ARUP LABORATORIES

Immediate Change HOTLINE: Effective July 2, 2018

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
2	2003204	Alpha-Galactosidase, Serum				x								
2	0091161	Gamma-Hydroxybutyric Acid (GHB), Urine - Screen with Reflex to Confirmation/Quantitation										x		
5	0092458	Orotic Acid and Orotidine, Urine												x
2	3000704	Orotic Acid, Urine											x	
3	2002257	Osmotic Fragility, Erythrocyte				x								
3	0020763	Procalcitonin		x		x	x	x						
4	3000240	Prostaglandin D2 (PG D2), Urine				x			x		x			

2003204 **Alpha-Galactosidase, Serum** **A GALACTO**

Specimen Required: Collect: Plain Red or Serum Separator Tube (SST).
Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.2 mL)
Storage/Transport Temperature: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**
Unacceptable Conditions: Thawed specimens.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 24 hours; Frozen: 2 weeks

0091161 **Gamma-Hydroxybutyric Acid (GHB), Urine - Screen with Reflex to Confirmation/Quantitation** **GHB U**

HOTLINE NOTE: There is a reflexive pattern change associated with this test.
Add component 0090696, Creatinine to reflexive orderable 0096081
Add component 3000735, GHB (Creatinine corrected) to reflexive orderable 0096081

New Test **3000704** **Orotic Acid, Urine** **OROTICACID**

Methodology: Liquid Chromatography-Tandem Mass Spectrometry
Performed: Thu
Reported: 2-9 days

Specimen Required: Collect: First Catch Urine. Also acceptable: Random Urine.
Specimen Preparation: Specimen must be stored refrigerated until frozen. Transfer 2 mL urine to an ARUP Standard Transport Tube and freeze immediately. (Min: 1 mL)
Storage/Transport Temperature: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**
Unacceptable Conditions: Urine specimens containing preservatives.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 24 hours; Frozen: 2 weeks (avoid repeated freeze/thaw cycles)

Reference Interval:

0-4 years	0.7-5.1 mmol/mol creatinine
5 years and older	0.2-1.5 mmol/mol creatinine

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

CPT Code(s): 83921

New York DOH approval pending. Call for status update.

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

2002257 Osmotic Fragility, Erythrocyte — OSM FRG

Time Sensitive

New York State Clients: Direct Submission Instructions

Specimen Required: Patient Prep: **New York State Clients:** Collect control specimen from a healthy, nonsmoking, unrelated individual at the same time as patient.
Collect: Green (Sodium or Lithium Heparin) or Lavender (EDTA).
New York State Clients: Lavender (EDTA) (patient) AND Lavender (EDTA) (control).
Specimen Preparation: Transport 2 unfixed, air-dried, and unstained smears. (Min: 2 smears made from the blood submitted) AND 5 mL whole blood. (Min: 1 mL) Specimens should be refrigerated within 30 minutes after collection. Place both slides and whole blood specimens in an osmotic fragility transport kit (ARUP supply #53821) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
New York State Clients: Transport 4 mL whole blood (patient) AND 4 mL whole blood (control) in original collection tubes. (Min: 2 mL patient and 2 mL control) Rubber band patient and control tubes together. Control must accompany patient specimen at all times to ensure reliability of testing results. **Do not send to ARUP Laboratories**. Specimens must be received at performing laboratory within 72 hours of collection. For specimen requirements and direct submission instructions please contact ARUP Referral Testing at (800) 242-2787, ext. 5145.
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Grossly hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 72 hours; Frozen: Unacceptable

0020763 Procalcitonin — PCT

Methodology: Immunoassay

Specimen Required: Patient Prep: The same specimen type (serum, plasma) should be used throughout the patient's clinical course.
Collect: Plasma Separator Tube (PST) or Serum Separator Tube (SST).
Specimen Preparation: Allow serum to sit for 15-20 minutes for proper clot formation and to ensure the absence of fibrin in the serum which can interfere with this assay. Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.3 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Specimens collected in citrate anticoagulant.
Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 5 days; Frozen: 15 days

Reference Interval:
Effective July 2, 2018
Less than 0.07 ng/mL

Interpretive Data: A correction has been applied to optimize cutoffs established for the BRAHMS PCT sensitive KRYPTOR assay.

Procalcitonin > 2.00 ng/mL: Procalcitonin levels above 2.00 ng/mL on the first day of ICU admission represent a high risk for progression to severe sepsis and/or septic shock.

Procalcitonin < 0.50 ng/mL: Procalcitonin levels below 0.50 ng/mL on the first day of ICU admission represent a low risk for progression to severe sepsis and/or septic shock.

If the procalcitonin measurement is performed shortly after the systemic infection process has started (usually less than 6 hours), these values may still be low. As various non-infectious conditions are known to induce procalcitonin as well, procalcitonin levels between 0.50 ng/mL and 2.00 ng/mL should be reviewed carefully to take into account the specific clinical background and condition(s) of the individual patient.

3000240 **Prostaglandin D2 (PG D2), Urine** **PROST D2U**

Specimen Required: Patient Prep: Aspirin, indomethacin, or anti-inflammatory medications should be discontinued, if possible, at least 48 hours prior to collection.
Collect: Random urine
Specimen Preparation: Transfer 10 mL urine to ARUP Standard Transport Tubes and freeze immediately. (Min: 5 mL)
Storage/Transport Temperature: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 6 months

HOTLINE NOTE: Remove information found in the Remarks for Specimen Required and the Notes fields.
There is a component change associated with this test.
Remove component 3000241, PG D2 - Volume
Remove component 3000242, PG D2 – Duration

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The following will be discontinued from ARUP's test menu on July 2, 2018.
Replacement test options are supplied if applicable.

Test Number	Test Name	Refer To Replacement
0092458	Orotic Acid and Orotidine, Urine	Orotic Acid, Urine (3000704)