### 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></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>46</td>
<td>2004127</td>
<td>S-100 Protein by Immunohistochemistry (DAB Detection)</td>
<td>x x</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>47</td>
<td>3003733</td>
<td>S-100 Protein by Immunohistochemistry (Red Detection)</td>
<td>x</td>
<td></td>
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</tbody>
</table>
### Summary of Changes by Test Name

<table>
<thead>
<tr>
<th>Hotline Page #</th>
<th>Test Number</th>
<th>Test Name</th>
<th>Methodology</th>
<th>Performed/Reported Schedule</th>
<th>Specimen Requirements</th>
<th>Reference Interval</th>
<th>Interpretive Data</th>
<th>Note</th>
<th>CPT Code</th>
<th>Component Change</th>
<th>Other Interface Change</th>
<th>New Test</th>
<th>Inactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>47</td>
<td>0070103</td>
<td>Serum, C-Peptide</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
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<tr>
<td>47</td>
<td>3001562</td>
<td>SOX-10 By Immunohistochemistry (DAB Detection)</td>
<td>x</td>
<td>x</td>
<td>x</td>
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<tr>
<td>48</td>
<td>3003737</td>
<td>SOX-10 by Immunohistochemistry (Red Detection)</td>
<td>x</td>
<td></td>
<td>x</td>
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<td>48</td>
<td>0090265</td>
<td>Theophylline</td>
<td>x</td>
<td></td>
<td>x</td>
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<tr>
<td>48</td>
<td>2011172</td>
<td>Urogenital Ureaplasma and Mycoplasma Species by PCR</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
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<td>49</td>
<td>3004071</td>
<td>von Willebrand Factor (VWF) GPIbM Activity</td>
<td>x</td>
<td></td>
<td>x</td>
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<td>49</td>
<td>0060132</td>
<td>Wound Culture and Gram Stain</td>
<td>x</td>
<td></td>
<td>x</td>
<td></td>
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</tr>
</tbody>
</table>

**3001495: Aggressive B-Cell Lymphoma Reflex Panel by FISH, Tissue DLBCL_RFLX**

Note: If Aggressive B-Cell Lymphoma Reflex Panel by FISH is positive, then *IGH-BCL2* Fusion, t(14;18) by FISH (ARUP test code 3001298) and *BCL6* (3q27) Gene Rearrangement by FISH (ARUP test code 3001311) will be added.

Additional charges apply.

CPT Code(s): 88366; if reflexed add 88366 x2
**New Test**  
3003923  Allergen, Food, Alpha-Gal (galactose-alpha-1,3-galactose) IgE  ALPHAGAL

**Available Now**  
Click for Pricing

**Methodology:**  
Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay

**Performed:**  
Sun-Sat 12:00 am-11:59 pm, continuously

**Reported:**  
1-2 days

**Specimen Required:**  
- **Patient Prep:** Multiple patient encounters should be avoided
- **Collect:** Plain Serum separator tube. Multiple specimen tubes should be avoided
- **Specimen Preparation:** Separate serum from cells ASAP or within 2 hours of collection. Transfer 0.25 mL serum plus 0.1 mL for each additional allergen ordered to an ARUP Standard Transport Tube. (Min: 0.25 mL plus 0.04 mL for each allergen ordered)
- **Storage/Transport Temperature:** Refrigerated.
- **Unacceptable Conditions:** Hemolyzed, icteric, or lipemic specimens.

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

**Reference Interval:**

<table>
<thead>
<tr>
<th>Reporting Range (reported in kU/L)</th>
<th>Probability of IgE Mediated Clinical Reaction</th>
<th>Class Scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 0.10</td>
<td>No significant level detected</td>
<td>0</td>
</tr>
<tr>
<td>0.10-0.34</td>
<td>Clinical relevance undetermined</td>
<td>0/1</td>
</tr>
<tr>
<td>0.35-0.70</td>
<td>Low</td>
<td>1</td>
</tr>
<tr>
<td>0.71-3.50</td>
<td>Moderate</td>
<td>2</td>
</tr>
<tr>
<td>3.51-17.50</td>
<td>High</td>
<td>3</td>
</tr>
<tr>
<td>17.51-50.00</td>
<td>Very high</td>
<td>4</td>
</tr>
<tr>
<td>50.01-100.00</td>
<td>Very high</td>
<td>5</td>
</tr>
<tr>
<td>Greater than 100.00</td>
<td>Very high</td>
<td>6</td>
</tr>
</tbody>
</table>

Allergen results of 0.10-0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. Even though increasing ranges are reflective of increasing concentrations of allergen-specific IgE, these concentrations may not correlate with the degree of clinical response or skin testing results when challenged with a specific allergen. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.

**CPT Code(s):**  
86008

New York DOH Approved.

**HOTLINE NOTE:** Refer to the Test Mix Addendum for interface build information.
New Test 3003924 Allergen, Food, Alpha-Gal (galactose-alpha-1,3-galactose) Panel ALPHAGALPN

Available Now
Click for Pricing

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat: 12:00 am-11:59 pm continuously
Reported: 1-2 days

Specimen Required:
- Patient Prep: Multiple patient encounters should be avoided
- Collect: Plain Serum separator tube. Multiple specimen tubes should be avoided
- Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 0.25 mL serum plus 0.1 mL for each additional allergen ordered to an ARUP Standard Transport Tube. (Min: 0.25 mL plus 0.04 mL for each allergen ordered)
- Storage/Transport Temperature: Refrigerated.
- Unacceptable Conditions: Hemolyzed, icteric, or lipemic specimens.
- Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval:

<table>
<thead>
<tr>
<th>Reporting Range (reported in kU/L)</th>
<th>Probability of IgE Mediated Clinical Reaction</th>
<th>Class Scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 0.10</td>
<td>No significant level detected</td>
<td>0</td>
</tr>
<tr>
<td>0.10-0.34</td>
<td>Clinical relevance undetermined</td>
<td>0/1</td>
</tr>
<tr>
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<td>Low</td>
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</tr>
<tr>
<td>17.51-50.00</td>
<td>Very high</td>
<td>4</td>
</tr>
<tr>
<td>50.01-100.00</td>
<td>Very high</td>
<td>5</td>
</tr>
<tr>
<td>Greater than 100.00</td>
<td>Very high</td>
<td>6</td>
</tr>
</tbody>
</table>

Interpretive Data:
Allergen results of 0.10-0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. Even though increasing ranges are reflective of increasing concentrations of allergen-specific IgE, these concentrations may not correlate with the degree of clinical response or skin testing results when challenged with a specific allergen. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.

CPT Code(s): 86008; 86003 x3

New York DOH Approved.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.
New Test  3002685  Alport Syndrome Panel, Sequencing and Deletion/Duplication  ALPORT NGS

Patient History for Alport Syndrome Testing

Methodology: Massively Parallel Sequencing/ Multiplex Ligation-dependent Probe Amplification
Performed: Varies
Reported: 3-6 weeks

Specimen Required:
- Collect: Lavender (EDTA) or Yellow (ACD Solution A or B).
- Specimen Preparation: Transport 3 mL whole blood. (Min: 2 mL)
- Storage/Transport Temperature: Refrigerated
- Unacceptable Conditions: Serum or plasma; grossly hemolyzed or frozen specimens
- Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:
Refer to report

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

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

Note: Genes tested: COL4A3**, COL4A4**, COL4A5, MYH9**
**Deletion/duplication detection is not performed for this gene.

CPT Code(s):  81407; 81408; 81479

New York DOH approval pending. Call for status update.

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

0020471  Amylase, Urine  UAMY

HOTLINE NOTE: There is a component change associated with this test.
Add component 3004185, Urine Creatinine - mg per dL
Add component 3004186, Urine Creatinine - per 24 hour
Add component 3004187, Urine Total Volume
Add component 3004188, Collected Hours
Remove component 0020207, Creatinine, Urine - per volume
Remove component 0020208, Creatinine, Urine - per 24h
Remove component 0097110, Total Volume
Remove component 0097111, Hours Collected
Additional Technical Information

Methodology: Semi-Quantitative Indirect Fluorescent Antibody/Semi-Quantitative Multiplex Bead Assay
Performed: Sun-Sat
Reported: 2-5 days

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: CSF, plasma, urine, or other body fluids. Contaminated, hemolyzed, or severely lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 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></td>
<td>ANCA IFA Titer</td>
<td>Less than 1:20</td>
</tr>
<tr>
<td></td>
<td>ANCA IFA Pattern</td>
<td>None Detected</td>
</tr>
<tr>
<td>0050526</td>
<td>Myeloperoxidase (MPO) Ab, IgG</td>
<td>Negative: 19 AU/mL or less</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Equivocal: 20-25 AU/mL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Positive: 26 AU/mL or greater</td>
</tr>
<tr>
<td>0050527</td>
<td>Serine Proteinase 3 (PR3) Ab, IgG</td>
<td>Negative: 19 AU/mL or less</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Equivocal: 20-25 AU/mL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Positive: 26 AU/mL or greater</td>
</tr>
</tbody>
</table>

Interpretive Data:
Refer to report.

Note: Specimens are screened for ANCA, MPO and PR3. ANCA IFA is simultaneously tested on ethanol- and formalin-fixed slides to allow differentiation of C- and P-ANCA patterns.

CPT Code(s): 83516 x2; 86255

New York DOH Approved.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.
Angelman Syndrome and Prader-Willi Syndrome by Methylation-Sensitive PCR, Fetal

Specimen Required: Collect: Fetal Specimen: Two (2) T-25 flasks at 80 percent confluence of cultured amniocytes. If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787. Or amniotic fluid.

AND Maternal Specimen: Lavender (EDTA), pink (K$_2$EDTA), or yellow (ACD Solution A or B).

Specimen Preparation: Cultured Amniocytes: Fill flasks with culture media. Transport two (2) T-25 flasks at 80 percent confluence of cultured amniocytes. Backup cultures must be retained until the client's institution until testing is complete.

OR Amniotic Fluid: Transport 20 mL unspun fluid. (Min: 10 mL)

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

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

Amniotic Fluid: Room temperature.

Maternal Specimen: Room temperature.

Remarks: Maternal specimen is recommended for proper test interpretation. Order Maternal Cell Contamination, Maternal Specimen. This can be arranged by contacting ARUP genetic counselors at (800) 242-2787 ext. 2141. Patient History Form is available on the ARUP Web site or by contacting ARUP Client Services.

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

Maternal Specimen: Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

ANCA-IIFA

New Test 3003747 Anti-Neutrophil Cytoplasmic Antibody, IgG by IFA

Methodology: Semi-Quantitative Indirect Fluorescent Antibody

Performed: Sun-Sat

Reported: 1-3 days

Specimen Required: Collect: Serum separator tube.

Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.15 mL)

Storage/Transport Temperature: Refrigerated.

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

Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 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></td>
<td>ANCA IFA Titer</td>
<td>Less than 1:20</td>
</tr>
<tr>
<td></td>
<td>ANCA IFA Pattern</td>
<td>None Detected</td>
</tr>
</tbody>
</table>

Interpretive Data:
Neutrophil Cytoplasmic Antibodies (C-ANCA = granular cytoplasmic staining, P-ANCA = perinuclear staining) are found in the serum of over 90 percent of patients with certain necrotizing systemic vasculitides, and usually in less than 5 percent of patients with collagen vascular disease or arthritis.

Note: ANCA IFA is simultaneously tested on ethanol- and formalin-fixed slides to allow differentiation of C- and P-ANCA patterns.

CPT Code(s): 86255

New York DOH Approved.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.
HOTLINE: Effective August 16, 2021

New Test 3004090 Apixaban Level APIX

Click for Pricing

Methodology: Chromogenic Assay
Performed: Tuesday
Reported: 1-8 days

Specimen Required:
Collect: Lt. blue (sodium citrate). Refer to Specimen Handling at aruplab.com for hemostasis/thrombosis specimen handling guidelines.
Specimen Preparation: Transport 2 mL platelet-poor plasma. (Min: 1 mL)
Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when additional tests are ordered.
Remarks: This test cannot be used to quantitate anticoagulants other than Apixaban. This includes but is not limited to Unfractionated Heparin, Low Molecular Weight Heparin, Rivaroxaban (Xarelto), Edoxaban (Savaysa), and Fondaparinux (Arixtra).
Unacceptable Conditions: Serum, EDTA, oxalate, heparin, or plasma separator tubes, hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 4 hours; Refrigerated: Unacceptable; Frozen: 1 month

Reference Interval: Not established

Interpretive Data:

When 5 mg apixaban was administered twice daily for treatment of DVT and PE, apixaban steady state levels were as follows:
Peak: 59-302 ng/mL
Trough: 22-177 ng/mL
The lower limit of detection for this assay is 23 ng/mL.
For additional information, please refer to www.arupconsult.com

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

CPT Code(s): 80299

New York DOH approval pending. Call for status update.

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

0050100 Aspergillus Antibody by CF ASPER

Performed: Sun-Sat
Reported: 2-5 days
New Test 3004070 Autoimmune Neurologic Disease Reflexive Panel, Serum NEURO R3

Click for Pricing

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 1 mL serum aliquots to ARUP Standard Transport Tubes. (Min: 0.5 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>2004221</td>
<td>N-methyl-D-Aspartate Receptor Antibody, IgG, Serum with Reflex to Titer</td>
<td>Less than 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>Less than 1:10</td>
</tr>
<tr>
<td>2004890</td>
<td>Voltage-Gated Potassium Channel (VGKC) Antibody, Serum</td>
<td>Negative, 31 pmol/L or less, Indeterminate, 32-87 pmol/L, Positive, 88 pmol/L or greater</td>
</tr>
<tr>
<td>2007961</td>
<td>Paraneoplastic Antibodies (PCCA/ANNA) by IFA with Reflex to Titer and Immunoblot</td>
<td>Neuronal Nuclear Antibody, IgG</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Neuronal Nuclear Antibody (ANNA) IFA Titer, IgG</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Purkinje Cell Antibody, Titer</td>
</tr>
<tr>
<td>3002917</td>
<td>Neuronal Nuclear Antibodies (Hu, Ri, Yo, Tr/DNER) IgG by Immunoblot, Serum</td>
<td>Less than 1:10</td>
</tr>
<tr>
<td>2008093</td>
<td>Amphiphysin Antibody, IgG</td>
<td>Negative</td>
</tr>
<tr>
<td>2013320</td>
<td>Aquaporin-4 Receptor Antibody, IgG by IFA with Reflex to Titer, Serum</td>
<td>Less than 1:10</td>
</tr>
<tr>
<td>2009456</td>
<td>Leucine-Rich, Glioma-Inactivated Protein 1 Antibody, IgG with Reflex to Titer, Serum</td>
<td>Less than 1:10</td>
</tr>
<tr>
<td>2009452</td>
<td>Contactin-Associated Protein-2 Antibody, IgG with Reflex to Titer, Serum</td>
<td>Less than 1:10</td>
</tr>
<tr>
<td>0080009</td>
<td>Acetylcholine Receptor Binding Antibody</td>
<td>Negative, 0.0-0.4 nmol/L, Positive, 0.5 nmol/L or greater</td>
</tr>
<tr>
<td>3001260</td>
<td>Alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic Acid (AMPA) Receptor Antibody, IgG by IFA with Reflex to Titer, Serum</td>
<td>Less than 1:10</td>
</tr>
<tr>
<td>3001270</td>
<td>Gamma Aminobutyric Acid Receptor, Type B (GABA-B) Antibody, IgG by IFA with Reflex to Titer, Serum</td>
<td>Less than 1:10</td>
</tr>
<tr>
<td>3001277</td>
<td>Myelin Oligodendrocyte Glycoprotein (MOG) Antibody, IgG by IFA with Reflex to Titer, Serum</td>
<td>Less than 1:10</td>
</tr>
<tr>
<td>3002885</td>
<td>SOX1 Antibody, IgG by Immunoblot, Serum</td>
<td>Negative</td>
</tr>
</tbody>
</table>

Interpretive Data:

Refer to Report

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

Note: If N-methyl-D-Aspartate Receptor Antibody is positive, then titer will be performed. Additional charges apply. If CV2.1 Antibody IgG Screen by IFA is positive, then titer will be performed. Additional charges apply. If Aquaporin-4 Receptor Antibody, IgG by IFA with Reflex to Titer, Serum is positive, then titer will be performed. 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, Yo, and Tr/DNER) IgG by Immunoblot will be performed. If the IFA screen is positive at 1:10 or greater, then a PCCA/ANNA antibodies titer and Neuronal Nuclear Antibodies (Hu, Ri, Yo, Tr/DNER) IgG by Immunoblot will be performed. Additional charges apply.

If Leucine-Rich, Glioma-Inactivated Protein 1 Antibody, IgG with Reflex to Titer, Serum is positive, then Leucine-Rich, Glioma-Inactivated Protein 1 Antibody Titer, IgG by IFA, Serum will be performed. Additional charges apply.

If Contactin-Associated Protein-2 Antibody, IgG with Reflex to Titer, Serum is positive, then Contactin-Associated Protein-2 Antibody Titer, IgG by IFA, Serum will be performed. Additional charges apply.

If Alpha-aminoo-3-hydroxy-5-methyl-4-isoxazolepropionic Acid (AMPA) Receptor Antibody, IgG by IFA with Reflex to Titer, Serum is positive, then an Alpha-aminoo-3-hydroxy-5-methyl-4-isoxazolepropionic Acid (AMPA) Receptor Antibody Titer, IgG, Serum will be performed. Additional charges apply.

If Gamma Aminobutyric Acid Receptor, Type B (GABA-Br) Antibody, IgG by IFA with Reflex to Titer, Serum is positive, then a Gamma Aminobutyric Acid Receptor, Type B (GABA-Br) Antibody Titer, IgG, Serum will be performed. Additional charges apply.

If Myelin Oligodendrocyte Glycoprotein (MOG) Antibody, IgG by IFA with Reflex to Titer, Serum is positive, then a Myelin Oligodendrocyte Glycoprotein (MOG) Antibody Titer, IgG will be performed. Additional charges apply.

CPT Code(s): 83519 x2; 84182 x2; 86255 x9; 86341; if reflexed, additional CPT codes may apply: 86256; 84182 x4

New York DOH Approved.

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

**2012201**

**Methodology:** Quantitative Gas Chromatography-Mass Spectrometry/Quantitative Liquid Chromatography-Tandem Mass Spectrometry

**Reference Interval:**

**Effective August 16, 2021**

<table>
<thead>
<tr>
<th>Drugs Covered</th>
<th>Cutoff Concentrations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butalbital</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>Pentobarbital</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>50 ng/mL</td>
</tr>
</tbody>
</table>

**Interpretive Data:**

**Methodology:** Quantitative Gas Chromatography-Mass Spectrometry/Quantitative Liquid Chromatography-Tandem Mass Spectrometry

**Positive cutoff:** 50 ng/mL

For medical purposes only; not valid for forensic use.

The absence of expected drug(s) and/or drug metabolite(s) may indicate non-compliance, inappropriate timing of specimen collection relative to drug administration, poor drug absorption, or limitations of testing. The concentration value must be greater than or equal to the cutoff to be reported as positive. Interpretive questions should be directed to the laboratory.

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

HOTLINE NOTE: There is a component change associated with this test.

Remove component 2012205, Amobarbital, S/P, Quant
Remove component 2012206, Secobarbital, S/P, Quant
HOTLINE: Effective August 16, 2021

2012213 Barbiturates, Urine, Quantitative BARB UR

Methodology:
Quantitative Gas Chromatography-Mass Spectrometry/Quantitative Liquid Chromatography-Tandem Mass Spectrometry

Reference Interval:
Effective August 16, 2021

<table>
<thead>
<tr>
<th>Drugs Covered</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Butalbital</td>
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<td>50 ng/mL</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>50 ng/mL</td>
</tr>
</tbody>
</table>

Interpretive Data:

Positive cutoff: 50 ng/mL.

For medical purposes only; not valid for forensic use.

The absence of expected drug(s) and/or drug metabolite(s) may indicate non-compliance, inappropriate timing of specimen collection relative to drug administration, poor drug absorption, diluted/adulterated urine, or limitations of testing. The concentration value must be greater than or equal to the cutoff to be reported as positive. Interpretive questions should be directed to the laboratory.

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

HOTLINE NOTE: There is a component change associated with this test.
Remove component 2012217, Amobarbital, Urn, Quant
Remove component 2012218, Secobarbital, Urn, Quant

0020063 Beta-hCG, Serum Qualitative BHCG-S

Specimen Required:
Collect: Serum separator tube.
Specimen Preparation: Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Plasma. Specimens exposed to repeated freeze/thaw cycles.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 72 hours; Frozen: 2 months

0020229 Beta-hCG, Urine Qualitative BHCG-U

Specimen Required:
Collect: Urine in a plastic container. First-morning urine is the preferred specimen as it usually contains the highest concentration of beta-hCG; however, any specimen is suitable for testing.
Specimen Preparation: Transfer 1 mL aliquot of urine to an ARUP Standard Transport Tube. If frozen, mix after thawing. Do not refreeze.
Storage/Transport Temperature: Frozen.
Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: 72 hours; Frozen: 6 months (one freeze/thaw cycle is acceptable)
New Test: 3003824  Brachyury by Immunohistochemistry  BRACHY IHC
Available Now  Click for Pricing

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

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

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

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

CPT Code(s):  88342

New York DOH Approved.

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

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0080392  Cancer Antigen 27.29  CA27.29

Specimen Required:  Collect: Plain red or serum separator tube or EDTA plasma.
                   Specimen Preparation:  Allow specimen to clot completely at room temperature. Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
                   Storage/Transport Temperature:  Frozen.
                   Stability (collection to initiation of testing):  After separation from cells: Ambient: 8 hours; Refrigerated: 7 days; Frozen: 3 months

Reference Interval:
Effective August 16, 2021
Less than or equal to 39 U/mL

Interpretive Data:
Test Information:  The CA 27.29 assay is intended for use in monitoring: 1) disease progression and/or response to therapy in patients with metastatic disease, and 2) disease recurrence in patients treated previously for stages II or III breast carcinoma who are clinically free of the disease. Serial testing in patients who are clinically free of disease should be used in conjunction with other clinical methods for early detection of cancer recurrence.

Limitations:  Patients with confirmed breast carcinoma frequently have CA 27.29 assay values in the same range as healthy individuals. Elevations may also be observed in patients with non-malignant disease. Results of this test must always be interpreted in the context of morphologic and other relevant data and should not be used alone for a diagnosis of malignancy.

Methodology:  Siemens Atellica IM BR 27.29 (BR) chemiluminescent immunoassay was used. Results obtained with different assay methods or kits cannot be used interchangeably.
New Test 3003992 Carbamylated Protein (CarP) Antibody, IgG CARP IGG
Click for Pricing

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay
Performed: Sun, Tue, Thu
Reported: 1-4 days

Specimen Required:
Collect: Serum separator tube.
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 0.5 mL serum to an ARUP Standard Transport Tube. (Min: 0.3 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Contaminated, heat-inactivated, hemolyzed, icteric, or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; 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></td>
<td>Carbamylated Protein Antibody, IgG</td>
<td>0-19 Units</td>
</tr>
</tbody>
</table>

Interpretive Data:
Anti-carbamylated protein (anti-CarP) IgG antibodies are present in about 34-53 percent of patients with RA, have specificities of greater than 90 percent and can occur in RA patients seronegative for both rheumatoid factor and anti-CCP. These autoantibodies may be present in the preclinical phase of disease, are associated with future RA development, and may predict radiographic joint destruction. Patients with weak positive results should be monitored and testing repeated.

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

CPT Code(s): 83516

New York DOH approval pending. Call for status update.

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

New Test 3002508 Clobazam and Metabolite, Quantitative, Serum or Plasma CLOBAZAM

Performed: Mon, Wed, Sat
Reported: 1-5 days

New Test 0050170 Coccioides Antibody by CF COCCI

Performed: Sun-Sat
Reported: 2-5 days
New Test 3003648  COVID-19 IgG, Semi-Quantitative by CIA COV19G SQ

**Methodology:** Semi-Quantitative Chemiluminescent Immunoassay

**Performed:** Sun-Sat

**Reported:** Within 24 hours

**Specimen Required:** Collect: Serum separator tube (SST). Also acceptable: EDTA or lithium heparin.

Specimen Preparation: Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)

Storage/Transport Temperature: Refrigerated.

Unacceptable Conditions: Specimens containing particulate material or otherwise obviously contaminated. Severely hemolyzed, heat-inactivated, or lipemic specimens.

Stability (collection to initiation of testing): After separation from cells: Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month (avoid repeated freeze/thaw cycles)

**Reference Interval:**

| Less than 1.00 Index Value | Negative |
| Greater than or equal to 1.00 Index Value | Positive |

**Interpretive Data:**

This test is for in vitro diagnostic use under the FDA Emergency Use Authorization (EUA). In compliance with this authorization, please visit https://www.aruplab.com/infectious-disease/coronavirus/testing for more information and to access the applicable fact sheets.

**CPT Code(s):** 86769

New York DOH Approved.

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

0050503  Coxackie A9 Virus Antibodies by CF COX A9

**Performed:** Sun-Sat

**Reported:** 2-5 days

3000479  Criteria Systemic Sclerosis Panel SSC PANEL

**Performed:** Sun, Tue, Thu

**Reported:** 1-4 days

2006267  Cytogenomic SNP Microarray Buccal Swab CMA BUCCAL

**Specimen Required:** Collect: One buccal swab using the Oracollect collection kit ensuring the sponge tip does not come into contact with any surface prior to collection. Donor should not eat, drink, smoke or chew gum for 30 minutes before collecting oral sample.

Specimen Preparation: Transport Buccal swab in ORAcollect Collection kit (ARUP supply #49295). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.

Storage/Transport Temperature: Room temperature.

Unacceptable Conditions: Specimen exposed to extreme temperatures. Specimens collected in or by any specimen device other than indicated.

Stability (collection to initiation of testing): Ambient: 7 days; Refrigerated: Unacceptable; Frozen: Unacceptable
Additional Technical Information

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

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

Reference Interval: By report

Interpretive Data:
Refer to report.

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

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

Note: Genes tested: ECEL1, FBN2, MYBPC1, MYH3, MYH8*, NALCN*, PIEZO2*, TNNI2, TNNT3, TPM2
*One or more exons are not covered by sequencing for the indicated gene; see Additional Technical Information.

CPT Code(s): 81479

New York DOH approval pending. Call for status update.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.
New Test | 3004092 | Edoxaban Level | EDOX
Click for Pricing

Methodology: Chromogenic Assay
Performed: Tuesday
Reported: 1-8 days

Specimen Required: Collect: Lt. blue (sodium citrate). Refer to Specimen Handling at aruplab.com for hemostasis/thrombosis specimen handling guidelines.
Specimen Preparation: Transport 2 mL platelet-poor plasma. (Min: 1 mL)
Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when additional tests are ordered.
Remarks: This test cannot be used to quantitate anticoagulants other than Edoxaban. This includes but is not limited to Unfractionated Heparin, Low Molecular Weight Heparin, Apixaban (Eliquis), Rivaroxaban (Xarelto), and Fondaparinux (Arixtra).
Unacceptable Conditions: Serum, EDTA, oxalate, heparin, or plasma separator tubes, hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 4 hours; Refrigerated: Unacceptable; Frozen: 1 month

Reference Interval: Not established

Interpretive Data:
When 60 mg edoxaban was administered daily for treatment of DVT and PE, edoxaban steady state levels were as follows:
Peak: 149-317 ng/mL
Trough: 10-39 ng/mL
The lower limit of detection for this assay is 20 ng/mL.
For additional information, please refer to www.arupconsult.com

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

CPT Code(s): 80299

New York DOH approval pending. Call for status update.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.
### New Test 3001839
Emery-Dreifuss Muscular Dystrophy Panel, Sequencing

**EDMD NGS**

**New York DOH approval pending. Call for status update.**

**Click for Pricing**

### Additional Technical Information

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

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

**Reference Interval:** By report

**Interpretive Data:**  
Refer to report.  

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

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

**Note:** Genes Tested: *EMD, FHL1, LMNA*

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

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

### 2002378
Eosinophilia Panel by FISH

**FISH EOS P**

**Interpretive Data:**  
Probes included: PDGFR-alpha, PDGFR-beta, and FGFR1.  

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

**CPT Code(s):** 88271 x3; 88275 x3

**HOTLINE NOTE:** There is a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.
Specimen Required: Patient Prep: Collect specimen prior to any activities or procedures that might disrupt the cervix, eg, coitus, digital cervical examination, vaginal ultrasound, collection of culture specimens, or pap smear. Testing should not be performed if the patient has had sexual intercourse within 24 hours prior to the sampling time because semen present may increase the possibility of a false-positive result. Contamination with lubricants, soaps, or disinfectants may cause invalid test results.

Collect: Insert the polyester-tipped swab provided in the specimen collection kit into the vagina and lightly rotate across the posterior fornix for approximately 10 seconds to absorb cervicovaginal secretions. Carefully remove the swab and place into the tube of buffer provided in the kit. Use only one specimen collection device per patient.

Specimen Preparation: Specimens that are not tested within eight hours of collection must be stored, refrigerated, and tested within 72 hours of collection. Avoid extreme temperatures. Transport swab in Fetal Fibronectin Specimen Collection Kit (ARUP supply #32748). Available online through eSupply using ARUP Connect™ or contact Client Services at (800) 522-2787. Required Information: Specimen must be labeled with gestational age and list patient condition as either "symptomatic" or "asymptomatic."

Unacceptable Conditions: Specimens collected in or by any specimen device other than Fetal Fibronectin Specimen Collection Kit, visible evidence of moderate or gross vaginal bleeding. Specimens from symptomatic patients who are less than 24 weeks or greater than or equal to 35 weeks gestation. Specimens from asymptomatic patients who are less than 22 weeks or greater than or equal to 35 weeks gestation.

Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: 3 days; Frozen: 2 weeks Only one freeze/thaw cycle acceptable.
HOTLINE NOTE: There is a component change associated with this test.
Add component 3004185, Urine Creatinine - mg per dL
Add component 3004186, Urine Creatinine - per 24 hour
Add component 3004187, Urine Total Volume
Add component 3004188, Collected Hours
Remove component 0020207, Creatinine, Urine - per volume
Remove component 0020208, Creatinine, Urine - per 24h
Remove component 0097110, Total Volume
Remove component 0097111, Hours Collected

Reference Interval: Effective August 16, 2021

<table>
<thead>
<tr>
<th>Age</th>
<th>0 days</th>
<th>1-6 days</th>
<th>7-13 days</th>
<th>14-29 days</th>
<th>30-60 days</th>
<th>61-180 days</th>
<th>6-23 months</th>
<th>2-5 years</th>
<th>6-11 years</th>
<th>12-17 years</th>
<th>18 years and older</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male (g/dL)</td>
<td>13.5-19.5</td>
<td>14.5-21.9</td>
<td>13.5-20.9</td>
<td>12.5-20.5</td>
<td>10.0-18.0</td>
<td>9.0-14.0</td>
<td>9.5-13.5</td>
<td>10.5-13.5</td>
<td>11.5-13.5</td>
<td>11.5-15.5</td>
<td>13.0-16.0</td>
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<tr>
<td>Female (g/dL)</td>
<td>13.5-19.5</td>
<td>14.5-21.9</td>
<td>13.5-20.9</td>
<td>12.5-20.5</td>
<td>10.0-18.0</td>
<td>9.0-14.0</td>
<td>9.5-13.5</td>
<td>10.5-13.5</td>
<td>11.5-13.5</td>
<td>11.5-15.5</td>
<td>12.0-16.0</td>
</tr>
</tbody>
</table>

Specimen Required: Collect: Cultured skin fibroblasts (preferred) or Whole blood: Lavender (EDTA) or yellow (ACD Solution A or B). or Skin punch biopsy: Thaw media prior to tissue inoculation. Place skin punch biopsy in a sterile, screw-top container filled with tissue culture transport medium (ARUP Supply #32788). Available online through eSupply using ARUP Connect. If cytogenetics tissue media is not available, collect in plain RPMI, Hanks solution, sterile saline, or ringsers. New York State Clients: Collect Monday-Thursday only.
Specimen Preparation: Cultured skin fibroblasts: 2 T-25 flasks at 80 percent confluency. Fill flasks with culture media. Backup cultures must be maintained at the client's institution until testing is complete. Skin punch biopsy DO NOT FREEZE. Do not place in formalin. Transport a 4 mm skin biopsy in a sterile, screw-top container filled with tissue transport medium.
Whole blood: Transport 3 mL whole blood. (Min: 1.5 mL) New York State Clients: Cultured skin fibroblasts: 2 T-25 flasks at 80 percent confluency. Whole blood: Transport 5 mL whole blood (min. 3 mL). Do not send cultured fibroblasts to ARUP Laboratories. Specimens must be received at performing laboratory within 48 hours of collection. For specimen requirements and direct submission instructions please contact ARUP Referral Testing at (800) 242-2787, ext. 5145.
Storage/Transport Temperature: Cultured skin fibroblasts: Critical room temperature. Must be received within 48 hours of shipment due to lability of cells Skin punch biopsy: Room temperature Whole Blood: Refrigerated.
Remarks: Cultured skin fibroblast backup cultures must be retained at the client's institution until testing is complete. Skin punch biopsies can be cultured at ARUP at an additional charge.
Unacceptable Conditions: Grossly hemolyzed or frozen specimens; formalin fixed tissue, FFPE
Stability (collection to initiation of testing): Cultured skin fibroblasts: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable, Skin punch biopsy: Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Unacceptable Whole blood: Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable New York State Clients: Cultured skin fibroblasts: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable, Whole blood: Ambient: 48 hours; Refrigerated: 1 week; Frozen: Unacceptable
New Test: 3002682
Heterotaxy and Situs Inversus Panel, Sequencing
HTX NGS

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

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

Reference Interval: By report
Interpretive Data:
Refer to report.

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

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

Note: Genes tested: ANKS6*, ARL2BP, ARMC4*, CCDC103*, CCDC114*, CCDC151, CCDC39, CCDC40*, CFAP298*, CFAP53, CRELD1, DNAF1, DNAAF2, DNAAF3, DNAAF4, DNAAF5*, DNAH1, DNAH11, DNAH5, DNAI1, DNAI2*, DNAL1, FOXH1, GATA4, GATA6*, INVS, LLRRC6, MMP21, NKX2-5, NME8, NODAL, PIHID3, PKD1L1*, SPAG1*, ZIC3, ZMYND10* One or more exons are not covered by sequencing for the indicated gene; see Additional Technical Information.

CPT Code(s): 81479

New York DOH approval pending. Call for status update.

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

Histoplasma Antibodies by CF

Performed: Sun-Sat
Reported: 2-5 days
**3000870 Human Immunodeficiency Virus 1 (HIV-1) by Quantitative NAAT with Reflex to HIV-1 Drug Resistance by Next Generation Sequencing**

**Methodology:** Quantitative Transcription-Mediated Amplification/Massively Parallel Sequencing

**Performed:** Sun-Sat

**Reported:** 2-14 days

**Reference Interval: Effective August 16, 2021**

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>3000867</td>
<td>Human Immunodeficiency Virus 1 (HIV-1) by Quantitative NAAT, Plasma</td>
<td>Not detected.</td>
</tr>
<tr>
<td>3003853</td>
<td>Human Immunodeficiency Virus 1, Drug Resistance by Next Generation Sequencing</td>
<td>By report</td>
</tr>
</tbody>
</table>

**Note:** If Human Immunodeficiency Virus 1 by Quantitative NAAT result is greater than or equal to 2.70 log copies/mL, then HIV-1 Drug Resistance by Next Generation Sequencing will be added. Additional charges apply.

**CPT Code(s):** 87536; if reflexed add 87900; 87901; 87906

**HOTLINE NOTE:** There is a reflexive pattern change associated with this test.

Add reflex to 3003853, Human Immunodeficiency Virus 1, Drug Resistance by Next Generation Sequencing

Remove reflex from 0055670, Human Immunodeficiency Virus 1, Genotype by Sequencing
**New Test** 3003853 Human Immunodeficiency Virus 1 Drug Resistance by Next Generation Sequencing

**Methodology:** Massively Parallel Sequencing  
**Performed:** Sunday-Saturday  
**Reported:** 4-10 days

**Specimen Required:**  
- **Collect:** Lavender (EDTA), pink (K$_2$EDTA) or plasma preparation tube.  
- **Specimen Preparation:** Separate plasma from cells within 24 hours. Transfer 2.5 mL plasma to an ARUP Standard Transport Tube. (Min: 1.5 mL)  
- **Storage/Transport Temperature:** Frozen.  
- **Remarks:** Please submit most recent viral load and test date, if available.  
- **Unacceptable Conditions:** Serum. Heparinized specimens.  
- **Stability (collection to initiation of testing):** After separation from cells: Ambient: 24 hours; Refrigerated: 72 hours; Frozen: 3 months

**Reference Interval:** By report

**Interpretive Data:**

This assay predicts HIV-1 resistance to protease inhibitors, nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors and integrase inhibitors. The protease gene, integrase gene and the reverse transcriptase gene of the viral genome are sequenced using Next Generation Sequencing. Drug resistance is assigned using the Stanford hivdb database.

This test should be used in conjunction with clinical presentation and other laboratory markers. A patient's response to therapy depends on multiple factors, including patient adherence, percentage of resistant virus population, dosing, and drug pharmacology issues.

This test detects populations down to 10 percent of the total population which may account for resistance interpretation differences between methods. Some insertions or deletions may be difficult to detect using this software.

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

**Note:** This test may be unsuccessful if the plasma HIV-1 RNA viral load is less than 500 copies per mL of plasma.

**CPT Code(s):** 87900; 87901; 87906

New York DOH approval pending. Call for status update.

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

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

**HOTLINE NOTE:** There is a component change associated with this test.  
Add component 2007358, IDH1 R132H Mutation Reference Number  
Remove component 2002148, Block ID
New Test 3003748 Inflammatory Bowel Disease Differentiation Panel IBD-PAN

Click for Pricing

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Semi-Quantitative Indirect Fluorescent Antibody

Performed: Sat-Sun

Reported: 1-4 days

Specimen Required: Patient Prep: N/A
Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1.5 mL serum to an ARUP Standard Transport Tube. (Min: 0.6 mL)
Storage/Transport Temperature: Refrigerated.
Remarks: N/A

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:

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Saccharomyces cerevisiae Antibody, IgG</td>
<td></td>
</tr>
<tr>
<td></td>
<td>20.0 Units or less</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>20.1-24.9 Units</td>
<td>Equivocal</td>
</tr>
<tr>
<td></td>
<td>25.0 Units or greater</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>Saccharomyces cerevisiae Antibody, IgA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>20.0 Units or less</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>20.1-24.9 Units</td>
<td>Equivocal</td>
</tr>
<tr>
<td></td>
<td>25.0 Units or greater</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>ANCA IFA Titer</td>
<td>Less than 1:20</td>
</tr>
<tr>
<td></td>
<td>ANCA IFA Pattern</td>
<td>None Detected</td>
</tr>
</tbody>
</table>

Interpretive Data:
Refer to report.

Note: This test may be a useful tool for distinguishing ulcerative colitis (UC) from Crohn disease (CD) in patients with suspected inflammatory bowel disease. ANCA IFA is simultaneously tested on ethanol- and formalin-fixed slides to allow differentiation of C- and P-ANCA patterns.

CPT Code(s): 86671 x2; 86255

New York DOH Approved.

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

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.4 mL)
Storage/Transport Temperature: Frozen.

Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 1 week; Frozen: 1 month
Specimen Required:
**Collect**: Serum Separator Tube (SST).

**Specimen Preparation**: Allow specimen to clot completely at room temperature. Separate from cells asap or within 2 hours of collection. Transport 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.4 mL)

**Storage/Transport Temperature**: Frozen.

**Unacceptable Conditions**: Heparinized plasma, I.V. fluid, or Vitreous fluid. Gray (sodium fluoride/potassium oxalate). Hemolyzed specimens.

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

---

**0070064** Insulin, 30 Minutes

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

**Specimen Preparation**: Allow specimen to clot completely at room temperature. Separate serum from cells asap or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.4 mL)

**Storage/Transport Temperature**: Frozen.


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

---

**0070066** Insulin, 60 Minutes

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

**Specimen Preparation**: Allow specimen to clot completely at room temperature. Separate serum from cells asap or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.4 mL)

**Storage/Transport Temperature**: Frozen.


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

---

**0070067** Insulin, 90 Minutes

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

**Specimen Preparation**: Allow specimen to clot completely at room temperature. Separate serum from cells asap or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.4 mL)

**Storage/Transport Temperature**: Frozen.


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

---

**0070063** Insulin, Fasting

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

**Specimen Preparation**: Allow specimen to clot completely at room temperature. Separate serum from cells asap or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.4 mL)

**Storage/Transport Temperature**: Frozen.

**Unacceptable Conditions**: Heparinized plasma. Vitreous or I.V. fluids. Specimens collected in gray (sodium fluoride/potassium oxalate). Hemolyzed specimens.

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

---

**Reference Interval**: Effective August 16, 2021

3-25 µIU/mL
**0070155** Insulin, Free and Total INS F&T

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

Specimen Preparation: Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1.1 mL)

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


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

**Reference Interval:**
Effective August 16, 2021

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Insulin, Free</td>
<td>3.25 µIU/mL</td>
</tr>
<tr>
<td></td>
<td>Insulin, Total</td>
<td>3.25 µIU/mL</td>
</tr>
</tbody>
</table>

**0070022** Insulin, Other INSULINOTH

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

Specimen Preparation: Allow sample to clot completely at room temperature. Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.4 mL)

Storage/Transport Temperature: Frozen.


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

**Interpretive Data:**
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 (< 3 percent). To convert to pmol/L, multiply µIU/mL by 6.0. The reference interval for fasting insulin is 3-25 µIU/mL.

**0070107** Insulin, Random INSULIN R

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

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

Storage/Transport Temperature: Frozen.


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

**Interpretive Data:**
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 (< 3 percent). To convert to pmol/L, multiply µIU/mL by 6.0. The reference interval for a fasting insulin is 3-25 µIU/mL.
### Additional Technical Information

**Methodology:** Droplet Digital PCR (ddPCR)

**Performed:**
- DNA Isolation: Sun-Sat
  - **Assay:** Varies

**Reported:** 2-7 days

**Specimen Required:**
- **Collect:** Whole blood or bone marrow: Lavender (EDTA), preferred. Also acceptable: Green (sodium heparin)
- **Specimen Preparation, Whole Blood:** Do not freeze. Transport 5 mL whole blood. (Min: 1 mL)
- **Bone Marrow:** Do not freeze. Transport 3 mL bone marrow. (Min: 1 mL)
- **Storage/Transport Temperature:** Refrigerated.

**Unacceptable Conditions:** Plasma, serum, FFPE tissue blocks/slides, or fresh or frozen tissue, DNA extracted by a non-CLIA certified lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.

**Stability (collection to initiation of testing):** Refrigerated: 7 days; Frozen: Unacceptable

**Interpretive Data:**
Refer to report.

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

**CPT Code(s):** 81270

New York DOH Approved.

**HOTLINE NOTE:** Refer to the Test Mix Addendum for interface build information.
New Test 3003800  

**JAK2 (V617F) Mutation by ddPCR, Qualitative with Reflex to CALR (Calreticulin) Exon 9 Mutation Analysis by PCR with Reflex to MPL Mutation Detection**

**Methodology:**  
Droplet Digital Polymerase Chain Reaction/Capillary Electrophoresis

**Performed:**  
DNA Isolation: Sun-Sat  
Assay: Varies

**Reported:**  
3-15 days

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

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

**Note:** If JAK2 QUAL is reported as “Not Detected” then CALR Exon 9 Mutation Analysis by PCR will be added. If CALR is reported as "Not Detected," then MPL Mutation Detection will be added. Additional charges apply.

**CPT Code(s):**  
81270; if reflexed add 81219; if reflexed again add 81338

New York DOH Approved.

**HOTLINE NOTE:** Refer to the Test Mix Addendum for interface build information.
New Test 3003801  
**JAK2 (V617F) Mutation by ddPCR, Qualitative with Reflex to JAK2 Exon 12 Mutation Analysis by PCR**  
PV RFX

Click for Pricing

### Additional Technical Information

**Methodology:** Droplet Digital Polymerase Chain Reaction/Polymerase Chain Reaction

**Performed:** DNA Isolation: Sun-Sat

**Assay:** Varies

**Reported:** 3-12 days

**Specimen Required:**
- **Collect:** Whole blood or bone marrow: Lavender (EDTA), preferred. Also acceptable: Green (sodium heparin).
- **Bone Marrow:** Do not freeze. Transport 3 mL bone marrow. (Min: 1 mL)
- **Storage/Transport Temperature:** Refrigerated.
- **Unacceptable Conditions:** Plasma, serum, FFPE tissue blocks/slides, or fresh or frozen tissue, DNA extracted by a non-CLIA certified lab. Specimens collected in anticoagulants other than EDTA or sodium heparin. Clotted or grossly hemolyzed specimens.

**Interpretive Data:**
Refer to report.

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

**Note:** If JAK2 QUAL is reported as “Not Detected” then JAK2 Exon 12 Mutation Analysis will be added. Additional charges apply.

**CPT Code(s):** 81270; if reflexed, add 81279

New York DOH Approved.

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

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**0055167**  
**Kappa/Lambda Quantitative Free Light Chains with Ratio, Serum**  
**KAP/LAM F**

**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: 0.5 mL)
- **Storage/Transport Temperature:** Refrigerated.
- **Unacceptable Conditions:** Plasma, Grossly Hemolyzed and Lipemic Samples
- **Stability (collection to initiation of testing):** After separation from cells: Ambient: Unacceptable; Refrigerated: 3 weeks; Frozen: 6 months

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**0020407**  
**Lactose Tolerance**  
**LACTOL**

**Specimen Required:**
- **Patient Prep:** Recommend drawing specimens for baseline (fasting), 30 minutes, 60 minutes, 120 minutes, and 180 minutes after lactose load (lactose may be obtained from a hospital pharmacy). Fasting patient should be given 50 g lactose in 200-300 mL water consumed in 5 to 10 minutes. Note: If severe lactase deficiency is suspected, the dose should be lowered.
- **Collect:** Gray (sodium fluoride/potassium oxalate). Collect separate tube for each timed point.
- **Specimen Preparation:** Separate plasma from cells ASAP or within 2 hours of collection. Transfer 1 mL plasma for each time point to individual ARUP Standard Transport Tubes. (Min: 0.5 mL per timed determination)
- **Storage/Transport Temperature:** Frozen.
- **Stability (collection to initiation of testing):** After separation from cells: Ambient: 24 hours; Refrigerated: 72 hours; Frozen: 1 year
New Test 3003947 Loeys-Dietz Syndrome Core Panel, Sequencing LDS NGS

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Patient History for Aortopathies Testing

Additional Technical Information

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

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

Reference Interval: By report

Interpretive Data:
Refer to report

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

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

Note: Genes tested: TGFBR1, TGFBR2
CPT Code(s): 81405

New York DOH approval pending. Call for status update.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.
**Specimen Required:** Collect: Serum separator tube or plasma separator tube. Also acceptable: Lithium heparin or EDTA plasma.

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

**Storage/Transport Temperature:** Frozen.

**Stability (collection to initiation of testing):** After separation from cells: Ambient: 8 hours; Refrigerated: 7 days; Frozen: 1 month

### Reference Interval:

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>0070115</td>
<td>Prolactin</td>
<td>Prolactin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1-9 years</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 years and older</td>
</tr>
<tr>
<td></td>
<td>Monomeric Prolactin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Age</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1-9 years</td>
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<td></td>
<td></td>
<td>10 years and older</td>
</tr>
<tr>
<td></td>
<td>Monomeric Prolactin Percent</td>
<td>Greater than 50%</td>
</tr>
</tbody>
</table>

**HOTLINE NOTE:** Remove information found in the Unacceptable Conditions field.
New Test  3002688  Malignant Hyperthermia Panel, Sequencing  MH NGS

Click for Pricing

Additional Technical Information  Patient History for Malignant Hyperthermia Testing

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

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

Reference Interval:  By report

Interpretive Data:
Refer to report.

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

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

Note:  Genes tested: CACNA1S, RYR1*
*One or more exons are not covered by sequencing for the indicated gene; see Additional Technical Information.

CPT Code(s):  81408, 81479

New York DOH approval pending. Call for status update.

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

2003996  Melan A by Immunohistochemistry (DAB Detection)  MELANA IHC

HOTLINE NOTE:  There is a clinically significant charting name change associated with this test.
Change the charting name for component 2003997, Melan A by IHC from Melan A by IHC to Melan A by IHC DAB Detection.
Change the charting name for component 2003998, Melan A Reference Number from Melan A Reference Number to Melan A DAB Detection Reference Number.
New Test 3003729 Melan A by Immunohistochemistry (Red Detection) MELA R IHC
Available Now
Click for Pricing

Immunohistochemistry Stain Form
Recommended (ARUP form #32978)

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

Specimen Required: Collect: Tissue or cells.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (ARUP supply #47808). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 2 slides). If sending precut slides, do not oven bake.
Storage/Transport Temperature: Room temperature or refrigerated. Ship in cooled container during summer months.
Remarks: IMMUNOHISTOCHEMISTRY ORDERING AND SUBMISSION DETAILS: Submit electronic request. If you do not have electronic ordering capability, use an ARUP Immunohistochemistry Stain Form (#32978) with an ARUP client number. For additional technical details, contact ARUP Client Services at (800) 522-2787.
Unacceptable Conditions: Specimens submitted with non-representative tissue type. Depleted specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

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

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

CPT Code(s): 88342
New York DOH Approved.

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

2003935 Melanoma Antibody, HMB45 by Immunohistochemistry (DAB Detection) HMB 45 IHC

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 2003936, Melanoma Antibody, HMB45 by IHC from Melanoma Antibody, HMB45 by IHC to HMB45 by IHC DAB Detection.
Change the charting name for component 2003937, Melanoma Antibody, HMB45 Ref Num from HMB45 Ref Num to HMB45 DAB Detection Reference Number.
New Test | 3003741 | Melanoma Antibody, HMB45 by Immunohistochemistry (Red Detection) | HMB45R IHC

Available Now
Click for Pricing

Immunohistochemistry Stain Form
Recommended (ARUP form #32978)

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

Specimen Required: Collect: Tissue or cells.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (ARUP supply #47808). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 2 slides). If sending precut slides, do not oven bake.
Storage/Transport Temperature: Room temperature or refrigerated. Ship in cooled container during summer months.
Remarks: IMMUNOHISTOCHEMISTRY ORDERING AND SUBMISSION DETAILS: Submit electronic request. If you do not have electronic ordering capability, use an ARUP Immunohistochemistry Stain Form (#32978) with an ARUP client number. For additional technical details, contact ARUP Client Services at (800) 522-2787.
Unacceptable Conditions: Specimens submitted with non-representative tissue type. Depleted specimens.

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

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

CPT Code(s): 88342

New York DOH Approved.

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

New Test | 3003971 | Multiple Myeloma, Daratumamab, Immunofixation | MM DARA

Click for Pricing

Methodology: Qualitative Immunofixation Electrophoresis
Performed: Varies
Reported: 4-9 days

Specimen Required: Patient Prep: Fasting specimen preferred.
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 1 mL)
Test is not performed at ARUP; separate specimens must be submitted when multiple tests are ordered.
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Stability (collection to initiation of testing): Ambient: 5 days; Refrigerated: 6 days; Frozen: 6 months

Reference Interval: By report

CPT Code(s): 86334

New York DOH Approved.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.
New Test 3003746: Myeloperoxidase (MPO) Antibody and Serine Proteinase 3 (PR3) Antibody with Reflex to Anti-Neutrophil Cytoplasmic Antibody, IgG by IFA

**Methodology:** Semi-Quantitative Indirect Fluorescent Antibody/Semi-Quantitative Multiplex Bead Assay

**Performed:** Sun-Sat

**Reported:** 2-5 days

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

**Specimen Preparation:** Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)

**Storage/Transport Temperature:** Refrigerated.

**Unacceptable Conditions:** CSF, plasma, urine, or other body fluids. Contaminated, hemolyzed, or severely lipemic specimens.

**Stability (collection to initiation of testing):** After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 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>3003747</td>
<td>Anti-Neutrophil Cytoplasmic Antibody IgG</td>
<td>Less than 1:20</td>
</tr>
<tr>
<td></td>
<td></td>
<td>None Detected</td>
</tr>
<tr>
<td>0050526</td>
<td>Myeloperoxidase (MPO) Ab, IgG</td>
<td>Negative 19 AU/mL or less</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Equivocal 20-25 AU/mL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Positive 26 AU/mL or greater</td>
</tr>
<tr>
<td>0050527</td>
<td>Serine Proteinase 3 (PR3) Ab, IgG</td>
<td>Negative 19 AU/mL or less</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Equivocal 20-25 AU/mL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Positive 26 AU/mL or greater</td>
</tr>
</tbody>
</table>

**Interpretive Data:**

Refer to report.

**Note:** If MPO and/or PR3 results are equivocal or positive, then ANCA by IFA will be added. Additional changes apply. Specimens are screened by IFA on ethanol-fixed neutrophils, formalin-fixed neutrophils, and HEP-2 slides that allow differentiation of C- and P-ANCA patterns.

**CPT Code(s):** 83516 x 2; if reflexed, add 86255

New York DOH Approved.

**HOTLINE NOTE:** Refer to the Test Mix Addendum for interface build information.
Patient History for Neurofibromatosis Type 1 and Legius Syndrome

Methodology: Massively Parallel Sequencing/Multiplex Ligation-dependent Probe Amplification
Performed: Varies
Reported: 3-6 weeks

Specimen Required:
- **Collect**: Lavender (EDTA) or Yellow (ACD Solution A or B).
- **Specimen Preparation**: Transport 3 mL whole blood. (Min: 2 mL)
- **Storage/Transport Temperature**: Refrigerated
- **Unacceptable Conditions**: Serum or plasma; grossly hemolyzed or frozen specimens

Reference Interval: By report

Interpretive Data:
Refer to report

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

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

**Note**: Genes tested: *NF1, SPRED1***
** -Deletion/duplication detection is not available for this gene.

**CPT Code(s)**: 81405, 81408, 81479

New York DOH approval pending. Call for status update.

**HOTLINE NOTE**: Refer to the Test Mix Addendum for interface build information.
### Reference Interval: Effective August 16, 2021

<table>
<thead>
<tr>
<th>Drugs Covered</th>
<th>Cutoff Concentrations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicotine</td>
<td>15 ng/mL</td>
</tr>
<tr>
<td>Cotinine (metabolite)</td>
<td>15 ng/mL</td>
</tr>
<tr>
<td>3-OH-Cotinine (metabolite)</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>Anabasine (tobacco biomarker)</td>
<td>5 ng/mL</td>
</tr>
</tbody>
</table>

### Interpretive Data:

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

**Positive cutoff:**
- Nicotine: 15 ng/mL
- Cotinine: 15 ng/mL
- 3-OH-Cotinine: 50 ng/mL
- Anabasine: 5 ng/mL

This test is designed to evaluate recent use of nicotine-containing products. Passive and active exposure cannot be discriminated definitively, although a cutoff of 100 ng/mL cotinine is frequently used for surgery qualification purposes. For smoking cessation programs or compliance testing, the absence of expected drug(s) and/or drug metabolite(s) may indicate non-compliance, inappropriate timing of specimen collection relative to drug administration, poor drug absorption, diluted/adulterated urine, or limitations of testing. The concentration value must be greater than or equal to the cutoff to be reported as positive. Anabasine is included as a biomarker of tobacco use, versus nicotine replacement. Interpretive questions should be directed to the laboratory.

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

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

*Remove component 0092360, Nornicotine, Urine*

### Oxalate, Plasma

**Reference Interval:**
- Effective August 16, 2021
- Less than or equal to 2.0 umol/L

### 1p/19q Deletion by FISH

**Reference Interval:**
- Effective August 16, 2021
- Add component 3003802, 1P Percent Deleted
- Add component 3003803, 19Q Percent Deleted

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

### 1p19q Deletion by FISH and IDH1 R132H Point Mutation by Immunohistochemistry with Reflex to IDH1 and IDH2 Mutation Analysis, Exon 4

**Reference Interval:**
- Effective August 16, 2021
- Add component 2007358, IDH1 R132H Mutation Reference Number
- Remove component 2002148, Block ID

**HOTLINE NOTE:** There is a component change associated with this test.
### Parainfluenza 1-4 by PCR

**Specimen Required:** Collect: Bronchoalveolar lavage (BAL), nasal wash, nasopharyngeal swab or sputum.

**Specimen Preparation:**
- **Fluid:** Transfer 2 mL respiratory specimen to a sterile container. (Min: 0.5 mL)
- Also acceptable: Transfer to viral transport media (ARUP supply #12884). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
- **Swabs:** Place in viral transport media.

**Storage/Transport Temperature:** Frozen.

**Remarks:** Specimen source required.

**Stability (collection to initiation of testing):**
- Ambient: Unacceptable
- Refrigerated: 4 days
- Frozen: 1 month

### Partial Thromboplastin Time

**Specimen Required:** Collect: Lt. blue (sodium citrate).

**Specimen Preparation:**
- Separate plasma from cells ASAP or within 2 hours of collection and freeze. Transfer 1 mL platelet-poor plasma to an ARUP Standard Transport Tube.
- **Unacceptable Conditions:** Serum, EDTA plasma, clotted or hemolyzed specimens.

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

**Remarks:** Specimen source required.

**Stability (collection to initiation of testing):**
- Ambient: 4 hours
- Refrigerated: Unacceptable
- Frozen: 2 weeks

**NOTE:** Specimens from patients on heparin must be centrifuged within 1 hour of collection and ambient stability is reduced to 2 hours.

### Parvovirus B19 by Qualitative PCR

**Specimen Required:** Collect: Lavender (EDTA), Pink (K2EDTA), or Serum Separator Tube (SST). Also acceptable: Amniotic fluid, CSF, tissue, paraffin embedded tissue, or synovial fluid.

**Specimen Preparation:**
- Separate serum or plasma from cells. Transfer 1 mL serum, plasma, bone marrow, amniotic fluid, CSF, or synovial fluid to a sterile container. (Min: 0.5 mL)
- **Fresh Tissue:** Transfer fresh tissue to a sterile container and freeze immediately.
- **Paraffin Embedded Tissue:** Transport in a Tissue Transport Kit (ARUP supply #47808), available online through eSupply using ARUP Connect or contact ARUP Client Services at (800) 522-2787.

**Bone Marrow:** Refrigerated.

**Paraffin Embedded Tissue:** Room temperature.

**Remarks:** Specimen source required.

**Unacceptable Conditions:** Heparinized specimens, tissues in optimal cutting temperature compound.

**Stability (collection to initiation of testing):**
- Ambient: 24 hours
- Refrigerated: 5 days
- Frozen: 6 months
- **Bone Marrow:** Ambient: 1 week
- Refrigerated: 1 week
- Frozen: 1 week
- **Fresh Tissue:** Ambient: Unacceptable
- Refrigerated: Unacceptable
- Frozen: 6 months
- **Paraffin Embedded Tissue:** Ambient: Indefinitely
- Refrigerated: Indefinitely
- Frozen: Unacceptable

### PCCA/ANNA by IFA with Reflex to Titer and Immunoblot

**HOTLINE NOTE:** Name change only.

**Specimen Required:** Collect: Green (Lithium Heparin).

**Specimen Preparation:** Separate from cells ASAP or within 2 hours of collection. Leave RBCs in the original container and replace stopper. Transport 2 mL RBCs in the original collection tube. (Min: 0.7 mL)

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

**Storage/Transport Temperature:** Refrigerated.

**Unacceptable Conditions:** Tubes containing potassium-based preservatives/anticoagulants. Light green (lithium heparin).

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

### Potassium, Total, RBC

**Specimen Required:** Collect: Green (Lithium Heparin).

**Specimen Preparation:** Separate from cells ASAP or within 2 hours of collection. Leave RBCs in the original container and replace stopper. Transport 2 mL RBCs in the original collection tube. (Min: 0.7 mL)

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

**Storage/Transport Temperature:** Refrigerated.

**Unacceptable Conditions:** Tubes containing potassium-based preservatives/anticoagulants. Light green (lithium heparin).

**Stability (collection to initiation of testing):**
- Ambient: Unacceptable
- Refrigerated: 1 month
- Frozen: Unacceptable
New Test 3001621 Primary Ciliary Dyskinesia Panel, Sequencing
Available Now  
Click for Pricing

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

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

Reference Interval: By report

Interpretive Data:
Refer to report.

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

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

Note: Genes tested: ARMC4*, CCDC103*, CCDC114*, CCDC151, CCDC39, CCDC40*, CCDC65, CCNO, CFAP298*, DNAAF1, DNAAF2, DNAAF3, DNAAF4, DNAAF5*, DNAH1, DNAH11, DNAH5, DNAI1, DNAI2*, DNAL1, DRC1, GAS8, LRRC6, MCIDAS, NME8, PIH1D3, RSPH1, RSPH3, RSPH4A, RSPH9, SPAG1*, ZMYND10
*One or more exons are not covered by sequencing for the indicated gene; see Additional Technical Information.

CPT Code(s): 81479

New York DOH approval pending. Call for status update.

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

0070115 Prolactin PROLAC

Specimen Required: Collect: Serum separator tube or plasma separator tube. Also acceptable: Lithium heparin or EDTA plasma.
Specimen Preparation: Allow specimen to clot completely at room temperature. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Frozen.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 7 days; Frozen: 1 months.

Reference Interval:
Effective August 16, 2021

<table>
<thead>
<tr>
<th>Age</th>
<th>Male</th>
<th>Female, nonpregnant</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-9 years</td>
<td>2.1-17.7 ng/mL</td>
<td>2.1-17.7 ng/mL</td>
</tr>
<tr>
<td>10 years and older</td>
<td>2.8-29.2 ng/mL</td>
<td></td>
</tr>
</tbody>
</table>

Note: Pregnancy, lactation, and the administration of oral contraceptives can increase prolactin concentrations.

HOTLINE NOTE: Remove information found in the Unacceptable Conditions field.
**HOTLINE: Effective August 16, 2021**

---

**0020724 Prolactin, Dilution Study PROLAC MAC**

**Specimen Required:** Collect: Serum separator tube or plasma separator tube. Also acceptable: Lithium heparin or EDTA plasma.

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

**Storage/Transport Temperature:** Frozen.

**Stability (collection to initiation of testing):** After separation from cells: Ambient: 8 hours; Refrigerated: 7 days; Frozen: 1 month

**Reference Interval:**

<table>
<thead>
<tr>
<th>Age</th>
<th>Prolactin</th>
<th>Male</th>
<th>Female, nonpregnant</th>
</tr>
</thead>
<tbody>
<tr>
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<td>10 years and older</td>
<td>2.8-29.2 ng/mL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note:** This test is intended for patients with prolactin-secreting macroadenomas, where a high-dose hook effect is a consideration. Pregnancy, lactation, and the administration of oral contraceptives can increase prolactin concentrations.

**HOTLINE NOTE:** Remove information found in the Unacceptable Conditions field.

---

**2002930 Prostate Specific Antigen, Complexed PSA COMP**

**Reference Interval:**

Effective August 16, 2021

Less than or equal to 3.6 ng/mL

**Interpretive Data:**

This test uses the Siemens' Atellica® IM cPSA methodology, which is FDA approved for use as an aid in the detection of prostate cancer in men age 50 and older when used in conjunction with a digital rectal exam. This methodology is also approved as an aid in the management/monitoring of prostate cancer patients. Results obtained with different assay methods or kits cannot be used interchangeably. Prostatic biopsy is required for the diagnosis of cancer. cPSA is generally not elevated in healthy men or with non-prostatic carcinoma. cPSA concentrations may be elevated in benign prostatic hyperplasia or inflammatory conditions of the prostate. Prostate cancer patients under treatment with antiandrogens and LHRH agonists and antagonists may exhibit markedly reduced levels of cPSA. Care should be taken when interpreting values from these individuals.

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**0060764 Respiratory Virus Mini Panel by PCR RESPMINI**

**Specimen Required:** Collect: Respiratory specimen: Bronchoalveolar lavage (BAL), nasal wash, nasopharyngeal swab, or pleural fluid.

**Specimen Preparation:** Fluid: Transfer 1 mL respiratory specimen to a sterile container. (Min: 0.5 mL) Also acceptable: Transfer to viral transport media (ARUP Supply #12884). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. Swabs: Place in viral transport media. Place each specimen in an individually sealed bag.

**Storage/Transport Temperature:** Refrigerated.

**Remarks:** Specimen source required.

**Stability (collection to initiation of testing):** Ambient: Unacceptable; Refrigerated: 4 days; Frozen: 1 month
**New Test**

**3004055 Rheumatoid Arthritis Panel**

**RA PANEL**

**Methodology:** Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Quantitative Immunoturbidimetry

**Performed:** Sun-Sat

**Reported:** 1-4 days

**Specimen Required:**
- **Patient Prep:** Fasting specimen preferred.
- **Collect:** Serum separator tube.
- **Specimen Preparation:** Allow serum to clot completely at room temperature before centrifuging. Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 1 mL) Serum is the only acceptable specimen type for this assay without a disclaimer.
- **Storage/Transport Temperature:** Refrigerated.
- **Unacceptable Conditions:** Contaminated, heat-inactivated, hemolyzed, icteric, or severely lipemic specimens.
- **Stability (collection to initiation of testing):** After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 1 month (should not be thawed more than once)

**Reference Interval:**

<table>
<thead>
<tr>
<th>Available Separately</th>
<th>Components</th>
<th>Reference Interval</th>
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</thead>
<tbody>
<tr>
<td>0055256</td>
<td>Cyclic Citrullinated Peptide (CCP) Antibody, IgG</td>
<td>19 Units or less Negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td>20-39 Units Weak positive</td>
</tr>
<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>0050465</td>
<td>Rheumatoid Factor</td>
<td>0-14 IU/mL</td>
</tr>
<tr>
<td>3003992</td>
<td>Carbamylated Protein (CarP) Antibody, IgG</td>
<td>0-19 Units</td>
</tr>
</tbody>
</table>

**Interpretive Data:**

Anticyclic citrullinated peptide (anti-CCP) IgG antibodies are present in about 69-83 percent of patients with rheumatoid arthritis (RA) and have specificities of 93-95 percent. Anticarbamylated protein (anti-CarP) IgG antibodies are present in about 34-53 percent of patients with RA, have specificities of greater than 90 percent and can occur in RA patients seronegative for both rheumatoid factor and anti-CCP. Anti-CCP and anti-CarP autoantibodies may be present in the preclinical phase of disease, are associated with future RA development, and may predict radiographic joint destruction. Patients with weak positive results should be monitored and testing repeated.

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

**CPT Code(s):** 86200; 86431; 83516

New York DOH approval pending. Call for status update.

**HOTLINE NOTE:** Refer to the Test Mix Addendum for interface build information.
New Test 3004056 Rheumatoid Arthritis Panel with Reflex to Rheumatoid Factors, RA PANEL R IgA, IgG, and IgM by ELISA

Click for Pricing

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Quantitative Immunoturbidimetry
Performed: Sun-Sat
Reported: 1-4 days

Specimen Required: Patient Prep: Fasting specimen preferred.
Collect: Serum separator tube (SST).
Specimen Preparation: Allow serum to clot completely at room temperature before centrifuging. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.8 mL) Serum is the only acceptable specimen type for this test without a disclaimer.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Contaminated, heat-inactivated, hemolyzed, icteric, or severely lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 1 month (should not be thawed more than once)

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<tr>
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<tr>
<td>0050465</td>
<td>Rheumatoid Factor</td>
<td>0-14 IU/mL</td>
</tr>
<tr>
<td>0051298</td>
<td>Rheumatoid Factors, IgA, IgG, and IgM by ELISA</td>
<td>Refer to report</td>
</tr>
<tr>
<td>3003992</td>
<td>Carbamylated Protein (CarP) Antibody, IgG</td>
<td>Refer to report</td>
</tr>
</tbody>
</table>

Interpretive Data:

Anticyclic citrullinated peptide (anti-CCP) IgG antibodies are present in about 69-83 percent of patients with rheumatoid arthritis (RA) and have specificities of 93-95 percent. Anticarbamylated protein (anti-CarP) IgG antibodies are present in about 34-53 percent of patients with RA, have specificities of greater than 90 percent and can occur in RA patients seronegative for both rheumatoid factor and anti-CCP. Anti-CCP and anti-CarP autoantibodies may be present in the preclinical phase of disease, are associated with future RA development, and may predict radiographic joint destruction. Patients with weak positive results should be monitored and testing repeated.

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

Note: If CCP IgG is 20 units or greater and/or rheumatoid factor is 15 IU/mL or greater, then Rheumatoid Factor, IgG/IgM/IgA by EIA will be performed. Additional charges apply.

CPT Code(s): 86200; 86431; 83516 if reflexed, add 83516 x3

New York DOH approval pending. Call for status update.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.
New Test 3004094  Rivaroxaban Level  RIVAROX

**Methodology:** Chromogenic Assay

**Performed:** Tuesday

**Reported:** 1-8 days

**Specimen Required:**
- Collect: Lt. blue (sodium citrate). Refer to Specimen Handling at aruplab.com for hemostasis/thrombosis specimen handling guidelines.
- Specimen Preparation: Transport 2 mL platelet-poor plasma. (Min: 1 mL)
- Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when additional tests are ordered.
- Remarks: This test cannot be used to quantitate anticoagulants other than Rivaroxaban. This includes but is not limited to Unfractionated Heparin, Low Molecular Weight Heparin, Apixaban (Eliquis), Edoxaban (Savaysa), and Fondaparinux (Arixtra).
- Unacceptable Conditions: Serum, EDTA, oxalate, heparin, or plasma separator tubes, hemolyzed specimens.
- Stability (collection to initiation of testing): After separation from cells: Ambient: 4 hours; Refrigerated: Unacceptable; Frozen: 1 month

**Reference Interval:** Not established

**Interpretive Data:**
When 20 mg rivaroxaban was administered daily for treatment of DVT and PE, rivaroxaban steady state levels were as follows:
- Peak: 189-419 ng/mL
- Trough: 6-87 ng/mL
- The lower limit of detection for this assay is 25 ng/mL.

For additional information, please refer to [www.arupconsult.com](http://www.arupconsult.com)

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

**CPT Code(s):** 80299

New York DOH approval pending. Call for status update.

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

New Test 2004127  S-100 Protein by Immunohistochemistry (DAB Detection)  S100 IHC

**HOTLINE NOTE:** There is a clinically significant charting name change associated with this test.
Change the charting name for component 2004128, S-100 Protein by IHC from S-100 Protein by IHC to S-100 Protein by IHC DAB Detection.
Change the charting name for component 2004129, S-100 Protein Reference Number from S-100 Protein Reference Number to S-100 Protein DAB Detection Ref Number.
New Test

3003733
S-100 Protein by Immunohistochemistry (Red Detection)

S100 R IHC

Available Now
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Immunohistochemistry Stain Form
Recommended (ARUP form #32978)

Methodology: Immunohistochemistry
Performed: Mon-Fri
Reported: 1-5 days

Specimen Required: Collect: Tissue or cells.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin is preferred) and paraffin embed specimen (cells must be prepared into a cellblock). Protect paraffin from excessive heat. Transport tissue block or 5 unstained (3-5 micron thick sections), on positively charged slides (Min: 2 slides). If sending precut slides, do not oven bake.
Storage/Transport Temperature: Room temperature or refrigerated. Ship in cooled container during summer months.
Remarks: IMMUNOHISTOCHEMISTRY ORDERING AND SUBMISSION DETAILS: Submit electronic request. If you do not have electronic ordering capability, use an ARUP Immunohistochemistry Stain Form (form #32978) with an ARUP client number. For additional technical details, please contact ARUP Client Services.
Unacceptable Conditions: Specimens submitted with non-representative tissue type. Depleted specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

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

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

CPT Code(s): 88342

New York DOH Approved.

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

0070103
Serum, C-Peptide

C PEP

Specimen Required: Patient Prep: Fasting specimen preferred.
Collect: Serum separator tube
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate serum from cells ASAP. Submit specimen in an ARUP Standard Transport Tube.
Storage/Transport Temperature: Transport 1 mL serum, frozen. (Min: 0.5 mL)
Unacceptable Conditions: Grossly hemolyzed specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 7 days; Frozen: 1 month

Reference Interval:
Effective August 16, 2021
0.5-3.3 ng/mL.

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 0070103, C-Peptide, Serum or Plasma from C-Peptide, Serum or Plasma to Serum, C-Peptide.

3001562
SOX-10 By Immunohistochemistry (DAB Detection)

SOX10 IHC

HOTLINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name for component 3001563, SOX-10 Reference Number from SOX-10 Reference Number to SOX-10 DAB Detection Reference Number.
Change the charting name for component 3001564, SOX-10 By Immunohistochemistry from SOX-10 By Immunohistochemistry to SOX-10 By IHC DAB Detection.
New Test 3003737 SOX-10 by Immunohistochemistry (Red Detection) SOX10R IHC

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

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

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

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

CPT Code(s): 88342

New York DOH Approved.

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

0090265 Theophylline THEO

Specimen Required: Collect: Plain red. Also acceptable: Green (sodium heparin).
Specimen Preparation: Separate serum from cells within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.2 mL)
Storage/Transport Temperature: Refrigerated.
Remarks: Lipemic specimens may cause an underestimation of Theophylline level
Unacceptable Conditions: Gel separator tubes are not acceptable, regardless of the tube additive
Stability (collection to initiation of testing): After separation from cells: Ambient: 8 hours; Refrigerated: 8 days; Frozen: 3 months

2011172 Urogenital Ureaplasma and Mycoplasma Species by PCR UR MYCOPCR

Performed: Mon, Wed, Fri
Reported: 2-5 days

Specimen Required: Collect: Genital swab, rectal swab, or urine. Also acceptable: upper respiratory swabs, bronchoalveolar lavage, sputum, and tracheal aspirates.
Specimen Preparation: Transfer genital swab, rectal swab, respiratory swab, or 1 mL urine to viral transport media (ARUP supply #12884) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
BAL, sputum, or tracheal aspirate: Transfer 1 mL to an empty sterile container. (Min: 0.5 mL)
Storage/Transport Temperature: Frozen
Remarks: Specimen source required.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 10 days; Frozen: 14 days
### New Test 3004071 von Willebrand Factor (VWF) GPIbM Activity VWF GPIBM

**Methodology:** Quantitative Enzyme-Linked Immunosorbent Assay  
**Performed:** Varies  
**Reported:** 7-10 days  

**Specimen Required:**  
- **Collect:** Light blue (sodium citrate).  
- **Specimen Preparation:** Transfer 0.5 mL plasma to an ARUP Standard Transport Tube. (Min: 0.3 mL)  
- **Test is not performed at ARUP; separate specimens must be submitted when multiple tests are ordered.**  
- **Storage/Transport Temperature:** CRITICAL FROZEN.  
- **Stability (collection to initiation of testing):** Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 2 weeks  

**Reference Interval:** By Report  

**CPT Code(s):** 85397  

New York DOH Approved.  

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

### New Test 0060132 Wound Culture and Gram Stain MC W

**Performed:** Sun-Sat  
**Reported:** Negative at 6 days  
**Positives as soon as detected**
The following will be discontinued from ARUP's test menu on August 16, 2021. 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>2007994</td>
<td>Allergen, Food, Alpha-Gal (galactose-alpha-1,3-galactose) IgE</td>
<td>Allergen, Food, Alpha-Gal (galactose-alpha-1,3-galactose) IgE (3003923)</td>
</tr>
<tr>
<td>2014011</td>
<td>Allergen, Food, Alpha-Gal (galactose-alpha-1,3-galactose) Panel</td>
<td>Allergen, Food, Alpha-Gal (galactose-alpha-1,3-galactose) Panel (3003924)</td>
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<tr>
<td>2002398</td>
<td>Alport Syndrome, X-linked (COL4A5) Sequencing and Deletion/Duplication</td>
<td>Alport Syndrome Panel, Sequencing and Deletion/Duplication (3002685)</td>
</tr>
<tr>
<td>2006480</td>
<td>ANCA-Associated Vasculitis Profile (ANCA/MPO/PR3) with Reflex to ANCA Titer</td>
<td>ANCA Vasculitis Profile (3003745)</td>
</tr>
<tr>
<td>2002068</td>
<td>Anti-Neutrophil Cytoplasmic Antibody with Reflex to Titer and MPO/PR3 Antibodies</td>
<td>MPO and PR3 with Reflex to ANCA (3003746)</td>
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<tr>
<td>0005811</td>
<td>Anti-Neutrophil Cytoplasmic Antibody, IgG</td>
<td>ANCA Vasculitis Profile (3003745)</td>
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<td>3003564</td>
<td>Apolipoprotein B (APOB) Mutation Detection</td>
<td>Autoimmune Neurologic Disease Reflexive Panel, Serum (3004070)</td>
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<tr>
<td>3000182</td>
<td>Bacterial Strain Characterization by Pulsed-Field Gel Electrophoresis</td>
<td>Bacterial Strain Typing by Next Generation Sequencing (3002528)</td>
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<tr>
<td>2012678</td>
<td>Gastrointestinal Bacterial Panel by PCR</td>
<td>Gastrointestinal Pathogens Panel by PCR (3003278)</td>
</tr>
<tr>
<td>2013572</td>
<td>Gastrointestinal Vizal Panel by PCR</td>
<td>Gastrointestinal Pathogens Panel by PCR (3003278)</td>
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<tr>
<td>2009256</td>
<td>HIV-1 Genotype and Integrase Inhibitor Resistance by Sequencing</td>
<td>Human Immunodeficiency Virus 1 Drug Resistance by Next Generation Sequencing (3003853)</td>
</tr>
<tr>
<td>2004457</td>
<td>HIV-1 Integrase Inhibitor Resistance by Sequencing</td>
<td>Human Immunodeficiency Virus 1 Drug Resistance by Next Generation Sequencing (3003853)</td>
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<tr>
<td>0005670</td>
<td>Human Immunodeficiency Virus 1, Genotype by Sequencing</td>
<td>Human Immunodeficiency Virus 1 Drug Resistance by Next Generation Sequencing (3003853)</td>
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<tr>
<td>3001234</td>
<td>Human Immunodeficiency Virus Type 1 (HIV-1) GenoSure MG</td>
<td>Human Immunodeficiency Virus 1 Drug Resistance by Next Generation Sequencing (3003853)</td>
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<tr>
<td>3001238</td>
<td>Human Immunodeficiency Virus Type 1 (HIV-1) GenoSure PRIme</td>
<td>Human Immunodeficiency Virus 1 Drug Resistance by Next Generation Sequencing (3003853)</td>
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<td>2013370</td>
<td>Inflammatory Bowel Disease Differentiation Panel</td>
<td>IBD Differentiation (3003748)</td>
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<td>JAK2 Gene, V617F Mutation, Qualitative (Inactive as of 8/16/2021, refer to 3000406)</td>
<td>JAK2 V617F Mutation by ddPCR Qualitative (3000406)</td>
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<td>JAK2 Gene, V617F Mutation, Qualitative with Reflex to CALR (Calreticulin) Exon 9 Mutation Analysis by PCR with Reflex to MPL Mutation Detection (Inactive as of 8/16/2021, refer to 3003800)</td>
<td>JAK2 V617F Mutation by ddPCR, Qualitative with Reflex to CALR (Calreticulin) Exon 9 Mutation Analysis by PCR with Reflex to MPL Mutation Detection (3003800)</td>
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<td>Legius Syndrome (SPRED1) Sequencing and Deletion/Duplication</td>
<td>Neurofibromatosis Type 1 Sequencing and Deletion/Duplication and Legius Syndrome Sequencing Panel (3003922)</td>
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<td>Rheumatoid Arthritis Panel</td>
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<td>Rheumatoid Arthritis Panel with Reflex to Rheumatoid Factors, IgA, IgG, and IgM by ELISA</td>
<td>Rheumatoid Arthritis Panel with Reflex to Rheumatoid Factors, IgA, IgG, and IgM by ELISA (3004056)</td>
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