HOTLINE: Effective July 6, 2020

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	2005010	*BCR-ABL1*, Qualitative with Reflex to *BCR-ABL1* Quantitative				x								
2	0060241	*Chlamydia trachomatis* and *Neisseria gonorrhoeae* by Transcription-Mediated Amplification (TMA)			x									
2	0060774	*Chlamydia trachomatis* and *Neisseria gonorrhoeae* by Transcription-Mediated Amplification (TMA), M4/UTM			x									
3	2001551	*Chlamydia trachomatis* and *Neisseria gonorrhoeae* by Transcription-Mediated Amplification (TMA), SurePath			x									

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	0060734	*Chlamydia trachomatis* and *Neisseria gonorrhoeae* by Transcription-Mediated Amplification (TMA), ThinPrep			x									
3	0060243	*Chlamydia trachomatis* by Transcription-Mediated Amplification (TMA)			x									
3	3002971	Explify Respiratory RNA Pathogen Detection											x	
3	2002715	Monoclonal Protein Study, Expanded Panel, Serum				x								
3	0060244	*Neisseria gonorrhoeae* by Transcription-Mediated Amplification (TMA)			x									
4	3002598	Phosphatidylethanol (PEth), Whole Blood, Quantitative (Pricing Change Only)												
4	2002098	Signal Recognition Particle (SRP) Antibody		x	x	x								

2005010 ***BCR-ABL1*, Qualitative with Reflex to *BCR-ABL1* Quantitative** **BCR RFLX**

Specimen Required: Collect: Lavender (EDTA) or bone marrow (EDTA). Also acceptable: RNA extracted by CLIA certified lab.
Specimen Preparation: **Whole Blood:** Transport 5 mL whole blood. (Min: 4 mL)
Bone Marrow: Transport 3 mL bone marrow. (Min: 1 mL)
Specimens must be received within 48 hours of collection due to lability of RNA.
Extracted RNA: Transport 40 uL RNA with at least 40 ng/uL concentration. (Min: 40 uL) Transport RNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: **Whole Blood or Bone Marrow**: CRITICAL REFRIGERATED. Separate specimens must be submitted when multiple tests are ordered.
Extracted RNA: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Unacceptable Conditions: Serum, plasma, CSF, extracted DNA, RNA extracted by a non-CLIA lab, bone core, or FFPE tissue. Specimens collected in anticoagulants other than indicated. Severely hemolyzed or clotted specimens.
Stability (collection to initiation of testing): Ambient: 1 hour; Refrigerated: 48 hours; Frozen: Unacceptable
Extracted RNA: Ambient: Unacceptable; Refrigerate: Unacceptable; Frozen: Indefinitely

0060241 ***Chlamydia trachomatis* and *Neisseria gonorrhoeae* by Transcription-Mediated Amplification (TMA)** **CGAMD**

Performed: Sun-Sat
Reported: 1-4 days

0060774 ***Chlamydia trachomatis* and *Neisseria gonorrhoeae* by Transcription-Mediated Amplification (TMA), M4/UTM** **CTNG M4**

Performed: Sun-Sat
Reported: 1-4 days

2001551 ***Chlamydia trachomatis* and *Neisseria gonorrhoeae* by Transcription-Mediated Amplification (TMA), SurePath** **CTNG SP**

Performed: Sun-Sat
Reported: 1-4 days

0060734 ***Chlamydia trachomatis* and *Neisseria gonorrhoeae* by Transcription-Mediated Amplification (TMA), ThinPrep** **CG MATP**

Performed: Sun-Sat
Reported: 1-4 days

0060243 ***Chlamydia trachomatis* by Transcription-Mediated Amplification (TMA)** **CTAMD**

Performed: Sun-Sat
Reported: 1-4 days

New Test **3002971** **Explify Respiratory RNA Pathogen Detection** **RESPAT RNA**
Click for Pricing

Methodology: Massively Parallel Sequencing
Performed: Varies
Reported: 3-6 days

Specimen Required: Collect: Bronchoalveolar lavage (BAL), sputum, tracheal aspirate, or nasopharyngeal swab.
Specimen Preparation: Transfer 2 mL BAL, sputum, or tracheal aspirate to an ARUP Standard Transport Tube. (Min: 1 mL) Place nasopharyngeal swab in viral transport media (ARUP Supply #12884) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. Place each specimen in an individually sealed bag.
Test is not performed at ARUP; separate specimens must be submitted when multiple tests are ordered.
Storage/Transport Temperature: Frozen
Remarks: Specimen source required.
Unacceptable Conditions: Thawed specimens. Nasopharyngeal swab not in viral transport media.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 4 days; Frozen: 1 month

Reference Interval: By report

CPT Code(s): 87999

New York DOH approval pending. Call for status update.

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

2002715 **Monoclonal Protein Study, Expanded Panel, Serum** **IFE FLC**

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 1.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma. Room temperature specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 1 month

0060244 ***Neisseria gonorrhoeae* by Transcription-Mediated Amplification (TMA)** **GCAMD**

Performed: Sun-Sat
Reported: 1-4 days

3002598 **Phosphatidylethanol (PEth), Whole Blood, Quantitative** **PETH**

HOTLINE NOTE: There is a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.

2002098 **Signal Recognition Particle (SRP) Antibody** **SRP**

Methodology: Radioimmunoassay
Performed: Varies
Reported: 16-19 days

Specimen Required: Collect: Plain Red or Serum Separator Tube (SST).
Specimen Preparation: Transfer 1 mL serum 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: Refrigerated. Also acceptable: Frozen.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 2 weeks; Frozen: 2 months