

**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
7	<a href="#">0051044</a>	Borrelia burgdorferi C6 Peptide Antibodies, Total by ELISA												x
7	<a href="#">0051046</a>	Borrelia burgdorferi C6 Peptide Antibodies, Total by ELISA (CSF)												x
7	<a href="#">0051043</a>	Borrelia burgdorferi C6 Peptide Antibodies, Total by ELISA with Reflex to IgG and IgM by Immunoblot												x
7	<a href="#">0051045</a>	Borrelia burgdorferi C6 Peptide Antibodies, Total by ELISA with Reflex to IgG by Immunoblot												x
3	<a href="#">3003253</a>	<i>Borrelia burgdorferi</i> VlsE1/pepC10 Antibodies, Total by ELISA											x	

HOTLINE: Effective November 2, 2020

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
4	<a href="#">3003254</a>	<i>Borrelia burgdorferi</i> VlsE1/pepC10 Antibodies, Total by ELISA with Reflex to IgG and IgM by Immunoblot											x	
5	<a href="#">3003255</a>	<i>Borrelia burgdorferi</i> VlsE1/pepC10 Antibodies, Total by ELISA with Reflex to IgG by Immunoblot											x	
6	<a href="#">3003142</a>	Chronic Lymphocytic Leukemia Minimum Residual Disease by Flow Cytometry											x	
6	<a href="#">0092068</a>	Hairstat 5 Reflexive Panel				x								
6	<a href="#">2013476</a>	Hepatitis B Virus (HBV) Drug Resistance, Genotype and BCP/Precore Mutations by Sequencing				x			x					
7	<a href="#">2012207</a>	KIT D816V Mutation Detection by PCR for Gleevec Eligibility in Aggressive Systemic Mastocytosis (ASM)												x
7	<a href="#">0020715</a>	Lipase, Fluid				x								
7	<a href="#">0020014</a>	Lipase, Serum or Plasma				x								
7	<a href="#">2012147</a>	PDGFRB FISH for Gleevec Eligibility in Myelodysplastic Syndrome/Myeloproliferative Disease (MDS/MPD)												x

HOTLINE: Effective November 2, 2020

**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:**

Reference Interval	
0.90 IV or less	Negative – VlsE1 and pepC10 antibodies to <i>B. burgdorferi</i> 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 <i>B. burgdorferi</i> detected.

**CPT Code(s):** 86618

New York DOH Approved.

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

HOTLINE: Effective November 2, 2020

**New Test**     [3003254](#)     ***Borrelia burgdorferi* VlsE1/pepC10 Antibodies, Total by ELISA**     **LPEP ACUTE 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:**

Test Number	Components	Reference Interval	
3003253	<i>Borrelia burgdorferi</i> VlsE1/pepC10 Antibodies, Total by ELISA	0.90 IV or less	Negative – VlsE1 and pepC10 antibodies to <i>B. burgdorferi</i> 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 <i>B. burgdorferi</i> detected.
0050254	<i>Borrelia burgdorferi</i> 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.

HOTLINE: Effective November 2, 2020

**New Test**     [3003255](#)     ***Borrelia burgdorferi* VlsE1/pepC10 Antibodies, Total by ELISA**     **LPEP CHRON**  
**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

**Reference Interval:**

Test Number	Components	Reference Interval	
3003253	<i>Borrelia burgdorferi</i> VlsE1/pepC10 Antibodies, Total by ELISA	0.90 IV or less	Negative – VlsE1 and pepC10 antibodies to <i>B. burgdorferi</i> 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 <i>B. burgdorferi</i> detected.
0050255	<i>Borrelia burgdorferi</i> Antibody, IgG 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 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**     **CLL MRD**

[Click for Pricing](#)



Additional Technical Information

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

**Specimen Required:** Collect: Whole Blood or Bone Marrow in Green (Sodium Heparin), Lavender (K<sub>2</sub>EDTA),  
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.**  
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Unacceptable

**Interpretive Data:**  
Refer to report.  
See Compliance Statement A: [www.aruplab.com/CS](http://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**     **HAIRSTAT 5**

**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**     **HBVGENOMUT**

**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.

HOTLINE: Effective November 2, 2020

**0020715**

**Lipase, Fluid**

**LIP FL**

**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**

**0020014**

**Lipase, Serum or Plasma**

**LIP**

**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.**

Test Number	Test Name	Refer To Replacement
<a href="#">0051044</a>	Borrelia burgdorferi C6 Peptide Antibodies, Total by ELISA	Borrelia burgdorferi VlsE1/pepC10 Antibodies, Total by ELISA ( <a href="#">3003253</a> )
<a href="#">0051046</a>	Borrelia burgdorferi C6 Peptide Antibodies, Total by ELISA (CSF)	
<a href="#">0051043</a>	Borrelia burgdorferi C6 Peptide Antibodies, Total by ELISA with Reflex to IgG and IgM by Immunoblot	Borrelia burgdorferi VlsE1/pepC10 Antibodies, Total by ELISA with Reflex to IgG and IgM by Immunoblot ( <a href="#">3003254</a> )
<a href="#">0051045</a>	Borrelia burgdorferi C6 Peptide Antibodies, Total by ELISA with Reflex to IgG by Immunoblot	Borrelia burgdorferi VlsE1/pepC10 Antibodies, Total by ELISA with Reflex to IgG by Immunoblot ( <a href="#">3003255</a> )
<a href="#">2012207</a>	KIT D816V Mutation Detection by PCR for Gleevec Eligibility in Aggressive Systemic Mastocytosis (ASM)	
<a href="#">2012147</a>	PDGFRB FISH for Gleevec Eligibility in Myelodysplastic Syndrome/Myeloproliferative Disease (MDS/MPD)	