ARUP LABORATORIES

HOTLINE: Effective November 14, 2022

## MEDICARE COVERAGE OF LABORATORY TESTING

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

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

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

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

| 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 7 | 0051265 | Achondroplasia (*FGFR3*) 2 Mutations, Fetal | | | x | x | | x | | | | | | |
| 8 | 2011708 | Alpha Globin (*HBA1* and *HBA2*) Sequencing and Deletion/Duplication | | | | | | x | | | | | | |
| 8 | 0050005 | Alpha-2-Macroglobulin | | | x | x | | | | | | | | |
| 8 | 3002685 | Alport Syndrome Panel, Sequencing and Deletion/Duplication | | x | x | x | | | x | | | | | |
| 9 | 2012232 | Angelman Syndrome and Prader-Willi Syndrome by Methylation-Sensitive PCR, Fetal | | | x | x | | x | | | | | | |
| 10 | 0051415 | Ashkenazi Jewish Diseases, 16 Genes | | | x | x | | x | x | x | | | | |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 10 | 0092057 | Basement Membrane Zone (Epithelial) Antibodies, IgA by IIF | x | x | | x | | x | | | | | | |
| 11 | 0092056 | Basement Membrane Zone (Epithelial) Antibodies, IgG by IIF | x | x | | x | | x | | | | | | |
| 11 | 0090299 | Basement Membrane Zone and Cell Surface (Epithelial) Antibodies, IgG and IgA by IIF | x | x | | x | | x | | | | | | |
| 11 | 3001410 | Basement Membrane Zone Antibody Panel | | x | | x | | | | | | | | |
| 52 | 2005017 | BCR-ABL1, Major (p210), Quantitative | | | | | | | | | | | | x |
| 52 | 2005010 | BCR-ABL1, Qualitative with Reflex to BCR-ABL1 Quantitative | | | | | | | | | | | | x |
| 12 | 3004550 | Beta Globin (*HBB*) Sequencing, Fetal | | | | x | | | | | | | | |
| 12 | 3005703 | Birt-Hogg-Dubé Syndrome (*FLCN*) Sequencing and Deletion/Duplication | | | | | | | | | | | x | |
| 52 | 0050216 | Borrelia burgdorferi Antibodies, Total by ELISA | | | | | | | | | | | | x |
| 12 | 2002498 | *BRAF* Codon 600 Mutation Detection by Pyrosequencing (Pricing Change) | | | | | | | x | x | | | | |
| 13 | 0051750 | *BRAF* Codon 600 Mutation Detection with Reflex to *MLH1* Promoter Methylation (Pricing Change) | | | | | | | x | x | | | | |
| 13 | 0092566 | Bullous Pemphigoid (BP180 and BP230) Antibodies, IgG by ELISA | x | | | x | | x | | | | | | |
| 13 | 3003634 | Capillary Malformation-Arteriovenous Malformation (CM-AVM) Panel, Sequencing and Deletion/Duplication | | x | x | x | | x | x | | | | | |
| 13 | 2011114 | *CBFB-MYH11* inv(16) Detection, Quantitative | | x | | x | | | | | | | | |
| 52 | 2003526 | CD14 by Immunohistochemistry | | | | | | | | | | | | x |
| 14 | 0090266 | Cell Surface (Epithelial) Antibodies, IgG by IIF | x | x | | x | | x | | | | | | |
| 14 | 3005593 | Claudin-4 by Immunohistochemistry | | | | | | | | | | | x | |
| 52 | 2003839 | Collagen IV by Immunohistochemistry | | | | | | | | | | | | x |
| 15 | 2010905 | Collagen Type VII Antibody, IgG by ELISA | x | x | x | x | | x | | | | | | |
| 15 | 3001513 | *CYP2D6* | | | x | | | x | | | | | | |
| 15 | 3001524 | Cytochrome P450 Genotyping Panel | | | x | | | x | | | | | | |
| 15 | 3004255 | Cytochrome P450 Genotyping Panel, with GeneDose Access | | | x | | | x | | | | | | |
| 16 | 3004275 | Cytogenomic Molecular Inversion Probe Array FFPE Tissue - Oncology | | | | | | | | x | | | | |
| 16 | 3004273 | Cytogenomic Molecular Inversion Probe Array FFPE Tissue - Products of Conception | | | | | | | | x | | | | |
| 16 | 3005895 | Cytomegalovirus by Quantitative NAAT, Plasma | | | | | | | | | | | x | |
| 52 | 0051813 | Cytomegalovirus by Quantitative PCR | | | | | | | | | | | | x |

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| 52 | 2006966 | Cytomegalovirus, Quantitative PCR with Reflex to Drug Resistance Testing by Sequencing | | | | | | | | | | | | x |
| 17 | 0090649 | Desmoglein 1 and Desmoglein 3 (Pemphigus) Antibodies, IgG by ELISA | x | | x | x | | x | | | | | | |
| 18 | 3005839 | Diagnostic Qualitative BCR-ABL1 Assay with Reflex to p190 or p210 Quantitative Assays | | | | | | | | | | | x | |
| 19 | 0092572 | Direct Immunofluorescence, Tissue Biopsy (Cutaneous, Mucosal, Epithelial) | x | | | x | | x | | | | | | |
| 19 | 3005714 | DNA Extract and Hold | | | | | | | | | | | x | |
| 52 | 0050757 | DNA Extraction and Storage | | | | | | | | | | | | x |
| 20 | 3005882 | Dysautonomia, Familial (ELP1), 2 Variants | | | | | | | | | | | x | |
| 52 | 0051463 | Dysautonomia, Familial (IKBKAP), 2 Variants | | | | | | | | | | | | x |
| 20 | 2002440 | *EGFR* Mutation Detection by Pyrosequencing (Pricing Change) | | | | | | | x | x | | | | |
| 20 | 3003830 | Electron Microscopy Technical Only Request | | | | x | | | x | | | | | |
| 21 | 2010921 | Eosinophil Granule Major Basic Protein, Tissue Biopsy | x | x | x | x | | x | x | | | | | |
| 21 | 2010902 | Epidermal Transglutaminase (eTG/TG3) Antibody, IgA by ELISA | x | | x | x | | x | | | | | | |
| 52 | 2007914 | EPOR Mutation Detection by Sequencing | | | | | | | | | | | | x |
| 21 | 0049178 | *ERBB2* (*HER2/neu*) (HercepTest) by Immunohistochemistry, Tissue with Reflex to FISH if 2+ | | | | | | | | | x | | | |
| 22 | 0049174 | *ERBB2* (*HER2/neu*) (HercepTest) with Interpretation by Immunohistochemistry, Tissue | | | | | | | | | x | | | |
| 22 | 2008603 | ERBB2 (HER2/neu) Gene Amplification by FISH with Reflex, Tissue | | | | | | | | | x | | | |
| 22 | 0049210 | Estrogen/Progesterone Receptor with Interpretation by Immunohistochemistry | | | | | | | | | x | | | |
| 52 | 2001961 | Familial Mutation, Targeted Sequencing | | | | | | | | | | | | x |
| 52 | 2001980 | Familial Mutation, Targeted Sequencing, Fetal | | | | | | | | | | | | x |
| 23 | 3005867 | Familial Targeted Sequencing | | | | | | | | | | | x | |
| 24 | 3005869 | Familial Targeted Sequencing, Fetal | | | | | | | | | | | x | |
| 24 | 3001161 | *FLT3* ITD and TKD Mutation Detection | | | | x | | | | | | | | |
| 24 | 3004279 | Gastrointestinal Stromal Tumor Mutations | | | | | | | | x | | | | |
| 25 | 2001510 | Glutarylcarnitine Quantitative, Urine | | | x | x | x | x | | | | | | |
| 52 | 2003860 | Hairy Cell Leukemia, DBA.44 by Immunohistochemistry | | | | | | | | | | | | x |
| 25 | 2006686 | *Helicobacter pylori* Culture | | | | x | | | | | | | | |

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| 52 | 0020457 | Hepatitis Panel, Acute with Reflex to HBsAg Confirmation | | | | | | | | | | | | x |
| 26 | 3001615 | Hereditary Bone Marrow Failure Panel, Sequencing and Deletion/Duplication | | | | | | | | | | | x | |
| 27 | 3005654 | Hereditary Breast Cancer Guidelines-Based Panel, Sequencing and Deletion/Duplication | | | | | | | | | | | x | |
| 28 | 3005721 | Hereditary Erythrocytosis Panel, Sequencing | | | | | | | | | | | x | |
| 29 | 3005697 | Hereditary Gastrointestinal Cancer High-Risk Panel, Sequencing and Deletion/Duplication | | | | | | | | | | | x | |
| 29 | 3000894 | Hereditary Hemolytic Anemia Cascade | | | | | | | | x | | x | | |
| 30 | 3005708 | Hereditary Pancreatic Cancer Panel, Sequencing and Deletion/Duplication | | | | | | | | | | | x | |
| 31 | 3005686 | Hereditary Prostate Cancer Panel, Sequencing and Deletion/Duplication | | | | | | | | | | | x | |
| 32 | 3005696 | Hereditary Retinoblastoma (*RB1*) Sequencing and Deletion/Duplication | | | | | | | | | | | x | |
| 52 | 0050385 | Heterophile Antibody (Infectious Mononucleosis) by Latex Agglutination, Qualitative | | | | | | | | | | | | x |
| 32 | 3002850 | HLA Antibody Screen, Class I and Class II | | | | x | | | | | | | | |
| 32 | 2006988 | HLA-C Genotype | | | | | | | | | | x | | |
| 33 | 2008863 | Holoprosencephaly Panel, Sequencing and Deletion/Duplication, Fetal | | x | | x | | | x | x | | | | |
| 34 | 3005632 | Hereditary Breast Cancer High-Risk Panel, Sequencing and Deletion/Duplication | | | | | | | | | | | x | |
| 34 | 3004267 | *IDH1* and *IDH2* Mutation Analysis Exon 4, Formalin-Fixed, Paraffin-Embedded (FFPE) Tissue | | | | | | | | x | | | | |
| 34 | 3002134 | IDH1 R132H Point Mutation by Immunohistochemistry with Reflex to IDH1 and IDH2 Mutation Analysis, Exon 4 | | | | | | | | x | | | | |
| 35 | 3001409 | Immunobullous Disease Antibody Panel | x | x | | x | | | | | | | | |
| 35 | 3002001 | Kell K/k (KEL) Antigen Genotyping | | | | x | | x | | | | | | |
| 35 | 2007182 | Ki-67 with Interpretation by Immunohistochemistry | | | | | | | | | x | | | |
| 35 | 3004283 | KIT Mutations Melanoma | | | | | | | | x | | | | |
| 36 | 0040248 | *KRAS* Mutation Detection (Pricing Change) | | | | | | | x | x | | | | |
| 36 | 3005874 | Kratom, Umbilical Cord Tissue, Qualitative | | | | | | | | | | | x | |
| 37 | 3004102 | Marfan Syndrome (*FBN1*) Sequencing and Deletion/Duplication | | x | x | x | | | | | | | | |
| 37 | 2009310 | *MGMT* Promoter Methylation Detection (Pricing Change) | | | | | | | x | x | | | | |

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| 37 | 3004277 | Microsatellite Instability (MSI) HNPCC/Lynch Syndrome by PCR (Temporary Referral as of 11/22/21) | | | | | | | | x | | | | |
| 37 | 2002327 | Mismatch Repair by Immunohistochemistry with Reflex to *BRAF* Codon 600 Mutation and *MLH1* Promoter Methylation | | | | | | | x | x | | | | |
| 37 | 2005270 | Mismatch Repair by Immunohistochemistry with Reflex to *MLH1* Promoter Methylation | | | | | | | | x | | | | |
| 37 | 3004308 | MLH1 Promoter Methylation | | | | | | | | x | | | | |
| 38 | 2009318 | *MYD88* L265P Mutation Detection by PCR, Quantitative | | | | x | | | | | | | | |
| 38 | 3003927 | Neurofibromatosis Type 1 and Legius Syndrome Panel, Sequencing and Deletion/Duplication | x | x | x | x | | x | x | | | | | |
| 52 | 2004052 | Neuron Specific Enolase, Polyclonal (NSE P) by Immunohistochemistry | | | | | | | | | | | | x |
| 38 | 2010769 | Noonan Spectrum Disorders Panel, Sequencing, Fetal | | | | x | | | | x | | | | |
| 39 | 3000066 | *NPM1* Mutation Detection by RT-PCR, Quantitative | | x | | x | | | | | | | | |
| 39 | 2003123 | *NRAS* Mutation Detection by Pyrosequencing (Pricing Change) | | | | | | | x | x | | | | |
| 39 | 3002135 | 1p19q Deletion by FISH and IDH1 R132H Point Mutation by Immunohistochemistry with Reflex to IDH1 and IDH2 Mutation Analysis, Exon 4 | | | | | | | | x | | | | |
| 39 | 0049250 | p53 with Interpretation by Immunohistochemistry | | | | | | | | | x | | | |
| 40 | 0092107 | Paraneoplastic Pemphigus (Paraneoplastic Autoimmune Multiorgan Syndrome) Antibody Screening Panel | x | x | | x | | x | x | | | | | |
| 52 | 2011158 | PD-L1 by Immunohistochemistry | | | | | | | | | | | | x |
| 40 | 0092001 | Pemphigoid Antibody Panel | x | x | | x | | x | | | | | | |
| 41 | 0092283 | Pemphigoid Gestationis, Complement-Fixing Basement Membrane Antibodies (Herpes Gestationis Factor) | x | x | | x | | x | x | | | | | |
| 41 | 0092106 | Pemphigus Antibodies, IgA by IIF | x | x | | x | | x | x | | | | | |
| 41 | 0090650 | Pemphigus Antibody Panel, IgG | x | x | x | x | | x | | | | | | |
| 42 | 3000193 | Platelet Antigen Genotyping Panel | | | | x | | x | | | | | | |
| 42 | 2002871 | *PML-RARA* Detection by RT-PCR, Quantitative | | | | x | | | | | | | | |
| 43 | 3005840 | Quantitative Detection of BCR-ABL1, Major Form (p210) | | | | | | | | | | | x | |
| 44 | 2003118 | Quetiapine, Serum or Plasma | | x | | x | x | x | | | | | | |
| 44 | 3001053 | Red Blood Cell Antigen Genotyping | | | x | x | | x | | | | | | |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 45 | 3002002 | RhC/c (RHCE) Antigen Genotyping | | | | x | | x | | | | | | |
| 45 | 0051368 | RhD Gene (*RHD*) Copy Number | | | | x | | x | | | | | | |
| 46 | 3002003 | RhE/e (RHCE) Antigen Genotyping | | | | x | | x | | | | | | |
| 46 | 2003347 | Rheumatoid Factor, Body Fluid | | | | x | | | | | | | | |
| 46 | 2010138 | *RUNX1-RUNX1T1* (*AML1-ETO*) t(8;21) Detection, Quantitative | | x | | x | | | | | | | | |
| 52 | 0098745 | Sertraline | | | | | | | | | | | | x |
| 47 | 3005859 | Sertraline, Serum or Plasma | | | | | | | | | | | x | |
| 47 | 2012010 | Skeletal Dysplasia Panel, Sequencing and Deletion/Duplication, Fetal | | | | x | | | x | x | | | | |
| 48 | 3004294 | Solid Tumor Mutation Panel, Sequencing | | | | | | | | x | | | | |
| 48 | 0055567 | T-Cell Clonality Screening by PCR | | | x | x | | | | | | | | |
| 52 | 0051690 | Transforming Growth Factor beta, Plasma | | | | | | | | | | | | x |
| 52 | 0051694 | Transforming Growth Factor beta, Serum | | | | | | | | | | | | x |
| 49 | 3005863 | Transforming Growth Factor beta1, Plasma | | | | | | | | | | | x | |
| 49 | 3005865 | Transforming Growth Factor beta1, Serum | | | | | | | | | | | x | |
| 52 | 0090316 | Trazodone | | | | | | | | | | | | x |
| 50 | 3005860 | Trazodone, Serum or Plasma | | | | | | | | | | | x | |
| 50 | 3002096 | Tuberous Sclerosis Complex Panel, Sequencing and Deletion/Duplication, Fetal | | x | x | x | | | x | x | | | | |
| 51 | 3004471 | Pharmacogenetics Panel: Psychotropics | | | x | | | | | | | | | |

## 0051265 Achondroplasia (*FGFR3*) 2 Mutations, Fetal — AD PCR FE

**Performed:** Varies
**Reported:** 2-7 days

**Specimen Required:** Collect: **Fetal specimen**: Amniotic fluid.
**OR Cultured amniocytes**: Two T-25 flasks at 80 percent confluency.
**OR cultured CVS:** Two T-25 flasks at 80 percent confluency.
**If the client is unable to culture, order test Cytogenetics Grow and Send (ARUP test code 0040182) in addition to this test and ARUP will culture upon receipt (culturing fees will apply). If you have any questions, contact ARUP's Genetics Processing at 800-522-2787 ext. 3301.**
**AND maternal whole blood specimen:** Lavender (EDTA), pink ($K_2$EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: **Amniotic fluid:** Transport 10 mL amniotic fluid in a sterile container. (Min: 5 mL).
**Cultured amniocytes AND cultured CVS:** Transport two T-25 flasks at 80 percent confluency filled with culture media. Backup cultures must be retained at the client's institution until testing is complete.
**Maternal Whole Blood Specimen:** Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: **Amniotic fluid, cultured amniocytes and cultured CVS: CRITICAL ROOM TEMPERATURE.** Must be received within 48 hours of shipment due to lability of cells.
**Maternal Whole Blood Specimen:** Refrigerated.
Remarks: **Please contact an ARUP genetic counselor at 800-242-2787 x2141 prior to sample submission.** Patient History Form is available on the ARUP Web site or by contacting ARUP Client Services.
Unacceptable Conditions: Frozen specimens in glass collection tubes.
Stability (collection to initiation of testing): **Amniotic fluid, cultured amniocytes and cultured CVS:** Room Temperature: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
**Maternal Whole Blood Specimen**: Room Temperature: 72 hours; Refrigerated: 1 week; Frozen: 1 month

**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.

## 2011708 Alpha Globin (*HBA1* and *HBA2*) Sequencing and Deletion/Duplication HBA FGA

**Interpretive Data:**
**Background Information for Alpha Globin (*HBA1* and *HBA2*) Sequencing and Deletion/Duplication**
**Characteristics:**
Alpha thalassemia is caused by decreased or absent synthesis of the hemoglobin alpha chain resulting in variable clinical presentations. Alpha (+) thalassemia results from variants of a single *HBA2* globin gene (-a/aa) and is clinically asymptomatic (silent carrier). Alpha (0) thalassemia (trait) is caused by variants of both *HBA2* globin
genes (-a/-a) or variants in the *HBA1* and *HBA2* globin genes on the same chromosome (--/aa) and results in mild microcytic anemia. Hemoglobin H disease occurs due to variants of three alpha globin genes (--/-a) and results in hemolysis with Heinz bodies, moderate anemia, and splenomegaly. Hb Bart Hydrops Fetalis Syndrome results when variants occur in all four alpha globin genes (--/--) and is lethal in the fetal or early neonatal period. Alpha globin gene triplications result in three active alpha globin genes on a single chromosome. Nondeletional alpha globin variants may be pathogenic or benign; both may result in an abnormal protein detectable by hemoglobin evaluation. Pathogenic nondeletional variants often have a more severe effect than single gene deletions.
**Incidence:** Carrier frequency in Mediterranean (1:30-50), Middle Eastern, Southeast Asian (1:20), African, African American (1:3).
**Inheritance:** Autosomal recessive.
**Cause:** Pathogenic variants in the alpha globin gene cluster.
**Clinical Sensitivity:** 99 percent.
**Methodology:** Bidirectional sequencing of the *HBA1* and *HBA2* coding regions, intron-exon boundaries and 3' polyadenylation signal. Multiplex ligation-dependent probe amplification (MLPA) of the alpha globin gene cluster (*HBZ, HBM, HBA1, HBA2, HBQ1*) and its HS-40 regulatory region.
**Analytical Sensitivity and Specificity:** 99 percent.
**Limitations:** Diagnostic errors can occur due to rare sequence variations. Sequence analysis will not detect all regulatory region variants or variants in alpha globin cluster genes other than *HBA1* and *HBA2*. Sequencing of both *HBA1* and *HBA2* may not be possible in individuals harboring large alpha globin deletions on both alleles. This assay is unable to sequence *HBA2-HBA1* fusion genes; thus, *HBA1* or *HBA2* sequence variants occurring in cis with a 3.7 kb deletion or other *HBA2-HBA1* hybrid gene will not be detected (e.g., HbG Philadelphia will not be detected when in cis with the 3.7 kb deletion). It may not be possible to determine phase of identified sequence variants. Specific breakpoints of large deletions/duplications will not be determined; therefore, it may not be possible to distinguish variants of similar size. Individuals carrying both a deletion and duplication within the alpha globin gene cluster may appear to have a normal number of alpha globin gene copies. Rare syndromic or acquired forms of alpha thalassemia associated with *ATRX* variants will not be detected.

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## 0050005 Alpha-2-Macroglobulin A2M

**Performed:** Sun-Sat
**Reported:** 1-5 days

**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: 0.4 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: CSF. Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 7 days; Frozen: 3 months (if frozen within 24 hours; avoid repeated freeze/thaw cycles)

## 3002685 Alport Syndrome Panel, Sequencing and Deletion/Duplication ALPORT NGS

**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.
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

**Note:** Genes tested: *COL4A3; COL4A4; COL4A5; MYH9*

## 2012232 Angelman Syndrome and Prader-Willi Syndrome by Methylation-Sensitive PCR, Fetal — AS PWS FE

**Performed:** Varies
**Reported:** 2-7 days

**Specimen Required:** Collect: **Fetal specimen**: Amniotic fluid**.**
**OR Cultured amniocytes**: Two T-25 flasks at 80 percent confluency.
**If the client is unable to culture, order test Cytogenetics Grow and Send (ARUP test code 0040182) in addition to this test and ARUP will culture upon receipt (culturing fees will apply). If you have any questions, contact ARUP's Genetics Processing at 800-522-2787 ext. 3301.**
**Amniotic fluid:** Transport 10 mL amniotic fluid in a sterile container. (Min: 10 mL).
**Cultured amniocytes:** 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: **Amniotic fluid, cultured amniocytes: CRITICAL ROOM TEMPERATURE.** Must be received within 48 hours of shipment due to lability of cells.
**Maternal Whole Blood Specimen:** Refrigerated.
Remarks: **Please contact an ARUP genetic counselor at 800-242-2787 x2141 prior to sample submission.** Patient History Form is available on the ARUP Web site or by contacting ARUP Client Services.
Unacceptable Conditions: Frozen specimens in glass collection tubes.
Stability (collection to initiation of testing): **Amniotic fluid, cultured amniocytes:** Room Temperature: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
**Maternal Whole Blood Specimen**: Room Temperature: 72 hours; Refrigerated: 1 week; Frozen: 1 month

**Interpretive Data:**
Refer to report

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

## 0051415 Ashkenazi Jewish Diseases, 16 Genes AJP

**Performed:** Varies
**Reported:** 5-10 days

**Specimen Required:** Collect: **Whole blood:** Lavender (EDTA), pink (K2EDTA), or yellow (ACD solution A or B).
**Fetal specimens: Cultured amniocytes**: Two T-25 flasks at 80 percent confluency.
OR **cultured CVS:** Two T-25 flasks at 80 percent confluency.
**If the client is unable to culture, order ARUP test Cytogenetics Grow and Send (test code 0040182) in addition to this test and ARUP will culture upon receipt (culturing fees will apply). If you have any questions, contact ARUP's Genetics Processing at 800-522-2787 ext. 3301.**
**WITH maternal cell contamination specimen:** Whole blood: Lavender (EDTA), pink (K2EDTA), or yellow (ACD solution A or B).
Specimen Preparation: **Whole blood:** Transport 3 mL whole blood. (Min: 1 mL)
**Cultured amniocytes OR 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 cell contamination specimen:** Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: **Whole blood or maternal cell contamination specimen**: Refrigerated.
**Cultured amniocytes OR cultured CVS:** CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of shipment due to lability of cells
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin tubes. Frozen specimens in glass collection tubes.
Stability (collection to initiation of testing): **Whole blood or maternal cell contamination specimen:** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
**Fetal specimens**: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

**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:** Cystic fibrosis (CF) carrier testing is NOT included as part of this panel. Please order Cystic Fibrosis (CFTR) Expanded Variant Panel (ARUP test code 2013661) to assess CF carrier status.

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

## 0092057 Basement Membrane Zone (Epithelial) Antibodies, IgA by IIF EBMZ IGA

Immunodermatology Required Clinical Information Form (Serum)

**Methodology:** Semi-Quantitative Indirect Immunofluorescence (IIF)

**Specimen Required:** Collect: Plain red or serum separator tube (SST).
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed or lipemic specimens. Plasma.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: Indefinitely

**Interpretive Data:** Refer to report

**0092056** **Basement Membrane Zone (Epithelial) Antibodies, IgG by IIF** **EBMZ IGG**

Immunodermatology Required Clinical Information Form (Serum)

**Methodology:** Semi-Quantitative Indirect Immunofluorescence (IIF)

**Specimen Required:** Collect: Plain red or serum separator tube (SST).
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed or lipemic specimens. Plasma.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: Indefinitely

**Interpretive Data:** Refer to report

**0090299** **Basement Membrane Zone and Cell Surface (Epithelial) Antibodies, IgG and IgA by IIF** **EPITHELIAL**

Immunodermatology Required Clinical Information Form (Serum)

**Methodology:** Semi-Quantitative Indirect Immunofluorescence (IIF)

**Specimen Required:** Collect: Plain red or serum separator tube (SST).
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed or lipemic specimens. Plasma.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: Indefinitely

**Interpretive Data:** Refer to report

**3001410** **Basement Membrane Zone Antibody Panel** **BMZ AB PAN**

Immunodermatology Required Clinical Information Form (Serum)

**Methodology:** Semi-Quantitative Indirect Immunofluorescence (IIF)/Semi-Quantitative Enzyme-Linked Immunosorbent Assay (ELISA)

**Specimen Required:** Collect: Plain Red or Serum Separator Tube (SST).
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed or lipemic specimens. Plasma
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: Indefinitely

**3004550** **Beta Globin (*HBB*) Sequencing, Fetal** **BG NGS FE**

**Specimen Required:** Collect: **Fetal specimen**: Two (2) 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 two (2) 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

**New Test** **3005703** **Birt-Hogg-Dubé Syndrome (*FLCN*) Sequencing and Deletion/Duplication** **FLCN NGS**

Click for Pricing

Birt-Hogg-Dubé Syndrome Testing Patient History Form

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: 3 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: *FLCN* (NM_144997)

**CPT Code(s):** 81479

New York DOH approval pending. Call for status update.

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

**2002498** ***BRAF* Codon 600 Mutation Detection by Pyrosequencing** **BRAF PCR**

**CPT Code(s):** 81210

**HOTLINE NOTE:** Remove information found in the Note field.
**HOTLINE NOTE:** There is a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.

**0051750** ***BRAF* Codon 600 Mutation Detection with Reflex to *MLH1* Promoter Methylation** **BRAF RFLX**

**Note:** If *BRAF* codon 600 Mutation Detection is negative, then *MLH1* Promoter Methylation will be added. Additional charges apply.

**CPT Code(s):** 81210; If reflexed, add 81288

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

**0092566** **Bullous Pemphigoid (BP180 and BP230) Antibodies, IgG by ELISA** **BP180 230G**

Immunodermatology Required Clinical Information Form (Serum)

**Specimen Required:** Collect: Plain red or serum separator tube (SST).
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed or lipemic specimens. Plasma.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: Indefinitely

**Interpretive Data:** Refer to report

**3003634** **Capillary Malformation-Arteriovenous Malformation (CM-AVM) Panel, Sequencing and Deletion/Duplication** **CMAVM NGS**

**Methodology:** Massively Parallel Sequencing
**Performed:** Varies
**Reported:** 3 weeks

**Specimen Required:** Collect: Lavender (EDTA) or yellow (ACD solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 3 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

**Interpretive Data:**
Refer to report

**Note:** *EPHB4* (NM_004444); *RASA1* (NM_002890)

**2011114** ***CBFB-MYH11* inv(16) Detection, Quantitative** **INV 16 QNT**

**Methodology:** Reverse Transcription Polymerase Chain Reaction

**Specimen Required:** Collect: Lavender (EDTA) or bone marrow (EDTA).
Specimen Preparation: **Whole Blood:** Transport 5 mL whole blood. (Min: 3 mL)
**Bone Marrow:** Transport 3 mL bone marrow. (Min: 1 mL)
**Refrigerate immediately. Specimens must be received within 48 hours of collection due to lability of RNA.**
Storage/Transport Temperature: **Whole Blood or Bone Marrow**: CRITICAL REFRIGERATED. Separate specimens must be submitted when multiple tests are ordered.
Unacceptable Conditions: Serum, plasma, ambient or frozen bone marrow or whole blood, CSF, or FFPE tissue. Specimens collected in anticoagulants other than EDTA. Severely hemolyzed or clotted specimens.
Ambient whole blood and ambient bone marrow specimens past 7 days will be cancelled. Refrigerated whole blood or bone marrow past 7 days will be canceled.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 48 hours; Frozen: Unacceptable

**0090266** **Cell Surface (Epithelial) Antibodies, IgG by IIF** **IGG EPI AB**

Immunodermatology Required Clinical Information Form (Serum)

**Methodology:** Semi-Quantitative Indirect Immunofluorescence (IIF)

**Specimen Required:** Collect: Plain red or serum separator tube (SST).
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed or lipemic specimens. Plasma.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: Indefinitely

**Interpretive Data:** Refer to report

**New Test** **3005593** **Claudin-4 by Immunohistochemistry** **CLAUD4 IHC**
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**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 highly recommended) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 2 slides). If sending precut slides, do not oven bake.
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:** This test is performed as a stain and return (technical) service only.

**CPT Code(s):** 88342

New York DOH Approved.

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

## 2010905 Collagen Type VII Antibody, IgG by ELISA — COLLAG 7

Immunodermatology Required Clinical Information Form (Serum)

**Methodology:** Semi-Quantitative Enzyme-Linked Immunosorbent Assay
**Performed:** Varies
**Reported:** 7-14 days

**Specimen Required:** Collect: Plain red or serum separator tube (SST).
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed or lipemic specimens. Plasma.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: Indefinitely

**Interpretive Data:** Refer to report

## 3001513 *CYP2D6* — 2D6GENO

**Performed:** Varies
**Reported:** 5-10 days
If reflexed: 5-7 additional days are required for LR-PCR and sequencing.

**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.

## 3001524 Cytochrome P450 Genotyping Panel — CYP PANEL

**Performed:** Varies
**Reported:** 5-10 days
If reflexed: 5-7 additional days are required for LR-PCR and sequencing.

**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.

## 3004255 Cytochrome P450 Genotyping Panel, with GeneDose Access — CYP GD

**Performed:** Varies
**Reported:** 5-10 days
If reflexed: 5-7 additional days are required for LR-PCR and sequencing.

**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.

| | | |
|---|---|---|
| 3004275 | **Cytogenomic Molecular Inversion Probe Array FFPE Tissue - Oncology** | **FFPEARRAY** |

**CPT Code(s):** 81277

| | | |
|---|---|---|
| 3004273 | **Cytogenomic Molecular Inversion Probe Array FFPE Tissue - Products of Conception** | **CMAPFFPE** |

**CPT Code(s):** 81229

**New Test** 3005895 **Cytomegalovirus by Quantitative NAAT, Plasma** **CMVQ**

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

**Specimen Required:** Collect: Lavender (EDTA), pink (K2EDTA), or plasma preparation tube (PPT).
Specimen Preparation: Separate from cells within 24 hours of collection. Transfer 2 mL plasma to an ARUP Standard Transport Tube (ARUP supply #15824). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at 800-522-2787. (Minimum volume, 1mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Heparinized specimens, whole blood, serum, respiratory specimens, CSF.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 6 days; Frozen: 12 weeks

**Reference Interval:** Not detected

**Interpretive Data:**
The quantitative range of this test is 1.54–7.00 log IU/mL (34.5–10,000,000 IU/mL).

An interpretation of "Not Detected" does not rule out the presence of inhibitors or CMV DNA concentration below the level of detection of the assay. Care should be taken in the interpretation of any single viral load determination.

International standardization has improved comparability of assay results across laboratories, but discrepancies still exist due to commutability issues with the standard.

**Note:** The limit of quantification for this assay is 1.54 log IU/mL (34.5 IU/mL). If the assay DETECTED the presence of the virus but was not able to accurately quantify the viral load, the test result will be reported as "Not Quantified, Detected."

**CPT Code(s):** 87497

New York DOH Approved.

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

**0090649** **Desmoglein 1 and Desmoglein 3 (Pemphigus) Antibodies, IgG by ELISA** **IGG DESMOG**

Immunodermatology Required Clinical Information Form (Serum)

**Performed:** Varies
**Reported:** 3-9 days

**Specimen Required:** Collect: Plain red or serum separator tube (SST).
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed or lipemic specimens. Plasma.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: Indefinitely

**Interpretive Data:** Refer to report

**New Test** **3005839** **Diagnostic Qualitative BCR-ABL1 Assay with Reflex to p190 or p210 Quantitative Assays** **DX BCR RFX**

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Time Sensitive

Additional Technical Information

**Methodology:** Reverse Transcription Polymerase Chain Reaction
**Performed:** **RNA isolation:** Sun-Sat
**Assay:** Varies
**Reported:** 4-10 days
**If reflexed:** TAT may be extended by 3-7 days

**Specimen Required:** Collect: Whole blood or bone marrow in lavender (EDTA).
Specimen Preparation: **Whole blood:** Transport 5 mL whole blood. (Min: 3 mL)
**Bone marrow:** Transport 3 mL bone marrow. (Min: 1 mL)
**Refrigerate immediately. Specimens must be received within 48 hours of collection due to lability of RNA.**
Storage/Transport Temperature: **Whole blood and bone marrow**: CRITICAL REFRIGERATED. Separate specimens must be submitted when multiple tests are ordered.
Remarks: **This qualitative test is intended as a screening test only for initial diagnosis**. For those patients with an established diagnosis, please order **3005840 Quantitative Detection of *BCR-ABL1*, Major Form (p210) or (ARUP Test code 2005016) *BCR-ABL1*, Minor (p190), Quantitative.**
Unacceptable Conditions: Serum, plasma, ambient or frozen bone marrow or whole blood, CSF, or FFPE tissue. Specimens collected in anticoagulants other than EDTA. Severely hemolyzed or clotted specimens.
Ambient whole blood and ambient bone marrow specimens past 7 days will be canceled. Refrigerated whole blood or bone marrow past 7 days will be canceled.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 48 hours; Frozen: Unacceptable

**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.

**Note:** This reflex assay is recommended when the BCR-ABL1 fusion form is not known or unclear. This reflex assay detects the presence of either the p210 (major breakpoint), p190 (minor breakpoint), or p230 (micro breakpoint). If the presence of either the common p210 or p190 BCR-ABL1 fusion is detected, then the appropriate quantitative test will be performed. Additional charges apply.

If the fusion form is known, refer to Quantitative Detection of BCR-ABL1, Major Form (p210) (ARUP test code 3005840) or BCR-ABL1, Minor (p190), Quantitative (ARUP test code 2005016).

**CPT Code(s):** 81206; 81207; 81208; If reflexed, add 81206 or 81207

New York DOH approval pending. Call for status update.

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

**0092572** **Direct Immunofluorescence, Tissue Biopsy (Cutaneous, Mucosal, Epithelial)** **CUTDIF**

Clinical Information for
Immunodermatology (Tissue Testing)

**Specimen Required:** Collect: Tissue: skin, mucosa (oral, conjunctival, genital, esophageal), other epithelium (gastrointestinal, respiratory, urinary).
Specimen Preparation: Transport tissue (optimal 4-6 mm) in Michel medium (ARUP supply #45462) available online through eSupply using ARUP Connector call ARUP Client Services at (800) 522-2787. Also acceptable: Zeus tissue fixative. Label container with transport medium type, if not an ARUP-supplied vial.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated.
Unacceptable Conditions: Formalin-fixed tissue. Frozen in Michel's medium. Solid organs or solid organ tissue. Tissue in container of unknown or unacceptable transport medium. Tissue sections on slides, prestained or unstained.
Stability (collection to initiation of testing): Ambient: 10 days; Refrigerated: 10 days; Frozen: Unacceptable

**Interpretive Data:** Refer to report

**New Test** **3005714** **DNA Extract and Hold** **GENOME EXT**
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**Methodology:** Extraction
**Reported:** 7-14 days

**Specimen Required:** Collect: Whole blood or bone marrow in yellow (ACD solution A or B) or lavender or pink (EDTA)
Specimen Preparation: Transport 2 mL whole blood (Min 1 mL)
Storage/Transport Temperature: Refrigerated
Unacceptable Conditions: Serum or plasma; grossly hemolyzed or frozen specimens; saliva, buccal brush, or swab; FFPE tissue, Heparinized specimens
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

**Reference Interval: N/A**

**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:** DNA will be held for 12 months for possible add-on testing. Extracted DNA is used exclusively for ARUP testing involving germline massively parallel sequencing, or somatic massively parallel sequencing or single-gene assays detecting somatic hotspot mutations. Extracted samples will not be sent back to clients or forwarded to vendor laboratories.

**CPT Code(s):** N/A

New York DOH approval pending. Call for status update.

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

**New Test** **3005882** **Dysautonomia, Familial (ELP1), 2 Variants** **ELP1**

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Additional Technical Information

**Methodology:** Polymerase Chain Reaction/Fluorescence Monitoring
**Performed:** Varies
**Reported:** 5-10 days

**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.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin 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

**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.

**CPT Code(s):** 81260

New York DOH Approved.

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

**2002440** ***EGFR* Mutation Detection by Pyrosequencing** **EGFR PCR**

**Note:** This test detects mutations in *EGFR* exons 18, 19, 20 and 21 (codons 719, 745-753, 768, 790, 858, and 861).

**CPT Code(s):** 81235

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

**3003830** **Electron Microscopy Technical Only Request** **EMTO REQ**

**Specimen Required:** Patient Prep: None
Collect: Contact ARUP's Electron Microscopy Laboratory at electronmicroscopy343@aruplab.com prior to specimen collection for preauthorization.

**Note:** This test is performed as a technical service only. No interpretation is available.

**HOTLINE NOTE:** Remove information found in the Specimen Preparation, Storage/Transport Temperature, Remarks, Unacceptable Conditions, Stability field.

## 2010921 Eosinophil Granule Major Basic Protein, Tissue Biopsy — EGMBP TIS

Clinical Information for
Immunodermatology (Tissue Testing)

**Methodology:** Indirect Immunofluorescence (IIF)
**Performed:** Varies
**Reported:** 1-3 weeks

**Specimen Required:** Collect: Tissue.
Specimen Preparation: Transport tissue (optimal 3-8 mm) in Michel medium (ARUP supply #45462) available online through eSupply using ARUP Connect or call ARUP Client Services at (800) 522-2787. (Min: 1 mm).
Also acceptable: Zeus tissue fixative, flash frozen fresh tissue, formalin fixed tissue, or formalin fixed and paraffin embedded tissue. Transport in formalin, tissue block, or slides with two 4-5-micron sections per slide in serial order and numbered. (Min: 8 slides).
Storage/Transport Temperature: Room temperature.
Flash Frozen Fresh Tissue: Frozen
Stability (collection to initiation of testing): Michel Medium or Zeus Tissue Fixative: Ambient: 10 days; Refrigerated: 10 days; Frozen: Unacceptable
Formalin Fixed Tissue: Ambient: 3 weeks; Refrigerated: 3 weeks; Frozen: Unacceptable
Flash Frozen Fresh Tissue: Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: Indefinitely
Paraffin Embedded Tissue: Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Indefinitely

**Interpretive Data:** Refer to report

**Note:** Turnaround time may be prolonged on specimens submitted as formalin-fixed, paraffin-embedded (FFPE) tissue; clients should consider contacting the Immunodermatology Laboratory when submitting FFPE tissue for Eosinophil Granule Major Basic Protein, Tissue to discuss specific clinical information that may indicate expedited testing and resulting. Contact ARUP Client Services at 1-800-242-2787, option 2, and ask to speak with the Immunodermatology Laboratory at the University of Utah regarding patient results and/or testing information.

## 2010902 Epidermal Transglutaminase (eTG/TG3) Antibody, IgA by ELISA — EPI TRANS

Immunodermatology Required Clinical
Information Form (Serum)

**Performed:** Varies
**Reported:** 14-28 days

**Specimen Required:** Collect: Plain red or serum separator tube (SST).
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed or lipemic specimens. Plasma.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: Indefinitely

**Interpretive Data:** Refer to report

## 0049178 *ERBB2* (*HER2/neu*) (HercepTest) by Immunohistochemistry, Tissue with Reflex to FISH if 2+ — HERCEP2IP

**HOTLINE NOTE:** There is a component change associated with this test.
Add component 3005643, Sample Adequacy
Add component 0049244, Fixative Used
Add component 0049246, Time from Bx to Fixative
Add component 0049247, Duration of Fixation
Add component 3005644, HER2 Reference Number
Add component 3005645, HER2 Tissue Source

| | | |
|---|---|---|
| 0049174 | ***ERBB2* (*HER2/neu*) (HercepTest) with Interpretation by Immunohistochemistry, Tissue** | **HERCEPIP** |

**HOTLINE NOTE:** There is a component change associated with this test.
Add component 3005643, Sample Adequacy
Add component 0049244, Fixative Used
Add component 0049246, Time from Bx to Fixative
Add component 0049247, Duration of Fixation
Add component 3005644, HER2 Reference Number
Add component 3005645, HER2 Tissue Source

| | | |
|---|---|---|
| 2008603 | **ERBB2 (HER2/neu) Gene Amplification by FISH with Reflex, Tissue** | **ERBB2 FISH** |

**HOTLINE NOTE:** There is a component change associated with this test.
Add component 3005658, Sample Adequacy
Add component 3005659, Fixative Used
Add component 3005660, Time from Bx to Fixative
Add component 3005661, Duration of Fixation
Add component 3005662, ERBB2 Reference Number
Add component 3005663, ERBB2 Tissue Source

| | | |
|---|---|---|
| 0049210 | **Estrogen/Progesterone Receptor with Interpretation by Immunohistochemistry** | **ERPR IP** |

**HOTLINE NOTE:** There is a component change associated with this test.
Add component 3005643, Sample Adequacy
Add component 0049244, Fixative Used
Add component 0049246, Time from Bx to Fixative
Add component 0049247, Duration of Fixation
Add component 3005650, ERPR Reference Number
Add component 3005651, ERPR Tissue Source

**New Test** **3005867** **Familial Targeted Sequencing** **FAM NGS**

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Patient History for Familial Targeted Sequencing Testing

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).
**New York State Clients**: ARUP cannot facilitate testing for New York patients. Please work directly with a New York-approved laboratory.
Specimen Preparation: Transport 2 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated
Remarks: Documentation of the familial gene variant from a relative's laboratory test report is required to perform testing. Testing will begin upon receipt of all necessary components, including an original laboratory report detailing the familial variant(s) to be tested.
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 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:** Documentation of the familial gene variant from a relative's laboratory test report is required to perform testing. Testing will begin upon receipt of all necessary components, including an original laboratory report detailing the familial variant(s) to be tested.

**CPT Code(s):** 81403

New York DOH approval pending. Call for status update.

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

**New Test** **3005869** **Familial Targeted Sequencing, Fetal** **FAM NGS FE**

Click for Pricing

Additional Technical Information

Patient History for Familial Targeted Sequencing Testing

**Methodology:** Massively Parallel Sequencing
**Performed:** Varies
**Reported:** 10-14 days; if culture is required, an additional 2 weeks is required for processing time

**Specimen Required:** Collect: **Submit fetal specimen and maternal whole blood specimen. To avoid delays due to inappropriate sample submission, contact ARUP's genetic counselors at 800-242-2787 ext. 2141 for specimen requirements prior to sending samples .**
**New York State Clients**: ARUP cannot facilitate testing for New York patients. Please work directly with a New York approved laboratory.
Remarks: Documentation of the familial gene variants from a relative's laboratory test report is required to perform testing. Testing will begin upon receipt of all necessary components, including an original laboratory report detailing the familial variant to be tested. A maternal specimen is recommended for proper fetal test interpretation. Order Maternal Cell Contamination on the maternal specimen. (ARUP test code 0050608).

**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:** Reported times are based on receiving the cultured fetal sample (at 80 percent confluency) and required documentation. Backup cultures must be retained at the client's institution until testing is complete. If the client is unable to culture the fetal sample, this can be arranged by contacting ARUP Client Services at 800-522-2787 prior to test submission. Cell culture time is independent of testing turnaround time. Maternal specimen is recommended for proper test interpretation. Order Maternal Cell Contamination, Maternal Specimen on the maternal specimen.

**CPT Code(s):** 81403; 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.

**3001161** ***FLT3* ITD and TKD Mutation Detection** **FLT3-PCR**

**Specimen Required:** Collect: Lavender (EDTA) or green (sodium heparin) whole blood or bone marrow.
Specimen Preparation: **Whole Blood:** Do not freeze. Transport 5 mL whole blood. (Min: 1 mL)
**Bone Marrow:** Do not freeze. Transport 3 mL bone marrow. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, serum, FFPE tissue blocks/slides, or frozen tissue. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable

**3004279** **Gastrointestinal Stromal Tumor Mutations** **GISTMUT**

**CPT Code(s):** 81272; 81314

## 2001510 Glutarylcarnitine Quantitative, Urine — C5DC URINE

**Performed:** Friday
**Reported:** 4-11 days

**Specimen Required:** Collect: Random urine. Avoid dilute urine when possible.
Specimen Preparation: Transfer 2.5 mL urine to an ARUP Standard Transport Tube and freeze immediately. (Min: 1.0 mL)
Storage/Transport Temperature: **Frozen. Separate specimens must be submitted when multiple tests are ordered**.
Remarks: **Clinical information is needed for appropriate interpretation.** Additional required information includes age, gender, diet (e.g., TPN therapy), drug therapy, and family history. **Biochemical Genetics Patient History Form is available on the ARUP Web site at http://www.aruplab.com/patienthistory or by contacting ARUP Client Services.**
Unacceptable Conditions: Specimens that have exposed to more than three freeze/thaw cycles.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 1 month

**Reference Interval:**
Reports include age appropriate reference interval.
Effective November 14, 2022

| Available Separately | Components | Reference Interval |
|---|---|---|
| No | Glutarylcarnitine, Urine | Less than or equal to 2.0 mmol/mol creatinine |

**Interpretive Data:**
Methodology: Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)

If patient is receiving carnitine supplements, results may not be informative. Clinical correlation is recommended for interpretation of the result.
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.

## 2006686 *Helicobacter pylori* Culture — MC HPYL

**Specimen Required:** Collect: Duodenal or gastric biopsy.
Specimen Preparation: Preserve in Brucella broth with 20% glycerol immediately (ARUP supply #57678) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. Also acceptable: Brucella broth, BHI, or equivalent with or without 10-20 percent glycerol.
Storage/Transport Temperature: Refrigerated.
Remarks: Specimen source required.
Unacceptable Conditions: Fecal specimens or swabs.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 48 hours; Frozen: Unacceptable

**New Test** **3001615** **Hereditary Bone Marrow Failure Panel, Sequencing and Deletion/Duplication** **BMF NGS**

Click for Pricing

Additional Technical Information

Patient History for Bone Marrow Failure Testing

**Methodology:** Massively Parallel Sequencing
**Performed:** Varies
**Reported:** 3 weeks. If specimen is a skin punch biopsy, add 2 weeks for culturing.

**Specimen Required:** Collect: Cultured skin fibroblasts (preferred) or
Whole blood: Lavender (EDTA) or yellow (ACD solution A or B). Or
Skin punch biopsy**:** Thaw media prior to tissue inoculation. Place skin punch biopsy in a sterile, screw-top container filled with tissue culture transport medium (ARUP Supply #32788). Available online through eSupply using ARUP Connect. If cytogenetics tissue media is not available, collect in plain RPMI, Hanks' solution, sterile saline, or Ringer's solution.
**New York State Clients: Collect Monday-Thursday only.**
Specimen Preparation: Cultured skin fibroblasts: 2 T-25 flasks at 80 percent confluency, Fill flasks with culture media. Backup cultures must be maintained at the client's institution until testing is complete.
Skin punch biopsy DO NOT FREEZE. Do not place in formalin. Transport a 4 mm skin biopsy in a sterile, screw-top container filled with tissue transport medium.
Whole blood: Transport 3 mL whole blood. (Min: 2 mL)
**New York State Clients:** Only whole blood: Transport 5 mL whole blood (min. 3 mL). **Do not send cultured fibroblasts to ARUP Laboratories**. Specimens must be received at performing laboratory within 48 hours of collection. For specimen requirements and direct submission instructions, please contact ARUP Referral Testing at (800) 242-2787, ext. 5145.
Storage/Transport Temperature: Cultured skin fibroblasts: Critical room temperature. Must be received within 48 hours of shipment due to lability of cells.
Skin punch biopsy: Room temperature
Whole Blood: Refrigerated
Remarks: Cultured skin fibroblast backup cultures must be retained at the client's institution until testing is complete. Skin punch biopsies can be cultured at ARUP at an additional charge.
Unacceptable Conditions: Grossly hemolyzed or frozen specimens; formalin fixed tissue, FFPE
Stability (collection to initiation of testing): Cultured skin fibroblasts: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable,
Skin punch biopsy: Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Unacceptable
Whole blood: Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable
**New York State Clients:** Only whole blood: Ambient: 48 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: *ACD; ALAS2; ANKRD26; ATM; BLM; BRCA1** (NM_007294)*; BRCA2* (NM_000059)*; BRIP1; CBL; CEBPA**; CSF3R; CTC1; CXCR4*; DDX41; DKC1; DNAJC21*; ELANE; ERCC4; ERCC6L2*; ETV6; FANCA*; FANCB; FANCC; FANCD2*; FANCE; FANCF; FANCG; FANCI; FANCL*; G6PC3; GATA1; GATA2; GFI1; HAX1; HOXA11; IKZF1; KRAS; MBD4; MPL; MYH9; NBN; NHP2; NOP10**; NRAS; PALB2; PARN; PTPN11; RAD51C; RMRP**; RPL11; RPL15**; RPL26; RPL35A; RPL5; RPS10; RPS19; RPS24; RPS26; RPS7; RTEL1; RUNX1; SAMD9; SAMD9L; SLX4; SRP72; TERC***; TERT; TET2; TINF2; TP53; UBE2T; USB1; VPS45; WAS; WRAP53*

*One or more exons are not covered by sequencing for the indicated gene; see Additional Technical Information.
**Deletion/duplication detection is not available for this gene.
***Duplication detection is not available for this gene.

If a skin punch biopsy is submitted, specimen will be reflexed for culturing. Additional charges apply.

**CPT Code(s):** 81443; for skin punch biopsy, add 88233.

New York DOH approval pending. Call for status update.

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

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**New Test** **3005654** **Hereditary Breast Cancer Guidelines-Based Panel, Sequencing and Deletion/Duplication** **BCGUIDENGS**

Click for Pricing

Patient History for Hereditary Breast Cancer Testing

Additional Technical Information

**Methodology:** Massively Parallel Sequencing/Sequencing
**Performed:** Varies
**Reported:** 3 weeks

**Specimen Required:** Collect: Lavender or pink (EDTA) or yellow (ACD solution A or B).
**New York State Clients:** Lavender (EDTA)
Specimen Preparation: Transport 3 mL whole blood. (Min: 3 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 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: *ATM*; *BARD1*; *BRCA1**; *BRCA2*; *CDH1**; *CHEK2**; *NF1*; *PALB2*; *PTEN**; *STK11*; *TP53*
*One or more exons are not covered by sequencing and/or deletion/duplication analysis for the indicated gene; see Additional Technical Information.

**CPT Code(s):** 81408; 81479; 81162; 81406; 81307; 81321; 81323; 81404; 81405; 81351

New York DOH approval pending. Call for status update.

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

**New Test** **3005721** **Hereditary Erythrocytosis Panel, Sequencing** **ECYT NGS**

Click for Pricing

Additional Technical Information

Patient History for Hereditary Erythrocytosis Testing

**Methodology:** Massively Parallel Sequencing
**Performed:** Varies
**Reported:** 3 weeks. If specimen is a skin punch biopsy, add 2 weeks for culturing.

**Specimen Required:** Patient Prep:
Collect: Cultured skin fibroblasts (preferred) or
Whole blood: Lavender (EDTA) or yellow (ACD solution A or B). or
Skin punch biopsy**:** Thaw media prior to tissue inoculation. Place skin punch biopsy in a sterile, screw-top container filled with tissue culture transport medium (ARUP Supply #32788). Available online through eSupply using ARUP Connect. If cytogenetics tissue media is not available, collect in plain RPMI, Hanks solution, sterile saline, or Ringers.
**New York State Clients:** Only whole blood, lavender (EDTA) tube, refrigerated
Specimen Preparation: Cultured skin fibroblasts: 2 T-25 flasks at 80 percent confluency, Fill flasks with culture media. Backup cultures must be maintained at the client's institution until testing is complete.
Skin punch biopsy DO NOT FREEZE. Do not place in formalin. Transport a 4 mm skin biopsy in a sterile, screw-top container filled with tissue transport medium.
Whole blood: Transport 3 mL (Min: 2 mL)
**New York State Clients:** Specimens must be received at performing laboratory within 48 hours of collection. For specimen requirements and direct submission instructions please contact ARUP Referral Testing at (800) 242-2787, ext. 5145.
Storage/Transport Temperature: Cultured skin fibroblasts: Critical room temperature. Must be received within 48 hours of shipment due to lability of cells
Skin punch biopsy: Room temperature
Whole Blood: Refrigerated.
Remarks: Cultured skin fibroblast backup cultures must be retained at the client's institution until testing is complete. Skin punch biopsies can be cultured at ARUP at an additional charge.
Unacceptable Conditions: Grossly hemolyzed or frozen specimens; formalin fixed tissue, FFPE
Stability (collection to initiation of testing): Cultured skin fibroblasts: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable,
Skin punch biopsy: Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Unacceptable
Whole blood: Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable
**New York State Clients:** Only whole blood: Ambient: 48 hours; Refrigerated: 2 weeks; 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: *BPGM*, *EGLN1* (*PHD2*), *EPAS1* (*HIF2A*), *EPOR*, *HBB*, *HIF1A*, *JAK2*, *SH2B3*, *VHL**

*One or more exons are not covered by sequencing for the indicated gene; see Additional Technical Information.

If a skin punch biopsy is submitted, specimen will be reflexed for culturing. Additional charges apply.

**CPT Code(s):** 81364, 81404; 81479; for skin punch biopsy, add 88233

New York DOH approval pending. Call for status update.

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

**New Test** **3005697** **Hereditary Gastrointestinal Cancer High-Risk Panel, Sequencing and Deletion/Duplication** **GIHR NGS**

Click for Pricing

Patient History for Hereditary Gastrointestinal Cancer Testing

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.
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:** Genes Tested: *APC**; *EPCAM***; *MLH1*; *MSH2*; *MSH6*; *MUTYH*; *PMS2*

*One or more exons are not covered by sequencing and/or deletion/duplication analysis for the indicated gene; see Additional Technical Information.
**Deletion/duplication analysis of *EPCAM* (NM_002354) exon 9 only, sequencing is not available for this gene.

**CPT Code(s):** 81201; 81203; 81292; 81294; 81295; 81297; 81298; 81300; 81406; 81317; 81319; 81479

New York DOH approval pending. Call for status update.

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

**3000894** **Hereditary Hemolytic Anemia Cascade** **HHACASCADE**

**CPT Code(s):** 84220; 88184; 82955; 83021. Reflex components billed separately. Additional CPT codes may apply, 85555; 85060; 85007; 83068; 81269; 81259; 81363; 81364; 81249; 81443; 85660; 83020; 81479.

**HOTLINE NOTE:** There is a reflexive pattern change associated with this test.
Add reflex to 3003509, Gamma Globin (HBG1 and HBG2) Seq Bill

**New Test** **3005708** **Hereditary Pancreatic Cancer Panel, Sequencing and Deletion/Duplication** **PANCAN NGS**

Click for Pricing

Patient History for Hereditary Pancreatic Cancer Testing

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)
**New York State Clients**: Transport 10 mL whole blood (Min: 7 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 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: *APC*; ATM; BRCA1*; BRCA2; CDK4; CDKN2A*; EPCAM**; MEN1*; MLH1; MSH2; MSH6; PALB2; PMS2; STK11; TP53; VHL**

*One or more exons are not covered by sequencing and/or deletion/duplication analysis for the indicated gene; see Additional Technical Information.
**Deletion/duplication analysis of EPCAM (NM_002354) exon 9 only, sequencing is not available for this gene.

**CPT Code(s):** 81201; 81203; 81408; 81162; 81292; 81294; 81295; 81297; 81298; 81300; 81307; 81317; 81319; 81404; 81405; 81351; 81403; 81479

New York DOH approval pending. Call for status update.

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

**New Test** **3005686** **Hereditary Prostate Cancer Panel, Sequencing and Deletion/Duplication** **PROCAN NGS**

Click for Pricing

Patient History for Hereditary Prostate Cancer Testing

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.
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.

**Note:** Genes Tested: *ATM; BRCA1*; BRCA2; CHEK2*; EPCAM**; HOXB13; MLH1; MSH2; MSH6; NBN; PALB2; PMS2; RAD51D; TP53*

*One or more exons are not covered by sequencing and/or deletion/duplication analysis for the indicated gene; see Additional Technical Information.
**Deletion/duplication analysis of EPCAM (NM_002354) exon 9 only, sequencing is not available for this gene.

**CPT Code(s):** 81408; 81162; 81403; 81292; 81294; 81295; 81297; 81298; 81300; 81307; 81317; 81319; 81351; 81479

New York DOH approval pending. Call for status update.

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

**New Test** **3005696** **Hereditary Retinoblastoma (*RB1*) Sequencing and Deletion/Duplication** **RB1 NGS**

Click for Pricing

Patient History for Hereditary Retinoblastoma Testing

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: 3 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 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: *RB1** (NM_000321)
*One or more exons are not covered by sequencing and/or deletion/duplication analysis; see Additional Technical Information.

**CPT Code(s):** 81479

New York DOH approval pending. Call for status update.

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

**3002850** **HLA Antibody Screen, Class I and Class II** **HLAABSCN**

**Specimen Required:** Collect: Plain red.
Specimen Preparation: Transfer 5 mL serum to ARUP Standard Transport Tubes. (Min. 2 mL)
**New York State Clients:** Transfer 7 mL serum to ARUP Standard Transport Tubes. (Min. 3 mL)
Storage/Transport Temperature: Refrigerated
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 month; Frozen: 2 years

**2006988** **HLA-C Genotype** **HLA C**

**HOTLINE NOTE:** There is a clinically significant charting name change associated with this test.
Change the charting name for component 2002808, HLA Class I, Locus Cw*, Allele 1 from HLA Class I, Locus Cw*, Allele 1 to HLA Class I, Locus C, Allele 1.
Change the charting name for component 2002809, HLA Class I, Locus Cw*, Allele 2 from HLA Class I, Locus Cw*, Allele 2 to HLA Class I, Locus C, Allele 2.

## 2008863 Holoprosencephaly Panel, Sequencing and Deletion/Duplication, Fetal — HPE PAN FE

**Methodology:** Massively Parallel Sequencing

**Specimen Required:** Collect: **Fetal specimen**: Two (2) 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 two (2) T-25 flasks at 80% 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: 3 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

**Note:** Determine the etiology of holoprosencephaly in an affected pregnancy or determine if parents of an affected pregnancy are carriers. Chromosome analysis should be performed in an affected pregnancy before ordering this test.

Genes tested: *CDON*; *FGFR1**; *GLI2*; *PTCH1*; *SHH*; *SIX3*; *TGIF1*; *ZIC2**

*One or more exons are not covered by sequencing and/or deletion/duplication analysis for the indicated gene; see Additional Technical Information.

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

**CPT Code(s):** 81479; 81265

**HOTLINE NOTE:** Remove information found in the Remarks field.

**New Test** **3005632** **Hereditary Breast Cancer High-Risk Panel, Sequencing and Deletion/Duplication** **BCHR NGS**

Click for Pricing

Patient History for Hereditary Breast Cancer Testing

Additional Technical Information

**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: 3 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 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: *BRCA1**; *BRCA2*; *CDH1**; *PALB2*; *PTEN**; *TP53*
*One or more exons are not covered by sequencing and/or deletion/duplication analysis for the indicated gene; see Additional Technical Information.

**CPT Code(s):** 81162; 81406; 81307; 81321; 81323; 81351; 81479

New York DOH approval pending. Call for status update.

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

**3004267** ***IDH1* and *IDH2* Mutation Analysis Exon 4, Formalin-Fixed, Paraffin-Embedded (FFPE) Tissue** **IDH12FFPE**

**CPT Code(s):** 81120; 81121

**3002134** **IDH1 R132H Point Mutation by Immunohistochemistry with Reflex to IDH1 and IDH2 Mutation Analysis, Exon 4** **IDH1 RFLX**

**CPT Code(s):** 88342; if reflexed, add 81120; 81121

## 3001409 Immunobullous Disease Antibody Panel — IMBULDZPAN

Immunodermatology Required Clinical Information Form (Serum)

**Methodology:** Semi-Quantitative Indirect Immunofluorescence (IIF)/Semi-Quantitative Enzyme-Linked Immunosorbent Assay (ELISA)

**Specimen Required:** Collect: Plain Red or Serum Separator Tube (SST).
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed or lipemic specimens. Plasma
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: Indefinitely

## 3002001 Kell K/k (KEL) Antigen Genotyping — KEL GENO

**Specimen Required:** Collect: **Fetal genotyping:** Amniotic fluid
**OR Cultured amniocytes:** Two T-25 flasks at 80 percent confluency.
**If the client is unable to culture, order test Cytogenetics Grow and Send (ARUP test code 0040182) in addition to this test and ARUP will culture upon receipt (culturing fees will apply). If you have any questions, contact ARUP's Genetics Processing at 800-522-2787 ext. 3301.**
**WITH maternal cell contamination specimen (see Note):** Lavender ($K_2$EDTA), Pink ($K_2$EDTA), or Yellow (ACD Solution A or B).
**Parental genotyping:** Lavender ($K_2$EDTA), Pink ($K_2$EDTA).
Specimen Preparation: Amniotic fluid: Transport 10 mL amniotic fluid in a sterile container. (Min: 5 mL).
**Cultured amniocytes:** 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 cell contamination specimen:** Transport 3 mL whole blood (Min: 1 mL)
**Whole blood (parental genotyping):** Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: **Amniotic fluid, cultured amniocytes: CRITICAL ROOM TEMPERATURE.** Must be received within 48 hours of shipment due to lability of cells.
**Whole blood or maternal cell contamination specimen:** Refrigerated.
Remarks: Patient History Form is available on the ARUP website or by contacting ARUP Client Services.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin tubes.
Stability (collection to initiation of testing): **Fetal specimens:** Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
**Whole blood or maternal cell contamination specimen:** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

**Interpretive Data:**
Refer to report

## 2007182 Ki-67 with Interpretation by Immunohistochemistry — KI-67 IP

**HOTLINE NOTE:** There is a component change associated with this test.
Add component 3005643, Sample Adequacy
Add component 0049244, Fixative Used
Add component 0049246, Time from Bx to Fixative
Add component 0049247, Duration of Fixation
Add component 3005653, Ki-67 Tissue Source

## 3004283 KIT Mutations Melanoma — KITMELAN

**CPT Code(s):** 81272; 81314

**0040248** ***KRAS* Mutation Detection** **KRAS**

**Note:** This assay detects mutations in codons 12, 13, and 61.

**CPT Code(s):** 81275; 81276

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

**New Test** **3005874** **Kratom, Umbilical Cord Tissue, Qualitative** **KRA QQQ CD**
Click for Pricing

Time Sensitive

Additional Technical Information

**Methodology:** Qualitative Liquid Chromatography-Tandem Mass Spectrometry
**Performed:** Wednesday
**Reported:** 8-9 days

**Specimen Required:** Collect: Umbilical cord (at least 8 inches, approximately the width of a sheet of paper)
Specimen Preparation: Drain and discard any blood. Rinse the exterior of the cord segment with normal saline or water. Pat the cord dry and transport at least 8 inches of umbilical cord in a 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. (Min: 6 inches)
Storage/Transport Temperature: Refrigerated
Unacceptable Conditions: Cords soaking in blood or other fluid. Formalin fixed. Tissue that is obviously decomposed.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 3 weeks; Frozen: 1 year

**Reference Interval:**

| Drugs/Drug Classes | Cutoff Concentrations (ng/g) |
|---|---|
| Mitragynine | 0.08 |
| Speciociliatine | 0.08 |

**Interpretive Data:**
Methodology: Qualitative Liquid Chromatography-Tandem Mass Spectrometry

This test is designed to detect and document exposure to alkaloids found in kratom, an herbal product derived from the Mitragyna speciosa tree or related plants, that occurred during approximately the last trimester of a full-term pregnancy. While mitragynine is considered the primary pharmacologically active alkaloid, speciociliatine is also widely detected in umbilical cord tissue. Regular use of or exposure to kratom can lead to dependency, and abstinence may contribute to signs and symptoms of drug withdrawal. Alternative testing is available to detect other drug exposures. The pattern and frequency of kratom used by the mother cannot be determined by this test. A negative result does not exclude the possibility that a mother used kratom during pregnancy. Detection of kratom alkaloids in umbilical cord tissue depends on extent of maternal use, as well as stability, unique characteristics of alkaloid deposition in umbilical cord tissue, and the performance of the analytical method. Detection of kratom alkaloids in umbilical cord tissue does not insinuate impairment and may not affect outcomes for the infant. Interpretive questions should be directed to the laboratory.

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

**Note:** Absolute minimum: 6 inches.

**CPT Code(s):** 80323 (Alt code: G0480)

New York DOH approval pending. Call for status update.

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

**3004102** **Marfan Syndrome (*FBN1*) Sequencing and Deletion/Duplication** **FBN1 NGS**

**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
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

**2009310** ***MGMT* Promoter Methylation Detection** **MGMT**

**CPT Code(s):** 81287

**HOTLINE NOTE:** Remove information found in the Note field.
**HOTLINE NOTE:** There is a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.

**3004277** **Microsatellite Instability (MSI) HNPCC/Lynch Syndrome by PCR (Temporary Referral as of 11/22/21)** **MSIPCR**

**CPT Code(s):** 81301

**2002327** **Mismatch Repair by Immunohistochemistry with Reflex to *BRAF* Codon 600 Mutation and *MLH1* Promoter Methylation** **MSI REFLEX**

**Note:** If MLH1 is abnormal for Mismatch Repair by IHC, then *BRAF* codon 600 will be added. If *BRAF* codon 600 is negative, *MLH1* Promoter Methylation will be added. Additional charges apply.

**CPT Code(s):** 88342; 88341 x3; if reflexed, add 81210; if further reflexed, add 81288

**2005270** **Mismatch Repair by Immunohistochemistry with Reflex to *MLH1* Promoter Methylation** **MSI MLH1**

**CPT Code(s):** 88342; 88341 x3; if reflexed, add 81288

**3004308** **MLH1 Promoter Methylation** **MLH1 PCR**

**CPT Code(s):** 81288

## 2009318 *MYD88* L265P Mutation Detection by PCR, Quantitative — MYD88

**Specimen Required:** Collect: Lavender (EDTA), bone marrow (EDTA), or FFPE tumor tissue.
Specimen Preparation: **Whole Blood**: Do not freeze. Transport 5 mL whole blood. (Min: 1 mL)
**Bone Marrow**: Do not freeze. Transport 3 mL bone marrow. (Min: 1 mL)
**FFPE Tumor Tissue**: Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Transport tissue in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: **Whole Blood, Bone Marrow**: Refrigerated.
**FFPE Tumor Tissue**: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks: If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.
Unacceptable Conditions: **Whole Blood, Bone Marrow**: Plasma, serum. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
**FFPE Tumor Tissue**: Specimens fixed/processed in alternative fixatives, heavy metal fixatives (B-4 or B-5), or tissue sections on slides. Decalcified specimens.
Stability (collection to initiation of testing): **Whole Blood or Bone Marrow:** Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable
**FFPE Tumor Tissue:** Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

## 3003927 Neurofibromatosis Type 1 and Legius Syndrome Panel, Sequencing and Deletion/Duplication — NF1 NGS

**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
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

**Interpretive Data:**
Refer to report

**Note:** Genes tested: *NF1* (NM_001042492); *SPRED1* (NM_152594)

## 2010769 Noonan Spectrum Disorders Panel, Sequencing, Fetal — NOONAN FE

**Specimen Required:** Collect: **Fetal specimen:** Two (2) T-25 flasks at 80% confluent of cultured amniocytes or cultured CVS. **If the client is unable to culture, this can be arranged by contacting ARUP Client Services at (800) 522-2787.**
AND **Maternal cell contamination 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 two (2) T-25 flasks at 80 percent confluent of cultured cells filled with culture media. Backup cultures must be retained at the client's institution until testing is complete.
AND **Maternal Cell Contamination Specimen:** Transport 3 mL whole blood (Min: 1 mL)
Storage/Transport Temperature: **Culture Amniocytes or Cultured CVS:** CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of shipment due to lability of cells.
**Maternal Cell Contamination Specimen:** Ambient.
Stability (collection to initiation of testing): **Fetal Specimen:** Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
**Maternal:** Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

**CPT Code(s):** 81442; 81265

**3000066** ***NPM1* Mutation Detection by RT-PCR, Quantitative** **NPM1 QNT**

**Methodology:** Reverse Transcription Polymerase Chain Reaction

**Specimen Required:** Collect: Whole blood or bone marrow in lavender (EDTA).
Specimen Preparation: **Whole Blood:** Transport 5 mL whole blood. (Min: 3 mL)
**Bone Marrow:** Transport 3 mL bone marrow. (Min: 1 mL)
**Refrigerate immediately. Specimens must be received within 48 hours of collection due to lability of RNA.**
Storage/Transport Temperature: **Whole Blood or Bone Marrow**: CRITICAL REFRIGERATED. Separate specimens must be submitted when multiple tests are ordered.
Unacceptable Conditions: Serum, plasma, ambient or frozen bone marrow or whole blood, CSF, or FFPE tissue. Specimens collected in anticoagulants other than EDTA. Severely hemolyzed or clotted specimens.
Ambient whole blood and ambient bone marrow specimens past 7 days will be canceled. Refrigerated whole blood or bone marrow past 7 days will be canceled.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 48 hours; Frozen: Unacceptable

**2003123** ***NRAS* Mutation Detection by Pyrosequencing** **NRAS**

**Note:** This assay detects mutations in codons 12, 13, and 61.

**CPT Code(s):** 81311

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

**3002135** **1p19q Deletion by FISH and IDH1 R132H Point Mutation by Immunohistochemistry with Reflex to IDH1 and IDH2 Mutation Analysis, Exon 4** **OLIGO PAN**

**CPT Code(s):** 88342; 88377 x2; if reflexed, add 81120; 81121

**0049250** **p53 with Interpretation by Immunohistochemistry** **P53 IP**

**HOTLINE NOTE:** There is a component change associated with this test.
Add component 3005643, Sample Adequacy
Add component 0049244, Fixative Used
Add component 0049246, Time from Bx to Fixative
Add component 0049247, Duration of Fixation
Add component 3005652, P53 Tissue Source

**0092107** **Paraneoplastic Pemphigus (Paraneoplastic Autoimmune Multiorgan Syndrome) Antibody Screening Panel** **PARA PEMPH**

Immunodermatology Required Clinical Information Form (Serum)

**Methodology:** Semi-Quantitative Indirect Immunofluorescence (IIF)

**Specimen Required:** Collect: Plain red or serum separator tube (SST).
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed or lipemic specimens. Plasma.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: Indefinitely

**Interpretive Data:** Refer to report

**Note:** The methodology is indirect immunofluorescence (IIF) of patient serum on substrates from rodents including rat bladder, mouse bladder, mouse heart, and mouse liver to detect characteristic antibody reactivity: simple columnar epithelial cell surface and basement membrane zone in bladders, intercalated discs in heart, and portal tracts in liver. Monkey esophagus substrate is included if other concurrent IIF testing does not. For specimens less than 0.5 mL, call the Immunodermatology Laboratory at (866) 266-5699.

This test should be distinguished from antibody testing of cerebral spinal fluid (CSF) for paraneoplastic neurologic syndromes; 3004510, 3004512, 3004517 are different tests.

**0092001** **Pemphigoid Antibody Panel** **PGOID PAN**

Immunodermatology Required Clinical Information Form (Serum)

**Methodology:** Semi-Quantitative Indirect Immunofluorescence (IIF)/Semi-Quantitative Enzyme-Linked Immunosorbent Assay (ELISA)

**Specimen Required:** Collect: Plain red or serum separator tube.
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed or lipemic specimens. Plasma.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: Indefinitely

**Interpretive Data:** Refer to report

**0092283** **Pemphigoid Gestationis, Complement-Fixing Basement Membrane Antibodies (Herpes Gestationis Factor)** **HG FACTOR**

Immunodermatology Required Clinical Information Form (Serum)

**Methodology:** Semi-Quantitative Complement Fixation/Indirect Immunofluorescence (IIF)/Semi-Quantitative Enzyme-Linked Immunosorbent Assay (ELISA)

**Specimen Required:** Collect: Plain red or serum separator tube (SST).
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed or lipemic specimens. Plasma.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: Indefinitely

**Interpretive Data:** Refer to report

**Note:** The methodology is indirect immunofluorescence (IIF) with added fresh human complement on human split skin substrate for detection of complement-fixing (herpes gestationis factor) and noncomplement-fixing IgG basement membrane zone antibodies together with IgG BP180 antibody level determination by ELISA in serum. For specimens less than 0.5 mL, call the Immunodermatology Laboratory at (866) 266-5699.

**0092106** **Pemphigus Antibodies, IgA by IIF** **IGA PEMPHI**

Immunodermatology Required Clinical Information Form (Serum)

**Methodology:** Semi-Quantitative Indirect Immunofluorescence (IIF)

**Specimen Required:** Collect: Plain red or serum separator tube (SST).
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed or lipemic specimens. Plasma.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: Indefinitely

**Interpretive Data:** Refer to report

**Note:** The methodology is indirect immunofluorescence (IIF) of serum on substrates with known epidermal (epithelial) cell surface desmosomal antigens (both intact human skin and monkey esophagus substrate). For specimens less than 0.5 mL, call the Immunodermatology Laboratory at (866) 266-5699.

**0090650** **Pemphigus Antibody Panel, IgG** **PEMPHI PAN**

Immunodermatology Required Clinical Information Form (Serum)

**Methodology:** Semi-Quantitative Indirect Immunofluorescence (IIF)/Semi-Quantitative Enzyme-Linked Immunosorbent Assay (ELISA)
**Performed:** Varies
**Reported:** 3-9 days

**Specimen Required:** Collect: Plain Red or Serum Separator Tube (SST).
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed or lipemic specimens. Plasma.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: Indefinitely

**Interpretive Data:** Refer to report

## 3000193 Platelet Antigen Genotyping Panel HPA GENO

**Specimen Required:** Collect: **Fetal genotyping:** Amniotic fluid
**Cultured amniocytes**: Two T-25 flasks at 80 percent confluency.
**If the client is unable to culture, order test Cytogenetics Grow and Send (ARUP test code 0040182) in addition to this test and ARUP will culture upon receipt (culturing fees will apply). If you have any questions, contact ARUP's Genetics Processing at 800-522-2787 ext. 3301.**
**WITH maternal cell contamination specimen:** Lavender (EDTA), Pink ($K_2$EDTA), or Yellow (ACD Solution A or B).
**Parental genotyping:** Lavender (EDTA).
Specimen Preparation: Amniotic fluid: Transport 10 mL amniotic fluid in a sterile container. (Min: 5 mL)
**OR Cultured amniocytes:** 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 cell contamination specimen:** Transport 3 mL whole blood. (Min: 1 mL)
**Whole blood (parental genotyping):** Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: **Amniotic fluid, cultured amniocytes: CRITICAL ROOM TEMPERATURE.** Must be received within 48 hours of shipment due to lability of cells.
**Whole blood or maternal cell contamination specimen:** Refrigerated.
Unacceptable Conditions: Frozen specimens in glass collection tubes.
Stability (collection to initiation of testing): **Fetal specimens Amniotic fluid or cultured amniocytes:** Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
**Whole blood or maternal cell contamination specimen:** 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 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.

**PA 1-6, 15 Polymorphism**

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

## 2002871 *PML-RARA* Detection by RT-PCR, Quantitative PML QNT

**Specimen Required:** Collect: Whole blood or bone marrow in lavender (EDTA).
Specimen Preparation: **Whole Blood:** Transport 5 mL whole blood. (Min: 3 mL)
**Bone Marrow:** Transport 3 mL bone marrow. (Min: 1 mL)
**Refrigerate immediately. Specimens must be received within 48 hours of collection due to lability of RNA.**
Storage/Transport Temperature: **Whole Blood and Bone Marrow**: CRITICAL REFRIGERATED. Separate specimens must be submitted when multiple tests are ordered.
Unacceptable Conditions: Serum, plasma, ambient or frozen bone marrow or whole blood, CSF, or FFPE tissue. Specimens collected in anticoagulants other than EDTA. Severely hemolyzed or clotted specimens.
Ambient whole blood and ambient bone marrow specimens past 7 days will be cancelled. Refrigerated whole blood or bone marrow past 7 days will be canceled.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 48 hours; Frozen: Unacceptable

**New Test** **3005840** **Quantitative Detection of BCR-ABL1, Major Form (p210)** **QNT BCR MAJ**

Click for Pricing

Time Sensitive

Additional Technical Information

**Methodology:** Reverse Transcription Polymerase Chain Reaction
**Performed:** **RNA isolation:** Sun-Sat
**Assay:** Varies
**Reported:** 5-9 days

**Specimen Required:** Collect: Whole blood or bone marrow in lavender (EDTA).
Specimen Preparation: **Whole blood:** Transport 5 mL whole blood. (Min: 3 mL)
**Bone marrow:** Transport 3 mL bone marrow. (Min: 1 mL)
**Refrigerate immediately. Specimens must be received within 48 hours of collection due to lability of RNA.**
Storage/Transport Temperature: **Whole blood and bone marrow**: CRITICAL REFRIGERATED. Separate specimens must be submitted when multiple tests are ordered.
Remarks: **This quantitative test is recommended for therapeutic monitoring and detection of minimal residual disease for patients with an established diagnosis**. For patients with uncertain diagnoses or unknown forms of *BCR-ABL1* fusion transcripts, please order 3005839 Diagnostic Qualitative *BCR-ABL1* Assay with Reflex to p190 or p210 Quantitative Assays.
Unacceptable Conditions: Serum, plasma, ambient or frozen bone marrow or whole blood, CSF, or FFPE tissue. Specimens collected in anticoagulants other than EDTA. Severely hemolyzed or clotted specimens.
Ambient whole blood and ambient bone marrow specimens past 7 days will be canceled. Refrigerated whole blood or bone marrow past 7 days will be canceled.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 48 hours; Frozen: Unacceptable

**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.

**Note:** This test does not detect the *BCR-ABL1* micro (p230) or minor (p190) fusion transcripts. This test does not detect rare *BCR-ABL1* major (p210) forms involving beyond *ABL1* exon 2.

For the p190 fusion form (minor breakpoint), order *BCR-ABL1*, Minor (p190), Quantitative (ARUP test code 2005016).

**CPT Code(s):** 81206

New York DOH approval pending. Call for status update.

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

## 2003118 Quetiapine, Serum or Plasma QUETIAP

**Methodology:** Liquid Chromatography-Tandem Mass Spectrometry

**Specimen Required:** Collect: Plain red. Also acceptable: Lavender ($K_2$ or $K_3$EDTA) or pink ($K_2$ EDTA).
Specimen Preparation: Separate serum or plasma from cells within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Whole blood. Gel separator tubes, light blue (citrate), or yellow (SPS or ACD solution).
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 2 weeks; Frozen: 4 months

**Reference Interval:**
Effective November 14, 2022

| | |
|---|---|
| Therapeutic Range: | 100-1000 ng/mL |
| Toxic: | Greater than 1000 ng/mL |

**Interpretive Data:**
Quetiapine is an antipsychotic drug indicated for the treatment of schizophrenia and bipolar disorder. The pharmacokinetics of quetiapine are influenced by drug-drug interactions that may inhibit or induce CYP3A4 metabolism. Adverse effects may include somnolence, hypotension, dizziness, fatigue, constipation, weight gain.

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.

## 3001053 Red Blood Cell Antigen Genotyping RBC GENO

**Performed:** Varies
**Reported:** 3-10 days

**Specimen Required:** Collect: **Fetal genotyping:** Amniotic fluid
**OR Cultured amniocytes:** Two T-25 flasks at 80 percent confluency.
**If the client is unable to culture, order test Cytogenetics Grow and Send (ARUP test code 0040182) in addition to this test and ARUP will culture upon receipt (culturing fees will apply). If you have any questions, contact ARUP's Genetics Processing at 800-522-2787 ext. 3301.**
**WITH maternal cell contamination specimen**: Lavender ($K_2$EDTA), Pink ($K_2$EDTA), or Yellow (ACD Solution A or B).
**OR Genotyping:** Lavender ($K_2$EDTA), Pink ($K_2$EDTA)
Specimen Preparation: **Genotyping:** Transport 3 mL whole blood. (Min: 1 mL)
**Amniotic fluid:** Transport 10 mL amniotic fluid in a sterile container. (Min: 5 mL)
**Cultured amniocytes:** 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 cell contamination 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.
**Whole blood or maternal cell contamination specimen:** Refrigerated.
Remarks: **Maternal specimen is recommended for proper test interpretation if contamination of the fetal specimen from the mother is suspected. Order Maternal Cell Contamination.**
Unacceptable Conditions: Plasma or serum; collection of specimens in sodium heparin tubes. Frozen specimens in glass collection tubes.
Stability (collection to initiation of testing): **Whole blood or maternal cell contamination specimen:** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month.
**Fetal specimens:** Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

**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.

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

## 3002002 RhC/c (RHCE) Antigen Genotyping RHC GENO

**Specimen Required:** Collect: **Fetal genotyping:** Amniotic fluid.
**OR Cultured amniocytes:** Two T-25 flasks at 80 percent confluency.
**If the client is unable to culture, order test Cytogenetics Grow and Send (ARUP test code 0040182) in addition to this test and ARUP will culture upon receipt (culturing fees will apply). If you have any questions, contact ARUP's Genetics Processing at 800-522-2787 ext. 3301.**
**WITH maternal cell contamination specimen** (see Note): Lavender ($K_2$EDTA), Pink ($K_2$EDTA), or Yellow (ACD Solution A or B).
**Parental genotyping:** Lavender ($K_2$EDTA), Pink ($K_2$EDTA)
Specimen Preparation: **Amniotic fluid:** Transport 10 mL amniotic fluid in a sterile container. (Min: 5 mL).
**Cultured amniocytes:** 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 cell contamination specimen:** Transport 3 mL whole blood (Min: 1 mL)
**Whole blood (parental genotyping):** 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.
**Whole blood or maternal cell contamination specimen:** Refrigerated.
Remarks: Patient History Form is available on the ARUP website or by contacting ARUP Client Services.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin tubes.
Stability (collection to initiation of testing): **Fetal specimens:** Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
**Whole blood or maternal cell contamination specimen:** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

**Interpretive Data:**
Refer to Report.

## 0051368 RhD Gene (*RHD*) Copy Number RHD

**Specimen Required:** Collect: **Fetal genotyping:** Amniotic fluid
**OR Cultured amniocytes**: Two T-25 flasks at 80 percent confluency.
**OR cultured CVS:** Two T-25 flasks at 80 percent confluency.
**If the client is unable to culture, order test Cytogenetics Grow and Send (ARUP test code 0040182) in addition to this test and ARUP will culture upon receipt (culturing fees will apply). If you have any questions, contact ARUP's Genetics Processing at 800-522-2787 ext. 3301.**
**WITH maternal cell contamination specimen** (see Remarks): Lavender (EDTA), pink ($K_2$EDTA), or yellow (ACD Solution A or B).
**Parental genotyping:** Lavender (EDTA), pink ($K_2$EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Amniotic fluid: Transport 10 mL amniotic fluid in a sterile container. (Min: 5 mL)
**Cultured amniocytes AND cultured CVS:** Transport two T-25 flasks at 80 percent confluency filled with culture media. Backup cultures must be retained at the client's institution until testing is complete.
**Maternal cell contamination specimen:** Transport 3 mL whole blood (Min: 1 mL)
**Whole blood (parental genotyping):** Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: **Amniotic fluid, cultured amniocytes and cultured CVS: CRITICAL ROOM TEMPERATURE.** Must be received within 48 hours of shipment due to lability of cells.
**Whole blood or maternal cell contamination specimen:** Refrigerated.
Remarks: Maternal specimen is recommended for proper test interpretation if contamination of the fetal specimen from the mother is suspected. Order Maternal Cell Contamination. Patient History Form is available on the ARUP website or by contacting ARUP Client Services.
Unacceptable Conditions: Frozen specimens in glass collection tubes.
Stability (collection to initiation of testing): **Amniotic fluid, cultured amniocytes and cultured CVS Fetal Specimen:** Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
**Whole blood or maternal cell contamination specimen:** 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 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.

## 3002003 RhE/e (RHCE) Antigen Genotyping — RHE GENO

**Specimen Required:** Collect: **Fetal genotyping**: Amniotic fluid.
**Cultured amniocytes**: Two T-25 flasks at 80 percent confluency.
**If the client is unable to culture, order test Cytogenetics Grow and Send (ARUP test code 0040182) in addition to this test and ARUP will culture upon receipt (culturing fees will apply). If you have any questions, contact ARUP's Genetics Processing at 800-522-2787 ext. 3301.**
**WITH maternal cell contamination specimen** (see Note): Lavender ($K_2$EDTA), Pink ($K_2$EDTA), or Yellow (ACD Solution A or B).
**Parental genotyping:** Lavender ($K_2$EDTA), Pink ($K_2$EDTA).
Specimen Preparation: **Amniotic fluid:** Transport 10 mL amniotic fluid in a sterile container. (Min: 5 mL).
**Cultured amniocytes:** 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 cell contamination specimen:** Transport 3 mL whole blood (Min: 1 mL)
**Whole blood (parental genotyping):** Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: **Amniotic fluid, cultured amniocytes: CRITICAL ROOM TEMPERATURE.** Must be received within 48 hours of shipment due to lability of cells.
**Whole blood or maternal cell contamination specimen:** Refrigerated.
Remarks: Patient History Form is available on the ARUP Web site or by contacting ARUP Client Services.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin tubes.
Stability (collection to initiation of testing): **Fetal specimens:** Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
**Whole blood or maternal cell contamination specimen:** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

**Interpretive Data:**
Refer to report

## 2003347 Rheumatoid Factor, Body Fluid — RA-FL

**Specimen Required:** Collect: CSF, Pericardial, Pleural, or Synovial fluid.
**New York State Clients:** Pericardial fluid requires NY clients to submit a Non-Permitted Laboratory Request (NPL) form to NYSDOH.
Specimen Preparation: Centrifuge to remove cellular material. Transfer 1 mL body fluid to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Remarks: **Specimen source must be provided.**
Unacceptable Conditions: Specimen types other than those listed. Specimens too viscous to be aspirated by instrument.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 1 week; Frozen: 1 month (should not be thawed more than once)

## 2010138 *RUNX1-RUNX1T1* (*AML1-ETO*) t(8;21) Detection, Quantitative — AML1-ETO Q

**Methodology:** Reverse Transcription Polymerase Chain Reaction

**Specimen Required:** Collect: Whole blood or bone marrow in lavender (EDTA).
Specimen Preparation: **Whole Blood:** Transport 5 mL whole blood. (Min: 3 mL)
**Bone Marrow:** Transport 3 mL bone marrow. (Min: 1 mL)
**Refrigerate immediately. Specimens must be received within 48 hours of collection due to lability of RNA.**
Storage/Transport Temperature: **Whole Blood or Bone Marrow**: CRITICAL REFRIGERATED. Separate specimens must be submitted when multiple tests are ordered.
Unacceptable Conditions: Serum, plasma, ambient or frozen bone marrow or whole blood, CSF, or FFPE tissue. Specimens collected in anticoagulants other than EDTA. Severely hemolyzed or clotted specimens.
Ambient whole blood and ambient bone marrow specimens past 7 days will be canceled. Refrigerated whole blood or bone marrow past 7 days will be canceled.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 48 hours; Frozen: Unacceptable

**New Test** **3005859** **Sertraline, Serum or Plasma** **SERTRAL SP**

Click for Pricing

**Methodology:** Liquid Chromatography-Tandem Mass Spectrometry
**Performed:** Wed
**Reported:** 1-8 days

**Specimen Required:** Patient Prep: Timing of specimen collection: Pre-dose (trough) draw - At steady state concentration.
Collect: Plain red. Also acceptable: Lavender ($K_2$ or $K_3$EDTA) or pink ($K_2$EDTA).
Specimen Preparation: Separate serum or plasma from cells within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Whole blood. Gel separator tubes, light blue (citrate), or yellow (SPS or ACD solution).
Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 2 weeks; Frozen: 4 months

**Reference Interval:**

| | |
|---|---|
| Therapeutic Range: | 30–200 ng/mL |
| Toxic: | Greater than 300 ng/mL |

**Interpretive Data:**
Sertraline is a selective serotonin reuptake inhibitor antidepressant drug indicated for the treatment of major depressive disorder, obsessive-compulsive disorder, posttraumatic stress disorder, social anxiety disorder, and premenstrual dysphoric disorder. Sertraline doses range from 50-200 mg/day to produce serum concentration that range from 30-200 ng/mL. Dosing above 200 mg/day may increase the risk of adverse effects. Adverse effects may include dry mouth, headache, dizziness, fatigue, somnolence, tremor, nausea, and diarrhea. The risk of serotonin syndrome is increased with concomitant use of other serotonergic drugs. Concomitant use of sertraline with anticoagulants and nonsteroidal anti-inflammatory drugs may increase the risk of bleeding.

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):** 80332 (Alt code: G0480)

New York DOH Approved.

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

**2012010** **Skeletal Dysplasia Panel, Sequencing and Deletion/Duplication, Fetal** **SKEL FE**

**Specimen Required:** Collect: **Fetal specimen:** Two (2) 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 two (2) T-25 flasks at 80% 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

**Note:** Genes Tested: *AGPS*, *ALPL*, *ARSL*, *CANT1*, *CCN6*, *CILK1*, *COL1A1*, *COL1A2**, *COL2A1*, *COL10A1*, *COL11A1*, *COL11A2*, *COMP*, *CRTAP*, *DDR2*, *DLL3*, *DYM*,* *DYNC2H1*, *EBP*, *EVC*,* *EVC2*, *FGFR1*,* *FGFR2*, *FGFR3*, *FKBP10*, *FLNA*, *FLNB*, *GDF5*, *GNPAT*, *HSPG2*, *IFT80*, *INPPL1*, *LBR*, *LIFR*, *NEK1*,* *NPR2*, *P3H1*, *PCNT*, *PEX7*, *POR*,* *PPIB*, *PTH1R*, *RUNX2*, *SERPINH1*, *SLC26A2*, *SLC35D1*, *SMARCAL1*, *SOX9*, *TRIP11*, *TRPV4*, *TTC21B*, *WDR19*, *WDR35*

*One or more exons are not covered by sequencing and/or deletion/duplication analysis for the indicated gene; see Additional Technical Information.

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

**CPT Code(s):** 81405; 81408; 81479; 81265

| | | |
|---|---|---|
| **3004294** | **Solid Tumor Mutation Panel, Sequencing** | **SOLIDNGS** |

**CPT Code(s):** 81445

| | | |
|---|---|---|
| **0055567** | **T-Cell Clonality Screening by PCR** | **T CELL-F** |

**Performed:** **DNA Isolation:** Sun-Sat
**Assay:** Varies
**Reported:** 5-9 days

**Specimen Required:** Collect: Lavender (EDTA) or green (sodium heparin) whole blood or bone marrow; tissue; formalin-fixed tissue.
Specimen Preparation: **Whole Blood**: Do not freeze. Transport 5 mL. (Min: 1 mL)
**Bone marrow:** Do not freeze. Transport 3 mL. (Min: 1 mL)
**Fresh Tissue:** Freeze immediately. Transport 100 mg or 0.5-2.0 cm3 tissue
**FFPE Tumor Tissue:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or four 10-micron shavings in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: **Whole Blood, Bone Marrow:** Refrigerated.
**Fresh Tissue:** Frozen on dry ice.
**FFPE Tumor Tissue:** Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks: If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.
Unacceptable Conditions: **Whole Blood, Bone Marrow**: Plasma, serum. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
**Tissue**: Specimens fixed/processed in alternative fixatives, heavy metal fixatives (B-4 or B-5), or tissue sections on slides. Decalcified specimens.
Stability (collection to initiation of testing): **Whole Blood or Bone Marrow:** Ambient: 24 hours; Refrigerated: 5 days; Frozen: Unacceptable
**Fresh Tissue:** Ambient: Unacceptable; Refrigerated: 2 hours; Frozen: 1 year
**FFPE Tumor Tissue:** Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

**New Test** **3005863** **Transforming Growth Factor beta1, Plasma** **TGFB1 PLA**
Click for Pricing

**Methodology:** Quantitative Enzyme-Linked Immunosorbent Assay
**Performed:** Mon
**Reported:** 1-8 days

**Specimen Required:** Collect: Lavender ( K2 EDTA plasma).
Specimen Preparation: Conventional specimen preparation practices frequently do not fully remove platelets from plasma and contribute to elevated TFG-b measurements. Centrifuge anticoagulated whole blood within 2 hours of collection at 1500g for 10 minutes. Collect plasma and transfer to a fresh tube. Immediately centrifuge plasma at 3000g for 10 minutes. Collect plasma from upper 2/3 of tube without disturbing lower 1/3 of tube and transfer to fresh tube for storage or transport. Separate plasma from cells ASAP or within 2 hours of collection. Transfer 1 mL plasma to an ARUP Standard Transport Tube. (Min 0.3 mL)
Storage/Transport Temperature: **CRITICAL FROZEN. Freeze <-20 C immediately**. **Separate specimens must be submitted when multiple tests are ordered.**
Unacceptable Conditions: Contaminated, severely hemolyzed, heat-inactivated or grossly lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 30 minutes; Refrigerated: Unacceptable; Frozen: 60 days

**Reference Interval:** 1654-19951 pg/mL

**Interpretive Data:**
Results are intended for research purposes or in attempts to understand the pathophysiology of unusual immune or inflammatory disorders.

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):** 83520

New York DOH approval pending. Call for status update.

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

**New Test** **3005865** **Transforming Growth Factor beta1, Serum** **TGFB1 SER**
Click for Pricing

**Methodology:** Quantitative Enzyme-Linked Immunosorbent Assay
**Performed:** Mon
**Reported:** 1-8 days

**Specimen Required:** Collect: Serum separator tube or plain red.
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min 0.3 mL)
Storage/Transport Temperature: **CRITICAL FROZEN. Freeze immediately at ≤-20 C**. **Separate specimens must be submitted when multiple tests are ordered.**
Unacceptable Conditions: Contaminated, severely hemolyzed, heat-inactivated or grossly lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 30 minutes; Refrigerated: Unacceptable; Frozen: 60 days.

**Reference Interval:** 16542-50426 pg/mL

**Interpretive Data:**
Results are intended for research purposes or in attempts to understand the pathophysiology of unusual immune or inflammatory disorders.

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):** 83520

New York DOH approval pending. Call for status update.

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

**New Test** **3005860** **Trazodone, Serum or Plasma** **TRAZO SP**
Click for Pricing

**Methodology:** Liquid Chromatography-Tandem Mass Spectrometry
**Performed:** Wed
**Reported:** 1-8 days

**Specimen Required:** Patient Prep: Timing of specimen collection: Pre-dose (trough) draw - At steady state concentration.
Collect: Plain red. Also acceptable: Lavender ($K_2$ or $K_3$EDTA) or pink ($K_2$EDTA ).
Specimen Preparation: Separate serum or plasma from cells within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Whole blood. Gel separator tubes, light blue (citrate), or yellow (SPS or ACD solution).
Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 2 weeks; Frozen: 4 months

**Reference Interval:**

| | |
|---|---|
| Therapeutic Range: | 800–1600 ng/mL |
| Toxic: | Not well established |

**Interpretive Data:**
Trazodone is a selective serotonin reuptake inhibitor antidepressant drug indicated for the treatment of major depressive disorder. The pharmacokinetics of trazodone is influenced by drug-drug interactions that induce or inhibit CYP3A4 metabolism. Adverse effects may include sedation, fatigue, headache, blurred vision, nausea, and cardiac arrhythmia. The risk of serotonin syndrome is increased with concomitant use of other serotonergic drugs. Concomitant use of trazodone with anticoagulants and nonsteroidal anti-inflammatory drugs may increase the risk of bleeding.

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):** 80338 (Alt code: G0480)

New York DOH Approved.

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

**3002096** **Tuberous Sclerosis Complex Panel, Sequencing and Deletion/Duplication, Fetal** **TSC NGS FE**

**Methodology:** Massively Parallel Sequencing
**Performed:** Varies
**Reported:** **2-3 weeks; if culture is required, an additional 1-2 weeks is required for processing time.**

**Specimen Required:** Collect: **Fetal specimen:** Two (2) 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 two (2) T-25 flasks at 80% 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. 2 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

**Note:** Genes tested: *TSC1 TSC2*

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

**CPT Code(s):** 81405; 81406; 81407; 81265

| | | |
|---|---|---|
| **3004471** | **Pharmacogenetics Panel: Psychotropics** | **PGX PSYCH** |

**Performed:** Varies
**Reported:** 5-10 days
If reflexed: 5-7 additional days are required for LR-PCR and sequencing.

HOTLINE: Effective November 14, 2022

**The following will be discontinued from ARUP's test menu on November 14, 2022.**
**Replacement test options are supplied if applicable.**

| Test Number | Test Name | Refer To Replacement |
|---|---|---|
| 2005017 | BCR-ABL1, Major (p210), Quantitative | Quantitative Detection of BCR-ABL1, Major Form (p210) (3005840) |
| 2005010 | BCR-ABL1, Qualitative with Reflex to BCR-ABL1 Quantitative | Diagnostic Qualitative BCR-ABL1 Assay with Reflex to p190 or p210 Quantitative Assays (3005839) |
| 0050216 | Borrelia burgdorferi Antibodies, Total by ELISA | Borrelia burgdorferi Antibodies, Total by ELISA with Reflex to IgG and IgM by Immunoblot (Early Disease) (0050267) |
| 2003526 | CD14 by Immunohistochemistry | |
| 2003839 | Collagen IV by Immunohistochemistry | |
| 0051813 | Cytomegalovirus by Quantitative PCR | Cytomegalovirus by Quantitative NAAT, Plasma (3005895) |
| 2006966 | Cytomegalovirus, Quantitative PCR with Reflex to Drug Resistance Testing by Sequencing | Cytomegalovirus by Quantitative NAAT, Plasma (3005895) |
| 0050757 | DNA Extraction and Storage | DNA Extract and Hold (3005714) |
| 0051463 | Dysautonomia, Familial (IKBKAP), 2 Variants | Dysautonomia, Familial (ELP1), 2 Variants (3005882) |
| 2007914 | EPOR Mutation Detection by Sequencing | Hereditary Erythrocytosis Panel, Sequencing (3005721) |
| 2001961 | Familial Mutation, Targeted Sequencing | |
| 2001980 | Familial Mutation, Targeted Sequencing, Fetal | |
| 2003860 | Hairy Cell Leukemia, DBA.44 by Immunohistochemistry | |
| 0020457 | Hepatitis Panel, Acute with Reflex to HBsAg Confirmation | Hepatitis Panel, Acute with Reflex to HBsAg Confirmation and Reflex to HCV by Quantitative NAAT (3002989) |
| 0050385 | Heterophile Antibody (Infectious Mononucleosis) by Latex Agglutination, Qualitative | |
| 2004052 | Neuron Specific Enolase, Polyclonal (NSE P) by Immunohistochemistry | |
| 2011158 | PD-L1 by Immunohistochemistry | |
| 0098745 | Sertraline | Sertraline, Serum or Plasma (3005859) |
| 0051690 | Transforming Growth Factor beta, Plasma | Transforming Growth Factor beta1, Plasma (3005863) |
| 0051694 | Transforming Growth Factor beta, Serum | Transforming Growth Factor beta1, Serum (3005865) |
| 0090316 | Trazodone | Trazodone, Serum/Plasma (3005860) |