

### Effective as of 05/20/2024

### Additional ordering and billing information

Test Number	Mnemonic	Test Name	New Test	Test Name Change	<b>Specimen Requirements</b>	Methodology	Performed/Reported	Note	Interpretive Data	<b>Reference Interval</b>	<b>Component Charting Name</b>	<b>Component Change</b>	Reflex Pattern	Result Type	Ask at Order Prompt	Numeric Map	Unit of Measure	CPT Code	Pricing Change	Inactivation w/ Replacement	Inactivation w/o Replacement
0010020	ABSC-R	Antibody Screen RBC with Reflex to Identification											x								
0013003	IRL-AB PKG	Antibody ID Package (IRL)																		x	
0013005	IRL-ABID	Antibody ID RBC Prenatal-Reflex to Titer																		x	
0020763	PCT	Procalcitonin			x	x			х												
0040248	KRAS	KRAS Mutation Detection																			x
0049000	LAP	Leukocyte Alkaline Phosphatase (Test on Delay as of 7/21/2023)																			x
0051750	BRAF RFLX	BRAF Codon 600 Mutation Detection with Reflex to MLH1 Promoter Methylation																		x	
0055567	T CELL-F	T-Cell Clonality Screening by PCR			x																
0080260	PBGQT	Porphobilinogen (PBG), Urine					x		x	x		x									
0090120	ЕТОН	Ethanol, Serum or Plasma - Medical														x					
0092099	CD20	B-Cell CD20 Expression (Change effective as of 03/20/24: Refer to 3016431)																		x	
2002181	PORUFPBG U	Porphyrins and Porphobilinogen (PBG), Urine					x		x	x		x									



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2002296	CHR ST	Chromosome Analysis, Solid Tumor			x																
2002300	CHR ONC	Chromosome Analysis, Lymph Node			x			x													
2002327	MSI REFLEX	Mismatch Repair by Immunohistochemistry with Reflex to BRAF Codon 600 Mutation and MLH1 Promoter Methylation		x			x	x					x								
2002440	EGFR PCR	EGFR Mutation Detection by Pyrosequencing																			x
2002498	BRAF PCR	BRAF Codon 600 Mutation Detection by Pyrosequencing																		x	
2003036	AQP4	Aquaporin-4 Receptor Antibody (Change effective as of 05/20/24: Refer to 2013320)																		x	
2003040	PM/SCL	PM/Scl-100 Antibody, IgG by Immunoblot			x																
2003123	NRAS	NRAS Mutation Detection by Pyrosequencing																			x
2005685	JPN M	Japanese Encephalitis Virus Antibody, IgM by ELISA (Change effective as of 05/20/24: Refer to 2005689)																		x	



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2005687	JPN G	Japanese Encephalitis Virus Antibody, IgG by ELISA (Change effective as of 05/20/24: Refer to 2005689)																		x	
2006193	BCELL SCRN	B-Cell Clonality Screening (IgH and IgK) by PCR			x																
2006444	IDH1-2	IDH1 and IDH2 Mutation Analysis, exon 4																			x
2009318	MYD88	MYD88 L265P Mutation Detection by PCR, Quantitative			x																
2010136	CDCO ETOH	Alcohol, Urine, Quantitative														x					
2011476	UPBGQTRA ND	Porphobilinogen (PBG), Random Urine(Change effective as of 05/20/24: Refer to 0080260 in the May Hotline)																		x	
2012052	HHA SEQ	Hereditary Hemolytic Anemia Panel Sequencing			x																
2012173	U3 FIB	Fibrillarin (U3 RNP) Antibody, IgG			x																
2013284	22C3 IP	PD-L1 22C3 IHC with Tumor Proportion Score (TPS) Interpretation, pembrolizumab (KEYTRUDA) and cemiplimab-rwlc (LIBTAYO)																		x	



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2013327	AQP4 R	Aquaporin-4 Receptor Antibody by ELISA with Reflex to Aquaporin-4 Receptor Antibody, IgG by IFA (Change effective as of 05/20/24: Refer to 2013320)																		x	
3000082	ANA IFA AB	Antinuclear Antibody (ANA) with HEp-2 Substrate, IgG by IFA			x	x															
3000197	22C3 GAST	PD-L1 22C3 IHC with Combined Positive Score (CPS) Interpretation, pembrolizumab (KEYTRUDA)																		x	
3000399	QFT-4	QuantiFERON-TB Gold Plus, 4-Tube																		х	
3000400	QFT-PLUS	QuantiFERON-TB Gold Plus, 1-Tube																		x	
3000479	SSC PANEL	Criteria Systemic Sclerosis Panel			x																
3001161	FLT3-PCR	FLT3 ITD and TKD Mutation Detection			x																
3002063	FISHMMP	Multiple Myeloma Panel by FISH			x			x													
3002105	U-PEP	Monoclonal Protein Study, 24 hour, Urine					x					x									



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3002134	IDH1 RFLX	IDH1 R132H Point Mutation by Immunohistochemistry with Reflex to IDH1 and IDH2 Mutation Analysis, Exon 4		x				x					x								
3002135	OLIGO PAN	1p19q Deletion by FISH and IDH1 R132H Point Mutation by Immunohistochemistry with Reflex to IDH1 and IDH2 Mutation Analysis, Exon 4		x				x					x								
3002479	LIVER PAN	Autoimmune Liver Disease Reflexive Panel			x	x															
3003086	FA PRO RBC	Fatty Acids Profile, Essential in Red Blood Cells			x																
3004267	IDH12FFPE	IDH1 and IDH2 Mutation Analysis Exon 4, Formalin-Fixed, Paraffin- Embedded (FFPE) Tissue																		x	
3004277	MSIPCR	Microsatellite Instability (MSI) HNPCC/Lynch Syndrome by PCR			x																
3004308	MLH1 PCR	MLH1 Promoter Methylation			x																
3005956	MGMT METH	MGMT Promoter Methylation Detection by ddPCR			x																



### Effective as of 05/20/2024

### Additional ordering and billing information

Information when ordering laboratory tests that are billed to Medicare/Medicaid

Information regarding Current Procedural Terminology (CPT)

Test Number	Mnemonic	Test Name	New Test	Test Name Change	<b>Specimen Requirements</b>	Methodology	Performed/Reported	Note	Interpretive Data	<b>Reference Interval</b>	<b>Component Charting Name</b>	<b>Component Change</b>	Reflex Pattern	Result Type	Ask at Order Prompt	Numeric Map	Unit of Measure	CPT Code	Pricing Change	Inactivation w/ Replacement	Inactivation w/o Replacement
3006049	AE CSF	Autoimmune Encephalitis Reflex Panel, CSF (Change effective as of 05/20/24: Refer to 3006202, 3006211)																		x	
3006050	ENCEPHEXT 2	Autoimmune Encephalitis Extended Panel, Serum (Change effective as of 05/20/24: Refer to 3006201, 3006210)																		x	
3006285	ADIPO SP	Adiponectin Quantitative, Serum/Plasma (Change effective as of 05/20/24: Refer to 3017195 in the May Hotline)																		x	
3016431	CD20 QUANT	B-Cell CD20 Expression by Flow Cytometry, Quantitative	x																		
3016444	PHOSPHO T	Phospho-Tau/Total- Tau/A Beta42, CSF (Change effective as of 05/20/24: Refer to 3017653 in the May Hotline)																		x	
3017050	RAPID AML	Rapid Acute Myeloid Leukemia Targeted Therapy Mutation Panel	x																		
3017195	ADIP SP	Adiponectin, Quantitative Serum/Plasma	x																		



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3017203	BRAF NGS	BRAF Mutation Detection	х																		
3017204	BRAF REFL	BRAF Mutation Detection with Reflex to MLH1 Promoter Methylation	x																		
3017209	CRC MUT	Colorectal Cancer Mutation Panel	x																		
3017222	IDH1-IDH2	IDH1 and IDH2 Mutation Detection	x																		
3017230	LUNG MUT	Lung Cancer Mutation Panel	x																		
3017233	MEL MUT	Melanoma Mutation Panel	x																		
3017372	TPMTGENO	TPMT Genotyping	х																		
3017373	NUDT15GEN O	NUDT15 Genotyping	x																		
3017399	TPSAB1	TPSAB1 Copy Number Analysis by ddPCR	х																		
3017440	MA2/TA CSF	Ma2/Ta Antibody, IgG by Immunoblot, CSF	x																		
3017441	MA2/TA SER	Ma2/Ta Antibody, IgG by Immunoblot, Serum	x																		
3017549	HLA B51	HLA-B51 Genotyping, Behcet Disease	x																		
3017554	QFT PLUS	QuantiFERON TB-Gold Plus, 1-Tube	x																		
3017562	QFT 4	QuantiFERON TB-Gold Plus, 4-Tube	x																		



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3017565	TRI A 19	Allergen, Food, Wheat Component rTri a 19 Omega 5-Gliadin, IgE	x																		
3017569	WHEAT R	Allergen, Food, Wheat and nGliadin With Reflex to Components, IgE	x																		
3017610	IRL AB PKG	RBC Antibody ID Package (IRL)	х																		
3017611	IRL ABID	RBC Antibody ID Prenatal - Reflex to Titer	х																		
3017615	PDL1 22C3	PD-L1 22C3 by IHC	х																		
3017651	VIT C IV	Vitamin C, Plasma (High-Dose Therapy)	x																		
3017653	ADMRKS CSF	Alzheimer's Disease Markers, CSF	x																		



### Antibody Screen RBC with Reflex to Identification 0010020, ABSC-R Specimen Requirements: Patient Preparation: Collect: Lavender (K2EDTA) or Pink (K2EDTA). **Specimen Preparation:** Do not freeze. Transport 7 mL whole blood. (Min: 3 mL) Transport Temperature: Refrigerated. Unacceptable Conditions: Plasma Separator Tubes. Remarks: Ambient: Unacceptable; Refrigerated: 1 week; Frozen: Stability: Unacceptable Methodology: Solid Phase Technology Performed: Mon-Fri Reported: 1-3 days If Antibody Screen is positive, Antibody Identification will be Note: added. Additional charges apply. CPT Codes: 86850; additional CPT codes may apply New York DOH Approval Status: This test is New York DOH approved. Interpretive Data:

Reference Interval:

Test Number		Reference Interval
	Antibody Screen Automated	Negative

# 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.

The same specimen type (serum, plasma) should be used throughout the patient's clinical course.
Plasma <u>separator tube</u> Separator Tube (PST) or <u>serum</u> <u>separator tube</u> Serum Separator Tube (SST).
ForAllow serum specimens, ensure that complete to sit for 15- 20 minutes for proper clot formation has taken place prior to centrifugation. If and to ensure the specimen is centrifuged before complete clot formation, the presence absence of fibrin may cause erroneous results. The use of plasma is recommended for rapid turnaround of results. For accurate results, in the serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. which can interfere with this assay. Separate 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: 0.3 mL)
Refrigerated.
Specimens collected in citrate anticoagulant. <u>Specimens that are heat-inactivated, pooled, grossly</u> <u>hemolyzed, contain obvious microbial contamination or fungal</u> growth should not be used.
After separation from cells: Ambient: 24 hours; Refrigerated: 5 days; Frozen: 15 days
<u>Quantitative Chemiluminescent</u> Immunoassay (CLIA)
Sun-Sat
Sun-Sat Within 24 hours



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

Interpretive Data:

<u>Procalcitonin >A correction has been applied to optimize cutoffs established for the BRAHMS PCT</u> sensitive KRYPTOR assay.

Procalcitonin > 2.00 ng/mL: Procalcitonin levels above 2.00 ng/mL on the first day of ICU admission represent a high risk for progression to severe sepsis and/or septic shock.

Procalcitonin < 0.50 ng/mL: Procalcitonin levels below 0.50 ng/mL on the first day of ICU admission represent a low risk for progression to severe sepsis and/or septic shock.

If the procalcitonin measurement is performed shortly after the systemic infection process has started (usually less than 6 hours), these values may still be low. As various <u>noninfectiousnon-infectious</u> conditions are known to induce procalcitonin as well, procalcitonin levels between 0.50 ng/mL and 2.00 ng/mL should be reviewed carefully to take into account the specific clinical background and condition(s) of the individual patient.

Reference Interval:

Less than 0.07 ng/mL



Specimen Requirements:	
Patient Preparation:	
Collect:	Whole blood or bone marrow in lavender (EDTA), tissue, formalin-fixed tissue.
Specimen Preparation:	Whole Blood: Do not freeze. Transport 5 mL. (Min: 1 mL) Bone Marrow: Do not freeze. Transport 3 mL. (Min: 1 mL) Fresh Tissue: Freeze immediately. Transport 100 mg or 0.5-2.0 cm3 tissue FFPE Tumor Tissue: Formalin fixed (10 percent neutral buffered formalin) and paraffin embedded tissue. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or four 10-micron shavings in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect(TM) or contact ARUP Client Services at 800-522-2787.
Transport Temperature:	Whole Blood, Bone Marrow: Refrigerated. Fresh Tissue: Frozer on dry ice. FFPE Tumor Tissue: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Unacceptable Conditions:	Plasma, serum. Specimens collected in anticoagulants other than EDTA. Clotted or grossly hemolyzed specimens. Tissue: FFPE specimens fixed in any fixative other than 10 percent neutral buffered formalin. <u>BoneDecalcified</u> specimens <u>submitted in non-EDTA decalcifier</u> .
Remarks:	If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) wil be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held unti clarification is provided.
Stability:	Whole Blood or Bone Marrow: Refrigerated: 7 days; Frozen: Unacceptable Fresh Tissue: Ambient: Unacceptable; Refrigerated: 2 hours; Frozen: 1 year FFPE Tumor Tissue: Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable



Methodology:	Capillary Electrophoresis/Polymerase Chain Reaction (PCR)
Performed:	Varies
Reported:	5-9 days
Note:	
CPT Codes:	81342
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
Refer to report.	
Reference Interval:	



Specimen Requirements:	
Patient Preparation:	
Collect:	Random or 24-hour urine. Refrigerate 24-hour specimens during collection.
Specimen Preparation:	Protect from light. Transfer <u>2</u> 8 mL aliquot from a random or well-mixed 24-hour collection to ARUP <u>amber transport</u> <u>tubes. Amber Transport Tubes.</u> (Min: <u>1</u> 3.5 mL) Record total volume and collection time interval on transport tube and test request form.
Transport Temperature:	Frozen.
Unacceptable Conditions:	Body fluids other than urine.
Remarks:	
Stability:	Ambient: Unacceptable; Refrigerated: <u>1 week</u> 4 days; Frozen: 1 month
Methodology:	Quantitative Ion Exchange Chromatography/Spectrophotometry
Performed:	Sun-SatMon-Fri
Reported:	1- <u>5</u> 4 days
Note:	Appropriate test to rule out acute intermittent porphyria (AIP) and other acute attack types of porphyrias associated with neurologic and/or psychiatric symptoms.
CPT Codes:	84110
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
<u>Porphobilinogen (PBG), Urine</u>	
Results for random urine specimer as a ratio of amounts (millimoles of	ns are normalized to creatinine (CRT) concentration and reported of PBG/mole of creatinine).

Porphobilinogen (PBG) in a random urine specimen is used to evaluate an attack of acute porphyria. Slight increases in urinary PBG are associated with acute porphyrias other than acute



intermittent porphyria (AIP) and may indicate a resolving or treated acute porphyria.

Urinary PBG in excess of two times the upper reference limit is consistent with acute porphyria.

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
	Porphobilinogen, Urine - per 24h	0. <u>4 - 1.5</u> 0-11.	<del>0</del> μmol/d	
	Porphobilinogen <u>, (PBG),</u> Urine - <u>ratio to</u> <u>CRT</u> per volume	0.0 <u>- 0.2 mmc</u>	ol/mol CRT <mark>-8.8</mark>	μ <mark>mol/L</mark>

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.



Ethanol, Serum or Plasma - Medical		
0090120, ETOH		
Specimen Requirements:		
Patient Preparation:	For medical purposes only. Timing of specimen collection: Dependent on time of exposure, test upon presentation to hospital.	
Collect:	Plain Red. Also acceptable: Lavender (EDTA), Pink (K2EDTA), or Gray (Potassium Oxalate/Sodium Fluoride).	
Specimen Preparation:	Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.3 mL) Cap tube tightly to minimize alcohol loss. When drawing a blood specimen for alcohol testing, use a nonalcohol-based cleanser at the venipuncture site.	
Transport Temperature:	Refrigerated.	
Unacceptable Conditions:	Whole blood. Plasma Separator Tubes (PST), Serum Separator Tubes (SST).	
Remarks:		
Stability:	After separation from cells: Ambient: 1 week; Refrigerated: 2 week; Frozen: 1 months	
Methodology:	Quantitative Gas Chromatography	
Performed:	Sun-Sat	
Reported:	1-3 days	
Note:		
CPT Codes:	80320 (Alt code: G0480)	
New York DOH Approval Status:	This test is New York DOH approved.	
Interpretive Data:		

Toxic concentrations may cause inebriation, CNS depression, respiratory depression, mental and motor impairment and liver damage. In children, ethanol ingestion may cause hypoglycemia.

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 19, 2013

Normal Range	Not established. Limit of detection varies based on instrumentation.
Therapeutic Range	(Therapy for methanol toxicity): 100-200 mg/dL
Toxic Level	Greater than 250 mg/dL

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



### **TEST CHANGE**

Porphyrins and Porphobilinoge 2002181, PORUFPBGU	
Specimen Requirements:	
Patient Preparation:	
Collect:	24-hour or random urine. Refrigerate 24-hour specimens during collection.
Specimen Preparation:	Protect from light. Transfer 8 mL aliquot to an ARUP <u>amber</u> <u>transport tubeAmber Transport Tube</u> . (Min: 4 mL) Record total volume and collection time interval on transport tube and test request form.
Transport Temperature:	Frozen.
Unacceptable Conditions:	Body fluids other than urine.
Remarks:	
Stability:	Ambient: Unacceptable; Refrigerated: 4 days; Frozen: 1 month
Methodology:	Quantitative High Performance Liquid Chromatography (HPLC)/ <del>Ion Exchange Chromatography/</del> Quantitative Spectrophotometry/ <u>Quantitative High Performance Liquid</u> <u>Chromatography-Tandem Mass Spectrometry</u>
Performed:	<u>Sun-Sat</u> Mon-Fri
Reported:	2-5 days
Note:	Urine porphyrins are useful for the evaluation of cutaneous photosensitivity to exclude porphyria cutanea tarda (PCT). Urine porphobilinogen (PBG) is useful for the evaluation of neurologic and/or psychiatric symptoms to exclude acute porphyrias such as acute intermittent porphyria (AIP).
CPT Codes:	84120; 84110
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
Results are normalized to creatini of porphyrin/moles of creatinine).	ne concentration and reported as a ratio of amounts (micromoles

Porphobilinogen (PBG), Urine



Results for random urine specimens are normalized to creatinine (CRT) concentration and reported as a ratio of amounts (millimoles of PBG/mole of creatinine).

Porphobilinogen (PBG) in a random urine specimen is used to evaluate an attack of acute porphyria. Slight increases in urinary PBG are associated with acute porphyrias other than acute intermittent porphyria (AIP) and may indicate a resolving or treated acute porphyria.

Urinary PBG in excess of two times the upper reference limit is consistent with acute porphyria.

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.

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 Int	erval	
	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
	Porphobilinogen <u>, <del>(PBG),</del> Urine - <u>ratio to</u> <u>CRTper volume</u></u>	0.0 <u>- 0.2 mm</u> c	ol/mol CRT <mark>-8.8</mark>	μ <mark>mol/L</mark>
	Uroporphyrin - ratio to CRT	0-4 μmol/mo	CRT	
	Heptacarboxylate - ratio to CRT	0-2 μmol/mo	CRT	
	Porphobilinogen (PBG), Urine -per 24h	0. <u>4 - 1.5</u> 0-11.	<del>θ</del> μmol/d	
	Coproporphyrin I - ratio to CRT	0-6 μmol/mo	CRT	
	Coproporphyrin III - ratio to CRT	0-14 μmol/m	ol CRT	

# 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.



Chromosome Analysis, Solid Tu	umor
2002296, CHR ST Specimen Requirements:	
Patient Preparation:	
Collect:	Thaw media prior to tissue inoculation. <u>Collect a 10mm solid tumor tissue biopsy (minimum of 5mm)</u> in a sterile, screw-top container filled with tissue culture transport medium.
Specimen Preparation:	DO NOT FREEZE. Do not place in formalin. Transport a 10 mm solid tumor tissue biopsy in a sterile, screw-top container filled with tissue culture transport medium. (Min: 5 mm).)
Transport Temperature:	Room temperature.
Unacceptable Conditions:	Frozen specimens. Specimens preserved in formalin.
Remarks:	
Stability:	Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Unacceptable
Methodology:	Giemsa Band
Performed:	Sun-Sat
Reported:	14-28 days
Note:	These studies involve culturing of living cells; therefore, turnaround times given represent average times, which are subject to multiple variables. 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. Place solid tumor biopsy in a sterile, screw-top container filled with tissue culture transport medium (ARUP Supply #32788). Available online through eSupply using ARUP <u>ConnectorConnect(TM) or</u> contact ARUP Client Services at (800 <sub>2</sub> )-522-2787. If cytogenetics tissue media is not available, collect in plain RPMI, Hanks solution, saline, or ringers. 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. This test must be ordered using Oncology test request form #43099 or through your ARUP interface.



CPT Codes:

88239; 88264

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.

Reference Interval:

By report



Chromosome Analysis, Lymph Node 2002300, CHR ONC	
Specimen Requirements:	
Patient Preparation:	
Collect:	Lymph nodeAny specimen type for oncology studies other than peripheral blood, bone marrow, and solid tumors. Thaw media prior to tissue inoculation. Collect <u>cerebral spinal fluid (CSF)</u> , <u>ocular fluid, and pleural fluidor other body fluids</u> in a-green (sodium heparin).
Specimen Preparation:	DO NOT FREEZE. Do not place in formalin. <u>Lymph nodes</u> Tissues: Transport 10 mm biopsy in a sterile, screw-top container filled with tissue culture transport media. Fluid: Transport 5 mL fluid in original collection tube.
Transport Temperature:	Room temperature.
Unacceptable Conditions:	Frozen specimens. <u>Lymph nodeTissue</u> submitted in formalin.
Remarks:	This test must be ordered using Oncology test request form #43099 or through your ARUP interface.
Stability:	Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Unacceptable
Methodology:	Giemsa Band
Performed:	Sun-Sat
Reported:	3-10 days
Note:	These studies involve culturing of living cells; therefore, turnaround times given represent average times, which are subject to multiple variables. 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. Collect <u>lymph node biopsytissue</u> in a sterile, screw-top container filled with tissue culture transport medium (ARUP Supply #32788). Available online through eSupply using ARUP <u>ConnectorConnect(TM) or</u> contact ARUP Client Services at (800-)-522-2787. If no transport media is available, collect in plain RPMI, Hanks solution, saline, or ringers. Contact ARUP Genetics Processing for other specimen types or information



and specific collection and transportation instructions.

CPT Codes:	88239; 88264	
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.		
Reference Interval:		
By report		



# Mismatch Repair by Immunohistochemistry with Reflex to BRAF Codon 600 Mutation and MLH1 Promoter Methylation

2002327, MSI REFLEX

Specimen Requirements:	
Patient Preparation:	
Collect:	Tumor tissue.
Specimen Preparation:	Tumor Tissue: Formalin fix (10 percent neutral buffered formalin is preferred) and paraffin embed tissue. If sending precut slides, do not oven bake. Transport tissue block or 15 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(TM) or contact ARUP Client Services at (800) 522-2787. (Min: 10 slides). Protect paraffin block and/or slides from excessive heat.
Transport Temperature:	Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Unacceptable Conditions:	Paraffin block with less than 25 percent tumor tissue. Specimens fixed in any fixative other than 10 percent neutral buffered formalin. Decalcified specimens.
Remarks:	Include surgical pathology report. Submit electronic request. If you do not have electronic ordering capability, use an ARUP requisition form complete with an ARUP client number. For additional technical details, please contact ARUP Client Services at (800) 522-2787. If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.
Stability:	Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Methodology:	Qualitative Immunohistochemistry (IHC)/Qualitative Real-Time Polymerase Chain Reaction
Performed:	Tue-Sat



Reported:	1-5 days	
Note:	If MLH1 is abnormal for Mismatch Repair by IHC, then BRAF codon 600 will be added. If BRAF codon 600 is negative, MLH1 Promoter Methylation will be added. Additional charges apply.	
CPT Codes:	88342; 88341 x3; if reflexed, add 81210; if further reflexed, add 81288	
New York DOH Approval Status:	This test is New York DOH approved.	
Interpretive Data:		
Refer to report.		
Refer to the Colorectal Cancer or Lynch Syndrome topic at arupconsult.com.		
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:

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.



PM/Scl-100 Antibody, IgG by I 2003040, PM/SCL	mmunoblot
Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube.
Specimen Preparation:	Transfer 1 mL serum to an ARUP <u>standard transport</u> <u>tube.</u> Standard Transport Tube. (Min: 0.3 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma. Contaminated, hemolyzed, or severely lipemic specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 <u>month (avoid repeated freeze/thaw</u> <u>cycles).year</u>
Methodology:	Qualitative Immunoblot
Performed:	Tue, Thu, Sat
Reported:	1-4 days
Note:	
CPT Codes:	86235

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

Interpretive Data:

The presence of PM/Scl-100 IgG antibody along with a positive ANA IFA nucleolar pattern is associated with connective tissue diseases such as polymyositis (PM), dermatomyositis (DM), systemic sclerosis (SSc), and polymyositis/systemic sclerosis overlap syndrome. The clinical relevance of PM/Scl-100 IgG antibody with a negative ANA IFA nucleolar pattern is unknown. PM/Scl-100 is the main target epitope of the PM/Scl complex, although antibodies to other targets not detected by this assay may occur.

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:

Negative



B-Cell Clonality Screening (IgH and IgK) by PCR 2006193, BCELL SCRN		
Specimen Requirements:		
Patient Preparation:		
Collect:	Whole blood or bone marrow in lavender (EDTA), tissue, formalin-fixed tissue.	
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) Fresh Tissue: Freeze immediately. Transport 100 mg or 0.5-2.0 cm3 tissue. FFPE Tumor Tissue: Formalin _fixed (10 percent neutral buffered formalin) and paraffin _embedded tissue. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or four 10-micron shavings in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect(TM) or contact ARUP Client Services at 800-522-2787.	
Transport Temperature:	Whole Blood, Bone Marrow: Refrigerated. Fresh Tissue: Frozen on dry ice. FFPE Tumor Tissue: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.	
Unacceptable Conditions:	Plasma, serum. Specimens collected in anticoagulants other than EDTA. Clotted or grossly hemolyzed specimens. Tissue: FFPE specimens fixed <del>/processed</del> in any fixative other than 10 percent neutral buffered formalin. <u>BoneDecalcified</u> specimens <u>submitted in non-EDTA decalcifier</u> .	
Remarks:	If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.	
Stability:	Whole Blood or Bone Marrow: Refrigerated: 7 days; Frozen: Unacceptable Fresh Tissue: Ambient: Unacceptable; Refrigerated: 2 hours; Frozen: 1 year FFPE Tumor Tissue: Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable	



Methodology:	Capillary Electrophoresis/Polymerase Chain Reaction (PCR)
Performed:	Varies
Reported:	5-9 days
Note:	
CPT Codes:	81261; 81264
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
Refer to report.	
Reference Interval:	



# MYD88 L265P Mutation Detection by PCR, Quantitative

2009318, MYD88	
Specimen Requirements:	
Patient Preparation:	
Collect:	Whole blood or bone marrow in lavender (EDTA) or FFPE tumor tissue.
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) FFPE Tumor Tissue : Formalin _fixed (10 percent neutral buffered formalin) and paraffin _embedded tissue. Protect from excessive heat. Transport tissue in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect(TM) or contact ARUP Client Services at 800-522-2787.
Transport Temperature:	Whole Blood, Bone Marrow: Refrigerated FFPE Tumor Tissue : Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Unacceptable Conditions:	Plasma, serum. Specimens collected in anticoagulants other than EDTA. Clotted or grossly hemolyzed specimens. FFPE Tumor Tissue : Specimens fixed in any fixative other than 10 percent neutral buffered formalin. <u>BoneDecalcified</u> specimens <u>submitted in non-EDTA decalcifier</u> .
Remarks:	If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) wil be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.
Stability:	Whole Blood or Bone Marrow: Refrigerated: 7 days; Frozen: Unacceptable FFPE Tumor Tissue: Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Methodology:	Real-Time Polymerase Chain Reaction
Performed:	Varies



Reported:	5-10 days
Note:	
CPT Codes:	81305
New York DOH Approval Status:	This test is New York DOH approved.
New York DOH Approval Status: Interpretive Data:	This test is New York DOH approved.
· ·	This test is New York DOH approved.



### **TEST CHANGE**

Alcohol, Urine, Quantitative 2010136, CDCO ETOH		
Specimen Requirements:		
Patient Preparation:		
Collect:	Random urine.	
Specimen Preparation:	Transfer 4 mL urine without additives or preservatives to an ARUP Standard Transport Tube. (Min: 1 mL)	
Transport Temperature:	Room temperature.	
Unacceptable Conditions:		
Remarks:		
Stability:	Ambient: 1 week; Refrigerated: 1 month; Frozen: 3 years (Avoid repeated freeze/thaw cycles)	
Methodology:	Quantitative Gas Chromatography	
Performed:	Sun-Sat	
Reported:	1-4 days	
Note:		
CPT Codes:	80320 (Alt code: G0480)	
New York DOH Approval Status:	This test is New York DOH approved.	
Interpretive Data:		
Methodology: Quantitative Gas Chromatography with Flame Ionization Detection Positive cutoff: 5 mg/dL		
For medical purposes only: not valid for forensic use		

For medical purposes only; not valid for forensic use.

The absence of expected drug(s) and/or drug metabolite(s) may indicate 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:** 



### Effective August 17, 2015

Drugs Covered	Cutoff Concentrations
Ethanol	5 mg/dL
Ethyl Alcohol	5 mg/dL

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



# Hereditary Hemolytic Anemia Panel Sequencing

2012052, HHA SEQ	
Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (EDTA) or yellow (ACD solution A or B).
Specimen Preparation:	Transport 3 mL whole blood. (Min: 1 mL) <u>New York State</u> <u>Clients: Transport 5 mL whole blood. (Min: 3 mL)</u>
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	
Remarks:	
Stability:	Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: Unacceptable
Methodology:	Massively Parallel Sequencing
Performed:	Varies
Reported:	14-21 days
Note:	Recent CBC result is required. GENES TESTED: AK1, ALDOA, ANK1, CDAN1, CYB5R3, EPB41, EPB42, G6PD, GCLC, GPI, GSR, GSS, HK1, NT5C3A, PFKM, PGK1, PIEZO1, PKLR, SEC23B, SLC4A1, SLC01B1, SLC01B3, SPTA1, SPTB, TPI1, UGT1A1, UGT1A6, UGT1A7
CPT Codes:	81443
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 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



Fibrillarin (U3 RNP) Antibody, IgG 2012173, U3 FIB Specimen Requirements: Patient Preparation: Collect: Serum separator tube. Specimen Preparation: Transfer 1 mL serum to an ARUP standard transport tube.Standard Transport Tube. (Min: 0.5 mL) Transport Temperature: Refrigerated. Also acceptable: Frozen. Unacceptable Conditions: Grossly hemolyzed or severely lipemic. Remarks: Stability: After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 month (avoid repeated freeze/thaw cycles).year Methodology: **Qualitative Immunoblot** Performed: Tue, Thu, Sat Reported: 1-4 days Note: CPT Codes: 86235

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

Interpretive Data:

The presence of fibrillarin (U3-RNP) IgG antibodies in association with an ANA IFA nucleolar pattern is suggestive of systemic sclerosis (SSc). In SSc, these antibodies are associated with distinct clinical features, such as younger age at disease onset, frequent internal organ involvement (pulmonary hypertension, myositis and renal disease). Fibrillarin antibodies are detected more frequently in African American patients with SSc compared to other ethnic groups. Strong correlation with ANA IFA results is recommended.

In a <u>multiethnic</u> cohort of SSc patients (n=98), U3-RNP antibodies detected by immunoblot had an agreement of 98.9 percent with the gold standard immunoprecipitation (IP) assay. Approximately 71 percent (5/7) of the borderline U3-RNP results with ANA nucleolar pattern in this cohort were IP negative.

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:

Negative



### Antinuclear Antibody (ANA) with HEp-2 Substrate, IgG by IFA

3000082, ANA IFA AB	
Specimen Requirements:	
Patient Preparation:	
Collect:	Serum <u>separator tube</u> Separator Tube (SST).
Specimen Preparation:	Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP <u>standard transport</u> <u>tube.Standard Transport Tube.</u> (Min: 0.15 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma. Contaminated, hemolyzed, or severely lipemic specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 <u>monthyear</u> (avoid repeated freeze/thaw cycles)
Methodology:	Semi-Quantitative Indirect Fluorescent Antibody (IFA)
Performed:	Sun-Sat
Reported:	1-3 days
Note:	ANA identified by indirect fluorescence assay (IFA) using HEp-2 substrate and IgG-specific conjugate at a screening dilution of 1:80. Positive nuclear patterns reported include homogeneous, speckled, centromere, nucleolar, or nuclear dots. Positive cytoplasmic patterns reported include reticular/AMA, discrete/GW body-like, polar/golgi-like, rods and rings, or cytoplasmic speckled patterns. All positive results are reported with endpoint titers at no additional charge.
CPT Codes:	86039
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
diseases (SARD). However, ANA la diseases (cancers, autoimmune, in	s (ANA) is a hallmark feature of systemic autoimmune rheumatic acks diagnostic specificity and is associated with a variety of nfectious, and inflammatory conditions) and may also occur in alence. The lack of diagnostic specificity requires confirmation



of positive ANA by more specific serologic tests. ANA (nuclear reactivity) positive patterns reported include centromere, homogeneous, nuclear dots, nucleolar, or speckled. ANA (cytoplasmic reactivity) positive patterns reported include reticular/AMA, discrete/GW body-like, polar/golgi-like, cytoplasmic speckled or rods and rings. All positive patterns are reported to endpoint titers (1:2560). Reported patterns may help guide differential diagnosis, although they may not be specific for individual antibodies or diseases. Mitotic staining patterns not reported. Negative results do not necessarily rule out SARD.

Reference Interval:

Less than 1:80



Criteria Syste 3000479, SSC	emic Sclerosis Par	nel
Specimen Req		
Patient Pre		
Collect:		Serum <u>separator tube</u> Separator Tube (SST).
Specimen F	Preparation:	Separate from cells ASAP or within 2 hours of collection. Transfer 3 mL serum to an ARUP <u>standard transport</u> <u>tube.Standard Transport Tube.</u> (Min: 0.25 mL)
Transport T	emperature:	Refrigerated.
Unacceptab	le Conditions:	Contaminated, hemolyzed, or severely lipemic specimens.
Remarks:		
Stability:		Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 <u>monthyear</u> (avoid repeated freeze/thaw cycles)
Methodology:		Semi-Quantitative Indirect Fluorescent Antibody/Semi- Quantitative Multiplex Bead Assay/Semi-Quantitative Enzyme- Linked Immunosorbent Assay
Performed:		Sun, Tue, Thu
Reported:		1-4 days
Note:		
CPT Codes:		86039; 86235; 83516
New York DOH	Approval Status:	This test is New York DOH approved.
Interpretive Da	ita:	
Component	Interpretation	
Scleroderma (Scl- 70) (ENA) Antibody, IgG	Negative 30-40 AU/mL Equivocal 41 AU/mL or greater Positive	
RNA Polymerase III Antibody, IgG	19 Units or less Negative 20-39 Units Weak Positive 40-80 Units Moderate Positive 81 Units or greater Strong Positive	



Reference Interval:

Test Number	Components	Reference Interval
	Scleroderma (Scl-70) (ENA) Antibody, IgG	40 AU/mL or less
	RNA Polymerase III Antibody, IgG	19 Units or less
	Antinuclear Antibody (ANA), HEp-2, IgG	Less than 1:80



FLT3 ITD and TKD Mutation De 3001161, FLT3-PCR	etection
Specimen Requirements:	
Patient Preparation:	
Collect:	Whole blood or bone marrow in lavender Lavender (EDTA). Also acceptable: Whole blood in ) or green (sodium heparin).) whole blood or bone marrow.
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 <u>-or</u> sodium heparin. Clotted or grossly hemolyzed specimens.
Remarks:	
Stability:	Ambient: 24 hours; Refrigerated: <u>7</u> 5 days; Frozen: Unacceptable
Methodology:	Capillary Electrophoresis
Performed:	Varies
Reported:	2-7 days
Note:	
CPT Codes:	81245; 81246
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
Refer to report.	
Reference Interval:	



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

Effective Date: May 20, 2024

#### **TEST CHANGE**

# Multiple Myeloma Panel by FISH

Specimen Requirements:	
Patient Preparation:	
Collect:	<u>Nondiluted</u> Non-diluted bone marrow collected in a heparinized syringe. Also acceptable: <u>whole blood collected in greenGreen</u> (sodium heparin).
Specimen Preparation:	Transfer 3 mL bone marrow to a green (sodium heparin) (Min: 1 mL). OR transport 5 mL whole blood (green, sodium heparin) (Min: 2 mL). <u>Additional specimen (recommend 2 mL) is</u> required if concurrent testing (chromosome analysis and/or genomic microarray) is ordered due to the need to perform <u>CD138+ cell enrichment process</u> .
Transport Temperature:	Room temperature.
Unacceptable Conditions:	Frozen specimens. Paraffin-embedded specimens. Clotted specimens.
Remarks:	
Stability:	Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Unacceptable
Methodology:	Fluorescence in situ Hybridization (FISH)
Performed:	Sun-Sat
Reported:	5-14 days
Note:	Fluorescence in situ hybridization (FISH) panel is performed on CD138+ <u>enrichedsorted</u> cells (assuming specimen is sufficient for <u>enrichmentsorting</u> ) for multiple myeloma prognosis-specific genomic abnormalities: <u>1p (CDKN2C loss/deletion)/1q (CKS1B)</u> gain/amplification), /17p (TP53) loss/deletion)/ <u>17q (NF1)</u> control, t(4;14) (IGH/FGFR3 <u>or NSD2 (and MMSET)</u> fusion), +9/9p (JAK2) enumeration, t(11;14) (IGH/CCND1 fusion and/or +11), t(14;16) (IGH/MAF fusion), t(14;20) (IGH/MAFB fusion). When this test is ordered in conjunction with a chromosome analysis, <u>and/or genomic microarray</u> , specimen prioritization <u>for low cellularity samples</u> will be given to FISH <u>&gt;microarray&gt;karyotype due to <u>for</u> the <u>need for CD138+</u> <u>cell enrichment prior to FISH and microarray testing.sorting of</u> <u>CD138+ cells</u>. This could impact <u>the</u> successful completion of</u>

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A nonprofit enterprise of the and its Department of Patho	University of Utab Effective Date: May 20, 2024	
	lower priority tests the chromosome analysis. If enrichmentsorting fails to yield sufficient CD138+ cells, testing will be performed using <u>unenrichedunsorted</u> cells, if available. 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 a complete analysis. This test must be ordered using Oncology test request form #43099 or through your ARUP interface. Contact ARUP Genetics Processing for other specimen types or information and specific collection and transportation instructions.	
CPT Codes:	88271 x7; 88275 x7	
New York DOH Approval Status:	This test is New York DOH approved.	
Interpretive Data:		
has not been cleared or approved	erformance characteristics determined by ARUP Laboratories. It by the US Food and Drug Administration. This test was ratory and is intended for clinical purposes.	Deleted Cells
Reference Interval:		
By report		



Monoclonal Protein Study, 24 hour, Urine 3002105, U-PEP Specimen Requirements: Patient Preparation: Collect: 24-hour urine. Refrigerate during collection. Also acceptable: Random urine specimens and urine supernate. **Specimen Preparation:** Transfer two 4 mL aliquots from well-mixed 24 hour collection to individual ARUP standard transport tubes. (Min: 4 mL) Transport Temperature: Refrigerated. Unacceptable Conditions: Remarks: Record total volume and collection time interval on transport tube and test request form. Stability: Ambient: 24 hours ; Refrigerated: 1 week; Frozen: 1 month Semi-Quantitative Electrophoresis/Qualitative Gel Methodology: Electrophoresis/ Quantitative Spectrophotometry Performed: Sun-SatMon-Fri Reported: 1-5 days Note: **CPT Codes:** 84156; 84166; 86335 New York DOH Approval Status: This test is New York DOH approved. Interpretive Data: Total urine protein measurement using this method characteristically underestimates urinary light chains. **Reference Interval:** Test Components **Reference Interval** Number **IFE Interpretation** By report Urine 24 Hour Protein 40-150 mg/d

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.





# IDH1 R132H Point Mutation by Immunohistochemistry with Reflex to IDH1 and IDH2 Mutation Analysis, Exon 4

3002134, IDH1 RFLX

Specimen Requirements:	
Patient Preparation:	
Collect:	Tumor tissue.
Specimen Preparation:	Formalin fix (10 percent neutral buffered formalin is preferred) and paraffin embed specimen. Protect paraffin block and/or slides from excessive heat. Transport tissue block or 7 unstained (5-micron thick sections), positively charged slides in a tissue transport kit (ARUP supply #47808) available online through eSupply using ARUP Connect(TM) or contact ARUP Client Services at (800)522-2787. (Min. 4 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:	Paraffin block with less than 25 percent tumor tissue. Specimens fixed in any fixative other than 10 percent neutral buffered formalin. Decalcified specimens.
Remarks:	Include surgical pathology report. If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.
Stability:	Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Methodology:	Immunohistochemistry
Performed:	Mon-Fri
Reported:	1-5 days



Note:	This test code includes pathologist interpretation. Negative IHC results will reflex to IDH1 and IDH2 Mutation Analysis, Exon 4, to assess for less common IDH mutations. Additional charges apply.
CPT Codes:	88342; if reflexed, add 81120; 81121
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
Refer to report.	
Reference Interval:	

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.



1p19q Deletion by FISH and IDH1 R132H Point Mutation by Immunohistochemistry with Reflex to IDH1 and IDH2 Mutation Analysis, Exon 4

3002135, OLIGO PAN

Specimen Requirements: Patient Preparation: Collect: Tumor tissue. Specimen Preparation: Formalin fix (10 percent neutral buffered formalin is preferred) and paraffin embed specimen. Protect paraffin block and/or slides from excessive heat. Transport tissue block or 10 unstained (5-micron thick sections), positively charged slides in a tissue transport kit (ARUP supply #47808) available online through eSupply using ARUP Connect(TM) or contact ARUP Client Services at (800)522-2787. (Min. 6 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: Paraffin block with less than 25 percent tumor tissue. Specimens fixed in any fixative other than 10 percent neutral buffered formalin. Decalcified specimens. Remarks: Include surgical pathology report. If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided. Stability: Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable Methodology: Fluorescence in situ Hybridization (FISH)/Immunohistochemistry/Polymerase Chain Reaction/Sequencing Performed: Mon-Fri



Reported:	1-7 days
Note:	This test code includes pathologist interpretation. Negative IDH1 IHC results will reflex to IDH1 and IDH2 Mutation Analysis, Exon 4, to assess for less common IDH mutations. Additional charges apply.
CPT Codes:	88342; 88377 x2; if reflexed, add 81120; 81121
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
Refer to report.	
Reference Interval:	

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.



#### Autoimmune Liver Disease Reflexive Panel

3002479, LIVER PAN	
Specimen Requirements:	
Patient Preparation:	
Collect:	Serum <u>separator tube</u> Separator Tube (SST).
Specimen Preparation:	Separate from cells ASAP or within 2 hours of collection. Transfer 1.5 mL serum to an ARUP <u>standard transport</u> <u>tube.Standard Transport Tube.</u> (Min: 1.0 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	NonserumNon-serum, heat-inactivated, contaminated, grossly icteric, severely lipemic, grossly hemolyzed specimens, or inclusion of fibrin clot.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 <u>monthyear</u> (avoid repeated freeze/thaw cycles)
Methodology:	Semi-Quantitative Enzyme-Linked Immunosorbent Assay (ELISA)//Semi-Quantitative Indirect Fluorescent Antibody (IFA)
Performed:	Sun-Sat
Reported:	1-8 days
Note:	If F-Actin, IgG by ELISA is 20 Units or greater, then Smooth Muscle Antibody (SMA), IgG by IFA titer will be added. Additional charges apply. ANA identified by indirect fluorescence assay (IFA) using HEp-2 substrate and IgG- specific conjugate at a screening dilution of 1:80. Positive nuclear patterns reported include homogeneous, speckled, centromere, nucleolar, or nuclear dots. Positive cytoplasmic patterns reported include reticular/AMA, discrete/GW body-like, polar/golgi-like, rods and rings, or cytoplasmic speckled patterns. All positive results are reported with endpoint titers at no additional charge.
CPT Codes:	86381; 83516; 86376; 86015; 86039; if reflexed, add 86256
New York DOH Approval Status:	This test is New York DOH approved.



#### Interpretive Data:

#### Reference Interval:

Test Number	Components	Reference Interval	
	Mitochondrial (M2) Antibody, IgG	24.9 Units or le	ess
	Soluble Liver Antigen Antibody, IgG	24.9 U or less	
	Liver-Kid Microsome-1 Ab, IgG by ELISA	24.9 U or less 19 Units or less	
	F-Actin (Smooth Muscle) Ab, IgG by ELISA		
	F-Actin (Smooth Muscle) Ab, IgG by ELISA		
		19 Units or less	Negative
		20-30 Units	Weak Positive - Suggest repeat testing in two to three weeks with a fresh specimen.
		31 Units or greater	Positive - Suggestive of autoimmune hepatitis or chronic active



	hepatitis.	
Antinuclear Antibody (ANA), HEp-2, IgG	Less than 1:80	



# Fatty Acids Profile, Essential in Red Blood Cells

3003086, FA PRO RBC	
Specimen Requirements:	
Patient Preparation:	
Collect:	Green (sodium heparin), lavender (K2EDTA), or yellow (ACD solution A). Green (Sodium Heparin), Lavender (K2EDTA), Yellow (ACD Solution A), or Protease Inhibitor tube (PPACK; Phe-Pro-Arg- chloromethylketone) (ARUP supply #49662), available online through eSupply using ARUP Connect(TM) or contact ARUP Client Services at (800) 522-2787. A winged collection set must be used.
Specimen Preparation:	DO NOT FREEZE. Transport 6 mL whole blood. (Min: 2 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Gross hemolysis, frozen whole blood.
Remarks:	Patient age is required on the test request form. Include information regarding treatment, family history, and tentative diagnosis.
Stability:	Ambient: 24 hours; Refrigerated: 7 days; Frozen: Unacceptable
Methodology:	Gas Chromatography-Mass Spectrometry (GC-MS)
Performed:	Varies
Reported:	7-10 days
Note:	
CPT Codes:	82542
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	
This test does not screen for diso	rders of peroxisomal biogenesis/function.
Reference Interval:	
By Report	





# Microsatellite Instability (MSI) HNPCC/Lynch Syndrome by PCR

3004277, MSIPCR	
Specimen Requirements:	
Patient Preparation:	
Collect:	Tumor AND normal epithelial tissue.
Specimen Preparation:	Tissue: Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Transport tissue block(s) or 10 unstained 5-micron slides (5 tumor and 5 normal epithelial). Transport block(s) and/or slide(s) in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect (TM) or contact ARUP Client Services at 800-522-2787.
Transport Temperature:	Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months
Unacceptable Conditions:	Less than 25 percent tumor or less than 50 percent normal epithelial tissue. Specimens fixed in any fixative other than 10 percent neutral buffered formalin. <u>BoneDecalcified</u> specimens submitted in non-EDTA decalcifier.
Remarks:	Include surgical pathology report. If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.
Stability:	Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Methodology:	Capillary Electrophoresis/Polymerase Chain Reaction (PCR)
Performed:	Varies
Reported:	10-20 days
Note:	



CPT Codes:

81301

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

Interpretive Data:

Refer to report.

Reference Interval:



MLH1 Promoter Methylation 3004308, MLH1 PCR		
Specimen Requirements:		
Patient Preparation:		
Collect:	Tumor tissue.	
Specimen Preparation:	Tumor Tissue: Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Transport tissue block or 5 unstained 5-micron slides. Transport block and/or slide(s) in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect( <u>TM</u> ) or contact ARUP Client Services at 800-522-2787.	
Transport Temperature:	Room temperature. Also Acceptable: Refrigerated. Ship in cooled container during summer months.	
Unacceptable Conditions:	<u>Less than 25 percent tumor.</u> Specimens fixed in any fixative other than 10 percent neutral buffered formalin. Less than 25 percent tumor. <u>BoneDecalcified</u> specimens <u>submitted in non-EDTA decalcifier</u> .	
Remarks:	Include surgical pathology report. If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.	
Stability:	Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable	
Methodology:	Real-Time Polymerase Chain Reaction/Fluorescence Resonance Energy Transfer (FRET)	
Performed:	Varies	
Reported:	7-12 days	
Note:		



CPT Codes:

81288

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

Interpretive Data:

Refer to report.

Reference Interval:



# MGMT Promoter Methylation Detection by ddPCR

3005956, MGMT METH	
Specimen Requirements:	
Patient Preparation:	
Collect:	Tumor tissue.
Specimen Preparation:	Tumor Tissue: Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or 5 unstained 5-micron slides. Transport block and/or slide(s) in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect( <u>TM</u> ) or contact ARUP Client Services at 800-522-2787.
Transport Temperature:	Room temperature. Ship in cooled container during summer months.
Unacceptable Conditions:	<u>Less than 25 percent tumor.</u> Specimens fixed in any fixative other than 10 percent neutral buffered formalin. <u>BoneDecalcified</u> specimens. <u>Less than 25 percent tumor.</u> <u>submitted in non-EDTA decalcifier.</u>
Remarks:	Include surgical pathology report. If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.
Stability:	Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Methodology:	Droplet Digital PCR (ddPCR)
Performed:	Varies
Reported:	8-12 days
Note:	



CPT Codes:

81287

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

Interpretive Data:

Refer to report.

Reference Interval:



# NEW TEST – Available Now

#### **Click for Pricing**

#### B-Cell CD20 Expression by Flow Cytometry, Quantitative

3016431, CD20 QUANT

Specimen Requirements:			
Patient Preparation:			
Collect:	Green (sodium heparin). Also acceptable: lavender (EDTA) or pink (K2EDTA).		
Specimen Preparation:	Transport 5 mL whole blood. (Min: 1 mL). Do not freeze.		
Transport Temperature:	Preferred transport temp: Room temperature. Also acceptable: Refrigerated. Specimen should be received within 72 hours ofcollection for optimal viable testing.		
Unacceptable Conditions:	Clotted, hemolyzed, or frozen specimens. Specimens received more than 72 hours from collection.		
Remarks:	Clinical history, differential diagnosis, and any relevant pathology reports.		
Stability:	Ambient: 72 hours; Refrigerated: 72 hours; Frozen: Unacceptable.		
Methodology:	Flow Cytometry		
Performed:	Sun-Sat		
Reported:	1-2 days		
Note:	Monoclonal antibody-based therapies, such as rituximab that target the CD20 antigen, are being used to treat patients with avariety of autoimmune disorders. The effectiveness of this therapy is dependent on the degree of B-cell suppression andvaries by disease state. This assay is designed to detect low levels of B cells and provide quantitative cell numbers in thesetting of rituximab-treated patients using both CD20 and CD19.		
CPT Codes:	86355; 86356		
New York DOH Approval Status:	This test is New York DOH approved.		
Interpretive Data:			



#### Reference Interval:

Refer to report.

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



# NEW TEST – Available Now

#### **Click for Pricing**

#### Rapid Acute Myeloid Leukemia Targeted Therapy Mutation Panel

 3017050, RAPID AML

 Specimen Requirements:

 Patient Preparation:

 Collect:
 Lavender (whole blood or bone marrow collected in EDTA), green (peripheral blood or bone marrow collected in sodium)

Conect.	green (peripheral blood or bone marrow collected in sodium heparin)
Specimen Preparation:	Whole Blood or Bone Marrow: Transport 2 mL (Min: 1.0 mL)
Transport Temperature:	Whole Blood or Bone Marrow: Refrigerated.
Unacceptable Conditions:	Serum, plasma, grossly hemolyzed specimens, buccal brush or swab, FFPE tissue, or frozen samples.
Remarks:	
Stability:	Whole blood: Ambient: 1 week, Refrigerated: 2 weeks, Frozen: Unacceptable Bone marrow: Ambient: 72 hours, Refrigerated: 1 week, Frozen: Unacceptable
Methodology:	Massively Parallel Sequencing
Performed:	Varies
Reported:	3-7 days
Note:	The following regions are targeted to detect clinically relevant hotspot mutations, unless otherwise indicated: CEBPA* (NM_004364) exon 1; FLT3 (NM_004119) exons 14, 15, 16, 20; IDH1 (NM_005896) exon 4; IDH2 (NM_002168) exon 4; KIT (NM_000222) exons 8, 9, 10, 11, 17; KRAS (NM_004985) exons 2, 3, 4; NPM1 (NM_002520) exon 11; NRAS (NM_002524) exons 2, 3, 4; TP53*(NM_000546) all coding exons *CEBPA and TP53 are fully covered; any clinically relevant or potentially relevant variants will be reported. More information about the targeted regions of this test is included in the Additional Technical Information.
CPT Codes:	81450
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:

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



# **NEW TEST**

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Adiponectin, Quantitative Seru 3017195, ADIP SP	m/Plasma
Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube (SST), light green (lithium heparin with gel separator), or plain red.
Specimen Preparation:	Allow serum to clot for 15-20 minutes at room temperature. Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 0.5 mL serum or plasma to an ARUP standard transport tube. (Min: 0.2 mL)
Transport Temperature:	Frozen
Unacceptable Conditions:	EDTA plasma.
Remarks:	
Stability:	After separation from cells: Ambient: 2 days; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Quantitative Radioimmunoassay (RIA)
Performed:	Wed
Reported:	1-8 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:	
Reference Interval:	



Age	Male (ug/mL)	Female(ug/mL)
0-7 years	2.33-26.5	2.33-26.5
8-9 years	3.96-14.9	3.96-14.9
10-11 years	3.36-13.8	3.36-13.8
12-13 years	4.50-13.2	4.50-13.2
14-15 years	3.67-13.7	3.67-13.7
16-19 years	2.74-13.3	2.74-13.3
greater than 19 years	2.00-13.9	4.00-19.4

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



# **NEW TEST**

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BRAF Mutation Detection 3017203, BRAF NGS		
Specimen Requirements:		
Patient Preparation:		
Collect:	Tumor tissue.	
Specimen Preparation:	Tumor Tissue: Formalin fix (10 percent neutral buffered formalin, not decalcified) and paraffin embedded tissue with at least 20 percent tumor burden. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or 8 unstained 5 micron slides. (Min: 5 slides). Transport block and/or slide(s) in a tissue transport kit (ARUP Supply # 47808) available online through eSupply using ARUP Connectcontact ARUP Client Services at 800-522-2787.	
Transport Temperature:	Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.	
Unacceptable Conditions:	Less than 20 percent tumor. Specimens fixed in any fixative other than 10 percent neutral buffered formalin. Decalcified specimens (except in EDTA). Decalcified specimens in EDTA will require a client approved disclaimer.	
Remarks:	Include surgical pathology report. If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided. Our pathologists will review every case to determine if there is an adequate tumor area for testing. Submitted specimens should contain >20 percent tumor. Specimens may be canceled, and a new block requested if there is not an acceptable area for extraction or if block/tissue has been decalcified (except in EDTA). Samples that produce less than the optimal concentration of DNA input and/or samples decalcified in EDTA will require a disclaimer for testing or be canceled.	
Stability:	Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen:	



	Unacceptable	
Methodology:	Massively Parallel Sequencing	
Performed:	Varies	
Reported:	10-15 days	
Note:	BRAF (NM_004333) exon 15 is evaluated to detect hotspot mutations. See Additional Technical Information for more information.	
CPT Codes:	81210	
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 Components Number	Reference Interval	

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



# NEW TEST

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#### BRAF Mutation Detection with Reflex to MLH1 Promoter Methylation

3017204, BRAF REFL Specimen Requirements:

Specimen Requirements:	
Patient Preparation:	
Collect:	Tumor tissue
Specimen Preparation:	Tumor Tissue: Formalin fix (10 percent neutral buffered formalin, not decalcified) and paraffin embedded tissue with at least 25 percent tumor burden. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or 8 unstained 5 micron slides. (Min: 5 slides). Transport block and/or slide(s) in a tissue transport kit (ARUP Supply # 47808) available online through eSupply using ARUP Connectcontact ARUP Client Services at 800-522-2787. New York State Clients: Transport tissue (Formalin-fixed, paraffin embedded) or 10 unstained, nonbaked slides and 1 slide stained with hematoxylin and eosin.
Transport Temperature:	Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Unacceptable Conditions:	Less than 25 percent tumor. Specimens fixed in any fixative other than 10 percent neutral buffered formalin. Decalcified specimens (except in EDTA). Decalcified specimens in EDTA will require a client approved disclaimer.
Remarks:	Include surgical pathology report. If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided. Our pathologists will review every case to determine if there is an adequate tumor area for testing. Submitted specimens should contain >25 percent tumor. Specimens may be canceled, and a new block requested if there is not an acceptable area for extraction or if block/tissue has been decalcified (except in EDTA). Samples that produce less than the optimal concentration of DNA input and/or samples decalcified in EDTA will require a disclaimer for testing



	or be canceled.		
Stability:	Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable		
Methodology:	Massively Parallel Sequencing		
Performed:	Varies		
Reported:	10-15 days		
Note:	BRAF (NM_004333) exon 15 is evaluated to detect hotspot mutations. If BRAF V600E mutation is not detected, then MLH1 Promoter Methylation will be added. Additional charges apply. See Additional Technical Information for more information.		
CPT Codes:	81210; If reflexed, add 81288		
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 Components Number		Reference Interval	

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



## **NEW TEST**

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Colorectal Cancer Mutation Panel 3017209, CRC MUT		
Specimen Requirements:		
Patient Preparation:		
Collect:	Tumor tissue	
Specimen Preparation:	Tumor Tissue: Formalin fix (10 percent neutral buffered formalin, not decalcified) and paraffin embedded tissue with at least 20 percent tumor burden. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or 8 unstained 5 micron slides. (Min: 5 slides). Transport block and/or slide(s) in a tissue transport kit (ARUP Supply # 47808) available online through eSupply using ARUP Connectcontact ARUP Client Services at 800-522-2787.	
Transport Temperature:	Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.	
Unacceptable Conditions:	Less than 20 percent tumor. Specimens fixed in any fixative other than 10 percent neutral buffered formalin. Decalcified specimens (except in EDTA). Decalcified specimens in EDTA will require a client approved disclaimer.	
Remarks:	Include surgical pathology report. If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided. Our pathologists will review every case to determine if there is an adequate tumor area for testing. Submitted specimens should contain >20 percent tumor. Specimens may be canceled, and a new block requested if there is not an acceptable area for extraction or if block/tissue has been decalcified (except in EDTA). Samples that produce less than the optimal concentration of DNA input and/or samples decalcified in EDTA will require a disclaimer for testing or be canceled.	
Stability:	Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen:	



	Unacceptable	
Methodology:	Massively Parallel Sequencing	
Performed:	Varies	
Reported:	10-15 days	
Note:	Hotspots Tested: BRAF (NM_004333) exon 15; KRAS (NM_004985) exons 2, 3, 4; NRAS (NM_002524) exons 2, 3, See Additional Technical Information for more information.	
CPT Codes:	81210, 81275, 81276, 81311	
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 Components Number	Reference Interval	



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#### IDH1 and IDH2 Mutation Detection 3017222, IDH1-IDH2 Specimen Requirements: Patient Preparation: Collect: Tumor tissue Specimen Preparation: Tumor Tissue: Formalin fix (10 percent neutral buffered formalin, not decalcified) and paraffin embedded tissue with at least 20 percent tumor burden. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or 8 unstained 5 micron slides. (Min: 5 slides). Transport block and/or slide(s) in a tissue transport kit (ARUP Supply # 47808) available online through eSupply using ARUP Connectcontact ARUP Client Services at 800-522-2787. New York State Clients: Transport tissue (Formalin-fixed, paraffin embedded) or 10 unstained, nonbaked slides and 1 slide stained with hematoxylin and eosin. Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months. Unacceptable Conditions: Less than 20 percent tumor. Specimens fixed in any fixative other than 10 percent neutral buffered formalin. Decalcified specimens (except in EDTA). Decalcified specimens in EDTA will require a client approved disclaimer. Include surgical pathology report. If multiple specimens Remarks: (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided. Our pathologists will review every case to determine if there is an adequate tumor area for testing. Submitted specimens should contain >20 percent tumor. Specimens may be canceled, and a new block requested if there is not an acceptable area for extraction or if block/tissue has been decalcified (except in EDTA). Samples that produce less than the optimal concentration of DNA input and/or samples decalcified in EDTA will require a disclaimer for testing



	or be canceled.
Stability:	Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Methodology:	Massively Parallel Sequencing
Performed:	Varies
Reported:	10-15 days
Note:	Hotspots Tested: IDH1 (NM_005896) exon 4 and IDH2 (NM_002168) exon 4. See Additional Technical Information for more information.
CPT Codes:	81120; 81121
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 Components Number	Reference Interval



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Lung Cancer Mutation Panel 3017230, LUNG MUT	
Specimen Requirements:	
Patient Preparation:	
Collect:	Tumor tissue
Specimen Preparation:	Tumor Tissue: Formalin fix (10 percent neutral buffered formalin, not decalcified) and paraffin embedded tissue with at least 20 percent tumor burden. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or 8 unstained 5 micron slides. (Min: 5 slides). Transport block and/or slide(s) in a tissue transport kit (ARUP Supply # 47808) available online through eSupply using ARUP Connectcontact ARUP Client Services at 800-522-2787. New York State Clients: Transport tissue (Formalin-fixed, paraffin embedded) or 10 unstained, nonbaked slides and 1 slide stained with hematoxylin and eosin .
Transport Temperature:	Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Unacceptable Conditions:	Less than 20 percent tumor. Specimens fixed in any fixative other than 10 percent neutral buffered formalin. Decalcified specimens (except in EDTA). Decalcified specimens in EDTA will require a client approved disclaimer.
Remarks:	Include surgical pathology report. If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided. Our pathologists will review every case to determine if there is an adequate tumor area for testing. Submitted specimens should contain >20 percent tumor. Specimens may be canceled, and a new block requested if there is not an acceptable area for extraction or if block/tissue has been decalcified (except in EDTA). Samples that produce less than the optimal concentration of DNA input and/or samples decalcified in EDTA will require a disclaimer for testing



	or be canceled.	
Stability:	Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable	
Methodology:	Massively Parallel Sequencing	
Performed:	Varies	
Reported:	10-15 days	
Note:	Hotspots Tested: BRAF (NM_004333) exon 15; EGFR (NM_005228) exons 18, 19, 20, 21; ERBB2 (NM_004448) exons 8, 19, 20; KRAS (NM_004985) exons 2, 3, 4; MET (NM_001127500) exons 14, 15. See Additional Technical Information for more information.	
CPT Codes:	81445, 81235, 81210, 81275, 81276	
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 Components Number	Reference Interval	



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Melanoma Mutation Panel 3017233, MEL MUT	
Specimen Requirements:	
Patient Preparation:	
Collect:	Tumor tissue
Specimen Preparation:	Tumor Tissue: Formalin fix (10 percent neutral buffered formalin, not decalcified) and paraffin embedded tissue with at least 20 percent tumor burden. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or 8 unstained 5 micron slides. (Min: 5 slides). Transport block and/or slide(s) in a tissue transport kit (ARUP Supply # 47808) available online through eSupply using ARUP Connectcontact ARUP Client Services at 800-522-2787. New York State Clients: Transport tissue (Formalin-fixed, paraffin embedded) or 10 unstained, nonbaked slides and 1 slide stained with hematoxylin and eosin.
Transport Temperature:	Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Unacceptable Conditions:	Less than 20 percent tumor. Specimens fixed in any fixative other than 10 percent neutral buffered formalin. Decalcified specimens (except in EDTA). Decalcified specimens in EDTA will require a client approved disclaimer.
Remarks:	Include surgical pathology report. If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided. Our pathologists will review every case to determine if there is an adequate tumor area for testing. Submitted specimens should contain >20 percent tumor. Specimens may be canceled, and a new block requested if there is not an acceptable area for extraction or if block/tissue has been decalcified (except in EDTA). Samples that produce less than the optimal concentration of DNA input and/or samples decalcified in EDTA will require a disclaimer for testing



	or be canceled.
Stability:	Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Methodology:	Massively Parallel Sequencing
Performed:	Varies
Reported:	10-15 days
Note:	Hotspots Tested: BRAF (NM_004333) exon 15; KIT (NM_000222) exons 9, 11, 13, 14, 17, 18; KRAS (NM_004985) exons 2, 3, 4; NRAS (NM_002524) exons 2, 3, 4. See Additional Technical Information for more information.
CPT Codes:	81210, 81272; 81275; 81276, 81311
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 Components Number	Reference Interval



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TPMT Genotyping	
3017372, TPMTGENO	
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; frozen yellow (ACD solution A or B)
Remarks:	
Stability:	Room temperature: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Polymerase Chain Reaction (PCR)/Flourescence 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
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.	
Counseling and informed consent available online.	are recommended for genetic testing. Consent forms are
Reference Interval:	
Py report	





### NEW TEST – Available Now

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NUDT15 Genotyping 3017373, NUDT15GENO	
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; frozen yellow (ACD solution A or B)
Remarks:	
Stability:	Room temperature: 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:	81306
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





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# TPSAB1 Copy Number Analysis by ddPCR

3017399, TPSAB1	
Specimen Requirements:	
Patient Preparation:	
Collect:	Whole blood or bone marrow in lavender (EDTA) preferred. Also acceptable: Green (sodium heparin)
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 (purple) or sodium heparin (green). Clotted or grossly hemolyzed specimens.
Remarks:	
Stability:	Refrigerated: 7 days; Frozen: Unacceptable
Methodology:	Droplet Digital PCR (ddPCR)
Performed:	Varies
Reported:	10-14 days
Note:	
CPT Codes:	81479
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:	



### NEW TEST - Available Now

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#### Ma2/Ta Antibody, IgG by Immunoblot, CSF

3017440, MA2/TA CSF	
Specimen Requirements:	
Patient Preparation:	
Collect:	CSF
Specimen Preparation:	Transfer 1 mL CSF to an ARUP standard transport tube. (Min: 0.60 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Urine, 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: This test is New York DOH approved.

#### Interpretive Data:

IgG antibodies to Ma2/Ta are associated with paraneoplastic neurologic syndromes with phenotypes most often including a combination of limbic encephalitis, diencephalic encephalitis, and brainstem encephalitis. Patients with anti-Ma2/Ta paraneoplastic neurologic syndromes should be thoroughly evaluated for cancer, including testicular cancer and adenocarcinoma, as neurologic symptoms often precede cancer diagnosis. Use of immune checkpoint inhibitors has also been associated with an increased risk of anti-Ma2 paraneoplastic neurologic disease. Consider sending testing in serum as well as CSF to improve diagnostic yield. Results (positive or negative) should be interpreted in the context of the patient's complete clinical picture, as false positives may occur and a negative result does not exclude the diagnosis of paraneoplastic neurologic disease.

#### Reference Interval:



Test Number	•	Reference Interval
	Ma2/Ta Antibody, IgG by Immunoblot, CSF	Negative



### NEW TEST - Available Now

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#### Ma2/Ta Antibody, IgG by Immunoblot, Serum

3017441, MA2/TA 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:	This test is New York DOH approved.

Interpretive Data:

IgG antibodies to Ma2/Ta are associated with paraneoplastic neurologic syndromes with phenotypes most often including a combination of limbic encephalitis, diencephalic encephalitis, and brainstem encephalitis. Patients with anti-Ma2/Ta paraneoplastic neurologic syndromes should be thoroughly evaluated for cancer, including testicular cancer and adenocarcinoma, as neurologic symptoms often precede cancer diagnosis. Use of immune checkpoint inhibitors has also been associated with an increased risk of anti-Ma2 paraneoplastic neurologic disease. Consider sending testing in CSF as well as serum to improve diagnostic yield. Results (positive or negative) should be interpreted in the context of the patient's complete clinical picture, as false positives may occur and a negative result does not exclude the diagnosis of paraneoplastic neurologic disease.

Reference Interval:



Test Number		Reference Interval
	Ma2/Ta Antibody, IgG by Immunoblot, Ser	Negative



HI A-B51 Genotyping, Behcet Disease

### **NEW TEST**

**Click for Pricing** 

HLA-B51 Genotyping, Bencet Disease			
3017549, HLA B51			
Specimen Requirements:			
Patient Preparation:			
Collect:	Lavender (EDTA), pink (K2EDTA), or yellow (ACD solution A or B).		
Specimen Preparation:	Transport 5 mL whole blood. (Min: 3 mL).		
Transport Temperature:	Refrigerated		
Unacceptable Conditions:	Specimens collected in green (sodium or lithium heparin).		
Remarks:			
Stability:	Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable		
Methodology:	Polymerase Chain Reaction/Massively Parallel Sequencing/Sequence-Specific Oligonucleotide Probe Hybridization		
Performed:			
Reported:	8-15 days		
Note:			
CPT Codes:	81381		
New York DOH Approval Status:	This test is New York DOH approved.		

Interpretive Data:

Background Information for HLA-B51 Genotyping for Behcet Disease:

Characteristics: Behcet disease (BD) is a multisystem chronic inflammatory disease, caused by vasculitis of arteries and veins of all sizes, involving the skin, mucosa, eyes, joints, cardiovascular, gastrointestinal, and nervous systems.

Prevalence: BD shows worldwide distribution, but it is most common in the Mediterranean basin, Middle East, and East Asian countries. Prevalence is high in Iran and Turkey with 80-370 cases/100,000 individuals, and comparatively low in the U.S. with 5.2 cases/100,000 individuals.

Inheritance: Multifactorial.

Cause: The disease-causing factors are unknown. HLA-B\*51 is strongly associated with BD with



approximately 60% of patients being positive, as opposed to about 15% positivity in healthy individuals across different ethnicities. Due to low specificity, HLA-B\*51 positivity is not diagnostic for BD. It may, however, affect clinical phenotypes of BD as it is more common in patients with ocular involvement, and less common in patients with gastrointestinal involvement.

Clinical Sensitivity: Approximately 50-80 percent, depending on ethnicity.

Methodology: Polymerase Chain Reaction/Massively Parallel Sequencing/Sequence-Specific Oligonucleotide Probe Hybridization.

Analytical Sensitivity and Specificity: >99 percent.

Limitations: Other genetic and nongenetic factors that influence BD are not evaluated. Other rare, or novel alleles may occur which may lead to false positive or false negative results. In cases where an HLA allele can not be resolved unambiguously, the allele assignment will be reported as the most common, based on allele frequencies from the Common, Intermediate and Well-Documented Alleles Catalogue version 3.0.0 (Hurley CK, et al, 2020).

Alleles tested: HLA-B\*51 alleles.

Disclaimer Information:

This test was developed and its performance characteristics determined by the Histocompatibility and Immunogenetics Laboratory at the University of Utah Health. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. Histocompatibility and Immunogenetics Laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing.

Performed at: Histocompatibility and Immunogenetics Laboratory, University of Utah Health, 417 Wakara Way, Suite 3220, Salt Lake City, UT 84108.

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

Reference Interval:



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#### QuantiFERON TB-Gold Plus, 1-Tube

3017554, QFT PLUS			
Specimen Requirements:			
Patient Preparation:			
Collect:	QuantiFERONGold Plus 1-tube (ARUP Supply #54015) available online through eSupply using ARUP Connect(TM) or contact ARUP Client Services at 800-522-2787. For collection and transport instructions, refer to QuantiFERON under Special Handling at https://www.aruplab.com/testing/quantiferon#collection. NOTE: The specimen must be submitted in the ARUP-provided collection tube due to the requirements of the laboratory automation.		
Specimen Preparation:	Transport 6 mL whole blood. (Min: 5 mL).		
Transport Temperature:	Refrigerated. Must be collected and shipped directly to ARUP the same calendar day.		
Unacceptable Conditions:	Clotted specimens.		
Remarks:	Do not collect or ship on holidays or the day before holidays.		
Stability:	Ambient: 3 hours; Refrigerated: 48 hours; Frozen: Unacceptable		
Methodology:	Semi-Quantitative Chemiluminescent Immunoassay (CLIA)/Semi-Quantitative Enzyme-Linked Immunosorbent Assay (ELISA)		
Performed:	Sun-Sat		
Reported:	1-4 days		
Note:	If the stability requirements cannot be met, please refer to ARUP test code 3017562, QuantiFERON-TB Gold Plus, 4-Tube.		
CPT Codes:	86480		
New York DOH Approval Status:	This test is New York DOH approved.		
Interpretive Data:			
	sured for specimens from each of the four collection tubes. A ve, or Indeterminate) is based on interpretation of the four		



values: NIL, MITOGEN minus NIL (MITOGEN-NIL), TB1 minus NIL (TB1-NIL), and TB2 minus NIL (TB2-NIL). The NIL value represents nonspecific reactivity produced by the patient specimen. The MITOGEN-NIL value serves as the positive control for the patient specimen, demonstrating successful lymphocyte activity. The TB1-NIL tube specifically detects CD4+ lymphocyte reactivity, specifically stimulated by the TB1 antigens. The TB2-NIL tube detects both CD4+ and CD8+ lymphocyte reactivity, stimulated by TB2 antigens. An overall Negative result does not completely rule out TB infection.

A false-positive result in the absence of other clinical evidence of TB infection is not uncommon. Refer to: Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium tuberculosis Infection -- United States, 2010

(http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5905a1.htm), for more information concerning test performance in low-prevalence populations and use in occupational screening.

Reference Interval:

Test Number	Components	Reference Interval
	QuantiFERON-Mitogen minus NIL	
		No Reference Interval
	QuantiFERON NIL	
		No Reference Interval
	Quantiferon-Plus TB1 minus NIL	
		0.34 IU/mL or less
	Quantiferon-Plus TB2 minus NIL	
		0.34 IU/mL or less



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#### QuantiFERON TB-Gold Plus, 4-Tube

3017562, QFT 4				
Specimen Requirements:				
Patient Preparation:				
Collect:	QuantiFERON-TB Gold Plus (Standard) 4-Tube Collection Kit (ARUP Supply #54012) or QuantiFERON-TB Gold Plus (HIGH ALTITUDE) 4-Tube Collection Kit (ARUP Supply #54010) available online through eSupply using ARUP Connect(TM) or contact ARUP Client Services at 800-522-2787. Specimens may remain ambient for up to 16 hours after collection before being placed in an incubator. For collection and transport instructions refer to QuantiFERON under Special Handling at https://www.aruplab.com/testing/quantiferon#collection.			
Specimen Preparation:	Transport plasma in the original containers. (Min: 0.8 mL per container)			
Transport Temperature:	Refrigerated			
Unacceptable Conditions:	Whole blood			
Remarks:				
Stability:	Ambient: 2 hours; Refrigerated: 1 month; Frozen: Unacceptable			
Methodology:	Semi-Quantitative Chemiluminescent Immunoassay (CLIA)/Semi-Quantitative Enzyme-Linked Immunosorbent Assay (ELISA)			
Performed:	Sun-Sat			
Reported:	1-4 days			
Note:				
CPT Codes:	86480			
New York DOH Approval Status:	This test is New York DOH approved.			
Interpretive Data:				

Interferon gamma release is measured for specimens from each of the four collection tubes. A qualitative result (Negative, Positive, or Indeterminate) is based on interpretation of the four values: NIL, MITOGEN minus NIL (MITOGEN-NIL), TB1 minus NIL (TB1-NIL), and TB2 minus NIL (TB2-NIL). The NIL value represents nonspecific reactivity produced by the patient specimen. The



MITOGEN-NIL value serves as the positive control for the patient specimen, demonstrating successful lymphocyte activity. The TB1-NIL tube specifically detects CD4+ lymphocyte reactivity, specifically stimulated by the TB1 antigens. The TB2-NIL tube detects both CD4+ and CD8+ lymphocyte reactivity, stimulated by TB2 antigens. An overall Negative result does not completely rule out TB infection.

A false-positive result in the absence of other clinical evidence of TB infection is not uncommon. Refer to: Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium tuberculosis Infection -- United States, 2010 (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5905a1.htm), for more information concerning

test performance in low-prevalence populations and use in occupational screening.

Reference Interval:

Test Number	Components	Reference Interval
	QuantiFERON-Mitogen minus NIL	
		No Reference Interval
	QuantiFERON NIL	
		No Reference Interval
	Quantiferon-Plus TB1 minus NIL	
		0.34 IU/mL or less
	Quantiferon-Plus TB2 minus NIL	
		0.34 IU/mL or less



## NEW TEST – Available Now

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### Allergen, Food, Wheat Component rTri a 19 Omega 5-Gliadin, IgE

3017565, TRI A 19

-	
Specimen Requirements:	
Patient Preparation:	Multiple patient encounters should be avoided.
Collect:	Serum separator tube.
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transfer 0.5 mL serum to an ARUP standard transport tube. (Min: 0.25 mL). For multiple allergen orders refer to "Allergen Specimen Collection Instructions" at www.aruplab.com/testing/resources/specimen.
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Hemolyzed, icteric, or lipemic specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 month
Methodology:	Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed:	Sun-Sat
Reported:	1-3 days
Note:	
CPT Codes:	86008
New York DOH Approval Status:	This test is New York DOH approved.
Interpretive Data:	



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

Reporting Range (reported in kU/L)	Probability of IgE Mediated Clinical Reaction	Class Scoring
Less than 0.10	No significant level detected	0
0.10-0.34	Clinical relevance undetermined	0/1
0.35-0.70	Low	1
0.71-3.50	Moderate	2
3.51-17.50	High	3
17.51-50.00	Very high	4
20.01-100.00	Very high	5
Greater than 100.00	Very high	6

#### Reference Interval:

Test Number		Reference Interval
	Wheat rTri a 19	Less than or equal to 0.09 kU/L



# NEW TEST – Available Now

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### Allergen, Food, Wheat and nGliadin With Reflex to Components, IgE

3017569, WHEAT R

Specimen Requirements:		
Patient Preparation:	Multiple patient encounters should be avoided.	
Collect:	Serum separator tube.	
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transfer 0.5 mL serum to an ARUP standard transport tube. (Min: 0.35 mL). For multiple allergen orders refer to "Allergen Specimen Collection Instructions" at www.aruplab.com/testing/resources/specimen.	
Transport Temperature:	Refrigerated.	
Unacceptable Conditions:	Hemolyzed, icteric, or lipemic specimens.	
Remarks:		
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 month	
Methodology:	Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay	
Performed:	Sun-Sat	
Reported:	1-3 days	
Note:	This assay will initially test wheat whole allergen and purified gliadin. If the wheat whole allergen result is greater than or equal to 0.1 kU/L, wheat component Tri a 14 will be ordered. If the purified gliadin is greater than or equal to 0.1 kU/L, wheat component Tri a 19 will be ordered. Additional charges apply.	
CPT Codes:	86003; 86008 if reflexed add 86008 x2	
New York DOH Approval Status:	This test is New York DOH approved.	
Interpretive Data:		



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

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

#### Reference Interval:

Test Number	Components	Reference Interval
	Allergen, Food, Wheat IgE	Less than or equal to 0.34 kU/L
	Wheat nGliadin	Less than or equal to 0.09 kU/L



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RBC Antibody ID Package (IRL)		
3017610, IRL AB PKG		
Specimen Requirements:		
Patient Preparation:		
Collect:	Lavender (K2EDTA) or pink (K2EDTA) AND plain red.	
Specimen Preparation:	Do not freeze. Transport 10 mL whole blood (plain red) AND 20 mL whole blood (EDTA). (Min: 7 mL plain red AND 10 mL EDTA).	
Transport Temperature:	Refrigerated. Deliver to lab immediately.	
Unacceptable Conditions:	Separator tubes.	
Remarks:		
Stability:	Ambient: Unacceptable; Refrigerated: 1 week; Frozen: Unacceptable	
Methodology:	Qualitative Hemagglutination (HA)	
Performed:	Mon-Fri	
Reported:	3-5 days	
Note:	Includes: ABO/Rh type, direct Coombs, RBC antibody identification, by various methods. Red blood cell antigen testing will be added as indicated. Depending on antibody complexity, additional testing may be required. Additional charges apply. Client must provide patient transfusion history.	
CPT Codes:	86900; 86901; 86880; 86870 x3; additional CPT codes may apply	
New York DOH Approval Status:	This test is New York DOH approved.	
Interpretive Data:		
Reference Interval:		
By report		



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### RBC Antibody ID Prenatal - Reflex to Titer

3017611, IRL ABID	
Specimen Requirements:	
Patient Preparation:	
Collect:	3 (7mL) lavender (K2EDTA) or pink (K2EDTA) AND 1 (7mL) plain red.
Specimen Preparation:	Do not freeze. Transport 3 (7 mL) whole blood EDTA AND 1 (7 mL) whole blood plain red. (Min: 10 mL EDTA and 3 mL plain red)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Separator tubes.
Remarks:	
Stability:	Ambient: Unacceptable; Refrigerated: 1 week; Frozen: Unacceptable
Methodology:	Qualitative Hemagglutination (HA)/Qualitative Solid Phase Red Cell Adherence
Performed:	Mon-Fri
Reported:	3-5 days
Note:	This test is for prenatal patients only. Includes: ABO/Rh type, direct Coombs, RBC antibody identification by one method. Titers will be performed, at an additional charge, on prenatal specimens for clinically significant antibodies. Red blood cell antigen testing will be added as indicated. Depending on antibody complexity, additional testing may be required. Additional charges apply.
CPT Codes:	86900; 86901; 86880; 86870; additional CPT codes may apply
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	Components	Reference Interval
Number		



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PD-L1 22C3 by IHC		
3017615, PDL1 22C3		
Specimen Requirements:		
Patient Preparation:		
Collect:	Tumor tissue	
Specimen Preparation:	Formalin fixed (10% neutral buffered formalin) and paraffin embedded (FFPE) specimen. Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (ARUP supply #47808 required), available online through eSupply using ARUP Connect(TM) or contact ARUP Client Services at 800-522-2787. (Min: 3 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:	Paraffin block with no tumor tissue remaining; specimens fixed in any fixative other than 10% neutral buffered formalin. Decalcified specimens. Specimens with fewer than 100 viable tumor cells.	
Remarks:	Include surgical pathology report and indicate tissue site with the test order. For additional technical details, please contact ARUP Client Services at 800-522-2787. If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.	
Stability:	Paraffin block: Ambient indefinitely, Refrigerated indefinitely, Frozen: Unacceptable Precut NSCLC slides: Ambient 6 months, Refrigerated 6 months, Frozen: Unacceptable Precut gastric/GEJ adenocarcinoma slides: Ambient: 5 months, Refrigerated 5 months, Frozen: Unacceptable Precut ESCC slides: Ambient 1 month, Refrigerated 4.5 months, Frozen: Unacceptable Precut cervical cancer slides: Ambient 1 month,	



	Refrigerated 5 months, Frozen: Unacceptable Precut HNSCC slides: Ambient 4 months, Refrigerated 6 months, Frozen: Unacceptable Precut TNBC slides: Ambient 4 months, Refrigerated 7.5 months, Frozen: Unacceptable
Methodology:	Immunohistochemistry (IHC)
Performed:	Mon-Fri
Reported:	3-7 days
Note:	This test code includes pathologist interpretation. At least 100 viable tumor cells are required for interpretation. Submission of slides that have been oven baked, or specimens that are decalcified and/or fixed in any fixative other than 10% neutral buffered formalin are not validated and should be interpreted with caution.
CPT Codes:	88360
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:	



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Vitamin C, Plasma (High-Dose Therapy) 3017651, VIT C IV		
Specimen Requirements:		
Patient Preparation:		
Collect:	Green (sodium or lithium heparin). Place specimen in ice bath immediately. Also acceptable: Plasma separator tube.	
Specimen Preparation:	Protect from light, centrifuge, transfer plasma, and freeze within 1 hour of collection. Transfer 0.5 mL plasma to an ARUP amber transport tube. (Min: 0.3 mL)	
Transport Temperature:	CRITICAL FROZEN AND LIGHT PROTECTED. Separate specimens must be submitted when multiple tests are ordered.	
Unacceptable Conditions:	EDTA plasma, whole blood, or body fluids. Grossly hemolyzed specimens.	
Remarks:	Thawing and refreezing of the specimen and exposure to light will result in decreased vitamin C concentration.	
Stability:	After separation from cells: Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 1 month	
Methodology:	Quantitative High Performance Liquid Chromatography- Tandem Mass Spectrometry	
Performed:	Sun-Sat	
Reported:	1-6 days	
Note:	Thawing and refreezing of the specimen and exposure to light will result in decreased vitamin C concentration.	
CPT Codes:	82180	
New York DOH Approval Status:	This test is New York DOH approved.	
Interpretive Data:		
Intravenous vitamin C (IVC) administration produces millimolar plasma ascorbate (vitamin C)		

Intravenous vitamin C (IVC) administration produces millimolar plasma ascorbate (vitamin C) concentrations. Therapeutic concentrations average 15 mmol/L and range from 1-30 mmol/L. The maximum plasma concentration achieved by oral supplementation of vitamin C is approximately 250



Vitamin C concentration is reported as micromoles per liter (). To convert concentration to millimoles per liter (mmol/L), multiply the result by 0.001.

Reference Interval:

Test Number	•	Reference Interval
	Vitamin C, Plasma	23-114 u mol/L



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Alzheimer's Disease Markers, CSF 3017653, ADMRKS CSF		
Specimen Requirements:		
Patient Preparation:		
Collect:	CSF	
Specimen Preparation:	Tube type: Preferred: 2.5 ml low-bind false bottom CSF tube (Sarstedt, 63.614.625) Acceptable: Sarstedt 72.703.600 (1.5 ml) or Sarstedt 72.694.600 (2 ml) Unacceptable: Polystyrene collection tubes are not acceptable as exposing of CSF to polystyrene tubes may decrease Abeta42 concentrations Collection instructions: 1. Perform lumbar puncture and discard the first 1 to 2 ml of CSF 2. Collect CSF directly into low-bind false bottom CSF tube using the drip method. Avoid use of syringes or extension tubing. Fill tube at least 50% full. 3. Send specimen in original collection tube (do not aliquot) using transport kit (ARUP Supply #55810) available online through eSupply using ARUP Connect (TM) or contract ARUP Client Services at 800-522-2787.	
Transport Temperature:	-20- Critical frozen	
Unacceptable Conditions:	Specimen types other than those listed and hemolyzed CSF. Specimens too viscous to be aspirated by instrument.	
Remarks:		
Stability:	Frozen: 8 weeks	
Methodology:	Quantitative Electrochemiluminescent Immunoassay (ECLIA)	
Performed:	Mon	
Reported:	1-7 days	
Note:		
CPT Codes:	83520 x3	
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:		



Interpretive information: The Alzheimer's Disease Markers, CSF panel is intended for use in adult patients aged 55 years and older being evaluated for Alzheimer's disease (AD) and other causes of cognitive impairment. The pTau181/Abeta42 and tTau/Abeta42 ratios provide better concordance with amyloid positron emission tomography (PET) imaging when compared to Abeta42, pTau181, and tTau individually.

Limitations: Failure to adhere to the sample collection instructions provided in the Lab Test Catalog may result in falsely reduced Abeta42 concentrations and therefore false elevations in the reported ratios. The ratios reported have not been established for predicting development of dementia or other neurologic conditions or for monitoring responses to therapies. Results of this test must always be interpreted in the context other clinical diagnostic evaluations and should not be used alone to establish a diagnosis of AD or other cognitive disorder.

Methodology: Roche Diagnostics Inc. electrochemiluminescence assay was used. Results obtained with different assay methods or kits may be different and cannot be used interchangeably.

Phospho-Tau (181P) CSF/ß- Amyloid (1-42) CSF ratio	Interpretation
<= 0.023	A negative result, defined as pTau181/Abeta42 ratio value below cutoff, is consistent with a negative amyloid positron emission tomography (PET) scan result. A negative result reduces the likelihood that a patient's cognitive impairment is due to AD.
> 0.023	A positive result, defined as pTau181/Abeta42 ratio value above cutoff, is consistent with a positive amyloid PET scan result. A positive result does not establish a diagnosis of AD or other cognitive disorder.
Total Tau CSF/ß- Amyloid (1-42) CSF ratio	Interpretation
<= 0.28	A negative result, defined as



#### Reference Interval:

Test Number	Components	Reference Interval
	Phospho-Tau(181)/Abeta42 Ratio, CSF	<= 0.023
	Total-Tau/Abeta42 Ratio, CSF	<= 0.28



# Inactivations

### The following will be discontinued from ARUP's test menu on May 20, 2024 Replacement test options are indicated when applicable.

Test Number	Test Name	Refer to Replacement Test
0013003	Antibody ID Package (IRL) (Change effective as of 05/20/24: Refer to 3017610 in the May Hotline)	RBC Antibody ID Package (IRL) (3017610)
0013005	Antibody ID RBC Prenatal-Reflex to Titer (Change effective as of 05/20/24: Refer to 3017610 in the May Hotline)	RBC Antibody ID Prenatal - Reflex to Titer (3017611)
0040248	KRAS Mutation Detection (Inactive as of 05/20/2024)	
0049000	Leukocyte Alkaline Phosphatase (Inactive as of 5/20/2024)	
0051750	BRAF Codon 600 Mutation Detection with Reflex to MLH1 Promoter Methylation (Change effective as of 05/20/24: Refer to 3017204)	BRAF Mutation Detection with Reflex to MLH1 Promoter Methylation (3017204)
0092099	B-Cell CD20 Expression (Change effective as of 03/20/24: Refer to 3016431)	B-Cell CD20 Expression by Flow Cytometry, Quantitative (3016431)
2002440	EGFR Mutation Detection by Pyrosequencing (Inactive as of 05/20/2024)	
2002498	BRAF Codon 600 Mutation Detection by Pyrosequencing (Change effectrive as of 05/20/24: Refer to 3017203)	BRAF Mutation Detection (3017203)
2003036	Aquaporin-4 Receptor Antibody (Change effective as of 05/20/24: Refer to 2013320)	Aquaporin-4 (AQP4) Antibody, IgG by CBA- IFA With Reflex to Titer, Serum (2013320)
2003123	NRAS Mutation Detection by Pyrosequencing (Inactive as of 05/20/2024)	



Test Number	Test Name	Refer to Replacement Test
2005685	Japanese Encephalitis Virus Antibody, IgM by ELISA (Change effective as of 05/20/24: Refer to 2005689)	Japanese Encephalitis Virus Antibodies, IgG and IgM by ELISA (2005689)
2005687	Japanese Encephalitis Virus Antibody, IgG by ELISA (Change effective as of 05/20/24: Refer to 2005689)	Japanese Encephalitis Virus Antibodies, IgG and IgM by ELISA (2005689)
2006444	IDH1 and IDH2 Mutation Analysis, exon 4 (Inactive as of 5/20/2024)	
2011476	Porphobilinogen (PBG), Random Urine(Change effective as of 05/20/24: Refer to 0080260 in the May Hotline)	Porphobilinogen (PBG), Urine(0080260)
2013284	PD-L1 22C3 IHC with Tumor Proportion Score (TPS) Interpretation, pembrolizumab (KEYTRUDA) and cemiplimab-rwlc (LIBTAYO) (Change effective as of 05/20/24: Refer to 3017615)	PD-L1 22C3 IHC (3017615)
2013327	Aquaporin-4 Receptor Antibody by ELISA with Reflex to Aquaporin-4 Receptor Antibody, IgG by IFA (Change effective as of 05/20/24: Refer to 2013320)	Aquaporin-4 (AQP4) Antibody, IgG by CBA- IFA With Reflex to Titer, Serum (2013320)
3000197	PD-L1 22C3 IHC with Combined Positive Score (CPS) Interpretation, pembrolizumab (KEYTRUDA) (Change effective as of 05/20/24: Refer to 3017615)	PD-L1 22C3 IHC (3017615)
3000399	QuantiFERON-TB Gold Plus, 4-Tube (Change effective as of 05/20/24: Refer to 3017562)	QuantiFERON TB-Gold Plus, 4-Tube (3017562)
3000400	QuantiFERON-TB Gold Plus, 1-Tube (Change effective as of 05/20/24: Refer to 3017554)	QuantiFERON-TB Gold Plus, 1-Tube (3017554)



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Test Number	Test Name	Refer to Replacement Test
3004267	IDH1 and IDH2 Mutation Analysis Exon 4, Formalin-Fixed, Paraffin-Embedded (FFPE) Tissue (Change effectrive as of 05/20/24: Refer to 3017222)	IDH1 and IDH2 Mutation Detection (3017222)
3006049	Autoimmune Encephalitis Reflex Panel, CSF (Change effective as of 05/20/24: Refer to 3006202, 3006211)	Autoimmune Encephalopathy/Dementia Panel, CSF (3006202), Autoimmune Pediatric CNS Disorders, CSF (3006211)
3006050	Autoimmune Encephalitis Extended Panel, Serum (Change effective as of 05/20/24: Refer to 3006201, 3006210)	Autoimmune Encephalopathy/Dementia Panel, Serum (3006201), Autoimmune Pediatric CNS Disorders, Serum (3006210)
3006285	Adiponectin Quantitative, Serum/Plasma (Change effective as of 05/20/24: Refer to 3017195 in the May Hotline)	Adiponectin, Quantitative Serum/Plasma (3017195)
3016444	Phospho-Tau/Total-Tau/A Beta42, CSF (Change effective as of 05/20/24: Refer to 3017653 in the May Hotline)	Alzheimer's Disease Markers, CSF (3017653)