### 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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<td>Insulin, 180 Minutes</td>
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<td>0080388</td>
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<td>Zika Virus by PCR, Blood</td>
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<td>Zika Virus by PCR, Urine</td>
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<td>2013942</td>
<td>Zika Virus IgM Antibody Capture (MAC), by ELISA</td>
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</table>
**Alkaline Phosphatase Isoenzymes, Serum or Plasma**

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

- **Specimen Preparation:** Allow serum specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube and refrigerate or freeze immediately. (Min: 1 mL)
- **Storage/Transport Temperature:** Refrigerated.
- **Unacceptable Conditions:** Specimens collected in EDTA, sodium fluoride, sodium citrate, or potassium oxalate. Grossly hemolyzed or lipemic specimens.
- **Stability (collection to initiation of testing):** Ambient: 1 week; Refrigerated: 1 week; Frozen: 2 months

---

**New Test**

<table>
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<tr>
<th>New Test Code</th>
<th>New Test Name</th>
<th>Methodology</th>
<th>Performed</th>
<th>Reported</th>
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<tbody>
<tr>
<td>2014007</td>
<td>Allergen, Food, Milk (Boiled) IgE</td>
<td>Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay</td>
<td>Varies</td>
<td>3-6 days</td>
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</tbody>
</table>

**Specimen Required:** Collect: Plain Red or Serum Separator Tube (SST).

- **Specimen Preparation:** Separate from cells ASAP or within 2 hours of collection. Transfer 0.5 mL serum plus 0.1 mL for each additional allergen ordered to an ARUP Standard Transport Tube. (Min: 0.34 mL plus 0.04 mL for each allergen ordered)
- **Storage/Transport Temperature:** Room temperature. Also acceptable: Refrigerated or frozen.
- **Unacceptable Conditions:** Lipemic specimens
- **Stability (collection to initiation of testing):** Ambient: 1 month; Refrigerated: 1 month; Frozen: 1 year

**Reference Interval:** By Report

**CPT Code(s):** 86003

New York DOH Approved.

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

---

**New Test**

<table>
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<th>New Test Name</th>
<th>Methodology</th>
<th>Performed</th>
<th>Reported</th>
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</thead>
<tbody>
<tr>
<td>2014003</td>
<td>Allergen, Fungi and Molds, <em>Aspergillus flavus</em> IgE</td>
<td>Quantitative Enzyme Immunoassay</td>
<td>Varies</td>
<td>3-6 days</td>
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</table>

**Specimen Required:** Collect: Plain Red or Serum Separator Tube (SST).

- **Specimen Preparation:** Separate from cells ASAP or within 2 hours of collection. Transfer 0.5 mL serum plus 0.1 mL for each additional allergen ordered to an ARUP Standard Transport Tube. (Min: 0.34 mL plus 0.04 mL for each allergen ordered)
- **Storage/Transport Temperature:** Room temperature. Also acceptable: Refrigerated or frozen.
- **Unacceptable Conditions:** Lipemic specimens
- **Stability (collection to initiation of testing):** Ambient: 1 month; Refrigerated: 1 month; Frozen: 1 year

**Reference Interval:** By report

**CPT Code(s):** 86003

New York DOH Approved.

**HOTLINE NOTE:** Refer to the Test Mix Addendum for interface build information.
### New Test 2014005

**Allergen, Fungi and Molds, *Fusarium solani* IgE**

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<th>Methodology</th>
<th>Quantitative Enzyme Immunoassay</th>
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<tbody>
<tr>
<td>Performed</td>
<td>Varies</td>
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<tr>
<td>Reported</td>
<td>3-5 days</td>
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</table>

**Specimen Required:**
- Collect: Plain Red or Serum Separator Tube (SST).
- Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 0.5 mL serum plus 0.1 mL for each additional allergen ordered to an ARUP Standard Transport Tube. (Min: 0.34 mL plus 0.04 mL for each allergen ordered)

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

**Unacceptable Conditions:** Lipemic specimens

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

**Reference Interval:** By report

**CPT Code(s):** 86003

New York DOH Approved.

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

### New Test 2014009

**Allergen, Weed, Wingscale (*Atriplex canescens*) IgE**

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<th>Quantitative Enzyme Immunoassay</th>
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<tbody>
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<td>Varies</td>
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<tr>
<td>Reported</td>
<td>3-6 days</td>
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</table>

**Specimen Required:**
- Collect: Plain Red or Serum Separator Tube (SST).
- Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 0.5 mL serum plus 0.1 mL for each additional allergen ordered to an ARUP Standard Transport Tube. (Min: 0.34 mL plus 0.04 mL for each allergen ordered)

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

**Unacceptable Conditions:** Lipemic specimens

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

**Reference Interval:** By report

**CPT Code(s):** 86003

New York DOH Approved.

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

### 0099266

**Aluminum, Serum**

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### 0099408

**Aluminum, Urine**

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### 0099007

**Antimony, Blood**

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**2008467**  
Anti-Nuclear Antibody (ANA), IgG by IFA with Reflex by IFA Pattern

**Methodology:**  
Semi-Quantitative Indirect Fluorescent Antibody/Qualitative Enzyme-Linked Immunosorbent Assay/Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Semi-Quantitative Multiplex Bead Assay/Qualitative Immunoblot

**Reference Interval:** Effective February 21, 2017

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<td>PM/SCL-100 Antibody, IgG by Immunoblot</td>
<td>Negative</td>
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<tr>
<td>2012173</td>
<td>Fibrillarin (U3 RNP) Antibody, IgG</td>
<td>Negative</td>
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<tr>
<td>0050215</td>
<td>Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA with Reflex to dsDNA Antibody, IgG by IFA</td>
<td>Components</td>
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<td>Double-Stranded DNA (dsDNA) Antibody, IgG by IFA (using <em>Crithidia luciliae</em>)</td>
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<td>Double-Stranded DNA (dsDNA) Antibody, IgG by IFA (using <em>Crithidia luciliae</em>)</td>
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<td>2005287</td>
<td>Chromatin Antibody, IgG</td>
<td>Components</td>
</tr>
<tr>
<td></td>
<td>19 Units or less</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>20-60 Units</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>61 Units or greater</td>
<td>Strong Positive</td>
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<tr>
<td>2001601</td>
<td>RNA Polymerase III Antibody, IgG</td>
<td>Components</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>
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<tr>
<td></td>
<td>40-80 Units</td>
<td>Moderate Positive</td>
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<tr>
<td></td>
<td>81 Units or greater</td>
<td>Strong Positive</td>
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<tr>
<td>0050599</td>
<td>Scleroderma (Scl-70) (ENA) Antibody, IgG</td>
<td>Components</td>
</tr>
<tr>
<td></td>
<td>29 AU/mL or less</td>
<td>Negative</td>
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<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>0050470</td>
<td>RNP (U1) (Ribonucleic Protein) (ENA) Antibody, IgG</td>
<td>Components</td>
</tr>
<tr>
<td></td>
<td>29 AU/mL or less</td>
<td>Negative</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>0050085</td>
<td>Smith (ENA) Antibody, IgG</td>
<td>Components</td>
</tr>
<tr>
<td></td>
<td>29 AU/mL or less</td>
<td>Negative</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>Components</td>
</tr>
<tr>
<td></td>
<td>SSA 52 (Ro) (ENA) Antibody, IgG</td>
<td>Components</td>
</tr>
<tr>
<td></td>
<td>29 AU/mL or less</td>
<td>Negative</td>
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<tr>
<td></td>
<td>30-40 AU/mL</td>
<td>Equivocal</td>
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<tr>
<td></td>
<td>41 AU/mL or greater</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>SSA 60 (Ro) (ENA) Antibody, IgG</td>
<td>Components</td>
</tr>
<tr>
<td></td>
<td>29 AU/mL or less</td>
<td>Negative</td>
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<td>30-40 AU/mL</td>
<td>Equivocal</td>
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<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>Components</td>
</tr>
<tr>
<td></td>
<td>29 AU/mL or less</td>
<td>Negative</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>

**Note:** The Anti-Nuclear Antibody (ANA), IgG by IFA with Reflex by IFA Pattern begins with Nuclear Antibody (ANA) by IFA, IgG. Depending on findings, one or more reflexive tests may be required. Tests added may include Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA; Double-Stranded DNA (dsDNA) Antibody, IgG by IFA (using *Crithidia luciliae*); Chromatin Antibody, IgG; RNP (U1) (Ribonucleic Protein) (ENA) Antibody, IgG; Fibrillarin (U3 RNP) Antibody, IgG; Smith (ENA) Antibody, IgG; SSA 52 (Ro) (ENA) Antibody, IgG; SSA 60 (Ro) (ENA) Antibody, IgG; SSB (La) (ENA) Antibody, IgG; Scleroderma (Scl-70) (ENA) Antibody, IgG; PM/Scl-100 Antibody, IgG, by Immunoblot; and/or RNA Polymerase III Antibody, IgG. Additional charges apply.

**CPT Code(s):**  
86039; if homogenous pattern add 86225 and 83516; if reflexed add 86256; if speckled pattern add 86235 x6; If nucleolar pattern add 86235 x3 and 83516

**HOTLINE NOTE:** There is a reflexive pattern change associated with this test.
Add reflex to 2012173, Fibrillarin (U3 RNP) Antibody, IgG
<table>
<thead>
<tr>
<th>Code</th>
<th>Arsenic, Fractionated, Urine</th>
<th>AS UF</th>
</tr>
</thead>
<tbody>
<tr>
<td>0020734</td>
<td>Arsenic, Fractionated, Urine</td>
<td></td>
</tr>
</tbody>
</table>

**Performed:** Sun, Tue, Thu, Sat  
**Reported:** 1-5 days
New Test 2013944 Autoimmune Neurologic Disease Reflexive Panel
Available Now

Methodology: Semi-Quantitative Indirect Fluorescent Antibody/Qualitative Immunoblot/Quantitative Radioimmunoassay/Semi-quantitative Enzyme-Linked Immunosorbent Assay

Performed: Tue
Reported: 3-10 days

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer three 3 mL serum aliquots to ARUP Standard Transport Tubes. (Min: 1.50 mL/ aliquot)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Amniotic fluid, ocular fluid, peritoneal fluid, synovial fluid, CSF, or plasma. Contaminated, hemolyzed, icteric, or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 1 month (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>0050746</td>
<td>Striated Muscle Antibodies, IgG with Reflex to Titer</td>
<td>Striated Muscle Antibodies, IgG Screen: Less than 1:40; Striated Muscle Antibodies, IgG Titer: Less than 1:40</td>
</tr>
<tr>
<td>2004221</td>
<td>N-methyl-D-Aspartate Receptor Antibody, IgG, Serum with Reflex to Titer</td>
<td>&lt;1:10</td>
</tr>
<tr>
<td>2001771</td>
<td>Glutamic Acid Decarboxylase Antibody</td>
<td>0.0-5.0 IU/mL</td>
</tr>
<tr>
<td>2013956</td>
<td>CV2.1 Screen by IFA with Reflex to Titer</td>
<td>CV2.1 Antibody IgG Screen by IFA: Less than 1:10; CV2.1 Antibody IgG Titer by IFA: Less than 1:10</td>
</tr>
<tr>
<td>0092628</td>
<td>Voltage-Gated Calcium Channel (VGCC) Antibody</td>
<td>Negative: 31 pmol/L or less; Indeterminate: 32-87 pmol/L; Positive: 88 pmol/L or greater</td>
</tr>
<tr>
<td>2005636</td>
<td>Titin Antibody</td>
<td>Titin Antibody</td>
</tr>
<tr>
<td>2004890</td>
<td>Voltage-Gated Potassium Channel (VGKC) Antibody</td>
<td>Voltage-Gated Potassium Channel (VGKC) Antibody: Negative: 31 pmol/L or less; Indeterminate: 32-87 pmol/L; Positive: 88 pmol/L or greater</td>
</tr>
<tr>
<td>2009456</td>
<td>Lexamine-Rich, Glioma-Inactivated Protein 1 Antibody, IgG with Reflex to Titer</td>
<td>Less than 1:10</td>
</tr>
<tr>
<td>2009452</td>
<td>Contactin-Associated Protein-2 Antibody, IgG with Reflex to Titer</td>
<td>Less than 1:10</td>
</tr>
<tr>
<td>2003036</td>
<td>Aquaporin-4 Receptor Antibody</td>
<td></td>
</tr>
</tbody>
</table>
### Quarterly HOTLINE: Effective February 21, 2017

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquaporin-4 Receptor Antibody</td>
<td>Negative: 2.9 U/mL or less Positive: 3.0 U/mL or greater</td>
<td></td>
</tr>
<tr>
<td>Aquaporin-4 Receptor Antibody, IgG by IFA with Reflex to Titer, Serum</td>
<td>Less than 1:10</td>
<td></td>
</tr>
</tbody>
</table>

#### Interpretive Data:
- **Refer to report.**
- See Compliance Statement D: www.aruplab.com/CS

#### Note:
- If Striated Muscle Ab is detected, then a titer will be added. Additional charges apply.
- If N-methyl-D-Aspartate Receptor Antibody is positive, then titer will be added. Additional charges apply.
- If CV2.1 Antibody IgG Screen by IFA is positive, then a titer will be added. Additional charges apply.
- If Aquaporin-4 Receptor Antibody IgG by ELISA is positive, then Aquaporin-4 Receptor Antibody, IgG by IFA will be added. If positive, then a titer will be added. Additional charges apply.
- If Voltage-Gated Calcium Channel (VGCC) Antibody is Indeterminate or Positive, then Leucine-Rich, Glioma-Inactivated Protein 1 Antibody IgG and Contactin-Associated Protein-2 Antibody IgG will be added. If LGI1 antibody IgG is positive, then LGI1 antibody IgG titer will be added. If CASPR2 antibody IgG is positive, then CASPR2 antibody IgG titer will be added. Additional charges apply.
- If Acetylcholine Receptor Binding Antibody result is greater than 0.4 nmol/L then Acetylcholine Receptor Modulating Antibody will be added. Additional charges apply.
- Purkinje Cell (PCCA) antibody and Neuronal Nuclear (ANNA) antibody IgG are screened by IFA. If the IFA screen is indeterminate, then a Neuronal Nuclear Antibodies (Hu, Ri, and Yo) IgG by Immunoblot will be added. If the IFA screen is positive at 1:10 or greater, then a PCCA/ANNA antibodies titer and Neuronal Nuclear Antibodies (Hu, Ri, and Yo) IgG by Immunoblot will be added. Additional charges apply.

**CPT Code(s):** 83519 x3; 83516 x4; 86255 x4; if reflexed add 86256; if reflexed add 86256; if reflexed add 86255; if further reflexed add 86256; if reflexed add 86255 x2; if further reflexed add 86256 per titer; if reflexed add 83516; if reflexed add 83516 and/or 86256

New York DOH approval pending. Call for status update.

**HOTLINE NOTE:** Refer to the Test Mix Addendum for interface build information.
## Quarterly HOTLINE: Effective February 21, 2017

### 2011603  Caffeine, Serum or Plasma  CAFFEINE S

**Reference Interval:** Effective February 21, 2017

<table>
<thead>
<tr>
<th>Age</th>
<th>0-28 days</th>
<th>29 days and older</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic Range:</td>
<td>8-20 µg/mL</td>
<td>Less than or equal to 20 (not well established)</td>
</tr>
<tr>
<td>Toxic:</td>
<td>Greater than 20 µg/mL</td>
<td>Greater than 20 µg/mL</td>
</tr>
</tbody>
</table>

### New Test  2014027  Calcium, RBC  CA RBC

**Available Now**

**Methodology:** Quantitative Inductively Coupled Plasma-Optical Emission Spectrometry

**Performed:** Varies

**Reported:** 3-10 days

**Specimen Required:**
- **Collect:** Green (Sodium Heparin).
- **Specimen Preparation:** Separate cells within 2 hours of collection. Transfer 2 mL RBCs to a trace metal-free or acid-washed plastic container. (Min: 0.7 mL)
- **Storage/Transport Temperature:** Refrigerated. Also acceptable: Frozen.
- **Unacceptable Conditions:** Lavender top (EDTA).
- **Stability (collection to initiation of testing):** Ambient: Unacceptable; Refrigerated: 1 month; Frozen: 1 month

**Reference Interval:** By Report

**CPT Code(s):** 82310

New York DOH Approved.

**HOTLINE NOTE:** Refer to the Test Mix Addendum for interface build information.
New Test 2013901  Candida FKS Drug Resistance by Sequencing  FKS SEQ

**Methodology:** Polymerase Chain Reaction/Sequencing
**Performed:** Sun, Mon, Wed
**Reported:** 3-5 days

**Specimen Required:** Collect: Body fluid, tissue, or pure isolate of *Candida* species on solid media.
Specimen Preparation: Body Fluid: Transfer 1 mL body fluid to a sterile container. (Min: 0.5 mL)
Tissue: Transfer to a sterile container and freeze immediately.
Isolate: Transport sealed container with pure isolate on solid media. Place each specimen in an individually sealed bag.
Storage/Transport Temperature: Frozen.
Remarks: Specimen source and organism identification required.
Unacceptable Conditions: Plasma, serum, or whole blood. Mixed cultures or isolates other than suspected *Candida* species. Isolates with no visible colonies.
Stability (collection to initiation of testing): Body Fluid: Ambient: 2 weeks; Refrigerated: 2 weeks; Frozen: 2 weeks
Tissue: Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 2 weeks
Isolate: Ambient: 1 week; Refrigerated: 2 weeks; Frozen: Unacceptable

**Interpretive Data:** This assay detects known resistance mutations in *C. albicans*, *C. glabrata*, *C. krusei*, *C. parapsilosis*, and *C. tropicalis* by sequencing. The *FKSI* and *FKS2* genes are sequenced. Mutations associated with resistance to Echinocandins are reported. Mutations in sub-populations below 20 percent of total may not be detected.

See Compliance Statement B: www.aruplab.com/CS

**Note:** This test may be unsuccessful if the specimen or isolate does not contain *C. albicans*, *C. glabrata*, *C. krusei*, *C. parapsilosis*, *C. tropicalis*, or if multiple *Candida* species are present.

**CPT Code(s):** 87900

New York DOH approval pending. Call for status update.

**HOTLINE NOTE:** Refer to the Test Mix Addendum for interface build information.
### New Test: 2013798

**Methodology:** Qualitative Polymerase Chain Reaction

**Performed:** Mon, Thu

**Reported:** 2-5 days

**Specimen Required:**
- **Collect:** Body fluid, tissue, or pure isolate of *Candida* species on solid media.
- **Specimen Preparation: Body Fluid:** Transfer 1 mL body fluid to a sterile container. (Min: 0.5 mL)
- **Tissue:** Transfer to a sterile container and freeze immediately.
- **Isolate:** Transport sealed container with pure isolate on solid media. Place each specimen in an individually sealed bag.
- **Storage/Transport Temperature: Body Fluid and Tissue:** Frozen.
- **Isolate:** Refrigerated.
- **Remarks:** Specimen source required.
- **Unacceptable Conditions:** Plasma, serum, or whole blood. Mixed cultures or isolates other than suspected *Candida* species. Isolates with no visible colonies.
- **Stability (collection to initiation of testing):**
  - **Body Fluid:** Ambient: 2 weeks; Refrigerated: 2 weeks; Frozen: 2 weeks
  - **Tissue:** Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 2 weeks
  - **Isolate:** Ambient: 1 week; Refrigerated: 2 weeks; Frozen: Unacceptable

**Interpretive Data:** A negative result does not rule out the presence of PCR inhibitors in the patient specimen or test-specific nucleic acid in concentrations below the level of detection by the test.

See Compliance Statement B: [www.aruplab.com/CS](http://www.aruplab.com/CS)

**Note:** This test detects and differentiates *C. albicans*, *C. glabrata*, *C. parapsilosis* complex (*C. parapsilosis*, *C. orthopsilosis*, *C. metapsilosis*), *C. tropicalis*, *C. krusei*, and *C. dubliniensis*.

**CPT Code(s):** 87481 x6

New York DOH approval pending. Call for status update.

**HOTLINE NOTE:** Refer to the Test Mix Addendum for interface build information.
New Test 2013784  Candida Species by PCR with Reflex to FKS Drug Resistance by Sequencing  CAND RFX

Methodology: Qualitative Polymerase Chain Reaction/Sequencing
Performed: Mon, Thu
Reported: 7-10 days

Specimen Required: Collect: Body fluid, tissue, or pure isolate of Candida species on solid media.
Specimen Preparation: Body Fluid: Transfer 2 mL body fluid to a sterile container. (Min: 1.5 mL)
Tissue: Transfer to a sterile container and freeze immediately.
Isolate: Transport sealed container with pure isolate on solid media. Place each specimen in an individually sealed bag.
Isolate: Refrigerated.
Remarks: Specimen source required.
Unacceptable Conditions: Plasma, serum, or whole blood. Mixed cultures or isolates other than suspected Candida species. Isolates with no visible colonies.

Stability (collection to initiation of testing): Body Fluid: Ambient: 2 weeks; Refrigerated: 2 weeks; Frozen: 2 weeks
Tissue: Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 2 weeks
Isolate: Ambient: 1 week; Refrigerated; 2 weeks; Frozen: Unacceptable

Reference Interval:

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013798</td>
<td>Candida Species by PCR</td>
<td>Not Detected</td>
</tr>
<tr>
<td>2013901</td>
<td>Candida FKS Drug Resistance by Sequencing</td>
<td>By report</td>
</tr>
</tbody>
</table>

Interpretive Data: Refer to report.

See Compliance Statement B: www.aruplab.com/CS

Note: The Candida Species by PCR detects and differentiates C. albicans, C. glabrata, C. parapsilosis complex (C. parapsilosis, C. orthopsilosis, C. metapsilosis), C. tropicalis, C. krusei, and C. dubliniensis. If Candida Species by PCR result is detected for a single Candida species (C. albicans, C. glabrata, C. krusei, C. parapsilosis complex, C. tropicalis) then Candida FKS Drug Resistance by Sequencing will be added. Additional charges apply. If Candida Species by PCR result is not detected, or detected for multiple Candida species, or detected for C. dubliniensis then Candida FKS Drug Resistance by Sequencing will be not be added.

CPT Code(s): 87481 x6; if reflexed, add 87900

New York DOH approval pending. Call for status update.

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

0098830 Chromium, Serum CR S

Performed: Mon, Wed-Sat
Reported: 1-4 days

0025068 Chromium, Urine CR-U

Performed: Mon, Wed, Fri, Sat
Reported: 1-5 days
HOTLINE NOTE: There is a clinically significant charting name change associated with this test. Change the charting name of component 0050188 from Cryoglobulin Quantitative Screen to Cryoglobulin Qualitative Screen.

New Test

Available Now

2013956

CV2.1 Screen by IFA with Reflex to Titer

CV2.1 SCRN

Additional Technical Information

Methodology:
Semi-Quantitative Indirect Fluorescent Antibody

Performed:
Thu

Reported:
1-8 days

Specimen Required:
Collect: Serum Separator Tube (SST) or Plain Red.
Specimen Preparation: Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.25 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed, contaminated, or severely lipemic specimens.

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

Reference Interval:
Less than 1:10

Interpretive Data:
CV2.1 antibodies aid in discriminating between chronic paraneoplastic neurological disorder (PND) and other inflammatory disorders of the nervous system. Anti-CV2.1 is associated with small-cell lung cancer and thymoma.

See Compliance Statement B: www.aruplab.com/CS

Note: If CV2.1 Antibody IgG Screen by IFA is positive, then CV2.1 Antibody IgG Titer by IFA will be added. Additional charges apply.

CPT Code(s):
86255; if reflexed, add 86256

New York DOH approval pending. Call for status update.

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

2000624

Cytology, Pap Smear

GG REQUEST

Performed:
Sun-Sat

Reported:
1-14 days

Specimen Required:
Collect: Unstained cervical or endocervical slides. For specific instructions, refer to Specimen Collection and Handling.
Specimen Preparation: Label and transport slides in slide holders.
Storage/Transport Temperature: Room temperature.
Unacceptable Conditions: Unlabeled slide(s).

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

Interpretive Data: Refer to report.

Note: A conventional pap smear is used as a screening test for evaluation of the lower female genital tract to detect the presence of inflammatory/infectious or benign proliferative conditions; detection of unsuspected or confirmation of suspected atypical, premalignant, or malignant changes; or follow-up of patients with known and/or treated premalignant or malignant lesions.

The Pap test is a screening test for cervical cancer and its precursors with an inherent false-negative rate.

HOTLINE NOTE: Remove information found in the Patient Preparation field.
### 2000134
**Cytology, SurePath Liquid-Based Pap Test**

**GA REQUEST**

<table>
<thead>
<tr>
<th>Performed</th>
<th>Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sun-Sat</td>
<td>1-14 days</td>
</tr>
</tbody>
</table>

**Specimen Required:**
- **Collect:** Cervical specimen in a SurePath collection kit, Rovers Cervex-Brush Kit (ARUP Supply #22216), PAP Perfect Plastic Spatula and Cytobrush Plus GT Collection Kit (ARUP Supply #41126), or Rovers Cervex-Brush Combi Collection Kit (ARUP Supply #45031) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. For specific instructions refer to Specimen Collection and Handling.
- **Specimen Preparation:** Transport cervical specimen in the original collection kit.
- **Storage/Transport Temperature:** Room temperature.
- **Unacceptable Conditions:** Specimens not collected in a SurePath collection kit. Expired preservative vials or vials received without the collection devices.

**Stability (collection to initiation of testing):**
- Ambient: 1 month
- Refrigerated: 6 months
- Frozen: Unacceptable

**Interpretive Data:** Refer to report.

**Note:** This test does not include HPV testing. The Pap test is a screening test for cervical cancer and its precursors with an inherent false-negative rate.

**HOTLINE NOTE:** Remove information found in the Patient Preparation field.

### 2000133
**Cytology, SurePath Liquid-Based Pap Test and Human Papillomavirus (HPV), High Risk by PCR, SurePath (for routine co-testing in women over 30)**

**GH REQUEST**

**Specimen Required:**
- **Collect:** Cervical specimen in a SurePath collection kit, Rovers Cervex-Brush Kit (ARUP Supply #22216), PAP Perfect Plastic Spatula and Cytobrush Plus GT Collection Kit (ARUP Supply #41126), or Rovers Cervex-Brush Combi Collection Kit (ARUP Supply #45031) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. For specific instructions refer to Specimen Collection and Handling.
- **Specimen Preparation:** Transport cervical specimen in the original collection kit.
- **Storage/Transport Temperature:** Room temperature.
- **Unacceptable Conditions:** Specimens not collected in a SurePath collection kit. Expired preservative vials or vials received without the collection devices.

**Stability (collection to initiation of testing):**
- Ambient: 1 month
- Refrigerated: 6 months
- Frozen: Unacceptable

**Interpretive Data:** Refer to report.

**Note:** If the SurePath Liquid-Based Pap Test is interpreted as Satisfactory, then Human Papillomavirus (HPV) High Risk by PCR, SurePath will be added. Additional charges apply. Unsatisfactory SurePath Liquid-Based Pap test specimens will not be tested for HPV.

The Pap test is a screening test for cervical cancer and its precursors with an inherent false-negative rate.

**HOTLINE NOTE:** Remove information found in the Patient Preparation field.

### 2000135
**Cytology, SurePath Liquid-Based Pap Test with Reflex to Human Papillomavirus (HPV), High Risk by PCR, SurePath**

**GR REQUEST**

**Specimen Required:**
- **Collect:** Cervical specimen in a SurePath collection kit, Rovers Cervex-brush Kit (ARUP Supply #22216), PAP Perfect Plastic Spatula and Cytobrush Plus GT Collection Kit (ARUP Supply #41126), or Rovers Cervex-Brush Combi Collection Kit (ARUP Supply #45031) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. For specific instructions refer to Specimen Collection and Handling.
- **Specimen Preparation:** Transport cervical specimen in the original collection kit.
- **Storage/Transport Temperature:** Room temperature.
- **Unacceptable Conditions:** Specimens not collected in a SurePath collection kit. Expired preservative vials or vials received without the collection devices.

**Stability (collection to initiation of testing):**
- Ambient: 1 month
- Refrigerated: 6 months
- Frozen: Unacceptable

**Interpretive Data:** Refer to report.

**HOTLINE NOTE:** Remove information found in the Patient Preparation field.
### Weekly HOTLINE: Effective February 21, 2017

#### 2000137  
Cytology, ThinPrep Pap Test

| Performed: | Sun-Sat |
| Reported:  | 1-14 days |

**Specimen Required:**
- **Collect:** Cervical specimen in a ThinPrep Pap Test collection kit, broom kit (ARUP Supply #12587) or brush/spatula kit (ARUP Supply #40624) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. For specific instructions refer to Specimen Collection and Handling.
- **Specimen Preparation:** Transport cervical specimen in the original collection kit.
- **Storage/Transport Temperature:** Room temperature.
- **Unacceptable Conditions:** Specimens not collected in a ThinPrep Pap Test collection kit or specimens submitted in an expired collection kit.
- **Stability (collection to initiation of testing):** Ambient: 3 weeks; Refrigerated: 3 weeks; Frozen: Unacceptable

**Interpretive Data:** Refer to report.

**Note:** The ThinPrep 2000 System is for use in screening for the presence of atypical cells, cervical cancer, or precursor lesions (LSIL, HSIL) as well as other cytologic categories as defined by the Bethesda System for Reporting Cervical Cytology, and is intended as a replacement for the conventional method of Pap smears.

The Pap test is a screening test for cervical cancer and its precursors with an inherent false-negative rate.

Store PreservCyt Solution without cytologic samples at 15°C to 30°C in the vials provided. Do not use solution beyond expiration date marked on the vial.

**HOTLINE NOTE:** Remove information found in the Patient Preparation field.

---

#### 2000136  
Cytology, ThinPrep Pap Test and Human Papillomavirus (HPV), High Risk, E6/E7 mRNA by Transcription-Mediated Amplification (TMA) (for routine co-testing in women over 30)

| Performed: | Sun-Sat |
| Reported:  | 1-14 days |

**Specimen Required:**
- **Collect:** Cervical specimen in a ThinPrep Pap Test collection kit, broom kit (ARUP Supply #12587) or brush/spatula kit (ARUP Supply #40624) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
- **Specimen Preparation:** Transport cervical specimen in the original collection kit.
- **Storage/Transport Temperature:** Room temperature.
- **Unacceptable Conditions:** Specimens not collected in a ThinPrep Pap Test collection kit or specimens submitted in an expired collection kit.
- **Stability (collection to initiation of testing):** Ambient: 3 weeks; Refrigerated: 3 weeks; Frozen: Unacceptable

**Interpretive Data:** Refer to report.

**Note:** Unsatisfactory ThinPrep Pap test specimens will not be tested for HPV.

The ThinPrep 2000 System is for use in screening for the presence of atypical cells, cervical cancer, or precursor lesions (LSIL, HSIL) as well as other cytologic categories as defined by the Bethesda System for Reporting Cervical Cytology, and is intended as a replacement for the conventional method of Pap smears.

The Pap test is a screening test for cervical cancer and its precursors with an inherent false-negative rate.

Store PreservCyt Solution without cytologic samples at 15°C to 30°C in the vials provided. Do not use solution beyond expiration date marked on the vial.

**HOTLINE NOTE:** Remove information found in the Patient Preparation field.
Cytology, ThinPrep Pap Test with Reflex to Human Papillomavirus (HPV), High Risk, E6/E7 mRNA by Transcription-Mediated Amplification (TMA)

Performed: Sun-Sat
Reported: 1-14 days

Specimen Required: Collect: Cervical specimen in a ThinPrep Pap Test collection kit, broom kit (ARUP Supply #12587) or brush/spatula kit (ARUP Supply #40624) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Specimen Preparation: Transport cervical specimen in the original collection kit.
Storage/Transport Temperature: Room temperature.
Unacceptable Conditions: Specimens not collected in a ThinPrep Pap Test collection kit or specimens submitted in an expired collection kit.
Stability (collection to initiation of testing): Ambient: 3 weeks; Refrigerated; 3 weeks; Frozen; Unacceptable

Interpretive Data: Refer to report.

Note: If the ThinPrep Pap Test is interpreted as atypical squamous cells of undetermined significance (ASC-US), then Human Papillomavirus (HPV), High Risk, E6/E7 mRNA by Transcription-Mediated Amplification (TMA) will be added. Additional charges apply.

The Pap test is a screening test for cervical cancer and its precursors with an inherent false-negative rate. The ThinPrep 2000 System is for use in screening for the presence of atypical cells, cervical cancer, or precursor lesions (LSIL, HSIL) as well as other cytologic categories as defined by the Bethesda System for Reporting Cervical Cytology, and is intended as a replacement for the conventional method of Pap smears.

Store PreservCyt Solution without cytologic samples at 15°C to 30°C in the vials provided. Do not use solution beyond expiration date marked on the vial.

HOT LINE NOTE: Remove information found in the Patient Preparation field.
Additional Technical Information

Methodology: Qualitative Immunoprecipitation/Qualitative Immunoblot
Performed: Mon, Tue, Thu, Fri
Reported: 7-15 days

Specimen Required:
- Collect: Serum Separator Tube (SST).
- Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer one 1 mL serum aliquots to ARUP Standard Transport Tubes. (Min: 0.5 mL/aliquot)
- Storage/Transport Temperature: Refrigerated.
- Unacceptable Conditions: Hemolyzed, hyperlipemic, icteric, heat-treated or contaminated specimens.
- Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval:

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Mi-2 (nuclear helicase protein) Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>P155/140 (TIF1-gamma) Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>SAE1 (SUMO activating enzyme) Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>MDA5 (CADM-140) Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>NXP-2 (Nuclear matrix protein-2) Ab</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>TIF1-gamma Antibody</td>
<td>Negative</td>
</tr>
</tbody>
</table>

Interpretive Data: Refer to report.
See Compliance Statement D: www.aruplab.com/CS

Note: Antibodies: Mi-2, P155/140, SAE1, MDA5, NXP2, TIF1-gamma

CPT Code(s): 83516 x6

New York DOH approval pending. Call for status update.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.
### DNA Cell Cycle Analysis - Ploidy and S-Phase

**Specimen Required:** Collect: Tumor tissue, body fluid, peripheral blood in Green (Sodium or Lithium Heparin), bone marrow in Green (Sodium or Lithium Heparin), OR urine/bladder washings.

**Specimen Preparation: Tissue:** Paraffin embed tissue block enriched with tumor.

**OR Body Fluid:** Transport: 100 mL body fluid. (Min: 10 mL)

**OR Peripheral Blood:** Transport 5 mL whole blood. (Min: 1 mL)

**OR Bone Marrow:** Transport 2 mL bone marrow. (Min: 1 mL) Specimens with low mononuclear cell counts may require more volume.

**OR Urine/Bladder Washings:** Centrifuge and remove supernatant. The cell pellet should then be re-suspended in a cell culture media such as Hank's Balanced Salt Solution or RPMI.

**Storage/Transport Temperature:** Tissue (paraffin embedded), Peripheral Blood or Bone Marrow: Refrigerated.

**Body Fluid or Urine/Bladder Washings:** Refrigerated.

**Remarks:** Provide the clinical information (pathology report) and specimen source.

**Peripheral Blood, Bone Marrow, or Urine/Bladder Washings:** Provide a Wright stained slide with specimens.

**Unacceptable Conditions:** Products of Conception. No tumor tissue remaining on block. Specimens fixed in Bouin's solution (picric acid), mercuric chloride containing fixatives (e.g., B5, Zenker solution) or ethanol-based fixatives containing ethylene glycol, acetic acid, or zinc chloride. Clotted or hemolyzed blood or bone marrow. Decalcified specimens.

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

**Body Fluid or Urine/Bladder Washings:** Ambient: Unacceptable; Refrigerated: 24 hours; Frozen: Unacceptable

### EGFR T790M Mutation Detection in Circulating Tumor DNA by Digital Droplet PCR

**Specimen Required:** Collect: Whole blood in two 10 mL Cell-Free DNA (cfDNA) BCT Tubes or CSF in one 10 mL Cell-Free DNA (cfDNA) BCT Tube. (ARUP Supply #52358) available online through eSupply or contacting ARUP Client Services at (800) 522-2787.

**Specimen Preparation:** Whole Blood: Transport 20 mL whole blood. (Min: 16 mL)

**CSF:** Transport 4 mL CSF. (Min: 4 mL)

**Storage/Transport Temperature:** Refrigerated.

**Unacceptable Conditions:** FFPE tissue. Specimens collected in non-cfDNA BCT tubes.

**Stability (collection to initiation of testing):** Whole Blood: Ambient: 5 days; Refrigerated: 5 days; Frozen: Unacceptable

CSF: Ambient: Unacceptable; Refrigerated: 5 days; Frozen: Unacceptable
New Test 2014108 Enterovirus Antibodies Panel ENT AB PAN

Methodology: Serum Neutralization/Complement Fixation
Performed: Mon-Fri
Reported: 6-9 days

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

Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.75 mL) Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Mark specimens plainly as "acute" or "convalescent."

Storage/Transport Temperature: Refrigerated.

Unacceptable Conditions: Contaminated, hemolyzed, or severely lipemic specimens.

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

Reference Interval:

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>0050503</td>
<td>Coxsackie A9 Virus Antibodies by CF</td>
<td>&lt; 1:8</td>
</tr>
</tbody>
</table>
| 0060055 | Coxsackie B Virus Antibodies | Coxsackie B1: Less than 1:10
Coxsackie B2: Less than 1:10
Coxsackie B3: Less than 1:10
Coxsackie B4: Less than 1:10
Coxsackie B5: Less than 1:10
Coxsackie B6: Less than 1:10 |
| 0060053 | Echovirus Antibodies | Echovirus 6: Less than 1:10
Echovirus 7: Less than 1:10
Echovirus 9: Less than 1:10
Echovirus 11: Less than 1:10
Echovirus 30: Less than 1:10 |
| 2014107 | Poliovirus (Types 1,3) Antibodies | Less than 1:10: No detectable poliovirus antibodies.
1:10 or greater: Antibody to poliovirus detected, which may represent prior immunization or current or past infection. |

Interpretive Data: Refer to report.

CPT Code(s): 86658 x14

New York DOH Approved.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.
### Expanded Carrier Screening Next Generation Sequencing

**New Test:** 2014000  
**Available Now**

**Methodology:** Massively Parallel Sequencing/Polymerase Chain Reaction

**Performed:** Varies

**Reported:** Within 3 weeks

**Specimen Required:**
- **Collect:** Lavender (EDTA).
- **Specimen Preparation:** Transport 4 mL whole blood. (Min: 1 mL)
- **Storage/Transport Temperature:** Room temperature. Also acceptable: Refrigerated.
- **Remarks:** Patient History form required.
- **Stability (collection to initiation of testing):** Ambient: 1 week; Refrigerated: 1 week; Frozen: Unacceptable

**Reference Interval:** By report

**CPT Code(s):** 81404; 81405; 81406; 81407; 81223; 81252; 81479; 81257

New York DOH Approved.

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

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### Familial Transthyretin Amyloidosis (TTR) Sequencing

**New Test:** 2014035  
**Available Now**

**Methodology:** Polymerase Chain Reaction/Sequencing

**Performed:** Sun-Sat

**Reported:** Within 2 weeks

**Specimen Required:**
- **Collect:** Lavender (EDTA), Pink (K₂EDTA).
- **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: Unacceptable

#### Interpretive Data: Background Information for Familial Transthyretin Amyloidosis (TTR) Sequencing:

- **Characteristics:** Familial Transthyretin Amyloidosis is caused by pathogenic variants of the TTR gene resulting in abnormal amyloid accumulation in various tissues and is generally categorized into three phenotypes: 1) familial amyloid polyneuropathy, a slowly progressive sensorimotor and autonomic neuropathy; 2) familial amyloid cardiomyopathy, a restrictive cardiomyopathy with cardiomegaly, conduction block, angina, congestive heart failure and aortic dissection/dilatation; and 3) leptomeningeal amyloidosis, primarily affecting the CNS, causing dementia, visual impairment, seizures, ataxia, psychosis, hemorrhage, and hydrocephalus. TTR variants can also be associated with benign familial euthyroid hyperthyroxinemia.

- **Incidence:** 1 in 568 individuals from Northern Portugal; 1 in 100,000 individuals of Northern European ancestry.

- **Inheritance:** Autosomal dominant.

- **Penetrance:** Incomplete.

- **Cause:** Pathogenic TTR gene variants.

- **Clinical Sensitivity:** 99 percent for Familial TTR Amyloidosis.

- **Methodology:** Bidirectional sequencing of all coding regions and intron-exon boundaries of the TTR gene.

- **Analytical Sensitivity and Specificity:** 99 percent.

- **Limitations:** Diagnostic errors can occur due to rare sequence variations. Regulatory region variants, deep intronic variants and large deletions/duplications in TTR will not be detected.

See Compliance Statement C: www.aruplab.com/CS

**CPT Code(s):** 81404

New York DOH approval pending. Call for status update.

**HOTLINE NOTE:** Refer to the Test Mix Addendum for interface build information.
**New Test** | 2013929 | **Growth Hormone, 150 Minutes** | **GH 150**

**Methodology:** Quantitative Chemiluminescent Immunoassay  
**Performed:** Sun-Sat  
**Reported:** 1-2 days  

**Specimen Required:**  
Collect: Plasma Separator Tube (PST) or Serum Separator Tube (SST). Collect one tube per timed specimen. Also acceptable: Green (sodium or lithium heparin), Lavender (EDTA), or Pink (K₂EDTA).  
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma per timed specimen to individual ARUP Standard Transport Tubes. (Min: 0.4 mL per timed specimen)  
Storage/Transport Temperature: Frozen. Also acceptable: Refrigerated.  
Unacceptable Conditions: Tissue or urine. Grossly hemolyzed or lipemic specimens.  
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 1 week; Frozen: 2 months

**Interpretive Data:** Growth hormone stimulation tests should induce a peak of greater than 5 ng/mL in children and greater than 4 ng/mL in adults; lower values suggest growth hormone deficiency. For children, some experts consider values of 5-8 ng/mL equivocal and only peak values of greater than 8 ng/mL as truly normal.  

For suppression testing, normal subjects have growth hormone concentrations of less than 0.8 ng/mL within 2 hours of ingestion of a 75 or 100 gram glucose dose. Patients with acromegaly fail to show normal suppression.  

**Note:** This Growth Hormone assay is now standardized to the Recombinant Second International Standard (IS): 98/574. Growth hormone results read approximately 25 percent lower than with the previous standards (First IS: 80/505). Reference ranges have also been modified according to the assay manufacturer.

**CPT Code(s):** 83003

New York DOH Approved.

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

2013927 Growth Hormone, 180 Minutes

Available Now

**Methodology:** Quantitative Chemiluminescent Immunoassay

**Performed:** Sun-Sat

**Reported:** 1-2 days

**Specimen Required:** Collect: Plasma Separator Tube (PST) or Serum Separator Tube (SST). Collect one tube per timed specimen. Also acceptable: Green (sodium or lithium heparin), Lavender (EDTA), or Pink (K$_2$EDTA).

**Specimen Preparation:** Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma per timed specimen to individual ARUP Standard Transport Tubes. (Min: 0.4 mL per timed specimen)

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

**Unacceptable Conditions:** Tissue or urine. Grossly hemolyzed or lipemic specimens.

**Stability (collection to initiation of testing):** Ambient: 24 hours; Refrigerated: 1 week; Frozen: 2 months

**Interpretive Data:**

Growth hormone stimulation tests should induce a peak of greater than 5 ng/mL in children and greater than 4 ng/mL in adults; lower values suggest growth hormone deficiency. For children, some experts consider values of 5-8 ng/mL equivocal and only peak values of greater than 8 ng/mL as truly normal.

For suppression testing, normal subjects have growth hormone concentrations of less than 0.8 ng/mL within 2 hours of ingestion of a 75 or 100 gram glucose dose. Patients with acromegaly fail to show normal suppression.

**Note:** This Growth Hormone assay is now standardized to the Recombinant Second International Standard (IS): 98/574. Growth hormone results read approximately 25 percent lower than with the previous standards (First IS: 80/505). Reference ranges have also been modified according to the assay manufacturer.

**CPT Code(s):** 83003

New York DOH Approved.

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

0065147 Helicobacter pylori Antigen, Fecal by EIA

**Performed:** Sun-Sat

**Reported:** Within 48 hours

2004672 HER2/neu Quantitative by ELISA

**Performed:** Varies

**Reported:** 5-10 days

**Specimen Required:** Collect: Plain red or serum separator tube.

**Specimen Preparation:** Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.2 mL)

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

**Unacceptable Conditions:** Hemolyzed or thawed specimens.

**Stability (collection to initiation of testing):** Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 1 month
# Histoplasma Antigen by EIA, Serum

**Reference Interval:**
- Negative - Less than 2.0 U/mL
- Weak Positive - 2.0-4.0 U/mL
- Positive - Greater than 4.0 U/mL

**Interpretive Data:** This EIA test should be used in conjunction with other diagnostic procedures, including microbiological culture, histological examination of biopsy samples, and/or radiographic evidence, to aid in the diagnosis of histoplasmosis. See Compliance Statement B: www.aruplab.com/CS

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# HLA-DP Genotyping

**New Test Available Now**

<table>
<thead>
<tr>
<th>Methodology:</th>
<th>Polymerase Chain Reaction/Sequence Specific Oligonucleotide Probe Hybridization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performed:</td>
<td>Mon-Fri</td>
</tr>
<tr>
<td>Reported:</td>
<td>3-7 days</td>
</tr>
</tbody>
</table>

**Specimen Required:**
- Collect: Lavender (EDTA), Pink (K2EDTA), or Yellow (ACD Solution A or B).
- Specimen Preparation: Transport 5 mL whole blood. (Min: 3 mL)
- Storage/Transport Temperature: Refrigerated.
- Unacceptable Conditions: Green (Sodium or Lithium Heparin) tubes.

**Reference Interval:** By report

**Interpretive Data:**
- **Background Information for HLA-DP Genotyping:**
  - **Purpose:** For immunization/vaccination trials or to aid the clinical diagnosis of diseases strongly associated with the HLA-DP locus.
  - **Methodology:** PCR followed by Sequence Specific Oligonucleotide Probe Hybridization of HLA-DP locus.
  - **Analytical Sensitivity & Specificity:** Medium to high resolution of HLA-DP locus.
  - **Limitations:** The presence of a disease-associated HLA combination does not establish a diagnosis. If fewer than 2 alleles are reported for a locus, the patient is likely homozygous. Rare diagnostic errors can occur due to primer or probe site mutations. This test is not sufficient for comprehensive HLA evaluation for clinical hematopoietic stem cell transplantation; for pre-transplant allele matching, consider HLA Class I (ABC) by Next Generation Sequencing (ARUP test code 2011264) and/or HLA Class II (DQA1 and DQB1) by Next Generation Sequencing (ARUP test code 2011272). Occasionally the specific allele cannot be determined; in this case, the most likely allele assignment is made followed by a sequence of letters indicating other possible allele assignments. Interpretation of allele codes can be found at https://bioinformatics.bethematchclinical.org/hla/alpha.v3.html.

  Counseling and informed consent are recommended for genetic testing. Consent forms are available online at www.aruplab.com.

- **Note:** Order this test for single antigen HLA-DP identification.

**CPT Code(s):** 81382

New York DOH approval pending. Call for status update.

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

**2014079** HLA-DQ Genotyping **HLADQ DNA**

**Methodology:** Polymerase Chain Reaction/Sequence Specific Oligonucleotide Probe Hybridization

**Performed:** Mon-Fri

**Reported:** 3-7 days

**Specimen Required:**
- **Collect:** Lavender (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:** Green (sodium or lithium heparin) tubes.

**Reference Interval:** By report

**Interpretive Data:**

**Background Information for HLA-DQ Genotyping:**

**Purpose:** For immunization/vaccination trials or to aid the clinical diagnosis of diseases strongly associated with the HLA-DQ locus.

**Methodology:** PCR followed by Sequence Specific Oligonucleotide Probe Hybridization of HLA-DQ locus.

**Analytical Sensitivity & Specificity:** Medium to high resolution of HLA-DQ locus.

**Limitations:** The presence of a disease-associated HLA combination does not establish a diagnosis. If fewer than 2 alleles are reported for a locus, the patient is likely homozygous. Rare diagnostic errors can occur due to primer or probe site mutations. This test is not sufficient for comprehensive HLA evaluation for clinical hematopoietic stem cell transplantation; for pre-transplant allele matching, consider HLA Class I (ABC) by Next Generation Sequencing (ARUP test code 2011264) and/or HLA Class II (DRB1 and DQB1) by Next Generation Sequencing (ARUP test code 2011272). Occasionally the specific allele cannot be determined; in this case, the most likely allele assignment is made followed by a sequence of letters indicating other possible allele assignments. Interpretation of allele codes can be found at https://bioinformatics.bethematchclinical.org/hla/alpha.v3.html.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online at www.aruplab.com.

**Note:** Order this test for single antigen HLA-DQ identification.

**CPT Code(s):** 81382

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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**2011942** Human Papillomavirus (HPV), High Risk by PCR, SurePath **SP HPV PCR**

**Specimen Required:**
- **Collect:** Cervical, anal or vaginal specimens with SurePath collection kit and place in SurePath media.
- **Specimen Preparation:** Mix well. Transfer 3 mL to an ARUP Standard Transport Tube. (Min 1.5 mL)
- **Storage/Transport Temperature:** Refrigerated.
- **Remarks:** Specimen source required.
- **Unacceptable Conditions:** Bloody or dark brown specimens. Specimens in any media other than indicated above.

**Stability (collection to initiation of testing):** Ambient: 1 month; Refrigerated: 6 months; Frozen: Unacceptable

**Interpretive Data:** This test amplifies DNA of 14 high-risk HPV types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) associated with cervical cancer and its precursor lesions. Sensitivity may be affected by specimen collection methods, stage of infection, and the presence of interfering substances. Results should be interpreted in conjunction with other available laboratory and clinical data. A negative high-risk HPV result does not exclude the presence of other high-risk HPV types, the possibility of future cytologic abnormalities, underlying CIN2-3, or cancer.

This test is intended for medical purposes only and is not valid for the evaluation of suspected sexual abuse or for other forensic purposes. HPV testing should not be used for screening or management of atypical squamous cells of undetermined significance (ASCUS) in women under age 21.
**Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by PCR,**

**Specimen Required:**
- **Collect:** Cervical specimen with SurePath collection kit and place in SurePath media.
- **Specimen Preparation:** Mix well. Transfer 3 mL to an ARUP Standard Transport Tube. (Min 1.5 mL)
- **Storage/Transport Temperature:** Refrigerated.
- **Remarks:** Specimen source required.
- **Unacceptable Conditions:** Bloody or dark brown specimens. Specimens in any media other than indicated above.
- **Stability (collection to initiation of testing):** Ambient: 1 month; Refrigerated: 6 months; Frozen: Unacceptable

**Interpretive Data:** This test amplifies DNA of HPV16, HPV18 and 12 other high-risk HPV types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) associated with cervical cancer and its precursor lesions. Sensitivity may be affected by specimen collection methods, stage of infection, and the presence of interfering substances. Results should be interpreted in conjunction with other available laboratory and clinical data. A negative high-risk HPV result does not exclude the presence of other high-risk HPV types, the possibility of future cytologic abnormalities, underlying CIN2-3, or cancer.

This test is intended for medical purposes only and is not valid for the evaluation of suspected sexual abuse or for other forensic purposes. HPV testing should not be used for screening or management of atypical squamous cells of undetermined significance (ASCUS) in women under age 21.

---

**Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by PCR,**

**Specimen Required:**
- **Collect:** Cervical specimen with brush or spatula from ThinPrep kit and place in PreservCyt Media.
- **Specimen Preparation:** Mix well. Transfer 3 mL to an ARUP Standard Transport Tube. (Min 1.5 mL). If test is being used for primary screening, submit specimen aliquot and retain the original specimen at the client site.
- **Storage/Transport Temperature:** Refrigerated.
- **Remarks:** Specimen source required.
- **Unacceptable Conditions:** Bloody or dark brown specimens. Specimens in any media other than indicated above.
- **Stability (collection to initiation of testing):** Ambient: 6 months; Refrigerated: 6 months; Frozen: Unacceptable

**Interpretive Data:** This test amplifies DNA of HPV16, HPV18 and 12 other high-risk HPV types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) associated with cervical cancer and its precursor lesions. Sensitivity may be affected by specimen collection methods, stage of infection, and the presence of interfering substances. Results should be interpreted in conjunction with other available laboratory and clinical data. A negative high-risk HPV result does not exclude the presence of other high-risk HPV types, the possibility of future cytologic abnormalities, underlying CIN2-3, or cancer.

This test is intended for medical purposes only and is not valid for the evaluation of suspected sexual abuse or for other forensic purposes. HPV testing should not be used for screening or management of atypical squamous cells of undetermined significance (ASCUS) in women under age 21.

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**IgA Deficiency (IgAD) Panel**

**Available Now**

**Methodology:** Quantitative Enzyme-Linked Immunosorbent Assay/Radial Immunodiffusion

**Specimen Required:**
- **Collect:** Plain Red or Serum Separator Tube (SST).
- **Specimen Preparation:** Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 1 mL)
- **Storage/Transport Temperature:** Refrigerated. Also acceptable: Frozen.
- **Unacceptable Conditions:** Lipemic specimens.
- **Stability (collection to initiation of testing):** Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 2 weeks

**Reference Interval:** By report

**CPT Code(s):** 82784, 83520

New York DOH Approved.

**HOTLINE NOTE:** Refer to the Test Mix Addendum for interface build information.
<table>
<thead>
<tr>
<th>Code</th>
<th>Test Name</th>
<th>Methodology</th>
<th>Performed</th>
<th>Reported</th>
<th>Specimen Required</th>
<th>Reference Interval</th>
<th>Interpretive Data</th>
<th>CPT Code(s)</th>
<th>New York DOH Approved</th>
<th>HOTLINE NOTE</th>
</tr>
</thead>
<tbody>
<tr>
<td>0080403</td>
<td>Indicans, Urine Qualitative</td>
<td></td>
<td>Tue, Thu, Sat</td>
<td>1-4 days</td>
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<tr>
<td>2013566</td>
<td>Insulin, 180 Minutes</td>
<td>Quantitative Chemiluminescent Immunoassay</td>
<td>Sun-Sat</td>
<td>Within 24 hours</td>
<td></td>
<td>180 minutes: 4-62 µIU/mL</td>
<td>This test reacts on a nearly equimolar basis with the analogs insulin aspart, insulin glargine, and insulin lispro. Insulin detemir exhibits approximately 50 percent cross-reactivity. Test reactivity with insulin glulisine is negligible (&lt; 3 percent). To convert to pmol/L, multiply by 6.0. The reference interval is based on a 75 g glucose challenge.</td>
<td>83525</td>
<td></td>
<td>Refer to the Test Mix Addendum for interface build information.</td>
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<tr>
<td>2003390</td>
<td>Interferon Beta Neutralizing Antibody with Reflex to Titer</td>
<td></td>
<td>Mon</td>
<td>1-15 days</td>
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</tr>
</tbody>
</table>
Additional Technical Information

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

Performed: Mon, Tue, Thu, Fri

Reported: 7-15 days

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer five 1 mL serum aliquots to ARUP Standard Transport Tubes. (Min: 0.5 mL/aliquot)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed, hyperlipemic, icteric, heat-treated or contaminated specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 1 weeks; Frozen: 1 month

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>
<tr>
<td></td>
<td>SSA 52 (Ro) (ENA) Antibody, IgG</td>
<td>29 AU/mL or less: Negative</td>
</tr>
<tr>
<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></td>
<td>SSA 60 (Ro) (ENA) Antibody, IgG</td>
<td>29 AU/mL or less: Negative</td>
</tr>
<tr>
<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>0050599</td>
<td>Scleroderma (Scl-70) (ENA) Antibody</td>
<td>29 AU/mL or less: Negative</td>
</tr>
<tr>
<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>0099592</td>
<td>Jo-1 Antibody, IgG</td>
<td>29 AU/mL or less: Negative</td>
</tr>
<tr>
<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></td>
<td>PL-7 (threonyl-tRNA synthetase) Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>PL-12 (alaninyl-tRNA synthetase) Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>EJ (glycyl-tRNA synthetase) Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>Ku Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>SRP (Signal Recognition Particle) Ab</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>OJ (isocitrylyl-tRNA synthetase) Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td>2003040</td>
<td>PM/Scl-100 Antibody, IgG by Immunoblot</td>
<td>Negative</td>
</tr>
<tr>
<td>0050465</td>
<td>Rheumatoid Factor</td>
<td>Negative</td>
</tr>
<tr>
<td>0055526</td>
<td>Cyclic Citrullinated Peptide (CCP) Antibody, IgG</td>
<td>19 Units or less: Negative</td>
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<td></td>
<td></td>
<td>20-39 Units: Weak positive</td>
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<tr>
<td></td>
<td></td>
<td>40-59 Units: Moderate positive</td>
</tr>
<tr>
<td></td>
<td></td>
<td>60 Units or Greater: Strong positive</td>
</tr>
<tr>
<td>0050639</td>
<td>Nuclear Antibody (ANA) by IFA, IgG</td>
<td>Less than 1:40</td>
</tr>
</tbody>
</table>

Interpretive Data: Refer to report.
See Compliance Statement D: www.aruplab.com/CS

Note: Antibodies: Ro52, Ro60, Jo-1, PL-7, PL12, EJ, Ku, SRP, OJ, PM/Scl-100, MDA5, CCP, Scl-70, RA, ANA, NXP-2
Quarterly HOTLINE: Effective February 21, 2017

CPT Code(s): 83516 x8; 86235 x5; 86200; 86431; 86039

New York DOH approval pending. Call for status update.

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Performance</th>
<th>Reporting</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>0099265</td>
<td>Manganese, Serum</td>
<td>Mon, Wed, Fri</td>
<td>1-5 days</td>
<td></td>
</tr>
<tr>
<td>0099272</td>
<td>Manganese, Whole Blood</td>
<td>Mon, Wed, Fri</td>
<td>1-5 days</td>
<td></td>
</tr>
<tr>
<td>0054440</td>
<td>Measles (Rubeola) Antibody, IgG, CSF</td>
<td>Collect: CSF</td>
<td>Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen. Unacceptable Conditions: Specimens other than CSF. Contaminated, heat-inactivated or hemolyzed specimens. Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: 2 weeks; Frozen: 1 year</td>
<td></td>
</tr>
<tr>
<td>0054442</td>
<td>Mumps Virus Antibody IgG, CSF</td>
<td>Collect: CSF</td>
<td>Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen. Unacceptable Conditions: Specimens other than CSF. Contaminated, heat-inactivated or hemolyzed specimens. Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: 2 weeks; Frozen: 1 year</td>
<td></td>
</tr>
</tbody>
</table>
New Test
Available Now

2013961
Myositis Extended Panel
MYOS PAN

Additional Technical Information

Methodology:
Qualitative Immunoprecipitation/Semi-Quantitative Multiplex Bead Assay/Qualitative Immunoblot

Performed:
Mon, Tue, Thu, Fri

Reported:
7-15 days

Specimen Required:
Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer three 1 mL serum aliquots to ARUP Standard Transport Tubes. (Min: 0.5 mL/aliquot)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed, hyperlipemic, icteric, heat-treated or contaminated specimens.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

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>29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive</td>
</tr>
<tr>
<td></td>
<td>SSA 52 (Ro) (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></td>
<td>SSA 60 (Ro) (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>RNP (U1) (Ribonucleoprotein) (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></td>
<td>Mi-2 (nuclear helicase protein) Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>PL-7 (threonyl-tRNA synthetase) Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>PL-12 (alanyl-tRNA synthetase) Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>P155/140 (TIF1-gamma) Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>EJ (glycyl-tRNA synthetase) Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>Ku Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>U2 sn (small nuclear) RNP Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>SRP (Signal Recognition Particle) Ab</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>OJ (isoacceptor tRNA synthetase) Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>SAE1 (SUMO activating enzyme) Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>MDA5 (CADM-140) Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>NXP-2 (Nuclear matrix protein-2) Ab</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>TIF1-gamma (TIF1-y) Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td>2012173</td>
<td>Fibrillarin (U3 RNP) Antibody, IgG</td>
<td>Negative</td>
</tr>
<tr>
<td>2003040</td>
<td>FM/Scl-100 Antibody, IgG by Immunoblot</td>
<td>Negative</td>
</tr>
</tbody>
</table>

Interpretive Data:
Refer to report.
Note: Antibodies: Mi-2, PL-7, PL12, P155/140, EJ, Ku, OJ, PM/ScI, SRP, U2RNP, U1RNP, Ro52, Ro60, Jo-1, U3 Fib, SAE1, NXP2, MDA5, TIF1-gamma

CPT Code(s): 83516 x13; 86235 x6

New York DOH approval pending. Call for status update.

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

<table>
<thead>
<tr>
<th>0099452</th>
<th>Nickel, Serum</th>
<th>NICKEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performed:</td>
<td>Mon, Wed, Fri</td>
<td></td>
</tr>
<tr>
<td>Reported:</td>
<td>1-8 days</td>
<td></td>
</tr>
</tbody>
</table>
New Test Available Now

**2013955 Paraneoplastic Reflexive Panel** (PNS PAN)

**Methodology:** Semi-Quantitative Indirect Fluorescent Antibody/Qualitative Immunoblot

**Performed:** Wed

**Reported:** 1-9 days

**Specimen Required:**
- **Collect:** Serum Separator Tube (SST).
- **Specimen Preparation:** Separate from cells ASAP or within 2 hours of collection. Transfer 3 mL serum aliquot to an ARUP Standard Transport Tube. (Min: 1.0 mL)
- **Storage/Transport Temperature:** Refrigerated.
- **Unacceptable Conditions:** Contaminated, heat-inactivated, hemolyzed, or lipemic specimens.
- **Stability (collection to initiation of testing):** After separation from cells: Ambient: 24 hours; Refrigerated: 2 weeks; Frozen: 1 year

### Reference Interval:

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013956</td>
<td>CV2.1 Screen by IFA with Reflex to Titer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CV2.1 Antibody IgG Screen by IFA</td>
<td>Less than 1:10</td>
</tr>
<tr>
<td></td>
<td>CV2.1 Antibody IgG Titer by IFA</td>
<td>Less than 1:10</td>
</tr>
<tr>
<td>2007961</td>
<td>Paraneoplastic Antibodies (PCCA/ANNA) by IFA with Reflex to Titer and Immunoblot</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Purkinje Cell/Neuronal Nuclear IgG Scrn</td>
<td>None Detected</td>
</tr>
<tr>
<td></td>
<td>Neuronal Nuclear Antibody (ANNA) IFA Titer, IgG</td>
<td>Less than 1:10</td>
</tr>
<tr>
<td></td>
<td>Purkinje Cell Antibody, Titer</td>
<td>Less than 1:10</td>
</tr>
<tr>
<td>2007963</td>
<td>Neuronal Nuclear Antibodies (Hu, Ri, Yo) IgG by Immunoblot</td>
<td>None Detected</td>
</tr>
<tr>
<td>2008893</td>
<td>Amphiphysin Antibody, IgG</td>
<td>Negative</td>
</tr>
</tbody>
</table>

### Components Reference Interval

<table>
<thead>
<tr>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>CV2.1 Antibody IgG Screen by IFA</td>
<td>Less than 1:10</td>
</tr>
<tr>
<td>CV2.1 Antibody IgG Titer by IFA</td>
<td>Less than 1:10</td>
</tr>
<tr>
<td>Purkinje Cell/Neuronal Nuclear IgG Scrn</td>
<td>None Detected</td>
</tr>
<tr>
<td>Neuronal Nuclear Antibody (ANNA) IFA Titer, IgG</td>
<td>Less than 1:10</td>
</tr>
<tr>
<td>Purkinje Cell Antibody, Titer</td>
<td>Less than 1:10</td>
</tr>
<tr>
<td>Neuronal Nuclear Antibodies (Hu, Ri, Yo) IgG by Immunoblot</td>
<td>None Detected</td>
</tr>
<tr>
<td>Amphiphysin Antibody, IgG</td>
<td>Negative</td>
</tr>
</tbody>
</table>

### Test Number

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007963</td>
<td>Neuronal Nuclear Antibodies (Hu, Ri, Yo) IgG by Immunoblot</td>
</tr>
<tr>
<td>2008893</td>
<td>Amphiphysin Antibody, IgG</td>
</tr>
</tbody>
</table>

### Interpretive Data:

Refer to report.

See Compliance Statement D: www.aruplab.com/CS

**Note:** Purkinje Cell (PCCA) antibody and Neuronal Nuclear (ANNA) antibody IgG are screened by IFA. If the IFA screen is indeterminate, then a Neuronal Nuclear Antibodies (Hu, Ri, and Yo) IgG by Immunoblot will be added. If the IFA screen is positive at 1:10 or greater, then a PCCA/ANNA antibodies titer and Neuronal Nuclear Antibodies (Hu, Ri, and Yo) IgG by Immunoblot will be added. Additional charges apply. If CV2.1 Antibody IgG Screen by IFA is positive, then CV2.1 Antibody IgG Titer by IFA will be added. Additional charges apply.

**CPT Code(s):** 86255 x2; 83516; if reflexed add 86256 and/or 83516; if reflexed add 86256

New York DOH approval pending. Call for status update.

**HOTLINE NOTE:** Refer to the Test Mix Addendum for interface build information.
**New Test** 2014107  
**Poliovirus (Types 1, 3) Antibodies**  
**POLIO AB**

**Methodology:** Semi-Quantitative Serum Neutralization

**Performed:** Mon-Fri

**Reported:** 6-9 days

**Specimen Required:**
- **Collect:** Serum Separator Tube (SST) or Plain Red.
- **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. Contaminated, hemolyzed, or severely lipemic specimens.
- **Stability (collection to initiation of testing):** After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

**Reference Interval:**

<table>
<thead>
<tr>
<th>Less than 1:10</th>
<th>No detectable poliovirus antibodies.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:10 or greater</td>
<td>Antibody to poliovirus detected, which may represent prior immunization or current or past infection.</td>
</tr>
</tbody>
</table>

**Interpretive Data:**
The presence of neutralizing antibodies against poliovirus implies immunity. The serum neutralization test is serotype specific. Antibodies against one type does not indicate immunity against the other type.

Reference interval applies to Poliovirus Antibodies Types 1 and 3.

**CPT Code(s):** 86658 x2

New York DOH Approved.

**HOTLINE NOTE:** Refer to the Test Mix Addendum for interface build information.
New Test  
**2013992 Polymyositis and Dermatomyositis Panel**

### Additional Technical Information

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

**Performed:** Mon, Tue, Thu, Fri

**Reported:** 7-15 days

**Specimen Required:**

- **Collect:** Serum Separator Tube (SST).
- **Specimen Preparation:** Separate from cells ASAP or within 2 hours of collection. Transfer two 1 mL serum aliquots to ARUP Standard Transport Tubes. (Min: 0.5 mL/aliquot)
- **Storage/Transport Temperature:** Refrigerated.
- **Unacceptable Conditions:** Hemolyzed, hyperlipemic, icteric, heat-treated or contaminated specimens.
- **Stability (collection to initiation of testing):** Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

### Reference Interval:

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<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>PL-7 (threonyl-tRNA synthetase) Antibody</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>PL-12 (alanyl-tRNA synthetase) Antibody</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>EJ (glycyl-tRNA synthetase) Antibody</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>SRP (Signal Recognition Particle) Ab</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>OJ (isoleucyl-tRNA synthetase) Antibody</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>Mi-2 (nuclear helicase protein) Antibody</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>P155/140 Antibody</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>SAE1 (SUMO activating enzyme) Antibody</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>MDA5 (CADM-140) Antibody</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>NXP-2 (Nuclear matrix protein-2) Ab</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>TIF1-gamma (TIF1-y) Antibody</td>
<td>Negative</td>
<td></td>
</tr>
</tbody>
</table>

### Interpretive Data:

- Refer to report.
- See Compliance Statement D: www.aruplab.com/CS

**Note:** Antibodies: PL-7, PL12, EJ, OJ, SRP, Jo-1, Mi-2, P155/140, SAE1, MDA5, NXP2, TIF1-gamma

**CPT Code(s):** 83516 x11; 86235

New York DOH approval pending. Call for status update.

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

## Additional Technical Information

### Methodology:
Qualitative Immunoprecipitation/Semi-Quantitative Multiplex Bead Assay

### Performed:
Mon, Tue, Thu, Fri

### Reported:
7-15 days

### Specimen Required:
- **Collect:** Serum Separator Tube (SST).
- **Specimen Preparation:** Separate from cells ASAP or within 2 hours of collection. Transfer two 1 mL serum aliquots to ARUP Standard Transport Tubes. (Min: 0.5 mL/aliquot)
- **Storage/Transport Temperature:** Refrigerated.
- **Unacceptable Conditions:** Hemolyzed, hyperlipemic, icteric, heat-treated or contaminated specimens.
- **Stability (collection to initiation of testing):** Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

### Reference Interval:

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>0099592</td>
<td>Jo-1 Antibody, IgG</td>
<td>29 AU/mL or less: Negative</td>
</tr>
<tr>
<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></td>
<td>PL-7 (threonyl-tRNA synthetase) Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>PL-12 (alanyl-tRNA synthetase) Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>EJ (glycyl-tRNA synthetase) Antibody</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>SRP (Signal Recognition Particle) Ab</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>OJ (isoleucyl-tRNA synthetase) Antibody</td>
<td>Negative</td>
</tr>
</tbody>
</table>

### Interpretive Data:
Refer to report.
See Compliance Statement B: www.aruplab.com/CS

### Note:
Antibodies: PL-7, PL12, EJ, OJ, SRP, Jo-1

### CPT Code(s):
83516 x5; 86235

New York DOH approval pending. Call for status update.

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

| Test | Code | Method | Performed | Reported | Specimen | Reference
|------|------|--------|-----------|----------|----------|-----------
| Potassium, RBC | K RBC | Quantitative Inductively Coupled Plasma-Optical Emission Spectrometry | Varies | 3-10 days | Green (Lithium Heparin). Separate cells within 2 hours of collection. Transfer 2 mL RBCs to a trace metal-free or acid-washed plastic container. (Min: 0.7 mL) Refrigerated. Also acceptable: Frozen. | By Report

CPT Code(s): 84132

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

Reducing Substances, Fecal

| Test | Code | Method | Performed | Reported | Specimen | Reference
|------|------|--------|-----------|----------|----------|-----------
| Intestinal | FECRED | Polymerase Chain Reaction/Sequencing/Gel Electrophoresis | Sun-Sat | 1-2 days | | |

CMT REFLEX

| Test | Code | Method | Performed | Reported | Specimen | Reference
|------|------|--------|-----------|----------|----------|-----------
| Charcot-Marie-Tooth (CMT) and Related Hereditary Neuropathies, PMP22 | CMT REFLEX | Deletion/Duplication with Reflex to Sequencing Panel | Varies | Within 2 weeks | If reflexed, add 56-70 days | |

Note: Deletion/Duplication analysis is performed on all samples. If no large deletions or duplications are detected and/or results do not explain the clinical scenario, then sequencing of the Charcot-Marie-Tooth and Related Hereditary Neuropathy gene will be added. Additional charges apply. If reflexed, an additional 8-10 weeks is required to complete testing.

78 Genes sequenced: AARS, AIFM1, ARHGEF10, ATL1, ATP7A, BAG3, BICD2, BSC1L2, CCT5, DCTN1, DHTKD1, DN4JB2, DNM2, DNMT1, DYNC1H1, EGR2, FAM134B, FBLN5, FGD4, FIG4, GAN, GARS, GDAP1, GJB1, GNB4, HARS, HEXA, HINT1, HK1, HOXD10, HSPB1, HSPB3, HSPB6, IGKMBP2, IKBP2, INF2, KARS, KIF1A, KIF1B, KIF5A, LASS1L, LITAF, LMNA, LRSAM1, MARS, MED25, MFN2, MPZ, MTMR2, MYH14, NDRG1, NERI, NGF, NTRK1, PDK3, PLEKHC1G, PMP22, PRNP, PRPS1, PRX, RAB7A, REEP1, SBF1, SBF2, SCN9A, SETX, SH3TC2, SLC12A6, SLC5A7, SOX10, SPTLC1, SPTLC2, TDP1, TFG, TRIM2, TRPV4, WNK1, YARS.

Tay-Sachs Disease (HEXA) Sequencing and 7.6kb Deletion

| Test | Code | Method | Performed | Reported | Specimen | Reference
|------|------|--------|-----------|----------|----------|-----------
| Intestinal | HEXA FGS | Polymerase Chain Reaction/Sequencing/Gel Electrophoresis | | | | |
New Test
Available Now

**0013410** Thermal Amplitude Test
IRL-THERM

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

**Specimen Required:** Collect: Lavender (EDTA) or Pink (K$_2$ EDTA) AND Plain Red.

**Specimen Preparation:** Maintain at 37°C until separated from cells. Transport 7 mL red blood cells and 5 mL plasma or serum in ARUP Standard Transport Tubes. (Min: 7 mL red blood cells and 3 mL plasma or serum)

**Storage/Transport Temperature:** Refrigerated.

**Unacceptable Conditions:** Separator or Gel Tubes.

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

**CPT Code(s):** 86870

New York DOH Approved.

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

**0051690** Transforming Growth Factor beta, Plasma
TGFB PLA

**Performed:** Tue
**Reported:** 1-8 days

**0051694** Transforming Growth Factor beta, Serum
TGFB SER

**Performed:** Tue
**Reported:** 1-8 days

**0090307** Tricyclic Antidepressant Detection
STAD

**Interpretive Data:** This test is positive when the total concentration of all detectable tricyclic antidepressants produces a response greater than the cutoff of 300 ng/mL nortriptyline. This is a screening test, results are unconfirmed. Unconfirmed results are to be used for medical (treatment) purposes only. Tricyclic antidepressants detectable with this assay include: amitriptyline, clomipramine, desipramine, doxepin, imipramine, nortriptyline, protriptyline, and trimipramine.

Levels of tricyclic antidepressants in the therapeutic range may not be detectable.

False-positive results may occur with the following drugs: Seroquel (quetiapine fumarate), Trileptal (oxcarbazepine), Benadryl (diphenhydramine) at toxic concentrations, Flexeril (cyclobenzaprine), Thoridazine, and Thorazine (chlorpromazine).
New Test
Available Now

**2014025** Trypsin
TRYPS

**Methodology:** Quantitative Radioimmunoassay

**Performed:** Tue, Fri

**Reported:** 1-5 days

**Specimen Required:** Collect: Serum Separator Tube (SST) or Plain Red.

**Specimen Preparation:** Allow specimen to clot for 15-20 minutes at room temperature. Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.3 mL)

**Storage/Transport Temperature:** Frozen.

**Unacceptable Conditions:** Plasma. Grossly hemolyzed or lipemic specimens.

**Stability (collection to initiation of testing):** After separation from cells: Ambient: 2 hours; Refrigerated: 24 hours; Frozen: 3 months

**Reference Interval:**

<table>
<thead>
<tr>
<th>Age</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-17 years</td>
<td>Not established</td>
</tr>
<tr>
<td>18 years and older</td>
<td>180.5-885.3 ng/mL</td>
</tr>
</tbody>
</table>

**Interpretive Data:** Results should be correlated with clinical presentation and other diagnostic data for the diagnosis of pancreatitis. Individuals with acute pancreatitis have significantly elevated trypsin concentrations. Concentrations in those with chronic pancreatitis are variable and may be below, within, or above the reference interval. Trypsin concentrations are not diagnostic for carcinoma of the pancreas. Results obtained with different assay methods or kits cannot be used interchangeably.

**CPT Code(s):** 83519

New York DOH approval pending. Call for status update.

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

**2001181** UroVysion FISH

**Specimen Required:** Collect: Second-morning, clean-catch voided urine specimen in UroVysion FISH Collection Kit (ARUP Supply #41440) available online through eSupply using ARUP Connector contact Client Services at (800) 522-2787. For specific instructions refer to Specimen Collection & Handling.

**Specimen Preparation:** Transport the entire collection in the original collection kit. (Min: 35 mL)

**Storage/Transport Temperature:** Refrigerated.

**Remarks:** Submit source information with the specimen.

**Unacceptable Conditions:** Specimens in inappropriate fixative. Specimens submitted in expired reagents.

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

**005444** Varicella-Zoster Virus Antibody, IgG, CSF

**Specimen Required:** Collect: CSF.

**Specimen Preparation:** Transfer 0.5 mL CSF to an ARUP Standard Transport Tube. (Min: 0.3 mL)

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

**Unacceptable Conditions:** Specimens other than CSF. Contaminated, heat-inactivated or hemolyzed specimens.

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

**0080388** Vitamin B₁ (Thiamine), Whole Blood

**Specimen Required:** Collect: Green (Sodium or Lithium) Heparin, Lavender (EDTA), or Pink (K₂EDTA).

**Specimen Preparation:** Transfer 3 mL whole blood to an ARUP Standard Tube. (Min: 0.6 mL)

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

**Unacceptable Conditions:** Any specimen other than whole blood. Plasma separator tubes. Glass tubes. Clotted or non-frozen specimens.

**Stability (collection to initiation of testing):** Ambient: Unacceptable; Refrigerated: 4 hours; Frozen: 6 months
<table>
<thead>
<tr>
<th>New Test</th>
<th>2013701</th>
<th>Vulvovaginal Candida Species by PCR</th>
<th>VCANPCR</th>
</tr>
</thead>
</table>

**Methodology:** Qualitative Polymerase Chain Reaction  
**Performed:** Mon, Thu  
**Reported:** 2-5 days

**Specimen Required:**  
**Collect:** Vaginal specimen with APTIMA Unisex Swab Specimen Collection kit (ARUP supply #28907). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.  
**Specimen Preparation:** Place blue swab in Swab Specimen Transport Tube, break off shaft at scoreline then recap tube.  
**Storage/Transport Temperature:** Frozen.  
**Unacceptable Conditions:** Heparinized specimens.  
**Stability (collection to initiation of testing):** Ambient: 2 months; Refrigerated: 2 months; Frozen: 2 months

**Interpretive Data:** Low positive results are reported as Equivocal. Low levels of Candida species can be found in asymptomatic women. A cutoff for low positive results for this test was determined in a study of asymptomatic women. A negative result does not rule out the presence of PCR inhibitors in the patient specimen or test-specific nucleic acid in concentrations below the level of detection by this test.

A negative result does not rule out the presence of PCR inhibitors in the patient specimen or test-specific nucleic acid in concentrations below the level of detection by this test.

See Compliance Statement B: www.aruplab.com/CS

**Note:** This test detects and differentiates C. albicans, C. glabrata, C. parapsilosis complex (C. parapsilosis, C. orthopsilosis, C. metapsilosis), C. tropicalis, C. krusei, and C. dubliniensis.

**CPT Code(s):** 87481 x6

New York DOH approval pending. Call for status update.

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

2014065 Zika Virus by PCR, Blood ZIKAPCR B

Methodology:
Qualitative Polymerase Chain Reaction

Performed:
Mon, Wed, Fri

Reported:
1-4 days

Specimen Required:
Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells. Transfer 2 mL serum to a sterile container. (Min: 1 mL)
Storage/Transport Temperature: Frozen.
Remarks: Specimen source required.
Unacceptable Conditions: Urine (refer to Zika Virus by PCR, Urine, ARUP test code 2014069).
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 5 days; Frozen: 6 weeks

Interpretive Data:

Zika Virus by PCR is a real-time RT-PCR test intended for the qualitative detection of Zika virus RNA from individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated).

A positive RT-PCR result confirms Zika virus infection, and no additional testing is indicated. When test results are negative, the serum should be tested as outlined in the current CDC-issued algorithm (http://www.cdc.gov/zika/laboratories/lab-guidance.html).

If serologic testing is needed as a follow-up to PCR, contact ARUP client services to order Zika Virus IgM Antibody Capture (MAC), by ELISA (ARUP test code 2013942). Additional charges apply.

The Zika Virus by PCR test is for in vitro diagnostic use under the FDA Emergency Use Authorization (EUA). This test has not been FDA cleared or approved. In compliance with this authorization, please visit https://aruplab.com/zika for more information and to access the applicable information sheets.

CPT Code(s): 87798

New York DOH Approved.

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

**2014069 Zika Virus by PCR, Urine**

**ZIKAPCR U**

**Methodology:** Qualitative Polymerase Chain Reaction

**Performed:** Mon, Wed, Fri

**Reported:** 1-4 days

**Specimen Required:**
- **Collect:** Urine and patient-matched Serum Separator Tube (SST).
- **Specimen Preparation:** Urine: Transfer 1 mL urine to a sterile container. (Min: 0.5 mL)
- **Serum:** Collect and retain 2 mL of patient-matched serum at the client site in the event that serological follow-up testing is needed. (Min: 1 mL)
- **Storage/Transport Temperature:** Frozen.
- **Remarks:** Specimen source required.

**Unacceptable Conditions:** Serum (refer to Zika Virus by PCR, Blood, ARUP test code 2014065).

**Stability (collection to initiation of testing):** Ambient: Unacceptable; Refrigerated: 5 days; Frozen: 6 weeks

**Interpretive Data:**

Zika Virus by PCR is a real-time RT-PCR test intended for the qualitative detection of Zika virus RNA from individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated).

Health care providers are strongly encouraged to collect serum specimens alongside other specimen types to provide additional opportunities for diagnosing Zika. A positive RT-PCR result confirms Zika virus infection, and no additional testing is indicated. When test results are negative for urine, the patient-matched serum should be tested as outlined in the current CDC-issued algorithm (http://www.cdc.gov/zika/laboratories/lab-guidance.html).

If serologic testing is needed on a patient-matched serum specimen, contact ARUP client services to order Zika Virus IgM Antibody Capture (MAC), by ELISA (ARUP test code 2013942). Additional charges apply.

The Zika Virus by PCR test is for in vitro diagnostic use under the FDA Emergency Use Authorization (EUA). This test has not been FDA cleared or approved. In compliance with this authorization, please visit https://aruplab.com/zika for more information and to access the applicable information sheets.

**CPT Code(s):** 87798

New York DOH Approved.

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

2013942 - Zika Virus IgM Antibody Capture (MAC), by ELISA

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay
Performed: Mon, Wed, Fri
Reported: 1-6 days

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 1.0 mL) Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Mark specimen plainly as "acute or convalescent."
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Contaminated, heat-inactivated, hemolyzed, or severely lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval: Negative

Interpretive Data: The ZIKV Detect IgM Capture ELISA assay is intended for in vitro diagnostic use under FDA Emergency Use Authorization (EUA). This test has not been FDA cleared or approved. In compliance with this authorization, please visit https://aruplab.com/zika for more information and to access the applicable information sheets.

The possibility of false-positive or false-negative results must be considered. RT-PCR testing on both a serum and urine specimen is recommended by the Centers for Disease Control and Prevention (CDC) to rule out false-negative IgM results in patients experiencing symptoms for less than 2 weeks. Specimens collected for IgM testing greater than or equal to 2 weeks after symptom onset do not require any additional testing. For more information, please review the current clinical guidelines for Zika virus testing at: www.cdc.gov/zika/.

CPT Code(s): 86790

New York DOH approval pending. Call for status update.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.
Quarterly HOTLINE: Effective February 21, 2017

The following will be discontinued from ARUP’s test menu on February 21, 2017.
Replacement test options are supplied if applicable.

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Test Name</th>
<th>Refer To Replacement</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005548</td>
<td>Chromium, Joint Fluid</td>
<td></td>
</tr>
<tr>
<td>2005549</td>
<td>Cobalt, Joint Fluid</td>
<td></td>
</tr>
<tr>
<td>0091349</td>
<td>Disulfiram (Antabuse) and Metabolite Quantitation, Serum or Plasma</td>
<td></td>
</tr>
<tr>
<td>2004250</td>
<td>Enterovirus Antibody Panel</td>
<td>Enterovirus Antibodies Panel (2014108)</td>
</tr>
<tr>
<td>2003917</td>
<td>Hepatitis B Surface Antigen by Immunohistochemistry</td>
<td></td>
</tr>
<tr>
<td>2002810</td>
<td>HLA-DQB Genotyping</td>
<td>HLA-DQ Genotyping (2014079) and/or HLA-DP Genotyping (2014073)</td>
</tr>
<tr>
<td>0080570</td>
<td>Lipoprotein Electrophoresis with Qualitative Band Assessment</td>
<td>Maternal Serum Screen, Alpha Fetoprotein, hCG, Estriol, and Inhibin A (0080269)</td>
</tr>
<tr>
<td>0080108</td>
<td>Maternal Serum Screen, Alpha Fetoprotein, hCG, and Estriol</td>
<td>Maternal Serum Screen, Alpha Fetoprotein, hCG, Estriol, and Inhibin A (0080269)</td>
</tr>
<tr>
<td>2003528</td>
<td>Metals, Joint Fluid</td>
<td></td>
</tr>
<tr>
<td>2010851</td>
<td>Myositis Antibody Comprehensive Panel</td>
<td>Myositis Extended Panel (2013996) or Polymyositis and Dermatomyositis Panel (2013992)</td>
</tr>
<tr>
<td>2010862</td>
<td>Myositis-Specific Antibody Panel</td>
<td>Polymyositis Panel (2013991), Dermatomyositis Panel (2013991), and Polymyositis and Dermatomyositis Panel (2013992)</td>
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<tr>
<td>0060054</td>
<td>Poliovirus Antibodies</td>
<td>Poliovirus (Types 1, 3) Antibodies (2014107)</td>
</tr>
<tr>
<td>0099132</td>
<td>Rabies Antibody, IgG (Vaccine Response)</td>
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<tr>
<td>2009331</td>
<td>Special Stain, Fibrin</td>
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<tr>
<td>2009391</td>
<td>Special Stain, Gridleys</td>
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</tr>
<tr>
<td>2009690</td>
<td>Special Stain, Methyl Green Pyronin (MPG)</td>
<td></td>
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<tr>
<td>2009725</td>
<td>Special Stain, Nissl Substance</td>
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</tbody>
</table>