodium fluoride/potassium oxalate anticoagulant.
Stability (collection to initiation of testing): After separation from cells: Ambient: **1 week**; Refrigerated: **1 week**; Frozen: 2 months

HOT LINE Effective May 17, 2010

0051835 Allergens, Food, Shell Fish Profile SHELLFISH

Methodology: ImmunoCAP®
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Collect: One 6 mL serum separator tube.
Transport: 0.85 mL serum at 2-8°C. (Min: 0.48 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Multiple specimen tubes and multiple patient encounters should be avoided. Separate serum from cells ASAP.
Unacceptable Conditions: Hemolyzed, icteric and lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 2 days; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval: Allergens included: Crab, Shrimp, Blue Mussel, Lobster, Clam, Scallop, and Oyster.

Less than 0.10 kU/L: No significant level detected
 0.10-0.34 kU/L: Clinical relevance undetermined
 0.35-0.70 kU/L: Low
 0.71-3.50 kU/L: Moderate
 3.51-17.50 kU/L: High
 17.51 kU/L or Greater: Very High

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

CPT Code(s): 86003 per allergen

HOT LINE NOTE: This test was previously unpublished. Refer to Test Mix Addendum for Interface build information.

0050001 Alpha-1-Antitrypsin A1A

Specimen Required: Collect: One 4 mL plasma separator tube or serum separator tube. **Also acceptable:** lavender (EDTA) and pink (K₂EDTA).
Storage/Transport Temperature: 0.5 mL serum at 2-8°C. (Min: 0.2 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Allow specimen to clot completely at room temperature. Separate serum or plasma from cells ASAP. Avoid repeated freeze/thaw cycles.
Unacceptable Conditions: Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 5 days; Frozen: 3 Months

HOT LINE Effective May 17, 2010

0051256 Alpha-1-Antitrypsin (SERPINA1) Enzyme Concentration and 2 Mutations with Reflex to Alpha-1-Antitrypsin Phenotype A1A GENO

Specimen Required: Collect: One 4 mL plasma separator tube or serum separator tube and one 3 mL whole blood lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).
Transport: 0.5 mL serum or plasma and 3 mL whole blood at 2-8°C.
Remarks: For serum and plasma: Allow specimen to clot completely at room temperature. Separate serum or plasma from cells ASAP.
Stability (collection to initiation of testing): **Serum Specimen:** Ambient: 8 hours; Refrigerated: 5 days; Frozen: 2 weeks
Whole Blood Specimen: Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

CPT Code(s): 82103 A1A; 83891 Isolation; 83898 x2 Amplification; 83896 x4 Nucleic acid probes; 83912 Interpretation and report. If reflexed, add 82104 Phenotype. Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

HOT LINE NOTE: Please remove information from the Unacceptable Conditions field in Specimen Requirements.

0080427 Alpha Fetoprotein (Amniotic Fluid) with Reflex to Acetylcholinesterase and Fetal Hemoglobin AFP AF



Prenatal Test Request Form Recommended

Performed: Sun-Sat
Reported: 3-4 days
 If reflexed, Acetylcholinesterase results are reported 7-10 days after completion of the AFP.

Specimen Required: Collect: 2.5 mL amniotic fluid.
Transport: 2.5 mL amniotic fluid at 2-8°C.
Remarks: Include gestational age at time of collection on the test request form. **The following information is required and must accompany the specimen in order for testing to be interpreted:** 1) Patient's date of birth, 2) due date, 3) weeks of gestation, and 4) physician's name and phone number.
Unacceptable Conditions: Specimens contaminated with fetal blood.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 year

Note: Information must include weeks of gestation. If the AFP (amniotic fluid) is elevated, then acetylcholinesterase will be added. Acetylcholinesterase testing requires an additional 7-10 days to be reported.

CPT Code(s): 82106 AFP; if reflexed, add 82013 Acetylcholinesterase and 83033 Fetal Hemoglobin.

HOT LINE NOTE: Please note the removal of the Alpha Fetoprotein recommended Request Forms icon.

0080428 Alpha Fetoprotein, Serum (Tumor Marker) AFP TM

Specimen Required: Collect: One 4 mL serum separator tube.
Transport: 1 mL serum at 2-8°C. (Min: 0.5 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Allow specimen to clot completely at room temperature. Separate serum from cells ASAP.
Unacceptable Conditions: Grossly hemolyzed specimens, plasma specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 3 months

HOT LINE Effective May 17, 2010

0051495 Alpha Thalassemia (HBA1 & HBA2) 7 Deletions ALPHA THAL

Specimen Required: Collect: One 3 mL lavender (EDTA), **pink** (K₂EDTA), or **yellow** (ACD Solution A or B).
Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:

Background Information for Alpha Thalassemia (HBA1 & HBA2) 7 Deletions:

Characteristics: Alpha (+) thalassemia (silent carrier): Mutation of a single alpha2 globin gene (-α/αα); asymptomatic. Alpha (0) thalassemia (trait): Mutation of both alpha2 globin genes, or deletion of alpha1 and alpha2 globin genes in cis (-α/-α; -α/αα); mild microcytic anemia possible. Hemoglobin H disease: Mutation of three alpha globin genes (-α/-α); hemolysis with Heinz bodies, moderate anemia, splenomegaly. Hb Bart Hydrops Fetalis Syndrome: Mutation of four alpha globin genes (-α/-α); lethal in fetal or early neonatal period.

Incidence: Carrier frequency in Mediterranean (1:30-50), Middle Eastern, Southeast Asian (1:20), African, African-American (1:3).

Inheritance: Autosomal recessive.

Cause: Mutations in the alpha globin gene **cluster**; 95 **percent** are deletions.

Mutations Tested: -α3.7, -α4.2, -(α)20.5, --SEA, --MED, --FIL, --THAI

Clinical Sensitivity: Varies by ethnicity, may be as high as 90 **percent**.

Methodology: Polymerase chain reaction and gel electrophoresis.

Analytical Sensitivity and Specificity: Greater than 99 **percent**.

Limitations: Rare alpha globin gene deletions, non-deletion mutations, gene duplications, and mutations of the regulatory region will not be detected.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

CPT Code(s): **83891** Isolation; 83900 Amplification multiplex; 83901 x8 Additional amplification; 83894 Gel separation; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

0051710 Alport Syndrome, X-linked (COL4A5) 3 Mutations ALPORT DNA

Specimen Required: Collect: One 3 mL lavender (EDTA), **pink** (K₂EDTA), or **yellow** (ACD Solution A or B).
Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

HOT LINE NOTE: Please remove information from Unacceptable Conditions in Specimen Required field.

0099266 Aluminum, Serum AL S

Specimen Required: Collect: One 6 mL royal blue (no additives), or royal blue EDTA.
Transport: 2 mL serum or plasma at 20-25°C. (Min: 0.5 mL) Submit specimen in an ARUP Trace Element-Free Transport Tube. (ARUP supply #43116).
Remarks: Centrifuge and pour off serum or plasma into an ARUP Trace Element-Free Transport **Tube**. Do not allow serum or plasma to remain on cells.
Unacceptable Conditions: Separator tubes and specimens that are not separated from the red cells, or clot, **within 6 hours**.
Stability (collection to initiation of testing): If the specimen is drawn and stored in the appropriate container, the trace element values do not change with time.

0080276 Amniotic Bilirubin Scan AMBIL

Specimen Required: Collect: 3 mL amniotic fluid.
Transport: 3 mL amniotic fluid at 2-8°C. (Min: 2 mL) **Submit specimen in an ARUP Amber Transport Tube**.
Remarks: Protect from light during collection, storage, and shipment.
Unacceptable Conditions: **Specimens not protected from light**.
Stability (collection to initiation of testing): If specimen is protected from light: Ambient: 2 days; Refrigerated: 1 week; Frozen: 1 year

HOT LINE Effective May 17, 2010

0020506 Amylase, Body Fluid AMY-FL

Specimen Required: Collect: Body fluid. **Also acceptable:** Fluid specimens collected in plain red or green (sodium or lithium heparin) tubes.
Storage/Transport Temperature: 1 mL body fluid at 2-8°C. (Min: 0.2 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Centrifuge to remove cellular material. Indicate source on test request form.
Stability (collection to initiation of testing): After separation from cellular material: Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month

0040208 Aneuploidy Panel by FISH FISHANEU

Performed: Sun-Sat
Reported: 1-3 days

0051113 Angelman Syndrome by Methylation ANGEL

Specimen Required: Collect: One 3 mL lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).
Transport: 3 mL whole blood at 2-8°C. (Min: 3 mL)
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:

Background Information for Angelman Syndrome by Methylation:

Characteristics: Seizures, microcephaly, severe mental retardation, attention deficit hyperactivity disorder, severe speech difficulties, gait ataxia, and shakiness of the limbs.

Incidence: 1 in 15,000

Inheritance: Varies depending upon molecular genetic mechanism

Cause: Absence of the maternally imprinted AS/PWS critical region on chromosome 15q11.2-q13

Molecular Genetic Mechanisms: Microdeletions of the AS/PWS critical region (68 percent), UBE3A mutations (11 percent), paternal uniparental disomy of chromosome 15 (7 percent), imprinting defects (3 percent), unbalanced chromosome translocation (less than 1 percent), and unknown (11 percent).

Methods: Bisulfite conversion and PCR amplification to detect methylation using melting curve analysis.

Clinical Sensitivity: 78 percent. Analytical specificity and sensitivity are greater than 99 percent.

Test Limitations: Mutations in the UBE3A gene or mechanisms not affecting methylation patterns will not be detected.

Informed consent: Recommended, forms are available online at www.aruplab.com.

This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

CPT Code(s): 83891 Isolation; 83898 Amplification; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

HOT LINE NOTE: Please remove information from Unacceptable Conditions under Specimen Requirements field.

0098974 Angiotensin Converting Enzyme, CSF ACE CSF

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

HOT LINE Effective May 17, 2010

0050392 Ankylosing Spondylitis (HLA-B27) Genotyping**HLAB27 PCR****Interpretive Data:****Background Information for Ankylosing Spondylitis (HLA-B27) Genotyping:**

Characteristics: Ankylosing spondylitis (AS) is a chronic inflammatory disease that primarily causes pain and inflammation of the joints between the vertebrae of the spine and the sacroiliac joints. Inflammation and pain may occur in other parts of the body as well. HLA-B27 is strongly associated with ankylosing spondylitis (AS) as well as with Reiter syndrome, anterior uveitis, psoriatic arthritis, and inflammatory bowel disease.

Incidence: Greater than 90 percent of patients with AS are HLA-B27 positive compared to 5-10 percent of the general population.

Penetrance: Two to eight percent of individuals with HLA-B27 will develop AS.

Methodology: Polymerase chain reaction (PCR) and fluorescent hybridization probes.

Analytical Sensitivity & Specificity: 99 percent

Limitations: Rare alleles present in less than 1 percent of most populations will not be detected.

This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

HOT LINE Effective May 17, 2010

New Test 2002656 Anti-Mullerian Hormone

AMH

Effective April 19, 2010

Methodology: Enzyme-Linked Immunosorbent Assay
Performed: Wed
Reported: Within 8 days

Specimen Required: Collect: One 4 mL serum separator tube or plain red.
Transport: 0.5 mL serum, frozen. (Min: 0.2 mL)
Remarks: Avoid repeated freezing and thawing.
Unacceptable Conditions: Lipemic, hemolyzed, or ambient specimens.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 48 hours; Frozen: 30 days

Reference Interval:

Female	Male
0-16 years: 0.0-7.1 ng/mL	0-13 days: 15.50-48.10 ng/mL
17-29 years: 0.85-14.24 ng/mL	14 days-11 months: 39.10-91.10 ng/mL
30-39 years: 0.51-7.27 ng/mL	12 months-6 years: 48.00-83.20 ng/mL
40-49 years: 0.00-6.21 ng/mL	7-8 years: 33.80-60.20 ng/mL
50 years and older: 0.00-0.82 ng/mL	9-12 years: 6.1-60.7 ng/mL
	13-16 years: 2.3-33.1 ng/mL
	Adult males (17 and older): 1.50-18.35 ng/mL

Interpretive Data: Please refer to Statement D in the compliance statements section of the Laboratory Test Directory.

CPT Code(s): 83516

New York DOH approval pending. Call for status update.

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

0050811 Anti-Neutrophil Cytoplasmic Antibody, IgG

ANCA IFA

Note: Specimens are screened on ethanol-fixed slides which allow differentiation of C and P patterns. Negatives are reported. Positives are serially diluted and tested on ethanol-fixed slides to establish titer and confirm pattern. All P-ANCA patterns are also tested on formalin-fixed slides to confirm P-ANCAs by removing ANA receptor sites and maintaining cytoplasmic localization of myeloperoxidase or other antigens.

IFA is considered the screening procedure of choice for ANCAs. However, if confirmation of Anti-PR3 or confirmation of Anti-MPO in specimens positive for ANCA is desired, please contact Client Services at ARUP to order specific ELISA testing offered by ARUP. We retain specimens in the laboratory for four weeks and the ELISA tests can usually be performed on the same specimen if sufficient specimen was received and the appropriate test request is added. Refer also to **Anti-Neutrophil Cytoplasmic Antibody with Reflex to Titer & MPO/PR3 Antibodies (2002068)**.

0030192 APC Resistance Profile with Reflex to Factor V Leiden

APC R

Specimen Required: Collect: One 5 mL lt. blue (sodium citrate) **and** one 3 mL lavender (EDTA), **pink (K₂EDTA), or yellow (ACD Solution A or B)**.
Transport: 1.5 mL platelet-poor plasma, frozen **and** one 3 mL whole blood (EDTA) at 2-8°C. (Min: 1 mL of each)
Unacceptable Conditions: **Nonfrozen** specimens for APC.
Stability (collection to initiation of testing): APC - Ambient: 2 hours; Refrigerated: 4 hours; Frozen: 2 weeks
 FACV - Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

CPT Code(s): 85307 APC; if reflexed, add 83891 Isolation; 83896 Nucleic acid probes; 83898 Amplification; 83912 Interpretation and report; - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

HOT LINE Effective May 17, 2010

0055654 Apolipoprotein B (APOB) Mutation Detection

APO B

Specimen Required: Collect: One 3 mL lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).

Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)

Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:

Background information for Apolipoprotein B Mutation Detection:

Characteristics: Familial defective *APOB*-100 (FDB) is a disorder which increases an individual's risk for coronary artery disease. FDB is caused by mutations in the *APOB* gene that prevents the *APOB*-LDL complex from binding to the LDL receptor.

Incidence: 1.5 percent of familial hypercholesterolemia is due to an *APOB* gene mutation. The most common mutation, Arg3500Gln, has a frequency of 1/500-1/700 in Caucasian populations of North America and Europe. The rare Arg3500Trp mutation originally described in the Scottish population also has been identified in FDB of Asian descent (approximately 2 percent of FDB patients).

Inheritance: Autosomal dominant

Penetrance: Heterozygous carriers of an *APOB* mutation have an increased risk for coronary artery disease, although with a reduced penetrance. 40 percent of males and 20 percent of females heterozygous for these mutations develop coronary artery disease. Homozygotes or compound heterozygotes for R3500Q/R3500W are at greater risk for disease.

Cause: Ligand-defective apolipoprotein B-100.

Methodology: Patient DNA is assayed for Arg3500Gln and Arg3500Trp mutations in the *APOB* gene by polymerase chain reaction (PCR) and fluorescence monitoring using hybridization probes.

Analytical Sensitivity & Specificity: Sensitivity and specificity for detection of this mutation are 99.9 percent.

Limitations: Mutations in other genes or other mutations in the *APOB* gene that may cause familial hypercholesterolemia or increased risk for coronary artery disease are not ruled out.

This test is not recommended for nonsymptomatic patients under 18 years of age.

This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

CPT Code(s): 83891 Isolation; 83898 Amplification; 83896 x2 Nucleic acid probes; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

HOT LINE NOTE: Please remove information from Unacceptable Conditions field under Specimen Requirements.

HOT LINE Effective May 17, 2010

0055566 Apolipoprotein E (APOE) 2 Mutations, Cardiovascular Risk APO E

Specimen Required: Collect: One 3 mL lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).
Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:

Background Information for Apolipoprotein E (APOE) 2 Mutations, Cardiovascular Risk:

Characteristics: Hyperlipoproteinemia III (HPL III) is characterized by increased cholesterol and triglyceride levels, presence of B-VLDL, xanthomas, and premature vascular disease including coronary heart disease (CHD) and peripheral artery disease.

Incidence of HPL III: Approximately 1 in 5,000.

Inheritance: Autosomal recessive.

Penetrance: 1 to 5 percent of individuals homozygous for the E2 allele and 26 percent of those heterozygous for both E2 and familial hypercholesterolemia will develop symptoms.

Cause: The E2 isoform binds the lipoprotein receptors with only 2 percent of the affinity of E3 and E4 resulting in impaired clearance of chylomicron and VLDL remnants and increased plasma cholesterol and triglyceride levels.

Mutations Tested: E2, E3 (normal) and E4 alleles of the apolipoprotein E gene.

Clinical Sensitivity: About 5 percent of individuals with premature CHD are homozygous for E2.

Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring using hybridization probes.

Analytical Sensitivity and Specificity: 99 percent.

Limitations: Rare isoforms of APOE will not be detected. If rare alleles are suspected, phenotyping by isoelectric focusing may be indicated. Rare diagnostic errors can occur due to primer site mutations.

This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

CPT Code(s): 83891 Isolation; 83898 Amplification; 83896 x2 Nucleic acid probes; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

HOT LINE NOTE: Please remove information from Unacceptable Conditions field under Specimen Requirements.

0020734 Arsenic, Fractionated, Urine AS UF

Interpretive Data: Specific toxic thresholds for arsenic are not well defined. The ACGIH Biological Exposure Index is 35 µg/L for the sum of the inorganic and methylated forms of arsenic. For specimens with a total arsenic concentration between 35-2000 µg/L, fractionation is performed to determine the proportion of organic, inorganic, and methylated forms. If low-level chronic poisoning is suspected, the µg/gCRT ratio may be more sensitive than the total arsenic concentration. It may be appropriate to fractionate specimens with a µg/gCRT ratio greater than 30 µg/gCRT despite a total arsenic concentration less than 35 µg/L. The laboratory will perform this fractionation on request.

The organic forms of arsenic, most commonly arsenobetaine, are considered nontoxic and arise primarily from food. Inorganic forms of arsenic [As(III) and As(V)] are most toxic. Methylated forms (MMA and DMA) arise primarily from metabolism of inorganic forms but may also come from dietary sources and are of moderate toxic potential. As this test does not detect all species of arsenic, it is expected that the sum of the organic, inorganic, and methylated forms will not equal the total arsenic concentration.

DELETE 0090216 Arsenic, Tissue ARSENIC T

HOT LINE NOTE: Please delete this test. No referral available.

HOT LINE Effective May 17, 2010

DELETE 0093013 Bacterial Antigen Detection BAD MRL

HOT LINE NOTE: Please delete this test. No referral available.

0055557 bcl-1/JH, t(11;14) Translocation by PCR, Fluid BCL1-F

Reference Interval: Refer to report

CPT Code(s): 83891 Isolation; 83898 x3 Amplification; 83894 x2 Gel separation; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

0055622 bcl-1/JH, t(11;14) Translocation by PCR, Paraffin BCL1-P

Specimen Required: Collect: Tumor tissue.

Transport: Four 10 micron shavings from a formalin-fixed, paraffin-embedded tissue block at 20-25°C.

Remarks: Tissue block is also an acceptable specimen type and will be returned after testing.

Unacceptable Conditions: Heavy metal based (B-4 or B-5) fixed paraffin-embedded tissue.

Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Indefinitely

Reference Interval: Refer to report

CPT Code(s): 83907 Lysis; 83891 Isolation; 83898 x3 Amplification; 83894 x2 Gel separation; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

0055564 bcl-1/JH, t(11;14) Translocation by PCR, Tissue BCL1-T

CPT Code(s): 83891 Isolation; 83898 x3 Amplification; 83894 x2 Gel separation; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

0040138 BCR-ABL1 Kinase Domain Mutation Analysis BCRABL MUT

Interpretive Data: Refer to report

Please refer to Statement B in the Compliance Statements section in the front of the Laboratory Test Directory.

CPT Code(s): 83891 Isolation; 83902 Reverse transcription; 83898 x4 Amplification; 83894 Gel detection; 83912 Interpretation and report. If sequencing is performed, add: 83892 Enzyme digestion; 83904 Sequencing and 83909 Capillary electrophoresis. Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

2002464 Bence Jones Protein Detection, Quantitation & Characterization with Reflex to Quantitative Free Kappa & Lambda Light Chains, Urine. (Test Orderable by University of Utah Only) BJP-U REFLEX

Specimen Required: Collect: Collect: 24-hour urine. Urine **supernatant** is also acceptable. Specimen needs to be refrigerated during collection.

Storage/Transport Temperature: Two 4.5 mL aliquots from a well-mixed 24-hour collection at 2-8Min: 4.5 mL) Submit specimen in two ARUP Standard Transport Tubes.

Remarks: Keep refrigerated at all times. Record total volume and collection time interval on transport tube and test request form.

Unacceptable Conditions: Specimens that are not refrigerated.

Stability (collection to initiation of testing): Ambient: 2 hours; Refrigerated: 1 week; Frozen: 1 month

Note: If Paraprotein%, Urine is **resulted as Trace or with a numeric value**, Kappa and Lambda Free Light Chains, Urine **will be added**.

HOT LINE Effective May 17, 2010

0051288

Beta-2-Adrenergic Receptor (*ADRB2*) Haplotyping

ADRB2 HAP

Specimen Required: Collect: One 3 mL lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).

Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)

Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:

Background Information for Beta-2-Adrenergic Receptor (*ADRB2*) Haplotyping:

Characteristics: The *ADRB2* gene encodes for the beta-2-adrenergic receptors expressed on many cell types including cells of the airways, the vascular and immune systems, and fat cells. Binding and release of epinephrine and norepinephrine, the natural ligands on the receptor, regulates cardiac, pulmonary, vascular, immunologic, and metabolic functions. The beta-2-adrenergic receptors are the targets of beta-agonists drugs. *ADRB2* appears to be one of the multiple genetic players in asthma, vascular disease, obesity and drug response.

Genetics: At least twelve haplotypes of the *ADRB2* gene have been described using 13 polymorphic sites. The three haplotypes (Gly16-Glu27, Arg16-Gln27 and Gly16-Gln27) are the most common. Arg16 and Gln27 are in strong linkage disequilibrium. Arg16 has been found associated with Glu27 in less than 0.5 percent of chromosomes.

Mutations Tested: Arg16Gly (c.46A>G), Gln27Glu (c.79C>G) and the three main haplotypes Gly16-Glu27, Arg16-Gln27, and Gly16-Gln27.

Methodology: PCR and fluorescence analysis by haplotyping hybridization probes. In addition to genotyping each mutation tested, this test directly establishes the haplotype (whether or not the two mutations are found on the same or different chromosomes).

Limitations: Mutations and haplotypes situated outside of the studied area of the gene are not analyzed. Other and non-described mutations and haplotypes can be revealed by the assay. Medical significance of the polymorphisms and their haplotypes in the different diseases (asthma, obesity, hypertension, and drug response) are continually being investigated.

Analytical Sensitivity: The assay determines the haplotypes of approximately 99 percent of chromosomes.

This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

CPT Code(s): 83891 Isolation; 83898 Amplification; 83896 x2 Nucleic acid probe; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

HOT LINE Effective May 17, 2010

2002569 Beta-2 Glycoprotein 1 Antibodies, IgG, IgM & IgA B2GPI PAN3

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

Specimen Required: Collect: Two 4 mL serum separator tubes.
Transport: 1.5 mL serum at 2-8°C. (Min: 0.5 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Separate serum from cells ASAP.
Unacceptable Conditions: Plasma or other body fluids. Severely lipemic, contaminated, or hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 2 days; Refrigerated: 2 weeks;
 Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval:

Available Separately	Components	Reference Interval
Yes as (0050321)	Beta-2 Glycoprotein 1 Antibody, IgG	0-20 SGU
	Beta-2 Glycoprotein 1 Antibody, IgM	0-20 SMU
Yes (0050324)	Beta-2 Glycoprotein 1 Antibody, IgA	0-20 SAU

Interpretive Data: An IgG and/or IgM result of greater than 20 SGU and/or SMU on at least two occasions and at least 12 weeks apart is suggestive of antiphospholipid syndrome. Diagnosis should NOT be made solely on the basis of a single specimen.

CPT Code(s): 86146 Beta-2 Glycoprotein I, IgG; 86146 Beta-2 Glycoprotein I, IgM; 86146 Beta-2 Glycoprotein I, IgA

HOT LINE NOTE: This test was previously unpublished. Refer to Test Mix Addendum for Interface build information.

0080054 Beta-2 Microglobulin, CSF B2M CSF

Specimen Required: Collect: CSF.
Storage/Transport Temperature: 0.5 mL CSF at 2-8°C. (Min: 0.4 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Centrifuge to remove cellular material. **Also acceptable: CSF specimens collected in plain red or green (sodium or lithium heparin) tubes.**
Stability (collection to initiation of testing): After separation from cellular material: Ambient: 8 hours; Refrigerated: 1 week;
 Frozen: 2 weeks

HOT LINE Effective May 17, 2010

0051421 Beta Globin (HBB) HbS, HbC, & HbE Mutations HB SCE

Specimen Required: Collect: One 3 mL lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).
Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:

Background information for Beta Globin (HBB) HbS, HbC, & HbE Mutations:

Characteristics: Sickle cell disease results in vascular occlusion and tissue ischemia, and acute or chronic organ dysfunction. Milder forms present with hemolytic anemia.

Incidence: Sickle cell affects 1 in 250-600 African-Americans. HbS causes 60 to 70 percent of sickle cell disease in the United States (1 in 2000 individuals). Carrier frequency of HbS is 8-10 percent in African-Americans. HbS is common in sub-Saharan Africa, India, and the Middle East. HbC is common in West Africa. HbE is common in Southeast Asia.

Inheritance: Autosomal recessive.

Cause: Beta globin gene (*HbB*) missense mutations. The three detected mutations, HbS, HbC, and HbE, have one amino acid change in the beta globin chain. While HbS and HbC result in abnormal beta chain structure, the HbE mutation affects splicing efficiency, resulting in decreased amounts of beta chain.

Mutations Tested: c.19G>A (HbC), c.20A>T (HbS), c.79G>A (HbE).

Clinical Sensitivity: Greater than 70 percent for sickle cell disease; other hemoglobinopathies vary depending upon patient's ethnicity.

Methodology: PCR and fluorescence resonance energy transfer.

Analytic Sensitivity: Greater than 99 percent.

Limitations: Mutations other than c.19G>A (HbC), c.20A>T (HbS), c.79G>A (HbE) will not be detected.

This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

CPT Code(s): 83891 Isolation; 83898 x2 Amplification; 83896 x3 Nucleic acid probe; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

0020730 Beta-hCG, Quantitative (Tumor Marker), CSF BHCG CSF

Specimen Required: Collect: CSF.
Storage/Transport Temperature: 0.5 mL CSF at 2-8°C. (Min: 0.2 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Also acceptable: CSF collected in plain red or green (sodium or lithium heparin) tubes.
Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: 1 week; Frozen: 2 months

0070029 Beta-hCG, Quantitative (Tumor Marker) BHCG TM

Specimen Required: Collect: One 4 mL serum separator tube. Also acceptable: lavender (EDTA), pink (K₂EDTA) or green (sodium or lithium heparin).
Storage/Transport Temperature: 1 mL serum or plasma at 2-8°C. (Min: 0.4 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Allow specimen to clot completely at room temperature. Separate from cells ASAP.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 2 months

0020032 Bilirubin, Total, Serum or Plasma BILIT

Specimen Required: Collect: One 4 mL plasma separator tube or serum separator tube. Also acceptable: lavender (EDTA), pink (K₂EDTA) or green (sodium or lithium heparin).
Storage/Transport Temperature: 1 mL serum or plasma at 2-8°C. (Min: 0.2 mL) Submit specimen in an ARUP Amber Transport Tube.
Remarks: Allow specimen to clot completely at room temperature. Separate serum or plasma from cells ASAP. Protect from light during collection, storage and shipment.
Stability (collection to initiation of testing): After separation from cells and if protected from light: Ambient: 4 hours; Refrigerated: 1 week; Frozen: 6 months

HOT LINE Effective May 17, 2010

New Test 2002926 *Blastomyces dermatitidis* Antigen EIA **BLAST DERM**

Effective April 19, 2010

Methodology: Enzyme Immunoassay
Performed: Varies
Reported: Varies

Specimen Required: Collect: Random urine, serum: plain red or serum separator tube, plasma: green (sodium or lithium heparin). CSF and BAL are also acceptable specimen types.
Specimen Preparation: Submit specimen in an ARUP Standard Transport Tube.
Transport: 2 mL urine, serum, or plasma at 20-25°C. (Min: 2 mL)
Unacceptable Conditions: EDTA plasma.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 month; Frozen: Indefinitely

Reference Interval: By report

CPT Code(s): 87449

This test is New York DOH approved.

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

0060102 Blood Culture MC BLD

Methodology: Bactec® continuous monitoring system. Standard reference procedures for identification of aerobic and anaerobic microorganisms

Specimen Required: Collect: Blood in a Bactec® aerobic resin bottle and standard anaerobic bottle using aseptic techniques, as defined for blood culture collection. Site of specimen draw is required (e.g. left antecubital, A-line, etc). Testing is limited to the University of Utah Health Sciences Center only.
Minimum pediatric: 1 mL blood (1-3 mL recommended).
Minimum adult: 3 mL blood; **aerobic: 8-10 mL recommended, anaerobic: 5-7 mL recommended.**
 * Low volume will result in decreased recovery of pathogens.
Transport: **Transport** immediately to ARUP at 20-25°C. Submit specimen according to Biological Substance, Category B, shipping guidelines.
Remarks: Client will be notified of positive cultures. Note **in the order if the patient** is suspected of having *Bartonella*, *Brucella*, or any other unusual organism. Refer to *Brucella* Culture (0060159) or *Legionella* Species Culture (0060113) for additional information.
Unacceptable Conditions: More than four blood culture sets per 24 hours.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

HOT LINE Effective May 17, 2010

0051433 Bloom (*BLM*) 2281del6/ins7 Mutation

BLM

Specimen Required: Collect: One 3 mL lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).

Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)

Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:

Background information for Bloom (*BLM*) 2281del6/ins7 Mutation:

Characteristics: Pre- and postnatal growth deficiency, sparse subcutaneous tissue, sun-sensitive telangiectatic hypo- and hyperpigmented skin lesions, and chromosome instability causing benign and malignant tumors early in life.

Incidence: 1 in 40,000 in Ashkenazi Jewish individuals, unknown in other ethnicities.

Inheritance: Autosomal recessive.

Cause: Deleterious *BLM* gene mutations.

Mutation Tested: 2281del6/ins7.

Clinical Sensitivity: 95 percent in Ashkenazi Jewish individuals.

Methodology: Genomic DNA is assayed by PCR and allele-specific primer extension by bead array with fluorescence detection.

Analytical sensitivity and specificity: Greater than 99 percent.

Limitations: Mutations other than 2281del6/ins7 will not be detected. Rare diagnostic errors may occur due to primer site mutations.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

HOT LINE Effective May 17, 2010

0050135 *Brucella* Total Antibody, Agglutination

BRUC

HOT LINE NOTE: Name change only.

***New Test* 2002853 *Brucella* Antibodies, IgG & IgM by ELISA & Bacterial Agglutination**

BRUCELLA

Effective April 19, 2010

Methodology: Enzyme-Linked Immunosorbent Assay/Bacterial Agglutination
Performed: Mon-Fri
Reported: 2-5 days

Specimen Required: Collect: One 4 mL serum separator tube or plain red.
Transport: 1 mL serum at 2-8°C. (Min: 0.5 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Acute and convalescent specimens must be labeled as such; parallel testing is preferred and convalescent specimens **must** be received within 30 days from receipt of the acute specimens. **Please mark specimen plainly as “acute” or “convalescent.”**
Unacceptable Conditions: Hemolyzed, lipemic, heat-inactivated, or contaminated specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 2 days; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval:

Available Separately	Components	Reference Interval
Yes (0050135)	<i>Brucella</i> Total Antibody, Agglutination	Less than 1:80 Negative
No	<i>Brucella</i> Antibody, IgG by ELISA	0.89 IV or less: Negative - No significant level of detectable <i>Brucella</i> IgG antibody. 0.90-1.10 IV: Equivocal - Questionable presence of <i>Brucella</i> IgG antibody. Repeat testing in 10-14 days may be helpful. 1.11 IV or greater: Positive - IgG antibody to <i>Brucella</i> detected, which may indicate current or past infection.
No	<i>Brucella</i> Antibody, IgM by ELISA	0.89 IV or less: Negative - No significant level of detectable <i>Brucella</i> IgM antibody. 0.90-1.10 IV: Equivocal - Questionable presence of <i>Brucella</i> IgM antibody. Repeat testing in 10-14 days may be helpful. 1.11 IV or greater: Positive - IgM antibody to <i>Brucella</i> detected, which may indicate current or recent infection. However, low levels of IgM antibodies may occasionally persist for more than 12 months post-infection.

Interpretive Data:

Brucella Total Antibody, Agglutination: Cross-reactions may occur between *Brucella* and *F. tularensis* antigens and antisera, therefore, parallel tests should be run with these antigens. A fourfold rise in titer greater than or equal to 1:160 is considered diagnostic. A single serum titer of 1:160 or 1:320 is suggestive of brucellosis when accompanied by a compatible clinical course in a patient with a history of potential exposures.

Brucella Antibody, IgG and IgM by ELISA: CDC has recommended that specimens testing positive or equivocal for *Brucella* antibodies by an ELISA method be confirmed by bacterial agglutination. The best evidence for current infection is a significant change on two appropriately timed specimens, where both tests are done in the same laboratory at the same time. This assay may not detect antibodies to *B. canis*.

Please refer to Statement D in the Compliance Statements section of the Laboratory Test Directory.

CPT Code(s): 86622 *Brucella* IgG; 86622 *Brucella* IgM; 86622 *Brucella* Antibody

New York DOH approval pending. Call for status update.

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

HOT LINE Effective May 17, 2010

0060159***Brucella Culture*****MC BRUC**

Specimen Required: Collect: Blood (optimum), CSF, body fluids, abscess, aspirate, tissues. Source of specimen is preferred.

Minimum pediatric: 1 mL blood (1 - 3 mL. recommended)

Minimum adult: 3 mL blood* (8 - 10 recommended) * Low volume will result in decreased recovery of pathogens.

Storage/Transport Temperature: Blood in **vacutainer, 8 mL SPS for microbiology (ARUP Supply #24964)** or Bactec® Blood Culture bottles; sterile container (others) at 20-25°C. Submit specimen according to Biological Substance, Category B, shipping guidelines.

Unacceptable Conditions: Nonsterile or leaking containers, swabs, clotted blood specimens, specimens submitted in anticoagulant other than SPS.

Stability (collection to initiation of testing): Ambient: **48 hours**; Refrigerated: Unacceptable; Frozen: Unacceptable

HOT LINE NOTE: Please remove the information from the Remarks field under Specimen Requirements.

HOT LINE Effective May 17, 2010

0030191 B-Type Natriuretic Peptide

BNP

Specimen Required: Collect: One 3 mL lavender (EDTA) or pink (K₂EDTA).

Transport: 2 mL plasma, frozen. (Min: 0.5 mL) Submit specimen in an ARUP Standard Transport Tube.

Remarks: **Separate** plasma from cells ASAP. **Freeze plasma within four hours of collection.**

Unacceptable Conditions: Hemolyzed specimens collected in non-EDTA tubes. Specimens frozen in separator tube. Frozen whole blood. Specimen exposed to repeated freeze/thaw cycles. Ambient or refrigerated specimens **more than 4 hours old.**

Stability (collection to initiation of testing): After separation from cells: Ambient: 4 hours; Refrigerated: 4 hours; Frozen: 4 months

0020472 Calcium, Urine

UCA

Reference Interval:

Available Separately	Components	Reference Interval		
No	Calcium free diet: 5-40 mg/d	5-40 mg/d		
No	Low Calcium Diet (800 mg/d or less):	50-150 mg/d		
No	Average Calcium diet (about 800 mg/d):	100-250 mg/d		
No	High Calcium diet (800 mg/d or greater):	250 mg/d or greater		
Yes (0020473)	Creatinine (24-hour)	Male	Female	
		3-8 years: 140-700 mg/d 9-12 years: 300-1300 mg/d 13-17 years: 500-2300 mg/d 18-50 years: 1000-2500 mg/d 51-80 years: 800-2100 mg/d 81 years and older: 600-2000 mg/d	3-8 years: 140-700 mg/d 9-12 years: 300-1300 mg/d 13-17 years: 400-1600 mg/d 18-50 years: 700-1600 mg/d 51-80 years: 500-1400 mg/d 81 years and older: 400-1300 mg/d	
No	Calcium/Creatinine Ratio, Urine	Age 0-11 months 12-23 months 24-35 months 3-4 years 5-6 years 7-9 years 10-12 years 13-15 years 16-17 years 18 years and older	Male 30-810 mg/g 30-560 mg/g 20-500 mg/g 20-410 mg/g 10-300 mg/g 6-431 mg/g 8-300 mg/g 6-293 mg/g 10-264 mg/g 20-240 mg/g	Female 30-810 mg/g 30-560 mg/g 20-500 mg/g 20-410 mg/g 10-300 mg/g 11-457 mg/g 12-309 mg/g 8-313 mg/g 20-271 mg/g 20-300 mg/g

0092303 Calprotectin, Fecal

CALPRO

HOT LINE NOTE: Additional component information associated with this test that affects interface clients only:

Code	Test Name	Change	Order/Result	Comments
0092303	Calprotectin, Fecal	Add Component	O	Add component 2002714

HOT LINE Effective May 17, 2010

0058002 *Campylobacter Antigen* **CAMPY**

Methodology: Immunochromatographic Assay

Specimen Required: Collect: Stool.

Specimen Preparation: Unpreserved stool in clean vial (5 g) (ARUP Supply # 40910) or stool in enteric transport media (Cary-Blair) within one hour of collection. (ARUP Supply #29799)

Storage/Transport Temperature: Unpreserved stool, frozen. (Min: 1 g) or stool in enteric transport media (Cary-Blair) at 2-8°C.

Submit specimen according to Biological Substance, Category B, shipping guidelines.

Unacceptable Conditions: Other transport medias, (i.e.10% formalin, SAF, or PVA).

Stability (collection to initiation of testing): Unpreserved/Preserved: Ambient: Unacceptable; Refrigerated: 4 days; Frozen: 2 weeks.

CPT Code(s): 87899

0051453 *Canavan Disease (ASPA) 4 Mutations* **ASPA**

Specimen Required: Collect: One 3 mL lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).

Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)

Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:

Background information for Canavan Disease (ASPA) 4 Mutations:

Characteristics: A neurodegenerative brain disorder resulting in macrocephaly and lack of head control by three to five months of age. Affected individuals fail to achieve sitting, ambulation, or speech, and often die in early childhood to teen years.

Incidence: 1 in 10,000 Ashkenazi Jewish individuals, unknown in other ethnicities.

Inheritance: Autosomal recessive.

Cause: Deleterious *ASPA* gene mutations.

Mutations Tested: Y231X(C>A), E285A, A305E, 433(-2)A>G; benign polymorphism Y231Y(C>T).

Clinical Sensitivity: 98 percent in Ashkenazi Jewish; 55 percent in non-Ashkenazi Jewish.

Methodology: Genomic DNA is assayed by PCR and allele-specific primer extension by bead array with fluorescence detection.

Analytical Sensitivity and Specificity: Greater than 99 percent.

Limitations: Deleterious mutations other than Y231X, E285A, A305E, 433(-2)A>G will not be detected. Rare diagnostic errors may occur due to primer site mutations.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

HOT LINE Effective May 17, 2010

0080055	Carotene, Serum Total	CARO
<p>Specimen Required: Patient Preparation: Fasting specimens preferred. <u>Collect:</u> One 4 mL serum separator tube. <u>Storage/Transport Temperature:</u> 3 mL serum, frozen. (Min: 1.1 mL) Submit specimen in an ARUP Amber Transport Tube. <u>Remarks:</u> CRITICAL - Protect from light during collection, storage, and shipping. Separate specimens must be submitted when multiple tests are ordered. <u>Unacceptable Conditions:</u> Ambient, refrigerated, icteric, or hemolyzed specimens. <u>Stability (collection to initiation of testing):</u> After separation from cells: Ambient: Unacceptable; Refrigerated: 4 hours; Frozen: 1 month</p>		
0021021	Carotenes, Fractionated, Plasma or Serum	CARO FRAC
Performed:	Mon, Wed, Fri	
Reported:	1-5 days	
0040203	Chorionic Villus, FISH	FISHCVS
Performed:	Sun-Sat	
Reported:	1-3 days	
0098830	Chromium, Serum	CR S
<p>Specimen Required: <u>Collect:</u> One 6 mL royal blue (no additive). <u>Transport:</u> 2 mL serum at 20-25°C. (Min: 0.5 mL) Submit specimen in an ARUP Trace Element-Free Transport Tube (ARUP supply #43116). <u>Remarks:</u> Centrifuge and pour off serum into an ARUP Trace Element-Free Transport Tube ASAP. Do not allow serum to remain on cells. <u>Unacceptable Conditions:</u> Separator tubes and specimens that are not separated from the red cells, or clot, within 6 hours. <u>Stability (collection to initiation of testing):</u> If the specimen is drawn and stored in the appropriate container, the trace element values do not change with time.</p>		
2002293	Chromosome Analysis, Amniotic Fluid	CHR AF
Performed:	Sun-Sat	
Reported:	7-14 Days	
2002292	Chromosome Analysis, Bone Marrow	CHR BM
Performed:	Sun-Sat	
Reported:	3-10 Days	
2002291	Chromosome Analysis, Chorionic Villus	CHR CVS
Performed:	Sun-Sat	
Reported:	7-14 days	
2002290	Chromosome Analysis, Leukemic Blood	CHR LKB
Performed:	Sun-Sat	
Reported:	3-10 days	
2002300	Chromosome Analysis, Lymph Node	CHR ONC
Performed:	Sun-Sat	
Reported:	3-10 days	

HOT LINE Effective May 17, 2010

2002289	Chromosome Analysis, Peripheral Blood	CHR PB
Performed:	Sun-Sat	
Reported:	3-10 days	
2002287	Chromosome Analysis, Rule Out Mosaicism	CHR R/OM
Performed:	Sun-Sat	
Reported:	3-10 days	
2002296	Chromosome Analysis, Solid Tumor	CHR ST
Performed:	Sun-Sat	
Reported:	7-14 days	
2002295	Chromosome FISH, CLL Panel	FISH CLLP
Performed:	Sun-Sat	
Reported:	3-10 days	
2002298	Chromosome FISH, Interphase	CHR FISHI
Performed:	Sun-Sat	
Reported:	3-10 days	
2002299	Chromosome FISH, Metaphase	CHR FISHM
Performed:	Sun-Sat	
Reported:	3-10 days	
2002297	Chromosome FISH, Prenatal	CHR FISHP
Performed:	Sun-Sat	
Reported:	1-3 days	
2002022	Chronic Urticaria Index™ Panel	INDEX PAN
<p>Specimen Required: <u>Patient Preparation:</u> Patients taking calcineurin inhibitors should stop their medication 72 hours prior to draw. Patients on prednisone should be off their medication 2 weeks prior to draw.</p> <p><u>Collect:</u> Plain red or serum separator tube.</p> <p><u>Specimen Preparation:</u> Allow specimen to clot completely at room temperature before centrifuging. Submit specimen in an ARUP Standard Transport Tube.</p> <p><u>Storage/Transport Temperature:</u> 3 mL serum at 20-25°C. (Min: 1.5 mL)</p> <p><u>Stability (collection to initiation of testing):</u> Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 1 year</p>		

HOT LINE NOTE: Please remove the information from the Remarks field under Specimen Requirements.

HOT LINE Effective May 17, 2010

New Test **2002552** ***Clostridium difficile* Cytotoxin Antibody** **CDIFF AB**

Effective April 19, 2010

Methodology: Neutralization
Performed: Varies
Reported: Varies

Specimen Required: Collect: One 5 mL plain red.
Transport: 1 mL serum at 2-8°C. Submit specimen in an ARUP Standard Transport Tube.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 1 week

Reference Interval: By report

CPT Code(s): 87230

New York DOH approval pending. Call for status update.

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

New Test **2002838** ***Clostridium difficile* toxin B gene (tcdB) by PCR** **CDIFF PCR**

Effective April 19, 2010

Methodology: Polymerase Chain Reaction
Performed: Sun-Sat
Reported: Within 1-2 days

Specimen Required: Collect: Soft or liquid stool in clean, unpreserved transport vial (ARUP Supply# 40910).
Transport: Liquid or soft stool specimens at 2 -8°C. Submit specimen according to Biological Substance, Category B shipping guidelines.
Unacceptable Conditions: Formed stool, specimens other than liquid or soft stool, stool collected in containers containing preservatives.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 5 days; Frozen: 1 month

Reference Interval: Not detected

CPT Code(s): 87493

This test is New York DOH approved.

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

0025037 **Cobalt, Serum or Plasma** **COBALT S**

Specimen Required: Collect: One 6 mL royal blue (no additive), or royal blue EDTA.
Transport: 2 mL serum or plasma at 20-25°C. (Min: 0.5 mL) Submit specimen in an ARUP Trace Element-Free Transport Tube. (ARUP supply #43116).
Remarks: Centrifuge and pour off serum or plasma into an ARUP Trace Element-Free Transport Tube. Do not allow serum to remain on cells.
Unacceptable Conditions: Separator tubes and specimens that are not separated from the red cells, or clot, **within 6 hours**.
Stability (collection to initiation of testing): If the specimen is drawn and stored in the appropriate container, the trace element values do not change with time.

HOT LINE Effective May 17, 2010

0050155 Complement Component 4 C4

Specimen Required: Collect: One 4 mL serum separator tube. **Also acceptable:** lavender (EDTA), pink (K₂EDTA), or green (sodium or lithium heparin)
Transport: 0.5 mL serum, frozen. (Min: 0.3 mL)
Remarks: Allow specimen to clot at 20-25°C. Separate serum from cells ASAP and freeze.
Unacceptable Conditions: Specimens left to clot at 2-8°C.
Stability (collection to initiation of testing): Ambient: **2 Days**; Refrigerated: **2 Days**; Frozen: 2 weeks (avoid repeated freeze/thaw cycles)

0020096 Copper, Serum COPPER

Specimen Required: Collect: One 6 mL royal blue (no additive), or royal blue EDTA.
Transport: 2 mL serum or plasma at 20-25°C. (Min: 0.5 mL) Submit specimen in an ARUP Trace Element-Free Transport Tube. (ARUP supply #43116).
Remarks: Centrifuge and pour off serum or plasma into an ARUP Trace Element-Free Transport **Tube**. Do not allow serum or plasma to remain on cells.
Unacceptable Conditions: Separator tubes and specimens that are not separated from the red cells, or clot, **within 6 hours**.
Stability (collection to initiation of testing): If the specimen is drawn and stored in the appropriate container, the trace element values do not change with time.

New Test 2002932 Coxsackie A Antibodies (A-2, 4, 7, 9, 10 & 16 Serotypes) COX A AB

Effective April 19, 2010

Methodology: Complement Fixation
Performed: Varies
Reported: Varies

Specimen Required: Collect: Plain red or serum separator tube.
Specimen Preparation: Submit specimen in an ARUP standard transport tube.
Transport: 2 mL serum at 20-25°C. (Min: 1 mL)
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 1 month

Reference Interval: By report

CPT Code(s): 86658 x6 A-2, 4, 7, 9, 10 and 16 serotypes

This test is New York DOH approved.

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

HOT LINE Effective May 17, 2010

0070103 C-Peptide, Serum or Plasma C PEP

Specimen Required: Collect: One 4 mL serum separator tube or plasma separator tube. Fasting specimen preferred. Also acceptable: green (sodium or lithium heparin), lavender (EDTA), or pink (K₂EDTA).
Transport: 1 mL serum or plasma, frozen. (Min: 0.5 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Allow specimen to clot completely at room temperature. Separate serum or plasma from cells ASAP.
Unacceptable Conditions: Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 2 days; Frozen: 1 month

2001613 Crohn Disease Prognostic Panel CROHN PAN

Specimen Required: Collect: One 4 mL serum separator tube.
Storage/Transport Temperature: 1 mL serum or plasma (EDTA or heparin) at 2-8°C (Min: 0.25 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Separate serum from cells ASAP.
Stability (collection to initiation of testing): After separation from cells: Ambient: 2 days; Refrigerated: 2 weeks; Frozen: 1 year

HOT LINE NOTE: Please remove the information from Unacceptable Conditions under Specimen Requirements.

0050098 Cystic Fibrosis (CFTR) 3199del6 Mutation CF3199DEL6

Specimen Required: Collect: One 3 mL lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).
Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:

Background Information for Cystic Fibrosis (CFTR) 3199Del6 Mutation:

Characteristics: The 3199del6 mutation is offered to individuals who have a documented I148T mutation from a previous CF mutation panel. Recent evidence indicates I148T may be a benign polymorphism unless it is located on the same chromosome (in cis) with 3199del6. I148T is represented in approximately 6 percent of CF carriers but only 0.06 percent of those affected with CF. Those with I148T who are affected with CF also have 3199del6 in cis.

Incidence of Classic CF: 1 in 3,000 Caucasians or Ashkenazi Jewish, 1 in 8,000 Hispanics, 1 in 15,000 African American, 1 in 32,000 Asians.

Carrier frequency: 1 in 25 in European Caucasians and Ashkenazi Jews, 1 in 46 Hispanics, 1 in 65 African Americans, 1 in 90 Asian Americans

Inheritance: Autosomal recessive

Penetrance: Homozygotes for 3199del6 have not been reported; therefore, the clinical severity of this mutation is unknown. However, compound heterozygotes for I148T/3199del6 and the common F508del mutation have symptoms of classical CF.

Cause: CF is caused by two CFTR mutations on opposite chromosomes

Methodology: Polymerase chain reaction (PCR) and fluorescent hybridization probes.

Analytical Sensitivity & Specificity: 99 percent

Limitations: This test is specific for the cystic fibrosis (CF) 3199del6 mutation. Other mutations in the CFTR gene will not be detected.

This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

CPT Code(s): 83891 Isolation; 83898 x2 Amplification; 83896 x4 Nucleic acid probes; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

HOT LINE Effective May 17, 2010

0051103 Cytochrome P450 2C9 (CYP2C9) 2 Mutations CYP2C9

Specimen Required: Collect: One 3 mL lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).
Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:

Background Information for Cytochrome P450 2C9 (CYP2C9) 2 Mutations:

Characteristics: Some CYP2C9 mutations cause impaired drug metabolism, a major cause of adverse drug reactions or lack of drug response. For example, CYP2C9 variants are associated with slowed clearance and lower dose requirements for warfarin.

Inheritance: Autosomal recessive.

Cause: CYP2C9 gene mutations.

Mutations Tested: CYP2C9 *2 (c.430C>T) decreased function allele and CYP2C9 *3 (c.1075A>C) non-functional allele.

Allele Frequencies: CYP2C9 *2: Caucasians 0.08-0.13, Asians 0.02-0.06, African Americans less than 0.01. CYP2C9 *3: Caucasians 0.06-0.10, Asians less than 0.01, African Americans 0.01-0.04.

Clinical Sensitivity: Greater than 90 percent of deleterious CYP2C9 mutations are detected in Caucasians; sensitivity is unknown in other ethnicities.

Methodology: Polymerase chain reaction and fluorescence monitoring.

Analytical Sensitivity and Specificity: 99 percent.

Limitations: Only two common CYP2C9 mutations will be detected. Additional mutations in this or other genes will not be detected. Rare diagnostic errors can occur due to primer site mutations. Mutation detection is not a substitute for therapeutic drug or other clinical monitoring. Non-genetic factors may also affect drug metabolism.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

0051104 Cytochrome P450 2C19 (CYP2C19) 7 Mutations CYP2C19

Specimen Required: Collect: One 3 mL lavender (EDTA) or pink (K₂EDTA) or yellow (ACD Solution A or B).
Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

CPT Code(s): 83891 Isolation; 83892 x2 Enzymatic Digestion; 83900 Amplification; 83914 x7 Mutation identification; 83909 Separation and identification; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

0050166 Cytomegalovirus Antibodies (Total) CMV SCN

Note: This test measures both IgG and IgM antibody. **This test does not discriminate between passively acquired and actively produced antibody.**

2002349 5- α -Dihydrotestosterone by Tandem Mass Spectrometry, Serum DHT TMS

Specimen Required: Collect: One 4 mL serum separator tube. **Specimen should be collected between 6-10 a.m.**
Storage/Transport Temperature: 1 mL serum, frozen. (Min: 0.6 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Separate serum from cells and freeze ASAP.
Unacceptable Conditions: Hemolyzed or lipemic specimens
Stability (collection to initiation of testing): After separation from cells: Ambient: 2 hours; Refrigerated: 24 hours; Frozen: 6 months

HOT LINE Effective May 17, 2010

0091372 Drugs of Abuse Confirmation/Quantitation - Amphetamine - Serum or Plasma AMPHETAM

Specimen Required: Collect: **One** 7 mL gray (sodium fluoride/potassium oxalate). Also acceptable: plain red, green (sodium heparin), lavender (EDTA), or pink (K₂EDTA).
Transport: 2 mL serum or plasma at 2-8°C. (Min: 1 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Remove serum/plasma from cells ASAP.
Unacceptable Conditions: Specimens exposed to repeated freeze/thaw cycles. Separator tubes and plasma or whole blood from lt. blue (sodium citrate).
Stability (collection to initiation of testing): After separation from cells: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 3 years

Interpretive Data:

Drugs covered: methamphetamine, amphetamine, methylenedioxymethamphetamine (MDMA - Ecstasy), **methylenedioxyethylamphetamine (MDEA - Eve)**, and methylenedioxyamphetamine (MDA).

Positive cutoff: 20 ng/mL

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.

For medical purposes only; not valid for forensic use.

0092310 Drugs of Abuse Confirmation/Quantitation - Amphetamines (Amphetamine & Methamphetamine) - Meconium CONFAMP M

Interpretive Data:

Drugs Covered: amphetamine, methamphetamine, methylenedioxymethamphetamine (MDMA-Ecstasy), **methylenedioxyethylamphetamine (MDEA - Eve)**, and methylenedioxyamphetamine (MDA).

Positive cutoff: 20 ng/g

Meconium begins to form between the 12th and 16th week of gestation. Meconium drug testing can detect maternal drug use during the last 4 to 5 months of pregnancy. A negative result does not exclude the possibility that a mother used drugs during pregnancy. Detection of drug use depends on the quantity and quality of the specimen tested as well as the pattern and frequency of drug(s) used by mother. 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.

For medical purposes only; not valid for forensic use.

0090439 Drugs of Abuse Confirmation/Quantitation - Amphetamines – Urine CDCO AMPS

Interpretive Data:

Drugs covered: methamphetamine, amphetamine, methylenedioxymethamphetamine (MDMA - Ecstasy), **methylenedioxyethylamphetamine (MDEA - Eve)**, and methylenedioxyamphetamine (MDA).

Positive cutoff: 200 ng/mL

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

For medical purposes only; not valid for forensic use.

HOT LINE Effective May 17, 2010

0051463 Dysautonomia, Familial (*IKBKAP*) 2 Mutations **IKBKAP**

Specimen Required: Collect: One 3 mL lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).
Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:

Background information for Dysautonomia, Familial (*IKBKAP*) 2 Mutations:

Characteristics: Debilitating disease of gastrointestinal dysfunction, vomiting and autonomic crises, recurrent pneumonia, altered sensitivity to pain and temperature, scoliosis, and cardiovascular instability. Other characteristics include infantile hypotonia, a broad-based ataxic gait that deteriorates, and decreased life expectancy.

Incidence: 1 in 3,600 Ashkenazi Jewish individuals, unknown in other ethnicities.

Inheritance: Autosomal recessive.

Cause: Deleterious *IKBKAP* gene mutations.

Mutations Tested: R696P and IVS20(+6)T>C.

Clinical Sensitivity: 99 percent in Ashkenazi Jewish individuals, unknown in other ethnicities.

Methodology: PCR and allele-specific primer extension by bead array with fluorescence detection.

Analytical Sensitivity and Specificity: 99 percent.

Limitations: Mutations other than R696P and IVS20(+6)T>C will not be detected. Rare diagnostic errors can occur due to primer site mutations.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

New Test 2002994 Ehrlichia chaffeensis DNA, Real-Time PCR **EHRlichIA**

Effective April 19, 2010

Methodology: Real-Time Polymerase Chain Reaction

Performed: Varies

Reported: Varies

Specimen Required: Collect: Lavender (EDTA) or yellow (ACD)

Specimen Preparation: Submit specimen in an ARUP Standard Transport Tube.

Storage/Transport Temperature: 0.7 mL whole blood or tick (in ethanol or live) at 2-8°C. (Min: 0.3 mL or 1 tick)

Unacceptable Conditions: Frozen whole blood.

Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 1 week;

Frozen: 1 month (frozen whole blood unacceptable)

Reference Interval: By report

CPT Code(s): 87798

New York DOH approval pending. Call for status update.

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

2002378 Eosinophilia Panel by FISH **FISH EOS P**

Performed: Sun-Sat

Reported: 3-10 days

HOT LINE Effective May 17, 2010

2001599	Epidermal Transglutaminase (TGe) Antibody, IgA	TGE IGA
Specimen Required: Collect: One 4 mL serum separator tube or plasma separator tube . Also acceptable: lavender (EDTA), pink (K ₂ EDTA), or green (sodium or lithium heparin). Storage/Transport Temperature: 1 mL serum or plasma at 2-8°C. (Min: 0.15 mL) Remarks: Remove serum from cells ASAP. Unacceptable Conditions: Other body fluids. Severely lipemic, contaminated, and hemolyzed specimens. Stability (collection to initiation of testing): Ambient: 2 Days; Refrigerated: 2 weeks; Frozen: 1 year		
0020610	Erythrocyte Porphyrin (EP), Whole Blood	FEP
Specimen Required: Collect: One 6 mL royal blue (EDTA) or one 5 mL lavender or pink (K ₂ EDTA). Storage/Transport Temperature: 1 mL whole blood at 2-8°C. (Min: 0.5 mL) Submit specimen in an ARUP Amber Transport Tube. CRITICAL - protect from light. Specimens not protected from light acceptable with a disclaimer. Remarks: CRITICAL - Protect from light during collection, storage, and shipment. Use royal blue (Na ₂ EDTA) tube when also testing for lead. Specimen should be tested for lead FIRST to avoid potential contamination problems. Unacceptable Conditions: Clotted specimens . Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 2 weeks; Frozen: 1 month		
0070051	Estriol, Serum	EST
Specimen Required: Collect: One 4 mL serum separator tube. Storage/Transport Temperature: 1 mL serum at 2-8°C. (Min: 0.6 mL) Submit specimen in an ARUP Standard Transport Tube. Remarks: Patient gestational age required. Avoid repeated freeze/thaw cycles. Unacceptable Conditions: Plasma . Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 1 month		
0090120	Ethanol, Serum or Plasma - Medical	ETOH
Effective Immediately		
Reference Interval:	No therapeutic range - Assay detection limit varies based on instrumentation. Therapy for methanol intoxication: 100-200 mg/dL Potentially toxic: greater than 100 mg/dL Critical: greater than 250 mg/dL	
0051220	Ewing Sarcoma by RT-PCR	EWS
CPT Code(s):	83891 Isolation; 83902 Reverse transcription; 83898 x3 Amplification; 83896 x3 Nucleic acid probes; 83912 Interpretation and report. Additional CPT code modifiers may be required for procedures performed to test for oncologic and inherited disorders.	
0097720	Factor V Leiden (F5) R506Q Mutation	FACV
Specimen Required: Collect: One 3 mL lavender (EDTA), pink (K ₂ EDTA), or yellow (ACD Solution A or B). Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL) Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable		

HOT LINE NOTE: Please remove information from the Unacceptable Conditions field in Specimen Requirements.

HOT LINE Effective May 17, 2010

DELETE 0030120 **Factor XIII, Qualitative** **F13**

HOT LINE NOTE: Please delete this test and refer to Factor XIII, Qualitative with Reflex to Factor XIII 1:1 Mix (2002819).

New Test 2002819 **Factor XIII, Qualitative, with Reflex to Factor XIII 1:1 Mix** **FACTOR 13**

Methodology: Solubility
Performed: Mon-Fri
Reported: 2-4 days

Specimen Required: Collect: One 5 mL lt. blue (sodium citrate). Refer to the Hemostasis/Thrombosis Specimens section in the front of the Laboratory Test Directory for collection instructions.
Transport: 2 mL platelet-poor plasma, frozen. (Min: 1 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**
Unacceptable Conditions: Serum. Nonfrozen or hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 4 hours; Refrigerated: 8 hours; Frozen: 2 weeks

Reference Interval:

Available Separately	Component	Reference Interval
No	Factor XIII, Qualitative	No lysis within 24 hours.
No	Factor XIII, 1:1 Mix	Not Applicable

Note: This is a qualitative screening test; clot lysis only occurs in specimens with severe factor XIII deficiency (less than 1% of normal activity). Severe deficiency may be inherited or acquired (typically due to a factor XIII antibody). If clot lysis occurs in the initial testing, the test is repeated using a 1:1 mix of patient plasma and pooled normal plasma to distinguish between FXIII deficiency and a FXIII inhibitor.

False-positive results (lysis) can be caused by heparin (therapy with unfractionated or low molecular weight heparin or contamination from a line), decreased or abnormal fibrinogen, increased fibrinolysis (inherited or acquired fibrinolytic disorders), fibrinolytic drugs, or other factors that affect clot structure or stability.

CPT Code(s): 85291 Factor XIII; if reflexed, add 85291 1:1 Mix

This test is New York DOH approved.

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

HOT LINE Effective May 17, 2010

0051468 Fanconi Anemia, Group C (FANCC) 2 Mutations FANCC

Specimen Required: Collect: One 3 mL lavender (EDTA), **pink** (K₂EDTA), or **yellow** (ACD Solution A or B).
Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:

Background information for Fanconi Anemia, Group C (FANCC) 2 Mutations:

Characteristics: Short stature, abnormal skin pigmentation, and multiple malformations including: eyes, ears, heart, oral cavity, thumbs, forearms, kidneys, urinary tract, hearing loss, hypogonadism, and developmental delay. Progressive bone marrow failure occurs during the first decade of life. Hematologic and nonhematologic malignancies occur in approximately 20 percent and approximately 30 percent of those affected, respectively.

Incidence: 1 in 32,000 Ashkenazi Jewish individuals; unknown in other ethnicities.

Inheritance: Autosomal recessive.

Cause: Deleterious *FANCC* gene mutations.

Mutations Tested: 322delG and IVS4(+4)A>T.

Clinical Sensitivity: 99 percent in Ashkenazi Jewish individuals, unknown in other ethnicities.

Methodology: PCR and allele-specific primer extension by bead array with fluorescence detection.

Analytical Sensitivity and Specificity: Greater than 99 percent.

Limitations: Mutations other than 322delG and IVS4(+4)A>T will not be detected. Rare diagnostic errors may occur due to primer site mutations.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

0060315 Fat, Body Fluid FATBF

Specimen Required: Collect: Body **fluid**. Source of specimen is required.
Transport: 5 mL body fluid at 2-8°C. (Min: 1 mL)
Unacceptable Conditions: Specimens in preservatives, or media. **Respiratory specimens. Breast milk.** Ambient or frozen specimens.
Stability (collection to initiation of testing): Ambient: 1 hour; Refrigerated: 36 hours; Frozen: Unacceptable

HOT LINE Effective May 17, 2010

2002350	Fat, Fecal Quantitative	FECQ FAT
<p>Specimen Required: <u>Patient Preparation:</u> The patient should be on a diet consisting of 50 to 150 g of fat per day for three days prior to the study. <u>Collect:</u> 24-, 48- or 72-hour stool collection. Refrigerate during collection. <u>Specimen Preparation:</u> Weigh entire collection. Homogenize entire collection (using a graduated cylinder, add sufficient water to give “milk shake” consistency) and aliquot 20 mL (20 g) into a clean, unpreserved vial (ARUP supply # 40910). Provide weight of entire collection, volume of water added for homogenization (if applicable), and duration of collection. Complete information is required in order to perform accurate calculations. Refer to instructions in Stool Collection—Timed Specimens (24, 48, 72 Hours) in the Laboratory Test Directory. <u>Transport:</u> 20 mL (20 g) homogenized aliquot, frozen. <u>Remarks:</u> If weight and time are not provided it is assumed the collection is random and alternative testing (Fat, Fecal Qualitative - 0020385) can be performed. <u>Unacceptable Conditions:</u> Specimens containing barium, charcoal, specimens in media or preservatives. Containers larger than 500 mL (500 g), such as paint cans, will be rejected and discarded. Random collections. Submissions without collection time and weight information. <u>Stability (collection to initiation of testing):</u> Ambient: 1 hour; Refrigerated: 96 hours; Frozen: 2 weeks</p>		
2002354	Fat, Fecal Quantitative 24-Hour Collection (Includes Homogenization)	FECQFAT24
<p>Specimen Required: <u>Patient Preparation:</u> The patient should be on a diet consisting of 50 to 150 g of fat per day for three days prior to the study. <u>Collect:</u> 24-hour stool. Refrigerate during collection. Provide patient a Timed Stool Collection Kit (ARUP Supply# 44192). <u>Specimen Preparation:</u> Refer to instructions in Stool Collection—Timed Specimens (24, 48, 72 Hours) in the Laboratory Test Directory. <u>Transport:</u> Submit entire 24-hour stool collection in an ARUP approved transport container(s) provided in kit using additional containers as needed for the full collection (available separately ARUP supply #28077), frozen. <u>Unacceptable Conditions:</u> Specimens containing barium, charcoal, specimens in media or preservatives. Containers larger than 500 mL (500 g), such as paint cans, will be rejected and discarded. Random collections. <u>Stability (collection to initiation of testing):</u> Ambient: 1 hour; Refrigerated: 96 hours; Frozen: 2 weeks</p>		
2002355	Fat, Fecal Quantitative 48-Hour Collection (Includes Homogenization)	FECQFAT48
<p>Specimen Required: <u>Patient Preparation:</u> The patient should be on a diet consisting of 50 to 150 g of fat per day for three days prior to the study. <u>Collect:</u> 48-hour stool. Refrigerate during collection. Provide patient Timed Stool Collection Kit (ARUP Supply# 44192) and an additional fecal fat container (ARUP Supply #28077). <u>Specimen Preparation:</u> Refer to instructions in Stool Collection—Timed Specimens (24, 48, 72 Hours) in the Laboratory Test Directory. <u>Transport:</u> Submit each 24-hour stool collection in an ARUP approved transport container provided in kit using additional containers as needed for the full collection (available separately ARUP supply #28077), frozen. <u>Unacceptable Conditions:</u> Specimens containing barium, charcoal, specimens in media or preservatives. Containers larger than 500 mL (500 g), such as paint cans, will be rejected and discarded. Random collections. <u>Stability (collection to initiation of testing):</u> Ambient: 1 hour; Refrigerated: 96 hours; Frozen: 2 weeks</p>		
2002356	Fat, Fecal Quantitative 72-Hour Collection (Includes Homogenization)	FECQFAT72
<p>Specimen Required: <u>Patient Preparation:</u> The patient should be on a diet consisting of 50 to 150 g of fat per day for three days prior to the study. <u>Collect:</u> 72-hour stool. Refrigerate during collection. Provide patient a Timed Stool Collection Kit (ARUP Supply# 44192) and 2 additional containers (ARUP Supply #28077). <u>Specimen Preparation:</u> Refer to instructions in Stool Collection—Timed Specimens (24, 48, 72 Hours) in the Laboratory Test Directory. <u>Transport:</u> Submit each 24-hour stool collection in an ARUP approved transport container, using additional containers as needed for the full collection (available separately ARUP supply #28077), frozen. <u>Unacceptable Conditions:</u> Specimens containing barium, charcoal, specimens in media or preservatives. Containers larger than 500 mL (500 g), such as paint cans, will be rejected and discarded. Random collections. <u>Stability (collection to initiation of testing):</u> Ambient: 1 hour; Refrigerated: 96 hours; Frozen: 2 weeks</p>		

HOT LINE Effective May 17, 2010

0051752 **FG Syndrome, FGS1 (MED12) R961W Mutation** **FGS 1**

Specimen Required: Collect: One 3 mL lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).
Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

CPT Code(s): 83891 Isolation; 83898 Amplification; 83896 x 2 Nucleic acid probes; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedure performed to test oncologic or inherited disorders.

HOT LINE NOTE: Please remove information from the Remarks field under Specimen Requirements. Additional component information associated with this test that affects interface clients only:

Code	Test Name	Change	Order/Result	Comments
2002914	FGS1 Specimen	Add Component	R	Add new component for source

0040011 **Fragile X (FMR1) Diagnostic** **FRAG X**

HOT LINE NOTE: Please remove the information from the Unacceptable Conditions field under Specimen Requirements.

0050543 **Fragile X (FMR1) Diagnostic, Fetal** **FRAG X FE**

Specimen Required: Collect and Transport:
Cultured cells: Four T-25 flasks at 80% confluent of cultured amniocytes. Fill flasks with culture media to ship at 20-25°C. Backup cultures must be retained at the client's institution until testing is complete. **If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787.**
Maternal specimen: One 3 mL lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B) at 20-25°C.
Amniotic fluid: 10 mL unspun fluid at 20-25°C. (Min: 5 mL)
Remarks: Fetal specimens are **CRITICAL AMBIENT** and must be received within 48 hours of shipment due to lability of cells. CVS tissue or CVS cultured cells are not acceptable.
Maternal specimen is recommended for proper test interpretation. Maternal Cell (MCC MAT) (0050608). Patient History Form is available on the ARUP Web site or by contacting ARUP Client Services.
Stability (collection to initiation of testing): **Fetal:** Ambient: 2 days; Refrigerated: 24 hours; Frozen: Unacceptable
Maternal: Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable

0060756 **Fungal Identification by ITS rDNA Sequencing** **MC YSTSEQ**

Specimen Required: Collect: Actively growing yeast/mould in pure culture, on agar slant. Specimen source is preferred.
Storage/Transport Temperature: Organism in pure culture in a sealed container at 20-25°C.
 Submit specimen according to Biological Substance, Category B, shipping guidelines.
Unacceptable Conditions: Non viable organisms, mixed cultures and leaking containers. Environmental isolates.
Stability (collection to initiation of testing): Ambient: 2 weeks; Refrigerated: 2 weeks; Frozen: Unacceptable

0020009 **Gamma Glutamyl Transferase, Serum or Plasma** **GT**

Specimen Required: Collect: One 4 mL serum separator tube or plasma separator tube. Also acceptable: K-EDTA
Transport: 1 mL serum or plasma at 2-8°C. (Min: 0.2 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Allow specimen to clot completely at room temperature. Separate serum or plasma from cells ASAP.
Unacceptable Conditions: Grossly hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 2 months

HOT LINE Effective May 17, 2010

0051438 Gaucher (GBA) 8 Mutations GBA

Specimen Required: Collect: One 3 mL lavender (EDTA), **pink** (K₂EDTA), or **yellow** (ACD Solution A or B).
Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:

Background information for Gaucher (GBA) 8 Mutations:

Characteristics: Lysosomal storage disease with extreme symptomatic variability from lack of symptoms to perinatal lethality. Three subtypes have been described based on their characteristics. Type 1 has bone disease, hepatosplenomegaly, anemia, thrombocytopenia, and lung disease but no primary CNS disease. Type 2 has CNS onset before age two and progresses rapidly to death by age four. Type 3 may have onset by age two but is slowly progressive, resulting in death usually in one's 20's or 30's.

Incidence: 1 in 900 Ashkenazi Jewish individuals, unknown in other ethnicities.

Inheritance: Autosomal recessive.

Cause: Deleterious *GBA* gene mutations.

Mutations Tested: 84G>GG, IVS2(+1)G>A, N370S, del55bp, V394L, D409H, L444P, R496H.

Clinical Sensitivity: 90 percent in Ashkenazi Jewish individuals, at least 55 percent in other ethnicities.

Methodology: PCR and allele-specific primer extension by bead array with fluorescence detection.

Analytical Sensitivity and Specificity: Greater than 99 percent.

Limitations: Mutations other than 84G>GG, IVS2(+1)G>A, N370S, del55bp, V394L, D409H, L444P, R496H will not be detected.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

0040201 Genomic Microarray, UARRAY Chip U ARRAY

Performed: Sat-Sun
Reported: 10-14 days (Results requiring the completion of FISH testing may exceed the standard TAT)

0049190 Glomerular Basement Membrane Antibody, IgA & IgG (IFA) GBM IFA

Effective Immediately

CPT Code: 86255 GBM IgA; 86255 GBM IgG

0049191 Glomerular Basement Membrane Antibody, IgG (IFA) GBM-G IFA

Effective Immediately

CPT Code: 86255

0051001 Glomerular Basement Membrane Antibody Panel GBM PAN

Effective Immediately

CPT Code: 83516 GBM ELISA; 86255 GBM IgA; 86255 GBM IgG

HOT LINE Effective May 17, 2010

0099165 Glucagon GLUCA

Specimen Required: Collect: 5 mL blood into any chilled container of EDTA, plus 0.2 cc of aprotinin **added immediately after collection**. (0.04 cc aprotinin per mL of whole blood.)
Transport: 1 mL plasma (EDTA plus aprotinin), frozen. (Min: 0.5 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.** Immediately centrifuge in a refrigerated centrifuge, separate plasma from cells and freeze ASAP. To prevent analyte degradation, aprotinin inhibitor is the required specimen preservative for this assay. Inhibitor vials are available through ARUP Client Services (ARUP Supply #16570).
Unacceptable Conditions: Specimens transported in glass tubes.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 3 months

0051684 Glucose-6-Phosphate Dehydrogenase (G6PD) 2 Mutations G6PD AFRIC

Specimen Required: Collect: One 3 mL lavender (EDTA), **pink** (K₂EDTA), **or** yellow (ACD Solution A **or** B).
Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

CPT Code(s): **83891** Isolation; 83898 Amplification; 83896 x2 Nucleic acid probe; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

HOT LINE NOTE: Please remove the information from the Unacceptable Conditions field under Specimen Requirements.

New Test 2002862 Glutamic Acid Decarboxylase Antibody (GAD65) & Insulin Antibodies with Reflex to IA-2 Antibody GADINS ABS

Effective April 19, 2010

Methodology: Radioimmunoassay/Enzyme-linked Immunosorbent Assay
Performed: Varies
Reported: 2-10 days

Specimen Required: Collect: One 4 mL serum separator tube or plain red.
Transport: 2 mL serum, frozen. (Min: 1 mL) Submit specimen in an ARUP Standard Transport Tube.
Unacceptable Conditions: Plasma. Hemolyzed or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 2 months

Reference Interval:

Available Separately	Component	Reference Interval
Yes (0099228)	Insulin Antibody	Negative = 0.4 Kronus units/mL or less Positive = 0.5 Kronus units/mL or greater
Yes (2001771)	Glutamic Acid Decarboxylase Antibody	0.0-5.0 IU/mL
Yes (0050202)	IA-2 Antibody	0.0-0.8 Kronus units/mL

Interpretive Data: The Insulin Antibody assay quantitatively measures human serum autoantibodies to endogenous insulin or antibodies to exogenous insulin.

Note: If either Insulin Antibody or Glutamic Acid Decarboxylase Antibody is negative, then IA-2 Antibody will be ordered.

Insulin Antibody: Kronus units are arbitrary units. Kronus units = U/mL

CPT Code(s): 86337 ANTI-INS; 83516 GAD-AB; if reflexed, add 86341 IA-2 Antibody

This test is New York DOH approved.

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

HOT LINE Effective May 17, 2010

0040116 Haptoglobin (HP) Genotyping HAPTO PCR

Specimen Required: Collect: One 3 mL lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).
Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

HOT LINE NOTE: Please remove information from Unacceptable Conditions field under Specimen Requirements.

0051383 Hearing Loss, Nonsyndromic, Connexin 26 (GJB2) 35delG Mutation CX 35DELG

Specimen Required: Collect: One 3 mL lavender (EDTA), pink (K₂EDTA), or yellow (ACD solution A).
Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 1 week; Frozen: Unacceptable

CPT Code(s): 83891 Isolation; 83896 x2 Nucleic acid probes; 83912 Interpretation and report

HOT LINE NOTE: Please remove information from the Remarks field as well as the Unacceptable Conditions field.

0099470 Heavy Metals Panel 3, Blood HY MET B

Specimen Required: Collect: One 7 mL royal blue (K₂EDTA) or (Na₂EDTA).
Transport: 7 mL whole blood at 20-25 °C in the original collection tube. (Min: 1.5 mL)
Unacceptable Conditions: Heparin anticoagulant.
Stability (collection to initiation of testing): If the specimen is drawn and stored in the appropriate container, the trace element values do not change with time.

0020584 Heavy Metals Panel 4, Blood HY MET B4

Methodology: Atomic Absorption/Inductively Coupled Plasma-Mass Spectrometry

0020591 Hepatitis A Virus Antibodies (Total) HAVAB

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

Specimen Required: Collect: One 4 mL serum separator tube.
Storage/Transport Temperature: 1 mL serum at 2-8°C. (Min: 0.5 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Potassium EDTA plasma is also acceptable. Separate serum or plasma from cells ASAP.
Unacceptable Conditions: Specimens containing particulate material. Severely hemolyzed or lipemic specimens. Heat-inactivated specimens, Heparinized plasma. Specimens collected in citrate-based anticoagulant.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 1 week; Frozen: Indefinitely (avoid repeated freeze/thaw cycles)

0020093 Hepatitis A Virus Antibody, IgM HAVABM

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

Specimen Required: Collect: One 4 mL serum separator tube.
Storage/Transport Temperature: 1 mL serum at 2-8°C. (Min: 0.5 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Potassium EDTA plasma is also acceptable. Separate serum or plasma from cells ASAP.
Unacceptable Conditions: Specimens containing particulate material. Severely hemolyzed or lipemic specimens. Heat-inactivated specimens. Specimens collected in citrate-based anticoagulant.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 1 week; Frozen: Indefinitely (avoid repeated freeze/thaw cycles)

HOT LINE Effective May 17, 2010

0020597	Hepatitis A Virus Antibodies Panel	HEP A PAN
Methodology:	Chemiluminescent Immunoassay	
Performed:	Sun-Sat	
Reported:	Within 24 hours	
Specimen Required:	<p><u>Collect:</u> One 4 mL serum separator tube.</p> <p><u>Storage/Transport Temperature:</u> 2 mL serum at 2-8°C. (Min: 0.5 mL) Submit specimen in an ARUP Standard Transport Tube.</p> <p><u>Remarks:</u> Potassium EDTA Plasma is also acceptable. Separate serum or plasma from cells ASAP.</p> <p><u>Unacceptable Conditions:</u> Specimens containing particulate material. Severely hemolyzed or lipemic specimens. Heat-inactivated specimens. Specimens collected in citrate-based anticoagulant.</p> <p><u>Stability (collection to initiation of testing):</u> After separation from cells: Ambient: Unacceptable; Refrigerated: 1 week; Frozen: Indefinitely (avoid repeated freeze/thaw cycles)</p>	
CPT Code(s):	86708 Hepatitis A antibodies (total); 86709 Hepatitis A antibody, IgM	

0065005	Herpes Simplex Virus Culture	V HSVC
Specimen Required:	<p><u>Collect:</u> Throat, buccal mucosa, eye, genital, rectal swab. Vesicle swab or fluid, bronchoalveolar lavage (BAL), or tissue. Immediately place vesicle fluid, swab, or tissue in viral transport media. Source of specimen is preferred.</p> <p><u>Storage/Transport Temperature:</u> Swab, fluid or tissue in viral transport media at 2-8°C. Submit specimen according to Biological Substance, Category B, shipping guidelines.</p> <p><u>Remarks:</u> Do not freeze.</p> <p><u>Unacceptable Conditions:</u> Serum and plasma. Dry swabs, wood swabs, and calcium alginate swabs.</p> <p><u>Stability (collection to initiation of testing):</u> Ambient: 2 hours; Refrigerated: 3 days; Frozen: Unacceptable</p>	

0065065	Herpes Simplex Virus Culture with Reflex to HSV Typing	V HSVCT
Specimen Required:	<p><u>Collect:</u> Throat, buccal mucosa, eye, genital, rectal swab. Vesicle swab or fluid, bronchoalveolar lavage (BAL), or tissue. Immediately place vesicle fluid, swab, or tissue in viral transport media. Source of specimen is preferred.</p> <p><u>Storage/Transport Temperature:</u> Swab, fluid, or tissue in viral transport media at 2-8°C. Submit specimen according to Biological Substance, Category B, shipping guidelines.</p> <p><u>Remarks:</u> Do not freeze.</p> <p><u>Unacceptable Conditions:</u> Serum or plasma. Dry swabs, wood swabs, and calcium alginate swabs.</p> <p><u>Stability (collection to initiation of testing):</u> Ambient: 2 hours; Refrigerated: 3 days; Frozen: Unacceptable</p>	

HOT LINE Effective May 17, 2010

New Test 2002829 Herpesvirus 6 Antibody, IgM HHV6 IGM

Effective April 19, 2010

Methodology: Immunofluorescence Assay
Performed: Varies
Reported: Varies

Specimen Required: Collect: Serum separator tube or plain red.
Transport: 0.5 mL serum at 2-8°C. (Min: 0.1 mL) Submit specimen in an ARUP Standard Transport Tube.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 1 month

Reference Interval: By report

CPT Code(s): 86790

This test is New York DOH approved.

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

New Test 2002996 Herpes Virus 8 DNA, Qualitative Real-Time PCR HERPES 8

Effective April 19, 2010

Methodology: Real-Time Polymerase Chain Reaction
Performed: Varies
Reported: Varies

Specimen Required: Collect: Lavender (EDTA), yellow (ACD), plain red, serum separator tube.
Specimen Preparation: Submit specimen in an ARUP standard transport tube.
Storage/Transport Temperature: 0.7 mL whole blood, plasma, or serum at 2-8°C. (Min: 0.3 mL)
Unacceptable Conditions: Frozen whole blood.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 1 month (frozen whole blood unacceptable)

Reference Interval: By report

CPT Code(s): 87798

This test is New York DOH approved.

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

HOT LINE Effective May 17, 2010

DELETE 0095859 **HLA Ab Detection Assay** **HLA AB SCN**

HOT LINE NOTE: Please delete this test and refer to HLA Antibody Detection (2002805).

New Test 2002805 **HLA Antibody Detection** **HLA ABSCN**

Methodology: Luminex/Multi-Analyte Fluorescent Detection
Performed: As needed
Reported: 1-5 days

Specimen Required: Collect: One 7 mL plain red.
Transport: 7 mL whole blood or 3-5 mL serum at 20-25°C.
Pediatric Collect/Transport: 2 mL blood in a pediatric plain red at 20-25°C.
Remarks: Store and transport at 20-25°C if specimen will be received within 48 hours of collection. Store and transport frozen serum if specimen is not to be analyzed immediately. Frozen specimen may be stored up to one month and must remain frozen during transport. Please refer to the Histocompatibility Testing section of the Laboratory Test Directory for further information on testing and holiday schedules.
Stability (collection to initiation of testing): Ambient: 2 days; Refrigerated: 1 month; Frozen: 2 years

Reference Interval: By report

Interpretive Data:

Background Information for HLA Antibody Detection:

Purpose: To detect HLA Class I IgG antibodies.

Methodology: Luminex/Multi-analyte fluorescent detection.

Analytical Sensitivity & Specificity: More sensitive than conventional lymphocyte cytotoxicity procedures.

Limitations: Only detects antibodies of the IgG isotype, not IgM antibodies.

Test Results: The results are reported as panel reactive (PRA) present or absent and do not provide a specificity.

CPT Code(s): 88184 First marker; 88185 x3 Each additional marker; 88187 Interpretation on 2-8 markers

New York DOH approval pending. Call for status update.

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

DELETE 0056019 **HLA-A Sequence-Based Typing** **HLAASBT**

HOT LINE NOTE: Please delete this test and refer to *HLA-A* Sequencing (2003085).

New Test

2003085

HLA-A Sequencing

SBT A



Consent Form Recommended



HLA Test Request Form Recommended

Methodology: Polymerase Chain Reaction/Nucleic Acid Sequencing
Performed: Mon, Thu
Reported: 7-11 days

Specimen Required: Collect: One 5 mL yellow (ACD Solution A), lavender (EDTA), or pink (K₂EDTA) peripheral blood.
Transport: 5 mL whole blood at 20-25°C. (Min 1.5 mL)
Unacceptable Conditions: Heparinized, clotted, or frozen whole blood specimens.
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 3 days; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Background Information for HLA-A Sequencing:

Purpose: To identify *HLA-A* allelic polymorphisms at the level of individual nucleotides.

Methodology: PCR followed by *HLA-A* sequencing.

Analytical Sensitivity & Specificity: 99 percent.

Limitations: If fewer than 2 alleles are reported for a locus, the patient is likely homozygous. Rare diagnostic errors can occur due to primer site mutations. Occasionally the specific allele cannot be determined; in this case, the most likely allele assignment is made followed by a sequence of letters indicating other possible allele assignments. Interpretation of allele codes can be found at <http://bioinformatics.nmdp.org/HLA/alpha.html>.

Test Results: Results are reported as HLA locus A* followed by the two digit serologic antigen equivalent and the two digit assigned allele.

Analyte Specific Reagents (ASR) are used in many laboratory tests necessary for standard medical care and generally do not require U.S. Food and Drug Administration (FDA) approval or clearance. This test was developed and its performance characteristics determined by **HistoGenetics Inc (ASHI accreditation #03-1-NY-26-2)**. It has not been approved or cleared by the U.S. Food and Drug Administration. This test should not be considered as investigational or for research use. Test is performed at HistoGenetics Inc.

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

CPT Code(s): 83891 Isolation; 83898 Amplification; 83904 x3 Sequencing; 83909 Separation and identification; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

This test is New York DOH approved.

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

HOT LINE Effective May 17, 2010

DELETE 0096046 **HLA A and B Oligotyping** **AB DNA**

HOT LINE NOTE: Please delete this test and refer to *HLA-A & B* Genotyping (2002801).

New Test 2002801 **HLA-A & B Genotyping** **HLA-AB DNA**



Consent Form Recommended



HLA Test Request Form Recommended

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

Specimen Required: Collect: One 5 mL lavender (EDTA) or pink (K₂EDTA), or 10 mL yellow (ACD Solution A or B).
Transport: 5 mL whole blood at 20-25°C. (Min: 3 mL)
Unacceptable Conditions: Specimens drawn in green (sodium or lithium heparin) tubes.
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Background Information for *HLA-A & B* Genotyping:

Purpose: For immunization/vaccination trials or to aid the clinical diagnosis of diseases strongly associated with the *HLA-A* and B loci.

Methodology: PCR followed by Sequence Specific Oligonucleotide Probe Hybridization of *HLA-A* and *HLA-B* loci.

Analytical Sensitivity & Specificity: Low to medium resolution of *HLA-A* and B loci.

Limitations: The presence of a disease-associated HLA combination does not establish a diagnosis. If less than 2 alleles are reported for a locus, the patient is likely homozygous. Rare diagnostic errors can occur due to primer or probe site mutations. This test is not sufficient for comprehensive HLA evaluation for clinical hematopoietic stem cell transplantation (refer to HLA Bone Marrow Transplantation Evaluation - 2002806).

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

Note: Order this test for *HLA-A* and B phenotype and single antigen *HLA-A* and B identification. Please specify antigens.

CPT Code(s): 83891 Isolation; 83900 x2 Multiplex Amplification; 83896 x10 Nucleic acid probes; 88384 Probes 11-50; 88385 Probes 51-250; 83912 Interpretation and report -Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

New York DOH approval pending. Call for status update.

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

HOT LINE Effective May 17, 2010

DELETE 0056018 **HLA-ABC Sequence-Based Typing** **HLA I SBT**

HOT LINE NOTE: Please delete this test and refer to *HLA-ABC* Sequencing (2002788).

New Test 2002788 **HLA-ABC Sequencing** **SBT ABC**



Consent Form Recommended



HLA Test Request Form Recommended

Methodology: Polymerase Chain Reaction/Nucleic Acid Sequencing
Performed: Mon, Thu
Reported: 7-11 days

Specimen Required: Collect: One 5 mL yellow (ACD Solution A), lavender (EDTA), or pink (K₂EDTA) peripheral blood.
Transport: 5 mL whole blood at 20-25°C. (Min: 1.5 mL)
Unacceptable Conditions: Heparinized, clotted, or frozen whole blood specimens.
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 3 days; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Background Information for *HLA-ABC* Sequencing:

Purpose: To identify *HLA-ABC* allelic polymorphisms at the level of individual nucleotides.

Methodology: PCR followed by sequencing of HLA loci A, B and C.

Analytical Sensitivity & Specificity: 99 percent.

Limitations: If fewer than 2 alleles are reported for a locus, the patient is likely homozygous. Rare diagnostic errors can occur due to primer site mutations. Occasionally the specific allele cannot be determined; in this case, the most likely allele assignment is made followed by a sequence of letters indicating other possible allele assignments. Interpretation of allele codes can be found at <http://bioinformatics.nmdp.org/HLA/alpha.html>.

Test Results: Results are reported as HLA locus (A, B, or C)* followed by the two digit serologic antigen equivalent and the two digit assigned allele.

Analyte Specific Reagents (ASR) are used in many laboratory tests necessary for standard medical care and generally do not require U.S. Food and Drug Administration (FDA) approval or clearance. This test was developed and its performance characteristics determined by **HistoGenetics Inc (ASHI accreditation #03-1-NY-26-2)**. It has not been approved or cleared by the U.S. Food and Drug Administration. This test should not be considered as investigational or for research use. Test is performed at **Histogenetics Inc**.

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

CPT Code(s): 83891 Isolation; 83898 x3 Amplification; 83904 x8 Mutation identification by sequencing; 83909 Separation and identification; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

This test is New York DOH approved.

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

HOT LINE Effective May 17, 2010

DELETE 0056020 **HLA-B Sequence-Based Typing** **HLABSBT**

HOT LINE NOTE: Please delete this test and refer to *HLA-B* Sequencing (2002784).

New Test 2002784 **HLA-B Sequencing** **SBT B**



Consent Form Recommended



HLA Test Request Form Recommended

Methodology: Polymerase Chain Reaction/Nucleic Acid Sequencing
Performed: Mon, Thu
Reported: 7-11 days

Specimen Required: Collect: One 5 mL yellow (ACD Solution A), lavender (EDTA), or pink (K₂EDTA) peripheral blood.
Transport: 5 mL whole blood at 20-25°C. (Min: 1.5 mL)
Unacceptable Conditions: Heparinized, clotted, or frozen whole blood specimens.
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 3 days; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Background Information for *HLA-B* Sequencing:

Purpose: To identify *HLA-B* allelic polymorphisms at the level of individual nucleotides.

Methodology: PCR followed by *HLA-B* sequencing.

Analytical Sensitivity & Specificity: 99 percent.

Limitations: If fewer than 2 alleles are reported for a locus, the patient is likely homozygous. Rare diagnostic errors can occur due to primer site mutations. Occasionally the specific allele cannot be determined; in this case, the most likely allele assignment is made followed by a sequence of letters indicating other possible allele assignments. Interpretation of allele codes can be found at <http://bioinformatics.nmdp.org/HLA/alpha.html>.

Test Results: Results are reported as HLA locus B* followed by the two digit serologic antigen equivalent and the two digit assigned allele.

Analyte Specific Reagents (ASR) are used in many laboratory tests necessary for standard medical care and generally do not require U.S. Food and Drug Administration (FDA) approval or clearance. This test was developed and its performance characteristics determined by **HistoGenetics Inc (ASHI accreditation #03-1-NY-26-2)**. It has not been approved or cleared by the U.S. Food and Drug Administration. This test should not be considered as investigational or for research use. Test is performed at **Histogenetics Inc**.

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

Note: HLA Class I Sequencing is intended to identify HLA allelic polymorphisms at the level of individual nucleotides using genomic DNA amplified by PCR.

CPT Code(s): 83891 Isolation; 83898 Amplification; 83904 x3 Sequencing; 83909 Separation and identification; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

This test is New York DOH approved.

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

HOT LINE Effective May 17, 2010

DELETE 0095844 **HLA Bone Marrow Transplantation Evaluation** **HLA BMT**

HOT LINE NOTE: Please delete this test and refer to HLA Bone Marrow Transplantation Evaluation (2002806).

New Test 2002806 **HLA Bone Marrow Transplantation Evaluation** **HLA-BMT**



Consent Form Recommended



HLA Test Request Form Recommended

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

Specimen Required: Collect: Two 5 mL lavender (EDTA) or pink (K₂EDTA). Also acceptable: one 10 mL yellow (ACD Solution A or B).
Transport: 10 mL whole blood at 20-25°C. (Min: 5 mL)
Remarks: Blood should **not** be collected in green (heparin) tubes as this inhibits PCR.
Unacceptable Conditions: Frozen specimens and whole blood specimens collected in green (sodium or lithium heparin) tubes.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Background Information for HLA Bone Marrow Transplantation Evaluation:

Purpose: To screen recipients and potential donors for allogeneic hematopoietic stem cell transplantation.

Methodology: PCR followed by Sequence Specific Oligonucleotide Probe Hybridization of *HLA-A,B* and *DRB1* alloantigens.

Analytical Sensitivity & Specificity: Low to medium resolution for *HLA-A* and *B* loci and medium to high resolution for *HLA-DRB1* loci.

Limitations: Additional testing is necessary to identify genotypic or allele level match. If less than 2 alleles are reported for a locus, the patient is likely homozygous. Rare diagnostic errors can occur due to primer or probe site mutations

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

Note: The relationship of each donor to the recipient must be denoted on each donor's test request form. If at all possible, submit specimens from all family members (including parents of the recipient) at the same time. Interpretation and evaluation of potential donors can only be performed if relationships for family members are established by the client.

CPT Code(s): 83891 Isolation; 83898 Amplification; 83900 Multiplex Amplification; 83896 x10 Nucleic acid probes; 88384 Probes 11-50; 88385 Probes 51-250; 83912 Interpretation and report -Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

New York DOH approval pending. Call for status update.

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

HOT LINE Effective May 17, 2010

DELETE 0095715 **HLA-C Oligotyping** **HLA C SSP**

HOT LINE NOTE: Please delete this test and refer to *HLA-C* Genotyping (2002807).

New Test 2002807 **HLA-C Genotyping** **HLA-C DNA**



Consent Form Recommended



HLA Test Request Form Recommended

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

Specimen Required: Collect: One 5 mL lavender (EDTA) or pink (K₂EDTA), or 10 mL yellow (ACD Solution A or B).
Transport: 5 mL whole blood at 20-25°C. (Min: 3 mL)
Unacceptable Conditions: Specimens drawn in green (sodium or lithium heparin) tubes.
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Background Information for *HLA-C* Genotyping:

Purpose: For immunization/vaccination trials or to aid the clinical diagnosis of diseases strongly associated with the *HLA-C* locus.

Methodology: PCR followed by Sequence Specific Oligonucleotide Probe Hybridization of *HLA-C* locus.

Analytical Sensitivity & Specificity: Low to medium resolution of the *HLA-C* locus.

Limitations: The presence of a disease-associated HLA combination does not establish a diagnosis. If less than 2 alleles are reported for a locus, the patient is likely homozygous. Rare diagnostic errors can occur due to primer or probe site mutations. This test is not sufficient for comprehensive HLA evaluation for clinical hematopoietic stem cell transplantation (refer to HLA Bone Marrow Transplantation Evaluation - 2002806).

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

Note: Order this test for single antigen *HLA-C* identification. Please specify antigens.

CPT Code(s): 83891 Isolation; 83900 Multiplex Amplification; 83896 x10 Nucleic acid probes; 88384 Probes 11-50; 88385 Probes 51-250; 83912 Interpretation and report -Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

New York DOH approval pending. Call for status update.

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

HOT LINE Effective May 17, 2010

DELETE 0056021 **HLA-C Sequence-Based Typing** **HLACSBT**

HOT LINE NOTE: Please delete this test and refer to *HLA-C* Sequencing (2002814).

New Test 2002814 **HLA-C Sequencing** **SBT C**



Consent Form Recommended



HLA Test Request Form Recommended

Methodology: Polymerase Chain Reaction/Nucleic Acid Sequencing
Performed: Mon, Thu
Reported: 7-11 days

Specimen Required: Collect: One 5 mL yellow (ACD Solution A), lavender (EDTA), or pink (K₂EDTA) tube of peripheral blood.
Transport: 5 mL whole blood at 20-25°C. (Min: 1.5 mL)
Unacceptable Conditions: Heparinized, clotted, or frozen whole blood specimens.
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 3 days; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Background Information for *HLA-C* Sequencing:

Purpose: To identify *HLA-C* allelic polymorphisms at the level of individual nucleotides.

Methodology: PCR followed by *HLA-C* sequencing.

Analytical Sensitivity & Specificity: 99 percent.

Limitations: If fewer than 2 alleles are reported for a locus, the patient is likely homozygous. Rare diagnostic errors can occur due to primer site mutations. Occasionally the specific allele cannot be determined; in this case, the most likely allele assignment is made followed by a sequence of letters indicating other possible allele assignments. Interpretation of allele codes can be found at <http://bioinformatics.nmdp.org/HLA/alpha.html>.

Test Results: Results are reported as HLA locus C* followed by the two digit serologic antigen equivalent and the two digit assigned allele.

Analyte Specific Reagents (ASR) are used in many laboratory tests necessary for standard medical care and generally do not require U.S. Food and Drug Administration (FDA) approval or clearance. This test was developed and its performance characteristics determined by **HistoGenetics Inc (ASHI accreditation #03-1-NY-26-2)**. It has not been approved or cleared by the U.S. Food and Drug Administration. This test should not be considered as investigational or for research use. Test performed at **HistoGenetics Inc**.

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

CPT Code(s): 83891 Isolation; 83898 Amplification; 83904 x2 Sequencing; 83909 Capillary electrophoresis; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

This test is New York DOH approved.

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

HOT LINE Effective May 17, 2010

DELETE 0095845 HLA-DQ Oligotyping HLA DQ DNA

HOT LINE NOTE: Please delete this test and refer to *HLA-DQB* Genotyping (2002810).

New Test 2002810 *HLA-DQB* Genotyping HLA-DQ DNA



Consent Form Recommended



HLA Test Request Form Recommended

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

Specimen Required: Collect: One 5 mL lavender (EDTA) or pink (K₂EDTA), or 10 mL yellow (ACD Solution A or B).
Transport: 5 mL whole blood at 20-25°C. (Min: 3 mL)
Unacceptable Conditions: Specimens drawn in green (sodium or lithium heparin) tubes.
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Background Information for *HLA-DQB* Genotyping:

Purpose: For immunization/vaccination trials or to aid the clinical diagnosis of diseases strongly associated with the *HLA-DQB* locus.

Methodology: PCR followed by Sequence Specific Oligonucleotide Probe Hybridization of *HLA-DQB* locus.

Analytical Sensitivity & Specificity: Medium to high resolution of *HLA-DQB* locus.

Limitations: The presence of a disease-associated HLA combination does not establish a diagnosis. If less than 2 alleles are reported for a locus, the patient is likely homozygous. Rare diagnostic errors can occur due to primer or probe site mutations. This test is not sufficient for comprehensive HLA evaluation for clinical hematopoietic stem cell transplantation (refer to HLA Bone Marrow Transplantation Evaluation - 2002806).

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

Note: Order this test for single antigen *HLA-DQB* identification. Please specify antigens. Refer to *HLA-DR* Genotyping for single antigen *HLA-DR* identification.

CPT Code(s): 83891 Isolation; 83900 Multiplex Amplification; 83896 x10 Nucleic acid probes; 88384 Probes 11-50; 83912 Interpretation and report
 -Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

New York DOH approval pending. Call for status update.

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

HOT LINE Effective May 17, 2010

DELETE 0055653 **HLA-DRB1 Sequence-Based Typing** **HLADRB1**

HOT LINE NOTE: Please delete this test and refer to *HLA-DRB1* Sequencing (2002779).

New Test 2002779 **HLA-DRB1 Sequencing** **SBT DRB1**



Consent Form Recommended



HLA Test Request Form Recommended

Methodology: Polymerase Chain Reaction/Nucleic Acid Sequencing
Performed: Mon, Thu
Reported: 7-11 days

Specimen Required: Collect: One 5 mL yellow (ACD Solution A), lavender (EDTA), or pink (K₂EDTA) peripheral blood.
Transport: 5 mL whole blood at 20-25°C. (Min: 1.5 mL)
Unacceptable Conditions: Heparinized, clotted, or frozen whole blood specimens.
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 3 days; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Background Information for *HLA-DRB1* Sequencing:

Purpose: To identify *HLA-DRB1* allelic polymorphisms at the level of individual nucleotides.

Methodology: PCR followed by sequencing of *HLA-DRB1*.

Analytical Sensitivity & Specificity: 99 percent.

Limitations: If fewer than 2 alleles are reported for a locus, the patient is likely homozygous. Rare diagnostic errors can occur due to primer site mutations. Occasionally the specific allele cannot be determined; in this case, the most likely allele assignment is made followed by a sequence of letters indicating other possible allele assignments. Interpretation of allele codes can be found at <http://bioinformatics.nmdp.org/HLA/alpha.html>.

Test Results: Results are reported as HLA-DRB1* followed by the two digit serologic antigen equivalent and the two digit assigned allele.

Analyte Specific Reagents (ASR) are used in many laboratory tests necessary for standard medical care and generally do not require U.S. Food and Drug Administration (FDA) approval or clearance. This test was developed and its performance characteristics determined by **HistoGenetics Inc (ASHI accreditation #03-1-NY-26-2)**. It has not been approved or cleared by the U.S. Food and Drug Administration. This test should not be considered as investigational or for research use. Test is performed at **Histogenetics Inc**.

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

CPT Code(s): 83891 Isolation; 83898 Amplification; 83904 x2 Sequencing; 83909 Separation and identification; 83912 Interpretation and report
 -Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

This test is New York DOH approved.

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

HOT LINE Effective May 17, 2010

DELETE 0098580 **HLA DR Oligotyping** **HLA INT DR**

HOT LINE NOTE: Please delete this test and refer to *HLA-DR* Genotyping (2002798).

New Test 2002798 **HLA-DR Genotyping** **HLA-DR DNA**



Consent Form Recommended



HLA Test Request Form Recommended

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

Specimen Required: Collect: One 5 mL lavender (EDTA) or pink (K₂EDTA), or 10 mL yellow (ACD Solution A or B).
Transport: 5 mL whole blood at 20-25°C. (Min: 3 mL)
Unacceptable Conditions: Specimens drawn in green (sodium or lithium heparin) tubes.
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Background Information for *HLA-DR* Genotyping:

Purpose: For immunization/vaccination trials or to aid the clinical diagnosis of diseases strongly associated with the *HLA-DR* locus.

Methodology: PCR followed by Sequence Specific Oligonucleotide Probe Hybridization of *HLA-DR* locus.

Analytical Sensitivity & Specificity: Medium to high resolution of *HLA-DR* locus.

Limitations: The presence of a disease-associated HLA combination does not establish a diagnosis. If less than 2 alleles are reported for a locus, the patient is likely homozygous. Rare diagnostic errors can occur due to primer or probe site mutations. This test is not sufficient for comprehensive HLA evaluation for clinical hematopoietic stem cell transplantation (refer to HLA Bone Marrow Transplantation Evaluation - 2002806).

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

Note: Order this test for single antigen *HLA-DR* identification. Please specify antigens. Refer to *HLA-DQB* Genotyping for single antigen *HLA-DQB* identification.

CPT Code(s): 83891 Isolation; 83898 Amplification; 83896 x10 Nucleic acid probes; 88384 Probes 11-50; 88385 Probes 51-250; 83912 Interpretation and report -Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

New York DOH approval pending. Call for status update.

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

HOT LINE Effective May 17, 2010

0051650

HNPCC/Lynch Syndrome (*MLH1*) Sequencing and Deletion/Duplication

MLH1 FGA

Reference Interval:

Available Separately	Components	Reference Interval
No	<i>MLH1</i> Sequencing	By report
No	<i>MLH1</i> Deletion/Duplication	By report

Interpretive Data:

Background Information for HNPCC/Lynch Syndrome (*MLH1*) Sequencing and Deletion/Duplication:

Characteristics: Increased risk of colorectal and extra-colonic cancers including endometrial, renal pelvis, ureter, ovary, stomach, small intestine, and hepatobiliary tract.

Incidence: 1-2 percent of colorectal cancer is due to mismatch repair gene mutations.

Inheritance: Autosomal dominant

Penetrance of *MLH1* Mutations: 80 percent lifetime risk of colorectal cancer; 20-60 percent risk for endometrial cancer.

Cause: Pathogenic germline *MLH1*, *MSH2*, *MSH6*, and *PMS2* gene mutations.

Gene Tested: *MLH1*

Clinical Sensitivity: Approximately 45 percent of Lynch syndrome is due to *MLH1* mutations.

Methodology: Bidirectional sequencing of *MLH1* coding regions and intron-exon boundaries; multiplex ligation-dependent probe amplification (MLPA) to detect large *MLH1* exonic deletions.

Analytical Sensitivity & Specificity: 99 percent.

Limitations: Rare diagnostic errors can occur due to primer and probe site mutations. The breakpoints of large deletions/duplications will not be determined. Regulatory region mutations, deep intronic mutations and mutations in genes other than *MLH1* will not be detected.

This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

HOT LINE Effective May 17, 2010

0051656 HNPCC/Lynch Syndrome (*MSH6*) Sequencing and Deletion/Duplication MSH6 FGA

Reference Interval:

Available Separately	Components	Reference Interval
No	<i>MSH6</i> Sequencing	By report
No	<i>MSH6</i> Deletion/Duplication	By report

Interpretive Data:

Background Information for HNPCC/Lynch Syndrome (*MSH6*) Sequencing and Deletion/Duplication:

Characteristics: Increased risk of colorectal and extra-colonic cancers including endometrial, renal pelvis, ureter, ovary, stomach, small intestine, and hepatobiliary tract.

Incidence: 1-2 percent of colorectal cancer is due to mismatch repair gene mutations.

Inheritance: Autosomal dominant

Penetrance of *MSH6* Mutations: Risk of colorectal cancer is 40 percent in men and 20 percent in women up to age 80. Women also have a 40 percent risk for endometrial cancer up to age 80.

Cause: Pathogenic germline *MLH1*, *MSH2*, *MSH6*, and *PMS2* gene mutations.

Gene Tested: *MSH6*

Clinical Sensitivity: Approximately 5 percent of Lynch syndrome is due to *MSH6* mutations.

Methodology: Bidirectional sequencing of *MSH6* coding regions and intron-exon boundaries; multiplex ligation-dependent probe amplification (MLPA) to detect large *MSH6* exonic deletions.

Analytical Sensitivity & Specificity: 99 percent.

Test Limitations: Rare diagnostic errors can occur due to primer and probe site mutations. The breakpoints of large deletions/duplications will not be determined. Regulatory region, deep intronic mutations and mutations in genes other than *MSH6* will not be detected.

This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

0051737 HNPCC/Lynch Syndrome (*PMS2*) Sequencing and Deletion/Duplication PMS2 FGA

Interpretive Data:

Background information for HNPCC/Lynch Syndrome (*PMS2*) Sequencing and Deletion/Duplication

Characteristics of Lynch Syndrome: Increased risk of colorectal and extra-colonic cancers including endometrial, renal pelvis, ureter, ovary, stomach, small intestine and hepatobiliary tract.

Incidence: 1-2 percent of colorectal cancer is due to mismatch repair gene mutations.

Inheritance: Autosomal dominant.

Penetrance: Unknown for *PMS2* mutations.

Cause: Pathogenic germline *MLH1*, *MSH2*, *MSH6*, and *PMS2* gene mutations.

Gene tested: *PMS2*

Clinical Sensitivity: Less than 5 percent of Lynch syndrome cases are due to *PMS2* mutations.

Methodology: Bidirectional sequencing of *PMS2* coding regions and intron-exon boundaries; multiplex ligation-dependent probe amplification (MLPA) to detect large *PMS2* exonic deletions.

Analytical Sensitivity & Specificity: 99 percent.

Limitations: Rare diagnostic errors can occur due to primer and probe site mutations. The breakpoints of large deletions/duplications will not be determined. Regulatory region mutations, deep intronic mutations and mutations in genes other than *PMS2* will not be detected. *PMS2* exons 3, 4, 12, 13, 14 or 15 are not evaluated for deletions/duplications.

This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

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

Please refer to Statement C in the Compliance section in the front of the Laboratory Test Directory.

✓ **HOT LINE NOTE:** The addition of the Roche statement to the 'Interpretive Data' field also applies to:

- Biotinidase Deficiency (*BTD*) 5 Mutations (0051700)
- Thanatophoric Dysplasia, Types 1 & 2 (*FGFR3*) 13 Mutations, Fetal (0051508)

HOT LINE Effective May 17, 2010

0099869 Homocysteine, Total HOMOCY-QNT

Note: False elevations of plasma or serum homocysteine may occur if the plasma or serum is not promptly separated from the cells at the time of collection.

0080422 Homovanillic Acid (HVA), Urine HVA U

HOT LINE NOTE: Additional component information associated with this test that affects interface clients only:

Code	Test Name	Change	Order/Result	Comments
0081305	HVA, Urine mg	Add Component	R	Add existing component

New Test 2003020 Human Epididymis Protein 4 (HE4) HE4

Effective April 19, 2010

Methodology: Enzyme Immunoassay
Performed: Varies
Reported: Varies

Specimen Required: Collect: Plain red or serum separator tube.
Specimen Preparation: Refrigerated and frozen specimens also acceptable. Submit specimen in ARUP Standard Transport Tube.
Storage/Transport Temperature: 0.5 mL serum at 20-25°C. (Min: 0.1 mL)
Unacceptable Conditions: Hemolyzed or lipemic specimens.
Stability (collection to initiation of testing): Ambient: 5 days; Refrigerated: 1 week; Frozen: 28 days

Reference Interval: By report

CPT Code(s): 86305

This test is New York DOH approved.

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

0091177 Hydrocarbon & Oxygenated Volatiles, Serum or Plasma HYDROX OXY

Methodology: Gas Chromatography

Specimen Required: Collect: One gray (potassium oxalate/sodium fluoride) or plain red.
Specimen Preparation: Submit specimen in an ARUP Standard Transport Tube.
Storage/Transport Temperature: 2 mL serum or plasma at 2-8°C. (Min: 1 mL)
Unacceptable Conditions: Separator tubes.
Stability (collection to initiation of testing): Ambient: Undetermined; Refrigerated: Undetermined; Frozen: Undetermined

HOT LINE Effective May 17, 2010

0092335 17-Hydroxypregnenolone Baseline Specimen

OHPRGNBASE

Reference Interval:

Females	Males
Premature (26-28 weeks): 1219-9799 ng/dL Premature (29-36 weeks): 346-8911 ng/dL Full Term (1-5 months): 229-3104 ng/dL 6 months - 364 days: 46-1499 ng/dL 1-2 years: less than or equal to 401 ng/dL 3-6 years: less than or equal to 281 ng/dL 7-9 years: less than or equal to 212 ng/dL 10-12 years: less than or equal to 398 ng/dL 13-15 years: less than or equal to 407 ng/dL 16-17 years: less than or equal to 423 ng/dL 18 years and older: Less than 226 ng/dL	Premature (26-28 weeks): 1219-9799 ng/dL Premature (29-36 weeks): 346-8911 ng/dL Full Term (1-5 months): 229-3104 ng/dL 6 months - 364 days: 46-1499 ng/dL 1-2 years: less than or equal to 482 ng/dL 3-6 years: less than or equal to 290 ng/dL 7-9 years: less than or equal to 187 ng/dL 10-12 years: less than or equal to 392 ng/dL 13-15 years: 35-465 ng/dL 16-17 years: 32-478 ng/dL 18 years and older: Less than 442 ng/dL
Tanner Stage I: less than or equal to 235 ng/dL Tanner Stage II: less than or equal to 367 ng/dL Tanner Stage III: less than or equal to 430 ng/dL Tanner Stage IV-V: less than or equal to 412 ng/dL	Tanner Stage I: less than or equal to 208 ng/dL Tanner Stage II: less than or equal to 355 ng/dL Tanner Stage III: less than or equal to 450 ng/dL Tanner Stage IV-V: 35-478 ng/dL

0092332 17-Hydroxyprogesterone Quantitative by LC-MS/MS, Serum or Plasma

OHPRGSTON

Reference Interval:

Females	Males
Premature (26-28 weeks): 124 to 841 ng/dL Premature (29-35 weeks): 26 to 568 ng/dL Full term Day 3: 7 to 77 ng/dL 4 days-30 days: 7-106 ng/dL 1-5 months: 13-106 ng/dL 6-35 months: less than or equal to 211 ng/dL 3-6 years: less than or equal to 278 ng/dL 7-9 years: less than or equal to 71 ng/dL 10-12 years: less than or equal to 129 ng/dL 13-15 years: 9 to 208 ng/dL 16-17 years: less than or equal to 178 ng/dL 18 years and older: Less than 207 ng/dL Follicular: 15 to 70 ng/dL Luteal: 35 to 290 ng/dL	Premature (26-28 weeks): 124 to 841 ng/dL Premature (29-35 weeks): 26 to 568 ng/dL Full term Day 3: 7 to 77 ng/dL 4 days-2 months: less than 200 ng/dL 3-5 months: 3-90 ng/dL 6-35 months: less than or equal to 181 ng/dL 3-6 years: less than or equal to 205 ng/dL 7-9 years: less than or equal to 63 ng/dL 10-12 years: less than or equal to 79 ng/dL 13-15 years: 9 to 140 ng/dL 16-17 years: 24 to 192 ng/dL 18 years and older: Less than 139 ng/dL
Tanner Stage I: less than or equal to 74 ng/dL Tanner Stage II: less than or equal to 164 ng/dL Tanner Stage III: 13 to 209 ng/dL Tanner Stage IV-V: 7 to 170 ng/dL	Tanner Stage I: less than or equal to 62 ng/dL Tanner Stage II: less than or equal to 104 ng/dL Tanner Stage III: less than or equal to 151 ng/dL Tanner Stage IV-V: 20 to 173 ng/dL

✓ **HOT LINE NOTE:** This change also applies to:

- Adrenal Steroid Quantitative Panel by LC-MS/MS, Serum or Plasma (0092330)
- CAH 11-Beta Hydroxylase Deficiency Panel (2002282)
- CAH 21 Hydroxylase Deficiency Panel (2002283)
- Congenital Adrenal Hyperplasia Treatment Panel (2002029)
- Virilization Panel 2 (2002281)

HOT LINE Effective May 17, 2010

2002348 25-Hydroxyvitamin D2 and D3 by Tandem Mass Spectrometry, Serum VITD2D3TMS

Reference Interval:

0-17 years:

Deficiency: Less than 20 ng/mL

Optimum level: Greater than or equal to 20 ng/mL*

*(Wagner CL et al. Pediatrics 2008; 122: 1128-38.)

18 years and older:

Deficiency: Less than 20 ng/mL

Insufficiency: 20-29 ng/mL

Optimum Level: 30-80 ng/mL

Possible Toxicity: Greater than 150 ng/mL

0051367 Hypochondroplasia (FGFR3) 1 Mutation HYPOCH

Specimen Required: Collect: Collect: One 3 mL lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).

Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)

Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:

Background Information for Hypochondroplasia (FGFR3) 1 Mutation:

Characteristics: Short stature, stocky build, large head, shortening of the proximal or middle segments of the extremities, short broad hands and feet, limitation of elbow extension, and mild joint laxity. Phenotype not evident in infancy, becomes apparent in childhood.

Incidence: 1:15,000-40,000

Inheritance: Autosomal dominant; usually arising from a *de novo* mutation.

Cause: 70 percent of cases result from an A or G nucleotide substitution for C at 1620 in the *FGFR3* gene.

Methods: PCR and fluorescent resonance energy transfer.

Limitations: Mutations in *FGFR3* and other than c.1620C>A/G will not be detected.

Analytic Sensitivity and Specificity: 99 percent

Clinical Sensitivity: 70 percent

This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

CPT Code(s): 83891 Isolation; 83898 x2 Amplification; 83896 x4 Nucleic acid probes; 83912 Interpretation and report. Additional CPT code modifiers may be required for procedures to test for oncologic or inherited disorders.

0098843 IGF Binding Protein-1 IGFBP-1

Specimen Required: Patient Preparation: Overnight fasting preferred.

Collect: Plain red or serum separator tube.

Specimen Preparation: EDTA plasma also acceptable. Refrigerated and frozen also acceptable. Submit specimen in an ARUP Standard Transport Tube.

Storage/Transport Temperature: 1 mL serum at 20-25°C. (Min: 0.2 mL)

Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 week; Frozen: 1 month

0040227 IgVH Mutation Analysis by Sequencing IGVH MUT

CPT Code(s): 83891 Isolation; 83902 Reverse transcription; 83898 x5 Amplification; 83894 Gel separation; 83912 Interpretation and report; if sequencing is performed, add 83892 Enzyme digestion; 83904 Sequencing, 83909 Capillary electrophoresis - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

HOT LINE Effective May 17, 2010

New Test 2002577 **Infliximab** **INFLIXIMAB**

Effective April 19, 2010

Methodology: Enzyme-Linked Immunosorbent Assay

Performed: Varies

Reported: Varies

Specimen Required: Collect: Serum, serum separator tube or plain red.

Transport: 2 mL serum at 2-8°C. Submit specimen in an ARUP Standard Transport Tube.

Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 1 month

Reference Interval: By report

CPT Code(s): 83520

New York DOH approval pending. Call for status update.

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

New Test 2002579 **Infliximab/HACA Measurement** **INFLIXHACA**

Effective April 19, 2010

Methodology: Enzyme-Linked Immunosorbent Assay

Performed: Varies

Reported: Varies

Specimen Required: Collect: Serum, serum separator tube or plain red.

Transport: 2 mL serum at 2-8°C. Submit specimen in an ARUP Standard Transport Tube.

Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 1 month

Reference Interval: By report

CPT Code(s): 83520

New York DOH approval pending. Call for status update.

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

HOT LINE Effective May 17, 2010

New Test 2002942 **Influenza Virus A & B DFA (Includes Respiratory Mini Panel with H1N1 (2009) Typing by RT-PCR 2002559)** **FLUFAPCRT**

Effective April 19, 2010

Methodology: Direct Fluorescent Antibody Stain
Performed: Sun-Sat
Reported: Within 24 hours

Specimen Required: Collect: Respiratory specimen: nasal swabs, nasopharyngeal swab, throat swabs or nasal aspirates. Transport in viral transport media (Microtest M4 or UTM) (ARUP Supply #12884). Source of specimen is required.
Storage/Transport Temperature: Specimen in viral transport media at 2-8°C. (Min: 2 mL) Source of specimen is required. Place each specimen in a separate, individually sealed bag. Submit specimen according to Biological Substance, Category B, shipping guidelines.
Unacceptable Conditions: Slides, dry swabs, leaking or nonsterile containers. Respiratory aspirates in collection containers with tubing. These containers tend to leak, compromising the specimen.
Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: 10 days; Frozen: 2 months

Reference Interval: Negative

Note: The Respiratory Mini Panel with H1N1 (2009) Typing by RT-PCR (2002559) will be automatically ordered and performed regardless of the DFA result.

CPT Code(s): 87276 Influenza A, FA; 87275 Influenza B, FA; 87798 H1N1 2009; 87801 Respiratory Mini Panel

This test is New York DOH approved.

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

0070413 Inhibin B INHIBINB
Effective Immediately

Reference Interval:

Male	Female
0-6 years: 40-630 pg/mL	0-6 years less than 10-73 pg/mL
7-10 years: 35-170 pg/mL	7-10 years less than 10-130 pg/mL
11-18 years: 50-475 pg/mL	11-12 years less than 10-186 pg/mL
19-45 years: 40-450 pg/mL	13-18 years less than 10-360 pg/mL
Greater than or equal to 46 years: less than 10-200 pg/mL	Pre-menopausal less than 10-290 pg/mL
	Follicular phase 10-290 pg/mL
	Post-menopausal greater than or equal to 16 pg/mL

HOT LINE NOTE: This update is to address a printing error in the February Hot Line document, where both the new reference intervals and old intervals were printed.

HOT LINE Effective May 17, 2010

0070063 Insulin, Fasting INSULIN FT

Specimen Required: Collect: One 4 mL serum separator tube. Also acceptable: lavender (EDTA) or pink (K₂EDTA).
Storage/Transport Temperature: 1 mL serum or plasma, frozen. (Min 0.5 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Allow serum to clot completely at room temperature. Separate serum or plasma from cells ASAP.
Unacceptable Conditions: Heparinized plasma, **vitreous and I.V. fluids**. Specimens collected in gray (sodium fluoride/potassium oxalate). Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 1 month

0070240 Insulin, I.V. Fluid INS IVF

Specimen Required: Collect: I.V. fluid.
Storage/Transport Temperature: 1 mL I.V. fluid, frozen. (Min: 0.4 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: **CRITICAL FROZEN. Additional specimens must be submitted when multiple tests are ordered.** Please specify concentration if known.
Unacceptable Conditions: **Any specimens that are not I.V. fluid.**
Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: Unacceptable; Frozen: 1 month

0070064 Insulin, 30 Minutes INSULIN 30

Specimen Required: Collect: One 4 mL serum separator tube. Also acceptable: lavender (EDTA) or pink (K₂EDTA).
Storage/Transport Temperature: 1 mL serum or plasma, frozen. (Min: 0.4 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Allow serum to clot completely at room temperature. Separate serum or plasma from cells ASAP.
Unacceptable Conditions: Heparinized plasma, **vitreous and I.V. fluids**. Specimens collected in gray (sodium fluoride/potassium oxalate). Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 1 month

Reference Interval: 30 minutes **post challenge:** 20-112 µIU/mL

Note: The reference intervals are based on a 75 **gram** glucose challenge.

0070690 Insulin, Veterinary VT INSULIN

Specimen Required: Collect: One 4 mL serum separator tube. Also acceptable: lavender (EDTA). (Veterinary specimens only)
Storage/Transport Temperature: 1.0 mL serum, frozen. (Min: 0.5 mL) Submit specimen in an ARUP Standard Transport Tube.
Unacceptable Conditions: Heparin plasma specimens, **vitreous and I.V. fluids**.
Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: 2 days; Frozen: 1 month

0051393 Interleukin-1-Receptor-Associated Kinase-4 (IRAK-4) Deficiency Screen IRAK-4

Performed: Tue-Fri
Reported: 4-9 days

DELETE 0091124 Iodide, Urine IODIDE URN

HOT LINE NOTE: Please delete this test and refer to Iodine, 24 Hour, Urine (0092487) or Iodine, Random, Urine (2002992).

HOT LINE Effective May 17, 2010

New Test 2002992 Iodine, Random, Urine **IODINE RAN**

Effective April 19, 2010

Methodology: Inductively Coupled Plasma/Mass Spectrometry
Performed: Varies
Reported: Varies

Specimen Required: Patient Preparation: If gadolinium-containing contrast media has been administered, a specimen cannot be collected for 48 hours.
Collect: Random urine.
Specimen Preparation: Submit specimen in an ARUP Standard Transport Tube.
Storage/Transport Temperature: 2 mL urine at 2-8°C. (Min: 0.2 mL)
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: Unacceptable

Reference Interval: By report

CPT Code(s): 83789

This test is New York DOH approved.

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

0091180 Ipecac Use Markers Screen, Serum or Plasma IPECAC SP

Specimen Required: Collect: Plain red, lavender (EDTA), or pink (K₂EDTA).
Specimen Preparation: Submit specimen in an ARUP Standard Transport Tube.
Storage/Transport Temperature: 2 mL serum or plasma at 2-8°C. (Min: 0.8 mL)
Remarks: Separate serum or plasma from cells within 10 minutes.
Unacceptable Conditions: Separator tubes.
Stability (collection to initiation of testing): Ambient: 16 days; Refrigerated: 16 days; Frozen: 16 days

CPT Code(s): 80101 if negative; add 82542 if positive

2000271 Isohemagglutinin Titer, IgG IRL ISO G

Note: Only IgG isohemagglutinin titers based on ABO screening results will be performed for this test. If both IgG and IgM titers are desired, order Isohemagglutinin Titer, IgG & IgM (2000280). Specimens are screened for antibodies; if positive, an antibody panel will be performed. Titers will be performed as indicated for specific blood groups. Additional charges will apply to antibody identification and titer testing.

2000280 Isohemagglutinin Titer, IgG & IgM IRL ISO MG

Note: Isohemagglutinin titers contain both IgM and IgG. Both IgG and IgM titers will be performed for this test. If only IgM or IgG titer is desired, order Isohemagglutinin Titer, IgG (2000271) or Isohemagglutinin Titer, IgM (2000270). Specimens are screened for antibodies; if positive, an antibody panel will be performed. Titers will be performed as indicated for specific blood groups. Additional charges will apply to antibody identification and titer testing.

2000270 Isohemagglutinin Titer, IgM IRL ISO M

Note: Only IgM isohemagglutinin titers based on ABO screening results will be performed for this test. If both IgG and IgM titers are desired, order Isohemagglutinin Titer, IgG & IgM (2000280). Specimens are screened for antibodies; if positive, an antibody panel will be performed. Titers will be performed as indicated for specific blood groups. Additional charges will apply to antibody identification and titer testing.

HOT LINE Effective May 17, 2010

0051644 Kell K/k Antigen (KEL) Genotyping KEL

Specimen Required: Collect and Transport:
Cultured cells: Two T-25 flasks at 80 percent confluent of cultured amniocytes. Fill flasks with culture media to ship at 20-25°C. Backup cultures must be retained at the client's institution until testing is complete. **If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787.**
Maternal specimen: One 3 mL whole blood, lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B) at 20-25°C.
Amniotic fluid: 10 mL unspun fluid at 20-25°C. (Min: 5 mL)
Remarks: Fetal specimens are CRITICAL AMBIENT and must be received within 48 hours of shipment due to liability of cells. **Maternal whole blood specimen is recommended for proper fetal test interpretation. Order Maternal Cell (MCC MAT) (0050608).**
Patient History Form is available on the ARUP Web site or by contacting ARUP Client Services.
Stability (collection to initiation of testing): **Cultured cells or amniotic fluid:** Ambient: 2 days; Refrigerated: Unacceptable; Frozen: Unacceptable
Whole blood: Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

CPT Code(s): 83891 Isolation; 83898 Amplification; 83896 x2 Nucleic acid probes; 83912 Interpretation and report. Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

0080940 Lamellar Body Counts LBC

Specimen Required: Patient Preparation: Amniocentesis
Collect: Amniotic fluid. Amniocentesis fluid preferred. **Do not centrifuge.**
Storage/Transport Temperature: 1 mL amniotic fluid at 2-8°C. (Min: 0.25 mL)
Unacceptable Conditions: Vaginal pools containing mucous; **specimens that are grossly bloody or that contain meconium;** frozen specimens.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 week; Frozen: Unacceptable

HOT LINE Effective May 17, 2010

0025016 Lead, Industrial Exposure Panel, Adults

LEAD-IND

Reference Interval:

Available Separately	Components	Reference Interval
No	Lead, Blood	16 years and older: 0.0-24.9 µg/dL
Yes as (0020614)	Zinc Protoporphyrin (ZPP), Whole Blood	0-40 µg/dL
	Zinc Protoporphyrin (ZPP) to Heme Ratio	0-69 µmol ZPP/mol heme

HOT LINE NOTE: Please remove 0-15 years: 0.0-9.9 ug/dL Reference Interval for Lead, Blood.

0060113 Legionella Species, Culture

MC LEGION

Specimen Required: Collect: Respiratory tract secretions, aspirates, tissues, fluids, sputum, abscess material; pericardial fluid, **blood in SPS**. Source of specimen is preferred.
Storage/Transport Temperature: Sterile container. Send immediately to ARUP at 2-8°C. (Min. 0.5 mL) If delay in transport (greater than 48 hours), transport frozen. **Transport blood in Vacutainer, 8 mL SPS for Microbiology (ARUP Supply #24964)** at 2-8°C. Place each specimen in a separate, individually sealed bag. Submit specimen according to Biological Substance, Category B, shipping guidelines.
Remarks: To prevent drying, submit specimen in sterile, nonbacteriostatic water. DO NOT use saline in specimen collection.
 BAL fluids containing saline are acceptable. Client will be notified of positive culture.
Unacceptable Conditions: Urine, stool, wounds, or other culture material from non-respiratory sites. Dry specimens, nonsterile or leaking containers, or specimens submitted in saline, formalin, or viral transport medium.
Stability (collection to initiation of testing): Ambient: 2 hours; Refrigerated: 48 hours; Frozen: 1 week

HOT LINE Effective May 17, 2010

New Test	2002945	Legius Syndrome (<i>SPRED1</i>) Sequencing and (<i>NF1</i>) Sequencing Exon 22 (Exon 17)	LS FGS
-----------------	----------------	---	---------------

Effective Immediately



Patient History for Legius Syndrome

Methodology: Polymerase Chain Reaction/Sequencing
Performed: Varies
Reported: Within 21 days

Specimen Required: Collect: One 3 mL lavender (EDTA), pink (K₂EDTA) or yellow (ACD Solution A or B).
Storage/Transport Temperature: 3 mL whole blood at 2-8°C. (Min: 1 mL)
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:

Background Information for Legius Syndrome (*SPRED1*) Sequencing and (*NF1*) Sequencing Exon 22 (Exon 17):

Characteristics: NF1-like syndrome with café au lait spots, axillary and inguinal freckling, learning disability and macrocephaly. Neurofibromas, lisch nodules and CNS tumors are not observed.

Incidence: Unknown; may represent 0.5 percent of NF1 diagnoses or 8 percent of those with isolated café au lait spots.

Inheritance: Autosomal dominant.

Cause: Pathogenic *SPRED1* gene mutations and a *NF1* gene 3 base pair exon 22 (exon 17) deletion.

Clinical Sensitivity: Unknown.

Methodology: Bidirectional sequencing of the entire *SPRED1* coding region and intron-exon boundaries. Bidirectional sequencing of the *NF1* gene, exon 22 (exon 17 by NF Consortium nomenclature).

Analytical Sensitivity and Specificity: 99 percent.

Limitations: Some *SPRED1* gene regulatory region mutations, deep intronic mutations, and large deletions/duplications will not be detected. In the *NF1* gene, only exon 22 (exon 17) is analyzed. Rare diagnostic errors can occur due to primer site mutations.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

CPT Code(s): 83891 Isolation; 83898 x9 Amplification; 83904 x9 Sequencing; 83909 Capillary electrophoresis, 83912 Interpretation and report. Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

New York DOH approval pending. Call for status update.

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

2002650	Lymphoma (Aggressive) Panel by FISH	FISH ALYMP
Performed:	Sun-Sat	
Reported:	3-10 days	

0051674	Macular Degeneration, Age-Related, 2 DNA Markers	AMD
Specimen Required:	<u>Collect:</u> One 3 mL lavender (EDTA), pink (K ₂ EDTA), or yellow (ACD Solution A or B). <u>Transport:</u> 3 mL whole blood at 2-8°C. (Min: 1 mL) <u>Stability (collection to initiation of testing):</u> Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable	

CPT Code(s): 83891 Isolation; 83900 Amplification; 83896 x4 Nucleic acid probe; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

HOT LINE NOTE: Please remove information from the Unacceptable Conditions field under Specimen Requirements.

HOT LINE Effective May 17, 2010

0099265 Manganese, Serum MANG

Specimen Required: Collect: One 7 mL royal blue (no additives).
Transport: 2 mL serum at 20-25°C. (Min: 0.5 mL) Submit specimen in an ARUP Trace Element-Free Transport Tube (ARUP supply #43116).
Remarks: Centrifuge and pour off serum into an ARUP Trace Element-Free Transport Tube. Do not allow serum to remain on cells.
Unacceptable Conditions: Separator tubes and specimens that are not separated from the red cells, or clot, **within 6 hours**.
Stability (collection to initiation of testing): If the specimen is drawn and stored in the appropriate container, the trace element values do not change with time.

0081293 Maternal Screening, Sequential, Specimen #1 MS SEQ-1

Methodology: **Chemiluminescent Immunoassay**

Specimen Required: Collect: One 7 mL serum separator tube or plain red. Specimen must be drawn between 11 weeks, 0 days and 13 weeks, 6 days gestation (Crown-Rump length (CRL) must be 4.2-7.9 cm).
Storage/Transport Temperature: 3 mL serum at 2-8°C. (Min: 1 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: This test requires a nuchal translucency (NT) measurement that has been performed by a certified ultrasonographer. The ultrasonographer MUST be certified to perform NT measurements by one of the following agencies: FASTER trial, Fetal Medicine Foundation (FMF) or Nuchal Translucency Quality Review (NTQR). To avoid possible test delays for an ultrasonographer that is new to our database, please contact the genetic counselor at 800-242-2787 x2020 prior to sending specimen.

If an NT is unobtainable, order Maternal Serum Integrated Screen (0081062 and 0081064), which can be interpreted without an NT value.

The sequential maternal screen also requires the following information: a crown-rump length measurement (cm), ultrasonographer's name and certification number, date of ultrasound, patient's date of birth, current weight, due date, number of fetuses present, patient's race, if the patient requires insulin, if there is a known family history of neural tube defects, if the patient has had a previous pregnancy with a chromosome abnormality, if the patient is taking valproic acid or carbamazepine (Tegretol), physician's name and phone number, and for in vitro fertilization pregnancies, the age of the egg donor. Separate serum from cells ASAP.

Unacceptable Conditions: Specimens exposed to repeated freeze/thaw cycles. Heparin, EDTA, or citrate plasma. Hemolyzed specimens. A crown rump length greater than 7.9 cm.

Stability (collection to initiation of testing): After separation from cells: Ambient: **8 hours**; Refrigerated: **2 weeks**; Frozen: **2 months**

HOT LINE NOTE: Additional component information associated with this test that affects interface clients only:

Code	Test Name	Change	Order/Result	Comments
2002856	EER Maternal Screening, INT-1	Add Component	R	Add new component for Enhanced Reporting application.

0080269 Maternal Serum Screen, Alpha Fetoprotein, hCG, Estriol, & Inhibin A AFP MS4

HOT LINE NOTE: Additional component information associated with this test that affects interface clients only:

Code	Test Name	Change	Order/Result	Comments
0080269	Maternal Serum Screen, Alpha Fetoprotein, hCG, Estriol, & Inhibin A	Add Component	O	Add component 2002850

HOT LINE Effective May 17, 2010

0081150 Maternal Serum Screen, First Trimester MS FT

Methodology: Chemiluminescent Immunoassay

Specimen Required: Patient Preparation: Patient History information is required.

Collect: One 7 mL serum separator tube or plain red. Specimen must be drawn in the first trimester between 11 weeks, 0 days and 13 weeks, 6 days. (Crown-Rump length (CRL) must be between 4.2-7.9 cm).

Storage/Transport Temperature: 3 mL serum at 2-8°C. (Min: 1 mL) Submit specimen in an ARUP Standard Transport Tube.

Remarks: This test requires a nuchal translucency (NT) measurement that has been performed by a certified ultrasonographer. The ultrasonographer MUST be certified to perform NT measurements by one of the following agencies: FASTER trial, Fetal Medicine Foundation (FMF) or Nuchal Translucency Quality Review (NTQR). To avoid possible test delays for an ultrasonographer that is new to our database, please contact the genetic counselor at 800-242-2787 x2020 prior to sending specimen.

If an NT is unobtainable, order Maternal Serum Integrated Screen (0081062 and 0081064), which can be interpreted without an NT value.

The First Trimester Maternal Screen also requires the following information: a crown-rump length measurement (cm), ultrasonographer's name and certification number, date of ultrasound, patient's date of birth, current weight, due date, number of fetuses present, patient's race, if the patient has had a previous pregnancy with a chromosome abnormality, physician's name and phone number; and for in vitro fertilization pregnancies, the age of the egg donor. Separate serum from cells ASAP.

Unacceptable Conditions: Specimens exposed to repeated freeze/thaw cycles. Hemolyzed specimens. Heparin, EDTA or citrated plasma. A crown-rump length greater than 7.9 cm.

Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 2 weeks; Frozen: 2 months

0081062 Maternal Serum Screening, Integrated, Specimen #1 MS INT-1

HOT LINE NOTE: Additional component information associated with this test that affects interface clients only:

Code	Test Name	Change	Order/Result	Comments
2002856	EER Maternal Screening, INT-1	Add Component	R	Add new component for Enhanced Reporting application.

HOT LINE Effective May 17, 2010

0050184 Metanephrines, Plasma (Free) META PF

Performed: Sun-Sat
Reported: 2-6 days

Specimen Required: Patient Preparation: Discontinue epinephrine and epinephrine-like drugs at least one week before obtaining the specimen. The patient must refrain from using acetaminophen for 48 hours before the specimen is drawn. The patient must refrain from using caffeine, medications, and tobacco; and from drinking coffee, tea, or alcoholic beverages for at least four hours before the specimen is drawn. Collect the specimen after the patient has had 15 minutes rest in a supine position. An overnight fast prior to specimen collection is recommended.

Collect: One 7 mL lavender (EDTA) or pink (K₂EDTA).

Transport: 4 mL plasma, frozen. (Min: 1.5 mL) Submit specimen in an ARUP Standard Transport Tube.

Remarks: **CRITICAL FROZEN.** Collect specimen and place in ice bath. Centrifuge at 4°C within 1 hour. **Remove plasma from cells and freeze immediately.**

Unacceptable Conditions: Grossly hemolyzed, ambient, or refrigerated specimens. Sodium citrate-preserved plasma.

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

New Test 2002928 Metformin, Urine METFORM U

Effective April 19, 2010

Methodology: High Performance Liquid Chromatography
Performed: Varies
Reported: Varies

Specimen Required: Collect: Random urine

Specimen Preparation: Submit specimen in an ARUP Standard Transport Tube.

Transport: 1 mL urine at 2-8°C. (Min: 0.3 mL)

Stability (collection to initiation of testing): Ambient: 21 days; Refrigerated: 21 days; Frozen: 5 months

Reference Interval: By report

CPT Code(s): 80299

This test is New York DOH approved.

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

HOT LINE Effective May 17, 2010

0051286 Methotrexate Sensitivity by MTHFR Genotyping MTX MTHFR

Specimen Required: Collect: One 3 mL lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).
Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

CPT Code(s): 83891 Isolation; 83900 Molecular diagnostics; 83896 x4 Nucleic acid probe; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

0055655 Methylenetetrahydrofolate Reductase (MTHFR) 2 Mutations MTHFR PCR

Specimen Required: Collect: One 3 mL lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).
Transport: 3 mL whole blood at 2-8°C.
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

HOT LINE NOTE: Please remove the information from the Unacceptable Conditions field under Specimen Requirements.

0051448 Mucopolipidosis, Type IV (MCOLN1) 2 Mutations MCOLN1

Specimen Required: Collect: One 3 mL lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).
Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:

Background information for Mucopolipidosis, Type IV (MCOLN1) 2 Mutations:

Characteristics: Early onset of severe psychomotor delay, progressive visual impairment from corneal clouding and retinal degeneration. 15 percent of affected will have progressive neurological degeneration. Affected persons may learn to say a few words or walk independently.

Incidence: 1 in 63,000 Ashkenazi Jewish individuals; unknown in other ethnicities.

Inheritance: Autosomal recessive.

Cause: Deleterious *MCOLN1* gene mutations.

Mutations Tested: del6.4kb and IVS3(-2)A>G.

Clinical Sensitivity: 95 percent in Ashkenazi Jewish individuals, unknown in other ethnicities.

Methodology: PCR and allele-specific primer extension by bead array with fluorescence detection.

Analytical Sensitivity and Specificity: Greater than 99 percent.

Limitations: Mutations other than del6.4kb and IVS3(-2)A>G will not be detected. Rare diagnostic errors may occur due to primer site mutations.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

HOT LINE Effective May 17, 2010

0051492 Multiple Endocrine Neoplasia, Type 2B (RET) 2 Mutations MEN 2 B

Specimen Required: Collect: One 3 mL lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).
Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:

Background Information for Multiple Endocrine Neoplasia, Type 2B (RET) 2 Mutations:
Characteristics: Medullary carcinoma of the thyroid, pheochromocytoma, mucosal neuromas, and Marfanoid body habitus.
Incidence: Approximately 1:600,000
Inheritance: Autosomal dominant; 50 percent of cases caused by *de novo* mutations.
Penetrance: 100 percent for medullary thyroid carcinoma, 50 percent for pheochromocytoma.
Cause: RET proto-oncogene mutations.
Mutations Tested: M918T, A883F
Clinical Sensitivity: 98 percent
Methodology: Polymerase chain reaction followed by unlabeled probe and melting curve analysis.
Analytical Sensitivity and Specificity: 99 percent
Limitations: RET mutations, other than M918T and A883F, will not be identified.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

CPT Code(s): 83891 Isolation; 83898 x2 Amplification; 83896 x2 Nucleic acid probes; 83912 Interpretation and report. Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

2002294 Multiple Myeloma Panel by FISH FISH MMP

Performed: Sun-Sat
Reported: 5-14 days

2002360 Myeloproliferative Disorders Panel by FISH FISH MPD P

Performed: Sun-Sat
Reported: 3-10 days

2001930 Neuromyelitis Optica (NMO) Autoantibody, IgG NMO AUTOAB

Specimen Required: Collect: One 5 mL plain red.
Specimen Preparation: Submit specimen in an ARUP Standard Transport Tube.
Storage/Transport Temperature: 2 mL serum at 2-8°C. (Min. 0.2 mL)
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 2 months

0051088 Neuronal Nuclear Antibodies (ANNA) IgG, Immunoblot, Serum ANNAG IB

Specimen Required: Collect: One 4 mL serum separator tube.
Transport: 1 mL serum, frozen. (Min: 0.5 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Separate serum from cells ASAP.
Unacceptable Conditions: Plasma, Lipemic, hemolyzed, contaminated, or heat-inactivated specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 5 days; Frozen: 1 year

0099452 Nickel, Serum NICKEL

Specimen Required: Collect: One 6 mL royal blue (no additive).
Transport: 2 mL serum at 20-25°C. (Min: 0.5 mL) Submit specimen in an ARUP Trace Element-Free Transport Tube (ARUP supply #43116).
Remarks: Centrifuge and pour off serum into an ARUP Trace Element-Free Transport Tube. Do not allow serum to remain on cells.
Unacceptable Conditions: Separator tubes and specimens that are not separated from the red cells, or clot, within 6 hours.
Stability (collection to initiation of testing): If the specimen is drawn and stored in the appropriate container, the trace element values do not change with time.

HOT LINE Effective May 17, 2010

0051458 Niemann-Pick, Type A (SMPD1) 4 Mutations

SMPD1

Specimen Required: Collect: One 3 mL lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).
Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:

Background information for Niemann-Pick, Type A (SMPD1) 4 Mutations:

Characteristics: Lysosomal storage disease causing hepatosplenomegaly, delayed physical and mental growth, hypotonia, rigidity, mental retardation, and death by age 3.

Incidence: 1 in 32,000 Ashkenazi Jewish individuals, unknown in other ethnicities.

Inheritance: Autosomal recessive.

Cause: Deleterious *SMPD1* gene mutations.

Mutations Tested: L302P, 1bp del fsP330, R496L, R608del.

Clinical Sensitivity: 99 percent in Ashkenazi Jewish individuals, unknown in other ethnicities.

Methodology: PCR and allele-specific primer extension by bead array with fluorescence detection.

Analytical Sensitivity and Specificity: Greater than 99 percent.

Limitations: Mutations other than L302P, 1bp del fsP330, R496L, R608del will not be detected. Rare diagnostic errors may occur due to primer site mutations.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

0060310 Occult Blood, Gastric

GASBLD

Reference Interval:

Available Separately	Components	Reference Interval
No	Occult Blood, Gastric	Negative
No	Gastric Fluid pH	1-7

CPT Code(s): 82271 Occult Blood; 83986 Gastric Fluid pH

HOT LINE NOTE: Additional component information associated with this test that affects interface clients only:

Code	Test Name	Change	Order/Result	Comments
2002870	Gastric Fluid pH	Add Component	R	

0020728 Osteocalcin by Electrochemiluminescent Immunoassay

OSTEO NMID

Performed: Tue-Sat
Reported: 1-4 days

HOT LINE Effective May 17, 2010

New Test 2002984 **Oxygen Dissociation (P50) by Hemoximetry** **HEMOX**

Effective April 19, 2010



Patient History form for Hemoglobinopathy/
Thalassemia testing



Time Sensitive

Methodology: Spectrophotometry/Clark Electrode
Performed: Mon-Fri
Reported: 1-3 days

Specimen Required: Patient Preparation: Collect and submit a control specimen along with a patient specimen.
Collect: One 5 mL lavender AND one normal control (5 mL lavender) from a healthy, non-smoking, unrelated individual.
Storage/Transport Temperature: 5 mL whole blood (Min: 1 mL) from patient AND 5 mL whole blood (Min: 1 mL) from a normal control, refrigerated. **Label the control tube as “control for (patient name)”** Send Sunday-Thursday only.
Remarks: Collect control specimen within 30 minutes of patient specimen and keep specimens together at all times. Ship together in the same shipment. Specimens should be received within 24 hours of collection. **Separate specimens must be submitted when multiple tests are ordered.**
Unacceptable Conditions: Ambient or frozen specimens. Specimens submitted without a control.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerate: 48 hours; Frozen: Unacceptable

Reference Interval: 24-30 mmHg

Note: Test is not orderable for New York clients because of short stability. New York clients should submit specimens directly to a New York approved laboratory.

For all other clients, if multiple patients are being drawn at one time, it is acceptable to submit one control for all patients. Label control specimen as: “Control for (list all patient names).”

CPT Code(s): 82820

New York DOH approval pending. Call for status update.

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

0093014 Parathyroid Hormone-Related Peptide (PTHrP) PTH RELPEP

Specimen Required: Collect: One 5 mL blood into any chilled container of EDTA, plus 0.2 cc aprotinin **added immediately after collection** (0.04 cc aprotinin per mL of whole blood).
Transport: 2 mL plasma (EDTA plus aprotinin), frozen. (Min: 0.5 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: To prevent analyte degradation, aprotinin inhibitor is the required additive for this assay. Inhibitor vials are available through ARUP Client Services (ARUP Supply #16570)
Stability (collection to initiation of testing): After **addition of aprotinin and** separation from cells: Ambient: Unacceptable; Refrigerated: 24 hours; Frozen: 3 months

HOT LINE Effective May 17, 2010

0020478 Phosphorus, Urine

UPHOS

Reference Interval:

Available Separately	Components	Reference Interval
No	Phosphorus, Urine - mg/d	400-1300 mg/d
No	Phosphorus/Creatinine Ratio, Urine	Male: 7-9 years: 165-1682 mg/g 10-12 years: 144-1234 mg/g 13-15 years: 101-1134 mg/g 16-17 years: 68-874 mg/g Female: 7-9 years: 153-1443 mg/g 10-12 years: 142-1321 mg/g 13-15 years: 81-930 mg/g 16-17 years: 58-846 mg/g

0051309 Platelet Antigen 1 Genotyping (HPA-1)

HPA1

Specimen Required: Collect and Transport:

Whole blood: One 3 mL whole blood, lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B) at 20-25°C.

Cultured cells: Two T-25 flasks at 80 percent confluent of cultured amniocytes. Fill flasks with culture media to ship at 20-25°C.

Backup cultures must be retained at the client's institution until testing is complete. **If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787.**

Amniotic fluid: 10 mL unspun fluid at 20-25°C. (Min: 5 mL)

Remarks: Fetal specimens are CRITICAL AMBIENT and must be received within 48 hours of shipment due to liability of cells.

Stability (collection to initiation of testing): **Whole blood:** Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Cultured cells or amniotic fluid: Ambient: 2 days; Refrigerated: Unacceptable; Frozen: Unacceptable

Interpretive Data:

Background Information for Platelet Antigen 1 Genotyping (HPA-1):

Characteristics: Spontaneous fetal intracranial bleeding in 20 percent of severe PAT affected pregnancies; risk of fetal death. Post-transfusion purpura in transfusion recipients with antibodies to a specific platelet antigen.

Incidence: Perinatal alloimmune thrombocytopenia (PAT) occurs in 1 in 5000 births.

Inheritance: For women homozygous for a rare "b" HPA allele with antibodies to the common "a" allele, there is a 50 percent risk a pregnancy will be affected if her partner is heterozygous for "a" allele and 100 percent risk if her partner is homozygous for "a" allele.

Mutations Tested: HPA-1 a (common) and b (variant) alleles.

Limitations: Mutations other than the one examined will not be detected; furthermore, mutations within the primer or probe regions could affect this assay.

Sensitivity: 99 percent

Informed consent: Recommended; forms are available at www.aruplab.com.

This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

CPT Code(s): 83891 Isolation; 83898 Amplification; 83896 x2 Nucleic acid probes; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

HOT LINE Effective May 17, 2010

0051310 Platelet Antigen 2 Genotyping (HPA-2) HPA2

Specimen Required: Collect and Transport:

Whole blood: One 3 mL whole blood, lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B) at 20-25°C.

Cultured cells: Two T-25 flasks at 80 percent confluent of cultured amniocytes. Fill flasks with culture media to ship at 20-25°C.

Backup cultures must be retained at the client's institution until testing is complete. **If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787.**

Amniotic fluid: 10 mL unspun fluid at 20-25°C. (Min: 5 mL)

Remarks: Fetal specimens are **CRITICAL AMBIENT** and must be received within 48 hours of shipment due to liability of cells.

Stability (collection to initiation of testing): **Whole blood:** Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Cultured cells or amniotic fluid: Ambient: 2 days; Refrigerated: Unacceptable; Frozen: Unacceptable

Interpretive Data:

Background Information for Platelet Antigen 2 Genotyping (HPA-2):

Characteristics: Spontaneous fetal intracranial bleeding in 20 percent of severe PAT affected pregnancies; risk of fetal death. Post-transfusion purpura in transfusion recipients with antibodies to a specific platelet antigen.

Incidence: Perinatal alloimmune thrombocytopenia (PAT) occurs in 1 in 5000 births.

Inheritance: For women homozygous for a rare "b" HPA allele with antibodies to the common "a" allele, there is a 50 percent risk a pregnancy will be affected if her partner is heterozygous for "a" allele and 100 percent risk if her partner is homozygous for "a" allele.

Mutations Tested: HPA-2 a (common) and b (variant) alleles.

Limitations: Mutations other than the one examined will not be detected; furthermore, mutations within the primer or probe regions could affect this assay.

Sensitivity: 99 percent

Informed consent: Recommended; forms are available at www.aruplab.com.

This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

CPT Code(s): 83891 Isolation; 83898 Amplification; 83896 x2 Nucleic acid probes; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

HOT LINE Effective May 17, 2010

0051311

Platelet Antigen 3 Genotyping (HPA-3)

HPA3

Specimen Required: Collect and Transport:

Whole blood: One 3 mL whole blood, lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B) at 20-25°C.

Cultured cells: Two T-25 flasks at 80 percent confluent of cultured amniocytes. Fill flasks with culture media to ship at 20-25°C.

Backup cultures must be retained at the client's institution until testing is complete. **If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787.**

Amniotic fluid: 10 mL unspun fluid at 20-25°C. (Min: 5 mL)

Remarks: Fetal specimens are CRITICAL AMBIENT and must be received within 48 hours of shipment due to liability of cells.

Stability (collection to initiation of testing): **Whole blood:** Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Cultured cells or amniotic fluid: Ambient: 2 days; Refrigerated: Unacceptable; Frozen: Unacceptable

Interpretive Data:

Background Information for Platelet Antigen 3 Genotyping (HPA-3):

Characteristics: Spontaneous fetal intracranial bleeding in 20 percent of severe PAT affected pregnancies; risk of fetal death. Post-transfusion purpura in transfusion recipients with antibodies to a specific platelet antigen.

Incidence: Perinatal alloimmune thrombocytopenia (PAT) occurs in 1 in 5000 births.

Inheritance: For women homozygous for a rare "b" HPA allele with antibodies to the common "a" allele, there is a 50 percent risk a pregnancy will be affected if her partner is heterozygous for "a" allele and 100 percent risk if her partner is homozygous for "a" allele.

Mutations Tested: HPA-3 a (common) and b (variant) alleles.

Limitations: Mutations other than the one examined will not be detected; furthermore, mutations within the primer or probe regions could affect this assay.

Sensitivity: 99 percent

Informed consent: Recommended; forms are available at www.aruplab.com.

This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

CPT Code(s): 83891 Isolation; 83898 Amplification; 83896 x2 Nucleic acid probes; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

HOT LINE Effective May 17, 2010

0051490	Platelet Antigen 4 Genotyping (HPA-4)	HPA4
<p>Specimen Required: Collect <u>and Transport:</u> Whole blood: One 3 mL whole blood, lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B) at 20-25°C. Cultured cells: Two T-25 flasks at 80 percent confluent of cultured amniocytes. Fill flasks with culture media to ship at 20-25°C. Backup cultures must be retained at the client's institution until testing is complete. If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787. Amniotic fluid: 10 mL unspun fluid at 20-25°C. (Min: 5 mL) <u>Remarks:</u> Fetal specimens are CRITICAL AMBIENT and must be received within 48 hours of shipment due to liability of cells. <u>Stability (collection to initiation of testing):</u> Whole blood: Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable Cultured cells or amniotic fluid: Ambient: 2 days; Refrigerated: Unacceptable; Frozen: Unacceptable</p>		
<p>Interpretive Data: Background Information for Platelet Antigen 4 Genotyping (HPA-4): Characteristics: Spontaneous fetal intracranial bleeding in 20 percent of severe perinatal alloimmune thrombocytopenia (PAT) affected pregnancies; risk of fetal death. Post-transfusion purpura in transfusion recipients with antibodies to a specific platelet antigen. Incidence: PAT occurs in 1 in 5000 births. Inheritance: Codominant expression of a and b alleles. Cause: Women homozygous for a rare b allele with antibodies to the common a allele have a 50 percent risk for an affected pregnancy if her partner is heterozygous for a allele and 100 percent risk if her partner is homozygous for a allele. Mutations Tested: HPA-4 a (common) and b (variant) alleles. Clinical Sensitivity: 98 percent Methodology: Polymerase chain reaction (PCR) followed by melting analysis using fluorescent resonance energy transfer (FRET) probes. Analytical Sensitivity and Specificity: 99 percent Limitations: Mutations other than in HPA 4 will not be detected; furthermore, mutations within the primer or probe regions could affect this assay.</p>		
<p>This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.</p>		
<p>Counseling and informed consent are recommended for genetic testing. Consent forms are available online at www.aruplab.com.</p>		
<p>Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.</p>		
<p>CPT Code(s): 83891 Isolation; 83898 Amplification; 83896 x2 Nucleic acid probes; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.</p>		

HOT LINE Effective May 17, 2010

0051312 Platelet Antigen 5 Genotyping (HPA-5) HPA5

Specimen Required: Collect and Transport:

Whole blood: One 3 mL whole blood, lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B) at 20-25°C.

Cultured cells: Two T-25 flasks at 80 percent confluent of cultured amniocytes. Fill flasks with culture media to ship at 20-25°C.

Backup cultures must be retained at the client's institution until testing is complete. **If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787.**

Amniotic fluid: 10 mL unspun fluid at 20-25°C. (Min: 5 mL)

Remarks: Fetal specimens are **CRITICAL AMBIENT** and must be received within 48 hours of shipment due to liability of cells.

Stability (collection to initiation of testing): **Whole blood:** Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Cultured cells or amniotic fluid: Ambient: 2 days; Refrigerated: Unacceptable; Frozen: Unacceptable

Interpretive Data:

Background Information for Platelet Antigen 5 Genotyping (HPA-5):

Characteristics: Spontaneous fetal intracranial bleeding in 20 percent of severe PAT affected pregnancies; risk of fetal death. Post-transfusion purpura in transfusion recipients with antibodies to a specific platelet antigen.

Incidence: Perinatal alloimmune thrombocytopenia (PAT) occurs in 1 in 5000 births.

Inheritance: For women homozygous for a rare "b" HPA allele with antibodies to the common "a" allele, there is a 50 percent risk a pregnancy will be affected if her partner is heterozygous for "a" allele and 100 percent risk if her partner is homozygous for "a" allele.

Mutations Tested: HPA-5 a (common) and b (variant) alleles.

Limitations: Mutations other than the one examined will not be detected; furthermore, mutations within the primer or probe regions could affect this assay.

Sensitivity: 99 percent

Informed consent: Recommended; forms are available at www.aruplab.com.

This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

CPT Code(s): 83891 Isolation; 83898 Amplification; 83896 x2 Nucleic acid probes; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

HOT LINE Effective May 17, 2010

0051313 Platelet Antigen 6 Genotyping (HPA-6) HPA6

Specimen Required: Collect and Transport:

Whole blood: One 3 mL whole blood, lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B) at 20-25°C.

Cultured cells: Two T-25 flasks at 80 percent confluent of cultured amniocytes. Fill flasks with culture media to ship at 20-25°C.

Backup cultures must be retained at the client's institution until testing is complete

Amniotic fluid: 10 mL unspun fluid at 20-25°C. (Min: 5 mL) **If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787.**

Remarks: Fetal specimens are **CRITICAL AMBIENT** and must be received within 48 hours of shipment due to liability of cells.

Stability (collection to initiation of testing): **Whole blood:** Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Cultured cells or amniotic fluid: Ambient: 2 days; Refrigerated: Unacceptable; Frozen: Unacceptable

Interpretive Data:

Background Information for Platelet Antigen 6 Genotyping (HPA-6):

Characteristics: Spontaneous fetal intracranial bleeding in 20 percent of severe PAT affected pregnancies; risk of fetal death. Post-transfusion purpura in transfusion recipients with antibodies to a specific platelet antigen.

Incidence: Perinatal alloimmune thrombocytopenia (PAT) occurs in 1 in 5000 births.

Inheritance: For women homozygous for a rare "b" HPA allele with antibodies to the common "a" allele, there is a 50 percent risk a pregnancy will be affected if her partner is heterozygous for "a" allele and 100 percent risk if her partner is homozygous for "a" allele.

Mutations Tested: HPA-6 a (common) and b (variant) alleles.

Limitations: Mutations other than the one examined will not be detected; furthermore, mutations within the primer or probe regions could affect this assay.

Sensitivity: 99 percent

Informed consent: Recommended; forms are available at www.aruplab.com.

This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

CPT Code(s): 83891 Isolation; 83898 Amplification; 83896 x2 Nucleic acid probes; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

HOT LINE Effective May 17, 2010

0051314 Platelet Antigen 15 Genotyping (HPA-15)

HPA15

Specimen Required: Collect and Transport:

Whole blood: One 3 mL whole blood, lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B) at 20-25°C.

Cultured cells: Two T-25 flasks at 80 percent confluent of cultured amniocytes. Fill flasks with culture media to ship at 20-25°C. Backup cultures must be retained at the client's institution until testing is complete.

Amniotic fluid: 10 mL unspun fluid at 20-25°C. (Min: 5 mL) **If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787.**

Remarks: Fetal specimens are CRITICAL AMBIENT and must be received within 48 hours of shipment due to liability of cells.

Stability (collection to initiation of testing): **Whole blood:** Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Cultured cells or amniotic fluid: Ambient: 2 days; Refrigerated: Unacceptable; Frozen: Unacceptable

Interpretive Data:

Background Information for Platelet Antigen 15 Genotyping (HPA-15):

Characteristics: Spontaneous fetal intracranial bleeding in 20 percent of severe PAT affected pregnancies; risk of fetal death. Post-transfusion purpura in transfusion recipients with antibodies to a specific platelet antigen.

Incidence: Perinatal alloimmune thrombocytopenia (PAT) occurs in 1 in 5000 births.

Inheritance: For women homozygous for a rare "b" HPA allele with antibodies to the common "a" allele, there is a 50 percent risk a pregnancy will be affected if her partner is heterozygous for "a" allele and 100 percent risk if her partner is homozygous for "a" allele.

Mutations Tested: HPA-15 a (common) and b (variant) alleles.

Limitations: Mutations other than the one examined will not be detected; furthermore, mutations within the primer or probe regions could affect this assay.

Sensitivity: 99 percent.

Informed consent: Recommended; forms are available at www.aruplab.com.

This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

CPT Code(s): 83891 Isolation; 83898 Amplification; 83896 x2 Nucleic acid probes; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

HOT LINE Effective May 17, 2010

0051308 Platelet Antigen Genotyping Panel

HPA PAN

Specimen Required: Collect and Transport:

Whole blood: One 3 mL whole blood, lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B) at 20-25°C.

Cultured cells: Two T-25 flasks at 80 percent confluent of cultured amniocytes. Fill flasks with culture media to ship at 20-25°C.

Backup cultures must be retained at the client's institution until testing is complete.

Amniotic fluid: 10 mL unspun fluid at 20-25°C. (Min: 5 mL) **If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787.**

Remarks: Fetal specimens are **CRITICAL AMBIENT** and must be received within 48 hours of shipment due to liability of cells.

Stability (collection to initiation of testing): **Whole blood:** Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Cultured cells or amniotic fluid: Ambient: 2 days; Refrigerated: Unacceptable; Frozen: Unacceptable

Interpretive Data:

Background Information for Platelet Antigen Genotyping Panel:

Characteristics: Spontaneous fetal intracranial bleeding in 20 percent of severe perinatal alloimmune thrombocytopenia (PAT) affected pregnancies; risk of fetal death. Post-transfusion purpura in transfusion recipients with antibodies to a specific platelet antigen.

Incidence: PAT occurs in 1 in 5000 births.

Inheritance: Codominant expression of a and b alleles.

Cause: Women homozygous for a rare b HPA allele with antibodies to the common a allele have a 50 percent risk for an affected pregnancy if her partner is heterozygous for a allele and 100 percent if her partner is homozygous for a allele.

Mutations Tested: HPA 1, 2, 3, 4, 5, 6, 15 a (common) and b (variant) alleles.

Clinical Sensitivity: 98 percent.

Methodology: Polymerase chain reaction (PCR) followed by melting analysis using fluorescent resonance energy transfer (FRET) probes.

Analytical Sensitivity and Specificity: 99 percent.

Limitations: Mutations other than in HPA 1, 2, 3, 4, 5, 6, 15 will not be detected; furthermore, mutations within the primer or probe regions could affect this assay.

This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

CPT Code(s): 83891 Isolation; 83898 x7 Amplification; 83896 x14 Nucleic acid probes; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

HOT LINE Effective May 17, 2010

2002363 PML/RAR α FISH FISH PML

Performed: Sun-Sat
Reported: 1-3 days

DELETE 0056100 PML/RAR α , t(15;17) by RT-PCR PML

HOT LINE NOTE: Please delete this test and refer to PML-RAR α , t(15;17) Translocation by RT-PCR, Quantitative (2002871).

New Test 2002871 PML-RAR α , t(15;17) Translocation by RT-PCR, Quantitative PML QNT



Time Sensitive

Methodology: Reverse Transcription Polymerase Chain Reaction
Performed: RNA isolation: Sun-Sat; Assay: Varies
Reported: 2-7 days

Specimen Required: Collect: Whole blood or bone marrow.
Transport: 5 mL whole blood or 3 mL bone marrow (EDTA) at 2-8°C. (Min: 1 mL)
Remarks: **Specimens must be received within 48 hours of collection due to lability of RNA.**
Stability (collection to initiation of testing): Ambient: 1 hour; Refrigerated: 2 days; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data: Refer to report.

Please refer to Statement D in the Compliance Statements section in the front of the Laboratory Test Directory.

CPT Code(s): 83891 Isolation; 83902 Reverse transcription; 83898 x3 Amplification; 83896 x3 Nucleic acid probes; 83912 Interpretation and report
 - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

This test is New York DOH approved.

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

0060054 Poliovirus Antibodies POLIO

Reference Interval:
 <1:10: No significant level of detectable poliovirus antibodies.
 1:10 or greater; Antibody to poliovirus detected, which may represent prior immunization or current or past infection.

0090800 Polychlorinated Biphenyls, Serum POLYCHL SP

Performed: Varies
Reported: Varies

Specimen Required: Collect: One 7 mL plain red.
Transport: 3 mL serum at 2-8°C. (Min: 1.2 mL) **Submit** specimen in an ARUP Standard Transport Tube.
Remarks: Plasma (lavender, EDTA) is acceptable, but not preferred. Remove serum or plasma from cells **within 10 minutes**.
Unacceptable Conditions: **Serum separator tubes.**
Stability (collection to initiation of testing): Ambient: 2 weeks; Refrigerated: 4 months; Frozen: 4 months

HOT LINE Effective May 17, 2010

0099824 Porphyrins, Fecal POR FECES

Note: Bacterial modification of fecal porphyrins is extensive. The recommended specimen for uroporphyrin and coproporphyrin is urine (random or 24-hour). Refer to **Porphyrins, Fractionation & Quantitation, Urine (2002058)**. The recommended specimen for protoporphyrin is serum. Refer to Porphyrins, Serum Total (0080429).

0080429 Porphyrins, Serum Total POR S

Specimen Required: Collect: One 6 mL plain red.
Transport: 2 mL serum, frozen. (Min: 1 mL) **CRITICAL - Protect from light. Submit specimen in an ARUP Amber Transport Tube.**
Remarks: **CRITICAL - Protect from light during collection, storage, and shipment.**
Unacceptable Conditions: Hemolyzed specimen. Frozen whole blood.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 4 days; Frozen: 1 month

0051116 Prader-Willi Syndrome by Methylation PRADER

Specimen Required: Collect: One 3 mL lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).
Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:

Background Information for Prader-Willi Syndrome by Methylation:

Incidence: 1 in 15,000

Inheritance: Varies depending upon the molecular mechanism

Characteristics: Neonatal hypotonia, childhood hyperphagia, obesity, learning disorders or mild mental retardation and behavioral problems

Cause: Absence of the paternally contributed PWS/AS critical region of chromosome 15q11.2-q13.

Molecular Genetic Mechanisms: Microdeletion of the PWS/AS critical region (70 percent), maternal uniparental disomy of chromosome 15 (25 percent), and an imprinting defect (less than 5 percent)

Methods: Bisulfite conversion and PCR amplification to detect methylation using melting curve analysis.

Clinical Sensitivity: Over 99 percent of individuals with PWS will be detected. Analytical specificity and sensitivity are greater than 99 percent.

Limitations: Mutations or mechanisms not affecting methylation patterns will not be detected

Informed Consent: Recommended; forms are available at www.aruplab.com

This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

CPT Code(s): 83891 Isolation; 83898 Amplification; 83912 Interpretation and report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

HOT LINE NOTE: Please remove the information from the Unacceptable Conditions field under Specimen Requirements.

HOT LINE Effective May 17, 2010

New Test 2002554 Pregabalin **PREGABALIN**

Effective April 19, 2010

Methodology: High Performance Liquid Chromatography/Tandem Mass Spectrometry (LC-MS/MS)
Performed: Varies
Reported: Varies

Specimen Required: Collect: One 5 mL plain red or lavender (EDTA).
Transport: 1 mL serum or plasma at 2-8°C. (Min: 0.4 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Separate serum or plasma from cells within 10 minutes.
Unacceptable Conditions: Serum separator tubes.
Stability (collection to initiation of testing): Ambient: 1 month; Refrigerated: 1 month; Frozen: 1 month

Reference Interval: By report

CPT Code(s): 82542

New York DOH approval pending. Call for status update.

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

0070110 Progesterone **PROGES**

Specimen Required: Collect: One 4 mL serum separator tube or plasma separator tube. Also acceptable: lavender (K₃EDTA) and green (sodium or lithium heparin).
Transport: 1 mL serum or plasma at 2-8°C. (Min: 0.5 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Allow specimen to clot completely at room temperature before centrifuging. Separate serum or plasma from cells ASAP.
Unacceptable Conditions: Specimens submitted in lt. blue (sodium citrate), or gray (sodium fluoride/potassium oxalate) transport tubes.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 4 days; Frozen: 3 months

0070256 Proinsulin/Insulin Ratio **PRO INS**

Specimen Required: Collect: One 4 mL serum separator tube. Also acceptable: lavender (EDTA) or pink (K₂EDTA).
Storage/Transport Temperature: 1 mL serum or plasma, frozen. (Min: 0.8 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Patient must fast 12-15 hours before collection. Separate serum from cells ASAP and freeze. Avoid repeated freeze/thaw cycles.
Unacceptable Conditions: Heparinized plasma, vitreous and I.V. fluids.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 3 months

HOT LINE Effective May 17, 2010

New Test 2002930 **Prostate Specific Antigen, Complexed** **PSA COMP**

Effective April 19, 2010

Methodology: Immunochemiluminometric Assay
Performed: Varies
Reported: Varies

Specimen Required: Collect: Plain red or serum separator tube.
Specimen Preparation: Submit specimen in an ARUP standard transport tube.
Transport: 0.5 mL serum at 2-8°C. (Min: 0.5 mL)
Unacceptable Conditions: Hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 week; Frozen: 1 month

Reference Interval: By report

CPT Code(s): 84152

This test is New York DOH approved.

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

0020029 Protein, Total, Plasma or Serum **TP**

Specimen Required: Collect: One 4 mL plasma separator tube or serum separator tube.
Transport: 1 mL plasma or serum, frozen. (Min: 0.2 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Allow specimen to clot completely at room temperature. Separate serum or plasma from cells ASAP.
Stability (collection to initiation of testing): After separation from cells: Ambient: 4 hours; Refrigerated: 1 month; Frozen: 6 months

0020479 Protein, Total, Urine **UTP**

Reference Interval:

Available Separately	Components	Reference Interval		
No	Protein, Total, Urine (measurement)	By report (reports may vary based on instrumentation).		
No	Total Protein - mg/dL	By report (reports may vary based on instrumentation).		
Yes (0020473)	Creatinine (24-hour)	Male 3-8 years: 140-700 mg/d 9-12 years: 300-1300 mg/d 13-17 years: 500-2300 mg/d 18-50 years: 1000-2500 mg/d 51-80 years: 800-2100 mg/d 81 years and older: 600-2000 mg/d	Female 3-8 years: 140-700 mg/d 9-12 years: 300-1300 mg/d 13-17 years: 400-1600 mg/d 18-50 years: 700-1600 mg/d 51-80 years: 500-1400 mg/d 81 years and older: 400-1300 mg/d	
No	Total Protein/Creatinine Ratio, Urine	Age 7-9 years 10-12 years 13-15 years 16-17 years 18 years and older	Male 61-220 mg/g 59-220 mg/g 41-371 mg/g 31-242 mg/g 15-68 mg/g	Female 70-548 mg/g 57-334 mg/g 33-307 mg/g 36-329 mg/g 10-107 mg/g

HOT LINE NOTE: Please remove the statement "Not established" from the Total Protein/Creatinine Ratio, Urine Reference Interval.

HOT LINE Effective May 17, 2010

0051302 Prothrombin Antibody, IgG PROTHROM G

Specimen Required: Collect: One 4 mL serum separator tube.
Storage/Transport Temperature: 1 mL serum **or citrated plasma (3.2% sodium citrate)** at 2-8°C. (Min: 0.1 mL)
 Submit specimen in an ARUP Standard Transport Tube.
Unacceptable Conditions: Hemolyzed or lipemic **specimens**.
Stability (collection to initiation of testing): After separation from cells: Ambient: 2 days; Refrigerated: 2 weeks; Frozen: 1 year

0051303 Prothrombin Antibody, IgM PROTHROM M

Specimen Required: Collect: One 4 mL serum separator tube.
Storage/Transport Temperature: 1 mL serum **or citrated plasma (3.2% sodium citrate)** at 2-8°C. (Min: 0.1 mL)
 Submit specimen in an ARUP Standard Transport Tube.
Unacceptable Conditions: Hemolyzed or lipemic **specimens**.
Stability (collection to initiation of testing): After separation from cells: Ambient: 2 days; Refrigerated: 2 weeks; Frozen: 1 year

0051729 QuantiFERON®-TB Gold In Tube QFTG-TB IT

Effective Immediately

Specimen Required: Collect: 1 mL whole blood in each of three Cellestis QuantiFERON®-TB Gold In Tube collection tubes (Nil, TB, and Mitogen tubes - ARUP Supply #45112. **High Altitude collection tubes (ARUP Supply #46261)**.
Transport: Original collection tubes, after incubation and centrifugation, at 2-8°C.
Remarks: Immediately following collection, each specimen tube must be mixed vigorously by shaking the tube up and down 10 times to ensure that the entire inner surface of the tube has been coated with blood.
After mixing, incubate upright at 37°C for 16-24 hours (within 16 hours of collection).
After incubation, centrifuge for 15 minutes at 2000-3000 RCF (g).
Unacceptable Conditions: Specimens that have not been centrifuged. Ambient specimens.
Stability (collection to initiation of testing): After incubation and centrifugation: Ambient: 2 hours; Refrigerated: 4 weeks; Frozen: 4 months

2002730 RASA1-Related Disorders (RASA1) Sequencing RASA1 FGS

CPT Code(s): 83891 Isolation; 83898 **x30** Amplification; 83904 **x30** Sequencing; 83909 Capillary electrophoresis, 83912 Interpretation and report. Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

2002565 Respiratory Viruses DFA with Reflex to Respiratory Virus Mini Panel by RT-PCR RSPFAPCR

Interpretive Data: If DFA is negative or inadequate **for influenza**, then a Respiratory Virus Mini Panel by RT-PCR (test code 0060764) will be added. Sensitivity of DFA methodology is dependent upon adequacy of the specimen. If there are fewer than 20 cells, the DFA result will be reported as "specimen inadequate."

0050465 Rheumatoid Factor RA

Specimen Required: Collect: One 4 mL serum separator tube **or plasma separator tube**. **Also acceptable: green (sodium or lithium heparin), lavender (EDTA) or pink (K₂EDTA)**.
Transport: 0.5 mL serum **or plasma** at 2-8°C. (Min: 0.5 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: **Allow** serum to clot completely at room temperature before centrifuging.
Unacceptable Conditions: **Hemolyzed** specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 2 weeks (should be thawed only once)

HOT LINE Effective May 17, 2010

0025023 Selenium, Serum SE S

Specimen Required: Collect: One 6 mL royal blue (no additive), or royal blue EDTA.
Transport: 2 mL serum or plasma at 20-25°C. (Min: 0.5 mL) Submit specimen in an ARUP Trace Element-Free Transport Tube (ARUP supply #43116).
Remarks: Centrifuge and pour off serum or plasma into an ARUP Trace Element-Free Transport Tube. Do not allow serum or plasma to remain on cells.
Unacceptable Conditions: Separator tubes and specimens that are not separated from the red cells, or clot, within 6 hours.
Stability (collection to initiation of testing): If the specimen is drawn and stored in the appropriate container, the trace element values do not change with time.

0099375 Sex Hormone Binding Globulin SHBG

Specimen Required: Collect: One 4 mL serum separator tube. Also acceptable: green (sodium or lithium heparin).
Transport: 0.5 mL serum or plasma at 2-8°C. (Min: 0.4 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Allow serum to clot completely at room temperature. Separate serum from cells ASAP.
Unacceptable Conditions: Specimens collected in lavender (EDTA) or pink (K₂EDTA).
Stability (collection to initiation of testing): After separation from cells: Ambient: 2 days; Refrigerated: 1 week; Frozen: 2 months

0070283 Soluble Transferrin Receptor STR

Specimen Required: Collect: One 4 mL serum separator tube, or one 3 mL green (sodium or lithium heparin).
Transport: 1 mL serum or plasma at 2-8°C. (Min: 0.3 mL) Submit specimen in an ARUP Standard Transport Tube.
Unacceptable Conditions: Severely hemolyzed, icteric, contaminated, or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 3 days; Refrigerated: 1 week; Frozen: 1 month at -20°C or 1 year at -70°C (avoid repeated freeze/thaw cycles)

0081054 Squamous Cell Carcinoma Antigen, Serum SCC

Performed: Mon
Reported: 1-8 days

HOT LINE Effective May 17, 2010

0060705 Streptococcus Group B by PCR GBS PCR

Specimen Required: Collect: Vaginal or rectal swab.
Transport: Swab in bacterial transport media at 2-8°C. Submit specimen according to Biological Substance, Category B, shipping guidelines.
Stability (collection to initiation of testing): Ambient: **24 hours**; Refrigerated: **6 days**; Frozen: Unacceptable

Reference Interval: **Not Detected**

HOT LINE NOTE: Please remove the information from the Interpretive Date field.

0090944 Sulfonylurea Hypoglycemics, Serum or Plasma SULFON SP

Methodology: High Performance Liquid Chromatography **with Fluorescence/High Performance Liquid Chromatography with Ultraviolet Detection**

Specimen Required: Collect: Plain red or green (sodium or lithium heparin).
Storage/Transport Temperature: 5 mL serum or plasma at 20-25°C. (Min: 1.2 mL) **Submit specimen in an ARUP Standard Transport Tube.**
Unacceptable Conditions: Separator tubes.
Stability (collection to initiation of testing): Ambient: 2 weeks; Refrigerated: 2 weeks; Frozen: 1 year

CPT Code(s): **82486**

0091100 Sulfonylurea Hypoglycemics, Urine SULFON UR

Methodology: High Performance Liquid Chromatography **with Fluorescence/High Performance Liquid Chromatography with Ultraviolet Detection**

Specimen Required: Collect: Random urine.
Specimen Preparation: **Submit specimen in an ARUP Standard Transport Tube.**
Storage/Transport Temperature: 5 mL urine at 20-25°C. (Min: 1.2 mL)
Stability (collection to initiation of testing): Ambient: 2 weeks; Refrigerated: 2 weeks; Frozen: 1 year

CPT Code(s): **82486**

0040114 SYT-SSX t(X;18) Translocations by RT-PCR SYT-SSX

Specimen Required: Collect: Tumor tissue.
Transport: **Four 10 micron shavings from a formalin-fixed, paraffin-embedded tissue block at 20-25°C.**
Remarks: **Tissue block is also an acceptable specimen type and will be returned after testing.**
Unacceptable Conditions: Heavy metal based (B-4 or B-5) fixed paraffin-embedded tissue.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Indefinitely

0070135 T3 Uptake T3 UP

Interpretive Data: **Thyroxine, Free (Free T4) (0070138) is the preferred test alternative for T3 uptake and Free Thyroxine Index tests.**

HOT LINE Effective May 17, 2010

0051428 Tay-Sachs (HEXA) 7 Mutations

HEXA

Specimen Required: Collect: One 3 mL lavender (EDTA) or pink (K₂EDTA) or yellow (ACD Solution A or B).
Transport: 3 mL whole blood at 2-8°C. (Min: 1 mL)
Stability (collection to initiation of testing): Ambient: 3 days; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:

Background information for Tay-Sachs (HEXA) 7 Mutations:

Characteristics: Lysosomal storage disease that in its severe form leads to loss of motor skills beginning at three to six months of age that progresses to blindness, seizures and total incapacitation and death by 4 years of age. A milder disease with later onset and slower progression is seen in affected adults. Adult-onset Tay-Sachs is associated with variable neurological findings including: progressive dystonia, spinocerebellar degeneration, motor neuron disease and bipolar form of psychosis.

Incidence: 1 in 3000 Ashkenazi Jewish individuals, unknown in other ethnicities.

Inheritance: Autosomal recessive.

Cause: Deleterious *HEXA* gene mutations.

Mutations Tested: Four severe (Delta7.6kb, IVS9(+1)G>A, 1278insTATC, IVS12(+1)G>C), one mild (G269S), and two pseudodeficiency alleles (R247W and R249W).

Clinical Sensitivity: 94 percent in Ashkenazi Jewish individuals, unknown in other ethnicities.

Methodology: PCR and allele specific primer extension by bead array with fluorescence detection.

Analytical sensitivity and specificity: Greater than 99 percent.

Limitations: *HEXA* mutations other than those specified above will not be detected. Rare diagnostic errors may occur due to primer site mutations.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

0081058 Testosterone, Females or Children

TESTOS MAS

Reference Interval:

Serum Total Testosterone, Determined by LC-MS/MS

Female	Male
Premature (26-28 weeks): 5-16 ng/dL	Premature (26-28 weeks): 59-125 ng/dL
Premature (31-35 weeks): 5-22 ng/dL	Premature (31-35 weeks): 37-198 ng/dL
Newborn: 20-64 ng/dL	Newborn: 75-400 ng/dL
1-7 months: Levels decrease during the first month to less than 10 ng/dL and remain at this level until puberty.	1-7 months: Levels decrease rapidly the first week to 20-50 ng/dL, and then increase to 60-400 ng/dL between 20-60 days. Levels then decline to pre-pubertal range levels of 3-10 ng/dL by seven months.
7-9 years: Less than 15 ng/dL	7-9 years: Less than 9 ng/dL
10-11 years: 2-42 ng/dL	10-11 years: 2-57 ng/dL
12-13 years: 6-64 ng/dL	12-13 years: 7-747 ng/dL
14-15 years: 9-49 ng/dL	14-15 years: 33-585 ng/dL
16-17 years: 8-63 ng/dL	16-17 years: 185-886 ng/dL
18-30 years: 11-59 ng/dL	18-39 years: 300-1080 ng/dL
31-40 years: 11-56 ng/dL	40-59 years: 300-890 ng/dL
41-51 years: 9-55 ng/dL	60 years and older: 300-720 ng/dL
Postmenopausal: 6-25 ng/dL	Tanner Stage I: Less than 20 ng/dL
Tanner Stage I: Less than 17 ng/dL	Tanner Stage II: 2-149 ng/dL
Tanner Stage II: 4-39 ng/dL	Tanner Stage III: 7-762 ng/dL
Tanner Stage III: 10-60 ng/dL	Tanner Stage IV: 165-854 ng/dL
Tanner Stage IV: 8-63 ng/dL	Tanner Stage V: 194-783 ng/dL
Tanner Stage V: 10-60 ng/dL	

✓HOT LINE NOTE: This change also applies to:

- CAH 11-Beta Hydroxylase Deficiency Panel (2002282)
- Congenital Adrenal Hyperplasia Treatment Panel (2002029)
- Hirsutism Evaluation Panel (2001763)
- Testosterone, Free & Total (Includes Sex Hormone Binding Globulin), Females or Children (0081056)
- Testosterone, Bioavailable & Sex Hormone Binding Globulin (Includes Total Testosterone), Females or Children (0081057)
- Virilization Panel 1 (2002028)
- Virilization Panel 2 (2002281)

HOT LINE Effective May 17, 2010

0081059 Testosterone Free, Females or Children TESTOS FR

Specimen Required: Collect: One 6 mL serum separator tube or green (sodium or lithium heparin). Specimen should be collected between 6-10 a.m.
Transport: 1 mL serum or plasma at 2-8°C. (Min: 0.4 mL) **Submit** specimen in an ARUP Standard Transport Tube.
Remarks: Separate serum from cells ASAP. **This test is suggested for women and children due to an improved sensitivity of testosterone by LC-MS/MS.**
Unacceptable Conditions: EDTA plasma.
Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 2 months

New Test 2002575 Thiopurine Metabolites THIOP MET

Effective April 19, 2010

Methodology: High Pressure Liquid Chromatography
Performed: Varies
Reported: Varies

Specimen Required: Collect: Whole blood, lavender (EDTA).
Transport: 5 mL whole blood, 2-8°C.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

CPT Code(s): 82491 x2

New York DOH approval pending. Call for status update.

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

0092066 Thiopurine Methyltransferase, RBC TPMT RBC

Specimen Required: Collect: One 5 mL lavender (EDTA), pink (K₂EDTA), **green (sodium or lithium heparin).**
Transport: 5 mL whole blood at 2-8°C. (Min: 3 mL) Submit specimen according to Biological Substance, Category B, shipping guidelines.
Unacceptable Conditions: Hemolyzed, ambient or frozen specimens.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 3 days; Frozen: Unacceptable

0030133 Thrombotic Risk, Inherited Etiologies (Most Common) with Reflex to Factor V Leiden THROM COM

CPT Code(s): 85730 PTT; 85240 F8; 83090 tHcy; **83891** Isolation; 83898 Amplification; 83896 Nucleic acid probes; 83912 Int/report; 85307 APC; if reflexed, add **83891** Isolation; 83898 Amplification; 83896 Nucleic acid probes; 83912 Int/report - Additional CPT code modifiers may be required for procedures performed to test for oncologic or inherited disorders.

0070421 Thyroglobulin, Serum or Plasma THYROG

Interpretive Data: Thyroglobulin (Tg) is measured by the Beckman Access method, which has a lower limit of quantification of 0.1 ng/mL. **Tg results less than 0.1 ng/mL are consistent with the absence of thyroglobulin-producing thyroid tissue.** Results obtained with different assay methods or kits cannot be used interchangeably. The Tg result, regardless of concentration, should not be interpreted as absolute evidence for the presence or absence of papillary or follicular thyroid cancer and is not recommended for use as a screening procedure to detect the presence of cancer in the general population.

Tg antibodies (Tg Ab) are known to interfere with the measurement of Tg. In patients with positive Tg Ab results (greater than 14.4 IU/mL), a recovery study is performed. A recovery of less than 80% in any specimen suggests a Tg Ab interference so the Tg concentration cannot be accurately quantified. A Tg result of greater than or equal to 0.1 ng/mL, in the presence of a positive Tg Ab result, qualitatively indicates that Tg is present in the specimen.

0070141 Thyroid Panel T7

Interpretive Data: Thyroxine, Free (FT4) (0070138) is the preferred test alternative for T3 uptake and Free Thyroxine Index tests.

HOT LINE Effective May 17, 2010

0070145 Thyroid Stimulating Hormone TSH

Reference Interval: Cord Blood: 2.00-40.00 mU/L
 0-3 days: 5.17-14.60 mU/L
 4-30 days: 0.43-16.10 mU/L
 1-24 months: 0.62-8.05 mU/L
 2-6 years: 0.54-4.53 mU/L
 7-11 years: 0.66-4.14 mU/L
 12-19 years: 0.53-3.59 mU/L
 20 years and older: 0.30-4.00 mU/L

0070225 Thyroid Stimulating Hormone 3rd Generation TSH 3

Reference Interval: Cord Blood: 2.000-40.000 mU/L
 0-3 days: 5.170-14.600 mU/L
 4-30 days: 0.430-16.100 mU/L
 1-24 months: 0.620-8.050 mU/L
 2-6 years: 0.540-4.530 mU/L
 7-11 years: 0.660-4.140 mU/L
 12-19 years: 0.530-3.590 mU/L
 20 years and older: 0.300-4.000 mU/L

0098720 Thyrotropin Releasing Hormone (TRH) TRH

Effective Immediately

Performed: Varies
Reported: Varies

Specimen Required: Collect: One 5 mL green (sodium heparin).
Transport: 2 mL plasma, frozen. (Min: 0.6 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: **CRITICAL FROZEN. Separate plasma from cells within 10 minutes and freeze immediately. Ship on dry ice. Separate specimens must be submitted when multiple tests are ordered. Patient should not receive any thyroid medication for at least 48 hours prior to collection, if possible.**
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 1 month

0070140 Thyroxine T4

Specimen Required: Collect: One 4 mL serum separator tube or plasma separator tube. Also acceptable: lavender (EDTA).
Storage/Transport Temperature: 1 mL serum or plasma at 2-8°C. (Min: 0.5 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Allow serum to clot completely at room temperature. Separate serum or plasma from cells ASAP.
Unacceptable Conditions: Grossly hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 1 month

Reference Interval: Cord blood: 6.60-17.50 µg/dL
 0-3 days: 5.37-22.40 µg/dL
 4-30 days: 5.24-23.20 µg/dL
 1-23 months: 5.37-16.00 µg/dL
 2-6 years: 5.26-14.80 µg/dL
 7-11 years: 5.70-14.10 µg/dL
 12-19 years: 4.74-14.60 µg/dL
 20 years and older: 5.10-14.10 µg/dL

✓ **HOT LINE NOTE:** This change also applies to Thyroid Panel (0070141).

HOT LINE Effective May 17, 2010

0093244 Thyroxine, Free by Equilibrium Dialysis/HPLC-Tandem Mass Spectrometry FT4 ED-TMS

Specimen Required: Collect: One 5 mL plain red.
Transport: 2 mL serum at 2-8°C. (Min: 0.5 mL) Submit specimen in an ARUP Standard Transport Tube.
Stability (collection to initiation of testing): After separation from cells: Ambient: 4 days; Refrigerated: 2 weeks; Frozen: 1 month

HOT LINE NOTE: Please remove the information from the Remarks field under Specimen Requirements.

0070138 Thyroxine, Free (Free T4) FT4

Reference Interval:
 0-3 days: 0.7-2.7 ng/dL
 4-30 days: 0.8-3.1 ng/dL
 1-23 months: 0.5-2.3 ng/dL
 2-6 years: 0.9-1.8 ng/dL
 7-11 years: 0.9-1.7 ng/dL
 12-19 years: 0.9-1.6 ng/dL
 20 years and older: 0.8-1.7 ng/dL

0099187 Tissue Plasminogen Activator, Antigen TPA AG

Specimen Required: Collect: One 5 mL lt. blue (sodium citrate). Please refer to the Hemostasis/Thrombosis Specimens section in the front of this User's Guide for specimen collection instructions.
Transport: 1 mL platelet-poor plasma, (lt. blue, sodium citrate), frozen. (Min: 0.5 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Separate plasma from cells and freeze ASAP.
Unacceptable Conditions: Serum. Specimens collected in sodium fluoride, and heparin.
Stability (collection to initiation of testing): Ambient: 4 hours; Refrigerated: 4 hours; Frozen: 2 months

New Test 2002550 Total Inhibin T INHIBIN
Effective April 19, 2010

Methodology: Enzyme-Linked Immunosorbent Assay
Performed: Varies
Reported: Varies

Specimen Required: Collect: One 4 mL serum separator tube or plain red.
Transport: 2 mL serum, frozen. (Min: 1 mL) Submit specimen in an ARUP Standard Transport Tube.
Unacceptable Conditions: Grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 3 months

Reference Interval: By report

CPT Code(s): 83520

This test is New York DOH approved.

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

HOT LINE Effective May 17, 2010

New Test 2002573 TPMT Genotype

TPMT GENO

Effective April 19, 2010

Methodology: Polymerase Chain Reaction
Performed: Varies
Reported: Varies

Specimen Required: Collect: Whole blood, lavender (EDTA).
Transport: 5 mL whole blood, 2-8°C. (Min: 3 mL)
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: Unacceptable

Reference Interval: By report

CPT Code(s): 83891 Isolation; 83898x3 Amplification; 83896x6 Nucleic Acid Probes; 83912 Interpretation and report.

New York DOH approval pending. Call for status update.

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

0093243 Triiodothyronine, Free by Equilibrium Dialysis/HPLC-Tandem Mass Spectrometry

FT3 ED-TMS

Specimen Required: Collect: One 5 mL plain red.
Transport: 2 mL serum at 2-8°C. (Min: 0.5 mL) Submit specimen in an ARUP Standard Transport Tube.
Stability (collection to initiation of testing): After separation from cells: Ambient: 4 days; Refrigerated: 2 weeks; Frozen: 1 month

HOT LINE NOTE: Please remove the information from the Remarks field under Specimen Requirements.

0070474 Triiodothyronine, Total (Total T3)

T3 TOTAL

Specimen Required: Collect: One 4 mL plasma separator tube or serum separator tube. Also acceptable: lavender (EDTA), or green (sodium or lithium heparin).
Storage/Transport Temperature: 1 mL serum or plasma at 2-8°C. (Min: 0.5 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Allow serum to clot completely at room temperature. Separate serum or plasma from cells ASAP.
Unacceptable Conditions: Grossly hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 1 month

Reference Interval:
 Cord blood: 14-86 ng/dL
 0-3 days: 96-292 ng/dL
 4-30 days: 62-243 ng/dL
 1-23 months: 81-281 ng/dL
 2-6 years: 83-252 ng/dL
 7-11 years: 92-219 ng/dL
 12-19 years: 83-215 ng/dL
 20 years and older: 80-200 ng/dL

HOT LINE Effective May 17, 2010

New Test 2002939 Tysabri® Antibodies

TYSABRI

Effective April 19, 2010

Methodology: Enzyme Linked Immunosorbent Assay
Performed: Varies
Reported: Varies

Specimen Required: Collect: Plain red or serum separator tube.
Specimen Preparation: Submit specimen in an ARUP Standard Transport Tube.
Transport: 1 mL serum at 2-8°C. (Min: 0.5 mL)
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 2 weeks; Frozen: 1 month

Reference Interval: By report

CPT Code(s): 83516

This test is New York DOH approved.

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

0051332 UDP Glucuronosyltransferase 1A1 (UGT1A1) Genotyping

UGT1A1

Interpretive Data:

Background Information for UDP Glucuronosyltransferase 1A1 (UGT1A1) Genotyping:

Characteristics: *UGT1A1* is responsible for the clearance of drugs (e.g., irinotecan) and endbiotic compounds (e.g., bilirubin). Irinotecan's major active and toxic metabolite (SN-38) is inactivated by *UGT1A1* and then eliminated via the bile. *UGT1A1* gene mutations cause accumulation of SN-38, which may lead to irinotecan-related toxicities (neutropenia, diarrhea).

Cause: Variations in TA repeat number in the TATAAA element of the 5' *UGT1A1*-promoter affects transcription efficiency. The common number of repeats is six [(TA) 6, *1 allele], while seven repeats [(TA) 7, *28 allele] is associated with reduced transcription activity. Homozygosity for the (TA) 7 allele is also associated with Gilbert's syndrome (benign familial hyperbilirubinemia).

Alleles detected: (TA)5, (TA)6, (TA)7 and (TA)8.

Clinical Sensitivity/Specificity: The risk of irinotecan toxicity by genotype is shown below (based on data from Br J Cancer (2004) 91:678-82).

TA genotype	Diarrhea	Neutropenia
6/6 (*1/*1)	17 percent	15 percent
6/7 (*1/*28)	33 percent	27 percent
7/7 (*28/*28)	70 percent	40 percent

Allelic Frequency: *1 (TA)6: Caucasians - 61 percent; Asians - 84 percent; African Americans - 47 percent
 *28 (TA)7: Caucasians - 39 percent; Asians - 16 percent; African Americans - 43 percent

Methodology: Polymerase chain reaction followed by size analysis using capillary electrophoresis.

Analytical Sensitivity: Greater than 99 percent

Limitations: Variations in the *UGT1A1* gene, other than those targeted, will not be detected. Clinical significance of the rare (TA)5 and (TA)8 alleles on risk of irinotecan toxicities is not well established.

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

Please refer to Statement C in the Compliance Statements section in the front of the Laboratory Test Directory.

HOT LINE Effective May 17, 2010

0020480 Urea Nitrogen, Urine UUN

Specimen Required: Collect: 24-hour urine (no additive). Also acceptable: random urine. Refrigerate during collection.
Transport: 5 mL aliquot from a well-mixed 24-hour collection at 2-8°C. (Min: 0.2 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: Record total volume and collection time interval on transport tube and test request form.
Unacceptable Conditions: Urine collected with acid. Specimens stored at 20-25°C. Specimens with a pH of 4 or less.
Stability (collection to initiation of testing): Ambient: **2 days**; Refrigerated: 1 week; Frozen: 1 month

0065031 Ureaplasma urealyticum & Mycoplasma hominis Culture V UREA

Performed: Sun-Sat
Reported: Within 7 days
 Final: Negative **within 7 days**
 Average time to positive: 3 days

Specimen Required: Collect: Urine, urethral or cervical swab, semen, tissue, body fluid, CSF, **respiratory**. **Source of specimen is required.**
Specimen Preparation: **Place swab or specimen in Mycoplasma/Ureaplasma transport media (ARUP supply #12884) (DO NOT USE M4 RT).**
Storage/Transport Temperature: **Specimen in Mycoplasma/Ureaplasma transport media frozen. (Min: 0.5 mL)** Use a sterile leak proof container for tissue or fluids if Mycoplasma/Ureaplasma transport media is unavailable. If transport time will exceed 24 hours, freeze **specimen** and transport on dry ice. Place each specimen in a separate, individually sealed bag. Submit specimen according to Biological Substance, Category B, shipping guidelines.
Remarks: This culture will recover both *Mycoplasma hominis* and *Ureaplasma urealyticum*, if present.
Unacceptable Conditions: **M4 RT**, swabs in culturettes, Nonpatient specimens, and dry swabs.
Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: 48 hours in Mycoplasma/Ureaplasma transport media; Frozen: 1 month (-70°C)

0060131 Urine Culture MC U

Specimen Required: Collect: Midstream urine, catheter, cystoscopic, or suprapubic urines. Indicate if specimen was collected by invasive method. Source of specimen is required.
Transport: Sterile, leak-proof container at 2-8°C or boric acid transport **tube** at 20-25°C. Submit specimen according to Biological Substance, Category B, shipping guidelines.
Remarks: Gram stain is performed by request only. Results indicate colony count plus identification of significant isolates. Suprapubic aspirates submitted in sterile-capped syringe (needle removed) are acceptable for anaerobe culture.
Unacceptable Conditions: Nonsterile or leaking containers, multiple specimens (more than one in 24 hours), 24-hour or pooled specimens, delayed transport to the lab (greater than two hours at room temperature or greater than 24 hours at 2-8°C), urine from catheter bag, Foley catheter tips (syringe with needle attached).
Stability (collection to initiation of testing): Ambient: 2 hours, (boric acid tube: Ambient: 48 hours); Refrigerated: 24 hours; Frozen: Unacceptable

0099435 Vasoactive Intestinal Peptide VIP

Specimen Required: Collect: 5 mL blood into any chilled container of EDTA, plus 0.2 cc of aprotinin **added immediately after collection**. (0.04 cc aprotinin per mL of whole blood.)
Transport: 1 mL plasma (EDTA plus aprotinin), frozen. (Min: 0.5 mL) Submit specimen in an ARUP Standard Transport Tube.
Remarks: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.** Immediately centrifuge, separate plasma from cells (Min: 0.5 mL plasma), and freeze. To prevent analyte degradation, aprotinin inhibitor is the required additive for this assay. Inhibitor vials are available through ARUP Client Services (ARUP Supply #16570).
Unacceptable Conditions: Nonfrozen or hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 3 months

HOT LINE Effective May 17, 2010

0080389 Vitamin B₁ (Thiamine), Plasma VIT B1 P

Specimen Required: Collect: One 7 mL green (sodium or lithium heparin) or two 5 mL lavender (EDTA) or pink (K₂ EDTA).
Transport: 3 mL plasma, frozen. (Min: 0.5 mL) Submit specimen in an ARUP Amber Transport Tube. Protect from light during collection, storage, and shipment.
Remarks: **Ship frozen. Separate specimens must be submitted when multiple tests are ordered.** Protect from light during collection, storage, and shipment. Separate plasma from cells ASAP. **Whole blood is preferred over plasma, which is more light sensitive.** Refer to Vitamin B₁ (Thiamine), Whole Blood (0080388).
Unacceptable Conditions: Nonfrozen specimens. Specimens not protected from light.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 6 months (-20°C)

0070150 Vitamin B₁₂ B12

Specimen Required: Collect: One 4 mL serum separator tube.
Transport: 1 mL serum, frozen. (Min: 0.5 mL) Protect from light. Submit specimen in an ARUP Amber Transport Tube.
Remarks: Allow serum to clot completely at room temperature before centrifuging. Protect from light during collection, storage, and shipment.
Unacceptable Conditions: **Hemolyzed specimens.**
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 2 days; Frozen: 3 months

0080385 Vitamin D, 1, 25-Dihydroxy VIT D 1,25

Specimen Required: Collect: **One 6 mL serum separator tube.** Also acceptable: lavender (EDTA) or pink (K₂ EDTA).
Storage/Transport Temperature: **2 mL** serum or plasma at 2-8°C. (Min: **1 mL**) Submit specimen in an ARUP Standard Transport Tube.
Stability (collection to initiation of testing): After separation from cells: Ambient: 3 days; Refrigerated: 1 week; Frozen: 6 months

Interpretive Data: This test is primarily indicated during patient evaluation for hypercalcemia and renal failure. A normal result does not rule out Vitamin D deficiency. The recommended test for diagnosing Vitamin D deficiency is Vitamin D 25-hydroxy (0080379).

HOT LINE Effective May 17, 2010

Test Mix Addendum - Interface Clients Only

Test Mix Addendum Audit Legend

Column A - TEST ID

This column contains ARUP test numbers for the different types of testing procedures (See Column C below). In ARUP's Test Directory, test numbers are 7 digits long and in most cases have two leading zeros. It is suggested that you do not use the leading zeros. The leading zeros are not included in the audit even though they are in the ARUP Laboratory Test Directory. If leading zeros are used, they need to be used consistently.

Column B - TEST NAME

This column contains the Test Description.

Column C - PARENT ID

If an assay is a member of a Group test, this column provides that Group test number or Parent ID. This is the order-only number for the Group assay.

Column D - TEST TYPE

O = ORDER CODE
 R = RESULT CODE
 P = PROMPT Tests, also known as "ask at order entry" questions transmitted to ARUP.

Column E - REFLEXIVE

This flag indicates the tests that may have further testing performed automatically based on results of initial testing.

Column F - CAT. A / B Shipping Guidelines

This column indicates the infectious nature of the assay and the Specimen Transport requirements as defined in the ARUP Laboratory Test Directory for Infectious Substance, Category A; Biological Substance, Category B; and Human Exempt specimens. (This information is used to help create separate specimen packing lists for specimens that must be shipped using alternative methods)

Column G - SHIP TEMP

This column indicates the required shipping temperature of each assay. (Each temperature should have a unique specimen packing list)

Column H - SPECIMEN REQUIREMENTS (Available on the online Test Mix only)

This column details the preferred specimen for each assay (Refer to individual test entry in the Hot Line for specific specimen Requirements - Specimen Requirements column is not displayed in this report)

Column I - UNITS OF MEASURE

This column provides the units of measure for each result assay or prompt.

Column J - MAX NUMERIC MAP

Maximum numeric map that will be transmitted in the result field.

Column K - MIN NUMERIC MAP

Minimum numeric map that will be transmitted in the result field.

Column M - CPT CODES

CPT (Current Procedural Terminology) codes are numbers assigned to every task and service a medical practitioner may provide to a patient including medical, surgical and diagnostic services. (Refer to the individual test entry for tests with multiple codes).

A	B	C	D	E	F	G	I	J	K	M
Test ID	Test Name	Parent ID	Test Type	Reflexive	CAT. A / B Shipping Guidelines	Shipping Temperature	Units of Measure	Max Numeric Map	Min Numeric Map	CPT Code
51835	Allergen, Food, Shell Fish Profile		O			Refrigerated				86003
55011	Allergen, Food, Crab IgE	51835	R				kU/L	XXXX.XX	X.XX	86003
55030	Allergen, Food, Shrimp IgE	51835	R							86003
55041	Allergen, Interp, Immuncap Score IgE	51835	R							
55425	Allergen, Food, Blue Mussel IgE	51835	R				kU/L	XXXX.XX	X.XX	86003
99062	Allergen, Food, Lobster IgE	51835	R				kU/L	XXXX.XX	X.XX	86003
99488	Allergen, Food, Clam IgE	51835	R							86003
99495	Allergen, Food, Scallop IgE	51835	R							86003
99638	Allergen, Food, Oyster IgE	51835	R				kU/L	XXXX.XX	X.XX	86003
2002656	Anti-Mullerian Hormone		O			Frozen				
2002657	Anti-Mullerian Hormone	2002656	R				ng/mL	XXX.XX	X.XX	
2002569	B2glycoprotein 1 Abs, IgG, IgM, IgA		O			Refrigerated				Multi
50322	B2Glycoprotein I, IgG Antibody	2002569	R				SGU	XXX	X	86146
50323	B2Glycoprotein I, IgM Antibody	2002569	R				SMU	XXX	X	86146
50324	B2Glycoprotein I, IgA Antibody	2002569	R				SAU	XXX	X	86146
2002926	Blastomyces dermatitidis Antigen EIA		O			Ambient				87449
2002927	Blastomyces dermatitidis Antigen	2002926	R							

HOT LINE Effective May 17, 2010
Test Mix Addendum - Interface Clients Only

A	B	C	D	E	F	G	I	J	K	M
Test ID	Test Name	Parent ID	Test Type	Reflexive	CAT. A / B Shipping Guidelines	Shipping Temperature	Units of Measure	Max Numeric Map	Min Numeric Map	CPT Code
2002853	Brucella Antibodies		O			Refrigerated				
50336	Brucella Antibody, IgM	2002853	R							86622
50135	Brucella Antibody Screen	2002853	R							86622
50334	Brucella Antibody, IgG	2002853	R							86622
2002552	C. Difficile Cytotoxin AB		O			Refrigerated				87230
2002553	C. Difficile Cytotoxin	2002552	R							
2002838	C. difficile toxin B gene (tdfB), RT-PCR		O							87493
2002839	C. difficile toxin B test source	2002838	P							
2002840	C. difficile toxin B gene (tdfB), PCR	2002838	R							
2002932	Coxsackie A Antibodies		O			Ambient				Multi
2002933	Coxsackie A2 Ab	2002932	R							
2002934	Coxsackie A4 Ab	2002932	R							
2002935	Coxsackie A7 Ab	2002932	R							
2002936	Coxsackie A9 Ab	2002932	R							
2002937	Coxsackie A10 Ab	2002932	R							
2002938	Coxsackie A16 Ab	2002932	R							
2002994	Ehrlichia chaffeensis DNA, Real-Time PCR		O			Refrigerated				87798
2002995	Ehrlichia chaffeensis DNA	2002994	R							
2002819	Factor XIII Qualitative		O			Frozen				
2002818	Factor XIII, 1:1 Mix	2002819	R							
2002915	Factor XIII, Qualitative	2002819	R							
51752	FG Syndrome, FGS1 (MED12) R961W Mutation		O			Refrigerated				Multi
2002914	FGS1 Specimen	51752	P							
51753	FG Syndrome, FGS1 (MED12) R961W Mutation	51752	R							
2002862	Gad65 & Anti-Ins Ab w/Reflex to IA-2 Ab		O	Y		Frozen				Multi
98223	Insulin Antibody	2002862	R							
2001772	Glutamic Acid Decarboxylase Antibody	2002862	R							
	Reflex:									
50202	IA-2 Antibody		O	Y		Refrigerated				86341
50202	IA-2 Antibody	50202	R				U/mL	xx.x	X.X	86341
2002996	Herpes Virus 8 DNA, Qualitative		O			Refrigerated				87798
2002998	HERPES 8 Source	2002996	P							
2002997	HHV 8 DNA QL	2002996	R							
2002829	Herpesvirus 6 Antibody, IgM		O			Refrigerated				86790
2002830	Herpesvirus 6 AB, IgM, IFA	2002829	R							
2002801	HLA AB Oligotyping		O			Ambient				
2002785	Class I, Locus B*, Allele 1	2002801	R							
2002786	Class I, Locus B*, Allele 2	2002801	R							

HOT LINE Effective May 17, 2010
Test Mix Addendum - Interface Clients Only

A	B	C	D	E	F	G	I	J	K	M
Test ID	Test Name	Parent ID	Test Type	Reflexive	CAT. A / B Shipping Guidelines	Shipping Temperature	Units of Measure	Max Numeric Map	Min Numeric Map	CPT Code
2002790	Class I, Locus A*, Allele 1	2002801	R							
2002791	Class I, Locus A*, Allele 2	2002801	R							
2002848	HLA AB Oligotyping Interp	2002801	R							
2002805	HLA Antibody Detection Assay		O			Frozen				
95858	HLA Antibody Screen Interp	2002805	R							
2002804	HLA Class I Antibody	2002805	R							
2002810	HLA DQ Oligotyping		O			Ambient				
2002811	Class II, Locus DQB, Allele 1	2002810	R							
2002812	Class II, Locus DQB, Allele 2	2002810	R							
2002813	HLA DQ Oligotyping Interp	2002810	R							
2003085	HLA-A Sequencing		O			Ambient				
2002790	Class I, Locus A*, Allele 1	2003085	R							
2002791	Class I, Locus A*, Allele 2	2003085	R							
2003084	HLA-A Sequencing Interpretation	2003085								
2002788	HLA-ABC Sequencing		O			Ambient				
2002785	Class I, Locus B*, Allele 1	2002788	R							
2002786	Class I, Locus B*, Allele 2	2002788	R							
2002790	Class I, Locus A*, Allele 1	2002788	R							
2002791	Class I, Locus A*, Allele 2	2002788	R							
2002808	Class I, Locus Cw*, Allele 1	2002788	R							
2002809	Class I, Locus Cw*, Allele 2	2002788	R							
2002846	HLA-ABC Sequencing Interpretation	2002788	R							
2002784	HLA-B Sequencing		O			Ambient				
2002785	Class I, Locus B*, Allele 1	2002784	R							
2002786	Class I, Locus B*, Allele 2	2002784	R							
2002787	HLA-B Sequencing Interpretation	2002784	R							
2002806	HLA-BMT Evaluation		O			Ambient				
95844	HLA BMT Evaluation Interpretation	2002806	R							Multi
2002780	Class II, Locus DRB1*, Allele 1	2002806	R							
2002781	Class II, Locus DRB1*, Allele 2	2002806	R							
2002785	Class I, Locus B*, Allele 1	2002806	R							
2002786	Class I, Locus B*, Allele 2	2002806	R							
2002790	Class I, Locus A*, Allele 1	2002806	R							
2002791	Class I, Locus A*, Allele 2	2002806	R							
2002807	HLA-C Oligotyping		O			Ambient				
95716	HLA C DNA Oligotyping Interp	2002807	R							
2002808	Class I, Locus Cw*, Allele 1	2002807	R							
2002809	Class I, Locus Cw*, Allele 2	2002807	R							

HOT LINE Effective May 17, 2010
Test Mix Addendum - Interface Clients Only

A	B	C	D	E	F	G	I	J	K	M
Test ID	Test Name	Parent ID	Test Type	Reflexive	CAT. A / B Shipping Guidelines	Shipping Temperature	Units of Measure	Max Numeric Map	Min Numeric Map	CPT Code
2002814	HLA-C Sequencing		O			Ambient				
2002808	Class I, Locus Cw*, Allele 1	2002814	R							
2002809	Class I, Locus Cw*, Allele 2	2002814	R							
2002817	HLA-C Sequencing Interpretation	2002814	R							
2002798	HLA-DR Oligotyping		O			Ambient				
2002780	Class II, Locus DRB1*, Allele 1	2002798	R							
2002781	Class II, Locus DRB1*, Allele 2	2002798	R							
2002847	HLA DR Oligotyping Interp	2002798	R							
2002779	HLA-DRB1 Sequencing		O			Ambient				
2002780	Class II, Locus DRB1*, Allele 1	2002779	R							
2002781	Class II, Locus DRB1*, Allele 2	2002779	R							
2002783	HLA-DRB1 Sequencing Interpretation	2002779	R							
80422	Homovanillic Acid (HVA), Urine		O			Refrigerated				83150
97110	Total Volume	80422	P				mL	XXXXX	X	
97111	Hours Collected	80422	P				hr	XX	X	
20207	Creatinine, Urine - mg/dL	80422	R							82570
20208	Creatinine, Urine - mg/day	80422	R							
80164	Homovanillic Acid (HVA)	80422	R				mg/d	XXX.X	X.X	83150
80399	HVA Interpretation	80422	R							
81305	HVA, Urine mg	80422	R				mg/L	XXXX.X	X.X	
81342	HVA, Urine mg/g CRT	80422	R				mg/g	XXX	X	
2003020	Human Epididymis Protein 4 (HE4)		O			Ambient				86305
2003021	Human Epididymis Prot 4	2003020	R							
2002577	Infliximab		O			Refrigerated				83520
2002578	Infliximab	2002577	R							
2002579	Infliximab/HACA Measurement		O			Refrigerated				83520
2002580	Infliximab/HACA Measurement	2002579	R							
2002942	Influenza Virus A & B DFA includes H1N1		O	Y						Multi
60294	Influenza A - DFA	2002942	R							87276
60295	Influenza B - DFA	2002942	R							87275
2002943	FLUFAPCRT Src	2002942	R							
2002992	Iodine, Random, Urine		O			Refrigerated				83789
2002993	Iodine Random	2002992	R							
2002945	Legius Syndrome Sequencing		O			Refrigerated				
2002946	LS FGS Specimen	2002945	P							
2002947	Legius Syndrome Sequencing Interp	2002945	R							
81062	Maternal Screening, INT-1		O			Refrigerated				84163
80241	Estimated Due Date	81062	R							

HOT LINE Effective May 17, 2010
Test Mix Addendum - Interface Clients Only

A	B	C	D	E	F	G	I	J	K	M
Test ID	Test Name	Parent ID	Test Type	Reflexive	CAT. A / B Shipping Guidelines	Shipping Temperature	Units of Measure	Max Numeric Map	Min Numeric Map	CPT Code
80917	Maternal Weight	81062	R				lbs	xxx	XX	
80926	Maternal Race	81062	R							
80920	Maternal Screen Interpretation	81062	R							
80927	Number of Fetuses	81062	R							
80932	Maternal Age At Delivery	81062	R				yr	XX.X	XX.X	
80938	Gestational Age (Exact)	81062	R				weeks	XX.XX	X.XX	
81065	Nuchal Translucency (NT)	81062	R				mm	X.XX	X.XX	
81066	Crown Rump Length	81062	R				cm	XX.XX	X.XX	
81067	Patient's PAPP-A	81062	R				mIU/L	XXXXX	X	84163
81068	MoM for PAPP-A	81062	R					XX.XX	X.XX	
81069	Sonographer Certification #	81062	R							
81070	Sonographer Name	81062	R							
81071	Ultrasound Date	81062	R							
81074	MoM for NT	81062	R					XX.XX	X.XX	
81158	Previous Downs	81062	R							
81331	Best date to draw sample #2 by	81062	R							
2002854	EER Maternal Screening, INT-1	81062	R							
81293	Maternal Screening, Sequential, Spec 1		O			Refrigerated				Multi
81068	MoM for PAPP-A	81293	R					XX.XX	X.XX	
80241	Estimated Due Date	81293	R							
80917	Maternal Weight	81293	R				lbs	xxx	XX	
80920	Maternal Screen Interpretation	81293	R							
80926	Maternal Race	81293	R							
80927	Number of Fetuses	81293	R							
80932	Maternal Age At Delivery	81293	R				yr	XX.X	XX.X	
80935	Patient's hCG	81293	R				IU/L	XXXXXX	X	84702
80937	MoM For hCG	81293	R					XX.XX	X.XX	
80938	Gestational Age (Exact)	81293	R				weeks	XX.XX	X.XX	
81065	Nuchal Translucency (NT)	81293	R				mm	X.XX	X.XX	
81066	Crown Rump Length	81293	R				cm	XX.XX	X.XX	
81067	Patient's PAPP-A	81293	R				mIU/L	XXXXX	X	84163
81069	Sonographer Certification #	81293	R							
81070	Sonographer Name	81293	R							
81071	Ultrasound Date	81293	R							
81074	MoM for NT	81293	R					XX.XX	X.XX	
81158	Previous Downs	81293	R							
81331	Best date to draw sample #2 by	81293	R							
2002856	EER Maternal Screening, Seq, Spec 1	81293	R							

HOT LINE Effective May 17, 2010

Test Mix Addendum - Interface Clients Only

A	B	C	D	E	F	G	I	J	K	M
Test ID	Test Name	Parent ID	Test Type	Reflexive	CAT. A / B Shipping Guidelines	Shipping Temperature	Units of Measure	Max Numeric Map	Min Numeric Map	CPT Code
80269	Maternal Serum Screen AFP, hCG, EST, INH		O			Frozen				Multi
97104	Doctor Name	80269	P							
97106	Maternal Date Of Birth	80269	P							
97107	Due Date	80269	P							
97108	Determined By:	80269	P							
97115	Maternal Weight	80269	P				lbs	XXX	X	
97118	Date of Last Menstrual Period	80269	P							
97122	Diabetic	80269	P							
97124	Race of Mother	80269	P							
97133	Family History of NTD or Other	80269	P							
97134	Twins	80269	P							
80021	Patient's AFP	80269	R				ng/mL	XXXX	X	82105
80241	Estimated Due Date	80269	R							
80267	MoM for DIA	80269	R					XX.XX	X.XX	
80268	Patient's DIA	80269	R				pg/mL	XXXX	X	86336
80917	Maternal Weight	80269	R				lbs	XXX	XX	
80918	MoM for AFP	80269	R					XX.XX	X.XX	
80920	Maternal Screen Interpretation	80269	R							
80922	Specimen	80269	R							
80923	Dating	80269	R							
80924	Insulin Req Maternal Diabetes	80269	R							
80925	Family Hx Neural Tube Defect	80269	R							
80926	Maternal Race	80269	R							
80927	Number of Fetuses	80269	R							
80932	Maternal Age At Delivery	80269	R				yr	XX.X	XX.X	
80935	Patient's hCG	80269	R				IU/L	XXXXXX	X	84702
80937	MoM For hCG	80269	R					XX.XX	X.XX	
80938	Gestational Age (Exact)	80269	R				weeks	XX.XX	X.XX	
80941	Patient's uE3	80269	R				ng/mL	XXX.XX	X.XX	82677
80943	MoM for uE3	80269	R					XX.XX	X.XX	
2002850	EER Maternal Screen AFP, hCG, EST, INH	80269	R							
2002928	Metformin, Urine		O			Refrigerated				80299
2002929	Metformin, Urine	2002928	R							
60310	Occult Blood, Gastric		O			Refrigerated				82271
60310	Occult Blood, Gastric Fluid	60310	R							82271
2002870	Gastric Fluid pH	60310	R					XX	X	
2002984	Oxygen Dissociation (P50) by Hemoximetry		O			Refrigerated				
2002986	Oxygen dissociation (P50)	2002984	R				mmHg	XX.X	X.X	

HOT LINE Effective May 17, 2010
Test Mix Addendum - Interface Clients Only

A	B	C	D	E	F	G	I	J	K	M
Test ID	Test Name	Parent ID	Test Type	Reflexive	CAT. A / B Shipping Guidelines	Shipping Temperature	Units of Measure	Max Numeric Map	Min Numeric Map	CPT Code
2002871	PML-RARA, t(15;17) by PCR, Quantitative		O			Refrigerated				
2002872	PML Result	2002871	R							
2002874	PML Quantitative Result	2002871	R					X.XXXXX	X.XXXXX	
2002554	Pregabalin		O			Refrigerated				82542
2002555	Pregabalin SP	2002554	R							
2002930	Prostate Specific Antigen, Complexed		O			Refrigerated				84152
2002931	PSA Complexed	2002930	R							
2002575	Thiopurine Metabolites		O			Refrigerated				82491x2
2002576	Thiopurine Metabolites	2002575	R							
2002550	Total Inhibin		O			Frozen				83520
2002551	Total Inhibin	2002550	R							
2002573	TPMT Genotype		O			Refrigerated				Multi
2002574	TPMT Genotype	2002573	R							
2002939	Tysabri Antibodies		O			Refrigerated				83516
2002940	Tysabri AB	2002939	R							