MEDIHCARE 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.

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</table>
| **Specimen Required:** Collect: Lavender (EDTA), Pink (K<sub>2</sub>EDTA), 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 |

<table>
<thead>
<tr>
<th>0051266</th>
<th>Achondroplasia (&lt;i&gt;FGFR3&lt;/i&gt;) 2 Mutations</th>
<th>AD PCR</th>
</tr>
</thead>
</table>
| **Specimen Required:** Collect: Lavender (EDTA), Pink (K<sub>2</sub>EDTA), or yellow (ACD Solution A or B).  
Specimen Preparation: Do not freeze. Transport 3 mL whole blood. (Min: 1 mL)  
Storage/Transport Temperature: Refrigerated.  
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month |

<table>
<thead>
<tr>
<th>0051265</th>
<th>Achondroplasia (&lt;i&gt;FGFR3&lt;/i&gt;) 2 Mutations, Fetal</th>
<th>AD PCR FE</th>
</tr>
</thead>
</table>
| **Specimen Required:** Collect: Fetal Specimen: Two T-25 flasks at 80% confluency of cultured amniocytes. If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787. Or amniotic fluid.  
AND Maternal Specimen: Lavender (EDTA), pink (K<sub>2</sub>EDTA), or yellow (ACD Solution A or B).  
Specimen Preparation: Cultured Amniocytes: Fill flasks with culture media. Transport two T-25 flasks at 80% confluency of cultured amniocytes. Backup cultures must be retained at the client's institution until testing is complete.  
OR Amniotic Fluid: Transport 10 mL unspun fluid. (Min: 5 mL)  
AND Maternal 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 liability of cells.  
Amniotic Fluid: Room temperature.  
Maternal Specimen: Room temperature.  
Remarks: Maternal specimen is recommended for proper test interpretation. Order Maternal Cell Contamination, Maternal Specimen. This can be arranged by contacting ARUP genetic counselors at (800) 242-2787 ext. 2141. 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): Fetal Specimen: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable  
Maternal Specimen: Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month |
### 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 (−α/−α) and is clinically asymptomatic (silent carrier). Alpha (0) thalassemia (trait) is caused by variants of both HBA2 globin genes (−α/−α) or variants in the HBA1 and HBA2 globin genes on the same chromosome (−α/−α). Alpha (-) thalassemia results in mild microcytic anemia. Hemoglobin H disease occurs due to variants of three alpha globin genes (−α/−α) 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. 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.

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.
New Test

New Test 3003651 Alpha Thalassemia (HBA1 and HBA2) Deletion/Duplication with HBA DDCS reflex to Hb Constant Spring

Available Now
Click for Pricing

Additional Technical Information

Methodology: Multiplex Ligation-dependent Probe Amplification with Sanger sequencing confirmation of HbCS
Performed: Varies
Reported: 10-14 days; 21 days if reflexed

Specimen Required:
Collect: Lavender (EDTA), pink (K2EDTA), or Yellow (ACD Solution A or B).
Specimen Preparation: Transport 2 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): Room Temperature: 7 days; Refrigerated: 1 month

Reference Interval: By report

Interpretive Data:
Background Information: Alpha Globin (HBA1 and HBA2) Deletion/Duplication
Characteristics: Decreased or absent synthesis of the hemoglobin (Hb) alpha-chain resulting in clinical presentations ranging from asymptomatic silent carriers to severe anemia and fetal lethality. Alpha thalassemia silent carrier commonly results from deletion of a single alpha globin gene (~α/αa) and is clinically asymptomatic. Alpha thalassemia trait may be caused by deletion of a single alpha globin gene from both chromosomes (~α/α), or deletion of the HBA1 and HBA2 globin genes from the same chromosome (~α/αα). Heterozygosity for Hb Constant Spring (HbCS) is usually asymptomatic but may be associated with mild microcytic anemia. Homozygous HbCS is characterized by overt hemolytic anemia, jaundice and splenomegaly. Hemoglobin H disease occurs due to inactivation of three alpha globin genes and results in hemolysis with Heinz bodies, moderate anemia, and splenomegaly. Hb Bart hydrops fetalis syndrome results from deletion of all four alpha globin genes (~α/αα) and is lethal in the fetal or early neonatal period. Alpha globin gene duplication results in three or more active alpha globin genes on a single chromosome.
Epidemiology: Carrier frequency of alpha thalassemia in African, African-American (1:3), Mediterranean (1:30-50), Middle Eastern, Southeast Asian (1:20).
Inheritance: Autosomal recessive.
Cause: Pathogenic variants in the alpha globin gene cluster (HBZ, HBM, HBA2, HBA1, HBQ1) or regulatory region.
Clinical Sensitivity: Varies by ethnicity, at least 90 percent.
Methodology: Multiplex ligation-dependent probe amplification (MLPA) for the HBZ, HBM, HBA2, HBA1, HBQ1 genes, the HS-40 regulatory region, and Hb Constant Spring (HbCS) HBA2 c.427T>C; p.Ter143Gln. To determine copy number of HbCS in absence of a concurrent deletion of HBA2, PCR and bidirectional sequencing for HbCS is performed.
Analytical Sensitivity and Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Specific breakpoints of large deletions/duplications will not be determined; therefore, it may not be possible to distinguish variants of similar size. Non-deletional variants within the coding or regulatory regions of the alpha globin cluster genes, other than HbCS, will not be targeted. 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 gene variants will not be detected.

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

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

Note: If a concurrent deletion of HBA2 is not identified, PCR and bidirectional sequencing for the HbCS copy number will be performed. Additional charges apply.

CPT Code(s): 81269; if reflexed, add 81257

New York DOH Approved.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.
Alpha Thalassemia (HBA1 and HBA2) Deletion/Duplication with reflex to Hb Constant Spring, Fetal

Methodology: Multiplex Ligation-dependent Probe Amplification with Sanger sequencing confirmation of HbCS

Specimen Required:
- **Collect:** Fetal Specimen: Two T-25 flasks at 80 percent confluency of cultured amniocytes or CVS. If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787. Or amniotic fluid.
- **AND Maternal Specimen:** Lavender (EDTA), Pink (K$_2$EDTA), or Yellow (ACD Solution A or B).
- **Specimen Preparation:** Cultured Amniocytes or Cultured CVS: Fill flasks with culture media. Transport two T-25 flasks at 80 percent confluency of cultured amniocytes or cultured CVS. Backup cultures must be retained at the client's institution until testing is complete.
- **OR Amniotic Fluid:** Transport 10 mL unspun fluid.
- **AND Maternal Specimen:** Transport 2 mL whole blood. (Min: 1 mL)
- **Storage/Transport Temperature:** Amniotic Fluid: Room temperature.
- **Cultured Fetal Cells:** CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of shipment due to viability of cells.
- **Maternal Specimen:** Room temperature.
- **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 at (800) 522-2787.
- **Unacceptable Conditions:** Stability (collection to initiation of testing): Fetal Specimen: Room temperature: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
- **Maternal Specimen:** Room temperature: 7 days; Refrigerated: 1 month

Reference Interval: By report

Interpretive Data:
- **Background Information:** Alpha Globin (HBA1 and HBA2) Deletion/Duplication
- **Characteristics:** Decreased or absent synthesis of the hemoglobin (Hb) alpha-chain resulting in clinical presentations ranging from asymptomatic silent carriers to severe anemia and fetal lethality. Alpha thalassemia silent carrier commonly results from deletion of a single alpha globin gene (α/αa) and is clinically asymptomatic. Alpha thalassemia trait may be caused by deletion of a single alpha globin gene from both chromosomes (α/αa), or deletion of the HBA1 and HBA2 alpha globin genes from the same chromosome (α/αa). Heterozygosity for Hb Constant Spring (HbCS) is usually asymptomatic but may be associated with mild microcytic anemia. Homozygous HbCS is characterized by overt hemolytic anemia, jaundice and splenomegaly. Hemoglobin H disease occurs due to inactivation of three alpha globin genes and results in hemolysis with Heinz bodies, moderate anemia, and splenomegaly. Hb Bart hydrops fetalis syndrome results from deletion of all four alpha globin genes (α−/α−) and is lethal in the fetal or early neonatal period. Alpha globin gene duplication results in three or more active alpha globin genes on a single chromosome.
- **Epidemiology:** Carrier frequency of alpha thalassemia in African, African-American (1:3), Mediterranean (1:30-50), Middle Eastern, Southeast Asian (1:20).
- **Inheritance:** Autosomal recessive.
- **Cause:** Pathogenic variants in the alpha globin gene cluster (HBZ, HBM, HBA2, HBA1, HBQ1) or regulatory region.
- **Clinical Sensitivity:** Varies by ethnicity, at least 90 percent.
- **Methodology:** Multiplex ligation-dependent probe amplification (MLPA) for the HBZ, HBM, HBA2, HBA1, and HBQ1 genes, the HS-40 regulatory region, and Hb Constant Spring (HbCS) HBA2 c.427T>C; p.Ter143Gln. To determine copy number of HbCS in absence of a concurrent deletion of HBA2, PCR and bidirectional sequencing for HbCS is performed.
- **Analytical Sensitivity and Specificity:** 99 percent.
- **Limitations:** Diagnostic errors can occur due to rare sequence variations. Specific breakpoints of large deletions/duplications will not be determined; therefore, it may not be possible to distinguish variants of similar size. Non-deletional variants within the coding or regulatory regions of the alpha globin cluster genes, other than HbCS, will not be detected. Fetuses 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 gene variants will not be detected.

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

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

**Note:** If a concurrent deletion of HBA2 is not identified, PCR and bidirectional sequencing for the HbCS copy number will be performed. Additional charges apply.
<table>
<thead>
<tr>
<th>CPT Code(s):</th>
<th>Specimen Required</th>
<th>Specimen Preparation</th>
<th>Storage/Transport Temperature</th>
<th>Unacceptable Conditions</th>
<th>Stability (collection to initiation of testing)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>0050002</strong> Alpha-1-Acid Glycoprotein</td>
<td>Collect: Serum separator tube or green (sodium or lithium heparin).</td>
<td>Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube.</td>
<td>Refrigerated.</td>
<td>After separation from cells: Ambient: 8 hours; Refrigerated: 8 days; Frozen: 3 months</td>
</tr>
<tr>
<td></td>
<td><strong>0051256</strong> Alpha-1-Antitrypsin (SERPINA1) Enzyme Concentration and 2 Mutations with Reflex to Alpha-1-Antitrypsin Phenotype</td>
<td>Collect: Serum separator tube AND lavender (EDTA), pink (K$_2$EDTA), or yellow (ACD Solution A or B).</td>
<td>Allow serum to clot completely at room temperature. Separate serum from cells ASAP or within 2 hours of collection. Transport 0.5 mL serum AND 3 mL whole blood.</td>
<td>Refrigerated.</td>
<td>After separation from cells: Ambient: 1 week; Refrigerated: 3 months; Frozen: 3 months (avoid repeat freeze/thaw cycles)</td>
</tr>
<tr>
<td></td>
<td><strong>2012209</strong> Amphetamines Urine Screen with Reflex to Quantitation</td>
<td>Collect: Random urine.</td>
<td>Transfer 4.0 mL urine with no additives or preservatives to an ARUP Standard Transport Tube.</td>
<td>Refrigerated.</td>
<td>Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month</td>
</tr>
<tr>
<td></td>
<td><strong>2005419</strong> Androstanediol Glucuronide Quantitative, Serum or Plasma</td>
<td>Collect: Plain Red, Lavender (EDTA), or Serum Separator Tube (SST).</td>
<td>Separate from cells within 45 minutes. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube.</td>
<td>Refrigerated.</td>
<td>Ambient: 6 days; Refrigerated: 6 days; Frozen: 3 years</td>
</tr>
<tr>
<td></td>
<td><strong>2005077</strong> Angelman Syndrome and Prader-Willi Syndrome by Methylation-Sensitive PCR</td>
<td>Collect: Lavender (EDTA), pink (K$_2$EDTA), or yellow (ACD Solution A or B).</td>
<td>Transport 3 mL whole blood.</td>
<td>Refrigerated.</td>
<td>Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month</td>
</tr>
</tbody>
</table>
### Angelman Syndrome and Prader-Willi Syndrome by Methylation-Sensitive PCR

**Specimen Required:**
- **Fetal Specimen:** Four (4) T-25 flasks at 80 percent confluency of cultured amniocytes. If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787.
- **Maternal Specimen:** Lavender (EDTA), pink (K<sub>2</sub>EDTA), or yellow (ACD Solution A or B).

**Specimen Preparation:** Cultured Amniocytes: Fill flasks with culture media. Transport four (4) T-25 flasks at 80 percent confluency of cultured amniocytes. Backup cultures must be retained at the client’s institution until testing is complete.

**Storage/Transport Temperature:** Cultured Amniocytes: CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of shipment due to liability of cells.

**Anntional Fluid:** Room temperature.

**Maternal Specimen:** Room temperature.

**Remarks:** Maternal specimen is recommended for proper test interpretation. Order Maternal Cell Contamination, Maternal Specimen. This can be arranged by contacting ARUP genetic counselors at (800) 242-2787 ext. 2141. 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):**
- **Fetal Specimen:** Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
- **Maternal Specimen:** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

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### Ankylosing Spondylitis (HLA-B27) Genotyping

**Specimen Required:**
- Lavender (EDTA), pink (K<sub>2</sub>EDTA), or yellow (ACD Solution A or B).

**Specimen Preparation:** Do not freeze. Transport 3 mL whole blood. (Min: 1 mL)

**Storage/Transport Temperature:** Refrigerated.

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

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

**Specimen Required:**
- Serum Separator Tube (SST).

**Specimen Preparation:** Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 1.0 mL)

**Storage/Transport Temperature:** Refrigerated.

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

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### APC Resistance Profile with Reflex to Factor V Leiden

**Specimen Required:**
- Light Blue (Sodium Citrate) AND Lavender (EDTA), Pink (K<sub>2</sub>EDTA), or Yellow (ACD Solution A or B). Refer to Specimen Handling at aruplab.com for hemostasis/thrombosis specimen handling guidelines.

**Specimen Preparation:** Transport 1.5 mL platelet-poor plasma AND 3 mL whole blood. (Min: 1 mL/each)

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

**Whole Blood:** Refrigerated.

**Stability (collection to initiation of testing):** Plasma: Ambient: 4 hours; Refrigerated: Unacceptable; Frozen at -20°C: 3 months; Frozen at -70°C: 6 months

**Whole Blood:** Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

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### Apolipoprotein B (APOB) Mutation Detection

**Specimen Required:**
- Lavender (EDTA), pink (K<sub>2</sub>EDTA), or yellow (ACD Solution A or B).

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

**Storage/Transport Temperature:** Refrigerated.

**Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
**2013341**  
**Apolipoprotein E (APOE) Genotyping, Alzheimer Disease Risk**  
**APOE AZ**

**Specimen Required:**  
Collect: Lavender (EDTA), Pink (K$_2$EDTA), or Yellow (ACD Solution A or B).

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

**Storage/Transport Temperature:**  
Refrigerated.

**Remarks:**  
Testing of fetal specimens or specimens from patients under the age of 18 years is not offered.

**Unacceptable Conditions:**  
Plasma or serum. Heparinized specimens. Frozen specimens in glass collection tubes.

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

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**2013337**  
**Apolipoprotein E (APOE) Genotyping, Cardiovascular Risk**  
**APOE CR**

**Specimen Required:**  
Collect: Lavender (EDTA), Pink (K$_2$EDTA), or Yellow (ACD Solution A or B).

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

**Storage/Transport Temperature:**  
Refrigerated.

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

**Unacceptable Conditions:**  
Plasma or serum. Heparinized specimens. Frozen specimens in glass collection tubes.

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

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**0051415**  
**Ashkenazi Jewish Diseases, 16 Genes**  
**AJP**

**Specimen Required:**  
Collect: Lavender (EDTA), Pink (K$_2$EDTA), 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.

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**3000724**  
**B-Lymphoblastic Leukemia (B-ALL) Minimum Residual Disease Detection by Flow Cytometry**  
**B-ALL MRD**

**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.

**Note:** This assay is a minimal residual disease assessment of B-ALL by flow cytometry.

**Available Markers:** CD3, CD9, CD10, CD13, CD19, CD20, CD33, CD34, CD38, CD45, CD58, CD71, Syto 16, CD66b, CD24, CD22

*Not all markers will be reported in all cases.

If COG panel is not specified, a 10 marker panel will be run: CD10, CD19, CD20, CD22, CD24, CD34, CD38, CD45, CD58, CD66b

If COG panel is specified, indicate time point and specimen type:

**DAY 8 Peripheral Blood sample** will have CD10, CD19, CD20, CD34, CD45, and Syto 16 run and reported. (6 markers total).

**Day 29 Bone Marrow sample** will have CD3, CD9, CD10, CD13, CD19, CD20, CD33, CD34, CD38, CD45, CD58, CD71, Syto 16 run and reported. (13 markers total).

The report will include a pathologist interpretation and a marker interpretation range corresponding to CPT codes of 2-8 markers, 9-15 markers interpreted. Charges apply per marker.

**HOTLINE NOTE:** There is a clinically significant charting name change associated with this test.  
Change the charting name for component 3000738, B-ALL MRD (COG Protocol) Interpretation from B-ALL MRD (COG Protocol) Interpretation to B-ALL MRD Interpretation.
New Test 3002528 Bacterial Strain Typing by Next Generation Sequencing STRAIN NGS

Available Now
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Methodology: Massively Parallel Sequencing
Performed: Varies; Batch tested every two weeks
Reported: 1-3 weeks

Specimen Required:
Collect: Multiple bacterial isolates that are epidemiologically related
Specimen Preparation: Transport individual isolates on agar slants or on swabs in bacterial transport media. Package isolates together in a sealed container.
Storage/Transport Temperature: Room temperature.
Remarks: Contact the Microbiology Laboratory at (800) 242-2787, extension 2576, prior to submission of the isolates. One report will be generated for each batch tested; billing is per isolate. Order one test, using “Infection control, ####” (your ARUP client number) as the patient name. Include a list of isolate identifiers (do not use patient names) on the requisition or as an order note for electronic orders. Identifiers on the requisition must match identifiers on the isolate samples.

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

Reference Interval: By report

Interpretive Data:
Method
Whole Genome Sequencing (WGS) is performed using Ion Torrent sequencing chemistry. Reference-free pairwise comparisons are performed using short, overlapping sequence matching (kmer) analysis. Relationships are determined by the percent of kmers that match between isolate pairs.

Interpretation
Predicted relatedness is based on the total number of differences between the isolates, applying the thresholds shown in the table. The dendrogram and relationship matrix (see enhanced report) illustrate isolate relatedness. Interpretation of strain relatedness should be performed by an investigator knowledgeable about whole genome strain typing procedures and based on all available epidemiological evidence. Inferred relationships based on any strain typing method should not be used for individual patient management.

WGS Strain Typing provides substantial improvements in resolution and reproducibility when compared to pulsed-field gel electrophoresis (PFGE) and can be performed on a broad range of microorganisms. Test was validated for Staphylococcus, Acinetobacter, Enterococcus, Escherichia, Pseudomonas, Stenotrophomonas, Serratia, and Klebsiella species.

<table>
<thead>
<tr>
<th>Category</th>
<th>Kmer Identity</th>
<th>Epidemiological Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indistinguishable</td>
<td>&gt;99.9</td>
<td>Part of the outbreak</td>
</tr>
<tr>
<td>Closely related</td>
<td>99.8-99.2</td>
<td>Probably part of the outbreak</td>
</tr>
<tr>
<td>Possibly related</td>
<td>99.1-95.0</td>
<td>Possibly part of the outbreak</td>
</tr>
<tr>
<td>Unrelated</td>
<td>&lt;95.0</td>
<td>Not part of the outbreak</td>
</tr>
</tbody>
</table>

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

Note: Each Isolate billed separately

CPT Code(s): 87153

New York DOH approval pending. Call for status update.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.
**Methodology:** Qualitative Transcription-Mediated Amplification

**Performed:** Tue, Thu, Sat

**Reported:** 1-4 days

**Specimen Required:**
*Patient Prep:* Patient must be 14 years of age or older.

*Collect:* Vaginal specimen collected with pink swab from Aptima MultiTest Swab Collection kit (ARUP supply #55224 PK/50 or #55229 PK/10) available online through eSupply using ARUP Connect or contact Client Services at (800) 522-2787.

*Specimen Preparation:* Place swab in MultiTest Swab Specimen Transport Tube, break shaft at scoreline then recap tube.

*Storage/Transport Temperature:* Refrigerated.

*Unacceptable Conditions:* Specimens in any transport media other than indicated above. Specimen in MultiTest swab transport media without a swab.

*Stability (collection to initiation of testing):* Ambient: 30 days; Refrigerated: 30 days; Frozen: 90 days

**Reference Interval:**

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bacterial Vaginosis by TMA</td>
<td>Negative</td>
</tr>
</tbody>
</table>

**Interpretive Data:**

A negative result does not preclude a possible infection.

A single qualitative result is determined based on relative amounts of the following target organisms: *Lactobacillus* (*L. gasseri, L. crispatus, and L. jensenii*), *Gardnerella vaginalis*, and *Atopobium vaginae*. This assay does not report individual organisms.

Results should be interpreted in conjunction with other clinical data. This test has not been validated for use with specimens collected by patients at home.

This test is intended for medical purposes only and is not valid for the evaluation of suspected sexual abuse or for other forensic purposes.

**CPT Code(s):**

81513

New York DOH Approved.

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

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**2012211**  **Barbiturates, Urine Screen with Reflex to Quantitation**  **BARB RFX U**

**Specimen Required:**

*Collect:* Random urine.

*Specimen Preparation:* Transfer 4.0 mL urine with no additives or preservatives to an ARUP Standard Transport Tube. (Min: 2.0 mL)

*Storage/Transport Temperature:* Room temperature.


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

---

**2012225**  **Benzodiazepines, Urine Screen with Reflex to Quantitation**  **BENZ RFX U**

**Specimen Required:**

*Collect:* Random urine.

*Specimen Preparation:* Transfer 4 mL urine with no additives or preservatives to an ARUP Standard Transport Tube. (Min: 2 mL)

*Storage/Transport Temperature:* Room Temperature.


*Stability (collection to initiation of testing):* Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month
0051433  Bloom Syndrome (BLM), 1 Variant

**Specimen Required:**
- Collect: Lavender (EDTA), pink (K$_2$EDTA), 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

2012273  Buprenorphine, Urine Screen with Reflex to Quantitation

**Specimen Required:**
- Collect: Random urine.
- **Specimen Preparation:** Transfer 4 mL urine with no additives or preservatives to an ARUP Standard Transport Tube (Min: 2 mL)
- **Storage/Transport Temperature:** Room temperature.
- **Unacceptable Conditions:** Unknown fluids, pharmaceutical preparations, and breast milk. Specimens exposed to repeated freeze/thaw cycles.
- **Stability (collection to initiation of testing):** Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month

0051453  Canavan Disease (ASPA), 4 Variants

**Specimen Required:**
- Collect: Lavender (EDTA), pink (K$_2$EDTA), 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
New Test 3002583 Candida glabrata, Candida species, and Trichomonas vaginalis by CVTV TMA

Click for Pricing

Methodology: Qualitative Transcription-Mediated Amplification
Performed: Tue, Thu, Sat
Reported: 1-4 days

Specimen Required: Patient Prep: Patient must be 14 years of age or older.
Collect: Vaginal specimen collected with pink swab from Aptima MultiTest Swab Collection kit (ARUP supply #55224 PK/50 or #55229 PK/10) available online through eSupply using ARUP Connect or contact Client Services at (800) 522-2787.
Specimen Preparation: Place swab in MultiTest Swab Specimen Transport Tube, break shaft at scoreline then recap tube.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Specimens in any transport media other than indicated above. Specimen in MultiTest swab transport media without a swab.
Stability (collection to initiation of testing): Ambient: 30 days; Refrigerated: 30 days; Frozen: 90 days

Reference Interval:

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Trichomonas vaginalis by TMA</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>Candida glabrata by TMA</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>Candida species (other) by TMA</td>
<td>Negative</td>
</tr>
</tbody>
</table>

Interpretive Data:
A negative result does not preclude a possible infection.

This test detects *Trichomonas vaginalis*, *Candida glabrata*, and other *Candida* species (*C. albicans*, *C. parapsilosis*, *C. dubliniensis*, and *C. tropicalis*). The assay does not differentiate among organisms in the *Candida* species group.

Results should be interpreted in conjunction with other clinical data. This test has not been validated for use with specimens collected by patients at home.

This test is intended for medical purposes only and is not valid for the evaluation of suspected sexual abuse or for other forensic purposes.

CPT Code(s): 87481, 87661

New York DOH Approved.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.
New Test: **3003634** Capillary Malformation-Arteriovenous Malformation (CM-AVM) Panel, Sequencing and Deletion/Duplication

Available Now
Click for Pricing

### Additional Technical Information

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

**Performed:** Varies

**Reported:** 3-6 weeks

**Specimen Required:**
- **Collect:** Lavender (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
- **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:** *EPHB4** (NM_004444), *RASA1* (NM_002890)

** Deletion/duplication detection is not available for this gene.

**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.

---

New Test: **2012278** Carisoprodol Urine with Reflex to Quantitation

**Specimen Required:**
- **Collect:** Random urine.
- **Specimen Preparation:** Transfer 4 mL urine with no additives or preservatives to an ARUP Standard Transport Tube. (Min: 2 mL)
- **Storage/Transport Temperature:** Refrigerated.
- **Unacceptable Conditions:** Breast milk. Pharmaceutical preparation. Specimens exposed to multiple freeze thaw cycles.
- **Stability (collection to initiation of testing):** Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month

**CARIS RFXU**
New Test  
3003704  
CD71 by Immunohistochemistry  
CD71 IHC

Methodology: Immunohistochemistry
Performed: Mon-Fri
Reported: 1-3 days

Specimen Required: Collect: Tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin-embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit recommended but not required. ARUP supply #47808 available online through eSupply using ARUP Connect or contact ARUP Client Services at (800) 522-2787. (Min: 2 slides) If sending precut slides, do not oven bake.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
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.

2005018  
Celiac Disease (HLA-DQ2, and HLA-DQ8) Genotyping  
HLA CELIAC

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: Frozen specimens in glass collection tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

2012155  
Charcot-Marie-Tooth (CMT) and Related Hereditary Neuropathies, PMP22 Deletion/Duplication with Reflex to Sequencing Panel  
CMT REFLEX

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

2012231  
Cocaine, Urine Screen with Reflex to Quantitation  
COCA RFX U

Specimen Required: Collect: Random urine.
Specimen Preparation: Transfer 4 mL urine with no additives or preservatives to an ARUP Standard Transport Tube. (Min: 2 mL)
Storage/Transport Temperature: Room temperature.
Unacceptable Conditions: Specimens exposed to repeated freeze/thaw cycles.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month
## Connective Tissue Disease First Line Panel with Reflex

### Reference Interval:

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>0050215</td>
<td>Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA with Reflex to dsDNA Antibody, IgG by IFA</td>
<td>Effective May 17, 2021</td>
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<tr>
<td>2002693</td>
<td>Double-Stranded DNA (dsDNA) Antibody, IgG by IFA (using Crithidia luciliae)</td>
<td>Less than 1:10</td>
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<tr>
<td>050470</td>
<td>Smith/RNP (ENA) Antibody, IgG</td>
<td>29 AU/mL or less: Negative</td>
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<td></td>
<td>30-40 AU/mL: Equivocal</td>
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<tr>
<td></td>
<td></td>
<td>41 AU/mL or greater: Positive</td>
</tr>
<tr>
<td>050085</td>
<td>Smith (ENA) Antibody, IgG</td>
<td>29 AU/mL or less: Negative</td>
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<td></td>
<td></td>
<td>30-40 AU/mL: Equivocal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>41 AU/mL or greater: Positive</td>
</tr>
<tr>
<td>2012074</td>
<td>SSA 52 and 60 (Ro) (ENA) Antibodies, IgG</td>
<td>SSA-52 (Ro52) (ENA) Antibody, IgG</td>
</tr>
<tr>
<td></td>
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<td>29 AU/mL or less: Negative</td>
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<td></td>
<td>30-40 AU/mL: Equivocal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>41 AU/mL or greater: Positive</td>
</tr>
<tr>
<td></td>
<td>SSA-60 (Ro60) (ENA) Antibody, IgG</td>
<td>29 AU/mL or less: Negative</td>
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<td></td>
<td></td>
<td>30-40 AU/mL: Equivocal</td>
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<tr>
<td></td>
<td></td>
<td>41 AU/mL or greater: Positive</td>
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<td>0050692</td>
<td>SSB (La) (ENA) Antibody, IgG</td>
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<td>30-40 AU/mL: Equivocal</td>
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<td></td>
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<td>41 AU/mL or greater: Positive</td>
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<td>0999592</td>
<td>Jo-1 Antibody, IgG</td>
<td>29 AU/mL or less: Negative</td>
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<td></td>
<td>41 AU/mL or greater: Positive</td>
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<td>0050599</td>
<td>Scleroderma (Scl-70) (ENA) Antibody, IgG</td>
<td>29 AU/mL or less: Negative</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>41 AU/mL or greater: Positive</td>
</tr>
</tbody>
</table>

**HOTLINE NOTE:** There is a numeric map change associated with this test.

- Change the numeric map for component 0050215, dsDNA Ab, IgG w/ Reflex to IFA Titer from no numeric map to XXXX.
- There is a result type change associated with this test.
- Change the result type for component 0050215, dsDNA Ab, IgG w/ Reflex to IFA Titer from Alpha to Numeric.
- There is a unit of measure change associated with this test.
- Change the unit of measure for component 0050215, dsDNA Ab, IgG w/ Reflex to IFA Titer from no unit of measure to IU.
New Test 3003756 Copper, Red Blood Cells CU RBC

Methodology: Quantitative Inductively Coupled Plasma-Mass Spectrometry
Performed: Sun-Sat
Reported: 1-4 days

Specimen Required: Collect: Royal Blue (EDTA).
Specimen Preparation: Centrifuge whole blood and separate RBCs from plasma within 2 hours of collection. Transfer 2 mL RBCs to an ARUP Trace Element-Free Transport Tube (ARUP supply #43116) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 0.6 mL)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated.
Unacceptable Conditions: Specimens collected in tubes other than royal blue (EDTA). Specimens transported in containers other than Royal Blue (EDTA) tube or Trace Element-Free Transport Tube. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): After separation from plasma: Ambient: 1 week; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: 59.0-91.0 mcg/dL

Interpretive Data:
Copper concentrations in RBCs reflect the intracellular stores and general homeostasis of Copper. Results may be falsely elevated if RBCs in the submitted specimen are lysed or not promptly separated from plasma.

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

CPT Code(s): 82525

New York DOH approval pending. Call for status update.

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

0050180 C-Reactive Protein CRP

Specimen Required: Collect: Serum separator tube. Also acceptable: Plasma separator tube, green (lithium heparin)
Specimen Preparation: Allow serum tube to clot completely at room temperature. Separate serum or plasma from cells within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.3 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 2 Weeks; Refrigerated: 3 Weeks; Frozen: 12 Months (if frozen within 24 hours)

0092572 Cutaneous Direct Immunofluorescence, Biopsy CUTDIF

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's 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. Solid organs or solid organ tissue. Tissue in container of unknown or unacceptable transport medium.
Stability (collection to initiation of testing): Ambient: 10 days; Refrigerated: 10 days; Frozen: Unacceptable
### 3001508  **CYP2C19**  2C19GENO

**Specimen Required:** Collect: Lavender (EDTA), Pink (K$_2$EDTA), or Yellow (ACD Solution A or B).  
**Specimen Preparation:** Transport 3 mL whole blood. (Min: 1 mL) OR Transport the Saliva Collection Device.  
**Storage/Transport Temperature:** Refrigerated.  
**Unacceptable Conditions:** Plasma or serum. Specimens collected in sodium heparin or lithium heparin. Frozen specimens in glass collection tubes.  
**Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

### 3001501  **CYP2C8 and CYP2C9**  2C8/2C9

**Specimen Required:** Collect: Lavender (EDTA), Pink (K$_2$EDTA), or Yellow (ACD Solution A or B).  
**Specimen Preparation:** Transport 3 mL whole blood. (Min: 1 mL) OR Transport the Saliva Collection Device.  
**Storage/Transport Temperature:** Refrigerated.  
**Unacceptable Conditions:** Plasma or serum. Specimens collected in sodium heparin or lithium heparin.  
**Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

### 3001513  **CYP2D6**  2D6GENO

**Specimen Required:** Collect: Lavender (EDTA), Pink (K$_2$EDTA), or Yellow (ACD Solution).  
**Specimen Preparation:** Transport 3 mL whole blood. (Min: 1 mL) OR Transport the Saliva Collection Device.  
**Storage/Transport Temperature:** Refrigerated.  
**Remarks:**  
**Unacceptable Conditions:** Plasma or serum. Specimens collected in sodium heparin or lithium heparin. Frozen specimens in glass collection tubes.  
**Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

### 3001518  **CYP3A4 and CYP3A5**  3A4/3A5

**Specimen Required:** Collect: Lavender (EDTA), Pink (K$_2$EDTA), or Yellow (ACD Solution A or B).  
**Specimen Preparation:** Transport 3 mL whole blood. (Min: 1 mL) OR Transport the Saliva Collection Device.  
**Storage/Transport Temperature:** Refrigerated.  
**Unacceptable Conditions:** Plasma or serum. Specimens collected in sodium heparin or lithium heparin. Frozen specimens in glass collection tubes.  
**Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

### 2013661  **Cystic Fibrosis (CFTR) 165 Pathogenic Variants**  CF VAR

**Specimen Required:** Collect: Lavender (EDTA), pink (K$_2$EDTA), or yellow (ACD Solution).  
**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

### 2013663  **Cystic Fibrosis (CFTR) 165 Pathogenic Variants with Reflex to Sequencing**  CF VAR SEQ

**Specimen Required:** Collect: Lavender (EDTA), pink (K$_2$EDTA), or yellow (ACD Solution).  
**Specimen Preparation:** Transport 3 mL whole blood. (Min: 2 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
Cystic Fibrosis (CFTR) 165 Pathogenic Variants with Reflex to Sequencing and Reflex to Deletion/Duplication

Specimen Required: Collect: Lavender (K$_2$EDTA), pink (K$_2$EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 5 mL whole blood. (Min: 3 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

Cystic Fibrosis (CFTR) 165 Pathogenic Variants, Fetal

Specimen Required: Collect: Fetal Specimen: Two T-25 flasks of cultured amniocytes at 80 percent confluency. *If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787.
Maternal Specimen: Lavender (EDTA), Pink (K$_2$EDTA), or Yellow (ACD Solution).
Specimen Preparation: Cultured Amniocytes: Fill flasks with culture media. Backup cultures must be retained at the client's institution until testing is complete.
Maternal Specimen: Transport 3 mL whole blood. (Min. 1 mL)
Storage/Transport Temperature: CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of shipment due to lability of cells.
Maternal Specimen: Refrigerated.
Remarks: Maternal sample is recommended for proper test interpretation; order Maternal Cell Contamination, Maternal Specimen. Patient History Form is available on the ARUP Web site or by contacting ARUP Client Services.
Unacceptable Conditions: Maternal Specimen: Plasma or serum. Specimens collected in sodium heparin or lithium heparin tubes. Frozen specimens in glass collection tubes.
Stability (collection to initiation of testing): Fetal Specimen: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Maternal Specimen: Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

Cytochrome P450 Genotyping Panel

Specimen Required: Collect: Lavender (K$_2$EDTA), pink (K$_2$EDTA), 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. Frozen specimens in glass collection tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

D-Dimer

Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Collect: Light blue (sodium citrate). Refer to Specimen Handling at aruplab.com for hemostasis/thrombosis specimen handling guidelines.
Specimen Preparation: Transfer 2 mL platelet poor plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Remarks:
Unacceptable Conditions: Serum, EDTA plasma, clotted or hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 1 month
University of Utah Clients: after separation from cells: Ambient: 8 hours; Refrigerated: Unacceptable; Frozen: 1 month

Interpretive Data:
The presence of rheumatoid factor may lead to false-positive results with the D-Dimer test. This test should not be used to rule out venous thromboembolism.
Maximal values less than 10 µg/mL FEU are rarely indicative of DIC.
Results are reported in Fibrinogen Equivalent Units (FEU).
HOTLINE: Effective May 17, 2021

2012166 Dihydropyrimidine Dehydrogenase (DPYD), 3 Variants

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

New Test

3001581 Dilated Cardiomyopathy Panel, Sequencing

Methodology: Massively Parallel Sequencing
Performed: Varies
Reported: 3-6 weeks

Specimen Required: Collect; Lavender (EDTA) or Yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Serum or plasma; grossly hemolyzed or frozen specimens.
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: ABCC9, ACTC1, ACTN2, ALMS1, BAG3, CRYAB, CSRP3, DES, DMD, DOLK, DSC2, DSG2, DSP, EMD, FKTN, FLNC*, GLA, JUP, LAMP2, LDB3, LMNA, MYBPC3, MYH6, MYH7, MYL2, MYL3, PKP2, PLN, PRDM16, PRKAG2*, RAF1, RBM20, RYR2, SCN5A, SGCD, TAZ, TCAP, TMEM43, TNNC1, TNNI3, TNNT2, TPM1, TTN*, TTR, VCL.

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

CPT Code(s): 81439

New York DOH approval pending. Call for status update.

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

0050215 Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA with Reflex to dsDNA Antibody, IgG by IFA

Reference Interval: Effective May 17, 2021

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002693</td>
<td>Double-Stranded DNA (dsDNA) Antibody, IgG by IFA (using Crithidia luciliae)</td>
<td>Less than 1:10</td>
</tr>
</tbody>
</table>

HOTLINE NOTE: There is a numeric map change associated with this test.
Change the numeric map for component 0050215, dsDNA Ab, IgG w/ Reflex to IFA Titer from no numeric map to XXXX.
There is a result type change associated with this test.
Change the result type for component 0050215, dsDNA Ab, IgG w/ Reflex to IFA Titer from Alpha to Numeric.
There is a unit of measure change associated with this test.
Change the unit of measure for component 0050215, dsDNA Ab, IgG w/ Reflex to IFA Titer from no unit of measure to IU.
<table>
<thead>
<tr>
<th>Code</th>
<th>Test Description</th>
<th>CDASU</th>
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<tbody>
<tr>
<td>0092184</td>
<td>Drug Panel 7, Urine - Screen with Reflex to Confirmation/Quantitation</td>
<td>CDASU 7</td>
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<tr>
<td>Specimen Required:</td>
<td>Collect; Random urine.</td>
<td></td>
</tr>
<tr>
<td>Specimen Preparation:</td>
<td>Transfer 8 mL urine with no additives or preservative to ARUP Standard Transport Tubes. (Min: 4 mL)</td>
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<tr>
<td>Storage/Transport Temperature:</td>
<td>Refrigerated.</td>
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<tr>
<td>Unacceptable Conditions:</td>
<td>Specimens exposed to repeated freeze/thaw cycles.</td>
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<tr>
<td>Stability (collection to initiation of testing):</td>
<td>Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month</td>
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<table>
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<tr>
<td>Specimen Required:</td>
<td>Collect; Random urine.</td>
<td></td>
</tr>
<tr>
<td>Specimen Preparation:</td>
<td>Transfer 8 mL urine with no additives or preservatives to ARUP Standard Transport Tubes. (Min: 4 mL)</td>
<td></td>
</tr>
<tr>
<td>Storage/Transport Temperature:</td>
<td>Refrigerated.</td>
<td></td>
</tr>
<tr>
<td>Unacceptable Conditions:</td>
<td>Specimens exposed to repeated freeze/thaw cycles.</td>
<td></td>
</tr>
<tr>
<td>Stability (collection to initiation of testing):</td>
<td>Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code</th>
<th>Test Description</th>
<th>CDASU 9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen Required:</td>
<td>Collect; Random urine.</td>
<td></td>
</tr>
<tr>
<td>Specimen Preparation:</td>
<td>Transfer 8 mL urine with no additives or preservatives to ARUP Standard Transport Tubes. (Min: 4 mL)</td>
<td></td>
</tr>
<tr>
<td>Storage/Transport Temperature:</td>
<td>Refrigerated.</td>
<td></td>
</tr>
<tr>
<td>Unacceptable Conditions:</td>
<td>Specimens exposed to repeated freeze/thaw cycles.</td>
<td></td>
</tr>
<tr>
<td>Stability (collection to initiation of testing):</td>
<td>Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month</td>
<td></td>
</tr>
</tbody>
</table>

**HOTLINE NOTE:** There is a reflexive pattern change associated with this test.
Add reflex to 3003726, Propoxyphene and Metabolite, Urine
Remove reflex from 2010468, Propoxyphene and Metabolite, Urine, Quantitative

<table>
<thead>
<tr>
<th>Code</th>
<th>Test Description</th>
<th>CDASU 9A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen Required:</td>
<td>Collect; Random urine.</td>
<td></td>
</tr>
<tr>
<td>Specimen Preparation:</td>
<td>Transfer 8 mL urine with no additives or preservatives in ARUP Standard Transport Tubes. (Min: 4 mL)</td>
<td></td>
</tr>
<tr>
<td>Storage/Transport Temperature:</td>
<td>Refrigerated.</td>
<td></td>
</tr>
<tr>
<td>Unacceptable Conditions:</td>
<td>Specimens exposed to repeated freeze/thaw cycles.</td>
<td></td>
</tr>
<tr>
<td>Stability (collection to initiation of testing):</td>
<td>Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month</td>
<td></td>
</tr>
</tbody>
</table>

**HOTLINE NOTE:** There is a reflexive pattern change associated with this test.
Add reflex to 3003726, Propoxyphene and Metabolite, Urine
Remove reflex from 2010468, Propoxyphene and Metabolite, Urine, Quantitative
**2012312**  
**Drug Profile, Screen with Reflex to Quantitation**

**PAIN RFX U**

**Specimen Required:** Collect: Random Urine.  
Specimen Preparation: Transfer 4 mL each into **two** (2) ARUP Standard Transport Tubes urine with no additives or preservatives. (Min: 2 mL each)  
Storage/Transport Temperature: Refrigerated.  
Unacceptable Conditions: Specimens exposed to multiple freeze/thaw cycles, Pharmaceutical preparation.  
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 month; frozen: 1 month

**Reference Interval:** Effective May 17, 2021

**Drugs covered and range of cutoff concentrations**

<table>
<thead>
<tr>
<th>Drugs/Drug Classes</th>
<th>Screen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamines</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>Barbiturates</td>
<td>200 ng/mL</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>200 ng/mL</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>5 ng/mL</td>
</tr>
<tr>
<td>Carisoprodol</td>
<td>100 ng/mL</td>
</tr>
<tr>
<td>Cocaine</td>
<td>150 ng/mL</td>
</tr>
<tr>
<td>Ethyl Glucuronide</td>
<td>500 ng/mL</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>1 ng/mL</td>
</tr>
<tr>
<td>MDMA (Ecstasy)</td>
<td>500 ng/mL</td>
</tr>
<tr>
<td>Meperidine</td>
<td>200 ng/mL</td>
</tr>
<tr>
<td>Methadone</td>
<td>150 ng/mL</td>
</tr>
<tr>
<td>Opiates</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>100 ng/mL</td>
</tr>
<tr>
<td>Phencyclidine</td>
<td>25 ng/mL</td>
</tr>
<tr>
<td>Propoxyphene</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>Tapentadol</td>
<td>200 ng/mL</td>
</tr>
<tr>
<td>Tramadol</td>
<td>100 ng/mL</td>
</tr>
<tr>
<td>THC (Cannabinoids)</td>
<td>20 ng/mL</td>
</tr>
<tr>
<td>Zolpidem</td>
<td>20 ng/mL</td>
</tr>
</tbody>
</table>

**HOTLINE NOTE:** There is a reflexive pattern change associated with this test.  
Add reflex to 3003726, Propoxyphene and Metabolite, Urine  
Remove reflex from 2010468, Propoxyphene and Metabolite, Urine, Quantitative

**2007479**  
**Drug Profile, Targeted by Tandem Mass Spectrometry and Enzyme Immunoassay, Urine**

**PAIN HYB U**

**HOTLINE NOTE:** There is a clinically significant charting name change associated with this test.  
Change the charting name for component 2007660, Tramadol (cutoff 200 ng/mL) from Tramadol (cutoff 200 ng/mL) to Tramadol (cutoff 100 ng/mL).

**2009288**  
**Drug Profile, Targeted with Interpretation by Tandem Mass Spectrometry and Enzyme Immunoassay, Urine**

**PAIN HYB 2**

**HOTLINE NOTE:** There is a clinically significant charting name change associated with this test.  
Change the charting name for component 2007660, Tramadol (cutoff 200 ng/mL) from Tramadol (cutoff 200 ng/mL) to Tramadol (cutoff 100 ng/mL).

**0090448**  
**Drugs of Abuse 7 Panel, Urine - Screen Only**

**CDTI7**

**Specimen Required:** Collect: Random urine.  
Specimen Preparation: Transfer 4 mL urine with no additives or preservatives to an ARUP Standard Transport Tube. (Min: 2 mL)  
Storage/Transport Temperature: Refrigerated.  
Unacceptable Conditions: Specimens exposed to repeated freeze/thaw cycles.  
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month
<table>
<thead>
<tr>
<th>Code</th>
<th>Test Description</th>
<th>Methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>0090449</strong></td>
<td>Drugs of Abuse 7A Panel, Urine - Screen Only</td>
<td>CDTI7A</td>
</tr>
<tr>
<td>Specimen Required:</td>
<td>Collect: Random urine.</td>
<td></td>
</tr>
<tr>
<td>Specimen Preparation:</td>
<td>Transfer 4 mL urine with no additives or preservatives to an ARUP Standard Transport Tube. (Min: 2 mL)</td>
<td></td>
</tr>
<tr>
<td>Storage/Transport Temperature:</td>
<td>Refrigerated.</td>
<td></td>
</tr>
<tr>
<td>Unacceptable Conditions:</td>
<td>Specimens exposed to repeated freeze/thaw cycles.</td>
<td></td>
</tr>
<tr>
<td>Stability (collection to initiation of testing):</td>
<td>Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month</td>
<td></td>
</tr>
<tr>
<td><strong>0090453</strong></td>
<td>Drugs of Abuse 9 Panel, Urine - Screen Only</td>
<td>CDTI9</td>
</tr>
<tr>
<td>Specimen Required:</td>
<td>Collect: Random urine.</td>
<td></td>
</tr>
<tr>
<td>Specimen Preparation:</td>
<td>Transfer 4 mL urine with no additives or preservatives to an ARUP Standard Transport Tube. (Min: 2 mL)</td>
<td></td>
</tr>
<tr>
<td>Storage/Transport Temperature:</td>
<td>Refrigerated.</td>
<td></td>
</tr>
<tr>
<td>Unacceptable Conditions:</td>
<td>Specimens exposed to repeated freeze/thaw cycles.</td>
<td></td>
</tr>
<tr>
<td>Stability (collection to initiation of testing):</td>
<td>Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month</td>
<td></td>
</tr>
<tr>
<td><strong>0090454</strong></td>
<td>Drugs of Abuse 9A Panel, Urine - Screen Only</td>
<td>CDTI9A</td>
</tr>
<tr>
<td>Specimen Required:</td>
<td>Collect: Random urine.</td>
<td></td>
</tr>
<tr>
<td>Specimen Preparation:</td>
<td>Transfer 4 mL urine with no additives or preservatives to an ARUP Standard Transport Tube. (Min: 2 mL)</td>
<td></td>
</tr>
<tr>
<td>Storage/Transport Temperature:</td>
<td>Refrigerated.</td>
<td></td>
</tr>
<tr>
<td>Unacceptable Conditions:</td>
<td>Specimens exposed to repeated freeze/thaw cycles.</td>
<td></td>
</tr>
<tr>
<td>Stability (collection to initiation of testing):</td>
<td>Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month</td>
<td></td>
</tr>
<tr>
<td><strong>0092280</strong></td>
<td>Drugs of Abuse Test, Alcohol, Urine - Screen with Reflex to Confirmation/Quantitation</td>
<td>CDASUALC</td>
</tr>
<tr>
<td>Specimen Required:</td>
<td>Collect: Random urine.</td>
<td></td>
</tr>
<tr>
<td>Specimen Preparation:</td>
<td>Transport 10 mL urine. (Min: 2 mL)</td>
<td></td>
</tr>
<tr>
<td>Remarks:</td>
<td>Newborn minimum: 1 mL for the initial test and 1 mL for the confirmation of screen positive.</td>
<td></td>
</tr>
<tr>
<td>Storage/Transport Temperature:</td>
<td>Room temperature.</td>
<td></td>
</tr>
<tr>
<td>Unacceptable Conditions:</td>
<td>Specimens exposed to repeated freeze/thaw cycles.</td>
<td></td>
</tr>
<tr>
<td>Stability (collection to initiation of testing):</td>
<td>Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month</td>
<td></td>
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<tr>
<td><strong>2011241</strong></td>
<td>Duchenne/Becker Muscular Dystrophy (DMD) Deletion/Duplication with Reflex to Sequencing</td>
<td>DMD REFLEX</td>
</tr>
<tr>
<td>Specimen Required:</td>
<td>Collect: Lavender (EDTA), or yellow (ACD Solution A or B).</td>
<td></td>
</tr>
<tr>
<td>Specimen Preparation:</td>
<td>Transport 3 mL whole blood. (Min: 2 mL)</td>
<td></td>
</tr>
<tr>
<td>Storage/Transport Temperature:</td>
<td>Refrigerated.</td>
<td></td>
</tr>
<tr>
<td>Unacceptable Conditions:</td>
<td>Serum or plasma; grossly hemolyzed or frozen specimens</td>
<td></td>
</tr>
<tr>
<td>Stability (collection to initiation of testing):</td>
<td>Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable</td>
<td></td>
</tr>
<tr>
<td><strong>0051463</strong></td>
<td>Dysautonomia, Familial (IKBKAP), 2 Variants</td>
<td>IKBKAP</td>
</tr>
<tr>
<td>Specimen Required:</td>
<td>Collect: Lavender (EDTA), pink (K2EDTA), or yellow (ACD Solution A or B).</td>
<td></td>
</tr>
<tr>
<td>Specimen Preparation:</td>
<td>Transport 3 mL whole blood. (Min: 1 mL)</td>
<td></td>
</tr>
<tr>
<td>Storage/Transport Temperature:</td>
<td>Refrigerated.</td>
<td></td>
</tr>
<tr>
<td>Unacceptable Conditions:</td>
<td>Plasma or serum. Specimens collected in sodium heparin or lithium heparin tubes. Frozen specimens in glass collection tubes.</td>
<td></td>
</tr>
<tr>
<td>Stability (collection to initiation of testing):</td>
<td>Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month</td>
<td></td>
</tr>
</tbody>
</table>
**0090518**  Ethanol, Urine, Qualitative - Medical  
ETOH URN

**Specimen Required:**
- **Patient Prep:** For medical purposes only.
- **Collect:** Fresh random urine.
- **Specimen Preparation:** Mix specimen well. Transfer 10 mL aliquot urine to a tightly sealed container for storage and transport. (Min: 0.5 mL)
- **Storage/Transport Temperature:** Refrigerated.
- **Stability (collection to initiation of testing):** Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month

**0212695**  Ethyl Glucuronide Screen Only, Urine  
ETG SCR UR

**Specimen Required:**
- **Collect:** Random urine.
- **Specimen Preparation:** Transfer 4 mL urine with no additives or preservatives to an ARUP Standard Transport Tube. (Min. 1 mL)
- **Storage/Transport Temperature:** Refrigerated.
- **Stability (collection to initiation of testing):** Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month

**0207912**  Ethyl Glucuronide Screen with Reflex to Confirmation, Urine  
ETG SCR

**Specimen Required:**
- **Collect:** Random urine.
- **Specimen Preparation:** Transfer 4 mL urine with no additives or preservatives to an ARUP Standard Transport Tube. (Min: 1 mL)
- **Unacceptable Conditions:** Plasma or serum; collection of specimen in sodium heparin tubes. Frozen specimens in glass collection tubes.
- **Stability (collection to initiation of testing):** Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month

**0097720**  Factor V Leiden (F5) R506Q Mutation  
FACV

**Specimen Required:**
- **Collect:** Lavender (EDTA), Pink (K₂EDTA), or Yellow (ACD Solution A or B).
- **Specimen Preparation:** Transport 3 mL whole blood. (Min: 1 mL)
- **Unacceptable Conditions:** Plasma or serum; collection of specimen in sodium heparin tubes. Frozen specimens in glass collection tubes.
- **Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

**0203220**  Factor XIII (F13A1) V34L Variant  
FAC 13 MUT

**Specimen Required:**
- **Collect:** Lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).
- **Specimen Preparation:** Transport 3 mL whole blood. (Min: 1 mL)
- **Unacceptable Conditions:** Frozen specimens in glass collection tubes.
- **Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
New Test 3002110 Familial Hypercholesterolemia Panel, Sequencing FH NGS

Available Now
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Additional Technical Information

Methodology: Massively Parallel Sequencing
Performed: Varies
Reported: 3-6 weeks

Specimen Required: Collect: Lavender (EDTA) or Yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Serum or plasma; grossly hemolyzed or frozen specimens
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: APOB, LDLR, LDLRAP1, PCSK9.

CPT Code(s): 81407; 81479; 81406

New York DOH approval pending. Call for status update.

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

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

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

2012284 Fentanyl, Urine Screen with Reflex to Quantitation FENT RFX U

Specimen Required: Collect: Random urine.
Specimen Preparation: Transfer 4 mL urine with no additives or preservatives in ARUP Standard Transport Tubes. (Min: 1 mL)
Storage/Transport Temperature: Room temperature.
Unacceptable Conditions: Specimens exposed to repeated freeze/thaw cycles. Samples collected in tubes with additives or preservatives.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month

Reference Interval:
Effective May 17, 2021
Screen cutoff Concentration: 1 ng/mL
### New Test

**0030279**  
**Gastrointestinal Pathogens Panel by PCR**  
**GIPPCR**

**Available Now**  
**Click for Pricing**

**Methodology:** Qualitative Polymerase Chain Reaction

**Performed:** Mon-Sun

**Reported:** 1-3 days

**Specimen Required:** Collect: Stool.

**Specimen Preparation:** Transfer stool to enteric transport media (Cary-Blair) (ARUP supply #29799) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 0.5 mL)

**Storage/Transport Temperature:** Refrigerated

**Remarks:** This test is New York DOH approved; however, per NYDOH regulations, testing cannot be performed for New York City clients.

**Unacceptable Conditions:** Unpreserved stool, stool in media other than Cary-Blair, rectal swabs, specimens outside stability.

**Stability (collection to initiation of testing):** In enteric transport media: Ambient: 4 days, Refrigerated: 4 days, Frozen: Unacceptable.


**CPT Code(s):** 87507

New York DOH Approved.

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

### 0051438

**Gaucher Disease (GBA), 8 Variants**  
**GBA**

**Specimen Required:** Collect: Lavender (EDTA), pink (K<sub>2</sub>EDTA), 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

### 3000258

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

**Specimen Required:** Collect: Lavender (K<sub>2</sub>EDTA). Also acceptable: Pink (K<sub>2</sub>EDTA) or Yellow (ACD Solution A).

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

### 0051684

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

**Methodology:** Real-Time Polymerase Chain Reaction

**Specimen Required:** Collect: Lavender (EDTA), pink (K<sub>2</sub>EDTA), or yellow (ACD Solution A or B).

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

**Storage/Transport Temperature:** Refrigerated.

**Unacceptable Conditions:** Frozen specimens in glass collection tubes.

**Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
2013740 Glycogen Storage Disease, Type 1A (G6PC), 9 Variants

Specimen Required: Collect: Lavender (EDTA), pink (K<sub>2</sub>EDTA), 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

0055656 Hemochromatosis (HFE) 3 Mutations

Specimen Required: Collect: Lavender (EDTA), pink (K<sub>2</sub>EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Frozen specimens in glass collection tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

0030144 Heparin Anti-Xa, Low Molecular Weight Heparin

Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Collect: Lt. blue (sodium citrate). Refer to Specimen Handling at aruplab.com for hemostasis/thrombosis specimen handling guidelines.
Specimen Preparation: Centrifuge specimen within one hour of collection. Transport 2 mL platelet-poor plasma. (Min: 1.5 mL)
Storage/Transport Temperature: Frozen.
Remarks: This test cannot be used to quantitate anticoagulants other than low molecular weight heparin. This includes, but is not limited to, direct oral anticoagulants and Fondaparinux (Arixtra).
Unacceptable Conditions: Serum. EDTA, oxalate, heparin, or plasma separator tubes. Specimens refrigerated more than eight hours. Hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 1 month

University of Utah Clients: After separation from cells: Ambient: 4 hours; Refrigerated: 8 hours; Frozen: 2 weeks

0030143 Heparin Anti-Xa, Unfractionated

Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Collect: Lt. blue (sodium citrate). Refer to Specimen Handling at aruplab.com for hemostasis/thrombosis specimen handling guidelines.
Specimen Preparation: Centrifuge specimen within one hour of collection. Transport 2 mL platelet-poor plasma. (Min: 1 mL)
Storage/Transport Temperature: Frozen.
Remarks: This test cannot be used to quantitate anticoagulants other than unfractionated heparin. This includes, but is not limited to, direct oral anticoagulants and Fondaparinux (Arixtra).
Unacceptable Conditions: Serum. EDTA, oxalate, heparin, or plasma separator tubes. Hemolyzed or clotted specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 1 month

University of Utah Clients: After separation from cells: Ambient: 4 hours; Refrigerated: 8 hours; Frozen: 2 weeks

2002429 HLA-B*57:01 for Abacavir Sensitivity

Specimen Required: Collect: Lavender (EDTA), pink (K<sub>2</sub>EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month.
**Human Epididymis Protein 4 (HE4)**

**Specimen Required:** Collect: Serum Separator Tube (SST). Also acceptable: Green (Lithium Heparin), Lavender (K$_2$ EDTA), or Lavender (K$_3$ EDTA).

**Specimen Preparation:** Allow specimen to clot completely at room temperature. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)

**Storage/Transport Temperature:** Frozen.

**Unacceptable Conditions:** Grossly hemolyzed specimens.

**Stability (collection to initiation of testing):** Ambient: 5 hours; Refrigerated: 48 hours; Frozen: 3 months

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**Human Immunodeficiency Virus 1 (HIV-1) by Qualitative NAAT**

**New Test 3003760**

**Methodology:** Qualitative Transcription-Mediated Amplification

**Performed:** Sun-Sat

**Reported:** 1-4 days

**Specimen Required:** Collect: Lavender (EDTA), Pink (K$_2$EDTA), Yellow (ACD), 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 and freeze. (Min: 0.8 mL)

**Storage/Transport Temperature:** Frozen

**Unacceptable Conditions:** Heparinized specimens.

**Stability (collection to initiation of testing):** After separation from cells: Ambient: Unacceptable; Refrigerated: 72 hours; Frozen: 90 days

**Reference Interval:** Not detected

**Interpretive Data:**

This test detects human immunodeficiency virus type 1 (HIV-1) RNA from Group M, N and O subtypes; it does not detect HIV-1 proviral DNA. A result of "Not Detected" does not rule out HIV-1 RNA concentrations below the limit of detection of the assay or the presence of inhibitors in the patient specimen. The diagnosis of HIV-1 infection should not be made solely on a single HIV-1 test result. Diagnosis requires repeat and confirmatory testing as recommended by U.S. Health and Human Services Guidelines. Improper specimen handling can cause false negatives or contamination.

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

**Note:** Assay detects HIV-1 virus RNA. Proviral DNA will not be detected.

**CPT Code(s):** 87535

New York DOH Approved.

**HOTLINE NOTE:** Refer to the Test Mix Addendum for interface build information.
HOTLINE: Effective May 17, 2021

New Test 3001579  Hypertrophic Cardiomyopathy Panel, Sequencing  HCM NGS

Click for Pricing

Methodology: Massively Parallel Sequencing
Performed: Varies
Reported: 3-6 weeks

Specimen Required: Collect: Lavender (EDTA) or Yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Serum or plasma; grossly hemolyzed or frozen specimens
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: ACTC1, ACTN2, AGL, ALPK3, BRAF, CACNA1C, CSRP3, DES, FHL1, FLNC, GAA, GLA, HRAS, JPH2, KRAS, LAMP2, MAP2K1, MAP2K2, MYBPC3, MYH7, MYL2, MYL3, NRAS, PLN, PRKAG2, PTEN11, RAF1, RIT1, SOS1, TNNC1, TNNT3, TNNT2, TPM1, TTR

CPT Code(s): 81439

New York DOH approval pending. Call for status update.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.
New Test 3003751 JAK2 (V617F) Mutation by ddPCR, Quantitative JAK2V617FQ

Additional Technical Information

Methodology: Droplet Digital Polymerase Chain Reaction
Performed: DNA Isolation: Sun-Sat
Assay: Varies
Reported: 2-7 days

Specimen Required: Collect: Whole blood or bone marrow: Lavender (EDTA), preferred. Also acceptable: Green (sodium heparin)
Specimen Preparation: Whole Blood: Do not freeze. Transport 5 mL whole blood. (Min: 1 mL)
Bone Marrow: Do not freeze. Transport 3 mL bone marrow. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, serum, FFPE tissue blocks/slides, or fresh or frozen tissue, DNA extracted by a non-CLIA certified lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.
Stability (collection to initiation of testing): Refrigerated: 7 days; 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 US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

CPT Code(s): 81270

New York DOH approval pending. Call for status update.

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

2013909 Joubert Syndrome Type 2 (TMEM216), 1 Variant TMEM216

Specimen Required: Collect: Lavender (EDTA), pink (K,EDTA), 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

2013735 Lipoamide Dehydrogenase Deficiency (DLD), 2 Variants DLD

Specimen Required: Collect: Lavender (EDTA), pink (K,EDTA), 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
New Test 3001603 Long QT Panel, Sequencing and Deletion/Duplication LQT NGS

Available Now
Click for Pricing

Methodology: Massively Parallel Sequencing / Exonic Oligonucleotide-based CGH Microarray
Performed: Varies
Reported: 3-6 weeks

Specimen Required:
Collect: Lavender (EDTA) or Yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Serum or plasma; grossly hemolyzed or frozen specimens
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: CACNA1C, CALM1**, CALM2**, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, SCN5A
** - Deletion/duplication detection is not available for this gene.

CPT Code(s): 81403; 81404; 81406; 81407; 81414; 81479

New York DOH approval pending. Call for status update.

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

0092079 Magnesium, RBC MG RBC

Reference Interval:
Effective May 17, 2021
3.6–7.5 mg/dL

Interpretive Data:
RBC magnesium results reflect the intracellular stores and general homeostasis of magnesium. Results may be falsely low if RBCs in the submitted specimen are lysed or not promptly separated from plasma.

RBC magnesium concentration is reported as milligrams per deciliter (mg/dL). To convert concentration to micromoles per liter (mmol/L), divide the result by 2.43.

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

HOTLINE NOTE: There is a unit of measure change associated with this test.
Change the unit of measure for component 0092079 Magnesium, RBC from mmol/L to mg/dL.
### Mammaglobin by Immunohistochemistry

**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 unstained (4-micron thick sections), positively charged slides in a tissue transport kit (ARUP supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 3 slides) If sending precut slides, do not oven bake.

**Storage/Transport Temperature:** Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.

**Unacceptable Conditions:** Specimens submitted with non-representative tissue type. Depleted specimens.

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

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### Maple Syrup Urine Disease, Type 1B (BCKDHB), 3 Variants

**Specimen Required:** Collect: Lavender (EDTA), pink (K$_2$EDTA), 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

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### Medium Chain Acyl-CoA Dehydrogenase (ACADM) 2 Mutations

**Specimen Required:** Collect: Lavender (EDTA), pink (K$_2$EDTA), or yellow (ACD Solution A or B).

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

**Storage/Transport Temperature:** Refrigerated.

**Unacceptable Conditions:** Frozen specimens in glass collection tubes.

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

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### Meperidine, Urine Screen with Reflex to Quantitation

**Specimen Required:** Collect: Random urine.

**Specimen Preparation:** Transfer 4 mL urine with no additives or preservatives to an ARUP Standard Transport Tube. (Min: 2 mL)

**Storage/Transport Temperature:** Refrigerated.

**Unacceptable Conditions:** Specimens collected in tubes with additives or preservatives.

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

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### Methadone, Urine Screen with Reflex to Quantitation

**Specimen Required:** Collect: Random urine.

**Specimen Preparation:** Transfer 4 mL urine with no additives or preservatives to an ARUP Standard Transport Tube. (Min: 2 mL)

**Storage/Transport Temperature:** Room temperature.

**Unacceptable Conditions:** Breast Milk. Specimens exposed to repeated freeze/thaw cycles.

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

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### Methylene tetrahydrofolate Reductase (MTHFR) 2 Variants

**Specimen Required:** Collect: Lavender (EDTA), pink (K$_2$EDTA), 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. Heparinized specimens. Frozen specimens in glass collection tubes.

**Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
**New Test**  
**3001593** MODY and Neonatal Diabetes Panel, Sequencing  
**MODY NGS**

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### Additional Technical Information

**Methodology:** Massively Parallel Sequencing  
**Performed:** Varies  
**Reported:** 3-6 weeks  

**Specimen Required:**  
- **Collect:** Lavender (EDTA) or Yellow (ACD Solution A or B).  
- **Specimen Preparation:** Transport 3 mL whole blood. (Min: 1.5 mL)  
- **Storage/Transport Temperature:** Refrigerated.  
- **Unacceptable Conditions:** Serum or plasma; grossly hemolyzed or frozen specimens.  
- **Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

### Reference Interval:  
By report

### Interpretive Data:  
Refer to report.

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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.


* **CELI** (NM_001807) exons 1, 8, 9, 11 are not sequenced due to technical limitations of the assay.

* **ABCC8** (NM_001351295) partial exon 14 (Chr11:17449973-17450018) is not sequenced due to technical limitations of the assay.

**CPT Code(s):**  
81403; 81404; 81405; 81406; 81479

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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**0051448** Mucolipidosis Type IV (MCOLN1), 2 Variants  
**MCOLN1**

**Specimen Required:**  
- **Collect:** Lavender (EDTA), pink (K<sub>2</sub>EDTA), or yellow (ACD Solution A or B).  
- **Specimen Preparation:** Transport 3 mL whole blood. (Min: 1 mL)  
- **Storage/Transport Temperature:** Refrigerated.  
- **Unacceptable Conditions:** 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

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**2005023** Narcolepsy (HLA-DQB1*06:02) Genotyping  
**NARCOLEPSY**

**Specimen Required:**  
- **Collect:** Lavender (EDTA), pink (K<sub>2</sub>EDTA), or yellow (ACD Solution A or B).  
- **Specimen Preparation:** Transport 3 mL whole blood. (Min: 1 mL)  
- **Storage/Transport Temperature:** Refrigerated.  
- **Unacceptable Conditions:** **Frozen specimens in glass collection tubes.**  
- **Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
**2013745**  NEB-Related Nemaline Myopathy, 1 Variant  NEB

**Specimen Required:**
- **Collect:** Lavender (EDTA), pink (K<sub>2</sub>EDTA), 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

**0051458**  Niemann-Pick Type A (SMPD1), 4 Variants  SMPD1

**Specimen Required:**
- **Collect:** Lavender (EDTA), pink (K<sub>2</sub>EDTA), 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

**2014599**  Non-Alcoholic Fatty Liver Disease Susceptibility (PNPLA3) Genotyping  PNPLA3

**Specimen Required:**
- **Collect:** Lavender (EDTA).
  
  **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. Frozen specimens in glass collection tubes.
  
  **Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

**2005096**  Opiates, Screen Only, Urine  OPI SCR UR

**Specimen Required:**
- **Collect:** Random urine.
  
  **Specimen Preparation:** Transfer 4 mL urine with no additives or preservatives to an ARUP Standard Transport Tube. (Min: 2 mL)
  
  **Storage/Transport Temperature:** Refrigerated.
  
  **Unacceptable Conditions:** Specimens exposed to repeated freeze/thaw cycles.
  
  **Stability (collection to initiation of testing):** Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month

**2005093**  Opiates, Urine Screen with Reflex to Quantitation  OPI RFX UR

**Specimen Required:**
- **Collect:** Random urine.
  
  **Specimen Preparation:** Transfer 4 mL urine with no additives or preservatives to an ARUP Standard Transport Tube. (Min: 2 mL)
  
  **Storage/Transport Temperature:** Refrigerated.
  
  **Unacceptable Conditions:** Specimens exposed to repeated freeze/thaw cycles.
  
  **Stability (collection to initiation of testing):** Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month

**2008767**  Opioid Receptor, mu OPRM1 Genotype, 1 Variant  OPRM1

**Specimen Required:**
- **Collect:** Lavender (EDTA), Pink (K<sub>2</sub>EDTA), 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. Heparinized specimens. Frozen specimens in glass collection tubes.
  
  **Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
New Test  
**3001607**  Osteogenesis Imperfecta and Low Bone Density Panel, Sequencing  
**OI NGS**

**HOTLINE:** Effective May 17, 2021

**Methodology:** Massively Parallel Sequencing  
**Performed:** Varies  
**Reported:** 3-6 weeks

**Specimen Required:**  
- **Collect:** Lavender (EDTA) or Yellow (ACD Solution A or B).  
- **Specimen Preparation:** Transport 3 mL whole blood. (Min: 1.5 mL)  
- **Storage/Transport Temperature:** Refrigerated.  
- **Unacceptable Conditions:** Serum or plasma; grossly hemolyzed or frozen specimens  
- **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: ALPL, ANOS1, BMP1, CASR, CLCN5, COLIA1, COLIA2, CREB3LI, CRTAP, CYP27B1, FKB10, GORAB, IFITM5, LRP5*, P3H1, P4HB, PLOD2, PL53, PP1B, SEC24D, SERPINF1, SERPINH1, SLC34A3, SP7, SPARC, TMEM38B, WNT1  
* One or more exons are not covered by sequencing for the indicated gene; see Additional Technical Information.

**CPT Code(s):** 81405; 81406; 81408; 81479

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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**2005103**  Oxycodone/Oxymorphone Screen Only, Urine  
**OXY SCR UR**

**Specimen Required:**  
- **Collect:** Random urine.  
- **Specimen Preparation:** Transfer 4 mL urine with no additives or preservatives to an ARUP Standard Transport Tube. (Min: 2 mL)  
- **Storage/Transport Temperature:** Refrigerated.  
- **Unacceptable Conditions:** Specimens exposed to repeated freeze/thaw cycles.  
- **Stability (collection to initiation of testing):** Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month

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**2005100**  Oxycodone/Oxymorphone, Urine Screen with Reflex to Quantitation  
**OXY RFX UR**

**Specimen Required:**  
- **Collect:** Random urine.  
- **Specimen Preparation:** Transfer 4 mL urine with no additives or preservatives to an ARUP Standard Transport Tube. (Min: 2 mL)  
- **Storage/Transport Temperature:** Refrigerated.  
- **Unacceptable Conditions:** Specimens exposed to repeated freeze/thaw cycles.  
- **Stability (collection to initiation of testing):** Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month

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**2012265**  Phencyclidine, Urine Screen with Reflex to Quantitation  
**PCP RFX UR**

**Specimen Required:**  
- **Collect:** Random urine.  
- **Specimen Preparation:** Transfer 4 mL urine with no additives or preservatives to an ARUP Standard Transport Tube. (Min: 2 mL)  
- **Storage/Transport Temperature:** Room temperature.  
- **Unacceptable Conditions:** Breast milk.  
- **Stability (collection to initiation of testing):** Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month
<table>
<thead>
<tr>
<th>Test Code</th>
<th>Test Name</th>
<th>Specimen Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004980</td>
<td>Plasminogen Activator Inhibitor-1, PAI-1 (SERPINE1) Genotyping</td>
<td><strong>PAI-1 GENO</strong>&lt;br&gt;<strong>Specimen Required:</strong> Collect: Lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).&lt;br&gt;<strong>Specimen Preparation:</strong> Transport 3 mL whole blood. (Min: 1 mL)&lt;br&gt;<strong>Storage/Transport Temperature:</strong> Refrigerated.&lt;br&gt;<strong>Unacceptable Conditions:</strong> Frozen specimens in glass collection tubes.&lt;br&gt;<strong>Stability (collection to initiation of testing):</strong> Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month</td>
</tr>
<tr>
<td>0030160</td>
<td>Platelet Aggregation Studies</td>
<td><strong>PLTAG</strong>&lt;br&gt;<strong>Specimen Required:</strong> Patient Prep: Instructions will be provided by the ARUP Hemostasis/Thrombosis lab upon receipt of Patient History for Platelet Aggregation Studies form.&lt;br&gt;<strong>Collect:</strong> Specimen collection to be scheduled by the ARUP Hemostasis/Thrombosis lab and performed at the ARUP Family Health Clinic.&lt;br&gt;<strong>Specimen Preparation:</strong> Performed by the ARUP Hemostasis/Thrombosis Lab.&lt;br&gt;<strong>Storage/Transport Temperature:</strong> CRITICAL ROOM TEMPERATURE.&lt;br&gt;<strong>Remarks:</strong> A completed Patient History Form must be submitted to <a href="mailto:Coagulation811@aruplab.com">Coagulation811@aruplab.com</a> and approved prior to scheduling specimen collection. The Patient History Form is available on the ARUP Web site or by contacting ARUP Client Services at (800) 522-2787.&lt;br&gt;<strong>Unacceptable Conditions:</strong> Specimens not scheduled by the ARUP Hemostasis/Thrombosis lab and not collected by ARUP.&lt;br&gt;<strong>Stability (collection to initiation of testing):</strong> Ambient: 1 hour; Refrigerated: Unacceptable; Frozen: Unacceptable</td>
</tr>
<tr>
<td>3001170</td>
<td>Platelet Antigen 1 Genotyping (HPA-1)</td>
<td><strong>HPA-1 GENO</strong>&lt;br&gt;<strong>Specimen Required:</strong> Collect: Fetal Specimen: Amniotic fluid OR cultured amniocytes. If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787.&lt;br&gt;<strong>WITH Maternal Cell Contamination Specimen</strong> (see Note): Lavender (EDTA), Pink (K₂EDTA), or Yellow (ACD Solution A or B).&lt;br&gt;<strong>Parental Specimen:</strong> Lavender (EDTA).&lt;br&gt;<strong>Specimen Preparation:</strong> Amniotic Fluid: Transport 10 mL unspun fluid. (Min: 5 mL)&lt;br&gt;<strong>Cultured Amniocytes:</strong> Transport two T-25 flasks at 80 percent confluence filled with culture media. Backup cultures must be retained at the client's institution until testing is complete.&lt;br&gt;<strong>Maternal Cell Contamination Specimen:</strong> Transport 3 mL whole blood. (Min: 1 mL)&lt;br&gt;<strong>Whole Blood (Parental Genotyping):</strong> Transport 3 mL whole blood. (Min: 1 mL)&lt;br&gt;<strong>Storage/Transport Temperature:</strong> Amniotic Fluid: Room temperature. Cultured Amniocytes: CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of shipment due to liability of cells.&lt;br&gt;<strong>Whole Blood or Maternal Cell Contamination Specimen:</strong> Refrigerated.&lt;br&gt;<strong>Unacceptable Conditions:</strong> Frozen specimens in glass collection tubes.&lt;br&gt;<strong>Stability (collection to initiation of testing):</strong> Fetal Specimen: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable&lt;br&gt;<strong>Whole Blood or Maternal Cell Contamination Specimen:</strong> Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month</td>
</tr>
<tr>
<td>3000193</td>
<td>Platelet Antigen Genotyping Panel</td>
<td><strong>HPA GENO</strong>&lt;br&gt;<strong>Specimen Required:</strong> Collect: Fetal Genotyping: Amniotic fluid OR cultured amniocytes. If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787.&lt;br&gt;<strong>WITH Maternal Cell Contamination Specimen</strong> (see Note): Lavender (EDTA), Pink (K₂EDTA), or Yellow (ACD Solution A or B).&lt;br&gt;<strong>Parental Genotyping:</strong> Lavender (EDTA).&lt;br&gt;<strong>Specimen Preparation:</strong> Amniotic Fluid: Transport 10 mL unspun fluid. (Min: 5 mL)&lt;br&gt;<strong>Cultured Amniocytes:</strong> Transport two T-25 flasks at 80 percent confluence filled with culture media. Backup cultures must be retained at the client's institution until testing is complete.&lt;br&gt;<strong>Maternal Cell Contamination Specimen:</strong> Transport 3 mL whole blood. (Min: 1 mL)&lt;br&gt;<strong>Whole Blood (Parental Genotyping):</strong> Transport 3 mL whole blood. (Min: 1 mL)&lt;br&gt;<strong>Storage/Transport Temperature:</strong> Amniotic Fluid: Room temperature. Cultured Amniocytes: CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of shipment due to liability of cells.&lt;br&gt;<strong>Whole Blood or Maternal Cell Contamination Specimen:</strong> Refrigerated.&lt;br&gt;<strong>Unacceptable Conditions:</strong> Frozen specimens in glass collection tubes.&lt;br&gt;<strong>Stability (collection to initiation of testing):</strong> Fetal Specimen: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable&lt;br&gt;<strong>Whole Blood or Maternal Cell Contamination Specimen:</strong> Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month</td>
</tr>
</tbody>
</table>
**New Test** 3003723  Propoxyphene and Metabolite, Serum or Plasma  PROPOX SP

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Quantitative Gas Chromatography-Mass Spectrometry (GC-MS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performed</td>
<td>Varies</td>
</tr>
<tr>
<td>Reported</td>
<td>8 – 11 days</td>
</tr>
</tbody>
</table>

**Specimen Required:**
- **Collect:** Plain red, Lavender (K₂EDTA or K₃EDTA) or Pink (K₂EDTA).
- **Specimen Preparation:** Separate from cells within 2 hours. Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.7 mL)

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

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

**Unacceptable Conditions:** Separator tubes.

**Stability (collection to initiation of testing):** Ambient: 2 weeks; Refrigerated: 2 weeks; Frozen: 3 months

**Reference Interval:** By report

**Note:** Amitriptyline is a known interference.

**CPT Code(s):** 80367 (Alt code: G0480)

New York DOH Approved.

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

---

**New Test** 3003726  Propoxyphene and Metabolite, Urine  PROPOX U

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Quantitative Gas Chromatography-Mass Spectrometry (GC-MS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performed</td>
<td>Varies</td>
</tr>
<tr>
<td>Reported</td>
<td>8 – 11 days</td>
</tr>
</tbody>
</table>

**Specimen Required:**
- **Collect:** Urine
- **Specimen Preparation:** Transfer 2 mL urine to an ARUP Standard Transport Tube. (Min: 0.7 mL)

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

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

**Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 3 months

**Reference Interval:** By report

**Note:** Amitriptyline is a known interference.

**CPT Code(s):** 80367 (Alt code: G0480)

New York DOH Approved.

**HOTLINE NOTE:** Refer to the Test Mix Addendum for interface build information.
2012269  Propoxyphene, Urine Screen with Reflex to Quantitation  PPXY RFX U

Specimen Required: Collect: Random urine.
Specimen Preparation: Transfer 4 mL urine with no additives or preservatives to an ARUP Standard Transport Tube. (Min: 2 mL)
Storage/Transport Temperature: Room temperature.
Unacceptable Conditions: Breast milk.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month

Note: If the specimen screens positive, then Confirmation/Quantitation by LC-MS/MS (ARUP test code 3003726) will be added to confirm result. Additional charges apply.

HOTLINE NOTE: There is a reflexive pattern change associated with this test.
Add reflex to 3003726, Propoxyphene and Metabolite, Urine
Remove reflex from 2010468, Propoxyphene and Metabolite, Urine, Quantitative

0056060  Prothrombin (F2) c.97G>A (G20210A) Pathogenic Variant  PT PCR

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; collection of specimen in sodium heparin tubes. Frozen specimens in glass collection tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

3001053  Red Blood Cell Antigen Genotyping  RBC GENO

Specimen Required: Collect: Lavender (EDTA)
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum; collection of specimen in sodium heparin tubes. Frozen specimens in glass collection tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

0051368  RhD Gene (RHD) Copy Number  RHD

Specimen Required: Collect: Fetal Genotyping: Amniotic fluid OR two T-25 flasks at 80 percent confluency of cultured amniocytes. If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787. WITH Maternal Cell Contamination Specimen (see Remarks): Lavender (EDTA), pink (K2EDTA), or yellow (ACD Solution A or B).
Parental Genotyping: Lavender (EDTA), pink (K2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Amniotic Fluid: Transport 10 mL unspun fluid. (Min: 5 mL)
Cultured Amniocytes: Fill flasks with culture media. Transport two T-25 flasks at 80 percent confluency of cultured amniocytes filled with culture media. Backup cultures must be retained 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: Room temperature.
Cultured Amniocytes: CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of shipment due to liability 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): 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
**2012618**  
**Risk of Ovarian Malignancy Algorithm**  
**ROMA**

**Specimen Required:** Collect: Serum Separator Tube (SST). Also acceptable: Green (Sodium or Lithium Heparin), Lavender (EDTA), or Pink (K₂ EDTA).

**Specimen Preparation:** Allow specimen to clot completely at room temperature. Transfer 1.5 mL serum to an ARUP Standard Transport Tube. (Min: 1 mL)

**Storage/Transport Temperature:** Frozen.

**Unacceptable Conditions:** Hemolyzed specimens.

**Stability (collection to initiation of testing):** Ambient: 5 hours; Refrigerated: 48 hours; Frozen: 3 months

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**2003382**  
**Ristocetin-Induced Platelet Aggregation**  
**RIPA**

**Specimen Required:**  
- **Patient Prep:** Instructions will be provided by the ARUP Hemostasis/Thrombosis lab upon receipt of Patient History for Platelet Aggregation Studies form.
- **Collect:** Specimen collection to be scheduled by the ARUP Hemostasis/Thrombosis lab and performed at the ARUP Family Health Clinic.

**Specimen Preparation:** Performed by the ARUP Hemostasis/Thrombosis lab.

**Storage/Transport Temperature:** CRITICAL ROOM TEMPERATURE.

**Remarks:** A completed Patient History Form must be submitted to Coagulation811@aruplab.com and approved prior to scheduling specimen collection. The Patient History Form is available on the ARUP Web site or by contacting ARUP Client Services at (800) 522-2787.

**Unacceptable Conditions:** Specimens not scheduled by the ARUP Hemostasis/Thrombosis lab and not collected by ARUP.

**Stability (collection to initiation of testing):** Ambient: 1 hour; Refrigerated: Unacceptable; Frozen: Unacceptable

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**2008426**  
**SLCO1B1, 1 Variant**  
**SLCO1B1**

**Specimen Required:**  
- **Collect:** Lavender (EDTA) or 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. Heparinized specimens. Frozen specimens in glass collection tubes.

**Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
### Stickler Syndrome Panel, Sequencing

**Test Code:** 3001613

**Methodology:** Massively Parallel Sequencing

**Performed:** Varies

**Reported:** 3-6 weeks

**Specimen Required:**
- **Collect:** Lavender (EDTA) or yellow (ACD Solution A or B).
- **Specimen Preparation:** Transport 3 mL whole blood. (Min: 1.5 mL)
- **Storage/Transport Temperature:** Refrigerated.
- **Unacceptable Conditions:** Serum or plasma; grossly hemolyzed or frozen specimens
- **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: COL11A1, COL11A2, COL2A1, COL9A1, COL9A2, COL9A3, VCAN

**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.

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### Tapentadol Urine Screen with Reflex to Quantitation

**Test Code:** 2012294

**Specimen Required:**
- **Collect:** Random urine.
- **Specimen Preparation:** Transfer 4 mL urine with no additives or preservatives to an ARUP Standard Transport Tube. (Min: 2 mL)
- **Storage/Transport Temperature:** Room temperature.
- **Unacceptable Conditions:** Breast milk. Pharmaceutical preparation. Specimens exposed to repeated freeze/thaw cycles.
- **Stability (collection to initiation of testing):** Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month

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### Tay-Sachs Disease (HEXA), 7 Variants

**Test Code:** 0051428

**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:** 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
### New Test 3003407 TDP43 by Immunohistochemistry  
TDP43 IHC

**Available Now**

**Click for Pricing**

**Methodology:** Immunohistochemistry

**Performed:** Mon-Fri

**Reported:** 1-3 days

**Specimen Required:**
- **Collect:** Tissue.
- **Specimen Preparation:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3-5 micron thick sections), positively charged slides in a tissue transport kit, recommended but not required. ARUP supply #47808 available online through eSupply using ARUP Connect or contact ARUP Client Services at (800) 522-2787. (Min: 2 slides) If sending precut slides, do not oven bake.
- **Storage/Transport Temperature:** Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
- **Unacceptable Conditions:** Specimens submitted with non-representative tissue type. Depleted specimens.
- **Stability (collection to initiation of testing):** Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

**Interpretive Data:**

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

**Note:** 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.

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### New Test 3003595 TCL1 by Immunohistochemistry  
TCL1 IHC

**Available Now**

**Click for Pricing**

**Methodology:** Immunohistochemistry

**Performed:** Mon-Fri

**Reported:** 1-3 days

**Specimen Required:**
- **Collect:** Tissue.
- **Specimen Preparation:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3-5 micron thick sections), positively charged slides in a tissue transport kit, recommended but not required. ARUP supply #47808 available online through eSupply using ARUP Connect or contact ARUP Client Services at (800) 522-2787. (Min: 2 slides) If sending precut slides, do not oven bake.
- **Storage/Transport Temperature:** Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
- **Unacceptable Conditions:** Specimens submitted with non-representative tissue type. Depleted specimens.
- **Stability (collection to initiation of testing):** Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

**Interpretive Data:**

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

**Note:** 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.
2012270  THC (Cannabinoids), Urine Screen with Reflex to Quantitation  THC RFX U

**Specimen Required:**

Collect: Random urine.

**Specimen Preparation:** Transfer 4 mL urine with no additives or preservatives to an ARUP Standard Transport Tube. (Min: 2 mL)

**Storage/Transport Temperature:** Room temperature.

**Unacceptable Conditions:** Breast milk.

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

0056200  Thrombotic Risk, DNA Panel  THROMDNA

**Specimen Required:**

Collect: Lavender (EDTA), pink (K2 EDTA) or yellow (ACD Solution A or B).

**Specimen Preparation:** Transport 4 mL whole blood. (Min: 3 mL)

**Storage/Transport Temperature:** Refrigerated.

**Unacceptable Conditions:** Plasma or serum; collection of specimen in sodium heparin tubes. Frozen specimens in glass collection tubes.

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

3001535  TPMT and NUDT15  TPMT2

**Specimen Required:**

Collect: Lavender (EDTA), Pink (K2 EDTA), or Yellow (ACD Solution A or B).

**Specimen Preparation:** Transport 3 mL whole blood. (Min: 1 mL) OR Transport the Saliva Collection Device.

**Storage/Transport Temperature:** Refrigerated.

**Unacceptable Conditions:** Plasma or serum. Specimens collected in sodium heparin or lithium heparin. Frozen specimens in glass collection tubes.

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

2012297  Tramadol, Urine Screen with Reflex to Quantitation  TRAM RFX U

**Specimen Required:**

Collect: Random urine.

**Specimen Preparation:** Transfer 4 mL urine with no additives or preservatives to an ARUP Standard Transport Tube. (Min: 2 mL)

**Storage/Transport Temperature:** Refrigerated.

**Unacceptable Conditions:** Pharmaceutical preparation. Specimens exposed to repeated freeze/thaw cycles.

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

Reference Interval:

Effective May 17, 2021

Screen Cutoff concentration 100 ng/mL

2013750  Usher Syndrome, Types 1F and 3 (PCDH15 and CLRN1), 2 Variants  USHER

**Specimen Required:**

Collect: Lavender (EDTA), pink (K2 EDTA), 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
New Test 123456 Vaginitis Panel by TMA VPAN TMA

Methodology: Qualitative Transcription-Mediated Amplification
Performed: Tue, Thu, Sat
Reported: 1-4 days

Specimen Required: Patient Prep: Patient must be 14 years of age or older.
Collect: Vaginal specimen collected with pink swab from Aptima MultiTest Swab Collection kit
Specimen Preparation: Place swab in MultiTest Swab Specimen Transport Tube, break shaft at scoreline, then recapture tube.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Specimens in any transport media other than indicated above. Specimen in MultiTest swab transport media without a swab.
Stability (collection to initiation of testing): Ambient: 30 days; Refrigerated: 30 days; Frozen: 90 days

Reference Interval:

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<th>Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
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</thead>
<tbody>
<tr>
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<td>Bacterial Vaginosis by Transcription-mediated Amplification (TMA)</td>
<td>Negative</td>
</tr>
<tr>
<td>3002583</td>
<td>Candida glabrata, Candida species, and Trichomonas vaginalis by Transcription-mediated Amplification (TMA)</td>
<td>Negative</td>
</tr>
</tbody>
</table>

Interpretive Data:
See report

CPT Code(s): 81513, 87481, 87661

New York DOH Approved.

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

New Test 123456 Vedolizumab Quantitation with Antibodies, Serum VEDOL AB

Methodology: Quantitative Liquid Chromatography/Mass Spectrometry (LC-MS/MS)/Electrochemiluminescent Immunoassay
Performed: Varies
Reported: 7-17 days

Specimen Required: Patient Prep: 12 hours prior to specimen collection discontinue multivitamins or dietary supplements containing biotin (vitamin B7), commonly found in hair, skin, and nail supplements. Nivolumab (Opdivo) must be discontinued at least 4 weeks prior to testing.
Collect: Plain red. Also acceptable: Serum separator tube (SST). Collect immediately before or within 2 hours of collection. Transfer 1.5 mL serum to an ARUP Standard Transport Tube. (Min: 0.75 mL).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1.5 mL serum to an ARUP Standard Transport Tube. (Min: 0.75 mL).
Test is not performed at ARUP; separate specimens must be submitted when multiple tests are ordered.
Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 28 days; Frozen: 28 days

Reference Interval: By Report

CPT Code(s): 80280; 82397

New York DOH Approved.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.
**HOTLINE: Effective May 17, 2021**

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**Warfarin Sensitivity (CYP2C8, CYP2C9, CYP4F2, VKORC1) Genotyping**

**Specimen Required:**
- **Collect:** Lavender (EDTA), Pink (K$_2$EDTA), or Yellow (ACD Solution A or B).
- **Specimen Preparation:** Transport 3 mL whole blood. (Min: 1 mL) OR Transport the Saliva Collection Device.
- **Storage/Transport Temperature:** Refrigerated.
- **Unacceptable Conditions:** Plasma or serum. Specimens collected in sodium heparin or lithium heparin. Frozen specimens in glass collection tubes.
- **Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

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**X-Chromosome Inactivation Analysis**

**Specimen Required:**
- **Collect:** Lavender (EDTA), pink (K$_2$EDTA), or yellow (ACD Solution A or B).
- **Specimen Preparation:** Transport 3 mL whole blood. (Min: 1 mL.)
- **Storage/Transport Temperature:** Refrigerated.
- **Stability (collection to initiation of testing):** Ambient: 1 week; Refrigerated: 1 week; Frozen: Unacceptable

**Interpretive Data:**
- **Characteristics:** Females usually have two copies of the X-chromosome, one of which becomes randomly inactivated early in embryonic development in a process known as lyonization. If either the paternally or maternally derived X-chromosome is preferentially inactivated, this results in a nonrandom or "skewed" pattern of X-chromosome inactivation (XCI). The pattern of XCI may vary among tissue types. XCI ratios of 50:50 to 74:26 suggest random XCI, ratios greater than 85:15 suggest nonrandom XCI, and ratios from 75:25 to 85:15 should be interpreted with caution.
- **Cause:** Nonrandom XCI may result by chance or from secondary cell selection in females who are heterozygous for X-chromosome rearrangements, carriers of pathogenic variants in X-linked genes, or affected with neoplastic disease.
- **Gene Tested:** The androgen receptor (AR) gene on the X chromosome.
- **Clinical Sensitivity:** Approximately 90 percent. An estimated 10-15 percent of females have skewed X-inactivation by chance. However, skewed XCI may be seen more frequently with increasing age.
- **Methodology:** Methylation-sensitive restriction digest followed by PCR and fragment analysis.
- **Limitations:** Testing is limited to XX females only. This assay will be uninformative in up to 20 percent of females due to homozygosity for the polymorphic AR gene locus analyzed. XCI patterns may differ among tissues; therefore, the XCI ratio reported is for the tissue type tested with a standard deviation 0.08 for XCI ratios of 50:50-79:50; 0.05 for XCI ratios 80:20 or greater. Although this test will detect the methylation status of the X-chromosomes, it will not determine if the X-inactivation pattern is associated with rearrangements of the X chromosome, pathogenic variants in X-linked genes or neoplastic disease. If a nonrandom XCI pattern is present, the parent of origin of the active X cannot be determined without testing parental samples. XCI ratios should not be used to predict prognosis for female carriers of X-linked disorders as variable expressivity may result due to other genetic or environmental modifiers. Because the level of XCI may differ in prenatal specimens and whole blood, this test is not recommended for prenatal diagnosis. Diagnostic errors can occur due to rare sequence variations.
New Test: Zinc, Red Blood Cells (ZN RBC)

Methodology: Quantitative Inductively Coupled Plasma-Mass Spectrometry
Performed: Sun-Sat
Reported: 1-4 days

Specimen Required: Collect: Royal Blue (EDTA).

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

Unacceptable Conditions: Specimens collected in tubes other than royal blue (EDTA). Specimens transported in containers other than Royal Blue (EDTA) tube or Trace Element-Free Transport Tube. Clotted or grossly hemolyzed specimens.

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

Reference Interval: 794.0-1470.0 mcg/dL

Interpretive Data:
Zinc concentrations in RBCs reflect the intracellular stores and general homeostasis of Zinc. Results may be falsely low if RBCs in the submitted specimen are lysed or not promptly separated from plasma.

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

CPT Code(s): 84630

New York DOH approval pending. Call for status update.

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

New Test: Zolpidem Urine with Reflex to Quantitation (ZOLP RFX U)

Specimen Required: Collect: Random urine.

Storage/Transport Temperature: Room temperature.

Unacceptable Conditions: Samples collected in tube with additives or preservatives.

Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 month; Frozen: 1 month
The following will be discontinued from ARUP's test menu on May 17, 2021.
Replacement test options are supplied if applicable.

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<td>Human Immunodeficiency Virus 1 (HIV-1) by Qualitative NAAT (3003760)</td>
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<td>Reti Syndrome (MECP2), Full Gene Sequencing</td>
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<td>Smith-Lemli-Opitz Syndrome (DHCR7) Sequencing, Fetal</td>
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<tr>
<td>2002001</td>
<td>Very Long-Chain Acyl-CoA Dehydrogenase Deficiency (ACADVL) Sequencing</td>
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