HOTLINE: Effective July 5, 2022

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.

Hotline Page #	Test Number	Summary of Changes by Test Name	Name Change	Methodology	Performed/Reported Schedule	Specimen Requirements	Reference Interval	Interpretive Data	Note	CPT Code	Component Change	Other Interface Change	New Test	Inactive
3	2002582	Aldosterone and Renin, Direct with Ratio		x	x	x	x							
3	0098727	Alpha-2-Antiplasmin, Activity					x							
3	3002787	Autoimmune Encephalitis Reflexive Panel, CSF								x				
3	3004547	Beta Globin (*HBB*) Sequencing				x								
4	3004745	Cystic Fibrosis (*CFTR*) Sequencing and Deletion/Duplication				x								
4	3001457	Exome Reanalysis (Originally Tested at ARUP - No Specimen Required)				x								
4	2006336	Exome Sequencing, Proband				x								

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4	2006332	Exome Sequencing, Trio				x								
4	0091116	Flunitrazepam and Metabolites, Serum or Plasma, Screen with Reflex to Confirmation/Quantitation		x	x									
4	3000183	Flunitrazepam and Metabolites, Urine Screen with Reflex to Confirmation/Quantitation		x	x									
5	3004716	Galactosemia (*GALT*) Sequencing and Deletion/Duplication				x								
5	0092399	HIV PhenoSense GT		x	x					x				
5	3000882	Human Immunodeficiency Virus Type 1 (HIV-1) PhenoSense		x	x					x				
5	3001246	Human Immunodeficiency Virus Type 1 (HIV-1) Trofile Co-Receptor Tropism		x	x									
5	3005636	Hypoglycemia Panel (Sulfonylureas), Serum or Plasma											x	
8	2010292	Hypoglycemia Panel, Sulfonylureas Qualitative, Serum or Plasma												x
6	3003680	*MET* Exon 14 Deletion Analysis by PCR											x	
6	3003684	*NTRK* Fusion Panel by Next Generation Sequencing											x	
6	3003913	Orthopedic Metals Panel (Chromium, Cobalt, Titanium)				x								
7	3004788	Pancreatitis Panel (*CFTR*, *CTRC*, *PRSS1*, *SPINK1*), Sequencing				x								
7	2001575	Renin, Direct		x	x	x	x							
7	3004603	SHOX Deficiency Disorders, Sequencing and Deletion/Duplication				x								
7	3002570	Trofile (DNA) Co-Receptor Tropism		x	x									

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.**
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection.
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: Unacceptable; Frozen: 1 month

Reference Interval:

Available Separately	Components	Reference Interval			
0070015	Aldosterone, Serum	Effective May 16, 2011			
		Age	**Posture Unspecified**	**Supine**	**Upright**
		0-6 days	5.0-102.0 ng/dL		
		1-3 weeks	6.0-179.0 ng/dL		
		1-11 months	7.0-99.0 ng/dL		
		1-2 years	7.0-93.0 ng/dL		
		3-10 years	4.0-44.0 ng/dL		
		11-14 years	4.0-31.0 ng/dL		
		15 years and older	Less than or equal to 31.0 ng/dL	Less than or equal to 16.0 ng/dL	4.0-31.0 ng/dL
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

3004745 **Cystic Fibrosis (*CFTR*) Sequencing and Deletion/Duplication** **CFTR 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

3001457 **Exome Reanalysis (Originally Tested at ARUP - No Specimen Required)** **EX REANLYZ**

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.**

2006336 **Exome Sequencing, Proband** **EXOSEQ PRO**

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
AND Maternal Specimen: Lavender (EDTA) or yellow (ACD Solution A or B). Peripheral blood required
AND Paternal Specimen: Lavender (EDTA) or yellow (ACD Solution A or B). Peripheral blood required
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)
AND Maternal Specimen: Transport 3 mL whole blood. (Min: 1 mL)
AND Paternal 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

2006332 **Exome Sequencing, Trio** **EXOME SEQ**

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.
AND Maternal Specimen: Lavender (EDTA) or yellow (ACD Solution A or B). Peripheral blood required.
AND Paternal Specimen: Lavender (EDTA) or yellow (ACD Solution A or B). Peripheral blood required.
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)
AND Maternal Specimen: Transport 3 mL whole blood. (Min: 1 mL)
AND Paternal 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

0091116 **Flunitrazepam and Metabolites, Serum or Plasma, Screen with Reflex to Confirmation/Quantitation** **FLUNITR SP**

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

3000183 **Flunitrazepam and Metabolites, Urine Screen with Reflex to Confirmation/Quantitation** **FLUNI URN**

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

3004716 **Galactosemia (*GALT*) Sequencing and Deletion/Duplication** **GALT 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 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

0092399 **HIV PhenoSense GT** **HIVPHENOGT**

Methodology: Polymerase Chain Reaction (PCR)/Culture
Performed: Varies
Reported: 16-25 days

CPT Code(s): 87900; 87901; 87903; 87904 x12

3000882 **Human Immunodeficiency Virus Type 1 (HIV-1) PhenoSense** **HIV PHENO**

Methodology: Polymerase Chain Reaction (PCR)/Culture
Performed: Varies
Reported: 16-26 days

CPT Code(s): 87903; 87904 x12

3001246 **Human Immunodeficiency Virus Type 1 (HIV-1) Trofile Co-Receptor Tropism** **HIV TROFIL**

Methodology: Polymerase Chain Reaction (PCR)/Culture
Performed: Varies
Reported: 27-38 days

New Test **3005636** **Hypoglycemia Panel (Sulfonylureas), Serum or Plasma** **HYPO PAN**
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Methodology: Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry (HPLC-MS/MS)
Performed: Varies
Reported: 4-7 days

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** **MET 14**
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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 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** **NTRK PAN**
Click for Pricing

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.

3003913 **Orthopedic Metals Panel (Chromium, Cobalt, Titanium)** **ORTHO PAN**

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

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

HOTLINE: Effective July 5, 2022

The following will be discontinued from ARUP's test menu on July 5, 2022.
Replacement test options are supplied if applicable.

Test Number	Test Name	Refer To Replacement
2010292	Hypoglycemia Panel, Sulfonylureas Qualitative, Serum or Plasma	Hypoglycemia Panel (Sulfonylureas), Serum or Plasma (3005636)