MEDICARE COVERAGE OF LABORATORY TESTING

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

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

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

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

Hotline Page #	Test Number	Summary of Changes by Test Name	Name Change	Methodology	Performed/Reported Schedule	Specimen Requirements	Reference Interval	Interpretive Data	Note	CPT Code	Component Change	Other Interface Change	New Test	Inactive
6	0051265	Achondroplasia (FGFR3) 2 Mutations, Fetal				X		X						
7	0050024	Albumin, Body Fluid			X									
7	0050200	Albumin, CSF			X									
7	3004753	Allergen, Food, Nut Component Panel IgE											X	
7	0080001	Angiotensin Converting Enzyme, Serum					X							
8	0050392	Ankylosing Spondylitis (HLA-B27) Genotyping					X	X						
43	0092311	Barbiturates - Confirmation – Meconium												X
43	0050578	Beta Globin (HBB) Gene Sequencing												X



Hotline Page #	Test Number	Summary of Changes by Test Name		Methodology	Performed/Reported Schedule	Specimen Requirements	Reference Interval	Interpretive Data	Note	CPT Code	Component Change	Other Interface Change	New Test	Inactive
8	3004547	Beta Globin (<i>HBB</i>) Sequencing											X	
43	2010117	Beta Globin (HBB) Sequencing and Deletion/Duplication (Temporary Referral as of 12/07/20)												X
43	0050388	Beta Globin (HBB) Sequencing, Fetal												X
9	3004550	Beta Globin (HBB) Sequencing, Fetal											X	
9	0050254	Borrelia burgdorferi Antibodies, IgG and IgM by Immunoblot				X								
10	0050255	Borrelia burgdorferi Antibody, IgG by Immunoblot				X								
10	0050253	Borrelia burgdorferi Antibody, IgM by Immunoblot				X								
43	2003445	Breast Carcinoma b72.3 by Immunohistochemistry												X
10	3004609	Breast Carcinoma Dual Stain by Immunohistochemistry											X	
43	<u>2011601</u>	Buprenorphine, Meconium, Quantitative												X
11	<u>3004795</u>	CD22 by Immunohistochemistry											X	
12	<u>3004745</u>	Cystic Fibrosis (<i>CFTR</i>) Sequencing and Deletion/Duplication											X	
12	2011812	Chikungunya Antibodies, IgG and IgM				X								
12	<u>2011808</u>	Chikungunya Antibody, IgG				X								
13	<u>2011810</u>	Chikungunya Antibody, IgM				X								
13	<u>3004430</u>	Circulating Immune Complex Panel											X	
14	0050301	Circulating Immune Complex, C1q Binding	X		X	X						X		
14	<u>3004431</u>	Circulating Immune Complex, C3 fragments											X	
43	0092312	Cocaine and Metabolites - Confirmation/Quantitation – Meconium												Х
15	0050170	Coccidioides Antibodies by Complement Fixation	X			X			X					
15	3002996	Coccidioides Antibodies by Complement Fixation and Immunodiffusion, CSF	X	X		X	x	X	X					
16	3002995	Coccidioides Antibodies by Complement Fixation and Immunodiffusion, Serum	X	х		x	X		х			X		
16	3000059	Coccidioides Antibodies by Complement Fixation, CSF	X			x		X	х					
17	3000055	Coccidioides Antibodies IgG by Immunoassay, CSF	X	X		X		X	X					
17	3000056	Coccidioides Antibodies IgM by Immunoassay, CSF	X	X		X		X	Х					
18	3000061	Coccidioides Antibodies Panel, CSF	X	X		X	X	X	X					
19	0050588	Coccidioides Antibodies Panel, Serum	X	X		X	X		X			X		
20	3001982	Coccidioides Antibodies Reflexive Panel, Serum	X	X		X	X		X					



Hotline Page #	Test Number	Summary of Changes by Test Name	Name Change	Methodology	Performed/Reported Schedule	Specimen Requirements	Reference Interval	Interpretive Data	Note	CPT Code	Component Change	Other Interface Change	New Test	Inactive
20	0050179	Coccidioides Antibodies, IgG by Immunoassay, Serum	v	v		v			v					
21	3000057	Coccidioides Antibodies, IgM and IgG by Immunoassay, CSF	X	X		X		X	X					
21	0050137	Coccidioides Antibodies, IgM and IgG by Immunoassay, Serum	Х	Х		X			X					
21	0050178	Coccidioides Antibodies, IgM by Immunoassay, Serum	X	X		X			X					
22	3004720	Connexin 26 (<i>GJB2</i>) Sequencing and Deletion/Duplication											х	
43	0051374	Connexin 26 (GJB2), Sequencing												Х
23	0070416	C-Telopeptide, Beta-Cross-Linked, Serum			Х		X							
23	2013661	Cystic Fibrosis (CFTR) Expanded Variant Panel	X			X		Х	Х			X		
24	2013663	Cystic Fibrosis (<i>CFTR</i>) Expanded Variant Panel with Reflex to Sequencing	X			X		X	x			X		
24	2013664	Cystic Fibrosis (<i>CFTR</i>) Expanded Variant Panel with Reflex to Sequencing and Reflex to Deletion/Duplication	Х			х		х	х			X		
25	2013662	Cystic Fibrosis (<i>CFTR</i>) Expanded Variant Panel, Fetal	X			X		x	x			X		
43	0051110	Cystic Fibrosis (CFTR) Sequencing (Temporary Referral as of 12/07/20)												Х
43	0051640	Cystic Fibrosis (CFTR) Sequencing with Reflex to Deletion/Duplication (Temporary Referral as of 12/07/20)												Х
25	0050210	Diphtheria Antibody, IgG			X									
25	0050779	Diphtheria, Tetanus, and H. Influenzae b Antibodies, IgG			х									
26	3004583	Drug Detection Panel, Meconium, Qualitative											X	
27	2006621	Drug Detection Panel, Umbilical Cord Tissue, Qualitative								X				
27	2007479	Drug Profile, Targeted by Tandem Mass Spectrometry and Enzyme Immunoassay, Urine								X				
27	2009288	Drug Profile, Targeted with Interpretation by Tandem Mass Spectrometry and Enzyme Immunoassay, Urine								X				
43	0092310	Drugs of Abuse Confirmation/Quantitation - Amphetamines (Amphetamine and Methamphetamine) – Meconium												X
43	0092520	Drugs of Abuse Confirmation/Quantitation - Benzodiazepines – Meconium												X



Hotline Page #	Test Number	Summary of Changes by Test Name	Name Change	Methodology	Performed/Reported Schedule	Specimen Requirements	Reference Interval	Interpretive Data	Note	CPT Code	Component Change	Other Interface Change	New Test	Inactive
43	0092313	Drugs of Abuse Confirmation/Quantitation - Methadone and Metabolite – Meconium												X
43	0092314	Drugs of Abuse Confirmation/Quantitation - Opiates – Meconium												X
43	0092516	Drugs of Abuse Panel, Meconium - Screen with Reflex to Confirmation/Quantitation												X
27	0051626	Epstein-Barr Virus Antibody to Viral Capsid Antigen, IgA				X								
43	<u>2014035</u>	Familial Transthyretin Amyloidosis (TTR) Sequencing												X
28	3004531	Familial Transthyretin Amyloidosis (<i>TTR</i>) Sequencing											X	
29	0050164	Fungal Antibodies by Immunodiffusion		Х		Х	X					X		
30	3004716	Galactosemia (GALT) Sequencing and Deletion/Duplication											х	
43	2006697	Galactosemia (GALT), Sequencing												X
31	3000258	Genetic Carrier Screen, (CF, FXS, and SMA) with Reflex to Methylation (Temporary Delay as of 01/21/2021 - no referral available)				X		X	х			X		
31	0050542	Haemophilus influenzae b Antibody, IgG			Х									
31	2001956	Hearing Loss, Nonsyndromic, Connexin 30 (<i>GJB6</i>) 2 Deletions				X		x						
32	2005792	Hemoglobin Evaluation Reflexive Cascade		X										
32	3000894	Hereditary Hemolytic Anemia Cascade		X						X				
32	0050641	Herpes Simplex Virus Type 1 and/or 2 Antibodies, IgM by ELISA				x								
32	0050408	Herpes Simplex Virus Type 1 and/or 2 Antibodies, IgM by ELISA, CSF				X								
32	2009418	Histoplasma Galactomannan Antigen Quantitative by EIA, Urine				X		X						
43	2003938	Human Placental Lactogen (HPL) by Immunohistochemistry												X
33	0040018	Huntington Disease (<i>HD</i>) Mutation by PCR (Extended TAT as of 11/20/20-no referral available)				X	X	x						
43	0050667	Immune Complex Panel												Х
33	0050340	Immunoglobulin A			X									
33	0050350	Immunoglobulin G			X									
33	<u>3003485</u>	Immunoglobulin G, CSF			X									
34	<u>0050676</u>	Immunoglobulin G, CSF Index			X									
34	0050355	Immunoglobulin M			X									



Hotline Page #	Test Number	Summary of Changes by Test Name	Name Change	Methodology	Performed/Reported Schedule	Specimen Requirements	Reference Interval	Interpretive Data	Note	CPT Code	Component Change	Other Interface Change	New Test	Inactive
34	0051069	Influenza A & B Virus Antibodies, IgG & IgM				X								
34	0051074	Influenza A Virus Antibody, IgG				X								
34	0051081	Influenza A Virus Antibody, IgM				X								
34	0051080	Influenza B Virus Antibody, IgG				X								
35	0051079	Influenza B Virus Antibody, IgM				X								
35	<u>3003801</u>	JAK2 (V617F) Mutation by ddPCR, Qualitative with Reflex to JAK2 Exon 12 Mutation Analysis by PCR				X								
35	2002357	JAK2 Exon 12 Mutation Analysis by PCR				X								
36	3004541	Kappa Lambda Dual Stain by Immunohistochemistry											X	
43	2003981	Kappa Light Chains by Immunohistochemistry												X
43	2003984	Lambda Light Chains by Immunohistochemistry												X
36	0051726	Leishmania Antibody, IgG (Visceral Leishmaniasis)				X								
37	3001605	Lynch Syndrome Panel, Sequencing and Deletion/Duplication											X	
37	0054441	Measles (Rubeola) Antibody, IgM, CSF				X								
43	0051390	Multiple Endocrine Neoplasia Type 2 (MEN2), <i>RET</i> Gene Mutations by Sequencing (Temporary Referral as of 12/07/20)												X
38	3004572	Multiple Endocrine Neoplasia Type 2 (MEN2), <i>RET</i> Sequencing											X	
38	0054443	Mumps Virus Antibody IgM, CSF				X								
43	<u>3001768</u>	Pancreatitis (PRSS1) Sequencing and Deletion/Duplication												X
43	2002012	Pancreatitis (SPINK1) Sequencing												X
39	<u>3004788</u>	Pancreatitis Panel (CFTR, CTRC, PRSS1, SPINK1), Sequencing											x	
43	<u>2010876</u>	Pancreatitis, Panel (CFTR, CTRC, <i>PRSS1</i> , <i>SPINK1</i>) Sequencing (Temporary Referral as of 12/7/20)												X
43	0092315	Phencyclidine (PCP) - Confirmation/Quantitation – Meconium												X
43	0050302	Raji Cell Immune Complex Assay												X
39	2001766	S-100B Protein, Serum					X							
40	3004727	SATB2 by Immunohistochemistry											X	
41	3004603	SHOX Deficiency Disorders, Sequencing and Deletion/Duplication											X	
43	3001401	SHOX-Related Disorders, Deletion/Duplication with Reflex to Sequencing												X
41	0050535	Tetanus Antibody, IgG			X									



Hotline Page #	Test Number	Summary of Changes by Test Name	Name Change	Methodology	Performed/Reported Schedule	Specimen Requirements	Reference Interval	Interpretive Data	Note	CPT Code	Component Change	Other Interface Change	New Test	Inactive
41	<u>2006550</u>	Thyroglobulin by LC-MS/MS, Serum or Plasma				X								
41	2006685	Thyroglobulin, Serum or Plasma with Reflex to LC-MS/MS or CIA				X								
42	0051076	Trypanosoma cruzi Antibody, IgG				X								
42	2005416	Urticaria-Induced Basophil Activation			X									

0051265 Achondroplasia (FGFR3) 2 Mutations, Fetal

AD PCR FE

Specimen Required: Collect: Fetal specimen: Cultured amniocytes: Two T-25 flasks at 80 percent confluency.

OR cultured CVS: Two T-25 flasks at 80 percent confluency.

If the client is unable to culture amniocytes or CVS, this can be arranged by contacting ARUP Client Services at (800) 522-2787

AND maternal whole blood specimen: Lavender (EDTA), pink (K2EDTA), or yellow (ACD Solution A or B).

Specimen Preparation: Cultured amniocytes AND cultured CVS: Transport two T-25 flasks at 80 percent confluency filled with culture media. Backup cultures must be retained at the client's institution until testing is complete.

Maternal Whole Blood Specimen: Transport 3 mL whole blood. (Min: 1 mL)

Storage/Transport Temperature: Cultured amniocytes and cultured CVS: CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of shipment due to lability of cells.

Maternal Whole Blood Specimen: Refrigerated.

<u>Remarks:</u> Please contact an ARUP genetic counselor at 800-242-2787 x2141 prior to sample submission. Patient History Form is available on the ARUP Web site or by contacting ARUP Client Services.

Unacceptable Conditions: Frozen specimens in glass collection tubes.

Stability (collection to initiation of testing): Cultured amniocytes and cultured CVS: Room Temperature: 48 hours; Refrigerated:

Unacceptable; Frozen: Unacceptable

Maternal Whole Blood Specimen: Room Temperature: 72 hours; Refrigerated: 1 week; Frozen: 1 month

Interpretive Data:

Background information for Achondroplasia (FGFR3) 2 Mutations, Fetal:

Characteristics: Short stature with disproportionately short arms and legs, a large head, usually normal life span and intelligence; increased risk for death in infancy from compression of spinal cord and/or upper airway obstruction.

Incidence: 1:25,000.

Inheritance: Autosomal dominant; 80 percent arise from de novo mutations.

Penetrance: 100 percent.

Cause: Pathogenic *FGFR3* gene mutation.

Clinical Sensitivity: Two mutations, c.1138G>A and c.1138G>C, in the FGFR3 gene account for greater than 99 percent of cases.

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

Analytical Sensitivity and Specificity: Greater than 99 percent.

Limitations: Mutations other than c.1138G>A and c.1138G>C will not be detected. Diagnostic errors can occur due to rare sequence variations.

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

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

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



0050024 Albumin, Body Fluid ALB-BF

Performed: Sun-Sat Reported: 1-3 days

0050200 Albumin, CSF ALB CSF

Performed: Sun-Sat Reported: 1-3 days

New Test 3004753 Allergen, Food, Nut Component Panel IgE NUT COMP

Click for Pricing

Methodology: Quantitative Enzyme Immunoassay/ImmunoCAP Fluorescent Enzyme Immunoassay

Performed: Varies **Reported:** 3-8 days

Specimen Required: Collect: Plain red or serum separator tube (SST).

Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 2 mL serum to an ARUP Standard

Transport Tube. (Min: 1 mL)

Test is not performed at ARUP; separate specimens must be submitted when multiple tests are ordered.

Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen

Stability (collection to initiation of testing): Ambient: 28 days; Refrigerated: 28 days; Frozen: 28 days

Note: Included: Cashew, hazelnut, walnut components.

CPT Code(s): 86008 x6

New York DOH Approved.

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

0080001 Angiotensin Converting Enzyme, Serum ACE

Reference Interval:

Effective May 16, 2022 0-6 years: 18-90 U/L 7-14 years: 24-121 U/L 15-17 years: 18-101 U/L 18 years and older: 16-85 U/L



0050392 Ankylosing Spondylitis (HLA-B27) Genotyping HLAB27 PCR

Reference Interval: By report

Interpretive Data:

Background Information for Ankylosing Spondylitis (HLA-B27) Genotyping:

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

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

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

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

Analytical Sensitivity & Specificity: 99 percent

Limitations: This test does not rule out the B*27:06 and 27:09 alleles, which are not associated with spondyloarthropathies. Certain rare alleles present in less than 1 percent of the population will not be detected. Other rare, or uncharacterized alleles may occur which may lead to false positive or false negative results.

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

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

New Test

3004547

Beta Globin (HBB) Sequencing

BG NGS

Click for Pricing



Additional Technical Information



Patient History for Hemoglobinopathy/Thalassemia Testing

Methodology: Massively Parallel Sequencing

Performed: Varies **Reported:** 3 weeks

Specimen Required: Collect: Lavender or pink (EDTA) or yellow (ACD solution A or B).

Specimen Preparation: Transport 3 mL whole blood. (Min: 3 mL)

Storage/Transport Temperature: Refrigerated

<u>Unacceptable Conditions:</u> Serum or plasma; grossly hemolyzed or frozen specimens; saliva, buccal brush, or swab; FFPE tissue.

Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Refer to report

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

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

Note: Gene Tested: HBB (NM_000518)

Deletion/duplication analysis is not available for this gene.

CPT Code(s): 81364

New York DOH approval pending. Call for status update.



New Test

3004550

Beta Globin (HBB) Sequencing, Fetal

BG NGS FE

Click for Pricing



Additional Technical Information



Patient History for Fetal Molecular **Testing**

Methodology: Massively Parallel Sequencing

Performed: Varies

Reported: 10-14 days; if culture is required, an additional 1 to 2 weeks is required for processing time

Specimen Required: Collect: Fetal Specimen: Four (4) T-25 flasks at 80% confluent of cultured amniocytes or cultured chorionic villus sampling (CVS).

AND Maternal Whole Blood Specimen: Lavender (EDTA), pink (K2EDTA), or yellow (ACD solution A or B).

Specimen Preparation: Cultured Amniocytes or Cultured CVS: Fill flasks with culture media. Transport four (4) T-25 flasks at 80 percent confluent of cultured amniocytes or cultured CVS filled with culture media. Backup cultures must be retained at the client's institution until testing is complete. If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client

Services at (800) 522-2787 ext. 2141 prior to test submission.

Maternal Whole Blood Specimen: Transport 3 mL whole blood. (Min: 2 mL).

Storage/Transport Temperature: Cultured Amniocytes or Cultured CVS: CRITICAL ROOM TEMPERATURE. Must be

received within 48 hours of shipment due to viability of cells.

Maternal Specimen: Room temperature

Stability (collection to initiation of testing): Cultured Amniocytes or Cultured CVS: Room temperature: 48 hours; Refrigerated:

Unacceptable; Frozen: Unacceptable

Maternal Whole Blood Specimen: Room temperature: 7 days; Refrigerated: 1 month; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data: Refer to report

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

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

Note: Gene tested: *HBB* (NM_000518)

Deletion/duplication analysis is not performed for this gene.

Reported times are based on receiving the four (4) T-25 flasks at 80 percent confluent. Cell culture time is independent of testing turn-around time. Maternal specimen is recommended for proper test interpretation. Order Maternal Cell Contamination.

CPT Code(s): 81364, 81265 Fetal Cell Contamination (FCC)

New York DOH approval pending. Call for status update.

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

0050254 Borrelia burgdorferi Antibodies, IgG and IgM by Immunoblot LYME WB

Specimen Required: Collect: Serum separator tube.

Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard

Transport Tube. (Min: 0.15 mL)

Storage/Transport Temperature: Refrigerated.

Unacceptable Conditions: CSF or plasma. Contaminated, heat-inactivated, severely hemolyzed, severely lipemic, and severely icteric

Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

(avoid repeated freeze/thaw cycles)



0050255 Borrelia burgdorferi Antibody, IgG by Immunoblot LYME G WB

Specimen Required: Collect: Serum separator tube.

Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard

Transport Tube. (Min: 0.1 mL)

Storage/Transport Temperature: Refrigerated.

Unacceptable Conditions: CSF or plasma. Contaminated, heat-inactivated, severely hemolyzed, severely lipemic, and severely icteric

specimens.

Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

(avoid repeated freeze/thaw cycles)

0050253

Borrelia burgdorferi Antibody, IgM by Immunoblot

LYME M WB

Specimen Required: Collect: Serum separator tube.

Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard

Transport Tube. (Min: 0.15 mL)

Storage/Transport Temperature: Refrigerated.

<u>Unacceptable Conditions:</u> CSF or plasma. Contaminated, heat-inactivated, severely hemolyzed, severely lipemic, and severely icteric

Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

(avoid repeated freeze/thaw cycles)

New Test Available Now 3004609

Breast Carcinoma Dual Stain by Immunohistochemistry

BRCARCDIHC

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Immunohistochemistry Stain Form Recommended (ARUP form #32978)

Methodology: Immunohistochemistry

Performed: Mon-Fri Reported: 1-3 days

Specimen Required: Collect: Tissue or cells.

Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (ARUP supply #47808) available online through eSupply using ARUP ConnectTM or contact ARUP Client Services at (800) 522-2787. Min: 2 slides. If sending precut slides, do not oven bake.

Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months. Remarks: IMMUNOHISTOCHEMISTRY ORDERING AND SUBMISSION DETAILS: Submit electronic request. If you do not have electronic ordering capability, use an ARUP Immunohistochemistry Stain Form (#32978) with an ARUP client number. For additional technical details, contact ARUP Client Services at (800) 522-2787.

Unacceptable Conditions: Specimens submitted with nonrepresentative tissue type. Depleted specimens.

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

Interpretive Data:

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.

Note: The following antibodies are utilized in this dual stain: CK5/CK14/p63 (brown) and CK8/CK18 (red).

This test is performed as a stain and return (technical) service only.

CPT Code(s): 88344

New York DOH Approved.



New Test 3004795 CD22 by Immunohistochemistry CD22IHC

Available Now Click for Pricing



Immunohistochemistry Stain Form Recommended (ARUP form #32978)

Methodology: Immunohistochemistry

Performed: Mon-Fri **Reported:** 1-3 days

Specimen Required: Collect: Tissue or cells.

Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a Tissue Transport Kit (ARUP supply #47808) available online through eSupply using ARUP ConnectTM or contact ARUP Client Services at (800) 522-2787. (Min: 2 slides). If sending precut slides, do not oven bake.

Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months. Remarks: IMMUNOHISTOCHEMISTRY ORDERING AND SUBMISSION DETAILS: Submit electronic request. If you do not have electronic ordering capability, use an ARUP Immunohistochemistry Stain Form (#32978) with an ARUP client number. For

additional technical details, contact ARUP Client Services at (800) 522-2787.

<u>Unacceptable Conditions:</u> Specimens submitted with nonrepresentative tissue type. Depleted specimens.

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

Interpretive Data:

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.

Note:

This test is performed as a stain and return (technical) service only.

CPT Code(s): 88342

New York DOH Approved.



New Test

3004745 Cystic Fibrosis (CFTR) Sequencing and Deletion/Duplication **CFTR NGS**

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Additional Technical Information



Patient History for Cystic Fibrosis (CF)

Methodology: Massively Parallel Sequencing/Sequencing

Performed: Varies Reported: 3 weeks

Specimen Required: Collect: Lavender or pink (EDTA) or yellow (ACD solution A or B).

Specimen Preparation: Transport 3 mL whole blood. (Min: 2 mL)

Storage/Transport Temperature: Refrigerated.

<u>Unacceptable Conditions:</u> Serum or plasma; grossly hemolyzed or frozen specimens; saliva, buccal brush, or swab; FFPE tissue.

Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Refer to report.

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

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

Note: Gene Tested: CFTR

CPT Code(s): 81222, 81223

New York DOH approval pending. Call for status update.

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

2011812 Chikungunya Antibodies, IgG and IgM

CHIKPAN

Specimen Required: Collect: Serum or plasma (heparin, citrate, or ETDA)

Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.15 mL) Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Mark specimens plainly as "acute or convalescent."

Storage/Transport Temperature: Refrigerated

<u>Unacceptable Conditions:</u> Contaminated, heat-inactivated, hemolyzed, or severely lipemic specimens.

Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

(avoid repeated freeze/thaw cycles)

2011808 Chikungunya Antibody, IgG

CHIKG

Specimen Required: Collect: Serum or plasma (heparin, citrate, or EDTA)

Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.15 mL) Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Mark specimens plainly as "acute or convalescent."

Storage/Transport Temperature: Refrigerated.

Unacceptable Conditions: Contaminated, heat-inactivated, hemolyzed, or severely lipemic specimens.

Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

(avoid repeated freeze/thaw cycles)



2011810 Chikungunya Antibody, IgM

CHIKM

Specimen Required: Collect: Serum or plasma (heparin, citrate, or EDTA)

Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.15 mL) Parallel testing is preferred and convalescent specimens **must** be received within 30 days from

receipt of the acute specimens. Mark specimens plainly as "acute or convalescent."

Storage/Transport Temperature: Refrigerated.

<u>Unacceptable Conditions:</u> Contaminated, heat-inactivated, hemolyzed, or severely lipemic specimens.

Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours, Refrigerated: 2 weeks; Frozen: 1 year

(avoid repeated freeze/thaw cycles)

New Test

3004430

Circulating Immune Complex Panel

CIC-C3,C1Q

Click for Pricing

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay

Performed: Saturday, Monday, Thursday

Reported: 2-9 days

Specimen Required: Collect: Plain red or serum separator tube (SST).

Specimen Preparation: Allow complete clotting of red blood cells (up to 1 hour), then separate serum from cells within 30 minutes and freeze immediately. Transfer TWO (2) 1 mL aliquots of serum to individual ARUP Standard Transport Tubes. (Min: 0.5 mL/aliquot) Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.

Unacceptable Conditions: Non-frozen specimens. Specimens exposed to repeated freeze/thaw cycles.

Grossly hemolyzed, lipemic, and icteric specimens

Stability (After separation from cells): Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 2 weeks

Reference Interval:

Available Separately	Components	Reference Interval
0050301	Circulating Immune Complex, C1q Binding	Effective February 19, 2019 Less than or equal to 3.9 µg Eq/mL
3004431	Circulating Immune Complex, C3 fragments	Less than or equal to 15 µg Eq/mL

Interpretive Data:

Many autoimmune disorders, chronic infections, and malignancies are associated with circulating immune complexes. Quantitation of immune complexes assists in staging immunologic disorders. Detection of circulating immune complexes is not essential to any specific diagnosis. Circulating immune complexes may be found without any evident pathology and positive results do not necessarily implicate immune complex-related disease process. Values between 15 and 20 ug Eq/mL are considered equivocal for the Circulating Immune Complex, C3 fragments assay. Repeat testing using a new specimen is recommended, if clinically indicated.

CPT Code(s): 86332 x2

New York DOH Approved.



0050301 Circulating Immune Complex, C1q Binding C1Q

Performed: Saturday, Monday, and Thursday

Reported: 2-9 days

Specimen Required: Collect: Plain red or serum separator tube (SST)

Specimen Preparation: Allow complete clotting of red blood cells (up to 1 hour), then separate serum from cells within 30 minutes and freeze immediately. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.3 mL) If ordered in conjunction with a Circulating Immune Complex, C3 fragments, transfer TWO (2) 1 mL aliquots of serum to individual ARUP Standard Transport

Tubes.

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

Unacceptable Conditions: Non-frozen specimens.

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

weeks (avoid repeated freeze/thaw cycles)

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.

Change the charting name for component 0050301, C1q Binding Assay from C1q Binding Assay to Circulating Immune Complex, C1q Binding.

New Test 3004431 Circulating Immune Complex, C3 fragments CIC-C3

Click for Pricing

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay

Performed: Saturday, Monday, Thursday

Reported: 2-9 days

Specimen Required: Collect: Plain red or serum separator tube (SST).

Specimen Preparation: Allow complete clotting of red blood cells (up to 1 hour), then separate serum from cells within 30 minutes and freeze immediately. Transport 1 mL serum. (Min: 0.5 mL) If ordered in conjunction with a C1q Binding Assay, transfer TWO (2) 1 mL aliquots of serum to individual ARUP Standard Transport Tubes.

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

<u>Unacceptable Conditions:</u> Non-frozen specimens. Specimens exposed to repeated freeze/thaw cycles.

Grossly hemolyzed, lipemic, and icteric specimens

Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 20 days

Reference Interval: Less than or equal to 15 µg Eq/mL

Interpretive Data:

Many autoimmune disorders, chronic infections, and malignancies are associated with circulating immune complexes. Quantitation of immune complexes assists in staging immunologic disorders. Detection of circulating immune complexes is not essential to any specific diagnosis. Circulating immune complexes may be found without any evident pathology and positive results do not necessarily implicate immune complex-related disease process. Values between 15 and 20 ug Eq/mL are considered equivocal for the Circulating Immune Complex, C3 fragments assay. Repeat testing using a new specimen is recommended, if clinically indicated

CPT Code(s): 86332

New York DOH Approved.



0050170 Coccidioides Antibodies by Complement Fixation

COCCI

Specimen Required: Collect: Serum Separator Tube (SST)

Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.6 mL) Parallel testing is preferred and convalescent specimens **must** be received within 30 days from receipt

of acute specimens.

Storage/Transport Temperature: Refrigerated.

Remarks: Mark specimens plainly as "acute" or "convalescent".

<u>Unacceptable Conditions:</u> Other body fluids. Contaminated, hemolyzed, icteric, or lipemic specimens.

Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw

cvcles)

HOTLINE NOTE: Remove information found in the Note field.

3002996 Coccidioides Antibodies by Complement Fixation and Immunodiffusion, CSF COCC.CFIDC

Methodology: Complement Fixation/Immunodiffusion

Specimen Required: Collect: CSF

Specimen Preparation: Transfer 2 mL CSF to an ARUP Standard Transport Tube. (Min: 1 mL). Parallel testing is preferred and

convalescent specimens must be received within 30 days from receipt of the acute specimens.

Storage/Transport Temperature: Refrigerated.

Remarks: Mark specimens plainly as "acute" or "convalescent".

<u>Unacceptable Conditions:</u> Other body fluids. Contaminated, hemolyzed, xanthochromic, or severely lipemic specimens.

Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw

cvcles)

Reference Interval:

Effective May 16, 2022

Test Number	Components	Reference Interval
	Coccidioides by Immunodiffusion, CSF	Not detected
3000059	Coccidioides Antibody by CF, CSF	Less than 1:2

Interpretive Data:

Refer to report.

Note: The immunodiffusion component of this test uses culture filtrates of Coccidioides immitis and includes CF and TP antigens.



3002995 Coccidioides Antibodies by Complement Fixation and Immunodiffusion, Serum COCC.CFIDS

Methodology: Complement Fixation/Immunodiffusion

Specimen Required: Collect: Serum Separator Tube (SST)

Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum to an ARUP Standard

Transport Tube. (Min: 0.6 mL). Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt

of the acute specimens.

Storage/Transport Temperature: Refrigerated.

Remarks: Mark specimens plainly as "acute" or "convalescent".

<u>Unacceptable Conditions:</u> Other body fluids. <u>Contaminated, hemolyzed, icteric, or lipemic specimens.</u>

Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw

cycles)

Reference Interval:

Effective May 16, 2022

Test Number	Components	Reference Interval						
	Coccidioides Antibody by ID	Not detected						
0050170	Coccidioides Antibody by CF	Less than 1:2						

Note: This immunodiffusion test uses culture filtrates of Coccidioides immitis and includes CF and TP antigens.

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.

Change the charting name for component 0050183, Coccidioides immitis Abs, Precipitin from Coccidioides immitis Abs, Precipitin to Coccidioides by Immunodiffusion, Serum.

3000059 Coccidioides Antibodies by Complement Fixation, CSF

COCCICFCSF

Specimen Required: Collect: CSF

Specimen Preparation: Transfer 1 mL CSF to an ARUP Standard Transport Tube. (Min 0.6 mL). Parallel testing is preferred and

convalescent specimens \boldsymbol{must} be received within 30 days from receipt of acute specimens.

Storage/Transport Temperature: Refrigerated.

Remarks: Mark specimens plainly as "acute" or "convalescent".

<u>Unacceptable Conditions:</u> Other body fluids. Contaminated, hemolyzed, xanthochromic, or severely lipemic specimens.

Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw

cycles)

Interpretive Data:

Any titer suggests past or current infection. However, greater than 30 percent of cases with chronic residual pulmonary disease have negative Complement Fixation (CF) tests. Titers of less than 1:32 (even as low as 1:2) may indicate past infection or self-limited disease anticoccidioidal CF antibody titers in excess of 1:16 may indicate disseminated infection. CF serology may be used to follow therapy. Antibody in CSF is considered diagnostic for coccidioidal meningitis, although 10 percent of patients with coccidioidal meningitis will not have antibody in CSF.

HOTLINE NOTE: Remove information found in the Note field.



3000055 Coccidioides Antibodies IgG by Immunoassay, CSF COCCIG CSF

Methodology: Enzyme-Linked Immunosorbent Assay (ELISA)

Specimen Required: Collect: CSF

Specimen Preparation: Transfer 1 mL CSF to an ARUP Standard Transport Tube. (Min: 0.3 mL). Parallel testing is preferred and

convalescent specimens must be received within 30 days from receipt of the acute specimens.

Storage/Transport Temperature: Refrigerated.

Remarks: Mark specimens plainly as "acute" or "convalescent".

<u>Unacceptable Conditions:</u> Other body fluids. Contaminated, hemolyzed, xanthochromic, or severely lipemic specimens.

Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw

cycles)

Interpretive Data:

IgG antibodies usually appear by the third week of infection and may persist for years. Both tube precipitin (TP) and CF antigens are represented in the ELISA tests.

Note: This immunoassay uses recombinant and native Coccidioides antigens, including CF and TP antigens.

3000056 Coccidioides Antibodies IgM by Immunoassay, CSF COCCIM CSF

Methodology: Enzyme-Linked Immunosorbent Assay (ELISA)

Specimen Required: Collect: CSF

Specimen Preparation: Transfer 1 mL CSF to an ARUP Standard Transport Tube. (Min: 0.3 mL). Parallel testing is preferred and

convalescent specimens must be received within 30 days from receipt of the acute specimens.

Storage/Transport Temperature: Refrigerated.

Remarks: Mark specimens plainly as "acute" or "convalescent".

<u>Unacceptable Conditions:</u> Other body fluids. Contaminated, hemolyzed, xanthochromic, or severely lipemic specimens.

Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw

cycles)

Interpretive Data:

In most symptomatic patients, IgM antibodies usually appear by the second week of infection and disappear by the fourth month. Both tube precipitin (TP) and CF antigens are represented in the ELISA tests.

Note: This immunoassay uses recombinant and native Coccidioides antigens, including CF and TP antigens.



3000061 COCCIABCSF Coccidioides Antibodies Panel, CSF

Methodology: Complement Fixation/Immunodiffusion/Enzyme-Linked Immunosorbent Assay (ELISA)

Specimen Required: Specimen Preparation: Transfer 2 mL CSF to an ARUP Standard Transport Tube. (Min: 1 mL) Parallel testing is preferred and

convalescent specimens must be received within 30 days from receipt of the acute specimens.

Storage/Transport Temperature: Refrigerated.

Remarks: Mark specimens plainly as "acute" or "convalescent".

Unacceptable Conditions: Other body fluids. Contaminated, hemolyzed, xanthochromic, or severely lipemic specimens.

Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw

cycles)

Reference Interval:

Effective May 16, 2022

Test Number	Components	Reference Interval	
	Coccidioides by Immunodiffusion, CSF	Not detected.	
3000059	Coccidioides Antibody by CF, CSF	Less than 1:2	
3000055	Coccidioides Antibody IgG ELISA, CSF		
		0.2 IV or less	Negative - No significant level of <i>Coccidioides</i> IgG antibody detected.
		0.3 IV or greater	Positive - Presence of IgG antibody to Coccidioides detected, suggestive of current or past infection.
			I
3000056	Coccidioides Antibody IgM ELISA, CSF		
		0.2 IV or less	Negative - No significant level of <i>Coccidioides</i> IgM antibody detected.
		0.3 IV or greater	Positive - Presence of IgM antibody to <i>Coccidioides</i> detected, suggestive of current or recent infection.

Interpretive Data:

Refer to report.

Note: The immunoassay component of this test uses recombinant and native Coccidioides antigens, including the CF and TP antigens. The immunodiffusion component of this test uses culture filtrates of Coccidioides immitis and includes CF and TP antigens.



0050588 Coccidioides Antibodies Panel, Serum COCCI PAN

Methodology: Complement Fixation/Immunodiffusion/Enzyme-Linked Immunosorbent Assay (ELISA)

Specimen Required: Collect: Serum Separator Tube (SST)

Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum to an ARUP Standard

Transport Tube. (Min: 0.6 mL) Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt

of the acute specimens.

Storage/Transport Temperature: Refrigerated.

 $\underline{Remarks:} \ \textbf{Mark specimens plainly as "acute" or "convalescent".}$

<u>Unacceptable Conditions:</u> Other body fluids. Contaminated, hemolyzed, icteric, or lipemic specimens.

Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw

cycles)

Reference Interval:

Effective May 16, 2022

Test Number	Components	Reference Interval	
0050170	Coccidioides Antibody by CF	Less than 1:2	
	Coccidioides Antibody by ID	Not detected	
0050179	Coccidioides Antibody, IgG by ELISA		
		0.9 IV or less	Negative - No significant level of <i>Coccidioides</i> IgG antibody detected.
		1.0-1.4 IV	Equivocal - Questionable presence of <i>Coccidioides</i> IgG antibody detected. Repeat testing in 10-14 days may be helpful.
		1.5 IV or greater	Positive - Presence of IgG antibody to <i>Coccidioides</i> detected, suggestive of current or past infection.
0050178	Coccidioides Antibody, IgM by ELISA		
		0.9 IV or less	Negative - No significant level of Coccidioides IgM antibody detected.
		1.0-1.4 IV	Equivocal - Questionable presence of <i>Coccidioides</i> IgM antibody detected. Repeat testing in 10-14 days may be helpful.
		1.5 IV or greater	Positive - Presence of IgM antibody to <i>Coccidioides</i> detected, suggestive of current or recent infection.

Note: The immunodiffusion component of this test uses culture filtrates of Coccidioides immitis and includes CF and TP antigens.

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.

Change the charting name for component 0050183, Coccidioides immitis Abs, Precipitin from Coccidioides immitis Abs, Precipitin to Coccidioides by Immunodiffusion, Serum.



3001982 Coccidioides Antibodies Reflexive Panel, Serum

COCCI R

Methodology: Complement Fixation/Immunodiffusion/Enzyme-Linked Immunosorbent Assay (ELISA)

Specimen Required: Collect: Serum Separator Tube (SST)

Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum to an ARUP Standard

Transport Tube. (Min: 0.6 mL). Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt

of the acute specimens.

Storage/Transport Temperature: Refrigerated.

Remarks: Mark specimens plainly as "acute" or "convalescent".

<u>Unacceptable Conditions:</u> Other body fluids. Contaminated, hemolyzed, icteric, or lipemic specimens.

Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw

cycles)

Reference Interval:

Effective May 16, 2022

Test Number	Components	Reference Interval	
0050179	Coccidioides Antibody, IgG by ELISA		
		0.9 IV or less	Negative - No significant level of <i>Coccidioides</i> IgG antibody detected.
		1.0-1.4 IV	Equivocal - Questionable presence of <i>Coccidioides</i> IgG antibody detected. Repeat testing in 10-14 days may be helpful.
		1.5 IV or greater	Positive - Presence of IgG antibody to <i>Coccidioides</i> detected, suggestive of current or past infection.
0050178	Coccidioides Antibody, IgM by ELISA		
		0.9 IV or less	Negative - No significant level of <i>Coccidioides</i> IgM antibody detected.
		1.0-1.4 IV	Equivocal - Questionable presence of <i>Coccidioides</i> IgM antibody detected. Repeat testing in 10-14 days may be helpful.
		1.5 IV or greater	Positive - Presence of IgM antibody to <i>Coccidioides</i> detected, suggestive of current or recent infection.
	Coccidioide Titer, Complement Fixation	Less than 1:2	
	Coccidioides Antibody by ID	Not detected	

Note: Coccidioides Antibodies, IgM and IgG by Immunoassay, Serum is used to screen for coccidioidal antibodies. If the immunoassay testing is equivocal or positive for IgM and/or IgG, then Coccidioides Antibodies by Immunodiffusion and Coccidioides Antibody Titer by Complement Fixation, Serum will be added. Additional charges apply.

<u>0050179</u> Coccidioides Antibodies, IgG by Immunoassay, Serum

COCCI G

Methodology: Enzyme-Linked Immunosorbent Assay (ELISA)

Specimen Required: Collect: Serum Separator Tube (SST)

Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.3 mL). Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt

of the acute specimens.

Storage/Transport Temperature: Refrigerated.

Remarks: Mark specimens plainly as "acute" or "convalescent".

<u>Unacceptable Conditions:</u> Other body fluids. Contaminated, hemolyzed, icteric, or lipemic specimens.

Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw

cycles)

Note: This immunoassay uses recombinant and native Coccidioides antigens, including CF and TP antigens.



3000057 Coccidioides Antibodies, IgM and IgG by Immunoassay, CSF COCCIGMCSF

Methodology: Enzyme-Linked Immunosorbent Assay (ELISA)

Specimen Required: Collect: CSF

Specimen Preparation: Transfer 2 mL CSF to an ARUP Standard Transport Tube. (Min: 0.3 mL). Parallel testing is preferred and

convalescent specimens **must** be received within 30 days from receipt of the acute specimens.

Storage/Transport Temperature: Refrigerated.

Remarks: Mark specimens plainly as "acute" or "convalescent".

Unacceptable Conditions: Other body fluids. Contaminated, hemolyzed, xanthochromic, or severely lipemic specimens.

Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw

cycles)

Interpretive Data:

Refer to report.

Note: This immunoassay uses recombinant and native Coccidioides antigens, including CF and TP antigens.

0050137 Coccidioides Antibodies, IgM and IgG by Immunoassay, Serum COCCI G/M

Methodology: Enzyme-Linked Immunosorbent Assay (ELISA)

Specimen Required: Collect: Serum Separator Tube (SST)

Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum to an ARUP Standard

Transport Tube. (Min: 0.6 mL) Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt

of the acute specimens.

Storage/Transport Temperature: Refrigerated.

Remarks: Mark specimens plainly as "acute" or "convalescent".

<u>Unacceptable Conditions:</u> Other body fluids. Contaminated, hemolyzed, icteric, or lipemic specimens

Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw

cycles)

Note: This immunoassay uses recombinant and native Coccidioides antigens, including CF and TP antigens.

0050178 Coccidioides Antibodies, IgM by Immunoassay, Serum COCCI M

Methodology: Enzyme-Linked Immunosorbent Assay (ELISA)

Specimen Required: Collect: Serum Separator Tube (SST)

Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard

Transport Tube. (Min: 0.3 mL) Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt

of the acute specimens.

 $\underline{Storage/Transport\ Temperature:}\ Refrigerated.$

Remarks: Mark specimens plainly as "acute" or "convalescent".

<u>Unacceptable Conditions:</u> Other body fluids. Contaminated, hemolyzed, icteric, or lipemic specimens. <u>Stability:</u> Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Note: This immunoassay uses recombinant and native Coccidioides antigens, including CF and TP antigens.



New Test

Connexin 26 (GJB2) Sequencing and Deletion/Duplication

CX26 NGS

Click for Pricing



Additional Technical Information

Methodology: Massively Parallel Sequencing

3004720

Performed: Varies Reported: 3 weeks

Specimen Required: Collect: Lavender or pink (EDTA) or yellow (ACD solution A or B).

Specimen Preparation: Transport 3 mL whole blood. (Min: 3 mL)

Storage/Transport Temperature: Refrigerated.

<u>Unacceptable Conditions:</u> Serum or plasma; grossly hemolyzed or frozen specimens; saliva, buccal brush, or swab; FFPE tissue.

Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Refer to report.

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

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

Note: Gene Tested: GJB2 (NM_004004)

CPT Code(s): 81252; 81479

New York DOH approval pending. Call for status update.



0070416 CTX C-Telopeptide, Beta-Cross-Linked, Serum

Performed: Sun - Sat Reported: Within 24 hours

Reference Interval:

Effective May 16, 2022

Age	Female	Male
6 months-6 years	500-1800 pg/mL	238-1019 pg/mL
7-9 years	566-1690 pg/mL	238-1019 pg/mL
10-12 years	503-2077 pg/mL	238-1019 pg/mL
13-15 years	160-1590 pg/mL	238-1019 pg/mL
16-17 years	167-933 pg/mL	238-1019 pg/mL
18-29 years		238-1019 pg/mL
30-39 years		225-936 pg/mL
40-49 years		182-801 pg/mL
50-59 years		161-737 pg/mL
60-69 years		132-752 pg/mL
70 years or greater		118-776 pg/mL
Premenopausal	136-689 pg/mL	
Postmenopausal	177-1015 pg/mL	

2013661 Cystic Fibrosis (CFTR) Expanded Variant Panel CF VAR

Specimen Required: Collect: Lavender (EDTA), pink (K2EDTA).

Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)

Storage/Transport Temperature: Refrigerated.

<u>Unacceptable Conditions:</u> Plasma or serum. Specimens collected in sodium heparin, yellow (ACD solution), or lithium heparin tubes.

Frozen specimens in glass collection tubes.

Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

Interpretive Data:

Refer to report.

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

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

Note: The Cystic Fibrosis (CFTR) Expanded Variant Panel includes the 23 pathogenic CF variants recommended by the American College of Medical Genetics for carrier screening as well as many more.

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.

Change the charting name for component 2013677, CF Common Variants Interp from CF Common Variants Interp to CF Expanded Variant Panel Interp.



2013663 Cystic Fibrosis (CFTR) Expanded Variant Panel with Reflex to Sequencing CF VAR SEQ

Specimen Required: Collect: Lavender (EDTA), pink (K2EDTA).

Specimen Preparation: Transport 3 mL whole blood. (Min: 2 mL)

Storage/Transport Temperature: Refrigerated.

Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin, yellow (ACD solution), or lithium heparin tubes.

Frozen specimens in glass collection tubes.

Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

Interpretive Data:

Refer to report.

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

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

Note: If less than two pathogenic variants are identified by the Cystic Fibrosis (CFTR) Expanded Variant Panel, then CFTR gene sequencing will be performed. Additional charges apply for each tier performed.

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.

Change the charting name for component 2013681, Cystic Fibrosis, 165 Var. w/Rflx, Interp from Cystic Fibrosis, 165 Var. w/Rflx, Interp to CF Expanded Var Rflx to Seq Interp.

2013664 Cystic Fibrosis (*CFTR*) Expanded Variant Panel with Reflex to Sequencing and CFVAR COMP

Reflex to Deletion/Duplication

Specimen Required: Collect: Lavender (K₂EDTA), pink (K₂EDTA).

Specimen Preparation: Transport 5 mL whole blood. (Min: 3 mL)

 $\underline{Storage/Transport\ Temperature:}\ Refrigerated.$

Remarks:

Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin, yellow (ACD solution A or B), or lithium heparin

tubes. Frozen specimens in glass collection tubes.

Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

Interpretive Data:

Refer to report.

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

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

Note: If less than two pathogenic variants are identified by the Cystic Fibrosis (*CFTR*) Expanded Variant Panel, then *CFTR* gene sequencing will be performed. Following sequencing, if less than two pathogenic variants are identified, then *CFTR* deletion/duplication analysis will be performed. Additional charges will apply for each tier performed.

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.

Change the charting name for component 2013682, CF 165 Exp Var. Rfx to Seq Rfx DD, Interp from CF 165 Exp Var. Rfx to Seq Rfx DD, Interp to CF Exp Var Rfx to Seq Rfx DD Interp.



2013662 Cystic Fibrosis (CFTR) Expanded Variant Panel, Fetal

CF VAR FE

Specimen Required: Collect: Fetal Specimen: Two T-25 flasks of cultured amniocytes at 80 percent confluency. *If the client is unable to culture

amniocytes, this can be arranged by contacting ARUP Client Services at $(800)\ 522-2787$.

Maternal Whole Blood Specimen: Lavender (EDTA), pink (K2EDTA).

Specimen Preparation: Cultured Amniocytes: Fill flasks with culture media. Backup cultures must be retained at the client's

institution until testing is complete.

Maternal Whole Blood Specimen: Transport 3 mL whole blood. (Min. 1 mL)

Storage/Transport Temperature: Cultured Amniocytes: CRITICAL ROOM TEMPERATURE. Must be received within 48 hours

of shipment due to lability of cells.

Maternal Whole Blood Specimen: Refrigerated.

Remarks: Maternal whole blood sample is recommended for proper test interpretation; order Maternal Cell Contamination,

Maternal Specimen. Patient History Form is available on the ARUP Web site or by contacting ARUP Client Services.

<u>Unacceptable Conditions:</u> Maternal Whole Blood Specimen: Plasma or serum. Specimens collected in sodium heparin, yellow

(ACD solution), or lithium heparin tubes. Frozen specimens in glass collection tubes.

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

Maternal Whole Blood Specimen: Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

Interpretive Data:

Refer to report.

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

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

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

Note: The Cystic Fibrosis (*CFTR*) Expanded Variant Panel includes 23 pathogenic *CFTR* variants recommended by the American College of Medical Genetics for population carrier screening.

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.

Change the charting name for component 2013680, Cystic Fibrosis, 165 Var Fetal, Interp from Cystic Fibrosis, 165 Var Fetal, Interp to CF, Expanded Var Pan Fetal, Interp.

0050210 Diphtheria Antibody, IgG DIP

Performed: Sun-Sat **Reported:** 1-3 days

0050779 Diphtheria, Tetanus, and *H. Influenzae b* Antibodies, IgG

Performed: Sun-Sat **Reported:** 1-3 days



New Test

Drug Detection Panel, Meconium, Qualitative

MEC PANEL

Click for Pricing



Time Sensitive

3004583



Drug Test Table Meconium

Additional Technical Information

Methodology: Qualitative Liquid Chromatography/Tandem Mass Spectrometry

Performed: Sun-Sat Reported: 1-3 days

Specimen Required: Collect: All meconium (blackish material) excreted until milk/formula-based stool (yellow-green) appears.

Specimen Preparation: Transport all available meconium (4 g is preferred) to routine urine collection cup or Security Kit for Meconium/Umbilical Drug Detection (ARUP supply #51548) available online through eSupply using ARUP Connect™ or by

contacting ARUP Client Services at (800) 522-2787. Storage/Transport Temperature: Refrigerated temperature.

Unacceptable Conditions: Unknown fluids, pharmaceutical preparation, and breast milk. Diapers, cotton swabs, baby wipes, tongue

depressors, bottles.

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

Reference Interval:

Drugs covered and range of cutoff concentrations.

Drugs/Drug Classes	Cutoff Concentrations (ng/g)	Drugs/Drug Classes	Cutoff Concentrations (ng/g)
Buprenorphine	20	Amphetamine	20
Norbuprenorphine	20	Benzoylecgonine	20
Naloxone	20	m-OH-Benzoylecgonine	20
Codeine	20	Cocaethylene	20
Dihydrocodeine	20	Cocaine	20
Fentanyl	10	MDMA (Ecstasy)	20
Hydrocodone	20	Methamphetamine	20
Norhydrocodone	20	Phentermine	20
Hydromorphone	20	Alprazolam	5
Meperidine	20	Alpha-OH-Alprazolam	5
Methadone	10	Butalbital	50
Methadone metabolite	10	Clonazepam	5
6-Acetylmorphine	20	7-Aminoclonazepam	5
Morphine	20	Diazepam	5
Methylphenidate	20	Lorazepam	20
Oxycodone	20	Midazolam	20
Noroxycodone	20	Alpha-OH-Midazolam	20
Oxymorphone	20	Nordiazepam	20
Tapentadol	20	Oxazepam	20
Tramadol	20	Phenobarbital	200
N-desmethyltramadol	20	Temazepam	20
O-desmethyltramadol	20	Zolpidem	10
Gabapentin	20	Phencyclidine (PCP)	10

Interpretive Data:

Methodology: Qualitative Liquid Chromatography/Tandem Mass Spectrometry

Detection of drugs in meconium is intended to reflect maternal drug use during approximately the last trimester of a full-term pregnancy. The pattern and frequency of drug(s) used by the mother cannot be determined by this test. A negative result does not exclude the possibility that a mother used drugs during pregnancy. Detection of drugs in meconium depends on the extent of maternal drug use, as well as drug stability, unique characteristics of drug deposition in meconium, and the performance of the analytical method. Drugs administered during labor and delivery may be detected. Detection of drugs in meconium does not insinuate impairment and may not affect outcomes for the infant. Interpretive questions should be directed to the laboratory.

For medical purposes only; not valid for forensic use.

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



CPT Code(s): 80326; 80347; 80364; 80355 (Alt code: G0481)

New York DOH Approved.

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

<u>2006621</u>	Drug Detection Panel, Umbilical Cord Tissue, Qualitative	TOF SCR CD
CPT Code(s):	80326, 80347, 80364, 80355 (Alt code: G0481)	
2007479	Drug Profile, Targeted by Tandem Mass Spectrometry and Enzyme Immunoassay, Urine	PAIN HYB U
CPT Code (s):	80326, 80347, 80364, 80355, 80307 (Alt code: G0481)	
2009288	Drug Profile, Targeted with Interpretation by Tandem Mass Spectrometry and Enzyme Immunoassay, Urine	PAIN HYB 2
CPT Code (s):	80326, 80347, 80364, 80355, 80307 (Alt code: G0481)	

0051626 Epstein-Barr Virus Antibody to Viral Capsid Antigen, IgA EBV A

Specimen Required: 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: 0.1 mL) Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Mark specimen plainly as "acute" or "convalescent."

Storage/Transport Temperature: Refrigerated.

<u>Unacceptable Conditions:</u> Contaminated or heat-inactivated specimens. Grossly hemolytic, icteric or, lipemic specimens.

Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 30 days



New Test

3004531

Familial Transthyretin Amyloidosis (TTR) Sequencing

TTR NGS

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Additional Technical Information

Methodology: Massively Parallel Sequencing

Performed: Varies Reported: 3 weeks

Specimen Required: Collect: Lavender or pink (EDTA), or yellow (ACD solution A or B).

Specimen Preparation: Transport 3 mL whole blood. (Min: 2 mL)

Storage/Transport Temperature: Refrigerated.

<u>Unacceptable Conditions:</u> Serum or plasma; grossly hemolyzed or frozen specimens; saliva, buccal brush, or swab; FFPE tissue.

Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Refer to report.

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

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

Note: Gene Tested: TTR (NM_000371)

CPT Code(s): 81404

New York DOH approval pending. Call for status update.



0050164 Fungal Antibodies by Immunodiffusion FUNG PPT

Methodology: Immunodiffusion

Specimen Required: Collect: Serum separator tube (SST)

Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard

Transport Tube. (Min: 0.4 mL)

Storage/Transport Temperature: Refrigerated.

<u>Unacceptable Conditions:</u> Other body fluids. Contaminated, hemolyzed, icteric, or lipemic specimens.

Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

(avoid repeated freeze/thaw cycles)

Reference Interval:

Effective May 16, 2022

Test Number	Components	Reference Interval
0050171	Aspergillus spp. Antibodies by Immunodiffusion	None detected
0050172	Blastomyces dermatitidis Antibodies by Immunodiffusion	None detected
	Coccidioides Antibodies by Immunodiffusion	Not Detected
0050174	Histoplasma spp. Antibodies by Immunodiffusion	None detected

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.

Change the charting name for component 0050183, Coccidioides immitis Abs, Precipitin from Coccidioides immitis Abs, Precipitin to Coccidioides by Immunodiffusion, Serum.



New Test

Galactosemia (GALT) Sequencing and Deletion/Duplication

GALT NGS

Click for Pricing



Additional Technical Information



Patient History for Galactosemia (GALT)

Methodology: Massively Parallel Sequencing

3004716

Performed: Varies Reported: 3 weeks

Specimen Required: Collect: Lavender or pink (EDTA) or yellow (ACD solution A or B).

Specimen Preparation: Transport 3 mL whole blood. (Min: 2 mL)

Storage/Transport Temperature: Refrigerated.

<u>Unacceptable Conditions:</u> Serum or plasma; grossly hemolyzed or frozen specimens; saliva, buccal brush, or swab; FFPE tissue.

Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Refer to report.

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

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

Note: Gene Tested: *GALT* (NM_000155)

CPT Code(s): 81406; 81479

New York DOH approval pending. Call for status update.



3000258 Genetic Carrier Screen, (CF, FXS, and SMA) with Reflex to Methylation

(Temporary Delay as of 01/21/2021 - no referral available)

CF FX SMA

Specimen Required: Collect: Lavender (K2EDTA). Also acceptable: Pink (K2EDTA).

Specimen Preparation: Transport 5 mL whole blood. (Min: 3 mL)

Storage/Transport Temperature: Refrigerated.

Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin, yellow (ACD solution A), or lithium heparin

tubes. Frozen specimens in glass collection tubes.

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

Interpretive Data:

Refer to report.

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

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

Note: Cystic Fibrosis (CF): The Cystic Fibrosis (CFTR) Expanded Variant Panel includes the 23 pathogenic CF variants recommended by the American College of Medical Genetics for population carrier screening as well as many others.

Fragile X: If a CGG repeat of 100 or greater is detected by PCR and Capillary Electrophoresis; methylation analysis will be added. Additional charges apply.

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.

Change the charting name for component 2013677, CFystic Fibrosis, Expanded 165 Variants Panel, Interp from CFystic Fibrosis, Expanded 165 Variants Panel, Interp to CF Expanded Variant Panel Interp.

0050542 Haemophilus influenzae b Antibody, IgG

HIBE IGG

Performed: Sun-Sat **Reported:** 1-3 days

2001956 Hearing Loss, Nonsyndromic, Connexin 30 (*GJB6*) 2 Deletions

GJB6 DEL

Specimen Required: Collect: Lavender (EDTA), pink (K2EDTA), or yellow (ACD Solution A or B).

Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)

Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature

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

Interpretive Data:

Background: Hearing Loss, Nonsyndromic, Connexin 30 (GJB6) 2 Deletions:

Characteristics: Moderate to profound nonsyndromic hearing loss (NSHL). Large *GJB6* gene deletions involving cis-regulatory elements for GJB2 (connexin 26) result in the loss of expression of GJB2. Thus, compound heterozygosity for a pathogenic *GJB2* variant and *GJB6* large deletion results in NSHI

Incidence: Approximately 1 in 30 individuals with NSHL has a *GJB6* deletion; 1 in 100,000 in the general population. Twenty percent of *GJB2* heterozygotes with nonsyndromic hearing loss have a *GJB6* deletion; homozygosity for *GJB6* deletions is rare.

Inheritance: Autosomal recessive.

Cause: Pathogenic germline variants in GJB6.

Variants Tested: 309kb del(GJB6-D13S1830, also known as 342kb) and 232kb del(GJB6-D13S1854).

Clinical Sensitivity: Dependent on ethnicity.

Methodology: Multiplex PCR using deletion-specific primers, followed by capillary gel electrophoresis.

Analytical Sensitivity and Specificity: Greater than 99 percent.

Limitations: *GJB6* variants other than the two targeted deletions will not be identified. The etiology of hearing loss due to other genetic or environmental causes will not be determined. Diagnostic errors can occur due to rare sequence variations. Interpretation of this test result may be impacted if this patient has had an allogeneic stem cell transplantation.

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

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



2005792 **Hemoglobin Evaluation Reflexive Cascade** **HB CASCADE**

Methodology:

High Performance Liquid Chromatography/Electrophoresis/RBC Solubility/Polymerase Chain Reaction/Fluorescence Resonance Energy Transfer/Sequencing/Massively Parallel Sequencing

3000894 Hereditary Hemolytic Anemia Cascade HHACASCADE

Methodology:

High Performance Liquid Chromatography (HPLC)/Electrophoresis/RBC Solubility/Polymerase Chain Reaction (PCR)/Fluorescence Resonance Energy Transfer/Sequencing/Spectrophotometry/Visual Identification/Quantitative Enzymatic/Quantitative Flow Cytometry/Cytochemical Stain/Multiplex Ligation-Dependent Probe Amplification/Massively Parallel Sequencing

Interpretive Data:

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

CPT Code(s): 84220; 88184; 82955; 83021. If reflexed additional CPT codes may apply; refer to the reflexed test code for applicable codes.

0050641 Herpes Simplex Virus Type 1 and/or 2 Antibodies, IgM by ELISA

HSV MC

Specimen Required: Collect: Serum Separator Tube (SST).

Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 0.5 mL serum to an ARUP Standard Transport Tube. (Min: 0.1 mL) Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Mark specimens plainly as "acute" or convalescent."

Storage/Transport Temperature: Refrigerated.

Unacceptable Conditions: Contaminated, heat-inactivated, hemolyzed, icteric, or severely lipemic specimens.

Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

(avoid repeated freeze/thaw cycles)

Herpes Simplex Virus Type 1 and/or 2 Antibodies, IgM by ELISA, CSF 0050408

HSVMCCSF

Specimen Required: Collect: CSF.

Specimen Preparation: Transfer 0.5 mL CSF to an ARUP Standard Transport Tube. (Min: 0.2 mL)

Storage/Transport Temperature: Refrigerated. Remarks: Indicate source on test request form.

Unacceptable Conditions: Contaminated, heat-inactivated, hemolyzed, icteric, or severely lipemic specimens.

Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: 2 weeks; Frozen: 1 year

2009418 Histoplasma Galactomannan Antigen Quantitative by EIA, Urine

HISTOGM U

Specimen Required: Collect: Random urine.

Specimen Preparation: Transfer 2 mL urine to an ARUP Standard Transport Tube.

Storage/Transport Temperature: Refrigerated.

Unacceptable Conditions: Specimens other than urine. Urine in boric acid. Serum; refer to test Histoplasma Antigen by EIA, Serum

(ARUP test code 0092522).

Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 2 weeks; Frozen: 2 weeks

Interpretive Data:

Less than 0.4 ng/ml = Not Detected

0.4-0.7 ng/mL = Detected (below the limit of quantification)

0.8-24.0 ng/mL = Detected

Greater than 24.0 ng/mL = Detected (above the limit of quantification)

The quantitative range of this assay is 0.8-24.0 ng/mL. Antigen concentrations between 0.4-0.7 or >24.0 ng/mL fall outside the linear range of the assay and cannot be accurately quantified.

This EIA test should be used in conjunction with other diagnostic procedures, including microbiological culture, histological examination of biopsy samples, and/or radiographic evidence, to aid in the diagnosis of histoplasmosis.

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.



<u>0040018</u> Huntington Disease (*HD*) Mutation by PCR (Extended TAT as of 11/20/20-no

HD

referral available)

Specimen Required: Collect: Lavender (EDTA), pink (K2EDTA), or yellow (ACD Solution A or B).

Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)

Storage/Transport Temperature: Preferred transport temp: Refrigerated. Also acceptable: Room temperature.

Remarks: A completed HD specific consent form, signed by the patient (or legal guardian) and physician, is required for all specimens. Testing for patients under the age of 18 years or fetal specimens is not offered. Presymptomatic patients are strongly encouraged to be tested through a counseling program approved by the Huntington Disease Society of America at (800) 345-4372.

Call Genetics Processing with additional questions at 800-242-2787 ext 3301.

Stability (collection to initiation of testing): Room temperature: 1 week; Refrigerated: 1 month; Frozen: unacceptable

Interpretive Data:

Background Information for Huntington Disease (HD) Mutation by PCR:

Characteristics: Neurodegenerative disorder causing progressive cognitive, motor, and psychiatric disturbances typically beginning at 35-44 years of age. An estimated 5 percent of individuals with HD are symptomatic as juveniles and 25 percent of individuals after age 50.

Incidence: 1 in 15,000.

Reported:

1-3 days

Inheritance: Autosomal dominant.

Cause: Expanded number of CAG repeats in the *HTT* gene. HD allele with reduced penetrance 36-39 CAG repeats; HD allele with full penetrance 40 or more CAG repeats.

Clinical Sensitivity and Specificity: 99 percent.

Methodology: Triplet repeat-primed polymerase chain reaction (PCR) followed by size analysis using capillary electrophoresis. Repeat sizing precision is +/- 2 for alleles less than or equal to 50 repeats, +/- 3 for alleles with 51 to 75 repeats, and +/- 4 for alleles greater than 75 repeats.

Analytical Sensitivity and Specificity: 99 percent.

Limitations: Other neurodegenerative disorders will not be detected. Diagnostic errors can occur due to rare sequence variations. Interpretation of this test result may be impacted if this patient has had an allogeneic stem cell transplantation.

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.

Allele type	Number of CAG Repeats
Normal allele	less than or equal to 26
Mutable normal (intermediate) allele	27-35
HD allele with reduced penetrance	36-39
HD allele with full penetrance	greater than or equal to 40

HOTLINE NOTE: Remove information found in the Reference Interval field.

0050340	Immunoglobulin A	IGA
Performed:	Sun-Sat	
Reported:	1-3 Days	
0050350	Immunoglobulin G	IGG
Performed:	Sun-Sat	
Reported:	1-3 Days	
3003485	Immunoglobulin G, CSF	IGGCSF
Performed:	Sun-Sat	



IGG SYN 0050676 Immunoglobulin G, CSF Index

Performed: Sun-Sat Reported: 1-3 days

> IGM 0050355 Immunoglobulin M

Performed: Sun-Sat **Reported:** 1-3 Days

0051069 Influenza A & B Virus Antibodies, IgG & IgM **INFLU ABS**

Specimen Required: Collect: Serum separator tube.

Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.05 mL) Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Mark specimens plainly as "acute" or "convalescent."

Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.

Unacceptable Conditions: Bacterially contaminated, heat-inactivated, hemolyzed, icteric, lipemic, or turbid specimens.

Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

0051074 Influenza A Virus Antibody, IgG **FLUA G**

Specimen Required: Collect: Serum separator tube.

Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.05 mL) Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Mark specimens plainly as "acute" or "convalescent."

Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.

Unacceptable Conditions: Bacterially contaminated, heat-inactivated, hemolyzed, icteric, lipemic, or turbid specimens.

Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

0051081 Influenza A Virus Antibody, IgM **FLUA M**

Specimen Required: Collect: Serum separator tube.

Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.05 mL) Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Mark specimens plainly as "acute" or "convalescent."

Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.

<u>Unacceptable Conditions:</u> <u>Bacterially</u> contaminated, heat-inactivated, hemolyzed, icteric, lipemic, turbid specimens.

Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

0051080 Influenza B Virus Antibody, IgG **FLUB G**

Specimen Required: Collect: Serum separator tube.

Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.05 mL) Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Mark specimens plainly as "acute" or "convalescent."

Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.

<u>Unacceptable Conditions:</u> Bacterially contaminated, heat-inactivated, hemolyzed, icteric, lipemic, or turbid specimens.

Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

0051079 Influenza B Virus Antibody, IgM FLUB M

Specimen Required: Collect: Serum separator tube.

Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.05 mL) Parallel testing is preferred and convalescent specimens must be received within 30 days from

receipt of the acute specimens. Mark specimens plainly as "acute" or "convalescent." Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.

<u>Unacceptable Conditions:</u> <u>Bacterially</u> contaminated, heat-inactivated, hemolyzed, icteric, lipemic, or turbid specimens.

Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

3003801

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

PV RFX

Specimen Required: Collect: Whole blood or bone marrow: Lavender (EDTA).

Specimen Preparation: Whole Blood: Do not freeze. Transport 5 mL whole blood. (Min: 1 mL) Bone Marrow: Do not freeze. Transport 3 mL bone marrow. (Min: 1 mL)

Storage/Transport Temperature: Refrigerated.

Unacceptable Conditions: Plasma, serum, FFPE tissue blocks/slides, or fresh or frozen tissue. Specimens collected in anticoagulants

other than EDTA. Clotted or grossly hemolyzed specimens.

Stability (collection to initiation of testing): Refrigerated: 4 days; Frozen: Unacceptable

2002357

JAK2 Exon 12 Mutation Analysis by PCR

JAK2 EX12

Specimen Required: Collect: Whole blood or bone marrow (EDTA). Also acceptable: DNA extracted by CLIA certified lab.

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)

Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-

Storage/Transport Temperature: Refrigerated.

Unacceptable Conditions: Plasma, serum, FFPE tissue blocks/slides, or frozen tissue. Specimens collected in anticoagulants other than

EDTA. Clotted or grossly hemolyzed specimens.

Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 4 days; Frozen: Unacceptable

Extracted DNA: Ambient: 1 month; Refrigerate: Indefinitely; Frozen: Indefinitely



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KLDUAL IHC

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Immunohistochemistry Stain Form Recommended (ARUP form #32978)

Methodology: Immunohistochemistry

3004541

Performed: Mon-Fri **Reported:** 1-3 days

Specimen Required: Collect: Tissue or cells.

Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a Tissue Transport Kit (ARUP supply #47808 highly recommended but not required) available online through eSupply using ARUP ConnectTM or contact ARUP Client Services at (800) 522-2787. (Min: 2 slides). If sending precut slides, do not oven bake.

Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months. Remarks: IMMUNOHISTOCHEMISTRY ORDERING AND SUBMISSION DETAILS: Submit electronic request. If you do not have electronic ordering capability, use an ARUP Immunohistochemistry Stain Form (#32978) with an ARUP client number. For

additional technical details, contact ARUP Client Services at (800) 522-2787.

<u>Unacceptable Conditions:</u> Specimens submitted with nonrepresentative tissue type. Depleted specimens.

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

Interpretive Data:

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

Note: The following antibodies are utilized in this dual stain: kappa (CH15) and lambda (SHL53).

This test is performed as a stain and return (technical) service only.

CPT Code(s): 88344

New York DOH Approved.

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

0051726 Leishmania Antibody, IgG (Visceral Leishmaniasis)

LEISH IGG

Specimen Required: Collect: Serum separator tube.

Specimen Preparation: Transfer 0.5 mL serum to an ARUP Standard Transport Tube. (Min: 0.1 mL)

Storage/Transport Temperature: Refrigerated.

Unacceptable Conditions: Serum containing glycerol or other viscous materials. Hemolyzed specimens.

Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year



New Test

3001605

Lynch Syndrome Panel, Sequencing and Deletion/Duplication

LS NGS

Click for Pricing



Patient History for Lynch Syndrome



Additional Technical Information

Methodology: Massively Parallel Sequencing/Sequencing/Multiplex Ligation-dependent Probe Amplification

Performed: Varies Reported: 3-6 weeks

Specimen Required: Collect: Lavender or pink (EDTA) or yellow (ACD solution A or B).

Specimen Preparation: Transport 3 mL whole blood. (Min: 2 mL)

Storage/Transport Temperature: Refrigerated.

<u>Unacceptable Conditions:</u> Serum or plasma; grossly hemolyzed or frozen specimens; saliva, buccal brush, or swab; FFPE tissue;

Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Refer to report.

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

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

Note: Genes Tested: *EPCAM**, *MLH1*, *MSH2*, *MSH6*, *PMS2*

*Deletion/duplication only; sequencing is not available for this gene.

CPT Code(s): 81292; 81294; 81295; 81297; 81298; 81300; 81317; 81319; 81403

New York DOH approval pending. Call for status update.

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

0054441 Measles (Rubeola) Antibody, IgM, CSF **MEASLMCSF**

Specimen Required: Collect: CSF.

Specimen Preparation: Transfer 0.5 mL CSF to an ARUP Standard Transport Tube. (Min: 0.2 mL)

Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen.

<u>Unacceptable Conditions:</u> <u>Contaminated</u>, heat-inactivated, or hemolyzed specimens.

Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: 2 weeks; Frozen: 1 year



New Test Available Now Click for Pricing Multiple Endocrine Neoplasia Type 2 (MEN2), RET Sequencing

MEN2 NGS

Click for Pricin



Patient History for Multiple Endocrine Neoplasia 2, RET Gene Testing



Additional Technical Information

Methodology: Massively Parallel Sequencing

3004572

Performed: Varies Reported: 3 weeks

Specimen Required: Collect: Lavender or pink (EDTA) or yellow (ACD solution A or B).

Specimen Preparation: Transport 3 mL whole blood. (Min: 2 mL)

Storage/Transport Temperature: Refrigerated.

Unacceptable Conditions: Serum or plasma; grossly hemolyzed or frozen specimens; saliva, buccal brush, or swab; FFPE tissue.

Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Refer to report.

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

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

Note: Gene Tested: RET (NM_020975)

CPT Code(s): 81406

New York DOH approval pending. Call for status update.

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

<u>0054443</u> Mumps Virus Antibody IgM, CSF

MUMPSMCSF

Specimen Required: Collect: CSF.

Specimen Preparation: Transfer 0.5 mL CSF to an ARUP Standard Transport Tube. (Min: 0.2 mL)

Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen.

<u>Unacceptable Conditions:</u> <u>Contaminated</u>, heat-inactivated, or hemolyzed specimens.

Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: 2 weeks; Frozen: 1 year



New Test

3004788

Pancreatitis Panel (CFTR, CTRC, PRSS1, SPINK1), Sequencing

PANC NGS

Click for Pricing



Additional Technical Information



Patient History for Pancreatitis Testing

Methodology: Massively Parallel Sequencing/Sequencing

Performed: Varies Reported: 3 weeks

Specimen Required: Collect: Lavender or pink (EDTA) or yellow (ACD solution A or B).

Specimen Preparation: Transport 3 mL whole blood. (Min: 2 mL)

Storage/Transport Temperature: Refrigerated.

<u>Unacceptable Conditions:</u> Serum or plasma; grossly hemolyzed or frozen specimens; saliva, buccal brush, or swab; FFPE tissue.

Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Refer to report.

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

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

Note: Genes Tested: CFTR, CTRC, PRSS1, SPINK1

CPT Code(s): 81223; 81404; 81405

New York DOH approval pending. Call for status update.

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

2001766 S-100B Protein, Serum S 100B

Reference Interval:

Effective May 16, 2

Age	Reference Interval
19 years and older:	0-96 ng/L
3 years to 19 years:	less than or equal to 160 ng/L
25 months to 3 years:	less than or equal to 170 ng/L
10 months to 25 months:	less than or equal to 230 ng/L
5 months to 10 months:	less than or equal to 350 ng/mL
0 days to 5 months:	less than or equal to 510 ng/mL



New Test Available Now Click for Pricing SATB2 by Immunohistochemistry

SATB2 IHC



Immunohistochemistry Stain Form Recommended (ARUP form #32978)

Methodology: Immunohistochemistry

3004727

Performed: Mon-Fri **Reported:** 1-3 days

Specimen Required: Collect: Tissue or cells.

Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a Tissue Transport Kit (ARUP supply #47808) available online through eSupply using ARUP ConnectTM or contact ARUP Client Services at (800) 522-2787. (Min: 2 slides). If sending precut slides, do not oven bake.

Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months. Remarks: IMMUNOHISTOCHEMISTRY ORDERING AND SUBMISSION DETAILS: Submit electronic request. If you do not have electronic ordering capability, use an ARUP Immunohistochemistry Stain Form (#32978) with an ARUP client number. For

additional technical details, contact ARUP Client Services at (800) 522-2787.

<u>Unacceptable Conditions:</u> Specimens submitted with nonrepresentative tissue type. Depleted specimens.

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

Interpretive Data:

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.

Note:

This test is performed as a stain and return (technical) service only.

CPT Code(s): 88342

New York DOH Approved.



New Test

3004603

SHOX Deficiency Disorders, Sequencing and Deletion/Duplication

SHOX NGS

Click for Pricing



Patient History for SHOX Deficiency Disorders Testing



Additional Technical Information

Methodology: Massively Parallel Sequencing/ Multiplex Ligation-dependent Probe Amplification

Performed: Varies Reported: 3-6 weeks

Specimen Required: Collect: Lavender or pink (EDTA) or yellow (ACD solution A or B).

Specimen Preparation: Transport 3 mL whole blood. (Min: 2 mL)

Storage/Transport Temperature: Refrigerated

Unacceptable Conditions: Serum or plasma; grossly hemolyzed or frozen specimens; saliva, buccal brush, or swab; FFPE tissue;

DNA.

Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Refer to report

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

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

Note: Gene Tested: SHOX (NM_000451), exon 6b (NM_006883) is not sequenced.

CPT Code(s): 81405; 81479

New York DOH approval pending. Call for status update.

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

0050535 Tetanus Antibody, IgG **TETANUS**

Performed: Sun-Sat Reported: 1-3 days

> 2006550 Thyroglobulin by LC-MS/MS, Serum or Plasma

THYROG MS

Specimen Required: Collect: Serum separator tube or green (sodium or lithium heparin), Potassium EDTA

Specimen Preparation: Separate from cells: Transport 1.5 mL serum or plasma. (Min: 0.7 mL)

Storage/Transport Temperature: Refrigerated or Frozen.

<u>Unacceptable Conditions:</u> Samples left ambient for greater than 1 day; <u>Grossly lipemic samples</u>.

Stability (collection to initiation of testing): After separation from cells: Ambient: 1 day; Refrigerated: 1 week; Frozen: 1 year

2006685 THYROGRFX Thyroglobulin, Serum or Plasma with Reflex to LC-MS/MS or CIA

Specimen Required: Collect: Serum Separator Tube (SST). Also acceptable: Green (Sodium or Lithium Heparin).

Specimen Preparation: Transfer 3 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1.5 mL)

Storage/Transport Temperature: Frozen.

Unacceptable Conditions: EDTA or K2EDTA plasma. Grossly lipemic samples. Any fluid other than noted above. (See

Thyroglobulin, Fine Needle Aspiration (FNA) (ARUP test code 0020753) for ordering alternate fluids).

Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 6 months



<u>0051076</u> Trypanosoma cruzi Antibody, IgG

CHAGAS G

Specimen Required: 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: 0.3 mL) Parallel testing is preferred and convalescent specimens must be received within 30 days of the acute specimens. Mark specimens plainly as "acute" or "convalescent."

Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.

<u>Unacceptable Conditions:</u> Plasma. Bacterially contaminated, heat-inactivated, hemolyzed, icteric, lipemic, or turbid specimens. <u>Stability (collection to initiation of testing):</u> After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

2005416 Urticaria-Induced Basophil Activation UIBA

Performed: Tuesday **Reported:** 7-16 days



The following will be discontinued from ARUP's test menu on May 16, 2022. Replacement test options are supplied if applicable.

Test Number	Test Name	Refer To Replacement
0092311	Barbiturates - Confirmation – Meconium	Drug Detection Panel, Meconium, Qualitative (3004583)
<u>0050578</u>	Beta Globin (HBB) Gene Sequencing	Beta Globin (HBB) Sequencing (3004547)
2010117	Beta Globin (HBB) Sequencing and Deletion/Duplication (Temporary Referral as of 12/07/20)	
<u>0050388</u>	Beta Globin (HBB) Sequencing, Fetal	Beta Globin (HBB) Sequencing, Fetal (3004550)
<u>2003445</u>	Breast Carcinoma b72.3 by Immunohistochemistry	
<u>2011601</u>	Buprenorphine, Meconium, Quantitative	Drug Detection Panel, Meconium, Qualitative (3004583)
<u>0092312</u>	Cocaine and Metabolites - Confirmation/Quantitation - Meconium	Drug Detection Panel, Meconium, Qualitative (3004583)
<u>0051374</u>	Connexin 26 (GJB2), Sequencing	Connexin 26 (GJB2) Sequencing and Deletion/Duplication (3004720)
<u>0051110</u>	Cystic Fibrosis (CFTR) Sequencing (Temporary Referral as of 12/07/20)	
0051640	Cystic Fibrosis (CFTR) Sequencing with Reflex to Deletion/Duplication (Temporary Referral as of 12/07/20)	Cystic Fibrosis (CFTR) Sequencing and Deletion/Duplication (3004745)
0092310	Drugs of Abuse Confirmation/Quantitation - Amphetamines (Amphetamine and Methamphetamine) – Meconium	Drug Detection Panel, Meconium, Qualitative (3004583)
0092520	Drugs of Abuse Confirmation/Quantitation - Benzodiazepines – Meconium	Drug Detection Panel, Meconium, Qualitative (3004583)
0092313	Drugs of Abuse Confirmation/Quantitation - Methadone and Metabolite - Meconium	Drug Detection Panel, Meconium, Qualitative (3004583)
0092314	Drugs of Abuse Confirmation/Quantitation - Opiates - Meconium	Drug Detection Panel, Meconium, Qualitative (3004583)
0092516	Drugs of Abuse Panel, Meconium - Screen with Reflex to Confirmation/Quantitation	Drug Detection Panel, Meconium, Qualitative (3004583)
<u>2014035</u>	Familial Transthyretin Amyloidosis (TTR) Sequencing	Familial Transthyretin Amyloidosis (TTR) Sequencing (3004531)
<u>2006697</u>	Galactosemia (GALT), Sequencing	Galactosemia (GALT) Sequencing and Deletion/Duplication (3004716)
2003938	Human Placental Lactogen (HPL) by Immunohistochemistry	
<u>0050667</u>	Immune Complex Panel	Circulating Immune Complex Panel (3004430)
<u>2003981</u>	Kappa Light Chains by Immunohistochemistry	Kappa Lambda Dual Stain by IHC (3004541)
<u>2003984</u>	Lambda Light Chains by Immunohistochemistry	Kappa Lambda Dual Stain by IHC (3004541)
0051390	Multiple Endocrine Neoplasia Type 2 (MEN2), <i>RET</i> Gene Mutations by Sequencing (Temporary Referral as of 12/07/20)	Multiple Endocrine Neoplasia Type 2 (MEN2), RET Sequencing (3004572)
3001768	Pancreatitis (PRSS1) Sequencing and Deletion/Duplication	
2002012	Pancreatitis (SPINK1) Sequencing	
<u>2010876</u>	Pancreatitis, Panel (CFTR, CTRC, PRSS1, SPINK1) Sequencing (Temporary Referral as of 12/7/20)	Pancreatitis Panel (CFTR, CTRC, PRSS1, SPINK1), Sequencing (3004788)
<u>0092315</u>	Phencyclidine (PCP) - Confirmation/Quantitation - Meconium	Drug Detection Panel, Meconium, Qualitative (3004583)
0050302	Raji Cell Immune Complex Assay	Circulating Immune Complex, C3 fragments (3004431)
3001401	SHOX-Related Disorders, Deletion/Duplication with Reflex to Sequencing	SHOX Deficiency Disorders, Sequencing and Deletion/Duplication (3004603)