# MEDICARE COVERAGE OF LABORATORY TESTING

Please remember when ordering laboratory tests that are billed to Medicare/Medicaid or other federally funded programs, the following requirements apply:

1. Only tests that are medically necessary for the diagnosis or treatment of the patient should be ordered. Medicare does not pay for screening tests except for certain specifically approved procedures and may not pay for non-FDA approved tests or those tests considered experimental.
2. If there is reason to believe that Medicare will not pay for a test, the patient should be informed. The patient should then sign an Advance Beneficiary Notice (ABN) to indicate that he or she is responsible for the cost of the test if Medicare denies payment.
3. The ordering physician must provide an ICD-10 diagnosis code or narrative description, if required by the fiscal intermediary or carrier.
4. Organ- or disease-related panels should be billed only when all components of the panel are medically necessary.
5. Both ARUP- and client-customized panels should be billed to Medicare only when every component of the customized panel is medically necessary.
6. Medicare National Limitation Amounts for CPT codes are available through the Centers for Medicare & Medicaid Services (CMS) or its intermediaries. Medicaid reimbursement will be equal to or less than the amount of Medicare reimbursement.

The CPT Code(s) for test(s) profiled in this bulletin are for informational purposes only. The codes reflect our interpretation of CPT coding requirements, based upon AMA guidelines published annually. CPT codes are provided only as guidance to assist you in billing. ARUP strongly recommends that clients reconfirm CPT code information with their local intermediary or carrier. CPT coding is the sole responsibility of the billing party.

The regulations described above are only guidelines. Additional procedures may be required by your fiscal intermediary or carrier.

## Summary of Changes by Test Name

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<td>Alpha-2-Antiplasmin, Activity</td>
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<td>Renin, Direct</td>
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2002582  Aldosterone and Renin, Direct with Ratio  A/DR

Methodology:  Quantitative Chemiluminescent Immunoassay  
Performed:  Mon, Wed, Fri  
Reported:  1-5 days  

Specimen Required:  
Patient Prep: Collect midmorning (i.e., 7am–10am) after patient has been sitting, standing, or walking for at least 30 minutes and seated for 5-15 minutes. If the patient is supine, ensure that the patient is in this position for at least 30 minutes prior to collection. Fasting specimens are recommended but not required.

Collect: Serum separator tube (SST) AND lavender (EDTA) from a supine or upright patient. Do not collect in refrigerated tubes nor store tubes on ice. Process blood at room temperature and centrifuge tubes in a nonrefrigerated centrifuge.

Serum: Transfer 1 mL serum to an ARUP Standard Transport Tube (Min: 0.5mL) AND Plasma: Transfer 2 mL EDTA plasma to an ARUP Standard Transport Tube and freeze immediately. (Min: 1 mL)

Storage/Transport Temperature: Both specimens should be collected and submitted together for testing.

Serum: Frozen. Also acceptable: Refrigerated.

Plasma: Frozen. 

Unacceptable Conditions: Refrigerated plasma or plasma collected in citrate, heparin, or oxalate. Grossly hemolyzed specimens.

Stability (collection to initiation of testing): Serum: Ambient: 8 hours; Refrigerated: 5 days; Frozen: 1 month Plasma: Ambient: 8 hours; Refrigerated: 5 days; Frozen: 1 month

Available Separately

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<tr>
<th>Available Separately</th>
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<tbody>
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<td>0070015</td>
<td>Aldosterone, Serum</td>
<td>Effective May 16, 2011</td>
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<td>Age</td>
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<td>0-6 days</td>
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<td>1-3 weeks</td>
<td>6.0-179.0 ng/dL</td>
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<td>1-11 months</td>
<td>7.0-99.0 ng/dL</td>
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<td>1-2 years</td>
<td>7.0-93.0 ng/dL</td>
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<td>3-10 years</td>
<td>4.0-44.0 ng/dL</td>
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<td>11-14 years</td>
<td>4.0-31.0 ng/dL</td>
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<td>15 years and older</td>
<td>Less than or equal to 31.0 ng/dL</td>
<td>Less than or equal to 16.0 ng/dL</td>
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2001575  Renin, Direct

Effective July 5, 2022

Upright ≤40 yr: 4.2-52.2 pg/mL
Upright >40 yr: 3.6-81.6 pg/mL
Supine ≤40 yr: 3.2-33.2 pg/mL
Supine >40 yr: 2.5-45.1 pg/mL

Aldosterone/Direct Renin Calculation

0.1-3.7

An aldosterone/direct renin ratio of greater than 3.7 is suggestive of hyperaldosteronism.

0098727  Alpha-2-Antiplasmin, Activity  ALPHA 2A

Reference Interval:  By Report

3002787  Autoimmune Encephalitis Reflexive Panel, CSF  AENCEPHCSF

CPT Code(s):  86052; 86255 x6; 83519; 86341; if reflexed, add 86256 per titer.

3004547  Beta Globin (HBB) Sequencing  BG NGS

Specimen Required:  Collect: Lavender or pink (EDTA) or yellow (ACD solution A or B).

New York State Clients:  Lavender (EDTA)

Specimen Preparation: Transport 3 mL whole blood. (Min: 2 mL)
New York State Clients: Transport 7 mL whole blood (Min. 3 mL)

Storage/Transport Temperature: Refrigerated

Remarks: Serum or plasma; grossly hemolyzed or frozen specimens; saliva, buccal brush, or swab; FFPE tissue.

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

Reference Interval:  Available Separately

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<td>3-10 years</td>
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<td>Less than or equal to 16.0 ng/dL</td>
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2001575  Renin, Direct

Effective July 5, 2022

Upright ≤40 yr: 4.2-52.2 pg/mL
Upright >40 yr: 3.6-81.6 pg/mL
Supine ≤40 yr: 3.2-33.2 pg/mL
Supine >40 yr: 2.5-45.1 pg/mL

Aldosterone/Direct Renin Calculation

0.1-3.7

An aldosterone/direct renin ratio of greater than 3.7 is suggestive of hyperaldosteronism.
### Cystic Fibrosis (CFTR) Sequencing and Deletion/Duplication

**Specimen Required:**
- Collect: Lavender or pink (EDTA) or yellow (ACD solution A or B).
- **New York State Clients:** Lavender or pink (EDTA).
- **Specimen Preparation:** Transport 3 mL whole blood. (Min: 2 mL)
- **Storage/Transport Temperature:** Refrigerated.
- **Unacceptable Conditions:** Serum or plasma; grossly hemolyzed or frozen specimens; saliva, buccal brush, or swab; FFPE tissue.
- **Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

### Exome Reanalysis (Originally Tested at ARUP - No Specimen Required)

**Specimen Required:**
- Collect: No new specimen is required to process this test.
- **New York State Clients:** ARUP cannot facilitate testing for New York patients. Please work directly with a New York-approved laboratory.
- **Remarks:** Patient History Form for Exome Reanalysis (REQUIRED); Fax to Genetics Processing at 801-584-5249.

### Exome Sequencing, Proband

**Specimen Required:**
- Collect: Lavender (EDTA) or yellow (ACD Solution A or B). Peripheral blood required. Contact ARUP's genetic counselor at (800) 242-2787 ext. 2141 prior to test submission
- **New York State Clients:** ARUP cannot facilitate testing for New York patients. Please work directly with a New York-approved laboratory.
- **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

### Exome Sequencing, Trio

**Specimen Required:**
- Collect: Lavender (EDTA) or yellow (ACD Solution A or B). Peripheral blood required. Contact ARUP's genetic counselor at (800) 242-2787 ext. 2141 if there are questions prior to test submission.
- **New York State Clients:** ARUP cannot facilitate testing for New York patients. Please work directly with a New York-approved laboratory.
- **Specimen Preparation:** Patient Specimen: 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

### Flunitrazepam and Metabolites, Serum or Plasma, Screen with Reflex to Confirmation/Quantitation

**Methodology:**
- Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry (HPLC-MS/MS)
- **Performed:** Varies
- ** Reported:** 5-13 days

### Flunitrazepam and Metabolites, Urine Screen with Reflex to Confirmation/Quantitation

**Methodology:**
- Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry (HPLC-MS/MS)
- **Performed:** Varies
- **Reported:** 5-13 days
### Galactosemia (GALT) Sequencing and Deletion/Duplication

**Specimen Required:**
- **Collect:** Lavender or pink (EDTA) or yellow (ACD solution A or B).
- **New York State Clients:** Lavender (EDTA).
- **Specimen Preparation:** Transport 3 mL whole blood. (Min: 2 mL)
- **New York State Clients:** Transport 3 mL whole blood. (Min: 3 mL)
- **Storage/Transport Temperature:** Refrigerated.
- **Unacceptable Conditions:** Serum or plasma; grossly hemolyzed or frozen specimens; saliva, buccal brush, or swab; FFPE tissue.
- **Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

### HIV PhenoSense GT

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<th>Test Code</th>
<th>Description</th>
<th>Methodology</th>
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<td>HIV PhenoSense GT</td>
<td>Polymerase Chain Reaction (PCR)/Culture</td>
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### Human Immunodeficiency Virus Type 1 (HIV-1) PhenoSense

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<td>16-26 days</td>
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### Human Immunodeficiency Virus Type 1 (HIV-1) Tropfile Co-Receptor Tropism

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<td>HIV TROFIL</td>
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### Hypoglycemia Panel (Sulfonylureas), Serum or Plasma

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<td>HYPO PAN</td>
<td>Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry (HPLC-MS/MS)</td>
<td>Varies</td>
<td>4-7 days</td>
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**Specimen Required:**
- **Collect:** Plain red or gray (sodium fluoride/potassium oxalate)
- **Specimen Preparation:** Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.3 mL)
- **Test is not performed at ARUP; separate specimens must be submitted when multiple tests are ordered.**
- **Storage/Transport Temperature:** Frozen. Also acceptable: Refrigerated
- **Unacceptable Conditions:** Separator tubes
- **Stability (collection to initiation of testing):** Ambient: 48 hours; Refrigerated: 28 days; Frozen: 24 months

**Reference Interval:** By report

**CPT Code(s):** 80377 (Alt Code: G0480)

New York DOH Approved.

**HOTLINE NOTE:** Refer to the Test Mix Addendum for interface build information.
### New Test
#### 3003680
**MET Exon 14 Deletion Analysis by PCR**

**Methodology:** Real-Time Polymerase Chain Reaction  
**Performed:** Varies  
**Reported:** 14-17 days

**Specimen Required:**  
- **Collect:** Tumor tissue  
- **Specimen Preparation:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Transport tissue block or 1 H&E slide plus 10 unstained (5-micron thick), 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: 5 slides). Protect from extreme temperatures.  
- **Test is not performed at ARUP; separate specimens must be submitted when multiple tests are ordered.**  
- **Storage/Transport Temperature:** Ambient. Also acceptable: Refrigerated  
- **Remarks:** Body site and reason for referral must be provided prior to testing.  
- **Unacceptable Conditions:** Fixed in any other fixative or other than 10% neutral buffered formalin.  
- **Stability (collection to initiation of testing):** Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

**Reference Interval:** By report

**CPT Code(s):** 84179

New York DOH approval pending. Call for status update.

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

### New Test
#### 3003684
**NTRK Fusion Panel by Next Generation Sequencing**

**Methodology:** Massively Parallel Sequencing  
**Performed:** Varies  
**Reported:** 21-24 days

**Specimen Required:**  
- **Collect:** Tumor tissue  
- **Specimen Preparation:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Transport tissue block or 1 H&E slide plus 10 unstained (5-micron thick), 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: 5 slides). Protect from extreme temperatures.  
- **Test is not performed at ARUP; separate specimens must be submitted when multiple tests are ordered.**  
- **Storage/Transport Temperature:** Refrigerated. Also acceptable: Ambient.  
- **Remarks:** Body site and reason for referral must be provided prior to testing.  
- **Unacceptable Conditions:** Fixed in any other fixative other than 10% neutral buffered formalin.  
- **Stability (collection to initiation of testing):** Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

**Reference Interval:** By report

**CPT Code(s):** 81194

New York DOH approval pending. Call for status update.

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

### New Test
#### 3003913
**Orthopedic Metals Panel (Chromium, Cobalt, Titanium)**

**Specimen Required:**  
- **Collect:** Body fluid.  
- **Specimen Preparation:** Transfer 5 mL body fluid to a trace element-free transport tube (ARUP supply #43116) or acid-washed transfer vial (ARUP supply #54350) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 2.2 mL.)  
- **Test is not performed at ARUP; separate specimens must be submitted when multiple tests are ordered.**  
- **Storage/Transport Temperature:** Refrigerated. Also acceptable: Room temperature or frozen.  
- **Stability (collection to initiation of testing):** Ambient: Undetermined; Refrigerated: Undetermined; Frozen: Undetermined
HOTLINE: Effective July 5, 2022

**3004788**  
Pancreatitis Panel (CFTR, CTRC, PRSS1, SPINK1), Sequencing  
PANC NGS

**Specimen Required:**  
Collect: Lavender or pink (EDTA) or yellow (ACD solution A or B).  
**New York State Clients:** Lavender or pink (EDTA).  
**Specimen Preparation:** Transport 3 mL whole blood. (Min: 2 mL)  
**Storage/Transport Temperature:** Refrigerated.  
**Unacceptable Conditions:** Serum or plasma; grossly hemolyzed or frozen specimens; saliva, buccal brush, or swab; FFPE tissue.  
**Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

**2001575**  
Renin, Direct  — RENIND

**Methodology:** Quantitative Chemiluminescence Immunoassay  
**Performed:** Mon, Wed, Fri  
**Reported:** 1-5 days

**Specimen Required:**  
**Patient Prep:** Collect midmorning (i.e., 7am – 10am) after patient has been sitting, standing, or walking for at least 30 minutes and seated for 5-15 minutes. If the patient is supine, ensure that the patient is in this position for at least 30 minutes prior to collection. Fasting specimens are recommended but not required.  
Collect: Lavender (EDTA) from a supine or upright patient. Do not collect in refrigerated tubes nor store tubes on ice. Process blood at room temperature and centrifuge tubes in a non-refrigerated centrifuge.  
**Specimen Preparation:** Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL plasma to an ARUP Standard Transport Tube and freeze immediately. (Min: 1 mL)  
**Storage/Transport Temperature:** Frozen.  
**Unacceptable Conditions:** Serum. Specimens collected in citrate, heparin, or oxalate. Grossly hemolyzed or refrigerated specimens.  
**Stability (collection to initiation of testing):** Ambient: 8 hours; Refrigerated: Unacceptable; Frozen: 4 weeks

**Reference Interval:**  
Effective July 5, 2022  
Upright ≤40 y: 4.2-52.2 pg/mL  
Upright >40 y: 3.6-81.6 pg/mL  
Supine ≤40 y: 3.2-33.2 pg/mL  
Supine >40 y: 2.5-45.1 pg/mL

**3004603**  
SHOX Deficiency Disorders, Sequencing and Deletion/Duplication  
SHOX NGS

**Specimen Required:**  
Collect: Lavender or pink (EDTA) or yellow (ACD solution A or B).  
**New York State Clients:** Transport 8 mL whole blood (Min. 6 mL)  
**Specimen Preparation:** Transport 8 mL whole blood (Min. 6 mL)  
**Storage/Transport Temperature:** Refrigerated  
**Unacceptable Conditions:** Serum or plasma; grossly hemolyzed or frozen specimens; saliva, buccal brush, or swab; FFPE tissue; DNA.  
**Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

**3002570**  
Trofile (DNA) Co-Receptor Tropism  
TROFI DNA

**Methodology:** Polymerase Chain Reaction (PCR)/Culture  
**Performed:** Varies  
**Reported:** 29-36 days
The following will be discontinued from ARUP's test menu on July 5, 2022.
Replacement test options are supplied if applicable.

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Test Name</th>
<th>Refer To Replacement</th>
</tr>
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<tbody>
<tr>
<td>2010292</td>
<td>Hypoglycemia Panel, Sulfonylureas Qualitative, Serum or Plasma</td>
<td>Hypoglycemia Panel (Sulfonylureas), Serum or Plasma (3005636)</td>
</tr>
</tbody>
</table>