HOTLINE: Effective October 4, 2021

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	0099007	Antimony, Blood				x		x	x					
2	0070029	Beta-hCG, Quantitative (Tumor Marker)								x				
2	3001186	Human Immunodeficiency Virus Type 1 (HIV-1) PhenoSense GT Plus Integrase								x				
2	3000197	PD-L1 22C3 IHC with Combined Positive Score (CPS) Interpretation, pembrolizumab (KEYTRUDA)				x								
3	0051075	Trypanosoma cruzi Antibody, IgM												x

0099007 Antimony, Blood — ANT B

Specimen Required: Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances. Patient should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician).
Collect: Greiner Bio-One Vacuette Tube 6 mL NH Trace Elements Sodium Heparin tube.
Specimen Preparation: Transport 6 mL whole blood in the original collection tube (ARUP supply #57238). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 4.0mL)
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated.
Unacceptable Conditions: Specimens collected in containers other than specified (including the BD Plastic Royal Blue (K_2EDTA) collection tubes), Specimens transported in containers other than specified. Clotted specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Interpretive Data:
Elevated results may be due to skin- or collection device-related contamination. If contamination concerns exist due to elevated levels of blood antimony, confirmation should be performed with a second specimen collected in the recommended collection device.

Blood antimony levels predominantly reflect recent exposure and are most useful in the diagnosis of acute poisoning. Blood concentrations in unexposed individuals rarely exceed 3 µg/L. The form of antimony greatly influences distribution and elimination. Trivalent antimony readily enters red blood cells, has an extended half-life on the order of weeks to months, and is eliminated predominantly through the bile. Pentavalent antimony resides in the plasma, has a relatively short half-life on the order of hours to days, and is eliminated predominantly through the kidneys. Reported symptoms after toxic antimony exposure vary based upon route of exposure, duration, and antimony source and may include abdominal pain, dyspnea, nausea, vomiting, dermatitis, and eye irritation. Clinical presentation is similar to that of inorganic arsenic exposure.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. This test was performed in a CLIA-certified laboratory and is intended for clinical purposes.

Note: BD Plastic Royal Blue (K_2EDTA) collection tubes are not acceptable for antimony testing and can cause an elevated result in unexposed individuals.

0070029 Beta-hCG, Quantitative (Tumor Marker) — BHCG TM

CPT Code(s): 84702

3001186 Human Immunodeficiency Virus Type 1 (HIV-1) PhenoSense GT Plus Integrase — HIVPS PLUS

CPT Code(s): 87900; 87901; 87903; 87904 x16; 87906

3000197 PD-L1 22C3 IHC with Combined Positive Score (CPS) Interpretation, pembrolizumab (KEYTRUDA) — 22C3 GAST

Specimen Required: Collect: Tumor tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) 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 (ARUP supply #47808 recommended but not required), available online through eSupply using ARUP Connector contact ARUP Client Services at (800) 522-2787. (Min: 3 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.
If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.
Unacceptable Conditions: Paraffin block with no tumor tissue remaining; specimens fixed in any fixative other than 10 percent neutral buffered formalin. Decalcified specimens. Specimens with fewer than 100 viable tumor cells. Nonindicated tumor types, including non-small cell lung carcinomas and urothelial carcinomas.
Stability (collection to initiation of testing): **Slides:** Ambient: 5 months (Must be stored in the dark); Refrigerated: 5 months (Must be stored in the dark); Frozen: Unacceptable
Paraffin Block: Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

HOTLINE: Effective October 4, 2021

The following will be discontinued from ARUP's test menu on October 4, 2021.
Replacement test options are supplied if applicable.

Test Number	Test Name	Refer To Replacement
0051075	Trypanosoma cruzi Antibody, IgM	