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.

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<td>0051044</td>
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<td>Chronic Lymphocytic Leukemia Minimum Residual Disease by Flow Cytometry</td>
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<td>Hairstat 5 Reflexive Panel</td>
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<td>KIT D816V Mutation Detection by PCR for Gleevec Eligibility in Aggressive Systemic Mastocytosis (ASM)</td>
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</table>
New Test 3003253 Borrelia burgdorferi VlsE1/pepC10 Antibodies, Total by ELISA LYME PEP
Available Now
Click for Pricing

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay
Performed: Mon-Fri
Reported: 1-4 days

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Remove serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.15 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, CSF. Contaminated, heat-inactivated, hemolyzed, icteric, or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 10 days; Frozen: 1 month

Reference Interval:

<table>
<thead>
<tr>
<th>Reference Interval</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>0.90 IV or less</td>
<td>Negative – VlsE1 and pepC10 antibodies to B. burgdorferi not detected.</td>
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<tr>
<td>0.91-1.09 IV</td>
<td>Equivocal – Repeat testing in 10-14 days may be helpful.</td>
</tr>
<tr>
<td>1.10 IV or greater</td>
<td>Positive – VlsE1 and pepC10 antibodies to B. burgdorferi detected.</td>
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</table>

CPT Code(s): 86618

New York DOH Approved.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.
**New Test** 3003254  *Borrelia burgdorferi* VlsE1/pepC10 Antibodies, Total by ELISA with Reflex to IgG and IgM by Immunoblot

**Available Now**

**Click for Pricing**

**Methodology:** Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Qualitative Immunoblot

**Performed:** Mon-Fri

**Reported:** 1-4 days

**Specimen Required:** Collect: Serum separator tube.

Specimen Preparation: Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.15 mL)

Storage/Transport Temperature: Refrigerated.

Unacceptable Conditions: Plasma, CSF. Contaminated, heat-inactivated, hemolyzed, icteric, or lipemic specimens.

Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 10 days; Frozen: 1 month

**Reference Interval:**

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<tr>
<th>Test Number</th>
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<tr>
<td>3003253</td>
<td><em>Borrelia burgdorferi</em> VlsE1/pepC10 Antibodies, Total by ELISA</td>
<td>0.90 IV or less</td>
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<tr>
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<td>1.10 IV or greater</td>
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</tbody>
</table>

| 0050254     | *Borrelia burgdorferi* Antibodies, IgG and IgM by Immunoblot | Effective August 15, 2011 |
|            | Negative |

**Interpretive Data:**

Refer to report.

**Note:** If VlsE1/pepC10 antibodies by ELISA is 0.91 IV or greater, then IgG and IgM Immunoblot will be added. Additional charges apply.

**CPT Code(s):** 86618; if reflexed, add 86617 x2

New York DOH Approved.

**HOTLINE NOTE:** Refer to the Test Mix Addendum for interface build information.
New Test 3003255 Borrelia burgdorferi VlsE1/pepC10 Antibodies, Total by ELISA with Reflex to IgG by Immunoblot

Available Now
Click for Pricing

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Qualitative Immunoblot
Performed: Mon-Fri
Reported: 1-4 days

Specimen Required: Collect: Serum separator tube.
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 2 mL serum to an ARUP Standard Transport Tube. (Min: 0.15 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma, CSF. Contaminated, heat-inactivated, hemolyzed, icteric, or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 10 days; Frozen: 1 month

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<td>Borrelia burgdorferi VlsE1/pepC10 Antibodies, Total by ELISA</td>
<td>0.90 IV or less: Negative – VlsE1 and pepC10 antibodies to B. burgdorferi not detected. 0.91-1.09 IV: Equivocal – Repeat testing in 10-14 days may be helpful. 1.10 IV or greater: Positive – VlsE1 and pepC10 antibodies to B. burgdorferi detected.</td>
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Note: If VlsE1/pepC10 antibodies by ELISA is 0.91 IV or greater, then IgG Immunoblot will be added. Additional charges apply.

CPT Code(s): 86618; if reflexed, add 86617

New York DOH Approved.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.
New Test 3003142 Chronic Lymphocytic Leukemia Minimum Residual Disease by Flow Cytometry

Methodology: Flow Cytometry
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Collect: Whole Blood or Bone Marrow in Green (Sodium Heparin), Lavender (K2EDTA), Specimen Preparation: Transport 3 mL Whole Blood or Bone Marrow. (Min: 1 mL) Do not freeze.
Storage/Transport Temperature: Room temperature. Also, acceptable: Refrigerated. Specimen should be received within 24 hours of collection for optimal cell viability.

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

CPT Code(s): 88184; 88185 x9; 88188

New York DOH approval pending. Call for status update.

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

0092068 Hairstat 5 Reflexive Panel

Specimen Required: Patient Prep: Ensure hair is not chemically treated or synthetic. Hair from the beard, underarms, chest, arms, legs or pubic hair may be collected. Body hair from different sites may be combined to get a final volume. Body hair and scalp hair should not be combined.
Collect: 100 mg hair. A kit must be ordered prior to collecting specimen (ARUP supply #40477). Available online through eSupply using ARUP Connect™ or by contacting Client Services at (800) 522-2787.
Specimen Preparation: Transport 100 mg hair (a ponytail 1.5 inches long and the diameter of a #2 pencil). (Min: 100 mg) Specimen must have a tamper evident seal affixed. Test is not performed at ARUP; separate specimens must be submitted when multiple tests are ordered.
Storage/Transport Temperature: Room temperature.
Unacceptable Conditions: Specimens without a tamper evident seal affixed cannot be tested.
Stability (collection to initiation of testing): Ambient: 1 year; Refrigerated: Undefined; Frozen: Undefined

2013476 Hepatitis B Virus (HBV) Drug Resistance, Genotype and BCP/Precore Mutations by Sequencing

Specimen Required: Collect: Plasma Preparation Tube (PPT). Also acceptable: Lavender (EDTA) or Serum Separator Tube (SST).
Specimen Preparation: Separate from cells ASAP or within 2 hours 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.
Remarks: Patient viral load must be greater than 600 IU/mL.
Unacceptable Conditions: Thawed specimens.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

HOTLINE NOTE: Remove information found in the Note field.
Specimen Required: Collect: Biliary/Hepatic, Drain, Pancreatic, Pericardial, Peritoneal/Ascites, Pleural or Synovial fluid.
Specimen Preparation: Centrifuge to remove cellular material. Transfer 1 mL body fluid to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Room temperature.
Remarks: Specimen source must be provided.
Unacceptable Conditions: Specimen types other than those listed. Specimens too viscous to be aspirated by instrument.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 week; Frozen: 2 months

Specimen Required: Collect: Plasma separator tube or serum separator tube.
Specimen Preparation: Allow serum tube to clot completely at room temperature. Separate serum or plasma from cells within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.2 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Body Fluids (refer to Lipase, Fluid, ARUP test code 0020715). Specimens collected in EDTA, oxalate/fluoride or citrate, or in tubes with glycerol lubricated stoppers.
Stability (collection to initiation of testing): After separation from cells: Ambient: 1 week; Refrigerated: 1 week; Frozen: 2 months

The following will be discontinued from ARUP’s test menu on November 2, 2020.
Replacement test options are supplied if applicable.

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<th>Test Name</th>
<th>Refer To Replacement</th>
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