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Information regarding Current Procedural Terminology (CPT)

Test Number	Mnemonic	Test Name	New Test	Test Name Change	Specimen Requirements	Methodology	Performed/Reported	Note	Interpretive Data	Reference Interval	Component Charting Name	Component Change	Reflex Pattern	Result Type	Ask at Order Prompt	Numeric Map	Unit of Measure	CPT Code	Pricing Change	Inactivation w/ Replacement	Inactivation w/o Replacement
0040018	HD	Huntington Disease (HD) Mutation by PCR (Change effective as of 11/13/2023: Refer to 3016908 in the November Hotline)																		x	
0050246	EBVPCR	Epstein-Barr Virus by Qualitative PCR			x	x			x												
0050345	IGE	Immunoglobulin E					x														
0050547	TWIN ZYG	Twin Zygosity Testing (Change effective as of 11/13/2023: Refer to 3016875 in the November Hotline)																		x	
0050734	EMA R	Tissue Transglutaminase (tTG) Antibody, IgA with Reflex to Endomysial Antibody, IgA by IFA (Change effective as of 11/13/23: Refer to 3016861 in the November Hotline)																		x	
0050736	EMAR TITER	Endomysial Antibody, IgA by IFA											x								
0051074	FLUA G	Influenza A Virus Antibody, IgG (Change effective as of 11/13/23: Refer to 0060764)																		x	
0051080	FLUB G	Influenza B Virus Antibody, IgG (Change effective as of 11/13/23: Refer to 0060764)																		x	

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0051265	AD PCR FE	Achondroplasia (FGFR3) 2 Mutations, Fetal										x									
0051357	GLIADPEP A	Deamidated Gliadin Peptide (DGP) Antibody, IgA			x	x		x	x	x			x			x	x				
0051358	GLIAD PAN	Deamidated Gliadin Peptide (DGP) Antibodies, IgA and IgG			x	x		x	x	x						x	x				
0051359	GLIADPEP G	Deamidated Gliadin Peptide (DGP) Antibody, IgG			x	x		x	x	x			x			x	x				
0051689	TTG DGP	Celiac Disease Dual Antigen Screen (Change effective as of 11/13/23: Refer to 3016817 in the November Hotline)																		x	
0055258	LYMEMWBC SF	Borrelia burgdorferi Antibody, IgM by Immunoblot (CSF) (Change effective as of 11/13/23: Refer to 0055260)																		x	
0055259	LYMEGWBC SF	Borrelia burgdorferi Antibody, IgG by Immunoblot (CSF) (Change effective as of 11/13/23: Refer to 0055260)																		x	
0056009	TTG G	Tissue Transglutaminase Antibody, IgG			x	x		x	x	x			x			x	x				

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0058902	C2CYA	Cyclosporine A, 2-Hour Post Dose (C2) by Tandem Mass Spectrometry					x														
0060040	CMVPCR	Cytomegalovirus by Qualitative PCR			x	x			x												
0070035	CYA	Cyclosporine A by Tandem Mass Spectrometry					x														
0080407	CATE UF	Catecholamines Fractionated by LC-MS/MS, Urine Free					x														
0081056	TESTOS F&T	Testosterone, Free and Total, Includes Sex Hormone-Binding Globulin (Adult Females, Children, or Individuals on Testosterone-Suppressing Hormone Therapy)				x	x														
0081057	BIO T MASS	Testosterone, Bioavailable and Total, Includes Sex Hormone-Binding Globulin (Adult Females, Children, or Individuals on Testosterone-Suppressing Hormone Therapy)				x	x														

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0081058	TESTOS MAS	Testosterone (Adult Females, Children, or Individuals on Testosterone-Suppressing Hormone Therapy)				x	x														
0081059	TESTOS FR	Testosterone, Free (Adult Females, Children, or Individuals on Testosterone-Suppressing Hormone Therapy)				x	x														
0081117	CORT SAL	Cortisol, Saliva (Change effective as of 11/13/23: Refer to 3016866 in the November Hotline)																		x	
0090010	ALPR	Alprazolam					x														
0090055	CLON	Clonazepam					x														
0090076	DIAZ	Diazepam and Nordiazepam					x														
0090148	LIB	Librium and Nordiazepam					x														
0090181	LORAZ	Lorazepam					x														
0090196	CLORAZ	Clorazepate (Assayed as Nordiazepam)					x														
0090612	TACRO	Tacrolimus by Tandem Mass Spectrometry					x														
0090672	PRAZE	Prazepam (Assayed as Nordiazepam)					x														
0090676	CANNAB SP	THC Metabolite, Serum or Plasma, Quantitative					x														

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0092118	EVEROLIMUS	Everolimus by Tandem Mass Spectrometry					x														
0092330	ADSTEROID	Adrenal Steroid Quantitative Panel by HPLC-MS/MS, Serum or Plasma				x	x														
0092331	DEOXYCORT	11-Deoxycortisol Quantitative by HPLC-MS/MS, Serum or Plasma				x	x														
0092332	OHPRGSTON	17-Hydroxyprogesterone Quantitative by HPLC-MS/MS, Serum or Plasma				x	x														
0092354	OPIS SP	Opiates, Serum or Plasma, Quantitative					x														
0093244	FT4 ED-TMS	Thyroxine, Free by Equilibrium Dialysis/HPLC-Tandem Mass Spectrometry			x	x	x		x												
0097709	TTG	Tissue Transglutaminase (tTG) Antibody, IgA (Change effective as of 11/13/23: Refer to 3016860 in the November Hotline)																		x	
0098467	RAPAMUNE	Sirolimus by Tandem Mass Spectrometry					x														

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0099483	LYME CSF	Borrelia burgdorferi Antibodies, Total by ELISA, CSF (Change effective as of 11/13/23: Refer to 3016760 in the November Hotline)																		x	
2001181	UF REQUEST	UroVysion FISH (Change effective as of 11/13/23: Refer to 3016627 in the November Hotline)																		x	
2001638	ANDRO TMS	Androstenedione				x	x														
2001640	DHEA TMS	Dehydroepiandrosterone, Serum or Plasma				x	x														
2002026	CELIAC SCRN	Celiac Disease Dual Antigen Screen with Reflex (Change effective as of 11/13/23: Refer to 3016817 in the November Hotline)																		x	
2002349	DHT TMS	5-a-Dihydrotestosterone by Tandem Mass Spectrometry, Serum					x														
2002357	JAK2 EX12	JAK2 Exon 12 Mutation Analysis by PCR										x									
2002366	ARRAY FE	Cytogenomic SNP Microarray - Fetal			x				x												
2002528	PF REQUEST	Pancreatobiliary FISH			x		x	x		x											

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2002819	FACTOR 13	Factor XIII, Qualitative, with Reflex to Factor XIII 1:1 Mix (Change effective as of 11/13/23: Refer to 3016927 in the November Hotline)																		x	
2003414	CMA SNP	Cytogenomic SNP Microarray			x				x												
2005545	MPL	MPL Mutation Detection by Capillary Electrophoresis										x									
2005633	ARRAY POC	Genomic SNP Microarray, Products of Conception			x				x												
2005978	OIL RED SS	Special Stain, Oil Red O			x																
2006550	THYROG MS	Thyroglobulin by LC-MS/MS, Serum or Plasma					x														
2007136	VWF C BIND	von Willebrand Factor (VWF) Collagen Binding (Change effective as of 11/13/23: Refer to 3016858 in the November Hotline)																		x	
2007335	LYMECSFR	Borrelia burgdorferi (Lyme Disease) Reflexive Panel (CSF) (Change effective as of 11/13/23: Refer to 3016760 in the November Hotline)																		x	

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2007479	PAIN HYB U	Drug Profile, Targeted by Tandem Mass Spectrometry and Enzyme Immunoassay, Urine									x										
2007996	META URINE	Metanephrines Fractionated by HPLC-MS/MS, Urine					x														
2008114	CELIAC REF	Celiac Disease Reflexive Cascade (Change effective as of 11/13/23: Refer to 3016817 in the November Hotline)																		x	
2008426	SLCO1B1	SLCO1B1, 1 Variant										x									
2008456	CORTC	Corticosterone Quantitative by HPLC-MS/MS, Serum or Plasma				x	x														
2008458	DCRN	11-Deoxycorticosterone Quantitative by HPLC-MS/MS, Serum or Plasma				x	x														
2008509	PGSN	Progesterone Quantitative by HPLC-MS/MS, Serum or Plasma				x	x														
2008665	BABPCR	Babesia Species by PCR			x																
2008767	OPRM1	Opioid Receptor, mu OPRM1, 1 Variant										x									
2009033	FRAG X PCR	Fragile X (FMR1) with Reflex to Methylation Analysis			x		x		x												

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2009288	PAIN HYB 2	Drug Profile, Targeted with Interpretation by Tandem Mass Spectrometry and Enzyme Immunoassay, Urine									x	x									
2009478	OHPRGSTN 30	17-Hydroxyprogesterone 30-Min Quantitative by HPLC-MS/MS, Serum or Plasma				x	x														
2009480	OHPRGSTN 60	17-Hydroxyprogesterone 60-Min Quantitative by HPLC-MS/MS, Serum or Plasma				x	x														
2010161	CEHP R	Chronic Enteric Hypersensitivity Reflexive Profile (Inactive as of 11/13/23)																			x
2010445	BENZO SP	Benzodiazepines, Serum or Plasma, Quantitative					x														
2010673	CALR	CALR (Calreticulin) Exon 9 Mutation Analysis by PCR										x									
2010784	HCV AB QR	Hepatitis C Virus Antibody by CIA with Reflex to HCV by Quantitative NAAT			x																
2011776	CDCO FNSP	Fentanyl and Metabolite, Serum or Plasma, Quantitative					x														

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2012166	DPYD	Dihydropyrimidine Dehydrogenase (DPYD), 3 Variants					x		x			x									
2012201	BARBS SP	Barbiturates, Serum or Plasma, Quantitative					x														
2012647	BUPRSP	Buprenorphine and Metabolites, Serum or Plasma, Quantitative					x														
2012652	ZOLPID SP	Zolpidem, Serum or Plasma, Quantitative					x														
2013436	SMA DD	Spinal Muscular Atrophy (SMA) Copy Number Analysis			x	x			x												
2013942	ZIKA M	Zika Virus IgM Antibody Capture (MAC), by ELISA										x									
3000193	HPA GENO	Platelet Antigen Genotyping Panel			x																
3000202	5 HIAA PLA	5-Hydroxyindoleacetic acid (5-HIAA), Plasma (Change effective as of 11/13/23: Refer to 3016920 in the November Hotline)																		x	
3000959	AAV5 TAB	AAV5 Detect CDxTM - AAV5 Total Antibody Assay for ROCTAVIAN (valoctocogene roxaparvovec-rvox) Eligibility in Hemophilia A	x																		
3001053	RBC GENO	Red Blood Cell Antigen Genotyping			x																

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3001501	2C8/2C9	CYP2C8, CYP2C9, and CYP2C cluster							x			x									
3001508	2C19GENO	CYP2C19							x			x									
3001513	2D6GENO	CYP2D6										x									
3001518	3A4/3A5	CYP3A4 and CYP3A5										x									
3001524	CYP PANEL	Cytochrome P450 Genotyping Panel										x									
3001535	TPMT2	TPMT and NUDT15										x									
3001541	WARF PAN	Warfarin Sensitivity (CYP2C9, CYP2C cluster, CYP4F2, VKORC1) Genotyping							x			x									
3001635	BWS-RSS DD	Beckwith-Wiedemann Syndrome (BWS) and Russell-Silver Syndrome (RSS) by Methylation-Specific MLPA			x	x			x												
3001801	CDIFF LFA	Toxigenic Clostridioides difficile by LFA with Reflex to PCR, Stool		x	x																
3001907	DM1 PCR	Myotonic Dystrophy Type 1 (DMPK) CTG Expansion			x	x			x												
3002001	KEL GENO	Kell K/k (KEL) Antigen Genotyping			x																
3002002	RHC GENO	RhC/c (RHCE) Antigen Genotyping			x																
3002003	RHE GENO	RhE/e (RHCE) Antigen Genotyping			x																

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3002508	CLOBAZAM	Clobazam and Metabolite, Quantitative, Serum or Plasma					x														
3002598	PETH	Phosphatidylethanol (PEth), Whole Blood, Quantitative										x									
3002989	HEPACUTEQR	Hepatitis Panel, Acute with Reflex to HBsAg Confirmation and Reflex to HCV by Quantitative NAAT			x																
3003745	ANCA-PRO	ANCA-Associated Vasculitis Profile (ANCA/MPO/PR3)			x																
3003747	ANCA-IFA	Anti-Neutrophil Cytoplasmic Antibody, IgG by IFA			x																
3003748	IBD-PAN	Inflammatory Bowel Disease Differentiation Panel			x																
3003800	ETPMF RFX	JAK2 (V617F) Mutation by ddPCR, Qualitative with Reflex to CALR (Calreticulin) Exon 9 Mutation Analysis by PCR with Reflex to MPL Mutation Detection (Change effective as of 11/13/23: Refer to 3016839 in the November Hotline)																		x	

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3003801	PV RFX	JAK2 (V617F) Mutation by ddPCR, Qualitative with Reflex to JAK2 Exon 12 Mutation Analysis by PCR (Change effective as of 11/13/23: Refer to 3016840 in the November Hotline)																		x	
3004092	EDOX	Edoxaban Level (Inactive as of 11/13/2023)																			x
3004255	CYP GD	Cytochrome P450 Genotyping Panel, with GeneDose Access										x									
3004310	2B6GENO	CYP2B6										x									
3004465	CELIAC ABS	Celiac Antibodies, Tissue Transglutaminase (tTG), IgA and IgA, Total (Change effective as of 11/13/23: Refer to 3016817 in the November Hotline)																		x	
3004471	PGX PSYCH	Pharmacogenetics Panel: Psychotropics										x									

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3004508	CMVNGS4	Cytomegalovirus Drug Resistance by Next Generation Sequencing, Ganciclovir, Foscarnet, Cidofovir, and Maribavir (Change effective as of 11/13/23: Refer to 3004615)																		x	
3004509	CMVNGS	Cytomegalovirus Drug Resistance by Next Generation Sequencing, Letermovir (Change effective as of 11/13/23: Refer to 3004615)																		x	
3006366	PGXPSYC GD	Pharmacogenetics Panel: Psychotropics, with GeneDose Access										x									
3016552	CD103 IHC	CD103 by Immunohistochemistry	x																		
3016561	ANNEX IHC	Annexin A1 by Immunohistochemistry	x																		
3016567	INSM1 IHC	INSM1 by Immunohistochemistry	x																		
3016627	BC REQUEST	Bladder Cancer by FISH	x																		
3016694	TRY	Trypsin, Serum	x																		
3016760	LYME STTTC	Borrelia burgdorferi VlsE1/pepC10 Antibodies, CSF, Total by ELISA With Reflex to IgM and IgG by Immunoblot (Standard Two-Tier Testing, CSF)	x																		

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3016767	ANTI-PLA2R	Anti-Phospholipase A2 Receptor (PLA2R) Antibody, IgG by ELISA	x																		
3016782	SSTR2 IHC	SSTR2 by Immunohistochemistry	x																		
3016788	OLIG2 IHC	OLIG2 by Immunohistochemistry	x																		
3016794	RECOV SER	Recoverin Antibody, IgG by Immunoblot, Serum	x																		
3016795	HIBL PCR	Histoplasma and Blastomyces by PCR	x																		
3016804	AIVLS	Autoimmune Vision Loss Panel, Serum	x																		
3016815	MC CANAUR	Candida auris Surveillance Culture	x																		
3016817	CELIACRFLX	Celiac Disease Reflexive Cascade, Serum	x																		
3016839	ETPMFRFX	JAK2 (V617F) Mutation by ddPCR, Qualitative With Reflex to CALR (Calreticulin) Exon 9 Mutation Analysis by PCR and MPL Mutation Detection	x																		
3016840	PV REFLEX	JAK2 (V617F) Mutation by ddPCR, Qualitative With Reflex to JAK2 Exon 12 Mutation Analysis by PCR	x																		

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3016853	MOG CSF	Myelin Oligodendrocyte Glycoprotein (MOG) Antibody, IgG by CBA-IFA With Reflex to Titer, CSF	x																		
3016858	VON WILLE	von Willebrand Factor (VWF) Collagen III Binding	x																		
3016860	TTG A	Tissue Transglutaminase Antibody, IgA	x																		
3016861	EMA RFLX	Tissue Transglutaminase Antibody, IgA With Reflex to Endomysial Antibody, IgA by IFA	x																		
3016866	CORT S TMS	Cortisol by LC-MS/MS, Salivary	x																		
3016875	TWINZYG	Twin Zygosity	x																		
3016879	CD30BM IHC	CD30 for Bone Marrow Specimens by Immunohistochemistry	x																		
3016908	HD PCR	Huntington Disease (HD) CAG Repeat Expansion	x																		
3016920	5HIAA PLA	5-Hydroxyindoleacetic Acid (HIAA), Plasma	x																		
3016927	FACTOR13	Factor 13, Qualitative, With Reflex to Factor 13 1:1 Mix	x																		

Hotline Table of Contents

ARUP LABORATORIES | A nonprofit enterprise of the University of Utah and its Department of Pathology

Effective Date: November 13, 2023

TEST CHANGE

Epstein-Barr Virus by Qualitative PCR

0050246, EBVPCR

Specimen Requirements:	
Patient Preparation:	
Collect:	~~Lavender (K2EDTA), Pink (K2EDTA), or Serum Separator Tube (SST). Also acceptable:~~ Bone marrow aspirate in lavender (EDTA) or pink~~Lavender~~ (K2EDTA)~~,) or Pink (K2EDTA), OR~~ CSF or tissue.
Specimen Preparation:	Transfer 1 mL ~~whole blood,~~ bone marrow or CSF to a sterile container~~.~~ (Min: 0.5 mL)~~.)~~ ~~Serum or Plasma: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum, plasma to a sterile container. (Min: 0.5 mL)~~ Tissue: Transfer to sterile container and freeze immediately.
Transport Temperature:	Frozen ~~Whole Blood or Bone Marrow: Refrigerated. All others: Frozen.~~
Unacceptable Conditions:	Heparinized specimens, tissues in optimal cutting temperature compound.
Remarks:	Specimen source required.
Stability:	CSF: Ambient: 24 hours; Refrigerated: 5 days; Frozen: 1 year ~~Whole Blood or~~ Bone Marrow: Ambient: 1 week; Refrigerated: 1 week; Frozen: 1 week ~~Fresh~~ Tissue: Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 1 year~~ All others: Ambient: 24 hours; Refrigerated: 5 days; Frozen: 1 year~~
Methodology:	Qualitative Polymerase Chain Reaction (PCR)
Performed:	Sun-Sat
Reported:	1-4 days
Note:	
CPT Codes:	87798
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Deleted Cells

Reference Interval:

Test Number	Components	Reference Interval

Inserted Cells

TEST CHANGE

Immunoglobulin E

0050345, IGE

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube~~Separator Tube~~ (SST) or plasma separator tube~~Plasma Separator Tube~~ (PST). Also acceptable: Green (s~~S~~odium or lithium heparin), lavender~~Lithium Heparin), Lavender~~ (K2EDTA), or p~~P~~ink (K2EDTA).
Specimen Preparation:	Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 0.3 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Hemolyzed, i~~l~~cteric, or lipemic specimens
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year
Methodology:	Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed:	Sun-Sat
Reported:	1-3~~2~~ days
Note:	
CPT Codes:	82785
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
Reference Interval:	

Effective November 17, 2014

Age	Reference Interval
0-5 months	13 kU/L or less
6-12 months	34 kU/L or less
1-2 years	97 kU/L or less
3 years	199 kU/L or less
4-6 years	307 kU/L or less
7-8 years	403 kU/L or less
9-12 years	696 kU/L or less
13-15 years	629 kU/L or less
16-17 years	537 kU/L or less
18 years and older	214 kU/L or less

TEST CHANGE

Endomysial Antibody, IgA by IFA

0050736, EMAR TITER

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube.
Specimen Preparation:	Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.15 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma. Severely lipemic, contaminated, or hemolyzed specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid freeze/thaw cycles)
Methodology:	Semi-Quantitative Indirect Fluorescent Antibody
Performed:	Mon-Fri
Reported:	1-5 days
Note:	
CPT Codes:	86231
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
The endomysial antigen has been identified as the protein cross-linking enzyme known as tissue transglutaminase.	
Reference Interval:	
Less than 1:10	

HOTLINE NOTE: There is a reflexive pattern change associated with this test. One or more orderable or component has been added or removed to the reflexive pattern. Refer to the Hotline Test Mix for interface build information.

TEST CHANGE

Achondroplasia (FGFR3) 2 Mutations, Fetal

0051265, AD PCR FE

Specimen Requirements:	
Patient Preparation:	
Collect:	Fetal specimen: Amniotic fluid. OR Cultured amniocytes: Two T-25 flasks at 80 percent confluency. OR cultured CVS: Two T-25 flasks at 80 percent confluency. If the client is unable to culture, order test Cytogenetics Grow and Send (ARUP test code 0040182) in addition to this test and ARUP will culture upon receipt (culturing fees will apply). If you have any questions, contact ARUP's Genetics Processing at 800-522-2787 ext. 3301. AND maternal whole blood specimen: Lavender (EDTA), pink (K2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation:	Amniotic fluid: Transport 10 mL amniotic fluid in a sterile container. (Min: 5 mL). Cultured amniocytes AND cultured CVS: Transport two T-25 flasks at 80 percent confluency filled with culture media. Backup cultures must be retained at the client's institution until testing is complete. Maternal Whole Blood Specimen: Transport 3 mL whole blood. (Min: 1 mL)
Transport Temperature:	Amniotic fluid, cultured amniocytes and cultured CVS: CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of shipment due to lability of cells. Maternal Whole Blood Specimen: Refrigerated.
Unacceptable Conditions:	Frozen specimens in glass collection tubes.
Remarks:	Please contact an ARUP genetic counselor at 800-242-2787 x2141 prior to sample submission. Patient History Form is available on the ARUP Web site or by contacting ARUP Client Services.
Stability:	Amniotic fluid, cultured amniocytes and cultured CVS: Room Temperature: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable Maternal Whole Blood Specimen: Room Temperature: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Polymerase Chain Reaction (PCR)/Fluorescence Monitoring
Performed:	Varies
Reported:	2-7 days

Note:	
CPT Codes:	81401; 81265 Fetal Cell Contamination (FCC)
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
Refer to report This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. This test was performed in a CLIA- certified laboratory and is intended for clinical purposes. Counseling and informed consent are recommended for genetic testing. Consent forms are available online.	
Reference Interval:	
By report	

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.

ARUP LABORATORIES | A nonprofit enterprise of the University of Utah and its Department of Pathology

Effective Date: November 13, 2023

TEST CHANGE

Deamidated Gliadin Peptide (DGP) Antibody, IgA

0051357, GLIADPEP A

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube (SST).~~.~~
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transport 1.0~~.5~~ mL serum. (Min: 0.5~~3~~ mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	~~Plasma or other body fluids.~~ Contaminated, grossly hemolyzed, grossly icteric, or grossly lipemic ~~specimens~~.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 1 week~~2 weeks~~; Frozen: 15 days~~1 year~~
Methodology:	Semi-Quantitative Particle-Based Multianalyte Technology (PMAT)~~Enzyme-Linked Immunosorbent Assay~~
Performed:	Sun-Sat
Reported:	1-2 days
Note:	The most sensitive and specific serologic test for celiac disease diagnosis is tissue transglutaminase (tTG) IgA isotype in individuals who produce sufficient total IgA. Deamidated gliadin (DGP), IgA should not be used for initial screening due to its low specificity and only a very small number of cases being missed by excluding DGP, IgA. For individuals who are IgA deficient, testing for tTG and deamidated gliadin (DGP), IgG antibodies is recommended. Preferred initial screening test for celiac disease diagnosis is the reflexive cascade (ARUP test code 3016817) While ordering for celiac disease diagnosis, all serology tests should be performed while the patient is on a gluten-containing diet. Upon initiation of gluten-free diet, antibody titers decline in the treatment responsive patients and the timeframe to normalize varies by case. If serology is negative and suspicion for celiac disease is strong, intestinal biopsy may still be warranted for establishing diagnosis.
CPT Codes:	86258

New York DOH Approval Status: This test is New York DOH approved.

Interpretive Data:

A positive deamidated gliadin (DGP) IgA antibody result is associated with celiac disease but is not to be used as an initial screening test due to its low specificity and only occasional positivity in celiac disease patients who are negative for tissue transglutaminase (tTG) IgA antibody.

Reference Interval:

Test Number	~~19 Units or less~~	~~Negative~~	Components	Reference Interval
	~~20-30 Units~~	~~Weak Positive~~		
	~~31 Units or greater~~	~~Positive~~		
			Deamidated Gliadin Peptide (DGP) Ab, IgA	0.00-4.99 FLU

HOTLINE NOTE: There is a reflexive pattern change associated with this test. One or more orderable or component has been added or removed to the reflexive pattern. Refer to the Hotline Test Mix for interface build information.

HOTLINE NOTE: There is a numeric map change associated with this test. Refer to the Hotline Test Mix for interface build information.

HOTLINE NOTE: There is a unit of measure change associated with this test. Refer to the Hotline Test Mix for interface build information.

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ARUP LABORATORIES | A nonprofit enterprise of the University of Utah and its Department of Pathology

Effective Date: November 13, 2023

TEST CHANGE

Deamidated Gliadin Peptide (DGP) Antibodies, IgA and IgG

0051358, GLIAD PAN

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube (SST).~~.~~
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transport 1 mL serum. (Min: 0.5~~3~~ mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	~~Plasma or other body fluids.~~ Contaminated, grossly hemolyzed, grossly icteric, or grossly lipemic ~~specimens~~.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 1 week~~2 weeks~~; Frozen: 15 days~~1 year~~
Methodology:	Semi-Quantitative Particle-Based Multianalyte Technology (PMAT)~~Enzyme-Linked Immunosorbent Assay~~
Performed:	Sun-Sat
Reported:	1-2 days
Note:	The most sensitive and specific serologic test for celiac disease diagnosis is tissue transglutaminase (tTG) IgA isotype in individuals who produce sufficient total IgA. Deamidated gliadin (DGP), IgA should not be used for initial screening due to its low specificity and only a very small number of cases being missed by excluding DGP, IgA. For individuals who are IgA deficient, testing for tTG and deamidated gliadin (DGP), IgG antibodies is recommended. Preferred initial screening test for celiac disease diagnosis is the reflexive cascade (ARUP test code 3016817). While ordering for celiac disease diagnosis, all serology tests should be performed while the patient is on a gluten-containing diet. Upon initiation of gluten-free diet, antibody titers decline in the treatment responsive patients and the timeframe to normalize varies by case. If serology is negative and suspicion for celiac disease is strong, intestinal biopsy may still be warranted for establishing diagnosis.
CPT Codes:	86258 x2

New York DOH Approval Status: This test is New York DOH approved.

Interpretive Data:

~~Component~~	~~Interpretation~~
~~Deamidated Gliadin Peptide (DGP) Antibody, IgA~~	~~19 Units or less Negative 20-30 Units Weak Positive 31 Units or greater Positive~~
~~Deamidated Gliadin Peptide (DGP) Antibody, IgG~~	~~19 Units or less Negative 20-30 Units Weak Positive 31 Units or greater Positive~~

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Reference Interval:

Test Number	Components	Reference Interval
	Deamidated Gliadin Peptide (DGP) Ab, IgA	0.00-4.99 FLU~~-19 Units~~
	Deamidated Gliadin Peptide (DGP) Ab, IgG	0.00-4.99 FLU~~-19 Units~~

HOTLINE NOTE: There is a numeric map change associated with this test. Refer to the Hotline Test Mix for interface build information.

HOTLINE NOTE: There is a unit of measure change associated with this test. Refer to the Hotline Test Mix for interface build information.

ARUP LABORATORIES | A nonprofit enterprise of the University of Utah and its Department of Pathology

Effective Date: November 13, 2023

TEST CHANGE

Deamidated Gliadin Peptide (DGP) Antibody, IgG

0051359, GLIADPEP G

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube (SST).~~.~~
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transport 1.0~~.5~~ mL serum. (Min: 0.5~~3~~ mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	~~Plasma or other body fluids.~~ Contaminated, grossly hemolyzed, grossly icteric, or grossly lipemic ~~specimens~~.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 1 week~~2 weeks~~; Frozen: 15 days~~1 year~~
Methodology:	Semi-Quantitative Particle-Based Multianalyte Technology (PMAT)~~Enzyme-Linked Immunosorbent Assay~~
Performed:	Sun-Sat
Reported:	1-2 days
Note:	The most sensitive and specific serologic test for celiac disease diagnosis is tissue transglutaminase (tTG) IgA isotype in individuals who produce sufficient total IgA. For individuals who are IgA deficient, testing for tTG and deamidated gliadin (DGP), IgG antibodies is recommended. Preferred initial screening test for celiac disease diagnosis is the reflexive cascade (ARUP test code 3016817). While ordering for celiac disease diagnosis, all serology tests should be performed while the patient is on a gluten-containing diet. Upon initiation of gluten-free diet, antibody titers decline in the treatment-responsive patients and the timeframe to normalize varies by case. If serology is negative and suspicion for celiac disease is strong, intestinal biopsy may still be warranted for establishing diagnosis.
CPT Codes:	86258
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

In individuals with low or deficient IgA, testing for tissue transglutaminase (tTG) and deamidated Gliadin (DGP) antibodies of the IgG isotype is performed. A positive tTG and/or DGP IgG antibody results indicate celiac disease, however, small intestinal biopsy is required to establish a diagnosis due to the lower accuracy of these markers, especially in patients without IgA deficiency.

Reference Interval:

Test Number	~~19 Units or less~~	~~Negative~~	Components	Reference Interval
	~~20-30 Units~~	~~Weak Positive~~		
	~~31 Units or greater~~	~~Positive~~		
			Deamidated Gliadin Peptide (DGP) Ab, IgG	0.00-4.99 FLU

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HOTLINE NOTE: There is a reflexive pattern change associated with this test. One or more orderable or component has been added or removed to the reflexive pattern. Refer to the Hotline Test Mix for interface build information.

HOTLINE NOTE: There is a numeric map change associated with this test. Refer to the Hotline Test Mix for interface build information.

HOTLINE NOTE: There is a unit of measure change associated with this test. Refer to the Hotline Test Mix for interface build information.

ARUP LABORATORIES | A nonprofit enterprise of the University of Utah and its Department of Pathology

Effective Date: November 13, 2023

TEST CHANGE

Tissue Transglutaminase Antibody, IgG

0056009, TTG G

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube (SST).~~.~~
Specimen Preparation:	Remove serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 0.5 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Contaminated, grossly hemolyzed, grossly icteric,~~Plasma. Hemolyzed~~ or grossly~~severely~~ lipemic ~~specimens.~~
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 1 week~~2 weeks~~; Frozen: 15 days~~1 year~~
Methodology:	Semi-Quantitative Particle-Based Multianalyte Technology (PMAT)~~Enzyme-Linked Immunosorbent Assay~~
Performed:	Sun-Sat
Reported:	1-2 days
Note:	The most sensitive and specific serologic test for celiac disease diagnosis is tissue transglutaminase (tTG) IgA isotype in individuals who produce sufficient total IgA. For individuals who are IgA deficient, testing for tTG and deamidated gliadin (DGP), IgG antibodies is recommended. Preferred initial screening test for celiac disease diagnosis is the reflexive cascade (ARUP test code 3016817). While ordering for celiac disease diagnosis, all serology tests should be performed while the patient is on a gluten-containing diet. Upon initiation of gluten-free diet, antibody titers decline in the treatment responsive patients and the timeframe to normalize varies by case. If serology is negative and suspicion for celiac disease is strong, intestinal biopsy may still be warranted for establishing diagnosis. ~~Human recombinant tTG antigen is utilized in this assay~~
CPT Codes:	86364

New York DOH Approval Status: This test is New York DOH approved.

Interpretive Data:

In individuals with low or deficient IgA, testing for tissue transglutaminase (tTG) and deamidated Gliadin (DGP) antibodies of the IgG isotype is performed. A positive tTG and/or DGP IgG antibody results indicate celiac disease, however, small intestinal biopsy is required to establish a diagnosis due to the lower accuracy of these markers, especially in patients without IgA deficiency. ~~The tTG IgG assay may aid in the diagnosis of gluten-sensitivity enteropathy (i.e., celiac disease, dermatitis herpetiformis) in tTG IgA negative patients with confirmed IgA deficiency. A negative tTG IgG test alone does not rule out gluten-sensitive enteropathy.~~

Reference Interval:

Test Number	~~5 U/mL or less~~	~~Negative~~	Components	Reference Interval
	~~6-9 U/mL~~	~~Weak Positive~~		
	~~10 U/mL or greater~~	~~Positive~~		
			Tissue Transglutaminase Antibody,IgG	0.00 - 4.99 FLU

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HOTLINE NOTE: There is a reflexive pattern change associated with this test. One or more orderable or component has been added or removed to the reflexive pattern. Refer to the Hotline Test Mix for interface build information.

HOTLINE NOTE: There is a numeric map change associated with this test. Refer to the Hotline Test Mix for interface build information.

HOTLINE NOTE: There is a unit of measure change associated with this test. Refer to the Hotline Test Mix for interface build information.

TEST CHANGE

Cyclosporine A, 2-Hour Post Dose (C2) by Tandem Mass Spectrometry

0058902, C2CYA

Specimen Requirements:	
Patient Preparation:	Two hour post-dose level should be drawn.
Collect:	Lavender (EDTA) or pink (K2EDTA).
Specimen Preparation:	Transport 1 mL whole blood. (Min: 0.25 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Serum or plasma. Specimens left at room temperature for longer than 24 hours. Clotted specimens.
Remarks:	
Stability:	Ambient: 24 hours; Refrigerated: 2 weeks; Frozen: 2 months
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Sun-Sat
Reported:	1-2 days ~~Within 24 hours~~
Note:	Cyclosporine (Sandimmune) whole blood concentrations can be measured by either chromatographic or immunoassay methodologies. These two methodologies are not directly interchangeable, the measured cyclosporine whole blood concentration depends on the methodology used. Reference ranges may vary according to the specific immunoassay or HPLC-MS/MS test. Generally, immunoassays have been reported to have a positive bias relative to HPLC-MS/MS assays due to the detection of antibody cross-reactivity with cyclosporine metabolites.
CPT Codes:	80158
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Cyclosporine A levels in specimens drawn 2 hours post-dose may estimate the AUC better than trough specimens. The optimal therapeutic range for a given patient may differ from this suggested range based on the indication for therapy, treatment phase (initiation or maintenance),

use in combination with other drugs, time of specimen collection relative to prior dose, type of transplanted organ, and/or the therapeutic approach of the transplant center. A suggested target range for renal transplant is 800-1700 ng/mL. A suggested target range for liver transplant is 600-1000 ng/mL. The higher ranges represent concentrations immediately post-transplant and the lower ranges represent concentrations during the maintenance phase.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

TEST CHANGE

Cytomegalovirus by Qualitative PCR

0060040, CMVPCR

Specimen Requirements:	
Patient Preparation:	
Collect:	Bone marrow aspirate in lavender~~Lavender~~ (EDTA) or pink~~),~~ ~~Pink~~ (K2EDTA), amniotic~~or Serum Separator Tube (SST). Also acceptable: Amniotic~~ fluid, bronchoalveolar lavage (BAL), CSF, ocular fluid, tissue, urine, or dried blood spot (DBS).
Specimen Preparation:	~~Separate serum or plasma from cells.~~ Transfer 1 mL ~~plasma, serum, whole blood,~~ bone marrow, amniotic fluid, BAL, CSF, ocular fluid, or urine to a sterile container~~.~~ (Min: 0.5 mL~~).)~~ Dried Blood Spot: Whole blood collected on newborn screening card (3/16 inch punch). Transport punch in an ARUP standard transport tube.~~Standard Transport Tube.~~ Tissue: Transfer to a sterile container and freeze immediately.
Transport Temperature:	~~Frozen. Whole Blood or Bone Marrow: Refrigerated.~~ Dried Blood Spot: Room temperature. All others: Frozen
Unacceptable Conditions:	Heparinized specimens, tissues in optimal cutting temperature compound. Saliva (Refer to ARUP test code 2008555, CMVPCR SAL.)
Remarks:	Specimen source is required.
Stability:	~~Ambient: 8 hours; Refrigerated: 72 hours; Frozen: 3 months Whole Blood or~~ Bone Marrow: Ambient: 1 week; Refrigerated: 1 week; Frozen: 1 week Dried Blood Spot: Ambient: 90~~28~~ days; Refrigerated: 8 days; Frozen: 8 days Tissue: Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 3 months All others: Ambient: 8 hours; Refrigerated: 72 hours; Frozen: 3 months
Methodology:	Qualitative Polymerase Chain Reaction (PCR)
Performed:	Sun-Sat
Reported:	1-3 days
Note:	
CPT Codes:	87496
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Test Number	Components	Reference Interval

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TEST CHANGE

Cyclosporine A by Tandem Mass Spectrometry

0070035, CYA

Specimen Requirements:	
Patient Preparation:	Predose~~Pre-dose~~ (trough) levels should be drawn.
Collect:	Lavender (EDTA) or pink (K2EDTA).
Specimen Preparation:	Transport 1 mL whole blood. (Min: 0.25 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Serum or plasma. Specimens left at room temperature for longer than 24 hours. Clotted specimens.
Remarks:	
Stability:	Ambient: 24 hours; Refrigerated: 2 weeks; Frozen: 2 months
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Sun-Sat
Reported:	1-2 days ~~Within 24 hours~~
Note:	Cyclosporine (Sandimmune) whole blood concentrations can be measured by either chromatographic or immunoassay methodologies. These two methodologies are not directly interchangeable, and the measured cyclosporine whole blood concentration depends on the methodology used. Reference ranges may vary according to the specific immunoassay or HPLC-MS/MS test. Generally, immunoassays have been reported to have a positive bias relative to HPLC-MS/MS assays due to the detection of antibody cross-reactivity with cyclosporine metabolites.
CPT Codes:	80158
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

The general therapeutic range for cyclosporine A is 100-400 ng/mL. The optimal therapeutic range for a given patient may differ from this suggested range based on the indication for therapy, treatment phase (initiation or maintenance), use in combination with other drugs, time of specimen

collection relative to prior dose, type of transplanted organ, and/or the therapeutic approach of the transplant center.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Effective November 17, 2014

	Therapeutic Range:
Cyclosporine A, Therapeutic Range	100-400 ng/mL
Kidney transplant (in combination with Everolimus)	1 month post-transplant: 100-200 ng/mL 2-3 months post-transplant: 75-150 ng/mL 4-5 months post-transplant: 50-100 ng/mL 6-12 months post-transplant: 25-50 ng/mL
Heart transplant	Up to 3 months post-transplant: 350-525 ng/mL 4 months and older post-transplant: 145-350 ng/mL
Liver transplant	290-525 ng/mL
Toxic value	Greater than 700 ng/mL

TEST CHANGE

Catecholamines Fractionated by LC-MS/MS, Urine Free

0080407, CATE UF

Specimen Requirements:	
Patient Preparation:	Drugs and medications may affect results and should be discontinued for at least 72 hours prior to specimen collection, if possible.
Collect:	24-hour or random urine. Refrigerate 24-hour specimen during collection.
Specimen Preparation:	Thoroughly mix entire collection (24-hour or random) in one container. Transfer a 4 mL aliquot to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 2.5 mL) Catecholamines are not stable above pH 7. The pH of such specimens must be adjusted by the addition of 6M HCl acid or sulfamic acid prior to transport. A pH less than 2 can cause assay interference. Specimen preservation can be extended to 1 month refrigerated by performing one of the following: Option 1: Transfer a 4 mL aliquot to an ARUP standard transport tube~~Standard Transport Tube~~ and adjust pH to 2.0-4.0 with 6M HCl. (Min: 2.5 mL) Option 2: Transfer a 4 mL aliquot to an ARUP standard transport tube~~Standard Transport Tube~~ containing 20 mg sulfamic acid (ARUP Supply #48098), available online through eSupply using ARUP Connect(TM) or contact ARUP Client Services at ~~(~~800~~-)~~ 522-2787. (Min: 2.5 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Specimens preserved with boric acid or acetic acid. Specimens with pH greater than 7.
Remarks:	Record total volume and collection time interval on transport tube and test request form.
Stability:	Unpreserved: Ambient: Unacceptable; Refrigerated: 1 week; Frozen: Undefined Preserved: Ambient: Unacceptable; Refrigerated: 1 month; Frozen: 6 months
Methodology:	Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Sun-Sat
Reported:	1-5~~4~~ days

Note:	Secreting neuroendocrine tumors are typically associated with catecholamine concentrations several times higher than the upper reference intervals. Large elevations can be seen in life-threatening illnesses and drug interferences. Common reasons for slight and moderate elevations include intense physical activity, emotional and physical stress, drug interferences, and improper specimen collection. Medications which may physiologically interfere with catecholamines and metabolites include amphetamines and amphetamine-like compounds, appetite suppressants, bromocriptine, buspirone, caffeine, carbidopa-levodopa (Sinemet), clonidine, dexamethasone, diuretics (in doses sufficient to deplete sodium), ethanol, isoproterenol, methyldopa (Aldomet), MAO inhibitors, nicotine, nose drops, propafenone (Rythmol), reserpine, theophylline, tricyclic antidepressants, and vasodilators. The effects of some drugs on catecholamine results may not be predictable. References: 1) Optimal collection and storage conditions for catecholamine measurements in human plasma and urine. (Clinical Chemistry. 1993; 39:2503-8.); 2) Effect of urine pH, storage time, and temperature on stability of catecholamines, cortisol, and creatinine. (Clinical Chemistry1998;~~Chemistry 1998;~~ 44: 1759-62.~~).~~
CPT Codes:	82384
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Smaller increases in catecholamine concentrations (less than two times the upper limit) usually are the result of physiological stimuli, drugs, or improper specimen collection. Significant elevation of one or more catecholamines (three or more times the upper reference limit) is associated with an increased probability of a neuroendocrine tumor.

Per 24h calculations are provided to aid interpretation for collections with a duration of 24 hours and an average daily urine volume. For specimens with notable deviations in collection time or volume, ratios of analytes to a corresponding urine creatinine concentration may assist in result interpretation.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Test Number	Components	Reference Interval
	Creatinine, Urine - per 24h	
		Age: Male (mg/d): Female (mg/d) 3-8 years: 140-700: 140-700 9-12 years: 300-1300: 300-1300 13-17 years: 500-2300: 400-1600 18-50 years: 1000-2500: 700-1600 51-80 years: 800-2100: 500-1400 81 years and older: 600-2000: 400-1300
	Dopamine, Urine - per 24h	
		Age: ug/d 0-3 years: Not established 4-10 years: 80-440 11-17 years: 100-496 18 years and older: 71-485
	Norepinephrine, Urine - per 24h	
		Age: ug/d 0-3 years: Not established 4-10 years: 7-65 11-17 years: 12-96 18 years and older: 14-120
	Epinephrine, Urine - per 24h	
		Age: ug/d 0-3 years: Not established 4-10 years: 1-14 11-17 years: 1-18 18 years and okder: 1-14
	Norepinephrine, Urine - ratio to CRT	
		Age: ug/g CRT 0-11 months: 25-310 1-3 years: 25-290 4-10 years: 27-110 11-17 years: 4-105 18 years and older: 0-45
	Dopamine, Urine - ratio to CRT	

		Age	ug/g CRT	
		0-11 months	240-1290	
		1-3 years	80-1220	
		4-10 years	220-720	
		11-17 years	120-450	
		18 years and older	0-250	
	Epinephrine, Urine - ratio to CRT			
		Age	ug/g CRT	
		0-11 months	0-380	
		1-3 years	0-82	
		4-10 years	5-93	
		11-17 years	3-58	
		18 years and older	0-20	

TEST CHANGE

Testosterone, Free and Total, Includes Sex Hormone-Binding Globulin (Adult Females, Children, or Individuals on Testosterone-Suppressing Hormone Therapy)

0081056, TESTOS F&T

Specimen Requirements:	
Patient Preparation:	Collect between 6-10 a.m.
Collect:	Serum separator tube or green (sodium or lithium heparin).
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 0.8 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	EDTA plasma.
Remarks:	
Stability:	After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 6 months
Methodology:	Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry/Electrochemiluminescent Immunoassay/Calculation
Performed:	Sun-Sat
Reported:	1-54 days
Note:	Please refer to individual components for stability of sample for this test. The concentration of free testosterone is derived from a mathematical expression based on the constant for the binding of testosterone to sex hormone binding globulin.
CPT Codes:	84402; 84403; 84270
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Free testosterone concentration is calculated using total testosterone (measured by mass spectrometry) and the binding constant of testosterone and sex hormone-binding globulin (SHBG).

For individuals on testosterone-suppressing hormone therapies (e.g., antiandrogens or estrogens), refer to cisgender female reference intervals. For a complete set of all established reference intervals, refer to ltd.aruplab.com/Tests/Pub/0081056.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. This test was performed in a CLIA-certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Test Number	Components	Reference Interval		
	Testosterone by Mass Spec			
		Age	Male (ng/dL)	Female (ng/dL)
		Premature (26-28 weeks)	59-125	5-16
		Premature (31-35 weeks)	37-198	5-22
		Newborn	75-400	20-64
		1-5 months	14-363	Less than 20
		6-24 months	Less than 37	Less than 9
		2-3 years	Less than 15	Less than 20
		4-5 years	Less than 19	Less than 30
		6-7 years	Less than 13	Less than 7
		8-9 years	2-8	1-11
		10-11 years	2-165	3-32
		12-13 years	3-619	6-50
		14-15 years	31-733	6-52
		16-17 years	158-826	9-58
		18-39 years	300-1080	9-55
		40-59 years	300-890	9-55
		60 years and older	300-720	5-32
		Premenopausal (18 years and older)	Not Applicable	9-55
		Postmenopausal	Not Applicable	5-32
		Tanner Stage I	2-15	2-17
		Tanner Stage II	3-303	5-40
		Tanner Stage III	10-851	10-63
		Tanner Stage IV-V	162-847	11-62
	Testosterone, Free by Mass Spec			

		Age	Male (pg/mL)	Female (pg/mL)
		1-6 years	Less than 0.6	Less than 0.6
		7-9 years	0.1-0.9	0.6-1.8
		10-11	0.1-6.3	0.1-3.5
		12-13	0.5-98.0	0.9-6.8
		14-15	3-138.0	1.2-7.5
		16-17	38.0-173.0	1.2-9.9
		18 years and older	47-244	Not Applicable
		18-30	Not Applicable	0.8-7.4
		31-40	Not Applicable	1.3-9.2
		41-51	Not Applicable	1.1-5.8
		Postmenopausal	Not Applicable	0.6-3.8
		Tanner Stage I	Less than or equal to 3.7	Less than 2.2
		Tanner Stage II	0.3-21	0.4-4.5
		Tanner Stage III	1.0-98.0	1.3-7.5
		Tanner Stage IV	35.0-169.0	1.1-15.5
		Tanner Stage V	41.0-239.0	0.8-9.2
	Sex Hormone Binding Globulin			
		Age	Male (nmol/L)	Female (nmol/L)
		1-30 days	13-85	14-60
		31-364 days	70-250	60-215
		1-3 years	50-180	60-190
		4-6 years	45-175	55-170
		7-9 years	28-190	35-170
		10-12 years	23-160	17-155
		13-15 years	13-140	11-120
		16-17 years	10-60	19-145
		18-49 years	17-56	25-122
		50 years and older	19-76	17-125
		Tanner Stage I	26-186	30-173
		Tanner Stage II	22-169	16-127
		Tanner Stage III	13-104	12-98
		Tanner Stage IV	11-60	14-151
		Tanner Stage V	11-71	23-165

TEST CHANGE

Testosterone, Bioavailable and Total, Includes Sex Hormone-Binding Globulin (Adult Females, Children, or Individuals on Testosterone-Suppressing Hormone Therapy)

0081057, BIO T MASS

Specimen Requirements:	
Patient Preparation:	Collect between 6-10 a.m.
Collect:	Serum separator tube or green (sodium or lithium heparin).
Specimen Preparation:	Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 0.8 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	EDTA plasma.
Remarks:	
Stability:	After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 6 months
Methodology:	Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry/Electrochemiluminescent Immunoassay/Calculation
Performed:	Sun-Sat
Reported:	1-54 days
Note:	The concentrations of free and bioavailable testosterone are derived from mathematical expressions based on constants for the binding of testosterone to albumin and/or sex hormone binding globulin.
CPT Codes:	84402; 84403; 84270
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Bioavailable testosterone concentration is calculated using total testosterone (measured by mass spectrometry) and the binding constant of testosterone and sex hormone-binding globulin (SHBG) and/or albumin.

For individuals on testosterone-suppressing hormone therapies (e.g., antiandrogens or estrogens),

refer to cisgender female reference intervals. For a complete set of all established reference intervals, refer to ltd.aruplab.com/Tests/Pub/0081057.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Test Number	Components	Reference Interval		
	Testosterone by Mass Spec			
		Age	Male (ng/dL)	Female (ng/dL)
		Premature (26-28 weeks)	59-125	5-16
		Premature (31-35 weeks)	37-198	5-22
		Newborn	75-400	20-64
		1-5 months	14-363	Less than 20
		6-24 months	Less than 37	Less than 9
		2-3 years	Less than 15	Less than 20
		4-5 years	Less than 19	Less than 30
		6-7 years	Less than 13	Less than 7
		8-9 years	2-8	1-11
		10-11 years	2-165	3-32
		12-13 years	3-619	6-50
		14-15 years	31-733	6-52
		16-17 years	158-826	9-58
		18-39 years	300-1080	9-55
		40-59 years	300-890	9-55
		60 years and older	300-720	5-32
		Premenopausal (18 years and older)	Not Applicable	9-55
		Postmenopausal	Not Applicable	5-32
		Tanner Stage I	2-15	2-17
		Tanner Stage II	3-303	5-40
		Tanner Stage III	10-851	10-63
		Tanner Stage IV-V	162-847	11-62
	Testosterone, Free by Mass Spec			

		Age	Male (pg/mL)	Female (pg/mL)
		1-6 years	Less than 0.6	Less than 0.6
		7-9 years	0.1-0.9	0.6-1.8
		10-11	0.1-6.3	0.1-3.5
		12-13	0.5-98.0	0.9-6.8
		14-15	3-138.0	1.2-7.5
		16-17	38.0-173.0	1.2-9.9
		18 years and older	47-244	Not Applicable
		18-30	Not Applicable	0.8-7.4
		31-40	Not Applicable	1.3-9.2
		41-51	Not Applicable	1.1-5.8
		Postmenopausal	Not Applicable	0.6-3.8
		Tanner Stage I	Less than or equal to 3.7	Less than 2.2
		Tanner Stage II	0.3-21	0.4-4.5
		Tanner Stage III	1.0-98.0	1.3-7.5
		Tanner Stage IV	35.0-169.0	1.1-15.5
		Tanner Stage V	41.0-239.0	0.8-9.2
	Testosterone, Bioavailable by Mass Spec			
		Age	Male (ng/dL)	Female (ng/dL)
		1-6 years	Less than 1.3	Less than 1.3
		7-9 years	0.3-2.8	0.3-5.0
		10-11 years	0.1-17.9	0.4-9.6
		12-13 years	1.4-288.0	1.7-18.8
		14-15 years	9.5-337.0	3.0-22.6
		16-17 years	35.0-509.0	3.3-28.6
		18 years and older	130.0-680.0	Not Applicable
		18-30 years	Not Applicable	2.2-20.6
		31-40 years	Not Applicable	4.1-25.5
		41-51 years	Not Applicable	2.8-16.5
		Postmenopausal	Not Applicable	1.5-9.4
		Tanner Stage I	0.3-13.0	0.3-5.5
		Tanner Stage II	0.3-59.0	1.2-15.0
		Tanner Stage III	1.9-296.0	3.8-28.0
		Tanner Stage IV	40.0-485.0	2.8-39.0
		Tanner Stage IV	124.0-596.0	2.5-23.0
	Sex Hormone Binding Globulin			

Age	Male (nmol/L)	Female (nmol/L)
1-30 days	13-85	14-60
31-364 days	70-250	60-215
1-3 years	50-180	60-190
4-6 years	45-175	55-170
7-9 years	28-190	35-170
10-12 years	23-160	17-155
13-15 years	13-140	11-120
16-17 years	10-60	19-145
18-49 years	17-56	25-122
50 years and older	19-76	17-125
Tanner Stage I	26-186	30-173
Tanner Stage II	22-169	16-127
Tanner Stage III	13-104	12-98
Tanner Stage IV	11-60	14-151
Tanner Stage V	11-71	23-165

TEST CHANGE

Testosterone (Adult Females, Children, or Individuals on Testosterone-Suppressing Hormone Therapy)

0081058, TESTOS MAS

Specimen Requirements:	
Patient Preparation:	Collect between 6-10 a.m.
Collect:	Serum separator tube or green (sodium or lithium heparin).
Specimen Preparation:	Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 0.2 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	EDTA plasma.
Remarks:	
Stability:	After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 6 months
Methodology:	Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Sun-Sat
Reported:	1-5~~4~~ days
Note:	
CPT Codes:	84403
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Free or bioavailable testosterone measurements may provide supportive information.

For individuals on testosterone-suppressing hormone therapies (e.g., antiandrogens or estrogens), refer to cisgender female reference intervals. For a complete set of all established reference intervals, refer to ltd.aruplab.com/Tests/Pub/0081058.

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Reference Interval:

Effective August 19, 2013

Age	Female	Male
Premature (26-28 weeks)	5-16 ng/dL	59-125 ng/dL
Premature (31-35 weeks)	5-22 ng/dL	37-198 ng/dL
Newborn	20-64 ng/dL	75-400 ng/dL
1-5 months	Less than 20 ng/dL	14-363 ng/dL
6-24 months	Less than 9 ng/dL	Less than 37 ng/dL
2-3 years	Less than 20 ng/dL	Less than 15 ng/dL
4-5 years	Less than 30 ng/dL	Less than 19 ng/dL
6-7 years	Less than 7 ng/dL	Less than 13 ng/dL
8-9 years	1-11ng/dL	2-8 ng/dL
10-11 years	3-32 ng/dL	2-165 ng/dL
12-13 years	6-50 ng/dL	3-619 ng/dL
14-15 years	6-52 ng/dL	31-733 ng/dL
16-17 years	9-58 ng/dL	158-826 ng/dL
18-39 years	9-55 ng/dL	300-1080 ng/dL
40-59 years	9-55 ng/dL	300-890 ng/dL
60 years and older	5-32 ng/dL	300-720 ng/dL
Premenopausal (18 years and older)	9-55 ng/dL	Does Not Apply
Postmenopausal	5-32 ng/dL	Does Not Apply
Tanner Stage I	2-17 ng/dL	2-15 ng/dL
Tanner Stage II	5-40 ng/dL	3-303 ng/dL
Tanner Stage III	10-63 ng/dL	10-851 ng/dL
Tanner Stage IV-V	11-62 ng/dL	162-847 ng/dL

TEST CHANGE

Testosterone, Free (Adult Females, Children, or Individuals on Testosterone-Suppressing Hormone Therapy)

0081059, TESTOS FR

Specimen Requirements:	
Patient Preparation:	Collect between 6-10 a.m.
Collect:	Serum separator tube or green (sodium or lithium heparin).
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 0.8 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	EDTA plasma.
Remarks:	
Stability:	After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 6 months
Methodology:	Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry/Electrochemiluminescent Immunoassay/Calculation
Performed:	Sun-Sat
Reported:	1-5~~4~~ days
Note:	Total t~~T~~estosterone and SHBG are measured and free testosterone is estimated from these measurements.
CPT Codes:	84402
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Free testosterone concentration is calculated using total testosterone (measured by mass spectrometry) and the binding constant of testosterone and sex hormone-binding globulin (SHBG).

For individuals on testosterone-suppressing hormone therapies (e.g., antiandrogens or estrogens), refer to cisgender female reference intervals. For a complete set of all established reference intervals, refer to ltd.aruplab.com/Tests/Pub/0081059.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It~~

~~has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Test Number	Components	Reference Interval		
	Testosterone, Free by Mass Spec			
		Age	Male (pg/mL)	Female (pg/mL)
		1-6 years	Less than 0.6	Less than 0.6
		7-9 years	0.1-0.9	0.6-1.8
		10-11	0.1-6.3	0.1-3.5
		12-13	0.5-98.0	0.9-6.8
		14-15	3-138.0	1.2-7.5
		16-17	38.0-173.0	1.2-9.9
		18 years and older	47-244	Not Applicable
		18-30	Not Applicable	0.8-7.4
		31-40	Not Applicable	1.3-9.2
		41-51	Not Applicable	1.1-5.8
		Postmenopausal	Not Applicable	0.6-3.8
		Tanner Stage I	Less than or equal to 3.7	Less than 2.2
		Tanner Stage II	0.3-21	0.4-4.5
		Tanner Stage III	1.0-98.0	1.3-7.5
		Tanner Stage IV	35.0-169.0	1.1-15.5
		Tanner Stage V	41.0-239.0	0.8-9.2

TEST CHANGE

Alprazolam

0090010, ALPR

Specimen Requirements:	
Patient Preparation:	Timing of specimen collection: Predose~~Pre-dose~~ (trough) draw at~~ At~~ steady state concentration.
Collect:	Gray (potassium oxalate/sodium fluoride).~~Potassium Oxalate/Sodium Fluoride).~~ Also acceptable: Plain red, green (sodium heparin), lavender~~Red, Green (Sodium Heparin), Lavender~~ (K2 or K3EDTA) or pink (K2EDTA).
Specimen Preparation:	Separate serum or plasma from cells within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Gel separator tubes. Plasma or whole blood collected in light blue (sodium citrate). Hemolyzed specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 3 years (Avoid repeated freeze/thaw cycles)
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Tue, Fri
Reported:	1-7~~5~~ days
Note:	
CPT Codes:	80346 (Alt code: G0480)
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Adverse effects may include somnolence, lightheadedness,~~light-headedness~~ and muscle tremors.

Reference Interval:

Effective November 18, 2013

	Dose-Related Range:
Anxiety	10-40 ng/mL (Dose: 1-4 mg/d)
Phobia & panic	50-100 ng/mL (Dose: 6-9 mg/d)
Toxic	Greater than 100 ng/mL

TEST CHANGE

Clonazepam

0090055, CLON

Specimen Requirements:	
Patient Preparation:	Timing of specimen collection: Predose~~Pre-dose~~ (trough) draw at~~ At~~ steady state concentration
Collect:	Gray (potassium oxalate/sodium fluoride).~~Potassium Oxalate/Sodium Fluoride).~~ Also acceptable: Plain red, green (sodium heparin), lavender~~Red, Green (Sodium Heparin), Lavender~~ (K2 or K3EDTA) or pink (K2EDTA).
Specimen Preparation:	Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Gel separator tubes. Plasma or whole blood collected in light blue (sodium citrate). Hemolyzed specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 3 years (Avoid repeated freeze/thaw cycles).
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Tue, Fri
Reported:	1-7~~5~~ days
Note:	
CPT Codes:	80346 (Alt code: G0480)
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Adverse effects may include drowsiness, headache, fatigue, and ataxia.

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Reference Interval:

Effective November 18, 2013

Dose-Related Range	20-70 ng/mL - Dose (Adult) 1-8 mg/d
Toxic	Greater than 80 ng/mL

TEST CHANGE

Diazepam and Nordiazepam

0090076, DIAZ

Specimen Requirements:	
Patient Preparation:	Timing of specimen collection: Predose~~Pre-dose~~ (trough) draw at~~- At~~ steady state concentration
Collect:	Gray (potassium oxalate/sodium fluoride).~~Potassium Oxalate/Sodium Fluoride).~~ Also acceptable: Plain red, green (sodium heparin), lavender~~Red, Green (Sodium Heparin), Lavender~~ (K2 or K3EDTA) or pink (K2EDTA).
Specimen Preparation:	Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Gel separator tubes. Plasma or whole blood collected in light blue (sodium citrate). Hemolyzed specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 3 years (Avoid repeated freeze/thaw cycles)
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Tue, Fri
Reported:	1-7~~5~~ days
Note:	
CPT Codes:	80346 (Alt code: G0480)
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Adverse effects may include drowsiness, fatigue, ataxia, and muscle weakness.

Reference Interval:

Test Number	Components	Reference Interval
	Diazepam	Effective November 16, 2015 200-1000 ng/mL - Based on normal dosage amounts
	Nordiazepam	Effective November 16, 2015 100-1500 ng/mL - Based on normal dosage amounts Toxic: Greater than 2500 ng/mL

Dose-Related Range:

TEST CHANGE

Librium and Nordiazepam

0090148, LIB

Specimen Requirements:	
Patient Preparation:	Timing of specimen collection: Predose~~Pre-dose~~ (trough) draw at~~- At~~ steady state concentration.
Collect:	Gray (potassium oxalate/sodium fluoride).~~Potassium Oxalate/Sodium Fluoride).~~ Also acceptable: Plain red, green (sodium heparin), lavender~~Red, Green (Sodium Heparin), Lavender~~ (K2 or K3EDTA) or pink (K2EDTA).
Specimen Preparation:	Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Gel separator tubes. Plasma or whole blood collected in light blue (sodium citrate). Hemolyzed specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 3 years (Avoid repeated freeze/thaw cycles)
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Tue, Fri
Reported:	1-7~~5~~ days
Note:	
CPT Codes:	80346 (Alt code: G0480)
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Adverse effects may include drowsiness, ataxia, nausea, and constipation.

Reference Interval:

Effective November 16, 2015

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

TEST CHANGE

Lorazepam

0090181, LORAZ

Specimen Requirements:	
Patient Preparation:	Timing of specimen collection: Predose~~Pre-dose~~ (trough) draw at~~- At~~ steady state concentration.
Collect:	Gray (potassium oxalate/sodium fluoride).~~Potassium Oxalate/Sodium Fluoride).~~ Also acceptable: Plain red, green (sodium heparin), lavender~~Red, Green (Sodium Heparin), Lavender~~ (K2 or K3EDTA) or pink (K2EDTA).
Specimen Preparation:	Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Gel separator tubes. Plasma or whole blood collected in light blue (sodium citrate). Hemolyzed specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 3 years (Avoid repeated freeze/thaw cycles)
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Tue, Fri
Reported:	1-7~~5~~ days
Note:	
CPT Codes:	80346 (Alt code: G0480)
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Adverse effects may include respiratory depression, sedation, dizziness, weakness, and lethargy.

Reference Interval:

Effective November 18, 2013

Dose-Related Range:	50-240 ng/mL - Dose (Adult): 1-10 mg/d

Toxic:	Greater than 300 ng/mL

TEST CHANGE

Clorazepate (Assayed as Nordiazepam)

0090196, CLORAZ

Specimen Requirements:	
Patient Preparation:	Timing of specimen collection: Predose~~Pre-dose~~ (trough) draw at~~- At~~ steady state concentration.
Collect:	Gray (potassium oxalate/sodium fluoride).~~Potassium Oxalate/Sodium Fluoride).~~ Also acceptable: Plain red, green (sodium heparin), lavender~~Red, Green (Sodium Heparin), Lavender~~ (K2 or K3EDTA) or pink (K2EDTA).
Specimen Preparation:	Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Gel separator tubes. Plasma or whole blood collected in light blue (sodium citrate). Hemolyzed specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 3 years (Avoid repeated freeze/thaw cycles)
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Tue, Fri
Reported:	1-7~~5~~ days
Note:	
CPT Codes:	80346 (Alt code: G0480)
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Clorazepate is assayed as nordiazepam. Toxic concentrations may cause central nervous system depression.

Reference Interval:

Effective November 16, 2015

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

TEST CHANGE

Tacrolimus by Tandem Mass Spectrometry

0090612, TACRO

Specimen Requirements:	
Patient Preparation:	Predose~~Pre-dose~~ (trough) levels should be drawn.
Collect:	Lavender (EDTA) or pink (K2EDTA).
Specimen Preparation:	Transport 1 mL whole blood. (Min: 0.25 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Serum or plasma. Specimens left at room temperature for longer than 24 hours. Clotted specimens.
Remarks:	
Stability:	Ambient: 24 hours; Refrigerated: 2 weeks; Frozen: 2 months
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Sun-Sat
Reported:	1-2 days ~~Within 24 hours~~
Note:	Tacrolimus (Prograf) whole blood concentrations can be measured by either chromatographic or immunoassay methodologies. These two methodologies are not directly interchangeable, and the measured tacrolimus whole blood concentration depends on the methodology used. Reference ranges may vary according to the specific immunoassay or HPLC-MS/MS test. Generally, immunoassays have been reported to have a positive bias relative to HPLC-MS/MS assays due to the detection of antibody cross-reactivity with tacrolimus metabolites.
CPT Codes:	80197
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Therapeutic range is based on a whole blood specimen drawn 12 hours postdose~~post-dose~~ or prior to next dose (the trough). The optimal therapeutic range for a given patient may differ from this suggested range based on the indication for therapy, treatment phase (initiation or maintenance),

use in combination with other drugs, time of specimen collection relative to prior dose, type of transplanted organ, and/or the therapeutic approach of the transplant center.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Effective February 18, 2014

	Therapeutic Range:
Kidney transplant:	0-3 months post-transplant: 7.0-20.0 ng/mL 3 months and older: 5.0-15.0 ng/mL
Heart transplant:	0-3 months post-transplant: 10.0-20.0 ng/mL 3 months and older: 5.0-15.0 ng/mL
Liver transplant:	1-12 months post-transplant: 5-20 ng/mL
Toxic value:	Greater than 25 ng/mL

TEST CHANGE

Prazepam (Assayed as Nordiazepam)

0090672, PRAZE

Specimen Requirements:	
Patient Preparation:	Timing of specimen collection: Predose~~Pre-dose~~ (trough) draw at~~-~~ ~~At~~ steady state concentration.
Collect:	Gray (potassium oxalate/sodium fluoride).~~Potassium Oxalate/Sodium Fluoride).~~ Also acceptable: Plain red, green (sodium heparin), lavender~~Red, Green (Sodium Heparin), Lavender~~ (K2 or K3EDTA) or pink (K2EDTA).
Specimen Preparation:	Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Gel separator tubes. Plasma or whole blood collected in light blue (sodium citrate). Hemolyzed specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 3 years (Avoid repeated freeze/thaw cycles)
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Tue, Fri
Reported:	1-7~~5~~ days
Note:	
CPT Codes:	80346 (Alt code: G0480)
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Prazepam is not detected in serum due to its rapid metabolism to nordiazepam. Adverse effects may include dizziness, fatigue, drowsiness, ataxia, and weakness. ~~and weakness.~~

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA-certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Effective November 16, 2015

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

TEST CHANGE

THC Metabolite, Serum or Plasma, Quantitative

0090676, CANNAB SP

Specimen Requirements:	
Patient Preparation:	
Collect:	Gray (sodium fluoride/potassium oxalate). Also acceptable: Plain red, green (sodium heparin), lavender (EDTA), or pink (K2EDTA).
Specimen Preparation:	Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 0.5 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Separator tubes. Plasma or whole blood collected in light~~.~~ blue (sodium citrate). Specimens exposed to repeated freeze/thaw cycles.
Remarks:	
Stability:	After separation from cells: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 3 years
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Sun, Tue, Thu, Fri~~-Sat~~
Reported:	1-5~~4~~ days
Note:	
CPT Codes:	80349 (Alt code: G0480)
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Methodology: Quantitative Liquid Chromatography-Tandem Mass Spectrometry

Positive cutoff: 5 ng/mL

For medical purposes only; not valid for forensic use.

The drug analyte detected in this assay, 9-carboxy THC, is a metabolite of delta-9-tetrahydrocannabinol (THC). Detection of 9-carboxy THC suggests use of, or exposure to, a

product containing THC. This test cannot distinguish between prescribed or nonprescribed~~non-prescribed~~ forms of THC, nor can it distinguish between active or passive use. The plasma half-life for 9-carboxy THC metabolite is estimated to range from 4-12 hours.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Effective August 17, 2015

Drugs Covered	Cutoff Concentrations	
11-Nor-9-carboxy-THC	5 ng/mL	

TEST CHANGE

Everolimus by Tandem Mass Spectrometry

0092118, EVEROLIMUS

Specimen Requirements:	
Patient Preparation:	Predose~~Pre-dose~~ (trough) levels should be drawn.
Collect:	Lavender (EDTA) or pink (K2EDTA).
Specimen Preparation:	Transport 1 mL whole blood. (Min: 0.25 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Serum or plasma. Specimens left at room temperature for longer than 24 hours. Clotted specimens.
Remarks:	
Stability:	Ambient: 24 hours; Refrigerated: 2 weeks; Frozen: 2 weeks
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Sun-Sat
Reported:	1-2 days ~~Within 24 hours~~
Note:	Everolimus (Zortress, Certican, Afinitor) whole blood concentrations can be measured by either chromatographic or immunoassay methodologies. These two methodologies are not directly interchangeable, and the measured everolimus whole blood concentration depends on the methodology used, and reference ranges may vary according to specific immunoassay or HPLC/MS/MS test. Generally, immunoassays have been reported to have a positive test bias relative to HPLC-MS/MS assays, due to the detection of antibody cross-reactivity with everolimus metabolites.
CPT Codes:	80169
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Everolimus marketed as Zortress is FDA approved for prophylaxis of organ rejection in adult patients receiving a kidney and liver transplant.

Everolimus marketed as Afinitor is FDA approved for the treatment of renal cell carcinoma and for the treatment of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS) in patients who are not candidates for curative surgical resection. The suggested therapeutic range for treatment of SEGA is 5-15 ng/mL, which is based on a predose (trough) specimen.

The optimal therapeutic range for a given patient may differ from this suggested range based on the indication for therapy, treatment phase (initiation or maintenance), use in combination with other drugs, time of specimen collection relative to prior dose, type of transplanted organ, and/or the therapeutic approach of the transplant center.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Effective February 18, 2014

	Therapeutic Range:
Kidney transplant (in combination with Cyclosporine):	3-8 ng/mL
Liver transplant (in combination with Tacrolimus):	3-8 ng/mL
Toxic value:	Greater than 15 ng/mL

TEST CHANGE

Adrenal Steroid Quantitative Panel by HPLC-MS/MS, Serum or Plasma

0092330, ADSTEROID

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube. Also acceptable: Plain red, pink (K2EDTA), or green (sodium or lithium heparin).
Specimen Preparation:	Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 1.2 mL serum or plasma to an ARUP standard transport tube~~Standard Transport Tube~~ and freeze immediately. (Min: 0.6 mL)
Transport Temperature:	CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Unacceptable Conditions:	Refrigerated or room temperature specimens.
Remarks:	
Stability:	After separation from cells: Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 6 months
Methodology:	Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Mon-Fri
Reported:	1-54 days
Note:	
CPT Codes:	82634; 83498; 84143; 84140
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Deleted Cells

Test Number	Components	Reference Interval		
	11-Deoxycortisol, HPLC-MS/MS			
		Age	Male (ng/dL)	Female (ng/dL)
		Premature (26-28 weeks)	110-1376	110-1376
		Premature (29-36 weeks)	70-455	70-455
		Full Term (1-5 months)	10-200	10-200
		6-11 months	10-276	10-276
		1-3 years	7-202	7-247
		4-6 years	8-235	8-291
		7-9 years	Less than or equal to 120	Less than or equal to 94
		10-12 years	Less than or equal to 92	Less than or equal to 123
		13-15 years	Less than or equal to 95	Less than or equal to 107
		16-17 years	Less than or equal to 106	Less than or equal to 47
		18 years and older	Less than 50	Less than 33
		Tanner Stage I	Less than or equal to 105	Less than or equal to 94
		Tanner Stage II	Less than or equal to 108	Less than or equal to 136
		Tanner Stage III	Less than or equal to 111	Less than or equal to 99
		Tanner Stage IV & V	Less than or equal to 83	Less than or equal to 50
		After metyrapone stimulation	Greater than 8000	Greater than 8000
	17-Hydroxyprogesterone, HPLC-MS/MS			

		Age	Male (ng/dL)	Female (ng/dL)
		Premature (26-28 weeks)	124-841	124-841
		Premature (29-35 weeks)	26-568	26-568
		Full term Day 3	7-77	7-77
		4 days-30 days	Less than 200	7-106
		1 month-2 months	Less than 200	13-106
		3 months-5 months	3-90	13-106
		6 months-1 year	Less than or equal to 148	Less than or equal to 148
		2-3 years	Less than or equal to 228	Less than or equal to 256
		4-6 years	Less than or equal to 208	Less than or equal to 299
		7-9 years	Less than or equal to 63	Less than or equal to 71
		10-12 years	Less than or equal to 79	Less than or equal to 129
		13-15 years	9-140	9-208
		16-17 years	24-192	Less than or equal to 178
		18 years and older	Less than 139	Less than 207
		Follicular	Not Applicable	15-70
		Luteal	Not Applicable	35-290
		Tanner Stage I	Less than or equal to 62	Less than or equal to 74
		Tanner Stage II	Less than or equal to 104	Less than or equal to 164
		Tanner Stage III	Less than or equal to 151	13-209
		Tanner Stage IV-V	20-173	7-170
	17-Hydroxypregnenolone Quant, MS/MS, Ser			

		Age	Male (ng/dL)	Female (ng/dL)
		Premature (26-28 weeks)	1219-9799	1219-9799
		Premature (29-36 weeks)	346-8911	346-8911
		Full Term (1-5 months)	229-3104	229-3104
		6-12 months	Less than or equal to 917	Less than or equal to 917
		13-23 months	Less than or equal to 592	Less than or equal to 592
		2-4 years	Less than or equal to 249	Less than or equal to 280
		5-6 years	Less than or equal to 319	Less than or equal to 350
		7-9 years	Less than or equal to 187	Less than or equal to 212
		10-12 years	Less than or equal to 392	Less than or equal to 398
		13-15 years	35-465	Less than or equal to 407
		16-17 years	32-478	Less than or equal to 423
		18 years and older	Less than 442	Less than 226
		Tanner Stage I	Less than or equal to 208	Less than or equal to 235
		Tanner Stage II	Less than or equal to 355	Less than or equal to 367
		Tanner Stage III	Less than or equal to 450	Less than or equal to 430
		Tanner Stage IV & V	35-478	Less than or equal to 412
	Pregnenolone			

		Age	Male (ng/dL)	Female (ng/dL)
		6-12 months	13-327	13-327
		13-23 months	12-171	12-171
		2-4 years	10-125	15-125
		5-6 years	10-156	13-191
		7-9 years	13-205	14-150
		10-12 years	15-151	19-220
		13-15 years	18-197	22-210
		16-17 years	17-228	22-229
		18 years and older	23-173	15-132
		Tanner Stage I	13-156	15-171
		Tanner Stage II	12-143	22-229
		Tanner Stage III	16-214	34-215
		Tanner Stage IV & V	19-201	26-235

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Effective Date: November 13, 2023

TEST CHANGE

11-Deoxycortisol Quantitative by HPLC-MS/MS, Serum or Plasma

0092331, DEOXYCORT

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube. Also acceptable: Plain red, pink (K2EDTA), plasma separator tube, green (sodium heparin), or green (lithium heparin).
Specimen Preparation:	Transfer 1 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 0.3 mL)
Transport Temperature:	Refrigerated. Also acceptable: Frozen.
Unacceptable Conditions:	Grossly hemolyzed specimens.
Remarks:	
Stability:	After separation from cells: Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 6 months
Methodology:	Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Mon, Wed, Fri
Reported:	1-8~~2-5~~ days
Note:	
CPT Codes:	82634
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Deleted Cells

Effective August 19, 2013

Age	Female	Male
Premature (26-28 weeks)	110-1376 ng/dL	110-1376 ng/dL
Premature (29-36 weeks)	70-455 ng/dL	70-455 ng/dL
Full Term (1-5 months)	10-200 ng/dL	10-200 ng/dL
6-11 months	10-276 ng/dL	10-276 ng/dL
1-3 years	7-247 ng/dL	7-202 ng/dL
4-6 years	8-291 ng/dL	8-235 ng/dL
7-9 years	Less than or equal to 94 ng/dL	Less than or equal to 120 ng/dL
10-12 years	Less than or equal to 123 ng/dL	Less than or equal to 92 ng/dL
13-15 years	Less than or equal to 107 ng/dL	Less than or equal to 95 ng/dL
16-17 years	Less than or equal to 47 ng/dL	Less than or equal to 106 ng/dL
18 years and older	Less than 33 ng/dL	Less than 50 ng/dL
Tanner Stage I	Less than or equal to 94 ng/dL	Less than or equal to 105 ng/dL
Tanner Stage II	Less than or equal to 136 ng/dL	Less than or equal to 108 ng/dL
Tanner Stage III	Less than or equal to 99 ng/dL	Less than or equal to 111 ng/dL
Tanner Stage IV & V	Less than or equal to 50 ng/dL	Less than or equal to 83 ng/dL
After metyrapone stimulation	Greater than 8000 ng/dL	Greater than 8000 ng/dL

ARUP LABORATORIES | A nonprofit enterprise of the University of Utah and its Department of Pathology

Effective Date: November 13, 2023

TEST CHANGE

17-Hydroxyprogesterone Quantitative by HPLC-MS/MS, Serum or Plasma

0092332, OHPRGSTON

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube~~Separator Tube~~ (SST). Also acceptable: Plain red, pink~~Red, Pink~~ (K2EDTA), plasma separator tube~~Plasma Separator Tube~~ (PST), green (sodium heparin~~Green (Sodium Heparin~~), or green (lithium heparin~~Green (Lithium Heparin~~).
Specimen Preparation:	Transfer 1 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 0.3 mL)
Transport Temperature:	Frozen. Also acceptable: Refrigerated.
Unacceptable Conditions:	Grossly hemolyzed specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 3 Days; Refrigerated: 1 week; Frozen: 6 months
Methodology:	Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Sun-Sat
Reported:	1-54 days
Note:	
CPT Codes:	83498
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Deleted Cells

Effective August 19, 2013

Age	Female	Male
Premature (26-28 weeks)	124-841 ng/dL	124-841 ng/dL
Premature (29-35 weeks)	26-568 ng/dL	26-568 ng/dL
Full term Day 3	7-77 ng/dL	7-77 ng/dL
4 days-30 days	7-106 ng/dL	Less than 200 ng/dL
1 month-2 months	13-106 ng/dL	Less than 200 ng/dL
3 months-5 months	13-106 ng/dL	3-90 ng/dL
6 months-1 year	Less than or equal to 148 ng/dL	Less than or equal to 148 ng/dL
2-3 years	Less than or equal to 256 ng/dL	Less than or equal to 228 ng/dL
4-6 years	Less than or equal to 299 ng/dL	Less than or equal to 208 ng/dL
7-9 years	Less than or equal to 71 ng/dL	Less than or equal to 63 ng/dL
10-12 years	Less than or equal to 129 ng/dL	Less than or equal to 79 ng/dL
13-15 years	9-208 ng/dL	9-140 ng/dL
16-17 years	Less than or equal to 178 ng/dL	24-192 ng/dL
18 years and older	Less than 207 ng/dL	Less than 139 ng/dL
Follicular	15-70 ng/dL	Does Not Apply
Luteal	35-290 ng/dL	Does Not Apply
Tanner Stage I	Less than or equal to 74 ng/dL	Less than or equal to 62 ng/dL
Tanner Stage II	Less than or equal to 164 ng/dL	Less than or equal to 104 ng/dL
Tanner Stage III	13-209 ng/dL	Less than or equal to 151 ng/dL
Tanner Stage IV-V	7-170 ng/dL	20-173 ng/dL

TEST CHANGE

Opiates, Serum or Plasma, Quantitative

0092354, OPIS SP

Specimen Requirements:	
Patient Preparation:	
Collect:	Gray (sodium fluoride/potassium oxalate). Also acceptable: Plain red, green (sodium heparin), lavender (EDTA), or pink (K2EDTA).
Specimen Preparation:	Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 0.5 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Separator tubes. Plasma or whole blood collected in light~~.~~ blue (sodium citrate). Specimens exposed to repeated freeze/thaw cycles. Hemolyzed specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 3 years
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Mon, Wed, Fri
Reported:	1-64~~4~~ days
Note:	
CPT Codes:	80361; 80365 (Alt code: G0480)
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Methodology: Quantitative Liquid Chromatography-Tandem Mass Spectrometry

Positive cutoff: 2 ng/mL

For medical purposes only; not valid for forensic use.

Identification of specific drug(s) taken by specimen donor is problematic due to common metabolites, some of which are prescriptions drugs themselves. The absence of expected drug(s)

and/or drug metabolite(s) may indicate noncompliancenon-compliance, inappropriate timing of specimen collection relative to drug administration, poor drug absorption, or limitations of testing. All drugs covered are the nonglucuronidatednon-glucuronidated (free) form. The concentration value must be greater than or equal to the cutoff to be reported as positive. A very small amount of an unexpected drug analyte in the presence of a large amount of an expected drug analyte may reflect pharmaceutical impurity. Interpretive questions should be directed to the laboratory.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Effective August 17, 2015

Drugs Covered	Cutoff Concentrations
Codeine	2 ng/mL
Morphine	2 ng/mL
6-acetylmorphine	2 ng/mL
Hydrocodone	2 ng/mL
Hydromorphone	2 ng/mL
Oxycodone	2 ng/mL
Oxymorphone	2 ng/mL

TEST CHANGE

Thyroxine, Free by Equilibrium Dialysis/HPLC-Tandem Mass Spectrometry

0093244, FT4 ED-TMS

Specimen Requirements:	
Patient Preparation:	
Collect:	Plain rRed or serum separator tubeSerum Separator Tube (SST).
Specimen Preparation:	Separate from cells or gel ASAP or within 2 hours of collection. Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.3 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma.
Remarks:	
Stability:	After separation from cells: Ambient: 4 days; Refrigerated: 2 weeks; Frozen: 1 month
Methodology:	Quantitative Equilibrium Dialysis/High Performance Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Sun, Tue, Thu
Reported:	2-65 days
Note:	
CPT Codes:	84439
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Some medications may induce transient changes in FT4 concentrations. This test is not recommended for patients currently on heparin treatment as FT4 concentrations may be falsely elevated. This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Reference Interval:

Effective May 16, 2011

Free Thyroxine ng/dL		
Age	Female	Male
25-30 weeks gestation	0.5-3.3 ng/dL	0.5-3.3 ng/dL
31-36 weeks gestation	1.3-4.7 ng/dL	1.3-4.7 ng/dL
Birth to 1 week	2.2-5.3 ng/dL	2.2-5.3 ng/dL
2-3 weeks	0.9-4.0 ng/dL	0.9-4.0 ng/dL
1-5 months	1.1-2.2 ng/dL	1.1-2.2 ng/dL
6 months-6 years	1.4-2.7 ng/dL	1.4-2.7 ng/dL
7 years-17 years	1.1-2.0 ng/dL	1.1-2.0 ng/dL
18 years and older	1.1-2.4 ng/dL	1.1-2.4 ng/dL
Pregnancy, 1{sp:st} Trimester	0.7-2.0 ng/dL	
Pregnancy, 2{sp:nd} Trimester	0.7-2.1 ng/dL	
Pregnancy, 3{sp:rd} Trimester	0.5-1.6 ng/dL	

TEST CHANGE

Sirolimus by Tandem Mass Spectrometry

0098467, RAPAMUNE

Specimen Requirements:	
Patient Preparation:	Predose~~Pre-dose~~ (trough) levels should be drawn.
Collect:	Lavender (EDTA) or pink (K2EDTA).
Specimen Preparation:	Transport 1 mL whole blood. (Min: 0.25 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Serum or plasma. Specimens left at room temperature for longer than 24 hours. Clotted specimens.
Remarks:	
Stability:	Ambient: 24 hours; Refrigerated: 1 week; Frozen: 2 months
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Sun-Sat
Reported:	1-2 days ~~Within 24 hours~~
Note:	Sirolimus (Rapamune) whole blood concentrations can be measured by either chromatographic or immunoassay methodologies. These two methodologies are not directly interchangeable and the measured sirolimus whole blood concentration depends on the methodology used. Reference ranges may vary according to the specific immunoassay or HPLC-MS/MS test. Generally, immunoassays have been reported to have a positive bias relative to HPLC-MS/MS assays due to the detection of antibody cross-reactivity with sirolimus metabolites.
CPT Codes:	80195
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

A range of 12-20 ng/mL has been suggested for liver transplant. The optimal therapeutic range for a given patient may differ from this suggested range based on the indication for therapy, treatment phase (initiation or maintenance), use in combination with other drugs, time of specimen collection

relative to prior dose, type of transplanted organ, and/or the therapeutic approach of the transplant center.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Effective February 18, 2014

	Therapeutic Range:
Kidney transplant (in combination with Cyclosporine):	4-12 ng/mL
Toxic value:	Greater than 25 ng/mL

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Effective Date: November 13, 2023

TEST CHANGE

Androstenedione

2001638, ANDRO TMS

Specimen Requirements:	
Patient Preparation:	Specimen should be collected between 6-10 a.m.
Collect:	Serum separator tube or green (sodium or lithium heparin).
Specimen Preparation:	Transfer 1 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 0.3 mL) Also acceptable: EDTA plasma.
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	
Remarks:	
Stability:	After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 6 months
Methodology:	Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Sun-Sat
Reported:	1-54 days
Note:	
CPT Codes:	82157
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Deleted Cells

Effective August 19, 2013

Age	Female	Male
Premature Infants, 26-28 weeks-Day 4	0.92-2.82 ng/mL	0.92-2.82 ng/mL
Premature Infants, 31-35 weeks-Day 4	0.80-4.46 ng/mL	0.80-4.46 ng/mL
Full-term Infants, 1-7 days	0.20-2.90 ng/mL	0.20-2.90 ng/mL
8-30 days	0.18-0.80 ng/mL	0.18-0.80 ng/mL
1-5 months	0.06-0.68 ng/mL	0.06-0.68 ng/mL
6-24 months	Less than 0.15 ng/mL	0.03-0.15 ng/mL
2-3 years	Less than 0.16 ng/mL	Less than 0.11 ng/mL
4-5 years	0.02-0.21 ng/mL	0.02-0.17 ng/mL
6-7 years	0.02-0.28 ng/mL	0.01-0.29 ng/mL
8-9 years	0.04-0.42 ng/mL	0.03-0.30 ng/mL
10-11 years	0.09-1.23 ng/mL	0.07-0.39 ng/mL
12-13 years	0.24-1.73 ng/mL	0.10-0.64 ng/mL
14-15 years	0.39-2.00 ng/mL	0.18-0.94 ng/mL
16-17 years	0.35-2.12 ng/mL	0.30-1.13 ng/mL
18-39 years	0.26-2.14 ng/mL	0.33-1.34 ng/mL
40 years and older	0.13-0.82 ng/mL	0.23-0.89 ng/mL
Pre-menopausal	0.26-2.14 ng/mL	Does Not Apply
Postmenopausal	0.13-0.82 ng/mL	Does Not Apply
Tanner Stage I	0.05-0.51 ng/mL	0.04-0.32 ng/mL
Tanner Stage II	0.15-1.37 ng/mL	0.08-0.48 ng/mL
Tanner Stage III	0.37-2.24 ng/mL	0.14-0.87 ng/mL
Tanner Stage IV-V	0.35-2.05 ng/mL	0.27-1.07 ng/mL

ARUP LABORATORIES | *A nonprofit enterprise of the University of Utah and its Department of Pathology*

Effective Date: November 13, 2023

TEST CHANGE

Dehydroepiandrosterone, Serum or Plasma

2001640, DHEA TMS

Specimen Requirements:	
Patient Preparation:	Collect between 6-10 a.m.
Collect:	Serum separator tube or green (sodium or lithium heparin). Also acceptable: Lavender (EDTA).
Specimen Preparation:	Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 0.3 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	
Remarks:	
Stability:	After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 6 months
Methodology:	Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Sun-Sat
Reported:	1-5~~4~~ days
Note:	
CPT Codes:	82626
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Deleted Cells

Effective August 19, 2013

Age	Female	Male
Premature	Less than 40 ng/mL	Less than 40 ng/mL
0-1 day	Less than 11 ng/mL	Less than 11 ng/mL
2-6 days	Less than 8.7 ng/mL	Less than 8.7 ng/mL
7 days-1 month	Less than 5.8 ng/mL	Less than 5.8 ng/mL
1-5 months	Less than 2.9 ng/mL	Less than 2.9 ng/mL
6-24 months	Less than 1.9 9 ng/mL	Less than 2.5 ng/mL
2-3 years	Less than 0.85 ng/mL	Less than 0.63 ng/mL
4-5 years	Less than 1.03 ng/mL	Less than 0.95 ng/mL
6-7 years	Less than 1.79 ng/mL	0.06-1.93 ng/mL
8-9 years	0.14-2.35 ng/mL	0.10-2.08 ng/mL
10-11 years	0.43-3.78 ng/mL	0.32-3.08 ng/mL
12-13 years	0.89-6.21 ng/mL	0.57-4.10 ng/mL
14-15 years	1.22-7.01 ng/mL	0.93-6.04 ng/mL
16-17 years	1.42-9.00 ng/mL	1.17-6.52 ng/mL
18-39 years	1.33-7.78 ng/mL	1.33-7.78 ng/mL
40 years and older	0.63-4.70 ng/mL	0.63-4.70 ng/mL
Postmenopausal	0.60-5.73 ng/mL	Does Not Apply
Tanner Stage I	0.14-2.76 ng/mL	0.11-2.37 ng/mL
Tanner Stage II	0.83-4.87 ng/mL	0.37-3.66 ng/mL
Tanner Stage III	1.08-7.56 ng/mL	0.75-5.24 ng/mL
Tanner Stage IV-V	1.24-7.88 ng/mL	1.22-6.73 ng/mL

ARUP LABORATORIES | *A nonprofit enterprise of the University of Utah and its Department of Pathology*

Effective Date: November 13, 2023

TEST CHANGE

5-a-Dihydrotestosterone by Tandem Mass Spectrometry, Serum

2002349, DHT TMS

Specimen Requirements:	
Patient Preparation:	
Collect:	Plain rRed or serum separator tubeSerum Separator Tube (SST).
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP standard transport tubeStandard Transport Tube and freeze immediately. (Min: 0.6 mL)
Transport Temperature:	Frozen.
Unacceptable Conditions:	Hemolyzed or lipemic specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 5 days; Frozen: 6 months
Methodology:	Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Sun, Wed, Thu, Fri, Tue-Sat
Reported:	1-54 days
Note:	
CPT Codes:	82642
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.	
Reference Interval:	

Deleted Cells

Test Number	Components	Reference Interval
	5-a-Dihydrotestosterone, LC-MS/MS	

Age	Male (pg/mL)	Female (pg/mL)
Premature	100.0-530.0	20.0-130.0
Full Term	50.0-600.0	20.0-150.0
1 week-6 months	120.0-850.0	Not Applicable
1 week-9 years	Not Applicable	0.0-49.9
7 months-9 years	0.0-49.9	Not Applicable
10-19 years	0.0-533.0	50.0-170.0
20 years and older	106.0-719.0	24.0-208.0
Tanner Stage I	1.0-47.6	1.0-64.3
Tanner Stage II	3.5-397.9	5.5-95.9
Tanner Stage III	14.8-574.6	11.4-158.3
Tanner Stage IV-V	44.9-511.8	18.7-193.8

TEST CHANGE

JAK2 Exon 12 Mutation Analysis by PCR

2002357, JAK2 EX12

Specimen Requirements:	
Patient Preparation:	
Collect:	Whole blood or bone marrow (EDTA).
Specimen Preparation:	Whole Blood: Do not freeze. Transport 5 mL whole blood. (Min: 1 mL) Bone Marrow: Do not freeze. Transport 3 mL bone marrow. (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma, serum, FFPE tissue blocks/slides, or frozen tissue. Specimens collected in anticoagulants other than EDTA. Clotted or grossly hemolyzed specimens.
Remarks:	
Stability:	Ambient: 24 hours; Refrigerated: 4 days; Frozen: Unacceptable
Methodology:	Polymerase Chain Reaction
Performed:	Varies
Reported:	3-9 days
Note:	
CPT Codes:	81279
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	

Refer to report.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. This test was performed in a CLIA-certified laboratory and is intended for clinical purposes.

Reference Interval:

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.

TEST CHANGE

Cytogenomic SNP Microarray - Fetal

2002366, ARRAY FE

Specimen Requirements:	
Patient Preparation:	
Collect:	Fetal Specimen: Amniotic fluid OR chorionic villi in cytogenetic tissue media (ARUP Supply #32788). If cytogenetic tissue media is not available, collect in plain RPMI, Hanks solution, saline, or ringers. OR fetal urine, ascites fluid, pleural fluid, cystic hygroma fluid.
Specimen Preparation:	Do not freeze specimen or expose to extreme temperatures. Do not place in formalin. Transport 15-30 mL amniotic fluid in a sterile container OR 5-20 mg CVS in a sterile, screw-top container filled with tissue culture transport medium. Fetal urine, ascites fluid, pleural fluid, or cystic hygroma fluid: 4-15 mL in sterile tube.
Transport Temperature:	Room temperature (all specimens).
Unacceptable Conditions:	Frozen or fixed specimens.
Remarks:	
Stability:	Ambient: 48 hours; Refrigerated: Acceptable; Frozen: Unacceptable
Methodology:	Genomic Microarray (Oligo-SNP Array)
Performed:	Sun-Sat
Reported:	7-21 days
Note:	Maternal Cell Contamination: Maternal cell contamination studies recommended. For aArray AND amniotic fluid chromosomes, also order Chromosome Analysis, Amniotic fluid (ARUP test code 2002293). For aArray AND CVS chromosomes, also order Chromosome Analysis, Chorionic Villus (ARUP test code 2002291). For maternal cell contamination studies or if submitting maternal blood, order Maternal Cell Contamination, Maternal Specimen (ARUP test code 0050608) accompanied by a test request form for the mother (this test is performed at no charge). For questions regarding ordering please contact ARUP's genetic counselor at (800-)-242-2787 ext. 2141. A processing fee will be charged if this procedure is canceled, at the client's request, after the test has been set up, or if the

	specimen integrity is inadequate to allow culture growth. The fee will vary based on specimen type. Turnaround times may be delayed if specimens are suboptimal or culturing is required prior to testing. This test must be ordered using Cytogenetic test request form 43098 or through your ARUP interface. Please submit the Patient History for Prenatal Cytogenetics form with the electronic packing list (http://ltd.aruplab.com/Tests/Pdf/65).
CPT Codes:	81229; 81265 Fetal Cell Contamination (FCC)
New York DOH Approval Status:	Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.

Interpretive Data:

See report.
~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Reference Interval:

By report

ARUP LABORATORIES | A nonprofit enterprise of the University of Utah and its Department of Pathology

Effective Date: November 13, 2023

TEST CHANGE

Pancreatobiliary FISH

2002528, PF REQUEST

Specimen Requirements:	
Patient Preparation:	
Collect:	Bile or pancreatic duct brushings, biliary stent, or fine needle aspirates of the pancreas in UroCyte~~UroVysion FISH~~ Collection Kit (ARUP Supply #41440) available online through eSupply using ARUP Connect(TM) or contact Client Services at (800) 522-2787. For specific instructions refer to Specimen Collection & Handling.
Specimen Preparation:	Place specimen in Cytolyt or PreservCyt fixative vial. If the specimen is a brushing, submit the brush in the fixative. Specimen should be placed in fixative vial immediately after collection.
Transport Temperature:	Ambient or Refrigerated.
Unacceptable Conditions:	Frozen specimens. Unfixed specimens not collected in Cytolyt or PreservCyt fixative. Specimens submitted in expired collection vials.
Remarks:	Specimen source is required.
Stability:	Ambient: 1 week from collection; Refrigerated: 1 week from collection; Frozen: Unacceptable
Methodology:	Fluorescence in situ Hybridization (FISH)/Computer Assisted Analysis/Microscopy
Performed:	Mon-Fri
Reported:	4-12 days
Note:	~~The UroVysion Kit (ARUP Supply #41440) is designed to detect aneuploidy for chromosomes 3, 7 and 17via fluorescence in situ hybridization (FISH).~~ Results of this test must be interpreted in conjunction with clinical evidence and other laboratory testing and should not be used alone,as a diagnosis of pancreatobiliary carcinoma. A positive fluorescence in situ hybridization (FISH) result does not identify location or type of malignancy. FISH abnormalities may be associated with high-grade dysplasia or carcinoma in situ. Cytology and biopsy may help clarify such

situations.

CPT Codes:	88366
New York DOH Approval Status:	Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.

Interpretive Data:

Refer to Report.

Reference Interval:

Negative: No evidence of numeric chromosomal aberrations associated with pancreatobiliary carcinoma identified.	~~Positive~~	~~(>=)5 cells with gains of two or more chromosomes are present~~
Positive: Numeric chromosomal aberrations associated with pancreatobiliary carcinoma identified.	~~Equivocal Tetrasomy~~	~~Cells present with tetrasomic or near tetrasomic signal patterns~~
	~~Equivocal Trisomy~~	~~(>=)10 cells with gains of a single chromosome, (Trisomy 7 or Trisomy 3)~~
	~~Negative~~	~~< 5 abnormal cells are present~~

Deleted Cells

TEST CHANGE

Cytogenomic SNP Microarray

2003414, CMA SNP

Specimen Requirements:	
Patient Preparation:	
Collect:	Collect: ~~Green (Sodium Heparin).~~ Peripheral blood in green (sodium heparin) or lavender~~required. Also acceptable: Lavender~~ (K2EDTA), cord blood in green (sodium heparin) or lavender (K2EDTA), or PUBS in green (sodium heparin) or lavender (K2EDTA).~~).~~ New York State Clients: Green (sodium heparin~~Sodium Heparin~~) AND l~~L~~avender (K2EDTA).
Specimen Preparation:	Whole Blood, Cord Blood, & PUBS: Transport 5 mL ~~whole blood.~~ (Min: 1 mL)~~.)~~ New York State Clients: Transport 4 mL whole blood in the original green (sodium heparin~~Green (Sodium Heparin~~) tube and 3 mL whole blood in the original l~~L~~avender (K2EDTA) tube. (Min: 2 mL sodium heparin~~Sodium Heparin~~ and 2 mL EDTA).
Transport Temperature:	Whole Blood, Cord Blood, & PUBS: Room temperature.
Unacceptable Conditions:	Clotted specimens.
Remarks:	
Stability:	Whole Blood, Cord Blood, & PUBS: Ambient: 48 hours; Refrigerated: 72 hours; Frozen: Unacceptable New York State Clients: Ambient: 1 week; Refrigerated: 1 week; Frozen: Unacceptable
Methodology:	Genomic Microarray (Oligo-SNP Array)
Performed:	Sun-Sat
Reported:	10-14 days
Note:	This test must be ordered using a Cytogenetic test request form 43097 or through your ARUP interface. Please submit the Genomic Microarray Patient Clinical Information Form with the electronic packing list (http://ltd.aruplab.com/Tests/Pdf/76).
CPT Codes:	81229
New York DOH Approval Status:	Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.

Interpretive Data:

Refer to report.~~Refer to report.~~

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Reference Interval:

TEST CHANGE

MPL Mutation Detection by Capillary Electrophoresis

2005545, MPL

Specimen Requirements:	
Patient Preparation:	
Collect:	Whole blood or bone marrow (EDTA).
Specimen Preparation:	Whole Blood: Do not freeze. Transport 5 mL whole blood. (Min: 1 mL) Bone Marrow: Transport 3 mL bone marrow. (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma, serum, FFPE tissue blocks/slides, or frozen tissue. Specimens collected in anticoagulants other than EDTA. Clotted or grossly hemolyzed specimens.
Remarks:	
Stability:	Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable
Methodology:	Capillary Electrophoresis
Performed:	Varies
Reported:	7-12 days
Note:	The test will detect MPL mutations W515K, W515L, W515A, and S505N.
CPT Codes:	81338
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
Refer to report.	
Reference Interval:	

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.

TEST CHANGE

Genomic SNP Microarray, Products of Conception

2005633, ARRAY POC

Specimen Requirements:	
Patient Preparation:	
Collect:	Thaw media prior to tissue inoculation. Products of conception in a sterile, screw-top container (wWide -mouth containers: ARUP supply #42710) filled with tissue culture transport medium (ARUP sSupply #32788). Available online through eSupply using ARUP Connect(TM) or contact ARUP Client Services at (800-) 522-2787. If cytogenetics tissue media is not available, collect in plain RPMI, Hanks solution, sterile saline, or ringers. If autopsy is performed: Facia lata, diaphragm, tendon, skin, tissue from internal organs (if fresh), chest wall cartilage (particularly if macerated) or placenta from fetal side . If no autopsy is performed: Placenta from fetal side is preferred (eg,e.g. villi). Also acceptable: Skin (POC), Cord Tissue, Umbilical cord, Decidua, or Achilles tendon.
Specimen Preparation:	Do not place in formalin. Transport products of conception, skin (POC), cord tissue, or decidua (min: 5mg) in sterile, screw-top container filled with tissue transport medium. If specimen size is too large for a normal collection tube, a larger sterile container can be used such as a sterile urine cup and can be flooded with several tubes of cytogenetic tissue media.
Transport Temperature:	Room temperature (fresh tissue or culture flask). Also acceptable: Refrigerated or frozen.
Unacceptable Conditions:	Intact fetus. Specimens preserved in formalin. Specimens consisting of maternal tissue (decidua) only. Autolyzed or contaminated specimens. Skin (POC), Decidua: formalin fixed. Cord Tissue: formalin fixed, decomposed.
Remarks:	If specimen collection time is greater than 72 hours, testing may be compromised. The laboratory will make every attempt to culture the specimen. Send specimen to lab for testing. NOTE: Decidua is acceptable but represents maternal rather than fetal tissue.
Stability:	Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Indefinitely
Methodology:	Genomic Microarray (Oligo-SNP Array)
Performed:	Sun-Sat

Reported:	14-21 days
Note:	A processing fee will be charged if this procedure is canceled, at the client's request, after the test has been set up. This test must be ordered using Cytogenetic test request form #43098 or through your ARUP interface. Please submit the Patient History for Prenatal Cytogenetics form with the electronic packing list (http://ltd.aruplab.com/Tests/Pdf/65).
CPT Codes:	81229
New York DOH Approval Status:	Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.

Interpretive Data:

Refer to report~~Refer to report.~~

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes~~.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Reference Interval:

TEST CHANGE

Special Stain, Oil Red O

2005978, OIL RED SS

Specimen Requirements:	
Patient Preparation:	
Collect:	~~Tissue. Also acceptable:~~ Cryostat sections, air-dried cytospin or air-dried smear slides.
Specimen Preparation:	~~Tissue: Transport 1 g fresh or frozen tissue in a sterile container. (Min: 0.5 g)~~ Cryostat Sections: Transport 2 frozen cryostat section slides (4-8 micron section). (Min: 1 slide) Air-dried Cytospin or Air-dried Smear Slides: Transport 2 slides. (Min: 1 slide)
Transport Temperature:	~~Tissue: Refrigerated. Also acceptable: Frozen.~~ Cryostat Sections: Frozen. Air-dried Cytospin or Air-dried Smear Slides: Room temperature.
Unacceptable Conditions:	Specimens submitted with nonrepresentative~~non-representative~~ tissue type. Depleted specimens.
Remarks:	
Stability:	~~Tissue: Ambient: Unacceptable; Refrigerated: 48 hours; Frozen: Indefinitely~~ Cryostat Sections: Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: Indefinitely Air-dried Cytospin or Air-dried Smear Slides: Ambient: Indefinitely; Refrigerated: Undefined; Frozen: Undefined
Methodology:	Special Stain
Performed:	Mon-Fri
Reported:	1-5 days
Note:	All stains will be handled as Stain and Return unless a consultation is requested. To request a consultation, submit the pathology report, all associated case materials (clinical history, blocks, slides, etc.), and the Anatomic Pathology Requisition Form (#32960).
CPT Codes:	88313
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	

Reference Interval:

Test Number	Components	Reference Interval

TEST CHANGE

Thyroglobulin by LC-MS/MS, Serum or Plasma

2006550, THYROG MS

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube or green (sodium or lithium heparin), pPotassium EDTA
Specimen Preparation:	Separate from cells: Transport 1.5 mL serum or plasma. (Min: 0.7 mL)
Transport Temperature:	Refrigerated or fFrozen.
Unacceptable Conditions:	Samples left ambient for greater than 1 day; gGrossly lipemic samples.
Remarks:	
Stability:	After separation from cells: Ambient: 1 day; Refrigerated: 1 week; Frozen: 1 year
Methodology:	High Performance Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Mon, Wed, Thu, Sat
Reported:	21-6 days
Note:	
CPT Codes:	84432
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Lower limit of detection for tThyroglobulin by LC-MS/MS is 0.5 ng/mL.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Age	Reference Interval
6 months - 3 years	7.4 - 48.7 ng/mL
4 - 7 years	4.1 - 40.5 ng/mL
8 - 17 years	0.8 - 29.4 ng/mL
18 years and older	1.3 - 31.8 ng/mL

TEST CHANGE

Drug Profile, Targeted by Tandem Mass Spectrometry and Enzyme Immunoassay, Urine

2007479, PAIN HYB U

Specimen Requirements:	
Patient Preparation:	
Collect:	Random urine.
Specimen Preparation:	Transfer 4 mL each into two (2) ARUP standard transport tubes of~~Standard Transport Tubes~~ urine with no additives or preservatives. (Min: 2 mL each)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Specimens exposed to repeated freeze/thaw cycles.
Remarks:	
Stability:	Ambient: 1 week (Clonazepam may be unstable at ambient condition beyond three days); Refrigerated: 1 month; Frozen: 1 month
Methodology:	Qualitative ~~Liquid Chromatography-~~Tandem Mass Spectrometry/Qualitative Enzyme Multiplied Immunoassay Technique (EMIT)/Qualitative Spectrophotometry
Performed:	Sun-Sat
Reported:	1-3 days
Note:	Creatinine concentration is also provided. The carisoprodol immunoassay has cross-reactivity to carisoprodol and meprobamate.
CPT Codes:	80326; 80347; 80364; 80355; 80307 (Alt code: G0481)
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Methodology: Qualitative Enzyme Immunoassay and Qualitative Liquid Chromatography-Tandem Mass Spectrometry, Quantitative Spectrophotometry

The absence of expected drug(s) and/or drug metabolite(s) may indicate noncompliance, inappropriate timing of specimen collection relative to drug administration, poor drug absorption, diluted/adulterated urine, or limitations of testing. The concentration must be greater than or equal to the cutoff concentration to be reported as present. If specific drug concentrations are required, contact the laboratory within two weeks of specimen collection to request confirmation and

quantification by a second analytical technique. Interpretive questions should be directed to the laboratory.

Results based on immunoassay detection that do not match clinical expectations should be interpreted with caution. Confirmatory testing by mass spectrometry for immunoassay-based results is available, if ordered within two weeks of specimen collection. Additional charges apply.

For medical purposes only; not valid for forensic use.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

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

Drugs/Drug Classes	Range of Cutoff Concentrations
Barbiturates	200 ng/mL
Benzodiazepine-like: alprazolam, clonazepam, diazepam, lorazepam, midazolam, nordiazepam, oxazepam, temazepam, zolpidem	20 - 60 ng/mL
Cannabinoids (11-nor-9-carboxy-THC)	50 ng/mL
Ethyl Glucuronide	500 ng/mL
Muscle Relaxant(s): carisoprodol, meprobamate	100 ng/mL
Opiates/Opioids: buprenorphine, codeine, fentanyl, heroin, hydrocodone, hydromorphone, meperidine, methadone, morphine, naloxone, oxycodone, oxymorphone, tapentadol, tramadol	2-200 ng/mL
GABA analogues: Gabapentin, pregabalin	3,000 ng/mL

Phencyclidine (PCP)	25 ng/mL	
Stimulants: amphetamine, cocaine, methamphetamine, methylphenidate, MDMA (Ecstasy), MDEA (Eve), MDA, phentermine	50-200 ng/mL	

TEST CHANGE

Metanephrines Fractionated by HPLC-MS/MS, Urine

2007996, META URINE

Specimen Requirements:	
Patient Preparation:	If possible, abstain from medications for 72 hours prior to collection.
Collect:	24-hour or random urine. Refrigerate 24-hour specimen during collection.
Specimen Preparation:	Thoroughly mix entire collection (24-hour or random) in one container. Transfer a 4 mL aliquot to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 2.5 mL) A pH lower than 2 can cause assay interference. Record total volume and collection time interval on transport tube and test request form. Specimen preservation can be extended to 1 month refrigerated by performing one of the following: Option 1: Transfer a 4 mL aliquot to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 2.5 mL) Adjust pH to 2.0-4.0 with 6M HCl. Option 2: Transfer a 4 mL aliquot to an ARUP standard transport tube~~Standard Transport Tube~~ containing 20 mg sulfamic acid (ARUP Supply #48098), available online through eSupply using ARUP Connect(TM)or contact ARUP Client Services at ~~(~~800~~-)~~ 522-2787. (Min: 2.5 mL)
Transport Temperature:	Refrigerated. Also acceptable: Frozen.
Unacceptable Conditions:	Specimens preserved with boric acid or acetic acid.
Remarks:	
Stability:	Ambient: Unacceptable; Refrigerated: 2 weeks (unpreserved), 1 month (preserved); Frozen: 1 month
Methodology:	Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Sun-Sat
Reported:	1-54 days
Note:	
CPT Codes:	83835
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Smaller increases in metanephrine and/or normetanephrine concentrations (less than two times the upper reference limit) usually are the result of physiological stimuli, drugs, or improper specimen collection. Essential hypertension is often associated with slight elevations (metanephrine less than 400 ug~~µg~~/d and normetanephrine less than 900 ug~~µg~~/d). Elevated concentrations may be due to intense physical activity, life-threatening illness, and drug interferences.

Significant elevation of one or both metanephrines (three or more times the upper reference limit) is associated with an increased probability of a neuroendocrine tumor.

Per 24h calculations are provided to aid interpretation for collections with a duration of 24 hours and an average daily urine volume. For specimens with notable deviations in collection time or volume, ratios of analytes to a corresponding urine creatinine concentration may assist in result interpretation.

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Reference Interval:

Test Number	Components	Reference Interval		
	Creatinine, Urine - per 24h			
		Age	Male (mg/d)	Female (mg/d)
		3-8 years	140-700	140-700
		9-12 years	300-1300	300-1300
		13-17 years	500-2300	400-1600
		18-50 years	1000-2500	700-1600
		51-80 years	800-2100	500-1400
		81 years and older	600-2000	400-1300
	Metanephrine, Urine - per 24h			
		Age	Male (ug/d)	Female (ug/d)
		0-6 years	Not Applicable	Not Applicable
		7-12 years	45-273	40-209
		13-17 years	56-298	40-209
		18 years and older	55-320	36-229
	Metanephrine, Urine - ratio to CRT			
		Age	ug/g CRT	
		0-3 months	0-700	
		4-6 months	0-650	
		7-11 months	0-650	
		1 year	0-530	
		2-5 years	0-500	
		6-17 years	0-320	
		18 years and older	0-300	
	Normetanephrine, Urine - per 24h			
		Age	Male (ug/d)	Female (ug/d)
		0-6 years	Not Applicable	Not Applicable
		7-12 years	58-670	48-474
		13-17 years	82-553	65-406
		18-29 years	81-667	18 years and older: 95-650
		30 years and older	114-865	Not Applicable
	Normetanephrine, Urine - ratio to CRT			

		Age	ug/g CRT	
		0-3 months	0-3400	
		4-6 months	0-2200	
		7-11 months	0-1100	
		1 year	0-1300	
		2-5 years	0-610	
		6-17 years	0-450	
		18 years and older	0-400	

TEST CHANGE

SLCO1B1, 1 Variant

2008426, SLCO1B1

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (EDTA) or pink (K2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation:	Transport 3 mL whole blood. (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma or serum. Heparinized specimens. Frozen specimens in glass collection tubes.
Remarks:	
Stability:	Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Polymerase Chain Reaction (PCR)/Fluorescence Monitoring
Performed:	Mon, Thu
Reported:	5-10 days
Note:	
CPT Codes:	81328
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Background Information for *SLCO1B1*, 1 Variant:
Characteristics: Simvastatin is a commonly prescribed hypolipidemic drug used for cholesterol reduction and control. Approximately 1-5 percent of exposed individuals may experience a dose-dependent myopathy (skeletal muscle toxicity). Symptoms may include pain, muscle weakness, and cramps. The organic anion transporter polypeptide 1B1, encoded by *SLCO1B1*, transports active simvastatin acid from the blood stream into the liver. This test detects a common variant that reduces the function of the transporter, resulting in an increased plasma concentration of the drug.
Inheritance: Autosomal co-dominant.
Cause: Simvastatin hypersensitivity reaction is strongly associated with the *SLCO1B1*5* allele. The mechanism is related to changes in the activity of organic anion-transporter polypeptide 1B1 (OATP1B1). The *1 allele (normal transporter function) is presumed when the *5 allele is not detected. One copy of the *5 allele predicts decreased transporter function; two copies of the *5 allele predicts poor transporter function.
Allele Tested: *SLCO1B1**5 (rs4149056, c.521T>C).

Allele Frequency: Middle Eastern 5 percent, Caucasian 1-3 percent, African 0-2 percent, Asian 0-2 percent, Less than 1 percent in other populations.
Clinical Sensitivity: Drug-dependent.
Methodology: Polymerase Chain Reaction (PCR) and Fluorescence Monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Only the targeted *SLCO1B1* variant will be detected. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with statins may be affected by genetic and non-genetic factors that are not detected by this test. This result does not replace the need for therapeutic or clinical monitoring.

Please note the information contained in this report does not contain medication recommendations, and should not be interpreted as recommending any specific medications. Any dosage adjustments or other changes to medications should be evaluated in consultation with a medical provider.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Reference Interval:

By report

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.

ARUP LABORATORIES | *A nonprofit enterprise of the University of Utah and its Department of Pathology*

Effective Date: November 13, 2023

TEST CHANGE

Corticosterone Quantitative by HPLC-MS/MS, Serum or Plasma

2008456, CORTC

Specimen Requirements:	
Patient Preparation:	A morning specimen is preferred.
Collect:	Serum separator tube. Also acceptable: Plain red, pink (K2EDTA), plasma separator tube, green (sodium heparin), or green (lithium heparin).
Specimen Preparation:	Transfer 1 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 0.3 mL)
Transport Temperature:	Refrigerated. Also acceptable: Frozen.
Unacceptable Conditions:	Grossly hemolyzed specimens.
Remarks:	
Stability:	After separation from cells: Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 6 months.
Methodology:	Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Mon, Wed, Fri
Reported:	1-8~~2-5~~ days
Note:	
CPT Codes:	82528
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Deleted Cells

Gestation Time, Age	Reference Interval
Premature (26-28 weeks)	235 - 1108 ng/dL
Premature (29-30 weeks)	Not Established
Premature (31-35 weeks)	150 - 1700 ng/dL
Full Term Newborn, 1-7 days	70 - 850 ng/dL
8-29 days	Not Established
30 days-11 months	80 - 1500 ng/dL
Age, Draw Time	Reference Interval
1-16 years, morning	135 - 1860 ng/dL
1-16 years, evening	70 - 620 ng/dL
17 years and older, morning	130 - 820 ng/dL
17 years and older, evening	60 - 220 ng/dL

ARUP LABORATORIES | *A nonprofit enterprise of the University of Utah and its Department of Pathology*

Effective Date: November 13, 2023

TEST CHANGE

11-Deoxycorticosterone Quantitative by HPLC-MS/MS, Serum or Plasma

2008458, DCRN

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube. Also acceptable: Plain red, pink (K2EDTA), plasma separator tube, green (sodium heparin), or green (lithium heparin).
Specimen Preparation:	Transfer 1 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 0.3 mL)
Transport Temperature:	Refrigerated. Also acceptable: Frozen.
Unacceptable Conditions:	Grossly hemolyzed specimens.
Remarks:	
Stability:	After separation from cells: Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 6 months
Methodology:	Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Mon, Wed, Fri
Reported:	1-8~~2-5~~ days
Note:	
CPT Codes:	82633
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Deleted Cells

Test Number	Components	Reference Interval	
	11-Deoxycorticosterone, HPLC-MS/MS		
		Age	ng/dL
		Premature (26-28 weeks)	20-105
		Premature (29-33 weeks)	Not Applicable
		Premature (34-36 weeks)	28-78
		Full Term Newborn	Elevated at birth; decreases to 7-49 ng/dL during first week
		1-11 months	7-49
		Prepubertal Children	Less than or equal to 34
		Adults	Less than or equal to 19

ARUP LABORATORIES | A nonprofit enterprise of the University of Utah and its Department of Pathology

Effective Date: November 13, 2023

TEST CHANGE

Progesterone Quantitative by HPLC-MS/MS, Serum or Plasma

2008509, PGSN

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube~~Separator Tube~~ (SST). Also acceptable: Plain red, pink~~Red, Pink~~ (K2EDTA), plasma separator tube~~Plasma Separator Tube~~ (PST), green (sodium heparin~~Green (Sodium Heparin~~), or green (lithium heparin~~Green (Lithium Heparin~~).
Specimen Preparation:	Transfer 1 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 0.3 mL)
Transport Temperature:	Refrigerated. Also acceptable: Frozen.
Unacceptable Conditions:	Grossly hemolyzed specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 3 Days; Refrigerated: 1 week; Frozen: 6 months.
Methodology:	Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Sun-Sat
Reported:	1-54 days
Note:	
CPT Codes:	84144
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Deleted Cells

Effective May 16, 2016

Age	Males
Less than 1 year	Not Established
1-16 years	Less than or equal to 0.15 ng/mL
17 years and older	Less than or equal to 0.11 ng/mL
Age	Females
Less than 1 year	Not Established
1-10 years	Less than or equal to 0.26 ng/mL
11 years	Less than or equal to 2.55 ng/mL
12 years	Less than or equal to 8.56 ng/mL
13 years	Less than or equal to 6.93 ng/mL
14 years	Less than or equal to 12.04 ng/mL
15 years	Less than or equal to 10.76 ng/mL
16 years	Less than or equal to 12.94 ng/mL
17 years and older	Based on Cycle Days
1-6 days	Less than or equal to 0.17 ng/mL
7-12 days	Less than or equal to 1.35 ng/mL
13-15 days	Less than or equal to 15.63 ng/mL
16-28 days	Less than or equal to 25.55 ng/mL
Post-Menopausal	Less than or equal to 0.10 ng/mL
Pregnancy, First Trimester	6.25 - 45.46 ng/mL
Pregnancy,	15.40 - 52.10

Second Trimester	ng/mL
Pregnancy, Third Trimester	24.99 - 99.92 ng/mL

TEST CHANGE

Babesia Species by PCR

2008665, BABPCR

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (EDTA) or p~~P~~ink (K2EDTA).
Specimen Preparation:	Transport 1 mL whole blood. (Min: 0.6 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Serum, plasma, and heparinized specimens.
Remarks:	
Stability:	Ambient: 24 hours; Refrigerated: 1 week; Frozen: 14 days~~1 month~~
Methodology:	Qualitative Polymerase Chain Reaction
Performed:	Sun-Sat
Reported:	1-3 days
Note:	This test detects and speciates B. microti. The nucleic acid from B. duncani, B. divergens, strain MO-1, and strain EU-1 will be detected by this test but cannot be differentiated.
CPT Codes:	87469; 87798
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

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

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

TEST CHANGE

Opioid Receptor, mu OPRM1, 1 Variant

2008767, OPRM1

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (EDTA), pPink (K2EDTA), or yYellow (ACD sSolution A or B).
Specimen Preparation:	Transport 3 mL whole blood. (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma or serum. Heparinized specimens. Frozen specimens in glass collection tubes.
Remarks:	
Stability:	Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Polymerase Chain Reaction (PCR)/Fluorescence Monitoring
Performed:	Varies
Reported:	5-10 days
Note:	
CPT Codes:	81479
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Refer to reportRefer to report

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Reference Interval:

By report.

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.

TEST CHANGE

Fragile X (FMR1) with Reflex to Methylation Analysis

2009033, FRAG X PCR

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (K2EDTA), p~~P~~ink (K2EDTA), or y~~Y~~ellow (ACD s~~S~~olution A or B)~~)~~.
Specimen Preparation:	Transport 2~~5~~ mL whole blood. (Min: 1~~.5~~ mL)
Transport Temperature:	Refrigerated. Also acceptable: Ambient.
Unacceptable Conditions:	
Remarks:	
Stability:	Room Temperature~~Ambient~~: 1 week; Refrigerated: 1 month; Frozen: Unacceptable~~6 months~~
Methodology:	Polymerase Chain Reaction/Capillary Electrophoresis
Performed:	Varies~~Sun-Sat~~
Reported:	4-14 days
Note:	If a CGG repeat of 100 or greater is detected by PCR and capillary electrophoresis~~Capillary Electrophoresis~~, methylation analysis will be added. Additional charges apply.
CPT Codes:	81243; if reflexed, add 81244
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Refer to report. ~~Background Information for Fragile X (*FMR1*) with Reflex to Methylation Analysis~~
~~Characteristics of Fragile X syndrome (FXS): Affected males have moderate intellectual disability, hyperactivity, perseverative speech, social anxiety, poor eye contact, hand flapping or biting, autism spectrum disorders and connective tissue anomalies in males. Females are usually less severely affected than males. FXS is caused by *FMR1* full mutations.~~
~~Characteristics of Fragile X Tremor Ataxia Syndrome (FXTAS): Onset of progressive ataxia and intention tremor typically after the fourth decade of life. Females also have a 21 percent risk for primary ovarian insufficiency. FXTAS is caused by *FMR1* premutations.~~
~~Incidence of FXS: 1 in 4,000 Caucasian males and 1 in 8,000 Caucasian females.~~
~~Inheritance: X-linked.~~
~~Penetrance of FXS: Complete in males; 50 percent in females.~~
~~Penetrance of FXTAS: 47 percent in males and 17 percent in females >50 years of age.~~
~~Cause: Expansion of the *FMR1* gene CGG triplet repeat.~~

Full mutation: typically >200 CGG repeats (methylated).
Premutation: 55 to approx 200 CGG repeats (unmethylated).
Intermediate: 45-54 CGG repeats (unmethylated).
Normal: 5-44 CGG repeats (unmethylated).
Clinical Sensitivity: 99 percent.
Methodology: Triplet repeat-primed polymerase chain reaction (PCR) followed by size analysis using capillary electrophoresis. Methylation-specific PCR analysis is performed for CGG repeat lengths of >100 to distinguish between premutation and full mutation alleles.
Analytic Sensitivity and Specificity: 99 percent; estimated precision of sizing for intermediate and premutation alleles is within 2-3 CGG repeats.
Limitations: Diagnostic errors can occur due to rare sequence variations. Rare *FMR1* variants unrelated to trinucleotide expansion will not be detected. A specific CGG repeat size estimate is not provided for full mutation alleles. AGG trinucleotide interruptions within the *FMR1* CGG repeat tract are not assessed.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Phenotype	Number of CGG Repeats
Unaffected	<45
Intermediate	45-54
Premutation	55-200
Affected	>200

Reference Interval:

By report

TEST CHANGE

Drug Profile, Targeted with Interpretation by Tandem Mass Spectrometry and Enzyme Immunoassay, Urine

2009288, PAIN HYB 2

Specimen Requirements:	
Patient Preparation:	Information on the patient's current medications must be submitted with the order. Include trade name, generic name, dosing frequency, and date of last dose, if known. Alternatively, please indicate if no prescription medication or drugs are being taken.
Collect:	Random urine.
Specimen Preparation:	Transfer 4 mL each into two (2) ARUP standard transport tubes of~~Standard Transport Tubes~~ urine with no additives or preservatives. (Min: 2 mL each)
Transport Temperature:	Refrigerated
Unacceptable Conditions:	Specimens exposed to repeated freeze/thaw cycles.
Remarks:	
Stability:	Ambient: 1 week (Clonazepam may be unstable at ambient condition beyond three days); Refrigerated: 1 month; Frozen: 1 month
Methodology:	Quantitative ~~Liquid Chromatography-~~Tandem Mass Spectrometry/Qualitative Enzyme Multiplied Immunoassay Technique (EMIT)/Quantitative Spectrophotometry
Performed:	Sun-Sat
Reported:	1-4 days
Note:	Creatinine concentration is also provided. The carisoprodol immunoassay has cross-reactivity to carisoprodol and meprobamate.
CPT Codes:	80326; 80347; 80364; 80355; 80307 (Alt code: G0481)
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
Methodology: Qualitative Enzyme Immunoassay and Qualitative Liquid Chromatography-Tandem Mass Spectrometry, Quantitative Spectrophotometry	

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 must be greater than or equal to the cutoff concentration to be reported as present. If specific drug concentrations are required, contact the laboratory within two weeks of specimen collection to request confirmation and quantification by a second analytical technique. Interpretive questions should be directed to the laboratory.

Results based on immunoassay detection that do not match clinical expectations should be interpreted with caution. Confirmatory testing by mass spectrometry for immunoassay-based results is available if ordered within two weeks of specimen collection. Additional charges apply.

For medical purposes only; not valid for forensic use.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

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

Drugs/Drug Classes	Range of Cutoff Concentrations
Barbiturates	200 ng/mL
Benzodiazepine-like: alprazolam, clonazepam, diazepam, lorazepam, midazolam, nordiazepam, oxazepam, temazepam, zolpidem	20 - 60 ng/mL
Cannabinoids (11-nor-9-carboxy-THC)	50 ng/mL
Ethyl Glucuronide	500 ng/mL
Muscle Relaxant(s): carisoprodol, meprobamate	100 ng/mL
Opiates/Opioids: buprenorphine, codeine, fentanyl, heroin, hydrocodone, hydromorphone, meperidine, methadone, morphine, naloxone,	2-200 ng/mL

oxycodone, oxymorphone, tapentadol, tramadol		
GABA analogues: Gabapentin, pregabalin	3,000 ng/mL	
Phencyclidine (PCP)	25 ng/mL	
Stimulants: amphetamine, cocaine, methamphetamine, methylphenidate, MDMA (Ecstasy), MDEA (Eve), MDA, phentermine	50-200 ng/mL	

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.

TEST CHANGE

17-Hydroxyprogesterone 30-Min Quantitative by HPLC-MS/MS, Serum or Plasma

2009478, OHPRGSTN30

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube. Also acceptable: Plain red, pink (K2EDTA), plasma separator tube, green (sodium heparin), or green (lithium heparin).
Specimen Preparation:	Transfer 1 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 0.3 mL)
Transport Temperature:	Refrigerated. Also acceptable: Frozen.
Unacceptable Conditions:	Grossly hemolyzed specimens.
Remarks:	
Stability:	After separation from cells: Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 6 months
Methodology:	Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Sun-Sat
Reported:	1-54 days
Note:	
CPT Codes:	83498
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Reference ranges for 17-h~~H~~ydroxyprogesterone following stimulation are not well defined, and are dependent on the stimulation method utilized.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

TEST CHANGE

17-Hydroxyprogesterone 60-Min Quantitative by HPLC-MS/MS, Serum or Plasma

2009480, OHPRGSTN60

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube. Also acceptable: Plain red, pink (K2EDTA), plasma separator tube, green (sodium heparin), or green (lithium heparin).
Specimen Preparation:	Transfer 1 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 0.3 mL)
Transport Temperature:	Refrigerated. Also acceptable: Frozen.
Unacceptable Conditions:	Grossly hemolyzed specimens.
Remarks:	
Stability:	After separation from cells: Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 6 months
Methodology:	Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Sun-Sat
Reported:	1-54 days
Note:	
CPT Codes:	83498
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Reference ranges for 17-h~~H~~ydroxyprogesterone following stimulation are not well defined and are dependent on the stimulation method utilized.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

TEST CHANGE

Benzodiazepines, Serum or Plasma, Quantitative

2010445, BENZO SP

Specimen Requirements:	
Patient Preparation:	
Collect:	Gray (sodium fluoride/potassium oxalate). Also acceptable: Plain red, green (sodium heparin), lavender (EDTA), or pink (K2EDTA).
Specimen Preparation:	Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Gel separator tubes. Plasma or whole blood collected in light~~-~~ blue (sodium citrate). Hemolyzed specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 3 years (Avoid repeated freeze/thaw cycles)
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Tue, Fri
Reported:	1-7~~5~~ days
Note:	
CPT Codes:	80346 (Alt code: G0480)
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Methodology: Quantitative Liquid Chromatography-Tandem Mass Spectrometry.

Positive cutoff: 20 ng/mL unless specified below:
Diazepam 5 ng/mL
Alprazolam 5 ng/mL
Alpha-hydroxyalprazolam 5 ng/mL
Clonazepam 5 ng/mL
7-aminoclonazepam 5 ng/mL

For medical purposes only; not valid for forensic use.

Identification of specific drug(s) taken by specimen donor is problematic due to common metabolites, some of which are prescription drugs themselves. The absence of expected drug(s) and/or drug metabolite(s) may indicate noncompliance~~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.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Effective November 16, 2015

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

TEST CHANGE

CALR (Calreticulin) Exon 9 Mutation Analysis by PCR

2010673, CALR

Specimen Requirements:	
Patient Preparation:	
Collect:	Whole blood or bone marrow (EDTA).
Specimen Preparation:	Whole Blood: Do not freeze. Transport 5 mL whole blood. (Min: 1 mL) Bone Marrow: Do not freeze. Transport 3 mL bone marrow. (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma, serum, FFPE tissue blocks/slides, or frozen tissue. Specimens collected in anticoagulants other than EDTA. Clotted or grossly hemolyzed specimens.
Remarks:	
Stability:	Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable
Methodology:	Capillary Electrophoresis
Performed:	Varies
Reported:	2-9 days
Note:	
CPT Codes:	81219
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
Refer to report.	
Reference Interval:	

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.

TEST CHANGE

Hepatitis C Virus Antibody by CIA with Reflex to HCV by Quantitative NAAT

2010784, HCV AB QR

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum Separator Tube (SST). Also acceptable: Lavender (EDTA) or Pink (K2EDTA).
Specimen Preparation:	Separate from cells within 6 hours of collection. Transfer 2.5 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1.5 mL) This test requires a dedicated transport tube submitted only for HCV AB QR testing.
Transport Temperature:	Frozen.
Unacceptable Conditions:	Specimens containing particulate material. Severely hemolyzed, heat-inactivated, or lipemic specimens. Heparinized plasma.
Remarks:	
Stability:	After separation from cells: Ambient: 24 hours~~Unacceptable~~; Refrigerated: 5 days; Frozen: 2 months (avoid freeze/thaw cycles)
Methodology:	Qualitative Chemiluminescent Immunoassay (CLIA) ~~/~~Quantitative Transcription-Mediated Amplification (TMA)
Performed:	Sun-Sat
Reported:	1-2 days
Note:	If the anti-HCV screening result is low positive or high positive, the Hepatitis C Virus by Quantitative NAAT will be added. Additional charges apply.
CPT Codes:	86803; if reflexed, add 87522
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

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

Components	Interpretation
Hepatitis C Antibody by CIA Index	0.79 IV or less Negative 0.80 to 0.99 IV Equivocal 1.00 to 10.99 IV Low Positive 11.00 IV or greater High Positive

Reference Interval:

Test Number	Components	Reference Interval
	Hepatitis C Antibody by CIA Interp	Negative

TEST CHANGE

Fentanyl and Metabolite, Serum or Plasma, Quantitative

2011776, CDCO FNSP

Specimen Requirements:	
Patient Preparation:	
Collect:	Plain red, lavenderRed, Lavender (K2EDTA), lLavender (K3EDTA), green (sodium heparin), gray (potassium oxalate/sodium fluorideGreen (Sodium Heparin), Gray (Potassium Oxalate/Sodium Fluoride), or pPink (K2EDTA).
Specimen Preparation:	Separate from cells ASAP or within 2 hours of collection. Transfer 4 mL serum or plasma to an ARUP standard transport tube.Standard Transport Tube. (Min: 2 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Whole blood. Serum separator tubes, light blue (sodium citrateLight Blue (Sodium Citrate), or pPlasma separator tubes. Specimens exposed to repeated freeze/thaw cycles.
Remarks:	
Stability:	Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 3 years
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Tue, Thu, Sat
Reported:	1-84 days
Note:	
CPT Codes:	80354 (Alt code: G0480)
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Methodology: Quantitative Liquid Chromatography-Tandem Mass Spectrometry

Positive cutoff: 0.1 ng/mL

For medical purposes only; not valid for forensic use.

The absence of expected drug(s) and/or drug metabolite(s) may indicate noncompliancenon-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.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Effective August 17, 2015

Drugs Covered	Cutoff Concentrations
Fentanyl	0.1 ng/mL
Norfentanyl	0.1 ng/mL

TEST CHANGE

Dihydropyrimidine Dehydrogenase (DPYD), 3 Variants

2012166, DPYD

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (EDTA), pink (K2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation:	Transport 3 mL whole blood. (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma or serum. Heparinized specimens. Frozen specimens in glass collection tubes.
Remarks:	
Stability:	Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month.
Methodology:	Polymerase Chain Reaction (PCR)/Fluorescence Monitoring
Performed:	VariesMon, Thu
Reported:	5-10 days
Note:	
CPT Codes:	81232
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	

Refer to report.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Reference Interval:

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.

TEST CHANGE

Barbiturates, Serum or Plasma, Quantitative

2012201, BARBS SP

Specimen Requirements:	
Patient Preparation:	
Collect:	Gray (sodium fluoride/potassium oxalate). Also acceptable: Plain red, green (sodium heparin), lavender (EDTA), or pink (K2EDTA).
Specimen Preparation:	Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 3.5 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 1.5 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Separator tubes. Plasma or whole blood collected in light~~.~~ blue (sodium citrate). Specimens exposed to repeated freeze/thaw cycles. Hemolyzed specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 3 years
Methodology:	Quantitative Gas Chromatography-Mass Spectrometry/Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Tue, Thu, Sat
Reported:	1-7~~4~~ days
Note:	
CPT Codes:	80345 (Alt code: G0480)
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Methodology: Quantitative Gas Chromatography-Mass Spectrometry/Quantitative Liquid Chromatography-Tandem Mass Spectrometry.

Positive cutoff: 50 ng/mL

For medical purposes only; not valid for forensic use.

The absence of expected drug(s) and/or drug metabolite(s) may indicate noncompliance~~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.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Drugs Covered	Cutoff Concentrations
Butalbital	50 ng/mL
Pentobarbital	50 ng/mL
Phenobarbital	50 ng/mL

TEST CHANGE

Buprenorphine and Metabolites, Serum or Plasma, Quantitative

2012647, BUPRSP

Specimen Requirements:	
Patient Preparation:	
Collect:	Gray (sodium fluoride/potassium oxalate). Also acceptable: Plain red, green (sodium heparin), lavender (EDTA), or pink (K2EDTA).
Specimen Preparation:	Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Separator tubes. Plasma or whole blood collected in light~~.~~ blue (sodium citrate). Specimens exposed to repeated freeze/thaw cycles. Hemolyzed specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 3 years
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Tue, Fri
Reported:	1-7~~5~~ days
Note:	
CPT Codes:	80348 (Alt code: G0480)
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Methodology: Quantitative Liquid Chromatography-Tandem Mass Spectrometry

Positive cutoff: 1 ng/mL

For medical purposes only; not valid for forensic use.

The presence of metabolite(s) without parent drug may indicate use of parent drug during the prior week. The absence of expected drug(s) and/or drug metabolite(s) may indicate noncompliance~~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.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Effective February 16, 2016

Drugs Covered	Cutoff Concentrations
Buprenorphine	1 ng/mL
Norbuprenorphine	1 ng/mL

TEST CHANGE

Zolpidem, Serum or Plasma, Quantitative

2012652, ZOLPID SP

Specimen Requirements:	
Patient Preparation:	
Collect:	Gray (sodium fluoride/potassium oxalate). Also acceptable: Plain red, green (sodium heparin), lavender (EDTA), or pink (K2EDTA).
Specimen Preparation:	Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 1 mL)
Transport Temperature:	Room temperature.
Unacceptable Conditions:	Gel s~~S~~eparator tubes. Plasma or whole blood collected in light~~-~~ blue (sodium citrate). Hemolyzed specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 1 week; Refrigerated: 1 month; Frozen: 3 years (Avoid repeated freeze/thaw cycles)
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Tue, Fri
Reported:	1-7~~5~~ days
Note:	
CPT Codes:	80368 (Alt code: G0480)
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

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

Positive cutoff: 20 ng/mL

For medical purposes only; not valid for forensic use.

The absence of expected drug may indicate noncompliance~~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.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

TEST CHANGE

Spinal Muscular Atrophy (SMA) Copy Number Analysis

2013436, SMA DD

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (EDTA), pPink (K2EDTA), or yYellow (ACD sSolution A or B).
Specimen Preparation:	Transport 23 mL whole blood. (Min: 12 mL)
Transport Temperature:	Refrigerated. Also acceptable: Ambient.
Unacceptable Conditions:	
Remarks:	
Stability:	Room TemperatureAmbient: 1 week; Refrigerated: 1 month; Frozen: Unacceptable6 months.
Methodology:	Multiplex Ligation-Ddependent Probe Amplification (MLPA)
Performed:	Varies
Reported:	7-14 days
Note:	
CPT Codes:	81329
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Refer to report. Background information for Spinal Muscular Atrophy (SMA) Copy Number Analysis
Characteristics: Spinal muscular atrophy (SMA) is the most common lethal genetic disease in children, and is characterized by progressive muscle weakness due to degeneration of the lower motor neurons. Onset ranges from before birth to adulthood and severity is highly variable. Individuals with SMA have no functioning copies of the *SMN1* gene. Most (95 percent) have homozygous loss of *SMN1* due to deletion or gene conversion, while a minority (5 percent) have a deletion of *SMN1* on one chromosome and a *SMN1* sequence variant on the other. The *SMN2* gene, adjacent and highly homologous to *SMN1*, produces lower levels of survival motor neuron protein compared to *SMN1*. Disease severity has been shown to be modified by *SMN2* gene copy number in some cases, though phenotype cannot be predicted with certainty. An *SMN1* variant, c.*3+80T>G (rs143838139), that is part of a haplotype associated with *SMN1* duplication in silent carriers (2 copies of *SMN1* on one chromosome and no copies on the other), particularly in Ashkenazi Jews, increases the likelihood that 2 copies of *SMN1* are on the same chromosome.
Inheritance: Autosomal recessive.
Cause: Pathogenic variants in the *SMN1* gene.
Variants Tested: For copy number: *SMN1* (NM_000344.3) exon 7 c.840C and exon 8 c.*239G, and

SMN2 (NM_017411.3) exon 7 c.840T. For haplotype associated with *SMN1* duplication (silent carriers): *SMN1* c.*3+80T>G (rs143838139).
Clinical sensitivity: 95-98 percent in individuals affected with SMA. Detection rate for carrier screening is 90 percent in African Americans, 93 percent in Ashkenazi Jewish, 93 percent in Asians, 95 percent in Caucasians, and 93 percent in Hispanics.
Methodology: Multiplex probe ligation-dependent amplification (MLPA) to detect *SMN1* and *SMN2* copy number and presence or absence of the *SMN1* linked variant c.*3+80T>G (rs143838139).
Analytical sensitivity and specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Single base pair substitutions, small deletions/duplications, regulatory region mutations, and deep intronic mutations will not be detected. This test is unable to determine chromosomal phase of *SMN1* or *SMN2* copies. Even if the linked variant associated with *SMN1* duplication is detected, the test cannot definitively differentiate between 1+ copies of *SMN1* on each chromosome from 2+ copies of *SMN1* on one chromosome and none on the other (silent carriers).

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Reference Interval:

By report

TEST CHANGE

Zika Virus IgM Antibody Capture (MAC), by ELISA

2013942, ZIKA M

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube~~Separator Tube~~ (SST).
Specimen Preparation:	Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum to an ARUP standard transport tube~~Standard Transport Tube~~. (Min: 1.0 mL) Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Mark specimen plainly as "acute or convalescent."
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Bacterially contaminated, heat-inactivated, hemolyzed, icteric, lipemic, or turbid specimens.
Remarks:	Submit patient history.
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)
Methodology:	Semi-Quantitative Enzyme-Linked Immunosorbent Assay
Performed:	Mon, ~~Wed,~~ Fri
Reported:	1-6 days
Note:	
CPT Codes:	86794
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

The possibility of false-positive or false-negative results must be considered. RT-PCR testing on both a serum and urine specimen is recommended by the Centers for Disease Control and Prevention (CDC) to rule out false-negative IgM results in patients experiencing symptoms for less than 2 weeks. Specimens collected for IgM testing greater than or equal to 2 weeks after symptom onset do not require any additional testing. For more information, please review the current clinical guidelines for Zika virus testing at: www.cdc.gov/zika/.

Reference Interval:

Negative

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.

TEST CHANGE

Platelet Antigen Genotyping Panel

3000193, HPA GENO

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (EDTA), pPink (K2EDTA~~), or Yellow (ACD Solution A or B~~).
Specimen Preparation:	Whole blood: Transport 3 mL whole blood. (Min: 1 mL)
Transport Temperature:	Whole blood specimen: Refrigerated.
Unacceptable Conditions:	Yellow (ACD solution A or B); frozen~~Frozen~~ specimens in glass collection tubes.
Remarks:	
Stability:	Whole blood specimen: Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Polymerase Chain Reaction (PCR)/Fluorescence Monitoring
Performed:	Varies
Reported:	7-14 days
Note:	
CPT Codes:	81105; 81106; 81107; 81108; 81109; 81110; 81112
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Refer to report.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

PA 1-6, 15 Polymorphism

HPA System	"a" Allele Common	"b" Allele Variant
HPA 1	T	C
HPA 2	C	T
HPA 3	T	G
HPA 4	G	A
HPA 5	G	A
HPA 6	G	A
HPA 15	C	A

Reference Interval:

NEW TEST – Available Now

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AAV5 Detect CDxTM -AAV5 Total Antibody Assay for ROCTAVIAN (valoctocogene roxaparvovec-rvox) Eligibility in Hemophilia A

3000959, AAV5 TAB

Specimen Requirements:	
Patient Preparation:	
Collect:	3.2% sodium citrate
Specimen Preparation:	Separate from cells ASAP or within 72 hours of collection. Transfer 1 mL plasma to an ARUP standard transport tube. (Min: 0.5 mL)
Transport Temperature:	Critical frozen
Unacceptable Conditions:	Hemolyzed specimens and lipemic specimens
Remarks:	Ship frozen specimens to ARUP as soon as possible. Collection Instructions: Collect the patient's whole blood in a 3.2% sodium citrate tube. Samples that exceed 7.3% sodium citrate cannot be evaluated and may require patient redraw. NOTE: When drawing blood for the AAV5 DetectCDx test, universal precautions for bloodborne pathogens should be observed. Centrifuge the specimen and separate the plasma within 72 hours of collection. Refer to your manufacturer's manual for recommended centrifuge speed and duration. Transfer 1 mL (minimum: 0.5 mL) of plasma into a polypropylene pour-off (transport) tube. Sample stability for the AAV5 DetectCDx has not been evaluated in tube types other than the ARUP transport tube (polypropylene). Failure to provide sufficient volume may result in the need for patient redraw. Label the transport tube with the patients first and last name, date of birth, and sex. Freeze plasma specimen at -10C or below. Ship frozen plasma specimens to ARUP as soon as possible. NOTE: Plasma specimens must be frozen before they are shipped to ARUP Laboratories.
Stability:	Frozen (-10 or colder): Acceptable, Refrigerated: Unacceptable, Ambient: Unacceptable
Methodology:	Qualitative Electrochemiluminescent Immunoassay (ECLIA)
Performed:	Mon-Fri
Reported:	8-10 days

Note:	Test validated for male patients only. 1. AAV5 DetectCDx is offered at no cost to evaluate eligibility for an FDA-approved indication. While the assay is provided at no cost, any other expenses, charges, services, costs, materials, or lab work that are not provided by ARUP are not covered under this program. No patient, private health plan, government health program, or any other individual or entity shall be billed for this serotype test and no reimbursement will be sought for any tests or materials provided at no cost in connection with such test. Access to the test at no cost is not contingent upon the recommendation, ordering, prescription, or purchase of any other product or service. 2. The test should be ordered using the ARUP test requisition form or via ARUP's web-based ordering interface (available only to existing ARUP clients). The full name of the ordering physician must be included on the ARUP form to ensure timely testing of the specimen. Specimens submitted with incomplete information may delay specimen testing. 3. To send a specimen to ARUP, contact your local hospital/reference lab to determine if they are an ARUP client and can send the specimen. If they cannot send the specimens to ARUP, contact ARUP Client Services at 800-522-2787 to be directed to an alternative ordering mechanism.
CPT Codes:	
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

The AAV5 Total Antibody Assay is indicated as an aid in the selection of adult hemophilia A patients for whom valoctocogene roxaparvovec treatment is being considered. Patients who have a result of Detected are not eligible for treatment with valoctocogene roxaparvovec; patients who have a result of Not Detected are eligible for treatment with valoctocogene roxaparvovec.

Reference Interval:

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

TEST CHANGE

Red Blood Cell Antigen Genotyping

3001053, RBC GENO

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (EDTA), Pink (K2EDTA~~), or Yellow (ACD Solution A or B~~).
Specimen Preparation:	Genotyping: Transport 3 mL whole blood. (Min: 1 mL)
Transport Temperature:	Whole blood: Refrigerated
Unacceptable Conditions:	Yellow (ACD solution A or B); plasma~~Plasma~~ or serum.~~;~~ C~~c~~ollection of specimens in sodium heparin tubes. Frozen specimens in glass collection tubes.
Remarks:	
Stability:	Whole blood specimen: Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month.
Methodology:	Polymerase Chain Reaction (PCR)/Fluorescence Monitoring
Performed:	Varies
Reported:	3-10 days
Note:	
CPT Codes:	0001U
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
Refer to report.	
Counseling and informed consent are recommended for genetic testing. Consent forms are available online.	
Reference Interval:	

TEST CHANGE

CYP2C8, CYP2C9, and CYP2C cluster

3001501, 2C8/2C9

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (EDTA), pink (K2EDTA), or yellow (ACD solution A or B).
Specimen Preparation:	Transport 3 mL whole blood. (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma or serum. Specimens collected in sodium heparin or lithium heparin. Frozen specimens in glass collection tubes.
Remarks:	
Stability:	Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Polymerase Chain Reaction (PCR)/Fluorescence Monitoring
Performed:	Varies
Reported:	5-10 days
Note:	Whole blood is the preferred specimen. Saliva samples that yield inadequate DNA quality and/or quantity will be reported as inconclusive if test performance does not meet laboratory-determined criteria for reporting.
CPT Codes:	81227; 81479
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Refer to report

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Couseling and informed consent are recommended for genetic testing. Consent forms are available online. ~~Background Information for CYP2C8, CYP2C9, and CYP2C cluster: Characteristics: The cytochrome P450 (CYP) isozymes 2C8 and 2C9 are involved in the metabolism of many drugs. Variants in the genes that code for CYP2C8 and CYP2C9 may influence pharmacokinetics of substrates, and may predict or explain nonstandard dose requirements,~~

~~therapeutic failure or adverse reactions. The CYP2C cluster variant (rs12777823) is associated with a decreased warfarin dose requirement in some people of African descent.~~
~~Inheritance: Autosomal codominant.~~
~~Cause: CYP2C8 and CYP2C9 gene variants and the CYP2C cluster variant affect enzyme function.~~
~~Variants Tested: See the "Additional Technical Information" document.~~
~~Clinical Sensitivity: Drug dependent.~~
~~Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.~~
~~Analytical Sensitivity and Specificity: Greater than 99 percent.~~
~~Limitations: Only the targeted CYP2C8,CYP2C9, and CYP2C cluster variants will be detected by this panel, and assumptions about phase and content are made to assign alleles. Publicly available sources such as the www.pharmvar.org or www.pharmgkb.org provide guidance on phenotype predictions and allele frequencies. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with CYP2C8 or CYP2C9 substrates may be affected by genetic and nongenetic factors that are not detected by this test. This result does not replace the need for therapeutic drug or clinical monitoring.~~

~~Please note the information contained in this report does not contain medication recommendations, and should not be interpreted as recommending any specific medications. Any dosage adjustments or other changes to medications should be evaluated in consultation with a medical provider.~~

~~Counseling and informed consent are recommended for genetic testing. Consent forms are available online.~~

Reference Interval:

By report

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.

TEST CHANGE

CYP2C19

3001508, 2C19GENO

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (EDTA), Pink (K2EDTA), or Yellow (ACD Solution A or B).
Specimen Preparation:	Transport 3 mL whole blood. (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma or serum. Specimens collected in sodium heparin or lithium heparin. Frozen specimens in glass collection tubes.
Remarks:	
Stability:	Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Polymerase Chain Reaction (PCR)/Fluorescence Monitoring
Performed:	Varies
Reported:	5-10 days
Note:	Whole blood is the preferred specimen. Saliva samples that yield inadequate DNA quality and/or quantity will be reported as inconclusive if test performance does not meet laboratory-determined criteria for reporting.
CPT Codes:	81225
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Refer to report~~Background Information for *CYP2C19*:~~
~~Characteristics: The cytochrome P450 (CYP) isozyme 2C19 is involved in the metabolism of many drugs. Variants in the gene that code for CYP2C19 will influence pharmacokinetics of CYP2C19 substrates, and may predict or explain non-standard dose requirements, therapeutic failure or adverse reactions.~~
~~Inheritance: Autosomal codominant.~~
~~Cause: *CYP2C19* gene variants affect enzyme function.~~
~~Variants Tested: See the Additional Technical Information document.~~
~~Clinical Sensitivity: Drug-dependent.~~
~~Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.~~
~~Analytical Sensitivity and Specificity: Greater than 99 percent.~~

~~Limitations: Only the targeted *CYP2C19* variants will be detected by this panel, and assumptions about phase and content are made to assign alleles. Publicly available sources such as the www.pharmvar.org or www.pharmgkb.org provide guidance on phenotype predictions and allele frequencies. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with CYP2C19 substrates may be affected by genetic and non-genetic factors that are not detected by this test. This result does not replace the need for therapeutic drug or clinical monitoring.~~

~~Please note the information contained in this report does not contain medication recommendations, and should not be interpreted as recommending any specific medications. Any dosage adjustments or other changes to medications should be evaluated in consultation with a medical provider.~~

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Cou~~n~~seling and informed consent are recommended for genetic testing. Consent forms are available online.

Reference Interval:

By report

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.

TEST CHANGE

CYP2D6

3001513, 2D6GENO

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (EDTA), p~~P~~ink (K2EDTA), or y~~Y~~ellow (ACD s~~S~~olution A or B).
Specimen Preparation:	Transport 3 mL whole blood. (Min: 1 mL)
Transport Temperature:	Refrigerated
Unacceptable Conditions:	Plasma or serum. Specimens collected in sodium heparin or lithium heparin. Frozen specimens in glass collection tubes.
Remarks:	
Stability:	Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Polymerase Chain Reaction (PCR)/~~/~~Fluorescence Monitoring/Sequencing
Performed:	Varies
Reported:	5-10 days
Note:	Whole blood is the preferred specimen type. Saliva samples that yield inadequate DNA quality and/or quantity will be reported as inconclusive if test performance does not meet laboratory-determined criteria for reporting. Saliva is only validated for the OpenArray and CNV portions of testing and not the long-range PCR/duplication testing. Long-range PCR/duplication testing will not be performed for saliva samples. If long-range PCR/duplication testing is performed, additional charges will apply. Approximately less than 5% of samples require 2D6 copy number determination.
CPT Codes:	81226; if reflexed, add 81479
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Refer to report~~Refer to report.~~

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was~~

~~performed in a CLIA certified laboratory and is inteded for clinical purposes~~.

Counseling and informed consent are recommended for genetic testing. Consent forms are avialable online.

Reference Interval:

By report

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.

TEST CHANGE

CYP3A4 and CYP3A5

3001518, 3A4/3A5

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (EDTA), p~~P~~ink (K2EDTA), or y~~Y~~ellow (ACD s~~S~~olution A or B).
Specimen Preparation:	Transport 3 mL whole blood. (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma or serum. Specimens collected in sodium heparin or lithium heparin. Frozen specimens in glass collection tubes.
Remarks:	
Stability:	Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Polymerase Chain Reaction (PCR)/Fluorescence Monitoring
Performed:	Varies
Reported:	5-10 days
Note:	Whole blood is the preferred specimen. Saliva samples that yield inadequate DNA quality and/or quantity will be reported as inconclusive if test performance does not meet laboratory-determined criteria for reporting.
CPT Codes:	81230; 81231
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Refer to report~~Refer to report~~

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Reference Interval:

By report

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.

TEST CHANGE

Cytochrome P450 Genotyping Panel

3001524, CYP PANEL

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (K2EDTA), p~~P~~ink (K2EDTA), or y~~Y~~ellow (ACD s~~S~~olution A or B).
Specimen Preparation:	Transport 3 mL whole blood. (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma or serum. Specimens collected in sodium heparin or lithium heparin. Frozen specimens in glass collection tubes.
Remarks:	
Stability:	Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Polymerase Chain Reaction (PCR)/~~/~~Fluorescence Monitoring/Sequencing
Performed:	Varies
Reported:	5-10 days
Note:	Whole blood is the preferred specimen type. Saliva samples that yield inadequate DNA quality and/or quantity will be reported as inconclusive if test performance does not meet laboratory-determined criteria for reporting. Saliva is only validated for the OpenArray and CNV portions of testing and not the long-range PCR/duplication testing. Long-range PCR/duplication testing will not be performed for saliva samples. If long-range PCR/duplication testing is performed, additional charges will apply. Approximately less than 5% of samples require 2D6 copy number determination.
CPT Codes:	81225; 81226; 81227; 81230; 81231; 81479; if reflexed, add 81479
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	

Refer to report~~Refer to report.~~

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It~~

~~has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes~~.

Couseling and informed consent are recommended for genetic testing. Consent forms are available online.

Reference Interval:

By report

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.

TEST CHANGE

TPMT and NUDT15

3001535, TPMT2

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (EDTA), p~~P~~ink (K2EDTA), or y~~Y~~ellow (ACD s~~S~~olution A or B).
Specimen Preparation:	Transport 3 mL whole blood. (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma or serum. Specimens collected in sodium heparin or lithium heparin. Frozen specimens in glass collection tubes.
Remarks:	
Stability:	Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Polymerase Chain Reaction (PCR)/Fluorescence Monitoring
Performed:	Varies
Reported:	5-10 days
Note:	Whole blood is the preferred specimen. Saliva samples that yield inadequate DNA quality and/or quantity will be reported as inconclusive if test performance does not meet laboratory-determined criteria for reporting.
CPT Codes:	81335; 81306
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Refer to report~~Refer to report~~

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Reference Interval:

By report

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.

TEST CHANGE

Warfarin Sensitivity (CYP2C9, CYP2C cluster, CYP4F2, VKORC1) Genotyping

3001541, WARF PAN

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (EDTA), Pink (K2EDTA), or Yellow (ACD Solution A or B).
Specimen Preparation:	Transport 3 mL whole blood. (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma or serum. Specimens collected in sodium heparin or lithium heparin. Frozen specimens in glass collection tubes.
Remarks:	
Stability:	Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Polymerase Chain Reaction (PCR)/Fluorescence Monitoring
Performed:	Varies
Reported:	5-10 days
Note:	Whole blood is the preferred specimen. Saliva samples that yield inadequate DNA quality and/or quantity will be reported as inconclusive if test performance does not meet laboratory-determined criteria for reporting.
CPT Codes:	81227; 81355; 81479
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Refer to report

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Couseling and informed consent are recommended for genetic testing. Consent forms are available online. ~~Background Information for Warfarin Sensitivity (*CYP2C9, CYP2C* cluster, *CYP4F2, VKORC1*) Genotyping:~~

~~Characteristics: Warfarin sensitivity can lead to a life-threatening overdose event such as excessive bleeding. Genetic variation is recognized to explain a large proportion of variability in~~

warfarin dose requirements. This test may predict individual warfarin sensitivity and non-standard dose requirements. The cytochrome P450 (CYP) isozyme 2C9 is involved in the metabolism of many drugs. Variants in the gene that codes CYP2C9 may influence pharmacokinetics of substrates such as warfarin, and may predict or explain nonstandard dose requirements, therapeutic failure, or adverse reactions. Variants in the *VKORC1* and *CYP4F2* genes may predict sensitivity to warfarin. The *CYP2C* cluster variant, rs12777823, common in people of African descent, with a minor allele frequency of approximately 25 percent, is found to be associated with warfarin dose in this population. Genetic information and nongenetic factors can be used in combination with warfarin dose calculators, such as through www.WarfarinDosing.org.
Inheritance: Autosomal codominant.
Cause: *CYP2C9* and *CYP2C* cluster variants are associated with reduced dose requirements. The *VKORC1*2* allele is associated with reduced expression of the warfarin target, vitamin K epoxide reductase (VKOR), and a reduced dose requirement. The *CYP4F2* variant is associated with an increased dose requirement.
Variants Tested: See the "Additional Technical Information" document.
Clinical Sensitivity: Genetic factors and known non-genetic factors account for approximately 50 percent of the variability in warfarin dose.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Only the targeted *CYP2C9, CYP2C* cluster, *CYP4F2,* and *VKORC1* variants will be detected by this panel, and assumptions about phase and content are made to assign alleles. Publicly available sources such as the www.pharmvar.org or www.pharmgkb.org provide guidance on phenotype predictions and allele frequencies. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with CYP2C9 substrates may be affected by genetic and nongenetic factors that are not detected by this test. This result does not replace the need for therapeutic drug or clinical monitoring.

Please note the information contained in this report does not contain medication recommendations, and should not be interpreted as recommending any specific medications. Any dosage adjustments or other changes to medications should be evaluated in consultation with a medical provider.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Reference Interval:

By report

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.

TEST CHANGE

Beckwith-Wiedemann Syndrome (BWS) and Russell-Silver Syndrome (RSS) by Methylation-Specific MLPA

3001635, BWS-RSS DD

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (EDTA), pPink (K2EDTA), or yYellow (ACD sSolution A)
Specimen Preparation:	Transport 3 mL whole blood. (Min: 12 mL)
Transport Temperature:	Refrigerated. Also acceptable: Ambient.
Unacceptable Conditions:	
Remarks:	
Stability:	Room temperatureAmbient: 1 week; Refrigerated: 1 month; Frozen: Unacceptable6 months
Methodology:	Multiplex Ligation-Ddependent Probe Amplification (MLPA)
Performed:	Varies
Reported:	12-14 days
Note:	
CPT Codes:	81401
New York DOH Approval Status:	Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.

Interpretive Data:

Refer to report. Characteristics of Beckwith-Wiedemann syndrome (BWS) and Russell-Silver syndrome (RSS): BWS is a phenotypically variable overgrowth syndrome associated with an increased risk for embryonal tumor development, neonatal hypoglycemia, macroglossia, macrosomia, hemihyperplasia, omphalocele, renal abnormalities, and ear creases or pits. RSS is characterized by pre- and postnatal growth deficiency, proportionate short stature, developmental delay, learning disabilities, limb-length asymmetry and distinctive faces.
Prevalence: BWS occurs 1 in 10,000-13,700 newborns; RSS 1 in 100,000 newborns.
Inheritance: BWS - 85 percent of cases are sporadic and 15 percent autosomal dominant; RSS - 60 percent of cases are sporadic, 40 percent unknown, rarely autosomal dominant or recessive.
Penetrance: RSS - complete; BWS - incomplete; individuals with a pathogenic CDKN1C variant will be asymptomatic if the variant is on the allele normally silenced due to imprinting.
Cause: BWS - 50 percent by loss of maternal methylation at imprinting center (IC)2, 20 percent by paternal uniparental disomy (UPD) of chromosome 11p15; 5 to 10 percent by pathogenic CDKN1C sequence variants, 5 percent by maternal methylation of IC1, 1 percent by chromosome rearrangements or duplications. RSS - 35 to 50 percent by paternal hypomethylation of IC1, 10

~~percent by maternal UPD of chromosome 7.~~
~~Clinical Sensitivity: 75 percent for BWS; 35-50 percent for RSS.~~
~~Methodology: Methylation-specific multiplex ligation probe amplification (MLPA).~~
~~Analytical Sensitivity and Specificity: 99 percent.~~
~~Limitations: This assay determines methylation patterns of IC1 and IC2 for chromosome 11p15. Disease mechanisms causing BWS and RSS that do not alter methylation patterns, such as sequence variants in *CDKN1C*, maternal UPD of chromosome 7 or chromosomal translocations, and inversions or duplications, will not be assessed. Diagnostic errors can occur due to rare sequence variations.~~

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

~~Counseling and informed consent are recommended for genetic testing. Consent forms are available online.~~

Reference Interval:

By r~~R~~eport

TEST CHANGE

Toxigenic Clostridioides~~um~~ difficile by LFA with Reflex to PCR, Stool

3001801, CDIFF LFA

Specimen Requirements:	
Patient Preparation:	
Collect:	Liquid or soft stool.
Specimen Preparation:	Transfer 1.0 mL stool to a clean, unpreserved transport vial (ARUP Supply# 40910). Available online through eSupply using ARUP Connect (TM)~~2~~ or contact ARUP Client Services at 800-522-2787. (Min: 0.5 mL).
Transport Temperature:	Refrigerated. Also acceptable: Frozen.
Unacceptable Conditions:	Specimens preserved in Cary Blair/C&S media, formalin-based fixative (eg, Formalin, SAF) or alcohol-based fixative (eg, PVA, Totalfix, Alcorfix, etc). Formed stool.
Remarks:	
Stability:	Ambient 2 hours; Refrigerated 72 hours; Frozen 1 week
Methodology:	Qualitative Lateral Flow Immunoassay/Qualitative Polymerase Chain Reaction (PCR)
Performed:	Sun-Sat
Reported:	Within 24 hours
Note:	If C. difficile GDH antigen is detected by LFA but C. difficile toxin is not detected, C. difficile tcdB gene by PCR will be performed;~~,~~ additional charges apply.
CPT Codes:	87324; 87899; if reflexed, add 87493
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
Refer to report	
Reference Interval:	
Not Detected	

TEST CHANGE

Myotonic Dystrophy Type 1 (DMPK) CTG Expansion

3001907, DM1 PCR

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (K2EDTA), p~~P~~ink (K2EDTA), or y~~Y~~ellow (ACD s~~S~~olution A or B).
Specimen Preparation:	Transport 3~~5~~ mL whole blood. (Min: 1~~3~~ mL)
Transport Temperature:	Refrigerated. Also acceptable: Ambient.
Unacceptable Conditions:	
Remarks:	
Stability:	Room temperature~~Ambient~~: 1 week; Refrigerated: 1 month; Frozen: Unacceptable~~6 months~~
Methodology:	Polymerase Chain Reaction(PCR)/~~/~~Capillary Electrophoresis
Performed:	Varies
Reported:	7-10 days
Note:	
CPT Codes:	81234
New York DOH Approval Status:	Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.

Interpretive Data:

Refer to report ~~Interpretive Data:~~
~~Background Information for Myotonic Dystrophy Type 1 (*DMPK*):~~
~~Characteristics: Myotonic dystrophy type 1 (DM1) is a multisystem disorder characterized by myotonic myopathy with involvement of the eye, heart, endocrine system and central nervous system. Clinical findings span a continuum from mild to severe, with overlap in the three recognized clinical subtypes of DM1: mild, classic and congenital. Mild DM1 is adult-onset and features include mild myotonia and premature cataracts or baldness. Onset of classic DM1 is typically between 10-30 years of age and findings include distal muscle weakness, myotonia, cataracts, GI disturbances, and cardiac conduction abnormalities. Congenital DM1 may present prenatally with polyhydramnios and reduced fetal movement, and postnatal features commonly include infantile hypotonia, respiratory insufficiency, facial diplegia, and intellectual disability.~~
~~Prevalence: 1:20,000.~~
~~Inheritance: Autosomal dominant.~~
~~Penetrance: Age-related, approaches 100 percent by age 50.~~
~~Cause: Expanded number of CTG repeats in the *DMPK* gene.~~

Normal: 5-34 CTG repeats, stably transmitted, not associated with DM1 manifestations.
Premutation: 35-49 CTG repeats, may be unstably transmitted, not associated with DM1 manifestations.
Full-penetrance disease allele: 50 or more CTG repeats, unstably transmitted, associated with DM1 manifestations.
Clinical Sensitivity: >99 percent for DM1.
Methodology: Triplet repeat-primed polymerase chain reaction (PCR) followed by size analysis using capillary electrophoresis to assess the CTG repeat in the *DMPK* 3' untranslated region.
Specific allele sizing estimates cannot be determined for CTG repeats of >150. Repeat sizing precision is approximately +/- 2 repeats for alleles with 5-24 repeats and +/- 4 repeats for alleles with 77 to 150 repeats.
Analytical Sensitivity and Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. This assay will not detect myotonic dystrophy type 2.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Phenotype	Number of CTG Repeats
Normal allele	Less than or equal to 34
Premutation	35-49
Mild	50-approx. 150
Classic	Approx.100-approx.100-approx 1000
Congenital	>1000

Reference Interval:

By report

TEST CHANGE

Kell K/k (KEL) Antigen Genotyping

3002001, KEL GENO

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (K2EDTA), pink (K2EDTA~~), or yellow (ACD Solution A or B~~).
Specimen Preparation:	Genotyping: Tranport 3 mL whole blood. (Min: 1 mL)
Transport Temperature:	Whole blood specimen: Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month.
Unacceptable Conditions:	Yellow (ACD solution A or B); plasma~~Plasma~~ or serum. Specimens collected in sodium heparin tubes. Frozen specimens in glass collection tubes.
Remarks:	Patient History Form is available on the ARUP website or by contacting ARUP Client Services.
Stability:	Whole blood: Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Polymerase Chain Reaction (PCR)/Fluorescence Monitoring
Performed:	Varies
Reported:	3-10 days
Note:	
CPT Codes:	0001U
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
Refer to report	
Counseling and informed consent are recommended for genetic testing. Consent forms are available online.	
Reference Interval:	
By report.	

TEST CHANGE

RhC/c (RHCE) Antigen Genotyping

3002002, RHC GENO

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (K2EDTA), pink (K2EDTA~~), or yellow (ACD Solution A or B~~).
Specimen Preparation:	Whole blood: Transport 3 mL whole blood. (Min: 1 mL)
Transport Temperature:	Whole blood specimen: Refrigerated.
Unacceptable Conditions:	Yellow (ACD solution A or B); plasma~~Plasma~~ or serum. Specimens collected in sodium heparin tubes. Frozen specimens in glass collection tubes.
Remarks:	Patient History Form is available on the ARUP website or by contacting ARUP Client Services.
Stability:	Whole blood: Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Polymerase Chain Reaction (PCR)/Fluorescence Monitoring
Performed:	Varies
Reported:	3-10 days
Note:	
CPT Codes:	0001U
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Refer to report.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Reference Interval:

By report

TEST CHANGE

RhE/e (RHCE) Antigen Genotyping

3002003, RHE GENO

Specimen Requirements:	
Patient Preparation:	
Collect:	Parental genotyping: Lavender (K2EDTA), pink (K2EDTA~~) or Yellow (ACD Solution A or B~~).
Specimen Preparation:	Whole blood: Transport 3 mL whole blood. (Min: 1 mL)
Transport Temperature:	Whole blood specimen: Refrigerated.
Unacceptable Conditions:	Yellow (ACD solution A or B); plasma~~Plasma~~ or serum. Specimens collected in sodium heparin tubes. Frozen specimens in glass collection tubes.
Remarks:	Patient History Form is available on the ARUP Web site or by contacting ARUP Client Services.
Stability:	Whole blood specimen: Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Polymerase Chain Reaction (PCR)/Fluorescence Monitoring
Performed:	Varies
Reported:	3-10 days
Note:	
CPT Codes:	0001U
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Refer to report.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Reference Interval:

By report

TEST CHANGE

Clobazam and Metabolite, Quantitative, Serum or Plasma

3002508, CLOBAZAM

Specimen Requirements:	
Patient Preparation:	
Collect:	Plain red, lavender~~Red, Lavender~~ (K2 or K3EDTA) or p~~P~~ink (K2EDTA).
Specimen Preparation:	Separate from cells ASAP or within two hours of collection. Transfer 2 mL serum or plasma to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 0.3 mL)
Transport Temperature:	Refrigerated. Also acceptable: Room temperature or frozen.
Unacceptable Conditions:	Gel separator tubes. Hemolyzed specimens.
Remarks:	
Stability:	Ambient: 3 days; Refrigerated: 2 weeks; Frozen: 2 months (Avoid repeated freeze thaw cycles)
Methodology:	Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Mon, Wed, Sat
Reported:	1-6~~5~~ days
Note:	
CPT Codes:	80339 (Alt code: G0480)
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Clobazam is a benzodiazepine drug indicated for adjunctive treatment for seizures associated with Lennox-Gastaut syndrome in patients 2 years and older. The therapeutic range is based on serum, predose~~pre-dose~~ (trough) draw collection at steady-state concentration. The pharmacokinetics of clobazam are influenced by drug-drug interactions and by poor CYP2C19 metabolism. Adverse effects may include constipation, somnolence, sedation, and skin rash. The concomitant use of clobazam with other central nervous system (CNS) depressants may increase the risk of somnolence and sedation.

Components	Interpretive Data
Clobazam	Toxic: Greater than 500 ng/mL
N-Desmethylclobazam	Toxic: Greater than 5000 ng/mL

Reference Interval:

Test Number	Components	Reference Interval
	Clobazam	30-300 ng/mL
	N-Desmethylclobazam	300-3000 ng/mL

TEST CHANGE

Phosphatidylethanol (PEth), Whole Blood, Quantitative

3002598, PETH

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (K2 or K3EDTA), pink~~K3 EDTA), Pink~~ (K2EDTA), g~~G~~reen (lithium heparin), or g~~G~~ray (potassium oxalate).
Specimen Preparation:	Transport 1 mL whole blood. (Min: 0.5 mL)
Transport Temperature:	Refrigerated. Also acceptable: Frozen.
Unacceptable Conditions:	Gel separator tubes, plain red~~Plain Red~~, light blue (citrate), or yellow (SPS or ACD solution).
Remarks:	
Stability:	Ambient: 2 hours; Refrigerated: 2 weeks; Frozen: 1 month (-20 Degrees C)
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Sun-Sat
Reported:	1-4 days
Note:	
CPT Codes:	80321 (Alt code: G0480)
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Phosphatidylethanol (PEth) is a group of phospholipids formed in the presence of ethanol, phospholipase D, and phosphatidylcholine. PEth is known to be a direct alcohol biomarker. The predominant PEth homologues are PEth 16:0/18:1 (POPEth) and PEth 16:0/18:2 (PLPEth), which account for 37-46% and 26-28% of the total PEth homologues, respectively. PEth is incorporated into the phospholipid membrane of red blood cells and has a general half-life of 4-~~-~~10 days and a window of detection of 2-~~-~~4 weeks. However, the window of detection is longer in individuals who chronically or excessively consume alcohol. Serial monitoring of PEth may be helpful in monitoring alcohol abstinence over time.~~;—~~PEth results should be interpreted in the context of the patient's clinical and behavioral history. Patients with advanced liver disease may have falsely elevated PEth concentrations (Nguyen VL, et al~~ 2018~~, Alcoholism: Clinical and~~&~~ Experimental Research, 2018).

Reference Interval:

Effective September 8, 2020

By Report

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.

TEST CHANGE

Hepatitis Panel, Acute with Reflex to HBsAg Confirmation and Reflex to HCV by Quantitative NAAT

3002989, HEPACUTEQR

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube (SST) or Pink (K2EDTA).
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transfer 3 mL serum to an ARUP Standard Transport Tube. (Min: 2.0 mL) Also acceptable: K2EDTA plasma. This test requires a dedicated transport tube submitted only for HEPACUTEQR testing.
Transport Temperature:	Frozen.
Unacceptable Conditions:	Heparinized plasma. Specimens containing particulate material. Heat-inactivated, severely hemolyzed, or lipemic specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 12 hours~~Unacceptable~~; Refrigerated: 5 days; Frozen: 2 months (avoid freeze/thaw cycles)
Methodology:	Qualitative Chemiluminescent Immunoassay (CLIA)/Quantitative Transcription-Mediated Amplification (TMA)
Performed:	Sun-Sat
Reported:	1-2 days
Note:	Order this panel when the patient has had clinical acute hepatitis of unknown origin for less than six months. If results for HBsAg are repeatedly reactive with an index value between 1.00 and 50.00, then HBsAg Confirmation will be added. If the anti-HCV antibody result is positive, then Hepatitis C Virus by Quantitative NAAT will be added. Additional charges apply.
CPT Codes:	80074; if reflexed, add 87341, and 87522
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	

Component	Interpretation
Hepatitis C Antibody by CIA Interp	0.79 IV or less Negative 0.80 to 0.99 IV Equivocal 1.00 to 10.99 IV Low Positive 11.00 IV or greater High Positive

Reference Interval:

Test Number	Components	Reference Interval
	Hepatitis B Surface Antigen	Negative
	Hepatitis C Antibody by CIA Interp	Negative
	Hepatitis B Core Antibody, IgM	Negative
	Hepatitis A Antibody, IgM	Negative

TEST CHANGE

ANCA-Associated Vasculitis Profile (ANCA/MPO/PR3)

3003745, ANCA-PRO

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube.
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 0.5 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	CSF, plasma, urine, or other body fluids. Contaminated, hemolyzed, or severely lipemic specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 30 days~~1 year~~ (avoid repeated freeze/thaw cycles)
Methodology:	Semi-Quantitative Indirect Fluorescent Antibody (IFA)/Semi-Quantitative Multiplex Bead Assay
Performed:	Sun-Sat
Reported:	2-5 days
Note:	Specimens are screened for ANCA, MPO, and PR3. ANCA IFA is simultaneously tested on ethanol- and formalin-fixed slides to allow differentiation of C- and P-ANCA patterns.
CPT Codes:	83516 x2; 86036
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Refer to report.

Component	Interpretation
Myeloperoxidase (MPO) Antibody	19 AU/mL or less: Negative 20-25 AU/mL: Equivocal 26 AU/mL or greater: Positive
Serine Proteinase	19 AU/mL or less:

3 (PR3) Antibody	Negative 20-25 AU/mL: Equivocal 26 AU/mL or greater: Positive

Reference Interval:

Test Number	Components	Reference Interval
	Myeloperoxidase (MPO) Ab, IgG	19 AU/mL or less
	Serine Proteinase 3 (PR3) Ab, IgG	19 AU/mL or less
	ANCA IFA Pattern	None Detected
	ANCA IFA Titer	Less than 1:20

TEST CHANGE

Anti-Neutrophil Cytoplasmic Antibody, IgG by IFA

3003747, ANCA-IFA

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube.
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP standard transport tube. ~~Standard Transport Tube.~~ (Min: 0.15 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma, urine, or other body fluids. Contaminated, hemolyzed, or severely lipemic specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 30 days ~~1 year~~ (avoid repeated freeze/thaw cycles)
Methodology:	Semi-Quantitative Indirect Fluorescent Antibody (IFA)
Performed:	Sun-Sat
Reported:	1-3 days
Note:	ANCA IFA is simultaneously tested on ethanol- and formalin-fixed slides to allow differentiation of C- and P-ANCA patterns.
CPT Codes:	86036
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Neutrophil Cytoplasmic Antibodies (C-ANCA = granular cytoplasmic staining, P-ANCA = perinuclear staining) are found in the serum of over 90 percent of patients with certain necrotizing systemic vasculitides, and usually in less than 5 percent of patients with collagen vascular disease or arthritis.

Reference Interval:

ANCA IFA Titer	Less than 1:20
ANCA IFA Pattern	None Detected

TEST CHANGE

Inflammatory Bowel Disease Differentiation Panel

3003748, IBD-PAN

Specimen Requirements:	
Patient Preparation:	N/A
Collect:	Serum Separator Tube (SST).
Specimen Preparation:	Separate from cells ASAP or within 2 hours of collection. Transfer 1.5 mL serum to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 0.6 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Contaminated, heat-inactivated, hemolyzed, or severely lipemic specimens.
Remarks:	N/A
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 30 days~~1 year~~ (avoid repeated freeze/thaw cycles)
Methodology:	Semi-Quantitative Indirect Fluorescent Antibody (IFA)/Semi-Quantitative Enzyme Immunoassay (EIA)
Performed:	Sun-Sat
Reported:	1-4 days
Note:	This test may be a useful tool for distinguishing ulcerative colitis (UC) from Crohn disease (CD) in patients with suspected inflammatory bowel disease. ANCA IFA is simultaneously tested on ethanol- and formalin-fixed slides to allow differentiation of C- and P-ANCA patterns.
CPT Codes:	86036; 86671 x2
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
Refer to report.	
Reference Interval:	

Test Number	Components	Reference Interval		
	S. cerevisiae Antibody, IgG			
		20.0 Units or less	Negative	
		20.1-24.9 Units	Equivocal	
		25.0 Units or greater	Positive	
	S. cerevisiae Antibody, IgA			
		20.0 Units or less	Negative	
		20.1-24.9 Units	Equivocal	
		25.0 Units or greater	Positive	
	ANCA IFA Titer	Less than 1:20		
	ANCA IFA Pattern	None Detected		

TEST CHANGE

Cytochrome P450 Genotyping Panel, with GeneDose Access

3004255, CYP GD

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (K2EDTA), p~~P~~ink (K2EDTA), or y~~Y~~ellow (ACD s~~S~~olution A or B).
Specimen Preparation:	Transport 3 mL whole blood. (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma or serum. Specimens collected in sodium heparin or lithium heparin. Frozen specimens in glass collection tubes.
Remarks:	
Stability:	Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Polymerase Chain Reaction/Fluorescence Monitoring/Sequencing
Performed:	Varies
Reported:	5-10 days
Note:	Whole blood is the preferred specimen type. Saliva samples that yield inadequate DNA quality and/or quantity will be reported as inconclusive if test performance does not meet laboratory-determined criteria for reporting. Saliva is only validated for the OpenArray and CNV portions of testing and not the long-range PCR/duplication testing. Long-range PCR/duplication testing will not be performed for saliva samples. If long-range PCR/duplication testing is performed, additional charges will apply. Approximately less than 5% of samples require 2D6 copy number determination.
CPT Codes:	81225; 81226; 81227; 81230; 81231; 81479; if reflexed, add 81479
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	

Refer to report~~Refer to report.~~

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It~~

~~has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes~~.

Couseling and informed consent are recommended for genetic testing. Consent forms are available online.

Reference Interval:

By report

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.

TEST CHANGE

CYP2B6

3004310, 2B6GENO

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (EDTA), pink (K2EDTA), or yellow (ACD solution A or B).
Specimen Preparation:	Transport 3 mL whole blood. (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma or serum. Specimens collected in sodium heparin or lithium heparin. Frozen specimens in glass collection tubes.
Remarks:	
Stability:	Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Polymerase Chain Reaction (PCR)/Fluorescence Monitoring
Performed:	Varies
Reported:	5-10 days
Note:	Whole blood is the preferred specimen. Saliva samples that yield inadequate DNA quality and/or quantity will be reported as inconclusive if test performance does not meet laboratory-determined criteria for reporting.
CPT Codes:	81479
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Refer to report.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online. ~~Refer to report.~~

Reference Interval:

By report

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.

TEST CHANGE

Pharmacogenetics Panel: Psychotropics

3004471, PGX PSYCH

Specimen Requirements:	
Patient Preparation:	
Collect:	Whole Blood: Lavender (EDTA), pink (K2EDTA), or yellow (ACD solution A or B).
Specimen Preparation:	Transport 3 mL whole blood. (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma or serum. Specimens collected in sodium heparin or lithium heparin. Frozen specimens in glass collection tubes.
Remarks:	
Stability:	Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Polymerase Chain Reaction (PCR)/~~/~~Fluorescence Monitoring/Sequencing
Performed:	Varies
Reported:	5-10 days
Note:	Whole blood is the preferred specimen type. Saliva samples that yield inadequate DNA quality and/or quantity will be reported as inconclusive if test performance does not meet laboratory-determined criteria for reporting. Saliva is only validated for the OpenArray and CNV portions of testing and not the long-range PCR/duplication testing. Long-range PCR/duplication testing will not be performed for saliva samples. If long-range PCR/duplication testing is performed, additional charges apply. Approximately less than 5% of samples require 2D6 copy number determination.
CPT Codes:	81225; 81226; 81227; 81230; 81231; 81291; 81479; if reflexed, add 81479
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	

Refer to report~~Refer to report~~

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It~~

has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Reference Interval:

By report

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.

TEST CHANGE

Pharmacogenetics Panel: Psychotropics, with GeneDose Access

3006366, PGXPSYC GD

Specimen Requirements:	
Patient Preparation:	
Collect:	Whole Blood: Lavender (EDTA), pink (K2EDTA), or yellow (ACD solution A or B).
Specimen Preparation:	Transport 3 mL whole blood. (Min: 1 mL)
Transport Temperature:	Refrigerated
Unacceptable Conditions:	Plasma or serum. Specimens collected in sodium heparin or lithium heparin. Frozen specimens in glass collection tubes.
Remarks:	
Stability:	Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Polymerase Chain Reaction (PCR)/Fluorescence Monitoring/Sequencing
Performed:	Varies
Reported:	5-10 days
Note:	Whole blood is the preferred specimen type. Saliva samples that yield inadequate DNA quality and/or quantity will be reported as inconclusive if test performance does not meet laboratory-determined cirteria for reporting. Saliva is only validated for the OpenArray and CNV portions of testing and not the long-range PCR/duplication testing. Long-range PCR/duplication testing will not be performed for saliva samples. If long-range PCR/duplication testing is performed, additional charges apply. Approximately less than 5% of samples require 2D6 copy number determination.
CPT Codes:	81225; 81226; 81227; 81230; 81231; 81291; 81479; if reflexed, add 81479
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	

Refer to report~~Refer to report.~~

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It~~

has not been cleared or approved by the U.S. Food and Drug Administration. This test was performed in a CLIA-certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Reference Interval:

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.

NEW TEST – Available Now

Click for Pricing

CD103 by Immunohistochemistry

3016552, CD103 IHC

Specimen Requirements:	
Patient Preparation:	
Collect:	Tissue
Specimen Preparation:	Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (ARUP supply #47808). Available online through eSupply using ARUP Connect or contact ARUP Client Services at 800-522-2787. (Min: 2 slides). If sending precut slides, do not oven bake.
Transport Temperature:	Room temperature or refrigerated. Ship in cooled container during summer months.
Unacceptable Conditions:	Tissue or cells not processed and placed in a paraffin block; serum, blood, or other body fluids; tissue not mounted on positively charged slides.
Remarks:	
Stability:	Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Methodology:	Immunohistochemistry (IHC)
Performed:	Mon-Fri
Reported:	1-3 days
Note:	This test is performed as a stain and return (technical) service only.
CPT Codes:	88342
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	

Reference Interval:

Test Number	Components	Reference Interval

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

NEW TEST – Available Now

Click for Pricing

Annexin A1 by Immunohistochemistry

3016561, ANNEX IHC

Specimen Requirements:	
Patient Preparation:	
Collect:	Tissue
Specimen Preparation:	Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a Tissue Transport Kit (ARUP supply #47808 highly recommended) available online through eSupply using ARUP Connect or contact ARUP Client Services at 800-522-2787 (Min: 2 slides). If sending precut slides, do not oven bake.
Transport Temperature:	Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Unacceptable Conditions:	Tissue or cells not processed and placed in a paraffin block; serum, blood, or other body fluids; tissue not mounted on positively charged slides.
Remarks:	
Stability:	Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Methodology:	Immunohistochemistry (IHC)
Performed:	Mon-Fri
Reported:	1-3 days
Note:	This test is performed as a stain and return (technical) service only.
CPT Codes:	88342
New York DOH Approval Status:	Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.
Interpretive Data:	

Reference Interval:

Test Number	Components	Reference Interval

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

NEW TEST – Available Now

Click for Pricing

INSM1 by Immunohistochemistry

3016567, INSM1 IHC

Specimen Requirements:	
Patient Preparation:	
Collect:	Tissue
Specimen Preparation:	Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (recommended but not required). ARUP supply #47808 available online through eSupply using ARUP Connect or contact ARUP Client Services at (800) 522-2787. (Min: 2 slides) If sending precut slides, do not oven bake.
Transport Temperature:	Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Unacceptable Conditions:	Specimens submitted with non-representative tissue type. Depleted specimens.
Remarks:	
Stability:	Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Methodology:	Immunohistochemistry
Performed:	Mon-Fri
Reported:	1-3 days
Note:	This test is performed as a stain and return (technical) service only.
CPT Codes:	88342
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
Reference Interval:	

Test Number	Components	Reference Interval

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

NEW TEST

Click for Pricing

Bladder Cancer by FISH

3016627, BC REQUEST

Specimen Requirements:	
Patient Preparation:	
Collect:	Second-morning, clean-catch voided urine specimen collected in PreservCyt collection vial included in UroCyte Urine Collection Kit (ARUP Supply #41440). Collection kit is available online through eSupply using ARUP Connector contact Client Services at 800-522-2787. For specific instructions refer to Specimen Collection & Handling.
Specimen Preparation:	Specimens must be transported in PreservCyt fixative. Acceptable sources are voided urine, bladder washings, ureteral washings, or urethral washings. (Min: 35 mL)
Transport Temperature:	Ambient or refrigerated
Unacceptable Conditions:	Unfixed specimens not in PreservCyt fixative. Frozen specimens. Specimens submitted in expired collection vials.
Remarks:	Submit source information with the specimen.
Stability:	Ambient: 1 week from collection; Refrigerated: 1 week from collection; Frozen: Unacceptable
Methodology:	Qualitative Fluorescence in situ Hybridization (FISH)/Computer Assisted Analysis/Microscopy
Performed:	Mon-Fri
Reported:	4-14 days
Note:	
CPT Codes:	88121
New York DOH Approval Status:	Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.

Interpretive Data:

NEGATIVE results indicate a lack of evidence for the presence of numeric chromosomal abnormalities commonly associated with urothelial carcinoma within the cells collected in this specimen. Negative results in the presence of other symptoms/signs of urothelial carcinoma may suggest the possibility of a false negative test. In this circumstance, additional clinical studies to

exclude urothelial carcinoma should be pursued, as clinically indicated. Although this test was designed to detect genetic abnormality associated with most urothelial cancers, there will be some urothelial cancers whose genetic changes cannot be detected by this test.

POSITIVE results indicate the presence of one or more numeric chromosomal abnormalities commonly associated with urothelial carcinoma within the cells collected in this specimen. Positive results in the absence of clinical documentation of urothelial carcinoma within the bladder suggest the possibility of urothelial carcinoma or other urologic malignancy from another site (including ureter, kidney, urethra, and prostate). In this circumstance, further clinical evaluation to exclude these as a source of the abnormal cells is justified.

The Oxford Gene Technology, Inc. probes were used to detect aneuploidy for chromosomes 3, 7, and 17 via fluorescence in situ hybridization (FISH). Results from this test are intended for use, in conjunction with and not in lieu of current standard diagnostic procedures, as an aid for initial diagnosis of urothelial carcinoma and for monitoring for tumor recurrence in conjunction with cystoscopy in patients with previously diagnosed bladder cancer.

Reference Interval:

Negative: No evidence of numeric chromosomal aberrations associated with urothelial carcinoma identified.
Positive: Numeric chromosomal aberrations associated with urothelial carcinoma identified.

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

NEW TEST – Available Now

Click for Pricing

Trypsin, Serum

3016694, TRY

Specimen Requirements:	
Patient Preparation:	Allow specimen to clot for 15-20 minutes at room temperature Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP standard transport tube. (Min: 0.3 mL)
Collect:	Serum separator tube (SST) or plain red.
Specimen Preparation:	Allow specimen to clot for 15-20 minutes at room temperature Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP standard transport tube. (Min: 0.3 mL)
Transport Temperature:	Frozen
Unacceptable Conditions:	Plasma or cord blood. Grossly hemolyzed or lipemic specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 2 hours; Refrigerated: 24 hours; Frozen: 3 months
Methodology:	Quantitative Radioimmunoassay (RIA)
Performed:	Tue, Fri
Reported:	1-5 days
Note:	
CPT Codes:	83519
New York DOH Approval Status:	Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.

Interpretive Data:

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

Reference Interval:

Test Number	Components	Reference Interval		
	Trypsin			
		Age	Reference Interval (ng/mL)	
		0-17 years	Not established	
		18 years and older	180.5-885.3	

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

NEW TEST

Click for Pricing

Borrelia burgdorferi VlsE1/pepC10 Antibodies, CSF, Total by ELISA With Reflex to IgM and IgG by Immunoblot (Standard Two-Tier Testing, CSF)

3016760, LYME STTTC

Specimen Requirements:	
Patient Preparation:	
Collect:	CSF.
Specimen Preparation:	Transfer 6 mL CSF to an ARUP standard transport tube. (Min: 2.5 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Bacterially contaminated, heat-inactivated, hemolyzed, or xanthochromic specimens.
Remarks:	
Stability:	Ambient: 8 hours; Refrigerated: 2 weeks; Frozen: 1 month (avoid repeated freeze/thaw cycles)
Methodology:	Semi-Quantitative Enzyme-Linked Immunosorbent Assay (ELISA)/Qualitative Immunoblot
Performed:	Sun-Sat
Reported:	1-4 days
Note:	If VlsE1/pepC10 antibodies by ELISA is 0.91 IV or greater, then B. burgdorferi IgG antibody by immunoblot and IgM antibody by immunoblot will be added. Additional charges apply.
CPT Codes:	86618; if reflexed, add 86617 x2
New York DOH Approval Status:	Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.

Interpretive Data:

The detection of antibodies to Borrelia burgdorferi in cerebrospinal fluid may indicate central nervous system infection. However, consideration must be given to possible contamination by blood or transfer of serum antibodies across the blood-brain barrier. Lyme disease diagnosis in serum is recommended prior to any CSF studies.

Component	Interpretation
B. burgdorferi VlsE1/pepC10	0.90 IV or less: Negative; VlsE1

Abs, ELISA	and pepC10 antibodies to B. burgdorferi not detected. 0.91-1.09 IV: Equivocal; repeat testing in 10-14 days may be helpful. 1.10 IV or greater: Positive; VlsE1 and pepC10 antibodies to B. burgdorferi detected.	

Reference Interval:

Test Number	Components	Reference Interval
	B. burgdorferi VlsE1/pepC10 Abs, CSF	0.90 IV or less

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

NEW TEST – Available Now

Click for Pricing

Anti-Phospholipase A2 Receptor (PLA2R) Antibody, IgG by ELISA

3016767, ANTI-PLA2R

Specimen Requirements:	
Patient Preparation:	Separate serum from cells ASAP or within 2 hours of collection.
Collect:	Serum separator tube.
Specimen Preparation:	Transfer 1 mL serum to an ARUP standard transport tube. (Min: 0.5 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Contaminated, heat-inactivated, grossly hemolyzed, grossly icteric, or grossly lipemic specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 2 weeks
Methodology:	Semi-Quantitative Enzyme-Linked Immunosorbent Assay (ELISA)
Performed:	Mon, Wed, Thu, Fri
Reported:	1-4 days
Note:	
CPT Codes:	83516
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

A positive anti-phospholipase A2 receptor (PLA2R) antibody result by ELISA or IFA in conjunction with clinical symptoms and other laboratory findings is suggestive of primary membranous nephropathy (pMN). Absence of circulating anti-PLA2R receptor autoantibodies does not rule out a diagnosis of pMN. Anti-PLA2R antibody titers, due to its high predictive value, can be useful for assessing disease severity and monitoring clinical remission. In patients with pMN undergoing treatment, low antibody titers are associated with disease remission and high titers indicate loss of kidney function and need for an aggressive therapeutic approach.

Component	Interpretive Data
Anti-Phospholipase A2 Receptor, IgG	Negative: Less than 14 RU/mL Borderline: 14-19

	RU/mL Positive: Greater than or equal to RU/mL	

Reference Interval:

Test Number	Components	Reference Interval
	Anti-Phospholipase A2 Receptor, IgG	< 14 RU/mL

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

NEW TEST – Available Now

Click for Pricing

SSTR2 by Immunohistochemistry

3016782, SSTR2 IHC

Specimen Requirements:	
Patient Preparation:	
Collect:	Tissue or cells.
Specimen Preparation:	Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a Tissue Transport Kit (ARUP supply #47808 highly recommended) available online through eSupply using ARUP Connect or contact ARUP Client Services at 800-522-2787 (Min: 2 slides). If sending precut slides, do not oven bake.
Transport Temperature:	
Unacceptable Conditions:	Tissue or cells not processed and placed in a paraffin block; serum, blood, or other body fluids; tissue not mounted on positively charged slides.
Remarks:	IMMUNOHISTOCHEMISTRY ORDERING AND SUBMISSION DETAILS: Submit electronic request. If you do not have electronic ordering capability, use an ARUP Immunohistochemistry Stain Form (#32978) with an ARUP client number. For additional technical details, contact ARUP Client Services at 800-522-2787.
Stability:	Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Methodology:	Immunohistochemistry
Performed:	Mon-Fri
Reported:	1-3 days
Note:	This test is performed as a stain and return (technical) service only.
CPT Codes:	88342

New York DOH Approval Status: This test is New York DOH approved.

Interpretive Data:

Reference Interval:

Test Number	Components	Reference Interval

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

NEW TEST – Available Now

Click for Pricing

OLIG2 by Immunohistochemistry

3016788, OLIG2 IHC

Specimen Requirements:	
Patient Preparation:	
Collect:	Tissue or cells.
Specimen Preparation:	Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a Tissue Transport Kit (ARUP supply #47808 highly recommended) available online through eSupply using ARUP Connect or contact ARUP Client Services at 800-522-2787 (Min: 2 slides). If sending precut slides, do not oven bake.
Transport Temperature:	
Unacceptable Conditions:	Specimens submitted with nonrepresentative tissue type. Depleted specimens.
Remarks:	IMMUNOHISTOCHEMISTRY ORDERING AND SUBMISSION DETAILS: Submit electronic request. If you do not have electronic ordering capability, use an ARUP Immunohistochemistry Stain Form (#32978) with an ARUP client number. For additional technical details, contact ARUP Client Services at 800-522-2787.
Stability:	Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Methodology:	Immunohistochemistry
Performed:	Mon-Fri
Reported:	1-3 days
Note:	This test is performed as a stain and return (technical) service only.
CPT Codes:	88342
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Reference Interval:

Test Number	Components	Reference Interval

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

NEW TEST

Click for Pricing

Recoverin Antibody, IgG by Immunoblot, Serum

3016794, RECOV SER

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube.
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP standard transport tube. (Min: 0.30 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma. Contaminated, heat-inactivated, hemolyzed, or lipemic specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 month
Methodology:	Qualitative Immunoblot
Performed:	Mon, Thu, Sat
Reported:	1-4 days
Note:	
CPT Codes:	84182
New York DOH Approval Status:	Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.

Interpretive Data:

Antibodies to recoverin are found in a subset of patients with cancer-associated retinopathy. Symptoms of rapidly progressive bilateral vision loss may precede detection of cancer, and a positive test result should prompt a search for malignancy, most often small cell lung adenocarcinoma. A negative test result does not rule out the diagnosis of autoimmune vision loss. Results should be interpreted in the context of the patient's clinical history, neurologic and ophthalmologic exam, and other laboratory findings.

Reference Interval:

Test Number	Components	Reference Interval

	Recoverin Ab, IgG by Immunoblot, Serum	Negative

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

NEW TEST

Click for Pricing

Histoplasma and Blastomyces by PCR

3016795, HIBL PCR

Specimen Requirements:	
Patient Preparation:	
Collect:	Bronchoalveolar lavage (BAL), sputum, or tissue
Specimen Preparation:	Transfer 2 mL bronchoalveolar lavage (BAL) or sputum to a sterile container (min: 1.2 mL). Tissue: Transfer to a sterile container and freeze immediately.
Transport Temperature:	Frozen
Unacceptable Conditions:	Formalin-fixed paraffin embedded tissue
Remarks:	Specimen source required
Stability:	Ambient: Unacceptable; Refrigerated: 14 days; Frozen: 14 days
Methodology:	Qualitative Polymerase Chain Reaction (PCR)
Performed:	Sun-Sat
Reported:	1-3 days
Note:	This test detects Histoplasma capsulatum and detects but does not differentiate Blastomyces dermatitidis and Blastomyces gilchristii.
CPT Codes:	87798 x2
New York DOH Approval Status:	Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.
Interpretive Data:	

Reference Interval:

Test Number	Components	Reference Interval

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

NEW TEST

Click for Pricing

Autoimmune Vision Loss Panel, Serum

3016804, AIVLS

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube.
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP standard transport tube. (Min: 0.30 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma. Contaminated, heat-inactivated, hemolyzed, or lipemic specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 month
Methodology:	Qualitative Immunoblot
Performed:	Varies
Reported:	1-8 days
Note:	If CV2.1 Antibody IgG Screen by IFA is positive, then CV2.1 Antibody IgG Titer by IFA will be added. Additional charges apply.
CPT Codes:	84182, 86255; if reflexed, add 86256
New York DOH Approval Status:	Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.
Interpretive Data:	
Refer to report	

Reference Interval:

Test Number	Components	Reference Interval
	CV2.1 Ab IgG CBA-IFA Screen, Serum	Less than 1:10
	Recoverin Ab, IgG by Immunoblot, Serum	Negative

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

NEW TEST – Available Now

Click for Pricing

Candida auris Surveillance Culture

3016815, MC CANAUR

Specimen Requirements:	
Patient Preparation:	
Collect:	Swab of patient's skin using an Eswab collection and transport system.
Specimen Preparation:	Transfer Eswab to a transport tube containing 1 mL liquid Amies medium. Place specimen in an individually sealed bag.
Transport Temperature:	Room temperature
Unacceptable Conditions:	Specimen types other than skin swabs. Environmental swabs.
Remarks:	Specimen source required. Please provide Candida auris PCR results if available.
Stability:	Ambient: 1 week Refrigerated: 1 week Frozen: Unacceptable
Methodology:	Culture/Methods may include biochemical, mass spectrometry, or sequencing.
Performed:	Sun-Sat
Reported:	2-5 days
Note:	Identification at an additional charge will be performed on any yeast recovered in culture suspected as Candida auris.
CPT Codes:	Culture: 87102, Identification: Varies based on method.
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
Reference Interval:	
Culture negative for Candida auris.	

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

NEW TEST

Click for Pricing

Celiac Disease Reflexive Cascade, Serum

3016817, CELIACRFLX

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube (SST).
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transfer 3 mL serum to an ARUP standard transport tube. (Min: 1.5 mL)
Transport Temperature:	Refrigerated
Unacceptable Conditions:	Contaminated, grossly hemolyzed, grossly icteric, or grossly lipemic.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 1 week; Frozen: 15 days
Methodology:	Semi-Quantitative Particle-Based Multianalyte Technology (PMAT)
Performed:	Sun-Sat
Reported:	2-6 days
Note:	The most sensitive and specific serologic test for celiac disease diagnosis is tissue transglutaminase (tTG) IgA isotype in individuals who produce sufficient total IgA. For individuals who are IgA deficient, testing for tTG and deamidated gliadin (DGP), IgG antibodies is recommended. The Celiac Disease Reflexive Cascade begins with the assessment of Immunoglobulin A (IgA) levels using internal control beads. The assay does not measure the actual IgA concentration but flags in the event of low or deficient IgA detected in the sample. In the presence of a low or deficient IgA flag, tTG IgG and DGP IgG antibody testing will be added. No flag indicates IgA competent state and tTG IgA results will be evaluated as an initial screening. If tTG IgA antibody result is negative, then no further testing will be performed. If tTG IgA antibody is weak or moderate positive with results greater than 5 FLU but less than 10 FLU, additional testing for endomysial (EMA) IgA and deamidated gliadin Peptide (DGP) Antibody, IgA antibodies will

	be added and reported. If tTG IgA antibody is positive with results greater than 10 FLU, then no further testing will be performed. If both tTG IgA (<1.02 FLU) and DGP IgA (<0.72 FLU) results are below the limit of detection, then tTG IgG and deamidated gliadin IgG antibody testing will be added even in the absence of IgA control flag due to a suspected low IgA state in the patient. While ordering for celiac disease diagnosis, all serology tests should be performed while the patient is on a gluten-containing diet. Upon initiation of gluten-free diet, antibody titers decline in the treatment responsive patients and the timeframe to normalize varies by case. If serology is negative and suspicion for celiac disease is strong, intestinal biopsy may still be warranted for establishing diagnosis. Dermatitis herpetiformis may exhibit uneven antibody patterns than in celiac disease. Preferred test for initial diagnosis is serum Immunobullous Disease Antibody Panel (ARUP test code 3001409) and should be used in conjunction with this celiac disease reflexive cascade (ARUP test code 3016817)
CPT Codes:	86364; if reflexed additional CPT codes may apply: 86364, 86231; 86258 x2
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Presence of the tissue transglutaminase (tTG) IgA antibody is associated with gluten-sensitive enteropathies such as celiac disease and dermatitis herpetiformis. Individuals with positive results should be confirmed with small intestinal biopsy to establish celiac disease diagnosis. tTG IgA antibody concentrations greater than 50 FLU exhibits higher correlation with results of duodenal biopsies consistent with celiac disease. For antibody concentrations greater than or equal to 5 FLU but less than 10 FLU, additional testing for endomysial (EMA) IgA concentrations may improve the positive predictive value for disease. A decrease in tTG IgA antibody concentration after initiation of a gluten-free diet may indicate a response to therapy.

Reference Interval:

Test Number	Components	Reference Interval
	Tissue Transglutaminase (tTG) Ab, IgA	0.00 - 4.99 FLU

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

NEW TEST

Click for Pricing

JAK2 (V617F) Mutation by ddPCR, Qualitative With Reflex to CALR (Calreticulin) Exon 9 Mutation Analysis by PCR and MPL Mutation Detection

3016839, ETPMFRFX

Specimen Requirements:	
Patient Preparation:	
Collect:	Whole blood or bone marrow: Lavender (EDTA).
Specimen Preparation:	Whole Blood: Do not freeze. Transport 5 mL whole blood. (Min: 1 mL) Bone Marrow: Do not freeze. Transport 3 mL bone marrow. (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma, serum, FFPE tissue blocks/slides, or fresh or frozen tissue. Specimens collected in anticoagulants other than EDTA. Clotted or grossly hemolyzed specimens.
Remarks:	
Stability:	Refrigerated: 7 days; Frozen: Unacceptable
Methodology:	Droplet Digital PCR (ddPCR)/Capillary Electrophoresis
Performed:	Varies
Reported:	3-15 days
Note:	If JAK2 qualitative is reported as "Not Detected," then CALR Exon 9 Mutation Analysis by PCR and MPL Mutation Detection will be added. Additional charges apply.
CPT Codes:	81270; if reflexed add 81219 and 81338
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
Refer to report.	
Reference Interval:	

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

NEW TEST

Click for Pricing

JAK2 (V617F) Mutation by ddPCR, Qualitative With Reflex to JAK2 Exon 12 Mutation Analysis by PCR

3016840, PV REFLEX

Specimen Requirements:	
Patient Preparation:	
Collect:	Whole blood or bone marrow: Lavender (EDTA).
Specimen Preparation:	Whole Blood: Do not freeze. Transport 5 mL whole blood. (Min: 1 mL) Bone Marrow: Do not freeze. Transport 3 mL bone marrow. (Min: 1 mL)
Transport Temperature:	Refrigerated
Unacceptable Conditions:	Plasma, serum, FFPE tissue blocks/slides, or fresh or frozen tissue. Specimens collected in anticoagulants other than EDTA. Clotted or grossly hemolyzed specimens.
Remarks:	
Stability:	Refrigerated: 7 days; Frozen: Unacceptable
Methodology:	Droplet Digital PCR (ddPCR)
Performed:	Varies
Reported:	3-12 days
Note:	If JAK2 qualitative is reported as "Not Detected," then JAK2 Exon 12 Mutation Analysis will be added. Additional charges apply.
CPT Codes:	81270; if reflexed, add 81279
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
Refer to report.	
Reference Interval:	

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

NEW TEST

Click for Pricing

Myelin Oligodendrocyte Glycoprotein (MOG) Antibody, IgG by CBA-IFA With Reflex to Titer, CSF

3016853, MOG CSF

Specimen Requirements:	
Patient Preparation:	
Collect:	CSF
Specimen Preparation:	Transfer 0.5 mL CSF to an ARUP standard transport tube. (Min: 0.15 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Hemolyzed, contaminated specimens, or severely lipemic specimens.
Remarks:	
Stability:	Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 month
Methodology:	Semi-Quantitative Cell-Based Indirect Fluorescent Antibody
Performed:	Mon, Wed, Fri
Reported:	1-6 days
Note:	If Myelin Oligodendrocyte Glycoprotein (MOG) Antibody, IgG by IFA with Reflex to Titer, CSF is positive, then a Myelin Oligodendrocyte Glycoprotein (MOG) Antibody Titer, IgG is performed. Additional charges apply.
CPT Codes:	86362; if reflexed, add 86256
New York DOH Approval Status:	Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.

Interpretive Data:

Myelin oligodendrocyte glycoprotein (MOG) antibody is found in a subset of patients with neuromyelitis optica spectrum disorders, including optic neuritis and transverse myelitis, brainstem encephalitis, and acute disseminated encephalomyelitis. Persistence of antibody positivity may be associated with a relapsing course; decreasing antibody levels may be associated with therapeutic response. A negative test result does not rule out a diagnosis of CNS demyelinating disease. Low antibody titers have a lower positive predictive value of disease, and should be carefully interpreted in the context of the patient's clinical history, neurologic exam, imaging, and other laboratory findings. Serum is the preferred specimen type, but in some cases

patients with MOG-associated disease may be positive only in CSF; CSF positivity may be associated with more severe clinical outcomes.

This indirect fluorescent antibody assay utilizes full-length MOG transfected cell lines for the detection and semiquantification of MOG IgG antibody.

Reference Interval:

Test Number	Components	Reference Interval
	MOG Ab IgG CBA-IFA Scrn, CSF	Less than 1:1

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

NEW TEST

Click for Pricing

von Willebrand Factor (VWF) Collagen III Binding

3016858, VON WILLE

Specimen Requirements:	
Patient Preparation:	
Collect:	Light blue (sodium citrate).
Specimen Preparation:	Transfer 0.5 mL citrated plasma to an ARUP standard transport tube. (Min: 0.5 mL) Test is not performed at ARUP; separate specimens must be submitted when multiple tests are ordered.
Transport Temperature:	CRITICAL FROZEN.
Unacceptable Conditions:	
Remarks:	
Stability:	Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 2 weeks
Methodology:	Enzyme-Linked Immunosorbent Assay
Performed:	Varies
Reported:	7-10 days
Note:	
CPT Codes:	0279U
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	

Reference Interval:

Test Number	Components	Reference Interval

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

NEW TEST

Click for Pricing

Tissue Transglutaminase Antibody, IgA

3016860, TTG A

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube.
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transfer 1.0 mL serum to an ARUP standard transport tube. (Min: 0.5 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Contaminated, grossly hemolyzed, grossly icteric, or grossly lipemic.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 1 week; Frozen: 15 days
Methodology:	Semi-Quantitative Particle-Based Multianalyte Technology (PMAT)
Performed:	Sun-Sat
Reported:	1-2 days
Note:	The most sensitive and specific serologic test for celiac disease diagnosis is tissue transglutaminase (tTG) IgA isotype in individuals who produce sufficient total IgA. For individuals who are IgA deficient, testing for tTG and deamidated gliadin (DGP), IgG antibodies is recommended. Preferred initial screening test for celiac disease diagnosis is the reflexive cascade (ARUP test code 3016817) While ordering for celiac disease diagnosis, all serology tests should be performed while the patient is on a gluten-containing diet. Upon initiation of gluten-free diet, antibody titers decline in the treatment responsive patients and the timeframe to normalize varies by case. If serology is negative and suspicion for celiac disease is strong, intestinal biopsy may still be warranted for establishing diagnosis. Dermatitis herpetiformis may exhibit uneven antibody patterns than in celiac disease. Preferred test for initial diagnosis is serum Immunobullous Disease Antibody Panel (ARUP test code 3001409) and should be used in

	conjunction with this celiac disease reflexive cascade (ARUP test code 3016817).
CPT Codes:	86364
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Presence of the tissue transglutaminase (tTG) IgA antibody is associated with gluten-sensitive enteropathies such as celiac disease and dermatitis herpetiformis. Individuals with positive results should be confirmed with small intestinal biopsy to establish celiac disease diagnosis. tTG IgA antibody concentrations greater than 50 FLU exhibits higher correlation with results of duodenal biopsies consistent with celiac disease. For antibody concentrations greater than or equal to 5 FLU but less than 10 FLU, additional testing for endomysial (EMA) IgA concentrations may improve the positive predictive value for disease. A decrease in tTG IgA antibody concentration after initiation of a gluten-free diet may indicate a response to therapy.

Reference Interval:

Test Number	Components	Reference Interval
	Tissue Transglutaminase (tTG) Ab, IgA	0.00 - 4.99 FLU

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

NEW TEST

Click for Pricing

Tissue Transglutaminase Antibody, IgA With Reflex to Endomysial Antibody, IgA by IFA

3016861, EMA RFLX

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube (SST).
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP standard transport tube. (Min: 0.5 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Contaminated, grossly hemolyzed, grossly icteric, or grossly lipemic.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 1 week; Frozen: 15 days (avoid freeze/thaw cycles)
Methodology:	Semi-Quantitative Particle-Based Multianalyte Technology (PMAT)/Semi-Quantitative Indirect Fluorescent Antibody (IFA)
Performed:	Sun-Sat
Reported:	1-4 days
Note:	Testing for tTG IgA antibodies is recommended as an initial screen to identify patients at risk for celiac disease, and in whom duodenal biopsy should be performed to confirm disease. Some patients may have positive tTG IgA but negative EMA IgA and/or deamidated gliadin peptide (DGP) IgA results, which may be associated with false positivity or may indicate early disease. Close clinical correlation with continued testing may be indicated in patients with a family history of or who are at increased risk for celiac disease. A positive serology but normal biopsy may also indicate a gluten-free diet (GFD) prior to testing, latent disease, or early enteropathy. Rechallenge with a gluten diet may be recommended if GFD had been initiated prior to subsequent testing. In the case of latent or early disease, HLA DQ2 and DQ8 testing may be necessary to determine risk for disease. For patients with a high degree of suspicion for celiac disease and who test negative for tTG, EMA, and/or DGP IgA tests, selective IgA-

	deficiency should be considered and testing for tTG, EMA, and/or DGP IgG antibodies performed. If serology is negative and suspicion of celiac disease is strong, intestinal biopsy may be warranted. Biopsy is particularly important for patients with diarrhea, steatorrhea, weight loss, failure to thrive, or with inherited genetic deficiencies such as Down or Turner syndromes. Specimen is screened using tissue transglutaminase IgA by ELISA. If tTG IgA is 5.00 FLU or greater, then EMA IgA by IFA testing will be added. Additional charges apply. All EMA IgA by IFA testing is titered to endpoint.
CPT Codes:	86364; if reflexed, add 86231
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Tissue Transglutaminase Antibody, IgA: Presence of the tissue transglutaminase (tTG) IgA antibody is associated with gluten-sensitive enteropathies such as celiac disease and dermatitis herpetiformis. Individuals with positive results should be confirmed with small intestinal biopsy to establish celiac disease diagnosis. tTG IgA antibody concentrations greater than 50 FLU exhibits higher correlation with results of duodenal biopsies consistent with celiac disease. For antibody concentrations greater than or equal to 5 FLU but less than 10 FLU, additional testing for endomysial (EMA) IgA concentrations may improve the positive predictive value for disease. A decrease in tTG IgA antibody concentration after initiation of a gluten-free diet may indicate a response to therapy.

Reference Interval:

Test Number	Components	Reference Interval
	Tissue Transglutaminase (tTG) Ab, IgA	0.00 - 4.99 FLU

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

NEW TEST

Click for Pricing

Cortisol by LC-MS/MS, Salivary

3016866, CORT S TMS

Specimen Requirements:	
Patient Preparation:	Do not collect specimen within 60 minutes after eating a meal, within 12 hours after consuming alcohol, immediately after brushing teeth, or after any activity that may cause gums to bleed. Rinse mouth thoroughly with water 10 minutes before specimen collection. Recommended collection time is between 11:00 p.m.-1:00 a.m.
Collect:	Saliva. Swab must be completely saturated to ensure sufficient volume for testing.
Specimen Preparation:	Transfer saturated swab to plain (noncitric acid) cotton Salivettecollection device (ARUP Supply #52056). Record the time of collection on the test request form, and on Salivettetransport container.
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Specimens not collected using the Salivettecollection device. Sodium azide preservative. Specimens with pH values greater than 9.0 or less than 3.5 must be recollected. Specimens visibly contaminated with blood, cellular debris, food particles, or mucus.
Remarks:	
Stability:	Ambient: 1 week Refrigerated: 3 weeks Frozen: 6 months
Methodology:	
Performed:	Mon-Sat
Reported:	1-4 days
Note:	Bovine hormones normally present in dairy products can cross-react with anticortisol antibodies and cause false results. Acidic or high sugar foods can compromise assay performance by lowering sample pH and influencing bacterial growth. Samples with pH values greater than 9.0 or less than 3.5 must be recollected.
CPT Codes:	82533

New York DOH Approval Status: This test is New York DOH approved.

Interpretive Data:

Reference Intervals: Based on Reference interval verification experiments conducted with Mayo Clinic, reference intervals for salivary cortisol are listed below:

7 a.m. to 9 a.m.: 0.1-0.75

3 p.m. to 5 p.m.: <0.401

11 p.m. to midnight: <0.1

Reference Interval:

By report

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

NEW TEST

Click for Pricing

Twin Zygosity

3016875, TWINZYG

Specimen Requirements:	
Patient Preparation:	
Collect:	From each twin: Lavender (EDTA), pink (K2EDTA), or yellow (ACD solution A or B).
Specimen Preparation:	From each twin: Transport 2 mL whole blood (Min: 1 mL)
Transport Temperature:	Refrigerated. Also acceptable: Ambient
Unacceptable Conditions:	
Remarks:	
Stability:	Room temperature: 1 week; Refrigerated: 1 month; Frozen: Unacceptable
Methodology:	Polymerase Chain Reaction (PCR)/Fragment Analysis
Performed:	Varies
Reported:	5-10 days
Note:	Results from both twins will be compared and reported; therefore, a test must be ordered for and sample submitted from each individual.
CPT Codes:	81265
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
Refer to report.	
Reference Interval:	
By report.	

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

NEW TEST – Available Now

Click for Pricing

CD30 for Bone Marrow Specimens by Immunohistochemistry

3016879, CD30BM IHC

Specimen Requirements:	
Patient Preparation:	
Collect:	Tissue or cells.
Specimen Preparation:	Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (ARUP supply #47808). Available online through eSupply using ARUP Connector contact ARUP Client Services at 800-522-2787. (Min: 2 slides). If sending precut slides, do not oven bake.
Transport Temperature:	
Unacceptable Conditions:	Tissue or cells not processed and placed in a paraffin block; serum, blood, or other body fluids; tissue not mounted on positively charged slides.
Remarks:	
Stability:	Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Methodology:	Qualitative Immunohistochemistry (IHC)
Performed:	Mon-Fri
Reported:	1-3 days
Note:	This test is performed as a stain and return (technical) service only.
CPT Codes:	88342
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Reference Interval:

Test	Components	Reference Interval

Number		

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

NEW TEST

Click for Pricing

Huntington Disease (HD) CAG Repeat Expansion

3016908, HD PCR

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (EDTA), pink (K2EDTA), or yellow (ACD solution A or B).
Specimen Preparation:	Transport 2 mL whole blood. (Min: 1 mL)
Transport Temperature:	Refrigerated. Also acceptable: Ambient.
Unacceptable Conditions:	
Remarks:	A completed HD-specific consent form, signed by the patient (or legal guardian) and physician, is required for all specimens. Testing for asymptomatic patients under the age of 18 years is not offered. Presymptomatic patients are strongly encouraged to be tested through a counseling program approved by the Huntington Disease Society of America at 800-345-4372. Call Genetics Processing with additional questions at 800-242-2787 ext. 3301.
Stability:	Room temperature: 1 week; Refrigerated: 1 month; Frozen: Unacceptable
Methodology:	Polymerase Chain Reaction (PCR)/Fragment Analysis
Performed:	Varies
Reported:	7-10 days
Note:	
CPT Codes:	81271
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
Refer to report.	
Reference Interval:	

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

NEW TEST

Click for Pricing

5-Hydroxyindoleacetic Acid (HIAA), Plasma

3016920, 5HIAA PLA

Specimen Requirements:	
Patient Preparation:	If clinically feasible, discontinue acetaminophen- and tryptophan-containing supplements at least 24 hours prior to specimen collection. The patient should abstain from eating nuts, especially walnuts, and limit fruits, vegetables, and caffeinated beverages or foods to one serving per day in the 24 hours prior to specimen collection.
Collect:	Green (sodium heparin). Also acceptable: Lavender (EDTA).
Specimen Preparation:	Transfer 0.5 mL plasma to an ARUP standard transport tube. (Min: 0.2 mL) Test is not performed at ARUP; separate specimens must be submitted when multiple tests are ordered.
Transport Temperature:	Frozen
Unacceptable Conditions:	
Remarks:	Patient age is required.
Stability:	Ambient: Unacceptable; Refrigerated: 72 hours; Frozen: 2 months
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Varies
Reported:	3-9 days
Note:	
CPT Codes:	83497
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	

Reference Interval:

Test Number	Components	Reference Interval

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

NEW TEST

Click for Pricing

Factor 13, Qualitative, With Reflex to Factor 13 1:1 Mix

3016927, FACTOR13

Specimen Requirements:	
Patient Preparation:	
Collect:	Lt. blue (sodium citrate). Refer to Specimen Handling at aruplab.com for hemostasis/thrombosis specimen handling guidelines.
Specimen Preparation:	Transfer 2 mL platelet-poor plasma to an ARUP standard transport tube. (Min: 1 mL)
Transport Temperature:	CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Unacceptable Conditions:	Serum. EDTA plasma, clotted or hemolyzed specimens.
Remarks:	
Stability:	Ambient: 4 hours; Refrigerated: Unacceptable; Frozen: 2 weeks
Methodology:	Qualitative Solubility Assay
Performed:	Sun-Sat
Reported:	2-3 days
Note:	This is a qualitative screening test; clot lysis only occurs in specimens with severe factor XIII deficiency (less than 1 percent 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, then Factor XIII 1:1 Mix will be added where 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. Additional charges apply. 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 Codes:	85291; if reflexed, add 85291

New York DOH Approval Status: This test is New York DOH approved.

Interpretive Data:

Reference Interval:

Test Number	Components	Reference Interval
	Factor XIII, Qualitative	No Lysis within 24 hours

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

ARUP LABORATORIES

A nonprofit enterprise of the University of Utah and its Department of Pathology

Inactivations

The following will be discontinued from ARUP's test menu on November 13, 2023
Replacement test options are indicated when applicable.

Test Number	Test Name	Refer to Replacement Test
0040018	Huntington Disease (HD) Mutation by PCR (Change effective as of 11/13/2023: Refer to 3016908 in the November Hotline)	Huntington Disease (HD) CAG Repeat Expansion (3016908)
0050547	Twin Zygosity Testing (Change effective as of 11/13/2023: Refer to 3016875 in the November Hotline)	Twin Zygosity (3016875)
0050734	Tissue Transglutaminase (tTG) Antibody, IgA with Reflex to Endomysial Antibody, IgA by IFA (Change effective as of 11/13/23: Refer to 3016861 in the November Hotline)	Tissue Transglutaminase Antibody, IgA with Reflex to Endomysial Antibody, IgA by IFA (3016861)
0051074	Influenza A Virus Antibody, IgG (Change effective as of 11/13/23: Refer to 0060764)	Respiratory Virus Mini Panel by PCR (0060764)
0051080	Influenza B Virus Antibody, IgG (Change effective as of 11/13/23: Refer to 0060764)	Respiratory Virus Mini Panel by PCR (0060764)
0051689	Celiac Disease Dual Antigen Screen (Change effective as of 11/13/23: Refer to 3016817 in the November Hotline)	Celiac Disease Reflexive Cascade, Serum (3016817)
0055258	Borrelia burgdorferi Antibody, IgM by Immunoblot (CSF) (Change effective as of 11/13/23: Refer to 0055260)	Borrelia burgdorferi Antibodies, IgG and IgM by Immunoblot (CSF) (0055260)
0055259	Borrelia burgdorferi Antibody, IgG by Immunoblot (CSF) (Change effective as of 11/13/23: Refer to 0055260)	Borrelia burgdorferi Antibodies, IgG and IgM by Immunoblot (CSF) (0055260)
0081117	Cortisol, Saliva (Change effective as of 11/13/23: Refer to 3016866 in the November Hotline)	Cortisol by LC-MS/MS, Salivary (3016866)

Test Number	Test Name	Refer to Replacement Test
0097709	Tissue Transglutaminase (tTG) Antibody, IgA (Change effective as of 11/13/23: Refer to 3016860 in the November Hotline)	Tissue Transglutaminase Antibody, IgA (3016860)
0099483	Borrelia burgdorferi Antibodies, Total by ELISA, CSF (Change effective as of 11/13/23: Refer to 3016760 in the November Hotline)	Borrelia burgdorferi VlsE1/pepC10 Antibodies, CSF, Total by ELISA With Reflex to IgM and IgG by Immunoblot (Standard Two-Tier Testing, CSF) (3016760)
2001181	UroVysion FISH (Change effective as of 11/13/23: Refer to 3016627 in the November Hotline)	Bladder Cancer FISH (3016627)
2002026	Celiac Disease Dual Antigen Screen with Reflex (Change effective as of 11/13/23: Refer to 3016817 in the November Hotline)	Celiac Disease Reflexive Cascade, Serum (3016817)
2002819	Factor XIII, Qualitative, with Reflex to Factor XIII 1:1 Mix (Change effective as of 11/13/23: Refer to 3016927 in the November Hotline)	Factor 13, Qualitative, with Reflex to Factor 13 1:1 Mix (3016927)
2007136	von Willebrand Factor (VWF) Collagen Binding (Change effective as of 11/13/23: Refer to 3016858 in the November Hotline)	von Willebrand Factor (VWF) Collagen III Binding (3016858)
2007335	Borrelia burgdorferi (Lyme Disease) Reflexive Panel (CSF) (Change effective as of 11/13/23: Refer to 3016760 in the November Hotline)	Borrelia burgdorferi VlsE1/pepC10 Antibodies, CSF, Total by ELISA With Reflex to IgM and IgG by Immunoblot (Standard Two-Tier Testing, CSF) (3016760)
2008114	Celiac Disease Reflexive Cascade (Change effective as of 11/13/23: Refer to 3016817 in the November Hotline)	Celiac Disease Reflexive Cascade, Serum (3016817)
2010161	Chronic Enteric Hypersensitivity Reflexive Profile (Inactive as of 11/13/23)	

Test Number	Test Name	Refer to Replacement Test
3000202	5-Hydroxyindoleacetic acid (5-HIAA), Plasma (Change effective as of 11/13/23: Refer to 3016920 in the November Hotline)	5-Hydroxyindoleacetic Acid (HIAA), Plasma (3016920)
3003800	JAK2 (V617F) Mutation by ddPCR, Qualitative with Reflex to CALR (Calreticulin) Exon 9 Mutation Analysis by PCR with Reflex to MPL Mutation Detection (Change effective as of 11/13/23: Refer to 3016839 in the November Hotline)	JAK2 (V617F) Mutation by ddPCR, Qualitative with Reflex to CALR (Calreticulin) Exon 9 Mutation Analysis by PCR and MPL Mutation Detection (3016839)
3003801	JAK2 (V617F) Mutation by ddPCR, Qualitative with Reflex to JAK2 Exon 12 Mutation Analysis by PCR (Change effective as of 11/13/23: Refer to 3016840 in the November Hotline)	JAK2 (V617F) Mutation by ddPCR, Qualitative with Reflex to JAK2 Exon 12 Mutation Analysis by PCR (3016840)
3004092	Edoxaban Level (Inactive as of 11/13/2023)	
3004465	Celiac Antibodies, Tissue Transglutaminase (tTG), IgA and IgA, Total (Change effective as of 11/13/23: Refer to 3016817 in the November Hotline)	Celiac Disease Reflexive Cascade, Serum (3016817)
3004508	Cytomegalovirus Drug Resistance by Next Generation Sequencing, Ganciclovir, Foscarnet, Cidofovir, and Maribavir (Change effective as of 11/13/23: Refer to 3004615)	Cytomegalovirus Drug Resistance by Next Generation Sequencing, Ganciclovir, Foscarnet, Cidofovir, Maribavir, and Letermovir (3004615)
3004509	Cytomegalovirus Drug Resistance by Next Generation Sequencing, Letermovir (Change effective as of 11/13/23: Refer to 3004615)	Cytomegalovirus Drug Resistance by Next Generation Sequencing, Ganciclovir, Foscarnet, Cidofovir, Maribavir, and Letermovir (3004615)