HOTLINE: Effective October 3, 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
2	0055284	Cysticercosis Antibody, IgG by ELISA				x	x					x		
2	0055285	Cysticercosis Antibody, IgG by ELISA (CSF)				x	x					x		
3	2014056	IgA Deficiency (IgAD) Panel												x
2	0090362	Methadone and Metabolite, Urine, Quantitative					x	x						
3	0081284	Soluble Mesothelin Related Peptides (MESOMARK®)				x		x			x			
3	2011793	Triiodothyronine (T3), Free by Equilibrium Dialysis/LC-MS/MS				x								
3	2014025	Trypsin (Test on Delay as of 7/12/2022)												x

0055284 Cysticercosis Antibody, IgG by ELISA — CYST SER

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.1 mL) Parallel testing is preferred and convalescent specimens **must** be received within 30 days from receipt of the acute specimens. **Mark specimens plainly as "acute" or "convalescent."**
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: CSF. Contaminated, heat-inactivated, hemolyzed, icteric, or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 month (avoid repeated freeze/thaw cycles)

Reference Interval:
Effective October 3, 2022

<9 U	Negative: No significant level of cysticercosis IgG antibody detected.
9–11 U	Equivocal: Recommend repeat testing in 2-4 weeks with fresh sample.
>11 U	Positive: IgG antibodies to cysticercosis detected, which may suggest current or past infection.

HOTLINE NOTE: There is a unit of measure change associated with this test.
Change the unit of measure for component 0055284, Cysticercosis Ab, IgG by ELISA from IV to U.

0055285 Cysticercosis Antibody, IgG by ELISA (CSF) — CYST CSF

Specimen Required: Collect: CSF.
Specimen Preparation: Transfer 1 mL CSF to an ARUP Standard Transport Tube. (Min: 0.3 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Serum. Contaminated, heat-inactivated, hemolyzed, icteric, or lipemic specimens.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 month (avoid repeated freeze/thaw cycles)

Reference Interval:
Effective October 3, 2022

<9 U	Negative: No significant level of cysticercosis IgG antibody detected.
9–11 U	Equivocal: Recommend repeat testing in 2-4 weeks with fresh sample.
>11 U	Positive: IgG antibodies to cysticercosis detected, which may suggest current or past infection.

HOTLINE NOTE: There is a unit of measure change associated with this test.
Change the unit of measure for component 0055285, Cysticercosis Ab, IgG by ELISA, CSF from IV to U.

0090362 Methadone and Metabolite, Urine, Quantitative — CDCO METH

Reference Interval:
Effective October 3, 2022

Drugs Covered	Cutoff Concentrations
Methadone	100 ng/mL
EDDP	100 ng/mL

Interpretive Data:
Methodology: Quantitative Liquid Chromatography-Tandem Mass Spectrometry

Positive cutoff: 100 ng/mL

For medical purposes only; not valid for forensic use.

The absence of expected drug(s) and/or drug metabolite(s) may indicate non-compliance, inappropriate timing of specimen collection relative to drug administration, poor drug absorption, diluted/adulterated urine, or limitations of testing. The concentration value must be greater than or equal to the cutoff to be reported as positive. Interpretive questions should be directed to the laboratory.

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

0081284 Soluble Mesothelin Related Peptides (MESOMARK®) MESO

Specimen Required: Collect: Serum Separator Tube (SST) or Plain Red.
Specimen Preparation: Allow specimen to clot completely at room temperature. Transfer 0.2 mL serum to an ARUP Standard Transport Tube. (Min: 0.1 mL)
Storage/Transport Temperature: Frozen.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 24 hours; Frozen: 3 months

Interpretive Data:
MESOMARK® is an enzyme-linked immunosorbent assay for the quantitative measurement of soluble mesothelin related peptides (SMRP) in serum. Measurement of SMRP may aid in the management of patients diagnosed with epithelioid or biphasic mesothelioma. Epidemiologic studies have established exposure to asbestos fibers as the primary cause of malignant mesothelioma. Results obtained with different assay methods or kits cannot be used interchangeably. Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease.

HOTLINE NOTE: There is a component change associated with this test.
Remove component 0081289, Mesothelin Ordering MD:
Remove information found in the Remarks field.

2011793 Triiodothyronine (T3), Free by Equilibrium Dialysis/LC-MS/MS T3 FREE SP

Methodology: Quantitative Equilibrium Dialysis/High Performance Liquid Chromatography-Tandem Mass Spectrometry (HPLC-MS/MS)

Specimen Required: Collect: Plain red or lavender (K2EDTA). Also acceptable: Serum separator tube, lavender (K3EDTA), pink (K2EDTA), or Green (Sodium Heparin).
Specimen Preparation: Separate from cells ASAP or within 45 minutes 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 or Room Temperature.
Unacceptable Conditions: Specimen submitted in gel-barrier tube.
Stability (collection to initiation of testing): Ambient: 5 days; Refrigerated: 5 days; Frozen: 10 weeks

The following will be discontinued from ARUP's test menu on October 3, 2022.
Replacement test options are supplied if applicable.

Test Number	Test Name	Refer To Replacement
2014056	IgA Deficiency (IgAD) Panel	
2014025	Trypsin (Test on Delay as of 7/12/2022)	