MEDICARE COVERAGE OF LABORATORY TESTING

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

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

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

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

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| 0051265       | Achondroplasia (FGFR3) 2 Mutations, Fetal | AD PCR FE |

**Performed:** Varies

**Reported:** 2-7 days

**Specimen Required:**
- **Collect:** Fetal specimen: **Cultured amniocytes:** Two T-25 flasks at 80 percent confluency.
- **OR cultured CVS:** Two T-25 flasks at 80 percent confluency.
- If the client is unable to culture amniocytes or CVS, this can be arranged by contacting ARUP Client Services at (800) 522-2787.
- **AND maternal cell contamination specimen:** Lavender (EDTA), pink (K2EDTA), or yellow (ACD Solution A or B).
- **Specimen Preparation:** Cultured amniocytes **AND cultured CVS:** Transport two T-25 flasks at 80 percent confluency filled with culture media. Backup cultures must be retained at the client's institution until testing is complete.
- **Maternal cell contamination specimen:** Transport 3 mL whole blood. (Min: 1 mL)
- **Storage/Transport Temperature:** **Cultured amniocytes and cultured CVS:** CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of shipment due to lability of cells.
- **Maternal cell contamination specimen:** Refrigerated.

**Remarks:** Maternal specimen is recommended for proper test interpretation. Order Maternal Cell Contamination, Maternal Specimen. Please contact an ARUP genetic counselor at 800-242-2787 x2141 prior to sample submission. Patient History Form is available on the ARUP Web site or by contacting ARUP Client Services.

**Unacceptable Conditions:** Frozen specimens in glass collection tubes.
- **Stability (collection to initiation of testing):** **Cultured amniocytes and cultured CVS:** Room Temperature: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
- **Maternal cell contamination specimen:** Room Temperature: 72 hours; Refrigerated: 1 week; Frozen: 1 month
**HOTLINE: Effective September 7, 2021**

### **0091328** Acyclovir, Serum or Plasma

**Methodology:** Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry (HPLC-MS/MS)

**Specimen Required:**
- **Collect:** Plain red, Lavender (K₂ EDTA), or Pink (K₂ EDTA).
- **Specimen Preparation:** Separate serum or plasma from cells within 2 hours. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.2 mL)
- **Test is not performed at ARUP; separate specimens must be submitted when multiple tests are ordered.**
- **Storage/Transport Temperature:** Refrigerated. Also acceptable: Room temperature and frozen.
- **Unacceptable Conditions:** Separator tubes.
- **Stability (collection to initiation of testing):** Ambient: 1 month; Refrigerated: 1 month; Frozen: 4 month

### **3003656** Alpha Thalassemia (HBA1 and HBA2) Deletion/Duplication with reflex to Hb Constant Spring, Fetal

**Specimen Required:**
- **Collect:** Cultured amniocytes or cultured CVS
  - **AND** Maternal Whole Blood Specimen: Lavender (EDTA), Pink (K₂ EDTA), or Yellow (ACD Solution A or B).
- **Specimen Preparation:** Cultured Amniocytes or cultured CVS. Transfer cultured amniocytes or cultured CVS to two T-25 flasks at 80 percent confluence. (Min: one T-25 flask at 80% confluence). Backup cultures must be retained at the client's institution until testing is complete. If the client is unable to culture amniocytes or CVS, this can be arranged by contacting ARUP Client Services at (800) 522-2787 ext. 2141 prior to test submission.
- **Maternal Whole Blood Specimen:** Transport 2 mL whole blood. (Min: 1 mL)
- **Storage/Transport Temperature:** Cultured Amniocytes or CVS: CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of collection due to viability of cells.
- **Maternal Whole Blood Specimen:** Room temperature.
- **Remarks:** Please contact an ARUP genetic counselor at 800-242-2787 ext. 2141 prior to sample submission. Patient History Form is available on the ARUP Web site or by contacting ARUP Client Services at (800) 522-2787.
- **Stability (collection to initiation of testing):** Cultured Amniocytes or cultured CVS: Room temperature: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
- **Maternal Whole Blood Specimen:** Room temperature: 7 days; Refrigerated: 1 month; Frozen: Unacceptable

### **2008682** Anabolic Steroids, Urine - Screen with Reflex to Confirmation

**CPT Code(s):** 80307; 82570; if positive add 80328 (Alt code: if positive add G0480)

### **2012232** Angelman Syndrome and Prader-Willi Syndrome by Methylation-Sensitive PCR, Fetal

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

**Specimen Required:**
- **Collect:** Contact ARUP’s genetic counselors at (800) 242-2787 extension 2141 prior to submission for specimen requirements and submission information.

**HOTLINE NOTE:** Remove information found in the Specimen Preparation, Storage/Transport Temperature, Remarks, Unacceptable Conditions, and Stability fields.
**Specimen Required:**
Collect: **Fetal Specimen:** Two T-25 flasks at 80% confluent of Cultured Amniocytes or Cultured Chorionic Villus Sampling (CVS).

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

**Specimen Preparation:**
**Cultured Amniocytes or Cultured CVS:** Fill flasks with culture media. Transport two T-25 flasks at 80% confluent of cultured amniocytes or cultured CVS filled with culture media. Backup cultures must be retained at the client's institution until testing is complete.

**AND Maternal Specimen:** Transport 2 mL whole blood. (Min: 1 mL) Lavender (EDTA), Pink (K$_2$EDTA), or Yellow (ACD Solution A or B).

**Storage/Transport Temperature:** Critical room temperature. Must be received within 48 hours of shipment due to liability of cells.

**Maternal Specimen:**
- Cultured Amniocytes or Cultured CVS: Critical 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.
- Stability (collection to initiation of testing): 
  - **Fetal Specimen:** Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
  - **Maternal Specimen:** Ambient: 1 week; Refrigerated: 1 month

**Reference Interval:**
- By report

**Interpretive Data:**
- By 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.

### Comprehensive Systemic Sclerosis Panel

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>0050599</td>
<td>Scleroderma (Scl-70) (ENA) Antibody, IgG</td>
<td>29 AU/mL or less: Negative; 30-40 AU/mL: Equivocal; 41 AU/mL or greater: Positive</td>
</tr>
<tr>
<td>0050470</td>
<td>Smith/RNP (ENA) Antibody, IgG</td>
<td>Effective September 7, 2021</td>
</tr>
<tr>
<td></td>
<td>19 Units or less: Negative; 20 to 39 Units: Weak Positive; 40 to 80 Units: Moderate Positive; 81 Units or greater: Strong Positive</td>
<td></td>
</tr>
<tr>
<td>3000082</td>
<td>Antinuclear Antibody (ANA) with HEP-2 Substrate, IgG by IFA</td>
<td>Less than 1:80</td>
</tr>
<tr>
<td>2012173</td>
<td>Fibrillarin (U3 RNP) Antibody, IgG</td>
<td>Negative</td>
</tr>
<tr>
<td>2003040</td>
<td>PM/Scl-100 Antibody, IgG by Immunoblot</td>
<td>Negative</td>
</tr>
<tr>
<td>2001601</td>
<td>RNA Polymerase III Antibody, IgG</td>
<td>19 Units or less: Negative; 20-39 Units: Weak Positive; 40-80 Units: Moderate Positive; 81 Units or greater: Strong Positive</td>
</tr>
</tbody>
</table>

**HOTLINE NOTE:** There is a unit of measure change associated with this test.
Change the unit of measure for component 0050470, Smith/RNP (ENA) Ab, IgG from AU/mL to Units.
### 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>
</tr>
<tr>
<td>2002693</td>
<td>dsDNA (Double Stranded DNA) Antibody, IgG</td>
<td>Refer to report</td>
</tr>
<tr>
<td></td>
<td>Double-Stranded DNA (dsDNA) Antibody, IgG by IFA (using Crithidia luciliae)</td>
<td>Refer to report</td>
</tr>
<tr>
<td>0050470</td>
<td>Smith/RNP (ENA) Antibody, IgG</td>
<td>Effective September 7, 2021</td>
</tr>
<tr>
<td></td>
<td>19 Units or less</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>20 to 39 Units</td>
<td>Weak Positive</td>
</tr>
<tr>
<td></td>
<td>40 to 80 Units</td>
<td>Moderate Positive</td>
</tr>
<tr>
<td></td>
<td>81 Units or greater</td>
<td>Strong Positive</td>
</tr>
<tr>
<td>0050085</td>
<td>Smith (ENA) Antibody, IgG</td>
<td>29 AU/mL or less</td>
</tr>
<tr>
<td></td>
<td>30-40 AU/mL</td>
<td>Equivocal</td>
</tr>
<tr>
<td></td>
<td>41 AU/mL or greater</td>
<td>Positive</td>
</tr>
<tr>
<td>2012074</td>
<td>SSA 52 and 60 (Ro) (ENA) Antibodies, IgG</td>
<td>29 AU/mL or less</td>
</tr>
<tr>
<td></td>
<td>30-40 AU/mL</td>
<td>Equivocal</td>
</tr>
<tr>
<td></td>
<td>41 AU/mL or greater</td>
<td>Positive</td>
</tr>
<tr>
<td>0050692</td>
<td>SSB (La) (ENA) Antibody, IgG</td>
<td>29 AU/mL or less</td>
</tr>
<tr>
<td></td>
<td>30-40 AU/mL</td>
<td>Equivocal</td>
</tr>
<tr>
<td></td>
<td>41 AU/mL or greater</td>
<td>Positive</td>
</tr>
<tr>
<td>0099592</td>
<td>Jo-1 Antibody, IgG</td>
<td>29 AU/mL or less</td>
</tr>
<tr>
<td></td>
<td>30-40 AU/mL</td>
<td>Equivocal</td>
</tr>
<tr>
<td></td>
<td>41 AU/mL or greater</td>
<td>Positive</td>
</tr>
<tr>
<td>0050599</td>
<td>Scleroderma (Scl-70) (ENA) Antibody, IgG</td>
<td>29 AU/mL or less</td>
</tr>
<tr>
<td></td>
<td>30-40 AU/mL</td>
<td>Equivocal</td>
</tr>
<tr>
<td></td>
<td>41 AU/mL or greater</td>
<td>Positive</td>
</tr>
</tbody>
</table>

**HOTLINE NOTE:** There is a unit of measure change associated with this test. Change the unit of measure for component 0050470, Smith/RNP (ENA) Ab, IgG from AU/mL to Units.
### Connective Tissue Diseases Profile

**Methodology:**
- Semi-Quantitative Enzyme-Linked Immunosorbent Assay
- Semi-Quantitative Multiplex Bead Assay

**Reference Interval:** Effective May 18, 2015

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>0050085</td>
<td>Smith (ENA) Antibody, IgG</td>
<td>29 AU/mL or less: Negative; 30-40 AU/mL: Equivocal; 41 AU/mL or greater: Positive</td>
</tr>
<tr>
<td>0050470</td>
<td>Smith/RNP (ENA) Antibody, IgG</td>
<td>Effective September 7, 2021; 19 Units: Negative; 20 to 39 Units: Weak Positive; 40 to 80 Units: Moderate Positive; 81 Units or greater: Strong Positive</td>
</tr>
<tr>
<td>2012074</td>
<td>SSA 52 and 60 (Ro) (ENA) Antibodies, IgG</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>SSA-60 (Ro60) (ENA) Antibody, IgG</td>
</tr>
<tr>
<td>0050692</td>
<td>SSB (La) (ENA) Antibody, IgG</td>
<td>29 AU/mL or less: Negative; 30-40 AU/mL: Equivocal; 41 AU/mL or greater: Positive</td>
</tr>
<tr>
<td>0099592</td>
<td>Jo-1 Antibody, IgG</td>
<td>29 AU/mL or less: Negative; 30-40 AU/mL: Equivocal; 41 AU/mL or greater: Positive</td>
</tr>
<tr>
<td>0099249</td>
<td>Ribosomal P Protein Antibody</td>
<td>29 AU/mL or less: Negative; 30-40 AU/mL: Equivocal; 41 AU/mL or greater: Positive</td>
</tr>
<tr>
<td>0050714</td>
<td>Centromere Antibody, IgG</td>
<td>29 AU/mL or less: Negative; 30-40 AU/mL: Equivocal; 41 AU/mL or greater: Positive</td>
</tr>
<tr>
<td>0050599</td>
<td>Scleroderma (Scl-70) (ENA) Antibody, IgG</td>
<td>29 AU/mL or less: Negative; 30-40 AU/mL: Equivocal; 41 AU/mL or greater: Positive</td>
</tr>
</tbody>
</table>

**HOTLINE NOTE:** There is a unit of measure change associated with this test. Change the unit of measure for component 0050470, Smith/RNP (ENA) Ab, IgG from AU/mL to Units.
**Specimen Required:**
- **COVID-19 IgG (Spike), Semi-Quantitative by CIA**
  - **COV19G SQ**
  - **Collect:** Serum separator tube (SST). Also acceptable: lithium heparin.
  - **Specimen Preparation:** Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)
  - **Storage/Transport Temperature:** Refrigerated.
  - **Unacceptable Conditions:** Specimens containing particulate material or otherwise obviously contaminated. Severely hemolyzed, heat-inactivated, severely icteric or lipemic specimens.
  - **Stability (collection to initiation of testing):** After separation from cells: Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month (avoid repeated freeze/thaw cycles)

**Specimen Required:**
- **C-Peptide, 120 Minutes**
  - **C PEP 120**
  - **Patient Prep:** Fasting specimen preferred.
  - **Collect:** Serum Separator Tube (SST)
  - **Specimen Preparation:** Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transport 1 mL serum to an ARUP Standard Transport Tube.
  - **Storage/Transport Temperature:** Frozen.
  - **Unacceptable Conditions:** Grossly hemolyzed specimens.
  - **Stability (collection to initiation of testing):** After separation from cells: Ambient: 8 hours; Refrigerated: 7 days; Frozen: 1 month

**Specimen Required:**
- **C-Peptide, 180 Minutes**
  - **C PEP 180**
  - **Patient Prep:** Fasting specimen preferred.
  - **Collect:** Serum Separator Tube (SST)
  - **Specimen Preparation:** Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transport 1 mL serum to an ARUP Standard Transport Tube.
  - **Storage/Transport Temperature:** Frozen.
  - **Unacceptable Conditions:** Grossly hemolyzed specimens.
  - **Stability (collection to initiation of testing):** After separation from cells: Ambient: 8 hours; Refrigerated: 7 days; Frozen: 1 month

**Specimen Required:**
- **C-Peptide, 30 Minutes**
  - **C PEP 30**
  - **Patient Prep:** Fasting specimen preferred.
  - **Collect:** Serum Separator Tube (SST)
  - **Specimen Preparation:** Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transport 1 mL serum 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):** After separation from cells: Ambient: 8 hours; Refrigerated: 7 days; Frozen: 1 month

**Specimen Required:**
- **C-Peptide, 60 Minutes**
  - **C PEP 60**
  - **Patient Prep:** Fasting specimen preferred.
  - **Collect:** Serum Separator Tube (SST)
  - **Specimen Preparation:** Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transport 1 mL serum 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):** After separation from cells: Ambient: 8 hours; Refrigerated: 7 days; Frozen: 1 month
Specimen Required: Patient Prep: Fasting specimen preferred.
Collect: Serum Separator Tube (SST)
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transport 1 mL serum in an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Grossly hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 7 days; Frozen: 1 month

Interpretive Data:
The reference interval for fasting c-peptide is 0.5-3.3 ng/mL. To convert to nmol/L, multiply ng/mL by 0.33.

Specimen Required: Collect: Cultured amniocytes or Cultured CVS
AND Maternal Whole Blood Specimen: Lavender (EDTA), pink (K$_2$EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Cultured Amniocytes or Cultured CVS: Transfer cultured amniocytes or cultured CVS to two T-25 flasks at 80 percent confluence. (Min: one T-25 flask at 80% confluence). Backup cultures must be retained at the client's institution until testing is complete. If the client is unable to culture amniocytes or CVS, this can be arranged by contacting ARUP Client Services at (800) 522-2787. Please contact an ARUP genetic counselor at (800) 242-2787 ext. 2141 prior to test submission.
Maternal Whole Blood Specimen: Transport 2 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Cultured Amniocytes or Cultured CVS: CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of collection due to viability of cells.
Maternal Whole Blood Specimen: Room temperature.
Remarks: Please contact an ARUP genetic counselor at (800) 242-2787 ext. 2141 prior to sample submission. Patient History Form is available on the ARUP Web site or by contacting ARUP Client Services at (800) 522-2787.
Stability (collection to initiation of testing): Cultured Amniocytes or Cultured CVS: Room temperature: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Maternal Whole Blood Specimen: Room temperature: 7 days; Refrigerated: 1 month; Frozen: Unacceptable
**3001781**  
Extended Myositis Panel  
MYOS EXT

**Methodology:**  
Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Qualitative Immunoprecipitation/Semi-Quantitative Multiplex Bead Assay/Qualitative Immunoblot

**Reference Interval:**

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012074</td>
<td>SSA 52 and 60 (Ro) (ENA) Antibodies, IgG</td>
<td></td>
</tr>
</tbody>
</table>
|             | SSA-52 (Ro52) (ENA) Antibody, IgG | 29 AU/mL or less: Negative  
30-40 AU/mL: Equivocal  
41 AU/mL or greater: Positive |
|             | SSA-60 (Ro60) (ENA) Antibody, IgG | 29 AU/mL or less: Negative  
30-40 AU/mL: Equivocal  
41 AU/mL or greater: Positive |
| 0050470     | Smith/RNP (ENA) Antibody, IgG | Effective September 7, 2021  
19 Units or less | Negative  
20 to 30 Units | Weak Positive  
40 to 80 Units | Moderate Positive  
81 Units or greater | Strong Positive |
| 0099592     | Jo-1 Antibody, IgG | 29 AU/mL or less | Negative  
30-40 AU/mL | Equivocal  
41 AU/mL or greater | Positive |
| 2012173     | Fibrillarin (U3 RNP) Antibody, IgG | Negative |
| 2003040     | PM/Scl-100 Antibody, IgG by Immunoblot | Negative |
| Mi-2 (nuclear helicase protein) Antibody | Negative |
| PL-7 (threonyl-tRNA synthetase) Antibody | Negative |
| PL-12 (alanyl-tRNA synthetase) Antibody | Negative |
| P155/140 Antibody | Negative |
| EL (glycyl-tRNA synthetase) Antibody | Negative |
| Ku Antibody | Negative |
| SRP (Signal Recognition Particle) Ab | Negative |
| OJ (isoleucyl-tRNA synthetase) Antibody | Negative |
| SAE1 (SUMO activating enzyme) Ab | Negative |
| MDA5 (CADM-140) Ab | Negative |
| NX2P2 (Nuclear matrix protein-2) Ab | Negative |
| TIF-1 gamma (155 kDa) Ab | Negative |

**HOTLINE NOTE:** There is a unit of measure change associated with this test.  
Change the unit of measure for component 0050470, Smith/RNP (ENA) Ab, IgG from AU/mL to Units.
## Extractable Nuclear Antigen Antibodies (Smith/RNP, Smith, SSA 52, SSA 60, and SSB)

### Methodology:
- Semi-Quantitative Enzyme-Linked Immunosorbent Assay
- Semi-Quantitative Multiplex Bead Assay

### Reference Interval:
Effective May 18, 2015

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>0050470</td>
<td>Smith/RNP (ENA) Antibody, IgG</td>
<td>Effective September 7, 2021</td>
</tr>
<tr>
<td></td>
<td>19 Units or less</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>20 to 29 Units</td>
<td>Weak Positive</td>
</tr>
<tr>
<td></td>
<td>40 to 80 Units</td>
<td>Moderate Positive</td>
</tr>
<tr>
<td></td>
<td>81 Units or greater</td>
<td>Strong Positive</td>
</tr>
<tr>
<td>0050085</td>
<td>Smith (ENA) Antibody, IgG</td>
<td>29 AU/mL or less: Negative</td>
</tr>
<tr>
<td></td>
<td>30-40 AU/mL: Equivocal</td>
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</tr>
<tr>
<td></td>
<td>41 AU/mL or greater: Positive</td>
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</tr>
<tr>
<td>2012074</td>
<td>SSA 52 and 60 (Ro) (ENA) Antibodies, IgG</td>
<td>SSA-52 (Ro52) (ENA) Antibody, IgG</td>
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<td></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>41 AU/mL or greater: Positive</td>
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<tr>
<td></td>
<td>SSA-60 (Ro60) (ENA) Antibody, IgG</td>
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<td>30-40 AU/mL: Equivocal</td>
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</tr>
<tr>
<td></td>
<td>41 AU/mL or greater: Positive</td>
<td></td>
</tr>
<tr>
<td>0050692</td>
<td>SSB (La) (ENA) Antibody, IgG</td>
<td>29 AU/mL or less: Negative</td>
</tr>
<tr>
<td></td>
<td>30-40 AU/mL: Equivocal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>41 AU/mL or greater: Positive</td>
<td></td>
</tr>
</tbody>
</table>

### HOTLINE NOTE:
There is a unit of measure change associated with this test.
Change the unit of measure for component 0050470, Smith/RNP (ENA) Ab, IgG from AU/mL to Units.

## Familial Mutation, Targeted Sequencing

### Specimen Required:
Collect: Contact ARUP's genetic counselor at (800) 242-2787 extension 2141 prior to test submission for specimen requirements and submission information.

**Remarks:** Documentation of the familial gene variant(s) is required to perform targeted sequencing. Submit a copy of a relative's laboratory test report documenting the gene and specific variant(s) for which testing is requested. Submit a positive control with the patient specimen for appropriate interpretation, order Sequencing Control (test code 0051650). Samples tested without a familial positive control may be subject to a disclaimer. Testing will begin upon receipt of all necessary components, including an original laboratory report detailing the familial variant(s) to be tested and a familial positive control sample.

### Interpretive Data:
By 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.

### CPT Code(s):
Varies by gene

### HOTLINE NOTE:
Remove information found in the Note field.
**Familial Mutation, Targeted Sequencing, Fetal**

**Specimen Required:** Collect: Contact ARUP’s genetic counselors at (800) 242-2787 extension 2141 prior to test submission for specimen requirements and submission information.

**Remarks:** Documentation of the familial gene variant(s) is required to perform targeted sequencing. Submit a copy of a relative's laboratory test report documenting the gene and specific variant(s) for which testing is requested. Submit a positive control with the patient specimen for appropriate interpretation, order Sequencing Control. Fetal samples tested without a familial positive control may be subject to a disclaimer.

A maternal specimen is recommended for proper fetal test interpretation. Order Maternal Cell Contamination, Maternal Specimen. Testing will begin upon receipt of all necessary components, including: an original laboratory report detailing the familial variant(s) to be tested, a maternal specimen for maternal cell contamination testing, and a familial positive control sample.

**Interpretive Data:** By 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.

**CPT Code(s):** Varies by gene; 81265 Fetal Cell Contamination.

**HOTLINE NOTE:** Remove information found in the Note, Specimen Preparation, and Stability fields.

---

**Fragile X (FMRI) with Reflex to Methylation Analysis, Fetal**

**Specimen Required:** Collect: **Cultured Amniocytes or Cultured CVS AND Maternal Whole Blood Specimen:** Lavender (EDTA), pink (K<sub>2</sub>EDTA), or yellow (ACD Solution A or B).

**Specimen Preparation:** **Cultured Amniocytes or Cultured CVS:** Transfer cultured amniocytes or cultured CVS to two T-25 flasks at 80 percent confluence (Min: one T-25 flask at 80% confluence). Backup cultures must be retained at the client's institution until testing is complete. **If the client is unable to culture amniocytes or CVS, this can be arranged by contacting ARUP Client Services at (800) 522-2787. Please contact an ARUP genetic counselor at (800) 242-2787 ext. 2141 prior to test submission.**

**Maternal Whole Blood Specimen:** Transport 2 mL whole blood. (Min: 1 mL)

**Storage/Transport Temperature:** **Cultured Amniocytes or Cultured CVS:** CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of collection due to viability of cells. **Maternal Whole Blood Specimen:** Room temperature.

**Remarks:** Please contact an ARUP genetic counselor at (800) 242-2787 ext. 2141 prior to sample submission. **Patient History Form** is available on the ARUP Web site or by contacting ARUP Client Services at (800) 522-2787.

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

**Maternal Whole Blood Specimen:** Room temperature: 7 days; Refrigerated: 1 month; Frozen: Unacceptable
Patient History for Fetal Molecular Testing

Additional Technical Information

Time Sensitive

Methodology: Polymerase Chain Reaction/Single Nucleotide Extension

Specimen Required:

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

Specimen Preparation: Cultured Amniocytes or Cultured CVS: Transfer cultured amniocytes or cultured CVS to two T-25 flasks at 80% confluence. (Min: one T-25 flask at 80% confluence). Backup cultures must be retained at the client’s institution until testing is complete. If the client is unable to culture amniocytes or CVS, this can be arranged by contacting ARUP Client Services at (800) 522-2787. Please contact an ARUP genetic counselor at (800) 242-2787 ext. 2141 prior to test submission.

Amniotic Fluid (direct): 10 milliliters

Maternal Whole Blood Specimen: 2 mL whole blood (Min: 1 mL).

Storage/Transport Temperature: Cultured Amniocytes or Cultured CVS: CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of collection due to viability of cells.

Amniotic fluid (direct): Room temperature.

Maternal Whole Blood Specimen: Room temperature.

Remarks: Please contact an ARUP genetic counselor at (800) 242-2787 ext. 2141 prior to sample submission. Patient History Forms are available on aruplab.com or by contacting ARUP Client Services at (800) 522-2787.

Stability (collection to initiation of testing):

Cultured Amniocytes or Cultured CVS: Room temperature: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

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

Specimen Required:

Collect: Plain Red, Lavender (EDTA), or Pink (K2EDTA).

Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 5 mL serum or Plasma to ARUP Standard Transport Tubes. (Min: 2.4 mL)

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

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

Unacceptable Conditions: Separator tubes or citrate buffered tubes.

Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 week; Frozen: 2 months

Specimen Required:

Collect: Transfer 5 mL urine to ARUP Standard Transport Tubes. (Min: 2.8 mL)

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

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

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

Specimen Required:

Methodology: Qualitative Gas Chromatography-Mass Spectrometry/Quantitative Gas Chromatography-Mass Spectrometry (HPLC-MS/MS)

Specimen Preparation: Transfer 5 mL urine to ARUP Standard Transport Tubes. (Min: 2.8 mL)

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

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

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

Specimen Required:

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

Specimen Preparation: Transfer cultured amniocytes or cultured CVS to two T-25 flasks at 80% confluence. (Min: one T-25 flask at 80% confluence). Backup cultures must be retained at the client’s institution until testing is complete. If the client is unable to culture amniocytes or CVS, this can be arranged by contacting ARUP Client Services at (800) 522-2787. Please contact an ARUP genetic counselor at (800) 242-2787 ext. 2141 prior to test submission.

Amniotic Fluid (direct): 10 milliliters

Maternal Whole Blood Specimen: 2 mL whole blood (Min: 1 mL).

Storage/Transport Temperature: Cultured Amniocytes or Cultured CVS: CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of collection due to viability of cells.

Amniotic fluid (direct): Room temperature.

Maternal Whole Blood Specimen: Room temperature.

Remarks: Please contact an ARUP genetic counselor at (800) 242-2787 ext. 2141 prior to sample submission. Patient History Forms are available on aruplab.com or by contacting ARUP Client Services at (800) 522-2787.

Stability (collection to initiation of testing):

Cultured Amniocytes or Cultured CVS: Room temperature: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

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

Specimen Required:

Collect: Plain Red, Lavender (EDTA), or Pink (K2EDTA).

Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 5 mL serum or Plasma to ARUP Standard Transport Tubes. (Min: 2.4 mL)

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

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

Unacceptable Conditions: Separator tubes or citrate buffered tubes.

Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 week; Frozen: 2 months

Specimen Required:

Collect: Transfer 5 mL urine to ARUP Standard Transport Tubes. (Min: 2.8 mL)

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

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

Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 week; Frozen: 3 months
### Hemophilia A (F8) 2 Inversions, Fetal

**Patient History for Fetal Molecular Testing**

**Additional Technical Information**

**Time Sensitive**

**Specimen Required:** Collect: **Cultured Amniocytes or Cultured CVS**

- **AND** Maternal Whole Blood Specimen: Lavender (EDTA) or yellow (ACD Solution A or B).

**Specimen Preparation:** Cultured Amniocytes or Cultured CVS: Transfer cultured amniocytes or cultured CVS to two T-25 flasks at 80% confluence. (Min: one T-25 flask at 80% confluence). Backup cultures must be retained at the client's institution until testing is complete. If the client is unable to culture amniocytes or CVS, this can be arranged by contacting ARUP Client Services at (800) 522-2787. Please contact an ARUP genetic counselor at (800) 242-2787 ext. 2141 prior to test submission.

**Maternal Whole Blood Specimen:** Transport 2 mL whole blood (Min: 1 mL).

**Storage/Transport Temperature:** Cultured Amniocytes or Cultured CVS: CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of collection due to viability of cells.

**Maternal Whole Blood Specimen:** Room temperature.

**Remarks:** Please contact an ARUP genetic counselor at (800) 242-2787 ext. 2141 prior to sample submission.

**Patient History Form** is available on the ARUP Web site or by contacting ARUP Client Services at (800) 522-2787.

**Stability (collection to initiation of testing):**
- Cultured Amniocytes or Cultured CVS: Room temperature: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
- Maternal Whole Blood Specimen: Room temperature: 7 days; Refrigerated: 1 month; Frozen: Unacceptable

### Heroin - Screen with Reflex to Confirmation/Quantitation - Serum or Plasma

**Specimen Required:** Collect: Plain Red or Gray (Sodium Fluoride/Potassium Oxalate).

**Specimen Preparation:** Separate from cells ASAP or within 2 hours of collection. Transfer 3 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1.3 mL)

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

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

**Unacceptable Conditions:** Separator tubes.

**Stability (collection to initiation of testing):** Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 month

### Kell K/k (KEL) Antigen Genotyping

**Specimen Required:** Collect: Fetal genotyping:

- **Cultured amniocytes:** Two T-25 flasks 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. **WITH maternal cell contamination specimen** (see Note): Lavender (K<sub>e</sub>EDTA), Pink (K<sub>e</sub>EDTA), or Yellow (ACD Solution A or B).

- **Parental genotyping:** Lavender (K<sub>e</sub>EDTA), Pink (K<sub>e</sub>EDTA).

**Specimen Preparation:** Cultured amniocytes: 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.

**Maternal cell contamination specimen:** Transport 3 mL whole blood (Min: 1 mL)

**Whole blood (parental genotyping):** Transport 3 mL whole blood. (Min: 1 mL)

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

**Whole blood or maternal cell contamination specimen:** Refrigerated.

**Remarks:** Patient History Form is available on the ARUP website or by contacting ARUP Client Services.

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

**Stability (collection to initiation of testing):**
- Fetal specimen: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
- Whole blood or maternal cell contamination specimen: Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
**0091224**  **LSD, Urine - Screen with Reflex to Confirmation/Quantitation**  **LSD URN**

**Specimen Required:** Collect: Urine.

Specimen Preparation: Transfer 2 mL urine to an ARUP Standard Transport Tube. (Min: 0.9 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: 24 hours; Refrigerated: 1 month; Frozen: 1 month

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**2014704**  **Maternal T Cell Engraftment in SCID, Maternal Specimen**  **SCID-MAT**

**Specimen Required:**

- **Collect:** Lavender (EDTA), Pink (K2 EDTA), or Yellow (ACD Solution A).
- **New York State Clients:** Lavender (EDTA) or Yellow (ACD Solution A). Collect Monday-Thursday only.

Specimen Preparation:

- Transport 2 mL whole blood. (Min: 1 mL)
- **New York State Clients:** Transport 9 mL whole blood. (Min: 4 mL). **Do not send to ARUP Laboratories.** Specimens must be received at performing laboratory within 48 hours of collection. For specimen requirements and direct submission instructions please contact ARUP Referral Testing at (800) 242-2787, ext. 5145.

Storage/Transport Temperature: Refrigerated

Stability (collection to initiation of testing):

- Room Temperature: 1 week; Refrigerated: 1 month; Frozen: unacceptable
- **New York State Clients:** Room Temperature: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

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**0091551**  **Phenobarbital, Total/Unbound/Bound, S/P**  **PHENOBAR**

**Methodology:** Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry (HPLC-MS/MS)

**CPT Code(s):** 80184 x2

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**3001170**  **Platelet Antigen 1 Genotyping (HPA-1)**  **HPA-1 GENO**

**Performed:** Varies

**Reported:** 7-14 days

**Specimen Required:**

- **Collect:** Fetal specimen: **Cultured** amniocytes: Two T-25 flasks at 80 percent confluency.
  - **WITH** maternal cell contamination specimen (see Note): Lavender (EDTA), Pink (K2 EDTA), or Yellow (ACD Solution A or B).
  - Parental specimen: Lavender (EDTA).

Specimen Preparation:

- **Cultured amniocytes:** Transport two T-25 flasks at 80 percent confluency filled with culture media. Backup cultures must be retained at the client's institution until testing is complete.
- **Maternal cell contamination specimen:** Transport 3 mL whole blood. (Min: 1 mL)
- **Whole blood (parental genotyping):** Transport 3 mL whole blood. (Min: 1 mL)

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
### Platelet Antigen Genotyping Panel

**Specimen Required:**
- **Fetal genotyping:** Culture amniocytes: Two T-25 flasks 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 cell contamination specimen:** Lavender (EDTA), Pink (K$_2$EDTA), or Yellow (ACD Solution A or B).
- **Parental genotyping:** Lavender (EDTA).
- **Specimen Preparation:** Culture amniocytes: Transport two T-25 flasks at 80 percent confluency filled with culture media. Backup cultures must be retained at the client's institution until testing is complete.
- **Whole blood (parental genotyping):** Transport 3 mL whole blood. (Min: 1 mL)
- **Storage/Transport Temperature:** Culture 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.
- **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

### Proinsulin, Intact/Insulin Ratio

**Specimen Required:**
- **Patient Prep:** Patient must be fasting for 12-15 hours prior to collection.
- **Collect:** Serum Separator Tube (SST).
- **Specimen Preparation:** Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube and freeze immediately. (Min: 0.8 mL)
- **Storage/Transport Temperature:** CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
- **Unacceptable Conditions:** Heparinized plasma. Vitreous or I.V. fluids. Hemolyzed specimens.
- **Stability (collection to initiation of testing):** After separation from cells: Ambient: Unacceptable; Refrigerated: 48 hours; Frozen: 2 months (avoid repeated freeze/thaw cycles)

#### Reference Interval:

<table>
<thead>
<tr>
<th>Available Separately</th>
<th>Component</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes (0070063)</td>
<td>Insulin, Fasting</td>
<td>Effective September 7, 2021 3-25 µIU/mL, 0.17 years: Not established 18 years and older: Less than or equal to 8.0 pmol/L</td>
</tr>
<tr>
<td>Yes (0070112)</td>
<td>Proinsulin, Intact</td>
<td>Proinsulin, Intact/Insulin Ratio as Percent: 0-17 years: Not established 18 years and older: 0.8-21.7 percent</td>
</tr>
<tr>
<td>No</td>
<td>Proinsulin, Intact/Insulin Ratio Calculation</td>
<td>Proinsulin, Intact/Insulin Ratio as Percent: 0-17 years: Not established 18 years and older: 0.8-21.7 percent</td>
</tr>
</tbody>
</table>

### Rabies Antibody Screen by RFFIT, Serum

**Specimen Required:**
- **Collect:** Plain Red or Serum Separator Tube (SST).
- **Specimen Preparation:** Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.25 mL)
- **Storage/Transport Temperature:** Refrigerated. Also acceptable: Room temperature or frozen.
- **Stability (collection to initiation of testing):** Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 1 month
**3001053**  Red Blood Cell Antigen Genotyping  RBC GENO

**Specimen Required:**
Collect: **Fetal genotyping:** *Cultured amniocytes:* Two T-25 flasks 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.*

**WITH maternal cell contamination specimen:** Lavender (K<sub>2</sub>EDTA), Pink (K<sub>e</sub>EDTA), or Yellow (ACD Solution A or B).

**OR Genotyping:** Lavender (K<sub>e</sub>EDTA), Pink (K<sub>e</sub>EDTA) OR

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

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

**Maternal cell contamination specimen:** Transport 3 mL whole blood (Min: 1 mL)

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

**Whole blood or maternal cell contamination specimen:** Refrigerated.

**Remarks:** Maternal specimen is recommended for proper test interpretation if contamination of the fetal specimen from the mother is suspected. Order Maternal Cell Contamination.

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

**Stability (collection to initiation of testing):** Whole blood or maternal cell contamination specimen: Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

**Fetal specimen:** Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

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

**Specimen Required:**
Collect: **Fetal genotyping:** *Cultured amniocytes:* Two T-25 flasks 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.*

**Parental genotyping:** Lavender (K<sub>e</sub>EDTA), Pink (K<sub>e</sub>EDTA)

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

**Maternal cell contamination specimen:** Transport 3 mL whole blood (Min: 1 mL)

**Whole blood (parental genotyping):** Transport 3 mL whole blood. (Min: 1 mL)

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

**Whole blood or maternal cell contamination specimen:** Refrigerated.

**Remarks:** Patient History Form is available on the ARUP website or by contacting ARUP Client Services.

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

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

**Whole blood or maternal cell contamination specimen:** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

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

**Performed:** Varies

**Reported:** 7-14 days

**Specimen Required:**
Collect: **Fetal genotyping:** *Cultured amniocytes:* Two T-25 flasks 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.*

**WITH maternal cell contamination specimen** (see Remarks): Lavender (EDTA), pink (K<sub>e</sub>EDTA), or yellow (ACD Solution A or B).

**Parental genotyping:** Lavender (EDTA), pink (K<sub>e</sub>EDTA), or yellow (ACD Solution A or B)

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

**Maternal cell contamination specimen:** Transport 3 mL whole blood (Min: 1 mL)

**Whole blood (parental genotyping):** Transport 3 mL whole blood. (Min: 1 mL)

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

**Whole blood or maternal cell contamination specimen:** Refrigerated.

**Remarks:** 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
Specimen Required: Collect: Fetal genotyping: **Cultured amniocytes**: Two T-25 flasks 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.

**WITH maternal cell contamination specimen** (see Note): Lavender (K<sub>2</sub>EDTA), Pink (K<sub>2</sub>EDTA), or Yellow (ACD Solution A or B).

Parental genotyping: Lavender (K<sub>2</sub>EDTA), Pink (K<sub>2</sub>EDTA).

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

Maternal cell contamination specimen: Transport 3 mL whole blood (Min: 1 mL).

Whole blood (parental genotyping): Transport 3 mL whole blood. (Min: 1 mL)

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

**Whole blood or maternal cell contamination specimen**: Refrigerated.

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

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

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

Whole blood or maternal cell contamination specimen: Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

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**Smith and Smith/RNP (ENA) Antibodies, IgG**

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay
Semi Quantitative Multiplex Bead Assay

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

Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.2 mL)

Storage/Transport Temperature: Refrigerated.

Unacceptable Conditions: Plasma or other body fluids. Contaminated, hemolyzed, or severely lipemic specimens.

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

(avoid repeated freeze/thaw cycles)

Reference Interval:

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>0050470</td>
<td>Smith/RNP (ENA) Antibody, IgG</td>
<td>Effective September 7, 2021</td>
</tr>
<tr>
<td></td>
<td>19 Units or less</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>20-39 Units</td>
<td>Weak Positive</td>
</tr>
<tr>
<td></td>
<td>40-80 Units</td>
<td>Moderate Positive</td>
</tr>
<tr>
<td></td>
<td>&gt;81 Units or greater</td>
<td>Strong Positive</td>
</tr>
</tbody>
</table>

| 0050085     | Smith (ENA) Antibody, IgG                       | 29 AU/mL or less                    |
|             |                                                | Negative                            |
|             | 30-40 AU/mL                                    | Equivocal                           |
|             | 41 AU/mL or greater                            | Positive                            |

**HOTLINE NOTE:** There is a unit of measure change associated with this test.

Change the unit of measure for component 0050470, Smith/RNP (ENA) Ab, IgG from AU/mL to Units.
### Methodology:
Semi-Quantitative Enzyme-Linked Immunosorbent Assay

### Specimen Required:
**Collect:** Serum separator tube.

**Specimen Preparation:** Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.2 mL)

**Storage/Transport Temperature:** Refrigerated.

**Unacceptable Conditions:** Plasma or other body fluids. Contaminated, hemolyzed, or severely lipemic specimens.

**Stability (collection to initiation of testing):** After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 30 days (avoid repeated freeze/thaw cycles)

### Reference Interval:

<table>
<thead>
<tr>
<th>Units</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>19 or less</td>
<td>Negative</td>
</tr>
<tr>
<td>20-39</td>
<td>Weak Positive</td>
</tr>
<tr>
<td>40-80</td>
<td>Moderate Positive</td>
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<tr>
<td>81 or greater</td>
<td>Strong Positive</td>
</tr>
</tbody>
</table>

### Interpretive Data:
Smith/RNP antibodies are frequently seen in patients with mixed connective tissue disease (MCTD) and are also associated with other systemic autoimmune rheumatic diseases (SARDs), such as systemic lupus erythematosus (SLE), systemic sclerosis, and myositis. Antibodies targeting the Smith/RNP antigenic complex also recognize Smith antigens, therefore, the Smith antibody response must be considered when interpreting these results.

**Note:** An affinity purified RNP/Sm antigen complex is used in this assay.

**HOTLINE NOTE:** There is a unit of measure change associated with this test.
Change the unit of measure for component 0050470, Smith/RNP (ENA) Ab, IgG from AU/mL to Units.

### Specimen Required:

**Patient History for Fetal Molecular Testing**

**Additional Technical Information**

**Time Sensitive**

**Specimen Required:**

**AND Maternal Whole Blood Specimen:** Lavender (EDTA), Pink (K3EDTA), or Yellow (ACD Solution A or B).

**Specimen Preparation:** Cultured Amniocytes or Cultured CVS. Transfer cultured amniocytes or cultured CVS to two T-25 flasks at 80 percent confluence (Min: one T-25 flask at 80% confluence). Backup cultures must be retained at the client's institution until testing is complete. **If the client is unable to culture amniocytes or CVS, this can be arranged by contacting ARUP Client Services at (800) 522-2787 ext. 2141 prior to test submission.**

**Maternal Whole Blood Specimen:** Transport 2 mL whole blood. (Min: 1 mL)

**Storage/Transport Temperature:** Cultured Amniocytes or Cultured CVS: CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of collection due to viability of cells.

**Maternal Whole Blood 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.

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

**Maternal Whole Blood Specimen:** Room Temperature: 7 days; Refrigerated: 1 month; Frozen: Unacceptable
**Specimen Required:**

**0051508** Thalassemia Carrier, HBB-Hb Bart's (HBB) 3 Mutations, Fetal

- **Specimen:** Cultured Amniocytes, Cultured CVS, or Amniotic fluid (direct).
- **Maternal Whole Blood Specimen:** Lavender (EDTA), pink (K<sub>2</sub>EDTA), or yellow (ACD Solution A or B).
- **Specimen Preparation:** Cultured Amniocytes or Cultured CVS: Transfer cultured amniocytes or cultured CVS to two T-25 flasks at 80% confluence. (Min: one T-25 flask at 80% confluence). Backup cultures must be retained at the client's institution until testing is complete. If the client is unable to culture amniocytes or CVS, this can be arranged by contacting ARUP Client Services at (800) 522-2787. Please contact an ARUP genetic counselor at (800) 242-2787 ext. 2141 prior to test submission.
- **Amniotic fluid (direct):** 10 milliliters
- **Maternal Whole Blood Specimen:** Lavender (EDTA), pink (K<sub>2</sub>EDTA), or yellow (ACD Solution A or B).
- **Specimen Preparation:** Transport 2 mL whole blood. (Min: 1 mL)
- **Storage/Transport Temperature:** Room temperature; Refrigerated: 72 hours; Frozen: Unacceptable

**0091585** Total Quantitative, Serum or Plasma

- **Specimen:** Royal Blue (K<sub>2</sub>EDTA), Royal Blue (Na<sub>2</sub>EDTA), or Royal Blue (No Additive).
- **Specimen Preparation:** Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to an Acid Washed Transfer Vial (ARUP supply #54350) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 0.4 mL)
- **Test is not performed at ARUP; separate specimens must be submitted when multiple tests are ordered.**
- **Storage/Transport Temperature:** Refrigerated. Also acceptable: Room temperature or frozen.
- **Unacceptable Conditions:** Separator tubes.
- **Stability (collection to initiation of testing):** Ambient: 28 days; Refrigerated: 28 days; Frozen: 28 days

**2005476** Thalassemia Select, HBB-Hb Bart's Select, Fetal

- **Methodology:** Polymerase Chain Reaction/Sequencing
- **Specimen Required:** Lavender (EDTA), pink (K<sub>2</sub>EDTA) 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):** Ambient: 7 days; Refrigerated: 1 month

**Interpretive Data: By report**

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.