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-9 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.

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<th>Hot Line Page #</th>
<th>Test Number</th>
<th>Test Name</th>
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<td>49</td>
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<td>50</td>
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<td>Tissue Plasminogen Activator, Antigen</td>
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<td>Trichomonas vaginalis by Transcription-Mediated Amplification (TMA)</td>
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<td>Tropheryma whippelii Detection by PCR, Blood</td>
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<td>53</td>
<td>2002093</td>
<td>Tropheryma whippelii DNA, Qualitative RT PCR</td>
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<td>52</td>
<td>2011172</td>
<td>Urogenital Ureaplasma and Mycoplasma Species by PCR Available Date 10/20/2014</td>
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<td>2005416</td>
<td>Urticaria-Induced Basophil Activation</td>
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<tr>
<td>52</td>
<td>2011039</td>
<td>Vigabatrin Quantitative, Serum or Plasma Available Date 10/20/2014</td>
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</tbody>
</table>
**New Test** 2011132

**Acute Myeloid Leukemia Panel by FISH**

**FISH AML**

**Time Sensitive**

**Additional Technical Information**

**Oncology Test Request Form Recommended (ARUP form #43099)**

**Methodology:** Fluorescence in situ Hybridization

**Performed:** Sun-Sat

**Reported:** 3-10 days

**Specimen Required:**
- Collect: Non-diluted bone marrow aspirate collected in a heparinized syringe. Also acceptable: Whole blood in green (sodium heparin).
- Other specimen types may be acceptable, contact the Cytogenetics Laboratory for specific specimen collection and transportation instructions.

**Specimen Preparation:**
- Transfer bone marrow to a green (sodium heparin). Transport 3 mL bone marrow. (Min: 1 mL) **OR** Transport 5 mL whole blood. (Min: 2 mL)
- Storage/Transport Temperature: Room temperature.
- Unacceptable Conditions: Clotted or paraffin-embedded specimens.
- Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Unacceptable

**Reference Interval:** Normal

**Interpretive Data:** Probes included: RPN1/MECOM (EVI1), EGR1, D7S486, RUNX1T1/RUNX1, KMT2A (MLL), and CBFB. The probe for PML/RARα is added automatically and is performed along with the panel. However, due to the longer turnaround time required for the panel, the result of this probe is reported as soon as available and is charged separately. (See PML-RARA Translocation by FISH, ARUP test code 2002363)

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

**Note:** If cell pellets or dropped cytogenetic slides are submitted, processing fee will not apply. Other specimen types may be acceptable, contact the Cytogenetics Laboratory for specific specimen collection and transportation instructions.

A processing fee will be charged if this procedure is canceled at the client's request after the test has been set up, or if the specimen integrity is inadequate to allow culture growth. Fee varies based on specimen type.

**CPT Code(s):** 88271 x6; 88275 x6; 88291

New York DOH Approved.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.
New Test | 2011248 | Adalimumab Activity and Neutralizing Antibody | ADA NAB

Available October 20, 2014

Methodology: Cell Culture/Quantitative Chemiluminescent Immunoassay/ Semi-Quantitative Chemiluminescent Immunoassay
Performed: Mon, Wed, Thu, Sat
Reported: 2-3 days

Specimen Required:
- Patient Prep: Collect specimens before adalimumab treatment.
- 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: 0.3 mL)
- Storage/Transport Temperature: Refrigerated.
- Unacceptable Conditions: Contaminated, hemolyzed, icteric, or lipemic specimens.
- Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 4 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval:

<table>
<thead>
<tr>
<th>Available Separately</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Adalimumab Activity</td>
<td>Not Detected</td>
</tr>
<tr>
<td>No</td>
<td>Adalimumab Neutralizing Antibody</td>
<td>Not Detected</td>
</tr>
</tbody>
</table>

Interpretive Data: This test measures the capacity of adalimumab to neutralize TNF-activity. Additionally, adalimumab neutralizing antibodies (NAb) are titered (reporting the highest dilution of patient sera in which NAb activity is detected).

This test is used to evaluate secondary response failures to adalimumab therapy. Secondary response failure is defined as loss of clinical response after initial improvement of clinical signs and symptoms. Therapeutic decision should rest on both the clinical response and the knowledge of the fate of the drug including the emergence of immunogenicity in individual patients.

Circulating adalimumab levels have been shown to vary considerably between patients. These differences relate to route and frequency of administration and patient-related features such as age, gender, weight, drug metabolism, and concomitant medications such as methotrexate and other immunosuppressants.

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

<table>
<thead>
<tr>
<th>IF Adalimumab Activity is....</th>
<th>AND Adalimumab Neutralizing Ab. Titer is....</th>
<th>THEN....</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Detected</td>
<td>Not Detected</td>
<td>A higher dosage of adalimumab or shortening the dosing interval may be appropriate.</td>
</tr>
<tr>
<td>Not Detected</td>
<td>1:20 or greater</td>
<td>A change to another anti-TNF-α drug may be appropriate.</td>
</tr>
<tr>
<td>0.65 ug/mL or greater</td>
<td>Not Detected</td>
<td>A change to another type of therapy (not targeting TNF-α) may be appropriate.</td>
</tr>
<tr>
<td>0.65 ug/mL or greater</td>
<td>1:20 or greater</td>
<td>Repeat testing is suggested to rule out decreasing adalimumab activity and/or increasing adalimumab neutralizing antibodies.</td>
</tr>
</tbody>
</table>

Note: This test is performed pursuant to an agreement with Biomonitor.

CPT Code(s): 86352 x2

New York DOH approval pending. Call for status update.

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

0030056 | ADAMTS13 Activity | ADAMTS-13

Methodology: Chromogenic Assay

Reference Interval:
Effective November 17, 2014
Greater than 60 percent.
New Test 2011151 Agammaglobulinemia Panel, Sequencing (9 Genes) and Deletion/Duplication (6 Genes) AGG PANEL

Available October 20, 2014

Patient History for Agammaglobulinemia

Additional Technical Information

Methodology: Massive Parallel Sequencing/Exonic Oligonucleotide-based CGH Microarray
Performed: Varies
Reported: 10-12 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.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data: Refer to report.

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

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

Note: Genes sequenced: BLNK, BTK, CD79A, CD79B, IGHM, IGLL1, LRRC8A, PIK3R1, SH2D1A
Genes deletion/duplication: BLNK, BTK, CD79A, CD79B, IGHM, IGLL1

CPT Code(s): 81404 (SH2D1A), 81406 (BTK), 81479 x2

New York DOH approval pending. Call for status update.

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

0050001 Alpha-1-Antitrypsin A1A

Reference Interval:
Effective November 17, 2014
90-200 mg/dL
Alpha-1-Antitrypsin (SERPINA1) Enzyme Concentration and 2 Mutations with Reflex to Alpha-1-Antitrypsin Phenotype

Reference Interval:

<table>
<thead>
<tr>
<th>Available Separately</th>
<th>Components</th>
<th>Reference Interval</th>
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</thead>
<tbody>
<tr>
<td>Yes (0050001)</td>
<td>Alpha-1-Antitrypsin</td>
<td>Effective November 17, 2014 90-200 mg/dL</td>
</tr>
<tr>
<td>No</td>
<td>Alpha-1-Antitrypsin Phenotype</td>
<td>By report</td>
</tr>
</tbody>
</table>

Interpretive Data:

Background Information for A1A (SERPINA1) Enzyme Concentration and 2 Mutations with Reflex to A1A Phenotype:

Characteristics: Coughing, wheezing, chronic obstructive pulmonary disease, emphysema, cirrhosis.

Incidence: 1 in 3000 to 1 in 5000.

Inheritance: Autosomal recessive.

Cause: Mutations in the AAT glycoprotein gene on chromosome 14q31-32.3; homozygosity for the Z allele is the most common cause.

Clinical Sensitivity: 95 percent.

Mutations Tested: S allele (c.791A>T) and Z allele (c.1024G>A).

Methods: Genotyping performed by PCR followed by fluorescent probe melting analysis; AAT protein concentration measured using immunoturbidmetric assay; phenotyping performed by isoelectric focusing. Genotyping and AAT serum protein concentration determination are performed on all specimens. Protein phenotyping is only performed on specimens that have AAT serum concentrations of less than 90 mg/dL and are not homozygous or compound heterozygous for the S or Z deficiency alleles by genotyping.

Analytical Sensitivity and Specificity: 99 percent.

Limitations: Mutations, other than the S (c.791A>T) and Z (c.1024G>A) alleles, will not be detected. Diagnostic errors can occur due to rare sequence variations.

This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

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

See Compliance Statement C: www.aruplab.com/CS
**New Test**  
**2011043**  
**Alpha-1-Antitrypsin Clearance, Quantitative by ELISA, Timed Stool**  
**A1ACLR**

**Methodology:** Enzyme-Linked Immunosorbent Assay/Quantitative Immunoturbidimetry  
**Performed:** Mon, Wed, Fri  
**Reported:** 1-3 days

**Specimen Required:**  
**Collect:** Serum or Plasma: Plasma separation tube (PST). Also acceptable: Lavender (EDTA) or pink (K₂EDTA). AND Stool: 24-, 48-, or 72-hour stool. Refrigerate during collection. Provide patient a Timed Stool Collection Kit (ARUP supply #44192). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.  
**Specimen Preparation:** Serum or Plasma: Collect blood during the stool collection time interval. Allow serum to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transfer 0.5 mL to an ARUP Standard Transport Tube. (Min: 0.2 mL)  
**Stool:** Refer to instructions in Stool Collection-Timed Specimens (24, 48, 72 Hours) under Specimen Handling at http://www.aruplab.com. Submit entire stool collection in an ARUP approved transport container(s) provided in kit using additional containers as needed for the full collection (available separately, ARUP supply #28077). (Min: 5 g)  
**Storage/Transport Temperature:** Frozen.  
**Unacceptable Conditions:** Serum or Plasma: Hemolyzed. Stool: Specimens in media or preservatives.  
**Stability (collection to initiation of testing):** Serum or Plasma: Ambient: 1 week; Refrigerated: 3 months; Frozen: 3 months (avoid freeze/thaw cycles). Stool: Ambient: 24 hours; Refrigerated: 7 days; Frozen: 3 months

**Reference Interval:**

<table>
<thead>
<tr>
<th>Available Separately</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Alpha-1-Antitrypsin Stool - Clearance</td>
<td>1 - 49 mL/24h</td>
</tr>
<tr>
<td>Yes (2011041)</td>
<td>Alpha-1-Antitrypsin Stool, ELISA</td>
<td>0.00 - 0.50 mg/g</td>
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<tr>
<td>Yes (0050001)</td>
<td>Alpha-1-Antitrypsin</td>
<td>90 - 200 mg/dL</td>
</tr>
</tbody>
</table>

**Interpretive Data:** See Compliance Statement D: www.aruplab.com/CS

**Note:** If serum or plasma specimen is not submitted in conjunction with a timed stool collection, order Alpha-1-Antitrypsin, Quantitative by ELISA, Random Stool (ARUP test code 2011041).

**CPT Code(s):** 82103 x 2

New York DOH approval pending. Call for status update.

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

**0080500**  
**Alpha-1-Antitrypsin Phenotype (Includes Alpha-1-Antitrypsin)**  
**A1A PHENO**

**Reference Interval:**

<table>
<thead>
<tr>
<th>Available Separately</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Phenotype</td>
<td>By report</td>
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</tbody>
</table>
| Yes (0050001)        | Alpha-1-Antitrypsin | Effective November 17, 2014  
90-200 mg/dL          |
### New Test: Alpha-1-Antitrypsin, Quantitative by ELISA, Random Stool

**Methodology:** Quantitative Enzyme-Linked Immunosorbent Assay  
**Performed:** Mon, Wed, Fri  
**Reported:** 1-3 days  

**Specimen Required:** Collect: Random stool. Provide patient a Kit, Stool Transport, Unpreserved (ARUP Supply # 40910). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.  
Specimen Preparation: Transfer 5 g stool to an unpreserved stool transport vial (ARUP supply #40910). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 1 g)  
Storage/Transport Temperature: Frozen.  
Unacceptable Conditions: Specimens in media or preservatives.  
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 7 days; Frozen: 3 months

**Reference Interval:** 0.00 - 0.50 mg/g

**Interpretive Data:** See Compliance Statement D: www.aruplab.com/CS

**CPT Code(s):** 82103

New York DOH approval pending. Call for status update.

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

---

### New Test: Aminolevulinic Acid Dehydratase (ALAD), Blood

**Available October 20, 2014**

**Methodology:** Quantitative Enzymatic/Spectrofluorometry  
**Performed:** Varies  
**Reported:** 3-10 days  

**Specimen Required:** Patient Prep: Patient should abstain from alcohol for 24 hours prior to collection.  
Collect: Green (sodium heparin). Also acceptable: Lavender (EDTA) or green (lithium heparin). Collect specimen and place in ice bath immediately.  
Specimen Preparation: Transport 5 mL whole blood in original collection container. (Min: 3 mL)  
Storage/Transport Temperature: Refrigerated.  
Remarks: Include a list of medications the patient is currently taking.  
Unacceptable Conditions: Grossly hemolyzed specimens.  
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 4 days; Frozen: Unacceptable

**Reference Interval:** By Report

**CPT Code(s):** 82657

New York DOH Approved.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.
<table>
<thead>
<tr>
<th>New Test</th>
<th>2011048</th>
<th>AMPA-Receptor (GluR1/2) Antibody IgG, CSF</th>
<th>AMPAR CSF</th>
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</thead>
<tbody>
<tr>
<td>Available</td>
<td>October 20, 2014</td>
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</tbody>
</table>

**Methodology:** Qualitative Immunofluorescence  
**Performed:** Varies  
**Reported:** 6-9 days  

**Specimen Required:**  
- Collect: CSF.  
- Specimen Preparation: Transfer 1 mL CSF to an ARUP Standard Transport Tube. (Min: 0.5 mL)  
- Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen.  
- Unacceptable Conditions: Hemolyzed, icteric or lipemic specimens.  
- Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 28 days; Frozen: 28 days  

**Reference Interval:** By Report  
**CPT Code(s):** 86255  
New York DOH Approved.  

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

<table>
<thead>
<tr>
<th>New Test</th>
<th>2011050</th>
<th>AMPA-Receptor (GluR1/2) Antibody IgG, Serum</th>
<th>AMPAR SER</th>
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<tbody>
<tr>
<td>Available</td>
<td>October 20, 2014</td>
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</tr>
</tbody>
</table>

**Methodology:** Qualitative Immunofluorescence  
**Performed:** Varies  
**Reported:** 6-9 days  

**Specimen Required:**  
- Collect: Plain red or serum separator tube (SST).  
- Specimen Preparation: Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)  
- Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen.  
- Unacceptable Conditions: Hemolyzed, icteric or lipemic specimens.  
- Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 28 days; Frozen: 28 days  

**Reference Interval:** By Report  
**CPT Code(s):** 86255  
New York DOH Approved.  

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.
New Test: **201152**  
**Amyotrophic Lateral Sclerosis (ALS) Panel, Sequencing and Deletion/Duplication, 11 Genes**

Available October 20, 2014

**Methodology:** Massive Parallel Sequencing/Exonic Oligonucleotide-based CGH Microarray

**Performed:** Varies

**Reported:** 10-12 weeks after receipt of fully completed ALS required consent form

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

**Reference Interval:** By report

**Interpretive Data:** Refer to report.

Informed consent is required for ALS genetic testing. Consent form is available online at www.aruplab.com.

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

**Note:** Genes tested, sequencing and deletion/duplication: **ALS2, ANG, FIG4, FUS, OPTN, SETX, SOD1, TARDBP, UBQLN2, VAPB, VCP**.

A completed ALS specific consent form, signed by the patient (or legal guardian) and physician, is required for all specimens. Testing for patients under the age of 18 years or fetal specimens is not offered. Presymptomatic counseling is recommended by a genetics professional prior to testing. Call Genetics Processing with additional questions at 800-242-2787 ext 3301.

**CPT Code(s):** 81403 (ANG), 81404 (SOD1), 81405 (TARDBP), 81406 x4 (FIG4, FUS, OPTN, SETX), 81479 x2

New York DOH approval pending. Call for status update.

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Test</th>
<th>Patient History for ALS</th>
<th>ALS Required Consent Form</th>
<th>Additional Technical Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>201152</td>
<td>Amyotrophic Lateral Sclerosis (ALS) Panel, Sequencing and Deletion/Duplication, 11 Genes</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**0013020**  
**Antigen Testing, RBC Phenotype Extended**  
IRL-EXPHEN

**Specimen Required:** Collect: Lavender (EDTA), or pink (K<sub>2</sub>EDTA).  
Specimen Preparation: Do not freeze. Transport 7 mL whole blood. (Min: 2 mL)  
Pediatric: Transport 0.5 mL whole blood. (Min: 0.5 mL)

**0013019**  
**Antigen Testing, Rh Phenotype**  
IRL-RPHEN

**Specimen Required:** Collect: Lavender (EDTA), or pink (K<sub>2</sub>EDTA).  
Specimen Preparation: Do not freeze. Transport 7 mL whole blood. (Min: 2 mL)  
Pediatric: Transport 0.5 mL whole blood. (Min: 0.5 mL)

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

**CPT Code(s):** 86039; If homogenous pattern add 86225 and 83516 - if reflexed add 86256; If speckled pattern add 86235 x5; If nucleolar pattern add 86235 x2 and 83516
New Test 2011144 Arginine:Glycine Amidinotransferase (GATM) Deficiency Sequencing

Available October 20, 2014

Patient History for Creatine Deficiency Syndrome Testing

Additional Technical Information

Methodology: Polymerase Chain Reaction/Sequencing
Performed: Varies
Reported: Within 3 weeks

Specimen Required: Collect: Lavender (EDTA), pink (K2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Background Information for Arginine/Glycine Amidinotransferase (GATM) Deficiency Sequencing:
Characteristics: Intellectual disability and seizure disorder of variable severity. May also include speech / language delays, movement disorder, and behavioral disorders such as autism, hyperactivity, and self-injury.
Incidence: Unknown. Less than 15 cases have been described.
Inheritance: Autosomal recessive.
Cause: Pathogenic GATM gene mutations.
Clinical Sensitivity: Based on limited data, may be has high as 99 percent.
Methodology: Bidirectional sequencing of the entire coding region and intron/exon boundaries of the GATM gene.
Analytical Sensitivity and Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Regulatory region mutations, deep intronic mutations, and large deletions/duplications will not be detected. Mutations in genes other than GATM are not evaluated.

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

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

CPT Code(s): 81479

New York DOH approval pending. Call for status update.

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

New Test 2011058 Arylsulfatase A, Leukocytes, Blood ARYL LEUK

Available October 20, 2014

Methodology: Quantitative Colorimetry
Performed: Varies
Reported: 8-18 days

Specimen Required: Collect: Yellow (ACD solution B). Also acceptable: Yellow (ACD solution A).
Specimen Preparation: Transport 7 mL whole blood in the original tube. (Min: 5 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature.
Unacceptable Conditions: Grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 4 days; Refrigerated: 4 days; Frozen: Unacceptable

Reference Interval: By Report

CPT Code(s): 82657

New York DOH Approved.

HOT LINE NOTE: Refer to the Test Mix Addendum for interface build information.
New Test 2011052  Beryllium Lymphocyte Proliferation, Blood BE LYM PRO
Available October 20, 2014

Time Sensitive

Methodology: Cell Culture
Performated: Varies
Reported: 14-17 days

Specimen Required: Collect: Green (sodium heparin). Send Monday-Thursday only.
Specimen Preparation: For direct submission instructions, please contact ARUP Referral Testing at (800) 242-2787, extension 5415. Specimen must be received at performing laboratory within 24 hours of collection. Gently invert several times to mix and prevent clotting. Do not centrifuge. Transport 40 mL whole blood in the original collection tube(s). (Min: 30 mL)
Storage/Transport Temperature: Ambient.
Unacceptable Conditions: Centrifuged specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

Reference Interval: By Report

CPT Code(s): 86353; 80500

New York DOH Approved.

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

0050047  Beta-2 Transferrin  B2TRNSF

Specimen Required: Specimen Preparation: Do not freeze. Transport 2 mL aural or nasal fluid in a tube without preservative. (Min: 1 mL aural or nasal fluid)

HOT LINE NOTE: Remove information found in the Unacceptable Conditions field.

New Test 2000183  Bladder Tumor Associated Antigen  BT REQUEST

Methodology: Qualitative Immunoassay
Performated: Mon-Fri
Reported: 1-5 days

Specimen Required: Collect: Voided urine or urine from a catheterized patient.
Specimen Preparation: Transfer 2 mL urine to an ARUP Standard Transport Tube.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Do not use paper or foam cups for urine specimen collection or storage.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 1 week; Frozen: 6 months

Negative: Bladder tumor associated antigen not detected.

Interpretive Data: Results of this test should not be interpreted as absolute evidence for the presence or absence of bladder cancer. Any disease that would cause endogenous human complement factor H (hCFH) to leak into the bladder can cause a positive test result. Positive results have been associated with renal stones, nephritis, renal cancer (including upper tract TCC), urinary tract infections, cystitis, sexually transmitted diseases and recent trauma to the bladder or urinary tract. This test should not be used as a screening test for individuals without biopsy confirmed bladder cancer. The result from the BTA star test should be used only in conjunction with information available from the clinical evaluation of the patient and other diagnostic procedures.

CPT Code(s): 86294

New York DOH Approved.

HOT LINE NOTE: Refer to the Test Mix Addendum for interface build information.
Carnitine, Free and Total, Urine
CARN URINE

Performed: Tue
Reported: 2-9 days

Catecholamines Fractionated by LC-MS/MS, Urine Free
CATE UF

Performed: Sun-Sat
Reported: 1-4 days

New Test

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

Time Sensitive
Additional Technical Information

Methodology:
Reverse Transcription Quantitative Polymerase Chain Reaction

Specimen Required:
Collect: Lavender (EDTA) or bone marrow (EDTA).
Specimen Preparation: Transport 5 mL whole blood. (Min: 1 mL) OR Transport 3 mL bone marrow. (Min: 1 mL) Specimens must be received within 48 hours of collection.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Serum or plasma. Specimens collected in anticoagulants other than EDTA. Severely hemolyzed or clotted specimens.
Stability (collection to initiation of testing): Ambient: 1 hour; Refrigerated: 48 hours; Frozen: Unacceptable

Interpretive Data:
Refer to report.

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

CPT Code(s): 81401

New York DOH approval pending. Call for status update.

Chlamydia trachomatis and Neisseria gonorrhoeae by Transcription-Mediated Amplification (TMA)
CGAMD

Specimen Required:
Collect: Vaginal, male urethral, rectal, pharyngeal or endocervical specimen with APTIMA Unisex Swab Specimen Collection kit (ARUP supply #28907). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
OR First catch urine. Refer to "Sample Collection for the Diagnosis of STD" under Specimen Handling at www.aruplab.com for specific specimen collection and transport instructions.
Specimen Preparation: Swab: place blue swab in Swab Specimen Transport Tube, break shaft off at scoreline then recap tube.
First Catch Urine: Transfer 2 mL urine to APTIMA Urine Specimen Transport Tube (ARUP supply #28908). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. Liquid level must be between fill lines on tube.
Unacceptable Conditions: Large white swab included in APTIMA Unisex Swab Specimen Collection kit is for preparatory cleaning of the endocervix and is unacceptable for testing. Specimens in any transport media other than indicated above. Specimens in swab transport media without a swab.
Stability (collection to initiation of testing): Swab in APTIMA Swab Specimen Transport Tube: Ambient: 2 months; Refrigerated: 2 months; Frozen: 1 year
Urine in APTIMA Urine Specimen Transport Tube: Ambient: 1 month; Refrigerated: 1 month; Frozen: 1 year

Interpretive Data:
This test is intended for medical purposes only and is not valid for the evaluation of suspected sexual abuse or for other forensic purposes. In certain contexts, culture may be required to meet applicable laws and regulations for diagnosis of C. trachomatis and N. gonorrhoeae infections. Per 2014 CDC recommendations, this test does not include confirmation of positive results by an alternative nucleic acid target.
### New Test

**New Test**  2011164  *Chlamydia trachomatis and Neisseria gonorrhoeae by Transcription-Mediated Amplification (TMA) with Confirmation*

**Methodology:** Qualitative Transcription-Mediated Amplification  
**Performed:** Sun-Sat  
**Reported:** 1-2 days

**Specimen Required:** Collect: Vaginal, male urethral, rectal, pharyngeal, or endocervical specimen with APTIMA Unisex Swab Specimen Collection kit (ARUP supply #28907). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.  
OR First catch urine.  
OR Cervical brush in ThinPrep Pap test collection kit. Refer to “Sample Collection for the Diagnosis of STD” under Specimen Handling at www.aruplab.com for specific specimen collection and transport instructions.  
**First Catch Urine:** Transfer 2 mL urine to APTIMA Urine Specimen Transport Tube (ARUP supply #28908). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. Liquid level must be between fill lines on tube.  
**ThinPrep:** Vortex ThinPrep PreservCyt solution and transfer 1 mL to an APTIMA Specimen Transfer Tube (ARUP supply #42711). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. To reduce the potential for contamination, ThinPrep specimens should be poured off, using sterile technique, into the APTIMA Specimen Transfer Tube prior to Cytology Testing.  
**Storage/Transport Temperature:** Refrigerated.  
**Remarks:** Specimen source is required.

**Reference Interval:** Negative

**Interpretive Data:** Positive results are confirmed using an alternative nucleic acid target. This test is intended for medical purposes only and is not valid for the evaluation of suspected sexual abuse or for other forensic purposes. In certain contexts, culture may be required to meet applicable laws and regulations for diagnosis of *C. trachomatis* and *N. gonorrhoeae* infections.

**CPT Code(s):** 87491; 87591

New York DOH Approved.

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

### New Test

**New Test**  0060774  *Chlamydia trachomatis and Neisseria gonorrhoeae by Transcription-Mediated Amplification (TMA), M4/UTM*

**Specimen Required:** Collect: Vaginal, endocervical, or male urethral swab in viral transport media (M4) or UTM (ARUP supply #12884). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. Refer to “Sample Collection for the Diagnosis of STD” under Specimen Handling at www.aruplab.com for specific specimen collection and transport instructions.  
**Unacceptable Conditions:** Specimens in any transport media other than indicated above. Specimens from patients less than 16 years of age.

**Interpretive Data:** Use of transport media other than the APTIMA specimen collection kit may result in reduced sensitivity. Specimens should be collected and transported following the instructions in “Sample Collection for the Diagnosis of STD Using Nucleic Acid Amplification Tests” under Specimen Handling at www.aruplab.com.  

This test is intended for medical purposes only and is not valid for the evaluation of suspected sexual abuse or for other forensic purposes. In certain contexts, culture may be required to meet applicable laws and regulations for diagnosis of *C. trachomatis* and *N. gonorrhoeae* infections. Per 2014 CDC recommendations, this test does not include confirmation of positive results by an alternative nucleic acid target.

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

**HOT LINE NOTE:** Remove information found in the Notes field.
Chlamydia trachomatis and Neisseria gonorrhoeae by Transcription-Mediated Amplification (TMA), SurePath

Specimen Required: Specimen Preparation: Vortex SurePath media and transfer 1 mL to APTIMA Specimen Transfer Tube (ARUP supply #42711) within 24 hours of collection. Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. To reduce the potential for contamination, SurePath specimens should be poured off, using sterile technique, into the APTIMA Specimen Transfer Tube prior to Cytology Testing.

SurePath Media: Ambient: 24 hours; Refrigerated: 48 hours; Frozen: 1 week

APTIMA Specimen Transfer Tube: Ambient: 2 weeks; Refrigerated: 1 month; Frozen: 1 month

Interpretive Data: Use of transport media other than the APTIMA specimen collection kit may result in reduced sensitivity. Specimens should be collected and transported following the instructions in "Sample Collection for the Diagnosis of STD Using Nucleic Acid Amplification Tests" under Specimen Handling at www.aruplab.com.

This test is intended for medical purposes only and is not valid for the evaluation of suspected sexual abuse or for other forensic purposes. In certain contexts, culture may be required to meet applicable laws and regulations for diagnosis of C. trachomatis and N. gonorrhoeae infections. Per 2014 CDC recommendations, this test does not include confirmation of positive results by an alternative nucleic acid target.

Specimen Required: Collect: Cervical specimen with the ThinPrep Pap Test Collection Kit. Refer to “Sample Collection for the Diagnosis of STD” under Specimen Handling at www.aruplab.com for specific specimen collection and transport instructions.

Specimen Preparation: Vortex ThinPrep PreservCyt solution and transfer 1 mL to an APTIMA Specimen Transfer Tube (ARUP supply #42711). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. To reduce the potential for contamination, ThinPrep specimens should be poured off, using sterile technique, into the APTIMA Specimen Transfer Tube prior to Cytology Testing.

ThinPrep PreservCyt solution: Ambient: 1 month; Refrigerated: 1 month; Frozen: Unacceptable

APTIMA Specimen Transfer Tube: Ambient: 2 weeks; Refrigerated: 1 month; Frozen: 12 months

Interpretive Data: This test is intended for medical purposes only and is not valid for the evaluation of suspected sexual abuse or for other forensic purposes. In certain contexts, culture may be required to meet applicable laws and regulations for diagnosis of C. trachomatis and N. gonorrhoeae infections. Per 2014 CDC recommendations, this test does not include confirmation of positive results by an alternative nucleic acid target.

HOT LINE NOTE: Remove information found in the Note field.
**0060243**  *Chlamydia trachomatis* by Transcription-Mediated Amplification (TMA)  CTAMD

**Specimen Required:** Collect: Vaginal, male urethral, rectal, pharyngeal, or endocervical specimen with APTIMA Unisex Swab Specimen Collection kit (ARUP supply #28907). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.

OR First catch urine.

OR Cervical brush in ThinPrep Pap test collection kit. Refer to “Sample Collection for the Diagnosis of STD” under Specimen Handling at [www.aruplab.com](http://www.aruplab.com) for specific specimen collection and transport instructions.

**Specimen Preparation:**

- **Swab:** place blue swab in Swab Specimen Transport Tube, break shaft off at scoreline then recap tube.
- **First catch urine:** Transfer 2 mL urine to APTIMA Urine Specimen Transport Tube (ARUP supply #28908). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. Liquid level must be between fill lines on tube.
- **ThinPrep:** Vortex ThinPrep PreservCyt solution and transfer 1 mL to an APTIMA Specimen Transfer Tube (ARUP supply #42711). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. To reduce the potential for contamination, ThinPrep specimens should be poured off, using sterile technique, into the APTIMA Specimen Transfer Tube prior to Cytology Testing.

**Unacceptable Conditions:** Large white swab included in APTIMA Unisex Swab Specimen Collection kit is for preparatory cleaning of the endocervix and is unacceptable for testing. Specimens in any transport media other than indicated above. Specimens in swab transport media without a swab.

**Stability (collection to initiation of testing):**

- **Swab in APTIMA Swab Specimen Transport Tube:** Ambient: 2 months; Refrigerated: 2 months; Frozen: 1 year
- **Urine in APTIMA Urine Specimen Transport Tube:** Ambient: 1 month; Refrigerated: 1 month; Frozen: 1 year
- **APTIMA Specimen Transfer Tube:** Ambient: 2 weeks; Refrigerated: 1 month; Frozen: 1 year
- **ThinPrep Media:** Ambient: 1 month; Refrigerated: 1 month; Frozen: Unacceptable

**Interprettive Data:** This test is intended for medical purposes only and is not valid for the evaluation of suspected sexual abuse or for other forensic purposes. In certain contexts, culture may be required to meet applicable laws and regulations for diagnosis of *C. trachomatis* and *N. gonorrhoeae* infections. Per 2014 CDC recommendations, this test does not include confirmation of positive results by an alternative nucleic acid target.
New Test 2011130 Chromosome FISH, Amniotic Fluid with Reflex to Chromosome Analysis or Genomic Microarray

Available October 20, 2014

Methodology: Fluorescence in situ Hybridization
Performed: Sun-Sat
Reported: 1-3 days
If reflexed: 1-2 weeks required for chromosome analysis or microarray

Specimen Required:
Collect: Amniotic fluid.
Specimen Preparation: Do not freeze or expose to extreme temperatures. Transport 30 mL amniotic fluid in sterile centrifuge tubes. (Min: 15 mL)
Storage/Transport Temperature: Room temperature.
Unacceptable Conditions: Bloody specimens.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Unacceptable

Reference Interval: Normal

Interpretive Data: Refer to report.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online at www.aruplab.com
See Compliance Statement C: www.aruplab.com/CS

Note: Fluorescence in situ hybridization (FISH) is performed for aneuploidy of chromosomes X, Y, 13, 18, and 21. FISH will be performed on amniotic fluid. If FISH results are normal, sample will be reflexed to genomic microarray. If FISH results are abnormal, sample will be reflexed to chromosome analysis. Additional charges apply.

Maternal Cell Contamination: For maternal cell contamination studies in the event that FISH is normal and testing is reflexed to genomic microarray, please submit maternal blood and order Microarray Genomic, Maternal Confirm (ARUP test code 2002369) accompanied by a test request form for the mother (this test is performed at no charge). For questions regarding ordering please contact ARUP's genetic counselor at (800) 242-2787 ext. 2141.

The FISH analysis does not detect structural chromosome abnormalities, mosaicism, and other numerical chromosome abnormalities (excluding X, Y, 13, 18, and 21). In addition, false-positive or negative results, as well as maternal cell contamination, have been demonstrated in prenatal FISH analysis. The American College of Medical Genetics recommends that irreversible therapeutic action should not be initiated on the basis of FISH results alone.

The chromosome analysis studies involve culturing of living cells; therefore, turnaround times given represent average times which are subject to multiple variables.

A processing fee will be charged if this procedure is canceled at the client's request, after the test has been set up, or if the sample integrity is inadequate to allow culture growth.

Specimen and completed test request form, including clinical indication, must be received within 48 hours of collection. This test must be ordered using Cytogenetic test request form #43097 or through your ARUP interface. Submit the Patient History for Prenatal Cytogenetics Testing form with the electronic packing list (available at http://www.aruplab.com genomics/forms.php).

CPT Code(s): 88271 x5; 88275 x5; 88291; if reflexed to chromosome analysis add 88269; 88235; 88291; if reflexed to microarray add 81229

New York DOH approval pending. Call for status update.

HOT LINE NOTE: Refer to the Test Mix Addendum for interface build information.
New Test 2011131 Chromosome FISH, Chorionic Villus with Reflex to Chromosome Analysis or Genomic Microarray

Available October 20, 2014

Methodology: Fluorescence in situ Hybridization
Performed: Sun-Sat
Reported: 1-3 days
If reflexed: 1-2 weeks required for chromosome analysis or microarray

Specimen Required: Collect: Thaw media prior to collection. Chorionic villus in a sterile, screw-top container filled with tissue culture transport medium (ARUP Supply #32788). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. If cytogenetics tissue media is not available, collect in plain RPMI Hanks solution, saline, or ringers.

Specimen Preparation: DO NOT FREEZE. Do not place in formalin. Transport 20-30 mg chorionic villus (CVS) specimen in a sterile, screw-top container filled with tissue culture transport medium. (Min: 10 mg)
Storage/Transport Temperature: Room temperature.
Unacceptable Conditions: Specimens preserved in formalin.

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

Reference Interval: Normal

Interpretive Data: Refer to report.

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

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

Note: Fluorescence in situ hybridization (FISH) is performed for aneuploidy of chromosomes X, Y, 13, 18, and 21. FISH will be performed on chorionic villus. If FISH results are normal, sample will be reflexed to genomic microarray. If FISH results are abnormal, sample will be reflexed to chromosome analysis. Additional charges apply.

Maternal Cell Contamination: For maternal cell contamination studies in the event that FISH is normal and testing is reflexed to genomic microarray, please submit maternal blood and order Microarray Genomic, Maternal Confirm (ARUP test code 2002369) accompanied by a test request form for the mother (this test is performed at no charge). For questions regarding ordering please contact ARUP's genetic counselor at (800) 242-2787 ext. 2414.

The FISH analysis does not detect structural chromosome abnormalities, mosaicism, and other numerical chromosome abnormalities (excluding X, Y, 13, 18, and 21). In addition, false-positive or negative results, as well as maternal cell contamination, have been demonstrated in prenatal FISH analysis. The American College of Medical Genetics recommends that irreversible therapeutic action should not be initiated on the basis of FISH results alone.

The chromosome analysis studies involve culturing of living cells; therefore, turnaround times given represent average times which are subject to multiple variables.

A processing fee will be charged if this procedure is canceled at the client's request, after the test has been set up, or if the sample integrity is inadequate to allow culture growth.

Specimen and completed test request form, including clinical indication, must be received within 48 hours of collection. This test must be ordered using Cytogenetic test request form #43097 or through your ARUP interface. Submit the Patient History for Prenatal Cytogenetics Testing form with the electronic packing list (available at http://www.aruplab.com/genetics/forms.php).

CPT Code(s): 88271 x5; 88275 x5; 88291; if reflexed to chromosome analysis add 88269, 88235; 88291; if reflexed to microarray add 81229

New York DOH approval pending. Call for status update.

HOT LINE NOTE: Refer to the Test Mix Addendum for interface build information.
Quarterly HOT LINE: Effective November 17, 2014

**New Test 2011157 Cobalamin/Propionate/Homocysteine Metabolism Related Disorders Panel, Sequencing (25 Genes) and Deletion/Duplication (24 Genes)**

*Available October 20, 2014*

**Patient History for Cobalamin/Propionate/Homocysteine Metabolism Related Disorders**

**Additional Technical Information**

**Methodology:** Massive Parallel Sequencing/Exonic Oligonucleotide-based CGH Microarray

**Performed:** Varies

**Reported:** 10-12 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.
- **Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

**Reference Interval:** By report

**Interpretive Data:** Refer to report.

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

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

**Note:** Genes Sequenced: ABCD4, ACSF3, AMN, CBS, CD320, CUBN, GIF, HCFC1, LMBRD1, MAT1A, MCEE, MMAA, MMAB, MMACHC, MMADHC, MTHFR, MTR, MTRR, MUT, PCCA, PCCB, SUCLA2, SUCLG1, TCN1, TCN2

Genes Deletion/Duplication: ABCD4, ACSF3, AMN, CBS, CD320, CUBN, GIF, LMBRD1, MAT1A, MCEE, MMAA, MMAB, MMACHC, MMADHC, MTHFR, MTR, MTRR, MUT, PCCA, PCCB, SUCLA2, SUCLG1, TCN1, TCN2

**CPT Code(s):** 81404 (MMACHC), 81405 x3 (MMAA, MMAB, PCCA), 81406 x4 (CBS, MUT, PCCA, PCCB), 81479 x2

New York DOH approval pending. Call for status update.

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

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**New Test 2011075 Coccidioides Antigen by EIA**

*Available October 20, 2014*

**Methodology:** Quantitative Enzyme Immunoassay

**Performed:** Varies

**Reported:** 3-8 days

**Specimen Required:**
- **Collect:** Urine, plain red, lavender (EDTA), pink (K2EDTA), green (sodium heparin), green (lithium heparin), light blue (sodium citrate), CSF or BAL.
- **Specimen Preparation:** Urine or BAL: Transfer 1 mL urine or BAL to an ARUP Standard Transport Tube. (Min: 0.5 mL)
- **Serum or Plasma:** Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1.2 mL)
- **CSF:** Transfer 1 mL CSF to an ARUP Standard Transport Tube. (Min: 0.8 mL)
- **Storage/Transport Temperature:** Refrigerated. Also acceptable: Frozen.
- **Stability (collection to initiation of testing):** Ambient: 24 hours; Refrigerated: 2 weeks; Frozen: Indefinite

**Reference Interval:** By Report

**CPT Code(s):** 87449

New York DOH approval pending. Call for status update.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.
0050175  Cold Agglutinins  COLD

**Performed:** Tue, Thu, Sat  
**Reported:** 2-5 days

New Test 2011056 Collagen Type II Antibody by ELISA, Serum  COLL 2 AB

Available October 20, 2014

**Methodology:** Quantitative Enzyme-Linked Immunosorbent Assay  
**Performed:** Varies  
**Reported:** 4-18 days

**Specimen Required:** Collect: Plain red or serum separator tube (SST).  
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.  
**Stability (collection to initiation of testing):** Ambient: 1 week; Refrigerated: 1 week; Frozen: 1 year

**Reference Interval:** By Report

**CPT Code(s):** 83520

New York DOH Approved.

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

0020944 Copper, Liver  CU-LIVER

**HOT LINE NOTE:** There is a clinically significant charting name change associated with this test:  
Change the charting name of component 0020697 from Hepatic Copper Concentration to Hepatic Copper Concentration by Weight

0060055 Coxsackie B Virus Antibodies  COX B

**Performed:** Mon-Fri  
**Reported:** 6-9 days

0070035 Cyclosporine A by Tandem Mass Spectrometry  CYA

Reference Interval:  
**Effective November 17, 2014**

<table>
<thead>
<tr>
<th>Therapeutic Range:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyclosporine A, Therapeutic Range</td>
</tr>
<tr>
<td>100-400 ng/mL</td>
</tr>
<tr>
<td>Kidney transplant (in combination with Everolimus)</td>
</tr>
<tr>
<td>1 month post-transplant: 100-200 ng/mL</td>
</tr>
<tr>
<td>2-3 months post-transplant: 75-150 ng/mL</td>
</tr>
<tr>
<td>4-5 months post-transplant: 50-100 ng/mL</td>
</tr>
<tr>
<td>6-12 months post-transplant: 25-50 ng/mL</td>
</tr>
<tr>
<td>Heart transplant</td>
</tr>
<tr>
<td>Up to 3 months post-transplant: 350-525 ng/mL</td>
</tr>
<tr>
<td>4 months and older post-transplant: 145-350 ng/mL</td>
</tr>
<tr>
<td>Liver transplant</td>
</tr>
<tr>
<td>290-525 ng/mL</td>
</tr>
<tr>
<td>Toxic value</td>
</tr>
<tr>
<td>Greater than 700 ng/mL</td>
</tr>
</tbody>
</table>

**Interpretive Data:** The general therapeutic range for cyclosporine A is 100-400 ng/mL. The optimal therapeutic range for a given patient may differ from this suggested range based on the indication for therapy, treatment phase (initiation or maintenance), use in combination with other drugs, time of specimen collection relative to prior dose, type of transplanted organ, and/or the therapeutic approach of the transplant center.

See Compliance Statement B: www.aruplab.com/CS
Quarterly HOT LINE: Effective November 17, 2014

2006267  Cytogenomic SNP Microarray Buccal Swab

Specimen Required: 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.

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

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

0030461  Dilute Russell Viper Venom Time (dRVVT) with Reflex to dRVVT 1:1 Mix and Confirmation

Methodology: Electromagnetic Mechanical Clot Detection

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

Unacceptable Conditions: Serum, EDTA plasma, or Hemolyzed specimens.

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

0095155  DNA Cell Cycle Analysis - Ploidy and S-Phase

HOT LINE NOTE: There is a clinically significant charting name change associated with this test:
Change the charting name of component 0095739 from DNA Content - Ploidy and S-Phase to DNA Analysis - Ploidy and S-Phase
Change the charting name of component 0095814 from S-Phase Interpretation to DNA Analysis-S-Phase Interpretation
Change the charting name of component 2008897 from DNA Index to DNA Analysis - Index
Change the charting name of component 2010871 from EER DNA Content, Ploidy and S-Phase to EER DNA. Ploidy and S-Phase

2003254  Drug Detection Panel by High-Resolution Time-of-Flight Mass Spectrometry, Serum or Plasma

Performed: Monday

Reported: 1-8 days

0090560  Drug Screen (Nonforensic), Comprehensive, Serum and Urine

CPT Code(s): 80100 x4, 80101 x5 (HCPCS:G0431)

0090499  Drug Screen (Nonforensic), Serum

CPT Code(s): 80100 x3, 80101 x2 (HCPCS:G0431)

0090500  Drug Screen (Nonforensic), Urine, Qualitative

CPT Code(s): 80100 x3, 80101 x3 (HCPCS:G0431)
New Test 2011235 Duchenne/Becker Muscular Dystrophy (DMD) DMD DD

Available October 20, 2014

Patient History for Duchenne/Becker Muscular Dystrophy

Additional Technical Information

Methodology: Multiplex Ligation-dependent Probe Amplification
Performed: Varies
Reported: Within 14 days

Specimen Required:
- Collect: Lavender (EDTA), pink (K$_2$EDTA), or yellow (ACD Solution A or B).
- Specimen Preparation: Transport 3 mL whole blood. (Min: 2 mL)
- Storage/Transport Temperature: Refrigerated.
- Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By Report

Interpretive Data:
Background information for Duchenne/Becker Muscular Dystrophy (DMD) Deletion/Duplication:
Characteristics: Symptoms of Duchenne muscular dystrophy (DMD) usually begin before age 6 and include fatigue, learning difficulties, muscle weakness (beginning in legs and pelvis), progressive difficulty walking with wheelchair needed at approximately 12 years and breathing difficulties and heart disease by age 20 years. Symptoms of Becker muscular dystrophy (BMD) are similar to DMD but start later and progress at a slower rate. Dilated cardiomyopathy has been observed in nearly all affected males and many female carriers of DMD and BMD.

Incidence: DMD: 1 in 3,500 male births, BMD: 1 in 19,000 male births.
Inheritance: X-linked; de novo mutations occur in one-third of cases.
Penetrance: Males: 100 percent Females: Varies with X-chromosome inactivation.
Cause: Pathogenic DMD mutations.

Clinical Sensitivity: DMD: 55-75 percent, BMD: 75-90 percent.
Methodology: Multiplex ligation-dependent probe amplification (MLPA) to detect large exonic deletions/duplications.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: DMD base pair substitutions, small deletions/duplications, deep intronic, and regulatory region mutations will not be detected. Large deletions/duplications of exons 1, 8, 14, 19, 39, 40, 49, 50, 56, 69, 71, 78, and 79 may not be detected. Breakpoints for large deletions/duplications will not be determined. Diagnostic errors can occur due to rare sequence variation.

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


CPT Code(s): 81161

New York DOH approval pending. Call for status update.

HOT LINE NOTE: Refer to the Test Mix Addendum for interface build information.
New Test  2011241  Duchenne/Becker Muscular Dystrophy (DMD)  Deletion/Duplication with Reflex to Sequencing

Available October 20, 2014

Patient History for Duchenne/Becker Muscular Dystrophy

Methodology:  Multiplex Ligation-dependent Probe Amplification/Massive Parallel Sequencing
Performed:  Varies
Reported:  Within 14 – 35 days

Specimen Required:  Collect: Lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).
                  Specimen Preparation: Transport 3 mL whole blood. (Min: 2 mL)
                  Storage/Transport Temperature: Refrigerated.
                  Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval:  By Report

Interpretive Data:
Background information for Duchenne/Becker Muscular Dystrophy (DMD) Deletion/Duplication with Reflex to Sequencing:
Characteristics:  Symptoms of Duchenne muscular dystrophy (DMD) usually begin before age 6 and include fatigue, learning difficulties, muscle weakness (beginning in legs and pelvis), progressive difficulty walking with wheelchair needed at approximately 12 years and breathing difficulties and heart disease by age 20 years. Symptoms of Becker muscular dystrophy (BMD) are similar to DMD but start later and progress at a slower rate. Dilated cardiomyopathy has been observed in nearly all affected males and many female carriers of DMD and BMD.
Incidence:  DMD: 1 in 3,500 male births, BMD: 1 in 19,000 male births.
Inheritance:  X-linked; de novo mutations occur in one-third of cases.
Penetrance:  Males: 100 percent   Females: Varies with X-chromosome inactivation.
Cause:  Pathogenic DMD mutations.
Clinical Sensitivity:  Approximately 95 percent.
Methodology:  Multiplex ligation-dependent probe amplification (MLPA) to detect large exonic deletions/duplications. If reflexed to sequencing, targeted capture of all coding exons and exon-intron junctions of the DMD gene, followed by massively parallel sequencing. Sanger sequencing is performed for bases with insufficient coverage and to confirm all clinically significant sequence variants. Hg 19 Human Genome build was used for data analysis.
Analytical Sensitivity and Specificity:  Greater than 99 percent.
Limitations:  Regulatory region mutations and deep intronic mutations will not be detected. Small deletions or insertions may not be detected by massively parallel sequencing. Large deletions/duplications of exons 1, 8, 14, 19, 39, 40, 49, 50, 56, 69, 71, 78, and 79 may not be detected. Deletion/duplication breakpoints will not be determined. Diagnostic errors can occur due to rare sequence variation.

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


Note:  Deletion/Duplication analysis is performed on all samples. If no large deletions or duplications are detected and/or results do not explain the clinical scenario, then sequencing of the DMD gene will be added. Additional charges apply.

CPT Code(s):  81161; if reflexed add 81408

New York DOH approval pending. Call for status update.

HOT LINE NOTE:  Refer to the Test Mix Addendum for interface build information.
New Test 2011231 Duchenne/Becker Muscular Dystrophy (DMD) DMD DD FE Deletion/Duplication, Fetal

Available October 20, 2014

Time Sensitive Patient History for Duchenne/Becker Muscular Dystrophy Additional Technical Information

Methodology: Multiplex Ligation-dependent Probe Amplification
Performed: Varies
Reported: 7-10 days

Specimen Required: Collect: Fetal Specimen: Two T-25 flasks at 80 percent confluency of cultured amniocytes. If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787.
AND Maternal Cell Contamination Specimen: Lavender (EDTA), pink (K2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Cultured Amniocytes: Fill flasks with culture media. Transport two T-25 flasks at 80 percent confluency of cultured amniocytes. Backup cultures must be retained at the client's institution until testing is complete.
Maternal Cell Contamination Specimen: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Amniotic Fluid: Room temperature.
Cultured Amniocytes: CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of shipment due to viability of cells.
Maternal Cell Contamination Specimen: Room temperature.
Remarks: Maternal specimen is recommended for proper test interpretation. Order Maternal Cell Contamination. Patient History Form is available on the ARUP Web site or by contacting ARUP Client Services at (800) 522-2787.
Stability (collection to initiation of testing): Fetal Specimen: Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Maternal Cell Contamination Specimen: Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:
Background information for Duchenne/Becker Muscular Dystrophy (DMD) Deletion/Duplication, Fetal:
Characteristics: Symptoms of Duchenne muscular dystrophy (DMD) usually begin before age 6 and include fatigue, learning difficulties, muscle weakness (beginning in legs and pelvis), progressive difficulty walking with wheelchair needed at approximately 12 years and breathing difficulties and heart disease by age 20 years. Symptoms of Becker muscular dystrophy (BMD) are similar to DMD but start later and progress at a slower rate. Dilated cardiomyopathy has been observed in nearly all affected males and many female carriers of DMD and BMD.
Incidence: DMD: 1 in 3,500 male births, BMD: 1 in 19,000 male births.
Inheritance: X-linked; de novo mutations occur in one-third of cases.
Penetrence: Males: 100 percent Females: Varies with X-chromosome inactivation.
Cause: Pathogenic DMD mutations.
Clinical Sensitivity: DMD: 55-75 percent. BMD: 75-90 percent.
Methodology: Multiplex ligation-dependent probe amplification (MLPA) to detect large exonic deletions/duplications.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: DMD base pair substitutions, small deletions/duplications, deep intronic, and regulatory region mutations will not be detected. Large deletions/duplications of exons 1, 8, 14, 19, 39, 40, 49, 50, 56, 69, 71, 78, and 79 may not be detected. Breakpoints for large deletions/duplications will not be determined. Diagnostic errors can occur due to rare sequence variation.

For quality assurance purposes, ARUP Laboratories will confirm the above result at no charge following delivery. Order Confirmation of Fetal Testing and include a copy of the original fetal report (or the mother's name and date of birth) with the test submission. Please contact an ARUP genetic counselor at (800) 242-2787 extension 2141 prior to specimen submission.

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


CPT Code(s): 81161; 81265
New York DOH approval pending. Call for status update.

HOT LINE NOTE: Refer to the Test Mix Addendum for interface build information.
**New Test**  
**2011153** Duchenne/Becker Muscular Dystrophy (DMD) Sequencing  
**DMD SEQ**

*Available October 20, 2014*

**Patient History for Duchenne/Becker Muscular Dystrophy**

**Methodology:** Massive Parallel Sequencing  
**Performed:** Varies  
**Reported:** 21-28 days

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

**Reference Interval:** By report

**Interpretive Data:** Refer to report.

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

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

**CPT Code(s):** 81408 (DMD)

New York DOH approval pending. Call for status update.

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

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**0060053** Echovirus Antibodies  
**ECHO**

**Performed:** Mon-Fri  
**Reported:** 6-9 days

**Reference Interval:**  
*Effective November 17, 2014*

<table>
<thead>
<tr>
<th>Age</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-5 months</td>
<td>less than or equal to 0.73 mmol/L</td>
</tr>
<tr>
<td>6 months-1 year</td>
<td>less than or equal to 0.99 mmol/L</td>
</tr>
<tr>
<td>2-17 years</td>
<td>less than or equal to 1.78 mmol/L</td>
</tr>
<tr>
<td>18 years or older</td>
<td>less than or equal to 0.78 mmol/L</td>
</tr>
</tbody>
</table>

**0080120** Fatty Acids, Free  
**FFA**

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

**HOT LINE NOTE:** Remove information found in the Remarks field.

---

**0030140** Fibrin/Fibrinogen Degradation Split Products  
**FDP**

**Specimen Required:** Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.  
**Unacceptable Conditions:** Serum. EDTA plasma or Hemolyzed specimens.
### Fibrinogen 0030130

**Specimen Required:**
- Specimen Preparation: Separate plasma from cells ASAP or within 2 hours of collection. Transfer 1 mL platelet-poor plasma to an ARUP Standard Transport Tube. (Min. 0.5 ml)
- Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
- Unacceptable Conditions: Serum, EDTA plasma or hemolyzed specimens.
- Stability (collection to initiation of testing): After separation from cells: Ambient: 4 hours; Refrigerated: Unacceptable; Frozen: 1 month

### Fibrinogen Antigen 0030135

**Specimen Required:**
- Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
- Unacceptable Conditions: Serum, EDTA plasma or hemolyzed specimens.
- Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: Unacceptable; Frozen: 1 month

### Fibrinogen Panel 0030137

**Specimen Required:**
- Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
- Unacceptable Conditions: Serum, EDTA plasma or hemolyzed specimens.
- Stability (collection to initiation of testing): Ambient: 4 hours; Refrigerated: Unacceptable; Frozen: 1 month

### New Test 2011017

**Fibroblast Growth Factor 23, Plasma**

**FIBRO GF23**

**Available October 20, 2014**

**Methodology:** Quantitative Enzyme Immunoassay

**Performed:** Varies

**Reported:** 8-11 days

**Specimen Required:**
- Collect: Lavender (EDTA).
- Specimen Preparation: Transfer 1.5 mL plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)
- Storage/Transport Temperature: Frozen. Also acceptable: Refrigerated.
- Unacceptable Conditions: Grossly hemolyzed specimens.
- Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 3 months

**Reference Interval:** By Report

**CPT Code(s):** 83520

New York DOH Approved.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.
Interpretive Data:

Background information for 5-Fluorouracil (5-FU) Toxicity and Chemotherapeutic Response, 5 Mutations:

Characteristics: 5-FU is the most frequently used chemotherapeutic drug for the treatment of many types of cancer, particularly colorectal adenocarcinoma. Grade III-IV drug toxicity attributed to 5-FU occurs in approximately 16 percent of patients, and may include hematologic, gastrointestinal, and dermatologic complications. In some cases, this toxicity can cause death. When 5-FU is metabolized in the body, approximately 80 percent is catabolized by the dihydropyrimidine dehydrogenase (DPD) enzyme. The remaining drug is further metabolized into an active form that inhibits the synthesis of both DNA and RNA by either competitive inhibition of the thymidylate synthase (TYMS) enzyme or by direct incorporation of cytotoxic metabolites into nucleic acids. Mutations in the DPYD gene can lead to reduced 5-FU catabolism, resulting in the aforementioned toxicity complications. The TYMS enzyme is the primary target of 5-FU. Mutations in the 5’-promoter enhancer region (5’-TSER) and the 3’-untranslated region (3’-UTR) of the TYMS gene have been correlated to TYMS expression levels, responsiveness to 5-FU therapy, and clinical outcome.

Clinical Sensitivity: Estimated at 31 percent for the DPYD variants analyzed.

Methodology: DPYD genotypes are determined by multiplex PCR, single nucleotide extension (SNE), and fragment analysis. TYMS genotypes are determined by PCR, restriction digest, and fragment analysis.

Analytical Sensitivity and Specificity: 99 percent.

Limitations: Only the targeted TYMS and DPYD mutations will be detected by this panel. Diagnostic errors can occur due to rare sequence variations. 5-FU drug metabolism, efficacy and risk for toxicity may be affected by genetic and non-genetic factors that are not evaluated by this test. Genotyping does not replace the need for therapeutic drug monitoring or clinical observation.

Variants Tested:

Table 1. DPYD mutations: nomenclature, allele frequency, and predicted consequences

<table>
<thead>
<tr>
<th>DPYD mutations</th>
<th>Alternative name</th>
<th>Allele frequency in indicated population</th>
<th>Predicted consequence in patients receiving 5-FU</th>
</tr>
</thead>
<tbody>
<tr>
<td>c.1679 T&gt;G</td>
<td>DPYD*13, rs5586062</td>
<td>0.001 - French Caucasians</td>
<td>Decreased DPD activity; Increased toxicity risk</td>
</tr>
<tr>
<td>c.1905+1 G&gt;A</td>
<td>DPYD*2A, IVS14+1 G&gt;A, rs3918290</td>
<td>0.0047 - 0.022-Dutch, German, French, Turkish, Finnish, Absent - Japanese, Korean, African American</td>
<td>Abolished DPD activity; Greatly increased toxicity risk</td>
</tr>
<tr>
<td>c.2846 A&gt;T</td>
<td>rs67376798</td>
<td>0.01 - French Caucasians</td>
<td>Decreased DPD activity; Increased toxicity risk</td>
</tr>
</tbody>
</table>

Table 2. TYMS mutations, allele frequency, and predicted consequences

<table>
<thead>
<tr>
<th>TYMS mutations</th>
<th>Allele</th>
<th>Allele frequency in indicated population</th>
<th>Predicted consequence in patients receiving 5-FU</th>
</tr>
</thead>
<tbody>
<tr>
<td>3'UTR 6 bp deletion (TAAAG) (rs16430)</td>
<td>DELETION</td>
<td>0.295 - Caucasian</td>
<td>Decreased TYMS expression; Increased 5-FU responsiveness; Increased risk of toxicity</td>
</tr>
<tr>
<td>5'-TSER 20bp VNTR (2R; 3R) (rs45445694)</td>
<td>2R</td>
<td>0.41-0.48 - Caucasian, Hispanic, African-American; 0.19 - Singapore, Chinese; 0.175 - Japanese</td>
<td>2R/3R: Increased TYMS expression; Decreased 5-FU responsiveness; Poor prognosis; 2R/2R or 2R/3RC: Decreased TYMS expression; Increased 5-FU responsiveness; Increased risk of toxicity</td>
</tr>
<tr>
<td>3R</td>
<td>0.51 - Singapore, Chinese; 0.427 - Japanese; 0.26-0.37 - Caucasian, Hispanic, African-American</td>
<td>3R/3RG, 3R/3RC or 2R/3RG: Increased TYMS expression; Decreased 5-FU responsiveness; Poor prognosis</td>
<td></td>
</tr>
<tr>
<td>5'-TSER G&gt;C SNP in 2nd repeat of 3R allele (3RC) (rs34743033)</td>
<td>3RC</td>
<td>0.399 - Japanese; 0.30 - Singapore, Chinese; 0.15-0.33 - Caucasian, Hispanic, African-American</td>
<td>3R/3RC: Increased TYMS expression; Decreased 5-FU responsiveness; Poor prognosis; 3RC/3RC or 2R/3RC: Decreased TYMS expression; Increased 5-FU responsiveness; Increased risk of toxicity</td>
</tr>
</tbody>
</table>

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

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

HOT LINE NOTE: There is a component change associated with this test:
Remove component 2002423, 5-FU Tox,Response - DPYD c.85T>C
Remove component 2002425, 5-FU Tox,Response - DPYD c.-1590T>C
### Fungal Culture

**CPT Code(s):** 87102; Identification CPT codes may vary based on method

<table>
<thead>
<tr>
<th>New Test</th>
<th>CPT Code(s)</th>
<th>Description</th>
<th>Methodology</th>
<th>Performed</th>
<th>Reported</th>
<th>Specimen Required</th>
<th>Specimen Preparation</th>
<th>Storage/Transport Temperature</th>
<th>Unacceptable Conditions</th>
<th>Stability (collection to initiation of testing)</th>
<th>Reference Interval</th>
<th>CPT Code(s)</th>
<th>New York DOH Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2011021</strong></td>
<td>86255</td>
<td><strong>New Test</strong> Gamma-Aminobutyric Acid-B (GABA-B) Receptor Antibody, CSF</td>
<td>Qualitative Immunofluorescence</td>
<td>Varies</td>
<td>3-10 days</td>
<td>Collect: CSF</td>
<td>Transfer 1 mL CSF to an ARUP Standard Transport Tube. (Min: 0.5 mL)</td>
<td>Refrigerated. Also acceptable: Frozen.</td>
<td>Hemolyzed, icteric or lipemic specimens.</td>
<td>Ambient: 72 hours; Refrigerated: 28 days; Frozen: 28 days</td>
<td>By Report</td>
<td>86255</td>
<td>New York DOH Approved.</td>
</tr>
</tbody>
</table>

**Available October 20, 2014**

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

<table>
<thead>
<tr>
<th>New Test</th>
<th>CPT Code(s)</th>
<th>Description</th>
<th>Methodology</th>
<th>Performed</th>
<th>Reported</th>
<th>Specimen Required</th>
<th>Specimen Preparation</th>
<th>Storage/Transport Temperature</th>
<th>Unacceptable Conditions</th>
<th>Stability (collection to initiation of testing)</th>
<th>Reference Interval</th>
<th>CPT Code(s)</th>
<th>New York DOH Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2011023</strong></td>
<td>86255</td>
<td><strong>New Test</strong> Gamma-Aminobutyric Acid-B (GABA-B) Receptor Antibody, Serum</td>
<td>Qualitative Immunofluorescence</td>
<td>Varies</td>
<td>3-10 days</td>
<td>Collect: Plain red or serum separator tube (SST)</td>
<td>Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)</td>
<td>Refrigerated. Also acceptable: Frozen.</td>
<td>Hemolyzed, icteric or lipemic specimens.</td>
<td>Ambient: 72 hours; Refrigerated: 28 days; Frozen: 28 days</td>
<td>By Report</td>
<td>86255</td>
<td>New York DOH Approved.</td>
</tr>
</tbody>
</table>

**Available October 20, 2014**

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.
New Test 2011150 Gastrointestinal Parasite Panel by PCR GI PARAPCR

Available October 20, 2014

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

Specimen Required: Collect: Stool.
   Specimen Preparation: Transfer 1 mL stool to an unpreserved stool transport vial (ARUP Supply #40910). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 0.5 mL)
   Storage/Transport Temperature: Frozen.
   Unacceptable Conditions: Formalin-fixed stool.
   Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 2 weeks; Frozen: 2 weeks

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

This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

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

Note: This test detects Cryptosporidium spp., Giardia, Entamoeba histolytica, Dientamoeba fragilis, and Cyclospora cayetanensis.

CPT Code(s): 87798 x5

New York DOH approval pending. Call for status update.

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

0080135 Glucose-6-Phosphate Dehydrogenase G6PD

Reference Interval:
Effective November 17, 2014
9.9-16.6 U/g Hb
New Test 2011140 Guanidinoacetate Methyltransferase (GAMT) Deficiency Sequencing

Available October 20, 2014

Patient History for Creatine Deficiency Syndrome Testing Additional Technical Information

Methodology: Polymerase Chain Reaction/Sequencing
Performed: Varies
Reported: Within 3 weeks

Specimen Required: Collect: Lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:
Background Information for Guanidinoacetate Methyltransferase (GAMT) Deficiency Sequencing:
Characteristics: Intellectual disability and seizure disorder of variable severity. May also include speech / language delays, movement disorder, and behavioral disorders such as autism, hyperactivity, and self-injury.
Incidence: Unknown. More than 50 cases have been described.
Inheritance: Autosomal recessive.
Cause: Pathogenic GAMT gene mutations.
Clinical Sensitivity: Based on limited data, may be as high as 99 percent.
Methodology: Bidirectional sequencing of the entire coding region and intron/exon boundaries of the GAMT gene.
Analytical Sensitivity and Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Regulatory region mutations, deep intronic mutations, and large deletions/duplications will not be detected. Mutations in genes other than GAMT are not evaluated.

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

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

CPT Code(s): 81479
New York DOH approval pending. Call for status update.

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

0051249 Heparin-Induced Thrombocytopenia (HIT) Antibodies, PF4 IgG/IgM/IgA by ELISA with Reflex to Serotonin Release Assay (Heparin Dependent Platelet Antibody), Unfractionated Heparin

Interpretive Data: By itself, a positive result on this ELISA test is relatively non-specific for a clinical diagnosis of heparin-associated antibody syndrome (HIT) (frequent false-positives) and a negative result does not exclude a diagnosis of HIT if the clinical suspicion remains high (occasional false-negatives). Results should be used in conjunction with clinical findings, platelet counts and other laboratory results.

For a clinical scoring system to assess pretest probability of HIT and other guidance for diagnosing HIT, refer to the Heparin-Associated Antibody Syndrome topic at arupconsult.com.

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

2009008 Hereditary Hemorrhagic Telangiectasia (ACVRL1 and ENG) Sequencing and Deletion/Duplication with Reflex to Juvenile Polyposis (SMAD4) Sequencing and Deletion/Duplication

Note: If the results of this test do not explain the clinical scenario, then SMAD4 testing will be added. Additional charges apply.

HOT LINE NOTE: There is a component change associated with this test:
Remove reflex component 2001971; if the results of this test do not explain the clinical scenario, then SMAD4 testing will be performed and 2010919, SMAD4 FGA BILL will be added.
New Test  2011148  Herpes Simplex Virus (HSV) by PCR with Reflex to HSV (HSV-1/HSV-2) Subtype by PCR

Available October 20, 2014

Methodology: Qualitative Polymerase Chain Reaction
Performed: Sun-Sat
Reported: 1-4 days

Specimen Required:
- **CSF**: Transfer 1 mL to a sterile container. (Min: 0.5 mL)
- **Vesicle Fluid**: Transfer to viral transport media (ARUP supply #12884). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.

Storage/Transport Temperature: Frozen.

Remarks: Specimen source required.

Stability (collection to initiation of testing):
- Ambient: 8 hours
- Refrigerated: 72 hours
- Frozen: 3 months

Reference Interval:

<table>
<thead>
<tr>
<th>Available Separately</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes (0060041)</td>
<td>Herpes Simplex Virus by PCR</td>
</tr>
<tr>
<td>Yes (2010095)</td>
<td>Herpes Simplex Virus (HSV-1/HSV-2) Subtype by PCR</td>
</tr>
</tbody>
</table>

Interpretive Data: Refer to report.

Note: If Herpes Simplex Virus by PCR result is detected, then Herpes Simplex Virus (HSV-1/HSV-2) Subtype by PCR will be added. Additional charges apply.

CPT Code(s): 87529; if reflexed, add 87529 x2

New York DOH approval pending. Call for status update.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.
**New Test** 2011283  HIV-1 Co-Receptor Tropism by Next Generation Sequencing (DEEPGEN)  
**Available October 20, 2014**

**Methodology:** Massive Parallel Sequencing  
**Performed:** Varies  
**Reported:** 15-18 days  

**Specimen Required:**  
- **Collect:** Lavender (EDTA). Also acceptable: Plasma separator tube (PST).  
- **Specimen Preparation:** Specimens collected in lavender (EDTA) must be separated from cells within 6 hours of collection. Specimens collected in plasma separator tube (PST) must be separated from cells within 2 hours of collection. Transfer 5 mL plasma to ARUP Standard Transport Tubes and freeze immediately. (Min: 1 mL)  
- **Storage/Transport Temperature:** Critical Frozen: Separate specimens must be submitted with multiple tests are ordered.  
- **Stability (collection to initiation of testing):** Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: Indefinitely

**Reference Interval:** By report  

**Note:** Provide patient’s most recent viral load with date of collection. This test should be used for patients with documented HIV-1 infection and a viral load greater than 1000 copies/mL.  

**CPT Code(s):** 87906  
New York DOH approval pending. Call for status update.

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

---

**New Test** 2011279  HIV-1 Genotyping and Tropism by Next Generation Sequencing (DEEPGEN)  
**Available October 20, 2014**

**Methodology:** Massive Parallel Sequencing  
**Performed:** Varies  
**Reported:** 15-18 days  

**Specimen Required:**  
- **Collect:** Lavender (EDTA). Also acceptable: Plasma separator tube (PST).  
- **Specimen Preparation:** Specimens collected in lavender (EDTA) must be separated from cells within 6 hours of collection. Specimens collected in plasma separator tube (PST) must be separated from cells within 2 hours of collection. Transfer 5 mL plasma to ARUP Standard Transport Tubes and freeze immediately. (Min: 1 mL)  
- **Storage/Transport Temperature:** Critical Frozen: Separate specimens must be submitted with multiple tests are ordered.  
- **Stability (collection to initiation of testing):** Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: Indefinitely

**Reference Interval:** By report  

**Note:** Provide patient’s most recent viral load with date of collection. This test should be used for patients with documented HIV-1 infection and a viral load greater than 1000 copies/mL.  

**CPT Code(s):** 87901; 87906 x2  
New York DOH approval pending. Call for status update.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.
New Test | **2011264**  
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology:</strong></td>
<td>Polymerase Chain Reaction/Massive Parallel Sequencing</td>
<td><strong>Performed:</strong></td>
<td>Varies</td>
</tr>
<tr>
<td><strong>Specimen Required:</strong></td>
<td>Collect: Lavender (EDTA).</td>
<td><strong>Reported:</strong></td>
<td>8-15 days</td>
</tr>
<tr>
<td><strong>Specimen Preparation:</strong></td>
<td>Transfer 4 mL whole blood to an ARUP Standard Transport Tube. (Min: 1 mL).</td>
<td><strong>Unacceptable Conditions:</strong></td>
<td>Clotted, grossly hemolized, or heparinized specimens.</td>
</tr>
<tr>
<td><strong>Storage/Transport Temperature:</strong></td>
<td>Refrigerated.</td>
<td><strong>Stability (collection to initiation of testing):</strong></td>
<td>Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable</td>
</tr>
</tbody>
</table>

**Reference Interval:** By report

**Interpretive Data:**

**Purpose:** To identify HLA-A, -B, and -C allelic polymorphisms on specimens for transplant candidates and their donors.

**Methodology:** PCR followed by next generation sequencing of HLA-A, -B and -C loci.

**Analytical Sensitivity & Specificity:** >99 percent.

**Limitations:** Rare diagnostic errors can occur due to primer site mutations.

**Test Results:** Results are reported as HLA locus (A, B, or C)* followed by the four digit assigned allele.

**CPT Code(s):** 81379

New York DOH approval pending. Call for status update.

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

---

New Test | **2011272**  
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology:</strong></td>
<td>Polymerase Chain Reaction/Massive Parallel Sequencing</td>
<td><strong>Performed:</strong></td>
<td>Varies</td>
</tr>
<tr>
<td><strong>Specimen Required:</strong></td>
<td>Collect: Lavender (EDTA).</td>
<td><strong>Reported:</strong></td>
<td>8-15 days</td>
</tr>
<tr>
<td><strong>Specimen Preparation:</strong></td>
<td>Transfer 4 mL whole blood to an ARUP Standard Transport Tube. (Min: 1 mL).</td>
<td><strong>Unacceptable Conditions:</strong></td>
<td>Clotted, grossly hemolized, or heparinized specimens.</td>
</tr>
<tr>
<td><strong>Storage/Transport Temperature:</strong></td>
<td>Refrigerated.</td>
<td><strong>Stability (collection to initiation of testing):</strong></td>
<td>Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable</td>
</tr>
</tbody>
</table>

**Reference Interval:** By report

**Interpretive Data:**

**Purpose:** To identify HLA-DRB1 and DQB1 allelic polymorphisms on specimens for transplant candidates and their donors.

**Methodology:** PCR followed by next generation sequencing of HLA-DRB1 and DQB1 loci.

**Analytical Sensitivity & Specificity:** >99 percent.

**Limitations:** Rare diagnostic errors can occur due to primer site mutations.

**Test Results:** Results are reported as HLA locus (DRB1, or DQB1)* followed by the four digit assigned allele.

**CPT Code(s):** 81382 x2

New York DOH approval pending. Call for status update.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.
New Test 2011154  Hyper IgM Syndrome Panel, Sequencing (12 Genes) and Deletion/Duplication (10 Genes)  HIGM PANEL

Available October 20, 2014

Patient History for Hyper IgM Syndrome Additional Technical Information

Methodology: Massive Parallel Sequencing/Exonic Oligonucleotide-based CGH Microarray
Performed: Varies
Reported: 10-12 weeks

Specimen Required: Collect: Lavender (EDTA) or yellow (ACD Solution A or B).
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data: Refer to report.

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

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

Note: Genes Sequenced: AICDA, ATM, BTK, CD40, CD40LG, IKBKG, MRE11A, NBN/NBS1, NFKBIA, PIK3CD, RAG2, UNG
Genes Deletion/Duplication: AICDA, ATM, BTK, CD40, CD40LG, MRE11A, NBN/NBS1, NFKBIA, RAG2, UNG

CPT Code(s): 81404 (CD40LG), 81406 (BTK), 81408 (ATM), 81479 x2

New York DOH approval pending. Call for status update.

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

0050345 Immunoglobulin E IGE

Reference Interval:
Effective November 17, 2014

<table>
<thead>
<tr>
<th>Age</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-5 months</td>
<td>13 kU/L or less</td>
</tr>
<tr>
<td>6-12 months</td>
<td>34 kU/L or less</td>
</tr>
<tr>
<td>1-2 years</td>
<td>97 kU/L or less</td>
</tr>
<tr>
<td>3 years</td>
<td>199 kU/L or less</td>
</tr>
<tr>
<td>4-6 years</td>
<td>307 kU/L or less</td>
</tr>
<tr>
<td>7-8 years</td>
<td>403 kU/L or less</td>
</tr>
<tr>
<td>9-12 years</td>
<td>696 kU/L or less</td>
</tr>
<tr>
<td>13-15 years</td>
<td>629 kU/L or less</td>
</tr>
<tr>
<td>16-17 years</td>
<td>537 kU/L or less</td>
</tr>
<tr>
<td>18 years and older</td>
<td>214 kU/L or less</td>
</tr>
</tbody>
</table>

HOT LINE NOTE: There is a unit of measure change associated with this test:
Change unit of measure on component 0050345, Immunoglobulin E, from IU/mL to kU/L

✓ HOT LINE NOTE: Reference interval and unit of measure changes also apply to:
- Allergens, Food, Common Adult Food IgE (0050486)
- Allergens, Food, West Kentucky Group IgE (0055218)
- Allergens, Inhalants Panel 11 IgE (0055113)
- Allergens, Inhalants, Comprehensive Profile IgE (0055312)
- Allergens, Inhalants, Western Environmental IgE (2006399)
- Allergens, Latex/Cross-Reactive Food Panel IgE (0055245)
- Allergens, Pediatric Allergy, March (Progression) Profile IgE (0050529)
- Allergens, Respiratory Panel, Region 1, North Atlantic (CT, MA, NJ, PA, VT, ME, NH, NY, RI) IgE (2005717)
- Allergens, Respiratory Panel, Region 10, Southwestern Grasslands (OK, TX) IgE (2006038)
- Allergens, Respiratory Panel, Region 11, Rocky Mountain (AZ, ID, NM, WY, CO, MT, UT) IgE (2006039)
Quarterly HOT LINE: Effective November 17, 2014

- Allergens, Respiratory Panel, Region 12, Arid Southwest (S. AZ, S.E. CA) IgE (2006040)
- Allergens, Respiratory Panel, Region 13, Southern Coastal (CA) IgE (2006041)
- Allergens, Respiratory Panel, Region 14, Central California (CA) IgE (2006042)
- Allergens, Respiratory Panel, Region 15, Intermountain West (NV, S. ID) IgE (2006043)
- Allergens, Respiratory Panel, Region 16, Inland Northwest (OR, Central and East WA) IgE (2006044)
- Allergens, Respiratory Panel, Region 17, Pacific Northwest (NW CA, W. OR, WA) IgE (2006045)
- Allergens, Respiratory Panel, Region 18, Alaska IgE (2006046)
- Allergens, Respiratory Panel, Region 19, Puerto Rico IgE (2006047)
- Allergens, Respiratory Panel, Region 2, Mid-Atlantic (DE, MD, VA, DC, NC) IgE (2005718)
- Allergens, Respiratory Panel, Region 20, Hawaii IgE (2006048)
- Allergens, Respiratory Panel, Region 3, South Atlantic (GA, SC, N. FL) IgE (2006025)
- Allergens, Respiratory Panel, Region 4, Subtropic Florida (S. of Orlando) IgE (2006026)
- Allergens, Respiratory Panel, Region 5, Ohio Valley (IN, OH, TN, WV, KY) IgE (2006031)
- Allergens, Respiratory Panel, Region 6, South Central (AL, AR, LA, MS) IgE (2006032)
- Allergens, Respiratory Panel, Region 7, Northern Midwest (MI, WI, MN) IgE (2006033)
- Allergens, Respiratory Panel, Region 8, Central Midwest (IL, MO, IA) IgE (2006034)
- Allergens, Respiratory Panel, Region 9, Great Plains (KS, NE, ND, SD) IgE (2006037)
- Allergens, Staphylococcal aureus Panel IgE (0092584)
- Allergic Bronchopulmonary Aspergillosis (ABPA) Panel (2004243)

0020175 Insecticide Exposure Panel CHE-SCRN

HOT LINE NOTE: There is a unit of measure change associated with this test:
Change unit of measure on component 0020448, Cholinesterase, RBC from U/mL to U/mL RBC
Change unit of measure on component 0020450, Cholinesterase, RBC (Ellman) from U/mL to U/mL WB

0028250 Iron, Liver FE LIVER

HOT LINE NOTE: There is a clinically significant charting name change associated with this test:
Change the charting name of component 0020816 from Hepatic Iron Concentration to Hepatic Iron Concentration by Weight

0050021 LDL Subclasses LDL SUBC

HOT LINE NOTE: There is a component change associated with this test:
Remove component 0050022, Mean LDL Particle Diameter

0050786 Leptospira Antibody LEPTO IHA

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

2005661 Liver Fibrosis, Chronic Viral Hepatitis (Echosens FibroMeter) FIBRO V

Specimen Required: Storage/Transport Temperature: Serum: Frozen. Plasma (citrated): CRITICAL FROZEN. Do not send the EDTA whole blood to ARUP.
Stability (collection to initiation of testing): Serum: Ambient: 8 hours; Refrigerated: Unacceptable; Frozen: 2 weeks
Plasma: Ambient: 24 hours; Refrigerated: Unacceptable; Frozen: 2 weeks

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

Note: This test requires an automated platelet count performed on the EDTA whole blood sample at the client site. Include the platelet count with the patient test submission information.

CPT Code(s): (83883; 84450; 84460; 8520; 82977) or 81599*
*The 2014 AMA CPT manual contains the component CPT Codes and the new MAAA codes. Please direct any questions regarding CPT coding to the payer being billed.

HOT LINE NOTE: Remove information found in the Remarks field. There is a component change associated with this test:
Add component 2010928, Aspartate Aminotransferase, FibroMeter
Add component 2010929, Alanine Aminotransferase, FibroMeter
Add component 2010930, Gamma Glutamyl Transferase, FibroMeter
Add component 2010931, Urea Nitrogen, Serum, FibroMeter
Add component 2010932, Alpha-2-Macroglobulin, FibroMeter
Remove component 0020007, Aspartate Aminotransferase
Remove component 0020008, Alanine Aminotransferase
Remove component 0020009, Gamma Glutamyl Transferase
Remove component 002023, Urea Nitrogen, Serum or Plasma
Remove component 0050005, Alpha-2-Macroglobulin
<table>
<thead>
<tr>
<th>Code</th>
<th>Test Description</th>
<th>Methodology</th>
<th>Performed</th>
<th>Reported</th>
<th>Specimen Required</th>
<th>Interpretive Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007254</td>
<td>Manganese, RBC</td>
<td>Varies</td>
<td>3-10 days</td>
<td></td>
<td>Specimen Preparation: Separate cells within 2 hours of collection. Transfer 1 mL RBCs to an ARUP Trace Element-Free Transport Tube (ARUP supply #43116). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 0.4 mL)</td>
<td></td>
</tr>
<tr>
<td>0099272</td>
<td>Manganese, Whole Blood</td>
<td></td>
<td></td>
<td></td>
<td>Specimen Preparation: Transport 7 mL whole blood in the original collection tube. (Min: 1 mL)</td>
<td></td>
</tr>
<tr>
<td>2007996</td>
<td>Metanephrines Fractionated by HPLC-MS/MS, Urine</td>
<td>Sun-Sat</td>
<td>1-4 days</td>
<td></td>
<td>Specimen Preparation: Collect: Yellow (ACD solution B). Also acceptable: Lavender (EDTA). Specimen Preparation: Transport 6 mL whole blood in the original tube. (Min: 1 mL)</td>
<td></td>
</tr>
<tr>
<td>2011015</td>
<td>Methemoglobin Reductase, Blood</td>
<td>Quantitative Spectrophotometry</td>
<td>Varies</td>
<td>6-9 days</td>
<td>Specimen Preparation: Collect: Yellow (ACD solution B). Also acceptable: Lavender (EDTA). Specimen Preparation: Centrifuge and remove serum or plasma from cells within 2 hours of collection. Transfer 1.2 mL serum or plasma to an ARUP Standard Transport Tube and refrigerate or freeze immediately. (Min: 0.6 mL)</td>
<td>Titin Antibody: The presence of titin antibody is associated with late onset of myasthenia gravis (MG) and a variable risk for thymoma. Titin antibody may be detected in 20-40 percent of all patients with MG; higher frequency in older population as a whole. Striated Muscle Antibodies, IgG: In the presence of acetylcholine receptor (AChR) antibody, striated muscle antibodies, which bind in a cross-striational pattern to skeletal and heart muscle tissue sections, are associated with late-onset myasthenia gravis (MG). Striated muscle antibodies recognize epitopes on three major muscle proteins, including: titin, ryanodine receptor (RyR) and Kv1.4 (an alpha subunit of voltage-gated potassium channel [VGKC]). Isolated cases of striated muscle antibodies may be seen in patients with certain autoimmune diseases, rheumatic fever, myocardial infarction, and after some cardiotomy procedures.</td>
</tr>
<tr>
<td>0099431</td>
<td>Methylmalonic Acid, Serum or Plasma (Vitamin B12 Status)</td>
<td></td>
<td>Sun-Sat</td>
<td>1-3 days</td>
<td>Specimen Preparation: Centrifuge and remove serum or plasma from cells within 2 hours of collection. Transfer 1.2 mL serum or plasma to an ARUP Standard Transport Tube and refrigerate or freeze immediately. (Min: 0.6 mL)</td>
<td></td>
</tr>
<tr>
<td>2005640</td>
<td>Muscle Weakness Autoimmune Reflexive Panel</td>
<td></td>
<td></td>
<td></td>
<td>Specimen Preparation: Collect: Yellow (ACD solution B). Also acceptable: Lavender (EDTA). Specimen Preparation: Centrifuge and remove serum or plasma from cells within 2 hours of collection. Transfer 1.2 mL serum or plasma to an ARUP Standard Transport Tube and refrigerate or freeze immediately. (Min: 0.6 mL)</td>
<td></td>
</tr>
</tbody>
</table>

**CPT Code(s):** 82657

New York DOH Approved.

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

See Compliance Statement B: www.aruplab.com/CS
See Compliance Statement D: www.aruplab.com/CS
New Test 2011117  Myeloid Malignancies Mutation Panel by Next Generation Sequencing

Available October 20, 2014

Additional Technical Information

Methodology: Massive Parallel Sequencing
Performed: Varies
Reported: 12-14 days

Specimen Required: Collect: Lavender (EDTA) OR bone marrow (EDTA).
Specimen Preparation: Do not freeze. Transport 5 mL whole blood. (Min: 1 mL) OR Transport 3 mL bone marrow. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Serum, plasma or tissue. Specimens collected in anticoagulants other than EDTA. Clotted or grossly hemolyzed specimens.

Reference Interval: By report

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

Note: The diagnosis under consideration is required information to order this test. Genes tested: ASXL1, BCOR, BCORL1, BRIP1, CALR, CBL, CEBPA, CSF3R, DNMT1, DNMT3A, EED, ETV6, EZH2, FLT3, GATA1, GATA2, HNRNPK, IDH1, IDH2, JAK2, JAK3, KDM6A, KIT, KMT2A, KRAS, LUC7L2, MPL, NPM1, NRAS, NRD1, PHF6, PRPF40B, PTPN11, RAD21, RUNX1, SETBP1, SF1, SF1A1, SF3B1, SMC1A, SMC3, SRSF2, STAG2, SUZ12, TET1, TET2, TP53, U2AF1, U2AF2, WT1, ZRSR2

CPT Code(s): 81245, 81270, 81275, 81310, 81402 (KIT), 81403x7 (CEBPA, DNMT3A, IDH1, IDH2, JAK2, KRAS, MPL), 81404 (NRAS), 81405 (TP53), 81406 (NDS1), 81479

New York DOH approval pending. Call for status update.

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

0020224  Myoglobin, Serum

Specimen Required: Collect: Plain red or serum separator tube. Also acceptable: Green (sodium or lithium heparin), or lavender (EDTA).
Neisseria gonorrhoeae by Transcription-Mediated Amplification (TMA)  GCAMC

Specimen Required: Collect: Vaginal, male urethral, rectal, pharyngeal, or endocervical specimen with APTIMA Unisex Swab Specimen Collection kit (ARUP supply #28907). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.

OR First catch urine.

OR Cervical brush in ThinPrep Pap test collection kit. Refer to “Sample Collection for the Diagnosis of STD” under Specimen Handling at www.aruplab.com for specific specimen collection and transport instructions.

Specimen Preparation: Swab: place blue swab in Swab Specimen Transport Tube, break shaft off at scoreline then recap tube.

First Catch Urine: Transfer 2 mL urine to APTIMA Urine Specimen Transport Tube (ARUP supply #28908). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. Liquid level must be between fill lines on tube.

ThinPrep: Vortex ThinPrep PreservCyt solution and transfer 1 mL to an APTIMA Specimen Transfer Tube (ARUP supply #42711). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. To reduce the potential for contamination, ThinPrep specimens should be poured off, using sterile technique, into the APTIMA Specimen Transfer Tube prior to Cytology Testing.

Unacceptable Conditions: Large white swab included in APTIMA Unisex Swab Specimen Collection kit is for preparatory cleaning of the endocervix and is unacceptable for testing. Specimens in any transport media other than indicated above. Specimens in swab transport media without a swab.

Stability (collection to initiation of testing): Swab in APTIMA Swab Specimen Transport Tube: Ambient: 2 months; Refrigerated: 2 months; Frozen: 1 year

Urine in APTIMA Urine Specimen Transport Tube: Ambient: 1 month; Refrigerated: 1 month; Frozen: 1 year

APTIMA Specimen Transfer Tube: Ambient: 2 weeks; Refrigerated: 1 month; Frozen: 1 year

ThinPrep Media: Ambient: 1 month; Refrigerated: 1 month; Frozen: Unacceptable

Interpretive Data: This test is intended for medical purposes only and is not valid for the evaluation of suspected sexual abuse or for other forensic purposes. In certain contexts, culture may be required to meet applicable laws and regulations for diagnosis of C. trachomatis and N. gonorrhoeae infections. Per 2014 CDC recommendations, this test does not include confirmation of positive results by an alternative nucleic acid target.

N-Methylhistamine, 24-Hour Urine

New Test: 2011034

Methodology: Quantitative Liquid Chromatography/Tandem Mass Spectrometry/Colorimetry

Performed: Varies

Reported: 7-10 days

Specimen Required: Collect: 24-hour urine.

Specimen Preparation: Transfer 5 mL urine to an ARUP Standard Transport Tube. (Min: 3 mL)

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

Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 8 days; Frozen: 2 weeks

Reference Interval: By Report

CPT Code(s): 83789

New York DOH Approved.

HOT LINE NOTE: Refer to the Test Mix Addendum for interface build information.
### Reference Interval:

**Effective November 17, 2014**

**Drugs covered and range of cutoff concentrations.**

*Note that some drugs are identified based on the presence of unique drug metabolites not listed below.*

<table>
<thead>
<tr>
<th>Drugs/Drug Classes</th>
<th>Range of Cutoff Concentrations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barbiturates</td>
<td>200 ng/mL</td>
</tr>
<tr>
<td>Benzodiazepine-like:</td>
<td></td>
</tr>
<tr>
<td>alprazolam, clonazepam, diazepam, lorazepam, midazolam, nordiazepam, oxazepam, temazepam, zolpidem</td>
<td>20 – 60 ng/mL</td>
</tr>
<tr>
<td>Cannabinoids (11-nor-9-carboxy-THC)</td>
<td>20 ng/mL</td>
</tr>
<tr>
<td>Ethyl Glucuronide</td>
<td>500 ng/mL</td>
</tr>
<tr>
<td>Muscle Relaxant(s):</td>
<td>100 ng/mL</td>
</tr>
<tr>
<td>Opiates/Opioids:</td>
<td></td>
</tr>
<tr>
<td>buprenorphine, codeine, fentanyl, heroin, hydrocodone, hydromorphone, meperidine, methadone, morphine, oxycodeone, oxymorphone, propoxyphene, tapentadol, tramadol</td>
<td>2-300 ng/mL</td>
</tr>
<tr>
<td>Phencyclidine (PCP)</td>
<td>25 ng/mL</td>
</tr>
<tr>
<td>Stimulants:</td>
<td></td>
</tr>
<tr>
<td>amphetamine, cocaine, methamphetamine, methylphenidate, MDMA (Ecstasy), MDEA (Eve), MDA, pheptermine</td>
<td>100-400 ng/mL</td>
</tr>
</tbody>
</table>

**HOT LINE NOTE:** There is a component change associated with this test:

Remove component 2007645, Dihydrocodeine (cutoff 20 ng/mL)
Remove component 2007650, Buprenorphine-G (cutoff 200 ng/mL)

---

### Reference Interval:

**Effective November 17, 2014**

**Drugs covered and range of cutoff concentrations.**

*Note that some drugs are identified based on the presence of unique drug metabolites not listed below.*

<table>
<thead>
<tr>
<th>Drugs/Drug Classes</th>
<th>Range of Cutoff Concentrations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barbiturates</td>
<td>200 ng/mL</td>
</tr>
<tr>
<td>Benzodiazepine-like:</td>
<td></td>
</tr>
<tr>
<td>alprazolam, clonazepam, diazepam, lorazepam, midazolam, nordiazepam, oxazepam, temazepam, zolpidem</td>
<td>20 – 60 ng/mL</td>
</tr>
<tr>
<td>Cannabinoids (11-nor-9-carboxy-THC)</td>
<td>20 ng/mL</td>
</tr>
<tr>
<td>Ethyl Glucuronide</td>
<td>500 ng/mL</td>
</tr>
<tr>
<td>Muscle Relaxant(s):</td>
<td>100 ng/mL</td>
</tr>
<tr>
<td>Opiates/Opioids:</td>
<td></td>
</tr>
<tr>
<td>buprenorphine, codeine, fentanyl, heroin, hydrocodone, hydromorphone, meperidine, methadone, morphine, oxycodeone, oxymorphone, propoxyphene, tapentadol, tramadol</td>
<td>2-300 ng/mL</td>
</tr>
<tr>
<td>Phencyclidine (PCP)</td>
<td>25 ng/mL</td>
</tr>
<tr>
<td>Stimulants:</td>
<td></td>
</tr>
<tr>
<td>amphetamine, cocaine, methamphetamine, methylphenidate, MDMA (Ecstasy), MDEA (Eve), MDA, pheptermine</td>
<td>100-400 ng/mL</td>
</tr>
</tbody>
</table>

**HOT LINE NOTE:** There is a component change associated with this test:

Remove component 2007645, Dihydrocodeine (cutoff 20 ng/mL)
Remove component 2007650, Buprenorphine-G (cutoff 200 ng/mL)

---

### Specimen Required:

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

**Unacceptable Conditions:** Serum, EDTA plasma or hemolyzed specimens.

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

---

Page 45
### New Test

<table>
<thead>
<tr>
<th>New Test</th>
<th>2011158</th>
<th>PD-L1 by Immunohistochemistry</th>
<th>PD-L1 IHC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Available October 20, 2014</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Immunohistochemistry Stain Form**
Recommended (ARUP form #32978)

<table>
<thead>
<tr>
<th>Methodology:</th>
<th>Immunohistochemistry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performed:</td>
<td>Mon-Fri</td>
</tr>
<tr>
<td>Reported:</td>
<td>1-3 days</td>
</tr>
</tbody>
</table>

**Specimen Required:** Collect: Tissue or cells.<br>
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. 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:** See Compliance statement B: www.aruplab.com/CS

**Note:** All stains will be handled as “Stain and Return” unless a consultation is requested. To request a consultation, submit the pathology report, all associated case materials (clinical history, blocks, slides, etc.), and the Anatomic Pathology requisition form (form # 32960) in place of the Immunohistochemistry Stain Form.

**CPT Code(s):** 88342

New York DOH approval pending. Call for status update.

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

---

<table>
<thead>
<tr>
<th>0090141</th>
<th>Phenytoin, Free and Total</th>
<th>FDIL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen Required:</td>
<td>Collect: Plain red.</td>
<td></td>
</tr>
<tr>
<td>Specimen Preparation:</td>
<td>Separate serum from cells within 2 hours of collection. Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 1 mL)</td>
<td></td>
</tr>
<tr>
<td>Unacceptable Conditions:</td>
<td>Citrated plasma. Serum separator tubes (SST). Tubes that contain liquid anticoagulant.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>0030190</th>
<th>Plasminogen Activity</th>
<th>PLG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen Required:</td>
<td>Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered. Unacceptable Conditions: Serum. EDTA plasma, or hemolyzed specimens.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2003040</th>
<th>PM/Scl-100 Antibody, IgG, by Immunoblot with Reflex to ANA IFA</th>
<th>PM/SCL</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT Code(s):</td>
<td>86235; if reflexed, add 86039</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>0060054</th>
<th>Poliovirus Antibodies</th>
<th>POLIO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performed:</td>
<td>Mon-Fri</td>
<td></td>
</tr>
<tr>
<td>Reported:</td>
<td>6-9 days</td>
<td></td>
</tr>
</tbody>
</table>
Quarterly HOT LINE: Effective November 17, 2014

New Test 2011156 Primary Antibody Deficiency Panel, Sequencing (35 Genes) and Deletion/Duplication (26 Genes) PAD PANEL

Available October 20, 2014

Patient History for Primary Antibody Deficiency

Additional Technical Information

Methodology: Massive Parallel Sequencing/Exonic Oligonucleotide-based CGH Microarray
Performed: Varies
Reported: 10-12 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.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data: Refer to report.

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

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

Note: Genes Sequenced: ADA, AICDA, ATM, BLNK, BTK, CD19, CD40, CD40LG, CD79A, CD79B, CD81, CR2, ICOS, IGHM, IGLL1, IKBKG, LRBA, LRRCSA, MRE11A, MSH4, NBN/NBS1, NFkB2, NFkbia, PIK3CD, PIK3R1, PLCG2, PPRC, RAG2, SH2D1A, TNFRSF13B, TNFRSF13C, UNG, VAV1, XIAP/BIRC4


CPT Code(s): 81404 x2 (CD40LG, SH2D1A), 81406 (BTK), 81408 (ATM), 81479 x2

New York DOH approval pending. Call for status update.

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

0090151 Procainamide and NAPA PROC

Interpretive Data: The commonly expected therapeutic range for the sum of NAPA and Procainamide is 5-30 µg/mL. However, the concentration of NAPA is dependent on many factors, including; time of last procainamide dose, mode of administration, concomitant drug therapy, sample condition, time of sample collection and individual variations in absorption, biotransformation, distribution and excretion. Therapeutic ranges are provided only as a guide for interpretation along with other clinical symptoms and patient history.

2006178 Products of Conception, Ploidy by Flow Cytometry DNA HYDAT

Specimen Required: Collect: Products of conception in paraffin tissue block.
Specimen Preparation: Paraffin embed products of conception in a tissue block

Interpretive Data: Flow Cytometry can be used to help identify partial hydatidiform moles. Partial moles are usually triploid while complete moles are diploid or tetraploid. [Clinical Medicine: Pathology, 2008, 1:61-67]. However, most products of conception are diploid by flow cytometry, so a diploid histogram does not suggest a complete hydatidiform mole unless supported clinically and microscopically. Of 35 cases of histologically apparent partial moles, no complications occurred in those that were triploid. However, 20 percent of those that were diploid had complications (persistence, metastasis). [Am J Ob Gyn, 1987, 157: 969-73]

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

HOT LINE NOTE: There is a clinically significant charting name change associated with this test:
Change the charting name of component 2006308 from DNA Content, Hydatidiform Mole to POC - DNA Analysis
Change the charting name of component 2008898 from DNA Index, Hydatidiform Mole to POC - DNA Index
Change the charting name of component 2010872 from EER DNA Content, POC to EER DNA, POC
Protein C, Functional

**Reference Interval:**

<table>
<thead>
<tr>
<th>Age</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>1–4 days</td>
<td>17–53%</td>
</tr>
<tr>
<td>5–29 days</td>
<td>20–64%</td>
</tr>
<tr>
<td>30–89 days</td>
<td>21–65%</td>
</tr>
<tr>
<td>90–179 days</td>
<td>28–80%</td>
</tr>
<tr>
<td>180–364 days</td>
<td>37.81%</td>
</tr>
<tr>
<td>1–6 years</td>
<td>40–92%</td>
</tr>
<tr>
<td>7–9 years</td>
<td>70–142%</td>
</tr>
<tr>
<td>10–11 years</td>
<td>68–143%</td>
</tr>
<tr>
<td>12–13 years</td>
<td>66–162%</td>
</tr>
<tr>
<td>14–15 years</td>
<td>69–170%</td>
</tr>
<tr>
<td>16–17 years</td>
<td>71–171%</td>
</tr>
<tr>
<td>18 years and older</td>
<td>83–168%</td>
</tr>
</tbody>
</table>

**HOT LINE NOTE:** This change also applies to:
- Protein C and S Panel, Functional (0030182)
- Protein C, Functional with Reflex to Protein C, Total and Protein S, Free with Reflex to Protein S, Total (2003386)
- Thrombotic Risk, Inherited Etiologies (Uncommon) (0030177)

Prothrombin Time

**Specimen Required:** Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
- Unacceptable Conditions: Serum, EDTA plasma, or hemolyzed, specimens.

Prothrombin Time/International Normalized Ratio

**Specimen Required:** Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
- Unacceptable Conditions: Serum, EDTA plasma, or hemolyzed specimens.

**New Test**

Purine and Pyrimidine Panel, Urine

Available October 20, 2014

**Methodology:** Quantitative Liquid Chromatography/Tandem Mass Spectrometry
**Performed:** Varies
**Reported:** 14–17 days

**Specimen Required:**
- **Collect:** Random urine.
- **Specimen Preparation:** Transfer 3 mL urine to an ARUP Standard Transport Tube. (Min: 1 mL)
- **Storage/Transport Temperature:** Frozen.
- **Stability (collection to initiation of testing):** Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 1 week

**Reference Interval:** By Report

**Interpretive Data:** Uracil, Uric Acid, Hypoxanthine, Xanthine are measured in millimole per mole of creatinine (mmol/mol Cr).

**Note:** Test includes: Uracil, Uric Acid, Hypoxanthine, Xanthine

**CPT Code(s):** 83789

New York DOH Approved.

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

Rabies Antibody, IgG (Vaccine Response)

**Specimen Required:**
- **Collect:** Serum separator tube. Also acceptable: lavender (EDTA), green (sodium heparin), Yellow (ACD solution A), or lt. blue (sodium citrate).
- **Specimen Preparation:** Transfer 0.5 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.1 mL)
- **Unacceptable Conditions:** CSF. Hemolyzed, icteric, or lipemic specimens.
**Quarterly HOT LINE: Effective November 17, 2014**

### 2006258
**Sexually Transmitted Disease Panel 1 by Transcription-Mediated Amplification**

**Performed:** Tue, Thu, Sat

**Reported:** 2-5 days

**Specimen Required:**
- Collect: Vaginal, endocervical or male urethral swab in APTIMA Unisex Swab Specimen Collection kit (ARUP supply #28907).
- Available online through eSupply using ARUP Connect™ or contact Client Services at (800) 522-2787.

**OR**
- First catch urine.
- Cervical brush in ThinPrep Pap test collection kit. Refer to “Sample Collection for the Diagnosis of STD” under Specimen Handling at www.aruplab.com for specific specimen collection and transport instructions.

**Specimen Preparation:**
- **Swab:** place blue swab in Swab Specimen Transport Tube, break shaft off at scoreline then recap tube.
- **First Catch Urine:** Transfer 2 mL urine to APTIMA Urine Specimen Transport Tube (ARUP supply #28908). Available online through eSupply using ARUP Connect™ or contact Client Services at (800) 522-2787. Liquid level must be between fill lines on tube.
- **ThinPrep:** Vortex ThinPrep PreservCyt solution and transfer 1 mL to an APTIMA Specimen Transfer Tube (ARUP supply #42711). Available online through eSupply using ARUP Connect™ or contact Client Services at (800) 522-2787.

**Remarks:**
- **Specimen source is required.**
- **Unacceptable Conditions:** Large white swab included in APTIMA Unisex Swab Specimen Collection kit is for preparatory cleaning of the endocervix and is unacceptable for testing. Specimens in any transport media other than indicated above. Specimen in swab transport media without a swab. Specimens from patients that are less than 14 years of age.

**Stability (collection to initiation of testing):**
- **Swab in APTIMA Swab Specimen Transport Tube:** Ambient: 2 months; Refrigerated: 2 months; Frozen: 1 year
- **Urine in APTIMA Urine Specimen Transport Tube:** Ambient: 1 month; Refrigerated: 1 month; Frozen: 1 year
- **APTIMA Specimen Transfer Tube:** Ambient: 2 weeks; Refrigerated: 1 month; Frozen: 1 year
- **ThinPrep Media:** Ambient: 1 month; Refrigerated: 1 month; Frozen: Unacceptable

**HOT LINE NOTE:** Remove information found in the Note field.

### 2011134
**Thiopurine Drug Metabolites**

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

**Performed:** Tue, Thu, Sun

**Reported:** 1-5 days

**Specimen Required:**
- Collect: Lavender (EDTA), pink (K<sub>2</sub>EDTA)
- Transport 5 mL whole blood. (Min: 3.5 mL)
- Storage/Transport Temperature: Refrigerated.
- Unacceptable Conditions: Frozen samples, Hemolyzed samples.

**Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 8 days; Frozen: Unacceptable

**Reference Interval:**

<table>
<thead>
<tr>
<th>Available Separately</th>
<th>Components</th>
<th>Therapeutic Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>6-TG Nucleotides RBC</td>
<td>230-400 pmol/8 x 10&lt;sup&gt;8&lt;/sup&gt; RBC</td>
</tr>
<tr>
<td>No</td>
<td>6-MMP Nucleotides RBC</td>
<td>Less than 5701 pmol/8 x 10&lt;sup&gt;8&lt;/sup&gt; RBC</td>
</tr>
</tbody>
</table>

**Interpretive Data:** Concentrations of 6-thioguanine nucleotide (6-TGN) less than 230 pmol/8 x 10<sup>8</sup> RBC may indicate a reduced response to therapy; 6-TGN concentrations greater than 400 pmol/8 x 10<sup>8</sup> RBC may indicate a higher risk for leukopenia. Concentrations of 6-methyl mercaptopurine nucleotide (6-MMPN) greater than 5700 pmol/8 x 10<sup>8</sup> RBC may indicate a higher risk for hepatotoxicity.

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

**CPT Code(s):** 82542

New York DOH approval pending. Call for status update.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.
### 0099187  Tissue Plasminogen Activator, Antigen  TPA AG

**Performed:** Tue  
**Reported:** 1-8 days  
**Specimen Required:** Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.  
**Unacceptable Conditions:** Serum, EDTA plasma, or hemolyzed specimens.  
**Stability (collection to initiation of testing):** Ambient: 4 hours; Refrigerated: Unacceptable; Frozen: 2 months

### 2005506  Trichomonas vaginalis by Transcription-Mediated Amplification (TMA)  TVAG AMD

**Specimen Required:** Collect: Vaginal, endocervical or male urethral swab in APTIMA Unisex Swab Specimen Collection kit (ARUP supply #28907). Available online through eSupply using ARUP Connect™ or contact Client Services at (800) 522-2787.  
OR First catch urine.  
OR Cervical brush in ThinPrep Pap test collection kit. Refer to “Sample Collection for the Diagnosis of STD” under Specimen Handling at www.aruplab.com for specific specimen collection and transport instructions.  
**Specimen Preparation: Swab:** place blue swab in Swab Specimen Transport Tube, break shaft off at scoreline then recap tube.  
**First Catch Urine:** Transfer 2 mL urine to APTIMA Urine Specimen Transport Tube (ARUP supply #28908). Available online through eSupply using ARUP Connect™ or contact Client Services at (800) 522-2787. Liquid level must be between fill lines on tube.  
**ThinPrep:** Vortex ThinPrep PreservCyt solution and transfer 1 mL to an APTIMA Specimen Transfer Tube (ARUP supply #42711). Available online through eSupply using ARUP Connect™ or contact Client Services at (800) 522-2787.  
**Remarks:** Specimen source required.  
**Unacceptable Conditions:** Large white swab included in APTIMA Unisex Swab Specimen Collection kit is for preparatory cleaning of the endocervix and is unacceptable for testing. Specimens in any transport media other than indicated above. Specimen in swab transport media without a swab. Specimens from patients that are less than 14 years of age.  
**Stability (collection to initiation of testing):**  
**Swab in APTIMA Swab Specimen Transport Tube:** Ambient: 2 months; Refrigerated: 2 months; Frozen: 1 year  
**Urine in APTIMA Urine Specimen Transport Tube:** Ambient: 1 month; Refrigerated: 1 month; Frozen: 1 year  
**APTIMA Specimen Transfer Tube:** Ambient: 2 weeks; Refrigerated: 1 month; Frozen: 1 year  
**ThinPrep Media:** Ambient: 1 month; Refrigerated: 1 month; Frozen: Unacceptable

**HOT LINE NOTE:** Remove information found in the Note field.

### 2007918  Triiodothyronine, Reverse by Tandem Mass Spectrometry  RT3 TMS

**Performed:** Sun-Sat  
**Reported:** 1-4 days

### 2008406  Triiodothyronine, Total and Triiodothyronine, Reverse with Ratio Calculation by Tandem Mass Spectrometry  T3RT3RATIO

**Performed:** Mon-Sun  
**Reported:** 1-4 days
New Test 2011072  *Tropheryma whippelii* Detection by PCR  TROPH WHIP

**Methodology:** Qualitative Polymerase Chain Reaction  
**Performed:** Varies  
**Reported:** 3-9 days

**Specimen Required:**  
- **Collect:** Biopsy, paraffin block or fluid (CSF, synovial or vitreous fluid).  
  - **Specimen Preparation:** Biopsy (fresh tissue): Transfer entire collection to a sterile container. (Min: 5 mm)  
  - **Paraffin block:** Formalin fix (Preserve in 10 percent formalin within one hour of collection.) and paraffin embed tissue. Transport entire specimen. (Min: 5 mm)  
  - **Fluid (CSF, synovial or vitreous humor):** Transfer 0.5 mL to an ARUP Standard Transport Tube. (Min: 0.5 mL)  
- **Storage/Transport Temperature:** Biopsy: Frozen. Paraffin block: Ambient. Also acceptable: Refrigerated Fluid (CSF, synovial or vitreous humor): Refrigerated. Also acceptable: Frozen.  
- **Stability (collection to initiation of testing):**  
  - **Biopsy:** Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 1 week  
  - **Paraffin block:** Ambient: 1 week; Refrigerated: 1 week; Frozen: Unacceptable  
  - **Fluid (CSF, synovial or vitreous humor):** Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 1 week

**Reference Interval:** By Report

**Note:** Specimens grossly contaminated with blood may inhibit PCR amplification and produce false-negative results. The high sensitivity of the PCR amplification requires the specimen to be processed in an environment where contamination by *Tropheryma whippelii* DNA is unlikely.

**CPT Code(s):** 87798

New York DOH Approved.

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

---

New Test 2011025  *Tropheryma whippelii* Detection by PCR, Blood  T WHIP B

**Methodology:** Qualitative Polymerase Chain Reaction  
**Performed:** Varies  
**Reported:** 3-7 days

**Specimen Required:**  
- **Collect:** Lavender (EDTA).  
  - **Specimen Preparation:** Transport 1 mL whole blood in the original tube. (Min: 0.5 mL)  
- **Storage/Transport Temperature:** Refrigerated. Also acceptable: Room temperature.  
- **Stability (collection to initiation of testing):** Ambient: 1 week; Refrigerated: 1 week; Frozen: Unacceptable

**Reference Interval:** By Report

**Note:** The high sensitivity of the PCR amplification requires the specimen to be processed in an environment where contamination by *Tropheryma whippelii* DNA is unlikely.

**CPT Code(s):** 87798

New York DOH Approved.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.
### New Test 2011172
#### Urogenital Ureaplasma and Mycoplasma Species by PCR

**Available October 20, 2014**

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

**Specimen Required:**  
- **Collect:** Genital swab, urine, or cervical or vaginal specimens with the ThinPrep Pap Test Collection kit.  
  - **Specimen Preparation:** Transfer genital 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. Vortex ThinPrep PreservCyt solution and transfer 1 mL to a sterile container. (Min: 0.5 mL)  
  - **Storage/Transport Temperature:** Frozen.  
  - **Remarks:** Specimen source required.  
  - **Stability (collection to initiation of testing):** Ambient: 24 hours; Refrigerated: 10 days; Frozen: 3 months

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

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

**Note:** This test detects and speciates *Ureaplasma parvum*, *Ureaplasma urealyticum*, *Mycoplasma hominis*, and *Mycoplasma genitalium*.

**CPT Code(s):** 87798 x4

New York DOH approval pending. Call for status update.

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

### New Test 2005416
#### Urticaria-Induced Basophil Activation

**Available October 20, 2014**

**Reference Interval:** 32 percent or less

**Interpretive Data:** A value of 33 percent or greater suggests the presence of basophil stimulating antibodies (or other serum factors).  

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

### New Test 2011039
#### Vigabatrin Quantitative, Serum or Plasma

**Available October 20, 2014**

**Methodology:** Quantitative High Performance Liquid Chromatography/Tandem Mass Spectrometry  
**Performed:** Varies  
**Reported:** 3-10 days

**Specimen Required:**  
- **Collect:** Plain red, lavender (EDTA) or pink (K2EDTA).  
  - **Specimen Preparation:** Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.3 mL)  
  - **Storage/Transport Temperature:** Refrigerated. Also acceptable: Room temperature or frozen.  
  - **Unacceptable Conditions:** Gel separator tubes.  
  - **Stability (collection to initiation of testing):** Ambient: 1 month; Refrigerated: 1 month; Frozen: 4 months

**Reference Interval:** By Report

**CPT Code(s):** 83789

New York DOH Approved.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.
Quarterly HOT LINE: Effective November 17, 2014

The following will be discontinued from ARUP’s test menu on November 17, 2014. 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>2002384</td>
<td>Acute Myelogenous Leukemia Panel by FISH</td>
<td>Acute Myeloid Leukemia Panel by FISH (2011132)</td>
</tr>
<tr>
<td>0099991</td>
<td>Alpha-1-Antitrypsin, Feces</td>
<td>Alpha-1-Antitrypsin, Quantitative by ELISA, Random Stool (2011041) or Alpha-1-Antitrypsin Clearance, Quantitative by ELISA, Timed Stool (2011043)</td>
</tr>
<tr>
<td>0091331</td>
<td>Atropine, Serum or Plasma</td>
<td></td>
</tr>
<tr>
<td>0095940</td>
<td>B-Cell Immunodeficiency Profile</td>
<td>B-Cell Memory and Naive Panel (2008901)</td>
</tr>
<tr>
<td>0091154</td>
<td>Beryllium, Urine</td>
<td></td>
</tr>
<tr>
<td>8100500</td>
<td>Bladder Tumor Associated Antigen Final Report</td>
<td>Bladder Tumor Associated Antigen (2000183)</td>
</tr>
<tr>
<td>0092209</td>
<td>CBFB-MYH11, inv(16) by RT-PCR</td>
<td>CBFB-MYH11 inv(16) Detection, Quantitative (2011114)</td>
</tr>
<tr>
<td>0091205</td>
<td>Ephedrine, Urine</td>
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<tr>
<td>2005526</td>
<td>High Avidity Double-Stranded DNA (HA dsDNA) Antibody, IgG</td>
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<tr>
<td>2002806</td>
<td>HLA Bone Marrow Transplantation Evaluation</td>
<td>HLA Class II (DRB1 and DQBI) by Next Generation Sequencing (2011272)</td>
</tr>
<tr>
<td>2002788</td>
<td>HLA-ABC Sequencing</td>
<td>HLA Class I (ABC) by Next Generation Sequencing (2011264)</td>
</tr>
<tr>
<td>0091276</td>
<td>Methylxopa, Serum or Plasma</td>
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</tr>
<tr>
<td>0055567</td>
<td>T-Cell Clonality Screening by PCR</td>
<td>T-Cell Clonality by Next Generation Sequencing (2008409)</td>
</tr>
<tr>
<td>2002572</td>
<td>Thiopurine Metabolites</td>
<td>Thiopurine Metabolites (2011134)</td>
</tr>
<tr>
<td>2002093</td>
<td>Tropheryma whipplei DNA, Qualitative RT PCR</td>
<td>Tropheryma whipplei Detection by PCR, Blood (2011025) or Tropheryma whipplei Detection by PCR (2011072)</td>
</tr>
</tbody>
</table>