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.

2008682 Anabolic Steroids, Urine - Screen with Reflex to Confirmation STEROIDS
HOT LINE NOTE: There is a component change associated with this test that affects interface clients only.

Delete 0091339 Canrenone, Serum or Plasma CANRENON
HOT LINE NOTE: Delete this test.

Delete 0040011 Fragile X (FMR1) Diagnostic FRAG X
This test is performed at ARUP Laboratories.
Vendor reagent change.
HOT LINE NOTE: Delete this test and refer to Fragile X (FMR1) with Reflex to Methylation Analysis (2009033).

Delete 0050543 Fragile X (FMR1) Diagnostic, Fetal FRAG X FE
This test is performed at ARUP Laboratories.
Vendor reagent change.
HOT LINE NOTE: Delete this test and refer to Fragile X (FMR1) with Reflex to Methylation Analysis, Fetal (2009034).

Delete 2001946 Fragile X (FMR1) Screen with Reflex to Fragile X (FMR1) Diagnostic FRAG X SCR
This test is performed at ARUP Laboratories.
Vendor reagent change.
HOT LINE NOTE: Delete this test and refer to Fragile X (FMR1) with Reflex to Methylation Analysis (2009033).
New Test 2009033 Fragile X (FMR1) with Reflex to Methylation Analysis FRAG X PCR

Patient History For Molecular Genetic Testing Additional Technical Information

Methodology: Polymerase Chain Reaction/Capillary Electrophoresis
Performed: Sun-Sat
Reported: 4-14 days

Specimen Required: Collect: Lavender (EDTA), pink (K2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 5 mL whole blood. (Min: 1.5 mL)
Storage/Transport Temperature: Room temperature. Also Acceptable: If transport time will exceed 48 hours: Refrigerated.
Remarks: Patient History Form is available on the ARUP website or by contacting ARUP Client Services.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Background Information for Fragile X (FMR1)
Characteristics: Fragile X syndrome, the most common heritable form of mental retardation, is characterized by moderate mental retardation in males and mild mental retardation in females, hyperactivity, perseverative speech, social anxiety, poor eye contact, hand flapping or biting, autism spectrum disorders behavioral phenotype, and connective tissue anomalies. Adult males may have physical findings including: macroorchidism, a long narrow face, prominent ears and jaw, and a single palmar crease.
Incidence: 1 in 4,000 Caucasian males and 1 in 8,000 Caucasian females; unknown in other ethnicities
Inheritance: X-linked dominant.
Penetrance: Reduced in females.
Cause: Expansion of the FMR1 gene CGG triplet repeat.
Full mutation: >200-230 CGG repeats (methylated)
Premutation: 55-200 CGG repeats (unmethylated)
Intermediate: 45-54 CGG repeats (unmethylated)
Normal: 5-44 CGG repeats (unmethylated)
Clinical Sensitivity: 99 percent.
Methodology: PCR/Capillary Electrophoresis. Methylation analysis is performed to distinguish between premutation and full mutation alleles.
Analytic Sensitivity and Specificity: 99 percent
Limitations: Diagnostic errors can occur due to rare sequence variations.

<table>
<thead>
<tr>
<th>Phenotype</th>
<th>Number of CGG Repeats</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unaffected</td>
<td>&lt;45</td>
</tr>
<tr>
<td>Intermediate</td>
<td>45-54</td>
</tr>
<tr>
<td>Premutation</td>
<td>55-200</td>
</tr>
<tr>
<td>Affected</td>
<td>&gt;200</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

Note: If an intermediate to expanded allele (≥45 CGG repeats) is detected by PCR and Capillary Electrophoresis; methylation analysis will be added to determine the size of the expanded CGG repeat. Additional charges apply.

CPT Code(s): 81243; if reflexed add 81244

New York DOH Approved.

HOT LINE NOTE: Refer to the Test Mix Addendum for interface build information.
Fragile X (FMR1) with Reflex to Methylation Analysis, Fetal

**Time Sensitive**

**Patient History for Fetal Molecular Testing**

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

**Performed:** Sun-Sat

**Reported:** Within 10 days

**Specimen Required:**
- **Collect:** Fetal Specimen: Amniotic fluid or two T-25 flasks at 80 percent confluency of cultured amniocytes. If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787.
- **AND Maternal Cell Contamination Specimen:** Lavender (EDTA), pink (K2EDTA), or yellow (ACD Solution A or B).

**Specimen Preparation:**
- **Amniotic Fluid:** Transport 10 mL unspun fluid. (Min: 5 mL)
- **Cultured Amniocytes:** Fill flasks with culture media. Transport four T-25 flasks at 80 percent confluency of cultured amniocytes. Backup cultures must be retained at the client's institution until testing is complete.

**Storage/Transport Temperature:**
- **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 Fragile X (FMR1), Fetal**

**Characteristics:** Fragile X syndrome, the most common heritable form of mental retardation, is characterized by moderate mental retardation in males and mild mental retardation in females, hyperactivity, perseverative speech, social anxiety, poor eye contact, hand flapping or biting, autism spectrum disorders behavioral phenotype, and connective tissue anomalies. Adult males may have physical findings including: macroorchidism, a long narrow face, prominent ears and jaw, and a single palmar crease.

**Incidence:** 1 in 4,000 Caucasian males and 1 in 8,000 Caucasian females; unknown in other ethnicities

**Inheritance:** X-linked dominant.

**Penetrance:** Reduced in females.

**Cause:** Expansion of the FMR1 gene CGG triplet repeat.
- Full mutation: >200-230 CGG repeats (methylated)
- Premutation: 55-200 CGG repeats (unmethylated)
- Intermediate: 45-54 CGG repeats (unmethylated)
- Normal: 5-44 CGG repeats (unmethylated)

**Clinical Sensitivity:** 99 percent.

**Methodology:** PCR/Capillary Electrophoresis. Methylation analysis is performed to distinguish between premutation and full mutation alleles.

**Analytic Sensitivity and Specificity:** 99 percent

**Limitations:** Diagnostic errors can occur due to rare sequence variations.

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.

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<td>55-200</td>
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<tr>
<td>Affected</td>
<td>&gt;200</td>
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</table>

**CPT Code(s):** 81243; 81265; if reflexed add 81244

New York DOH Approved.

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

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

**Note:** If an intermediate to expanded allele (≥ 45 CGG repeats) is detected by PCR and Capillary Electrophoresis; methylation analysis will be added to determine the size of the expanded CGG repeat. Additional charges apply.
**IMMEDIATE HOT LINE: Effective January 6, 2014**

<table>
<thead>
<tr>
<th>Test Code</th>
<th>Test Name</th>
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<tr>
<td>0092522</td>
<td><em>Histoplasma Antigen by EIA, Serum</em></td>
</tr>
<tr>
<td>2006110</td>
<td><em>Histoplasma Antigen Detection EIA, Urine</em></td>
</tr>
<tr>
<td>2009418</td>
<td><em>Histoplasma Galactomannan Antigen Quantitative by EIA, Urine</em></td>
</tr>
<tr>
<td>0051186</td>
<td><em>Human Immunodeficiency Virus 1, vircoTYPE by Sequencing</em></td>
</tr>
<tr>
<td>2007537</td>
<td><em>Non-Invasive Prenatal Testing for Fetal Aneuploidy (Panorama)</em></td>
</tr>
</tbody>
</table>

**Histoplasma Antigen by EIA, Serum**

This test is performed at ARUP Laboratories. ARUP is offering a new assay to provide improved sensitivity and specificity for Histoplasma antigen detection.

**Specimen Required:** Unacceptable Conditions: Urine (refer to test *Histoplasma Galactomannan Antigen Quantitative by EIA, Urine* (ARUP test code 2009418)). Specimens other than serum.

**Histoplasma Galactomannan Antigen Quantitative by EIA, Urine**

This test is performed at ARUP Laboratories. ARUP is offering a new assay to provide improved sensitivity and specificity for Histoplasma antigen detection.

**New Test**

**Histoplasma Galactomannan Antigen Quantitative by EIA, Urine**

**Methodology:** Quantitative Enzyme Immunoassay

**Performed:** Sun-Sat

**Reported:** 1-2 days

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

**Specimen Preparation:** Transfer 2 mL urine to an ARUP Standard Transport Tube.

**Storage/Transport Temperature:** Refrigerated.

**Unacceptable Conditions:** Specimens other than urine. Urine in boric acid. Serum (refer to test *Histoplasma Antigen by EIA, Serum* (ARUP test code 0092522)).

**Stability (collection to initiation of testing):** Ambient: Unacceptable; Refrigerated: 2 weeks; Frozen: 2 weeks (avoid repeated freeze/thaw cycles)

**Reference Interval:** Not Detected

**Interpretive Data:**

- Less than 3.2 ng/mL - Detected (below the limit of quantification)
- 3.2 - 20.0 ng/mL - Detected
- Greater than 20.0 ng/mL - Detected (above the limit of quantification)

The quantitative range of this assay is 3.2 - 20.0 ng/mL. Antigen concentrations between 0.4 - 3.1 or >20.0 ng/mL fall outside the linear range of the assay and cannot be accurately quantified.

This EIA test should be used in conjunction with other diagnostic procedures, including microbiological culture, histological examination of biopsy samples, and/or radiographic evidence, to aid in the diagnosis of histoplasmosis.

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

**CPT Code(s):** 87385

New York DOH Approved.

**Histoplasma Antigen Detection EIA, Urine**

**New York DOH Approved.**

**Human Immunodeficiency Virus 1, vircoTYPE by Sequencing**

**Delete:**

This test is performed at ARUP Laboratories.

Vendor discontinuing vircoTYPE service.

**HOT LINE NOTE:** Delete this test and refer to Human Immunodeficiency Virus 1, Genotype by Sequencing (0055670).

**Non-Invasive Prenatal Testing for Fetal Aneuploidy (Panorama)**

**Delete:**

This test is performed at ARUP Laboratories.

Vendor discontinuing non-invasive prenatal testing for fetal aneuploidy.

**HOT LINE NOTE:** There is a component change associated with this test that affects interface clients only.
### Scleroderma Antibodies Panel

**Note:** Panel includes: Anti-Nuclear Ab (ANA) Titer, Anti-Nuclear Ab (ANA) Pattern, Anti-Scl-70, Anti-RNA Polymerase III Ab, Anti-Centromere Ab, Anti-Th/Tö, Anti-U1 RNP Ab, Anti-Fibrillarin (U3 RNP), Anti-PM/Scl Ab

**HOT LINE NOTE:** There is a component change associated with this test that affects interface clients only.

<table>
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<tr>
<th>Test Code</th>
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<tr>
<td>2006462</td>
<td>Scleroderma Antibodies Panel</td>
<td>SCLER PAN</td>
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<th>Test Name</th>
<th>Methodology</th>
<th>Performed</th>
<th>Reported</th>
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<tbody>
<tr>
<td>2008796</td>
<td>Somatostatin by CLIA, Plasma</td>
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</table>

**HOT LINE NOTE:** Delete this test and refer to Somatostatin Quantitative, Plasma (2010001).

<table>
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<tr>
<th>New Test Code</th>
<th>New Test Name</th>
<th>Methodology</th>
<th>Performed</th>
<th>Reported</th>
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<tbody>
<tr>
<td>2010001</td>
<td>Somatostatin Quantitative, Plasma</td>
<td>SOMATOS P</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Methodology:** Quantitative Extraction/Immunoassay
**Performed:** Varies
**Reported:** 6-13 days

**Specimen Required:** Collect: Lavender (EDTA), Collect in a pre-chilled tube.
**Specimen Preparation:** Separate plasma from cells ASAP. Transfer 1.8 mL plasma to an ARUP Standard Transport Tube and freeze immediately. (Min: 0.6 mL)
**Storage/Transport Temperature:** CRITICAL FROZEN. Additional specimens must be submitted when multiple tests are ordered.
**Unacceptable Conditions:** Thawed specimens. Grossly icteric or lipemic specimens.
**Stability (collection to initiation of testing):** Ambient: 8 hours; Refrigerated: 8 hours; Frozen: 1 month

**Reference Interval:** By report

**CPT Code(s):** 84307

New York DOH approval pending. Call for status update.

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