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.

Delete  
0091246 Actifed, Serum or Plasma  
ACTIFED SP

HOT LINE NOTE: Delete this test.

2001549 Factor V, R2 Mutation  
F5 R2

Performed: Varies  
Reported: 3-10 days  
Specimen Required: Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 week; Frozen: Unacceptable

0098299 Human Anti-Mouse Antibody (HAMA), ELISA  
HAMA

Performed: Varies  
Reported: 7-17 days  

0093148 Interferon-Alpha by ELISA, Serum  
INTERFERON

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay  
Performed: Varies  
Reported: 7-17 days  
Specimen Required: Collect: Plain red. Specimen Preparation: Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL) Freeze within 30 minutes of collection. Unacceptable Conditions: Separator tubes. Grossly hemolyzed, icteric, or lipemic specimens.
**IMMEDIATE HOT LINE: Effective March 3, 2014**

<table>
<thead>
<tr>
<th>2007537</th>
<th>Non-Invasive Prenatal Testing for Fetal Aneuploidy (Panorama)</th>
<th>NIPT ANEU</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Specimen Required:</strong></td>
<td>Collect: Whole blood in Cell-Free DNA BCT Tube. All specimens must be collected using the NIPT ANEU kit (ARUP Supply #50223). Available online through eSupply or contacting ARUP Client Services at (800) 522-2787. Required Specimen: Maternal specimens must be collected in 2 Cell-Free DNA BCT tubes. Optional Specimen: Paternal specimens must be collected in buccal brush.</td>
<td></td>
</tr>
<tr>
<td><strong>CPT Code(s):</strong></td>
<td>(81479) or (81507)*</td>
<td></td>
</tr>
<tr>
<td>*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.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Add component(s):
- 2010353, Report del 22q11.2 (DiGeorge / VCFS)
- 2010354, del 22q11.2 (DiGeorge / VCFS)

**Delete**

| 0093304 | Leflunomide (Teriflunomide), Blood | LEFLUNO B |

**HOT LINE NOTE:** Delete this test effective March 17, 2014.

**Delete**

| 2001999 | PCA3 - Prostate Cancer Biomarker | PCA3 |

**HOT LINE NOTE:** Delete this test and refer to PCA3 - Prostate Cancer Biomarker by Transcription-Mediated Amplification (2010102).

**New Test**

| 2010102 | PCA3 - Prostate Cancer Biomarker by Transcription-Mediated Amplification | PCA3 TMA |

**Methodology:** Transcription-mediated Amplification

**Performed:** Tue, Fri

**Reported:** 3-6 days

**Specimen Required:**
- **Patient Prep:** Collection must follow Digital Rectal Exam (DRE).
- **Collect:** 20-30 mL first catch urine following DRE in preservative-free urine collection cup.
- **Specimen Preparation:** Invert urine container 5 times to mix, then transfer 2.5 mL urine to Progensa PCA3 Urine Specimen Transport Tube (ARUP Supply #45682). Liquid level must be between black lines on transport tube. Cap transport tube and invert 5 times to mix. Transport tubes are available online through eSupply using ARUP Connect or contact ARUP Client Services at (800) 522-2787.
- **Storage/Transport Temperature:** Frozen.
- **Unacceptable Conditions:** Urine in original collection cup. Specimens in APTIMA Combo 2 Urine Specimen transport media (ARUP Supply #28908).
- **Stability (collection to initiation of testing):** Ambient: 5 days; Refrigerated: 5 days; Frozen: 3 months

**Reference Interval:** PCA3/PSA ratio score greater than or equal to 25 is considered positive.

**Interpretive Data:** The Progensa PCA3 assay is an in vitro nucleic acid amplification test utilizing target capture, transcription-mediated amplification, and a hybridization-protection assay for amplicon detection. PCA3 Score is calculated as the ratio of PCA3 RNA copies to PSA RNA copies, multiplied by 1000.

**Sensitivity and Specificity:** 77.5 percent and 57.1 percent respectively (relative to prostate biopsy outcome), based on a PCA3 score cutoff value of 25.

**Limitations:** This test should not be used for men with a result of Atypical Small Acinar Proliferation (ASAP) on their most recent biopsy. Performance has not been established in men who undergo a repeat biopsy less than 3 months or more than 7 years after their most recent negative biopsy. The effect of medications known to influence serum PSA levels or therapeutic and/or diagnostic procedures such as prostatectomy, radiation, or prostate biopsy that may impact the viability of prostatic tissue and PCA3 Score have not been evaluated.

Values obtained with different assay methods or kits cannot be used interchangeably. Results should be interpreted in correlation with clinical history and other relevant data.

**CPT Code(s):** 81479

New York DOH Approved.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.
IMMEDIATE HOT LINE: Effective March 3, 2014

**New Test** 2010248 Prosigna Breast Cancer Prognostic Gene Signature PROSIGNA

### Additional Technical Information

**Methodology:** Hybridization/gene expression

**Performed:** Varies

**Reported:** 12-14 days

**Specimen Required:**
- **Collect:** Tumor tissue.
- **Specimen Preparation:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat.
- **Transport:** Tissue block or 6 unstained 10-micron slides (Min: 3 slides). Transport block(s) and/or slide(s) in a tissue transport kit (ARUP supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
- **Storage/Transport Temperature:** Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.

**Remarks:** Surgical pathology report required.

**Unacceptable Conditions:** Specimens fixed/processed in alternative fixatives (alcohol, Prefer). Decalcified specimens. Less than 10 percent tumor.

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

**Interpretive Data:** Refer to report.

**CPT Code(s):** 88381; 81599

New York DOH Approved.

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

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**0098878** Reticulin Antibody, IgG with Reflex to Titer by Immunoassay RETIC IGG

**Methodology:** Semi-Quantitative Immunoassay

**Performed:** Varies

**Reported:** 3-10 days

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**0050772** TORCH Antibodies, IgG TORCH IGG

*This test is performed at ARUP Laboratories.
Vendor reagent change.

**Reference Interval:**

<table>
<thead>
<tr>
<th>Available Separately</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes (0050165)</td>
<td>Cytomegalovirus Antibody, IgG</td>
<td>0.59 U/mL or less: Not Detected. 0.59 U/mL or less: Indeterminate - Repeat testing in 10-14 days may be helpful. 0.70 U/mL or greater: Detected.</td>
</tr>
<tr>
<td>Yes (0050293)</td>
<td>Herpes Simplex Virus Type 1 and/or 2 Antibodies, IgG</td>
<td>0.89 IV or less: Not Detected. 0.90-1.09 IV: Indeterminate - Repeat testing in 10-14 days may be helpful. 1.10 IV or greater: Detected.</td>
</tr>
<tr>
<td>Yes (0050771)</td>
<td>Rubella Antibody, IgG</td>
<td>Less than 9 IU/mL: Not Detected. 9-9.9 IU/mL: Indeterminate - Repeat testing in 10-14 days may be helpful. 10 IU/mL or greater: Detected.</td>
</tr>
<tr>
<td>Yes (0050770)</td>
<td>Toxoplasma gondii Antibody, IgG</td>
<td>Effective March 3, 2014 7.1 IU/mL or less: Not Detected. 7.2-8.7 IU/mL: Indeterminate - Repeat testing in 10-14 days may be helpful. 8.8 IU/mL or greater: Detected.</td>
</tr>
</tbody>
</table>
**IMMEDIATE HOT LINE:** Effective March 3, 2014

**0050521  Toxoplasma gondii Antibodies, IgG and IgM**
*This test is performed at ARUP Laboratories.
Vendor reagent change.

### Reference Interval:

<table>
<thead>
<tr>
<th>Available Separately</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
</table>
| Yes (0050770)        | *Toxoplasma gondii* Antibody, IgG | Effective March 3, 2014  
7.1 IU/ml or less: Not Detected.  
7.2-8.7 IU/ml: Indeterminate - Repeat testing in 10-14 days may be helpful.  
8.8 IU/ml or greater: Detected. |
| Yes (0050557)        | *Toxoplasma gondii* Antibody, IgM | Effective March 3, 2014  
7.9 AU/ml or less: Not Detected.  
8.0-9.9 AU/ml: Indeterminate - Repeat testing in 10-14 days may be helpful.  
10.0 AU/ml or greater: Detected - Significant level of *Toxoplasma gondii* IgM antibody detected and may indicate a current or recent infection. However, low levels of IgM antibodies may occasionally persist for more than 12 months post-infection. |

**2007064  Toxoplasma gondii Antibody, IgA by ELISA**

Specimen Required: Stability (collection to initiation of testing): Ambient: 4 days; Refrigerated: 1 week; Frozen: 1 month

**0050770  Toxoplasma gondii Antibody, IgG**
*This test is performed at ARUP Laboratories.
Vendor reagent change.

### Reference Interval:

<p>| | |</p>
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<tbody>
<tr>
<td>Effective March 3, 2014</td>
<td></td>
</tr>
<tr>
<td>7.1 IU/ml or less:</td>
<td>Not Detected.</td>
</tr>
<tr>
<td>7.2-8.7 IU/ml:</td>
<td>Indeterminate - Repeat testing in 10-14 days may be helpful.</td>
</tr>
<tr>
<td>8.8 IU/ml or greater:</td>
<td>Detected.</td>
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</table>