ARUP LABORATORIES

IMMEDIATE CHANGE HOT LINE – Effective October 5, 2015

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.

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

0070031 Adrenocorticotropic Hormone Stimulation, 0 Minutes CORTISOL 0

*This test performed at ARUP Laboratories.
Kit change. Plasma is no longer acceptable.

Specimen Required: Patient Prep: Collect 1 timed specimen at 0 minutes.
Collect: Serum separator tube (SST).
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.4 mL) Specimen must be labeled with time drawn.
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): After separation from cells: Ambient: 1 week; Refrigerated: 1 week; Frozen: 3 months

HOT LINE NOTE: Remove information found in the Unacceptable Conditions field.

0070032 Adrenocorticotropic Hormone Stimulation, 30 Minutes CORTISOL30

*This test performed at ARUP Laboratories.
Kit change. Plasma is no longer acceptable.

Specimen Required: Patient Prep: Collect 1 timed specimen at 30 minutes.
Collect: Serum separator tube (SST).
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.4 mL) Specimen must be labeled with time drawn.
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): After separation from cells: Ambient: 1 week; Refrigerated: 1 week; Frozen: 3 months

HOT LINE NOTE: Remove information found in the Unacceptable Conditions field.

0070033 Adrenocorticotropic Hormone Stimulation, 60 Minutes CORTISOL60

*This test performed at ARUP Laboratories.
Kit change. Plasma is no longer acceptable.

Specimen Required: Patient Prep: Collect 1 timed specimen at 60 minutes.
Collect: Serum separator tube.
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.4 mL) Specimen must be labeled with time drawn.
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): After separation from cells: Ambient: 1 week; Refrigerated: 1 week; Frozen: 3 months

HOT LINE NOTE: Remove information found in the Unacceptable Conditions field.

0070030 Cortisol, Serum CORTISOL

*This test performed at ARUP Laboratories.
Kit change. Plasma is no longer acceptable.

Specimen Required: Collect: Serum separator tube (SST).
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.6 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Saliva (refer to Cortisol, Saliva, ARUP test code 0081117).
Stability (collection to initiation of testing): After separation from cells: Ambient: 1 week; Refrigerated: 1 week; Frozen: 3 months

New Test 2012868 *EGFR* T790M Mutation Detection in Circulating Cell-Free DNA by Digital Droplet PCR EGFR T790M

*This test performed at ARUP Laboratories.
An ultrasensitive circulating tumor DNA assay for lung cancer chemotherapy resistance.

Methodology: Polymerase Chain Reaction
Performed: Varies
Reported: 10-12 days

Specimen Required: Collect: Whole blood in two 10mL Cell-Free DNA (cfDNA) BCT Tubes. Specimens must be collected using the kit (ARUP Supply #52358) available online through eSupply or contacting ARUP Client Services at (800) 522-2787.
Specimen Preparation: Transport 20 mL whole blood in cfDNA BCT Tubes. (Min: 16 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: FFPE tissue. Whole blood collected in non-cfDNA BCT tubes.
Stability (collection to initiation of testing): Ambient: 5 days; Refrigerated: 5 days; Frozen: Unacceptable

Interpretive Data: Refer to report

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

CPT Code(s): 81235

New York DOH approval pending. Call for status update.

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

0091203 Heroin - Screen with Reflex to Confirmation/Quantitation - Serum or Plasma HEROIN SP

Specimen Required: Collect: Plain red or Gray (sodium fluoride/potassium oxalate) or lavender (EDTA) or pink (K_2EDTA).
Specimen Preparation: Transfer 3 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1.3 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen.
Unacceptable Conditions: Separator tubes.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 month

2007935 Lactate to Pyruvate Ratio, Whole Blood — LP RATIO

*This test performed at ARUP Laboratories.
Specimen collection updated to remove risk of falsely elevated patient results.

Specimen Required: Patient Prep: Patient should be fasting and at complete rest. Patient should avoid any exercise of the arm or hand before or during collection. Draw the specimen without the use of a tourniquet or within three minutes of applying the tourniquet, but before releasing the tourniquet.
Collect: Green (sodium or lithium heparin).
Specimen Preparation: 1) Immediately after blood is drawn, add exactly 1 mL whole blood to a chilled pyruvate collection tube containing 2 mL 8 percent (w/v) perchloric acid (ARUP supply #16567) available online through eSupply using ARUP Connect™ or contact Client Services at (800) 522-2787.
2) Mix well for 30 seconds then place in an ice bath for 10 minutes.
3) Centrifuge for 10 minutes at 1500 x g.
4) Decant 2 mL supernatant to an ARUP Standard Transport Tube and freeze. (Min: 1 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: If less than 1 mL of blood is added to collection tube, pH of the supernatant will be too low for testing.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 2 days; Frozen: 4 weeks.

0055655 Methylenetetrahydrofolate Reductase (*MTHFR*) 2 Variants — MTHFR PCR

*This test performed at ARUP Laboratories.
The clinical interpretive information of *MTHFR* genotypes updated based on current literature.

Performed: Sun-Sat
Reported: 2-6 days

Reference Interval: **Negative:** Neither of the common *MTHFR* gene variants tested, c.665C>T (previously designated C677T) and c.1286A>C (previously designated A1298C), were detected. Other causes of elevated homocysteine levels, coronary heart disease, or thrombosis were not assessed. This genotype is associated with a normal folate metabolism.

Interpretive Data:
Background Information for Methylenetetrahydrofolate Reductase (*MTHFR*) 2 Variants:
Characteristics: Variants in the *MTHFR* gene (c.665C>T and c.1286A>C) correlate with reduced enzyme activity; however, only homozygotes for the c.665C>T variant have been significantly associated with elevated plasma homocysteine levels and with an increased risk for premature cardiovascular disease. These individuals may also show toxicity from medications (ie, methotrexate) that affect folate metabolism.
Incidence: The allele frequency of c.665C>T is 0.35 in European Caucasians and 0.12 in African Americans. The allele frequency of c.1286A>C is 0.31 in European Caucasians and 0.15 in African Americans.
Inheritance: Autosomal recessive.
Cause: Homozygosity for *MTHFR* gene mutation c.665C>T.
Mutations Tested: c.665C>T (previously designated C677T); p.Ala222Val and c.1286A>C (previously designated A1298C); p.Glu429Ala.
Clinical Sensitivity: Undefined. Sensitivity is dependent upon multiple contributing factors.
Methodology: Polymerase chain reaction followed by high resolution melt analysis.
Analytical Sensitivity & Specificity: 99 percent.
Limitations: Only the two *MTHFR* gene mutations (c.665C>T and c.1286A>C) will be targeted. Diagnostic errors can occur due to rare sequence variations.

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

2009077 Non-Invasive Prenatal Testing for RhD Genotyping, Fetal — NIPT RHD

Specimen Required: Collect: Whole blood in two cell-free DNA BCT tubes (ARUP Supply #52543) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Specimen Preparation: Transport 20 mL maternal whole blood. (Min: 16 mL)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated.
Remarks: Mother must have Rh-negative blood type and be at least 12 weeks gestation. Gestational age at time of collection is required for testing.
Unacceptable Conditions: Multiple fetuses.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 week; Frozen: Unacceptable

HOT LINE NOTE: Remove information found in the Patient Prep field.

New Test 2012918 PD-1 and PD-L1 by Immunohistochemistry with Interpretation PD1L1PANEL

*This test performed at ARUP Laboratories.
New panel of two stains typically ordered together to streamline ordering and improve patient care.

Available October 5, 2015

Methodology: Immunohistochemistry
Performed: Mon-Fri
Reported: 1-5 days

Specimen Required: Collect: Tumor tissue.
Specimen Preparation: Formalin fix and paraffin embed specimen. Protect paraffin block and/or slides from excessive heat. Transport tissue block or 6 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (recommended but not required), (ARUP supply #47808) available online through eSupply using ARUP Connect or contact ARUP Client Services at (800) 522-2787. (Min. 5 slides) If sending precut slides, do not oven bake.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks: Include surgical pathology report and indicate tissue site with the test order. For additional technical details, please contact ARUP Client Services at (800) 522-2787.
Unacceptable Conditions: Paraffin block with no tumor tissue remaining; specimens fixed in any fixative other than 10 percent neutral buffered formalin.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

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

Note: This test code includes pathologist interpretation.

CPT Code(s): 88342; 88360

New York DOH Approved.

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

New Test 2012912 PD-1 by Immunohistochemistry with Interpretation PD1 IP

This test performed at ARUP Laboratories.
Offering stain with interpretation to improve patient care.

Available October 5, 2015

Methodology: Immunohistochemistry
Performed: Mon-Fri
Reported: 1-5 days

Specimen Required: Collect: Tumor tissue.
Specimen Preparation: Formalin fix and paraffin embed specimen. Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (recommended but not required), (ARUP supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min. 5 slides) If sending precut slides, do not oven bake.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks: Include surgical pathology report and indicate tissue site with the test order. For additional technical details, please contact ARUP Client Services at (800) 522-2787.
Unacceptable Conditions: Paraffin block with no tumor tissue remaining. Specimens fixed in any fixative other than 10 percent neutral buffered formalin.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

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

Note: This test code includes pathologist interpretation.

CPT Code(s): 88342

New York DOH Approved.

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

0080310 Pyruvic Acid PYRU

*This test performed at ARUP Laboratories.
Specimen change and requirements updated to reflect significantly decreased stability.

Specimen Required: Patient Prep: Patient should be fasting and at complete rest. Patient should avoid any exercise of the arm or hand before or during collection. Draw the specimen without the use of a tourniquet or within three minutes of applying the tourniquet, but before releasing the tourniquet.
Collect: Green (sodium or lithium heparin).
Specimen Preparation: 1) Immediately after blood is drawn, add exactly 1 mL whole blood to a chilled pyruvate collection tube containing 2 mL 8 percent (w/v) perchloric acid (ARUP supply #16567) available online through eSupply using ARUP Connect or contact Client Services at (800) 522-2787.
2) Mix well for 30 seconds then place in an ice bath for 10 minutes.
3) Centrifuge for 10 minutes at 1500 x g.
4) Decant 2 mL supernatant to an ARUP Standard Transport Tube and freeze. (Min: 1 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: If less than 1 mL of blood is added to collection tube, pH of the supernatant will be too low for testing.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 2 days; Frozen: 4 weeks

0080312 Pyruvic Acid, CSF PYRU CSF

*This test performed at ARUP Laboratories.
Specimen requirements updated to reflect significantly decreased stability.

Specimen Required: Patient Prep: Patient should be fasting and at complete rest. Patient should avoid any exercise of the arm or hand before or during collection. Draw the specimen without the use of a tourniquet or within three minutes of applying the tourniquet, but before releasing the tourniquet.
Collect: CSF.
Specimen Preparation: 1) Immediately after CSF is drawn, add exactly 1 mL CSF to a chilled pyruvate collection tube containing 2 mL 8 percent (w/v) perchloric acid (ARUP supply #16567) available online through eSupply using ARUP Connect™ or contact Client Services at (800) 522-2787.
2) Mix well for 30 seconds then place in an ice bath for 10 minutes.
3) Centrifuge for 10 minutes at 1500 x g.
4) Decant 2 mL supernatant to an ARUP Standard Transport Tube and freeze. (Min: 1 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: If less than 1 mL of CSF is added to collection tube, pH of the supernatant will be too low for testing.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 2 days; Frozen: 4 weeks