

HOTLINE: Effective April 4, 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	2013034	Alpha Subunit, Free, Pituitary Glycoprotein Hormones (PGH)				X								
2	2003222	Antiphospholipid Syndrome Reflexive Panel				X								
3	0030192	APC Resistance Profile with Reflex to Factor V Leiden				X								
3	3001855	BRCA1 and BRCA2-Associated HBOC Syndrome Panel, Sequencing and Deletion/Duplication		X		X		X	X					
3	0070416	C-Telopeptide, Beta-Cross-Linked, Serum				X								
3	0020454	Hepatitis B Virus Panel, Chronic with Reflex to HBsAg Confirmation	X	X	X	X								

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4	0020095	Hepatitis Be Virus Antibody	x	x	x	x		x						
4	2012141	Hepatitis Be Virus Antigen and Antibody Panel	x	x	x	x								
4	3001784	Interstitial Lung Disease Autoantibody Panel								x				
4	2007370	Periodic Fever Syndromes Panel, Sequencing and Deletion/Duplication								x				
6	2013008	Periprosthetic Joint Infection (PJI) Detection (Synovasure)												x
4	2006385	Thrombotic Risk Reflexive Panel				x								
5	0030133	Thrombotic Risk, Inherited Etiologies (Most Common) with Reflex to Factor V Leiden				x								
5	2006502	Tick Identification with Reflex to Borrelia Species by PCR (Lyme Disease)		x		x								

[2013034](#) Alpha Subunit, Free, Pituitary Glycoprotein Hormones (PGH) A SUB PGH

Specimen Required: Collect: Serum separator tube (SST) or plain **red**.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL **serum** to an ARUP Standard Transport Tube. (Min: 0.25 mL) Freeze immediately.
Test is not performed at ARUP; separate specimens must be submitted when multiple tests are ordered.
Storage/Transport Temperature: Frozen.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 24 hours; Frozen: 6 months

[2003222](#) Antiphospholipid Syndrome Reflexive Panel PHOS SYN

Specimen Required: Collect: Light Blue (Sodium Citrate) **AND** Serum Separator Tube (SST). Refer to Specimen Handling at aruplab.com for hemostasis/thrombosis specimen handling guidelines.
Specimen Preparation: Transport 2 mL platelet poor plasma in an ARUP Standard Transport Tube. (Min: 2 mL) **AND** Transport 1 mL serum in an ARUP Standard Transport Tube. (Min: 0.6 mL)
Storage/Transport Temperature: **Plasma: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**
Serum: Frozen.
Unacceptable Conditions: **For Lupus Anticoagulant Reflexive Panel (Plasma):** Serum. EDTA plasma, clotted or hemolyzed specimens.
For cardiolipin and beta-2 glycoprotein antibodies (Serum): Plasma and other body fluids, heat-inactivated, hemolyzed, lipemic, or contaminated specimens.
Stability (collection to initiation of testing): **Plasma:** Ambient: 4 hours; Refrigerated: Unacceptable; Frozen at -20°C or below: 3 months; Frozen at -70°C or below: 18 months
Serum: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

<u>0030192</u>	APC Resistance Profile with Reflex to Factor V Leiden	APC R
<p>Specimen Required: <u>Collect:</u> Light Blue (Sodium Citrate) AND Lavender (EDTA), Pink (K₂EDTA), or Yellow (ACD Solution A or B). Refer to Specimen Handling at aruplab.com for hemostasis/thrombosis specimen handling guidelines. <u>Specimen Preparation:</u> Transport 1.5 mL platelet-poor plasma AND 3 mL whole blood. (Min: 1 mL/each) <u>Storage/Transport Temperature:</u> Plasma: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered. Whole Blood: Frozen. <u>Unacceptable Conditions:</u> Serum, clotted or hemolyzed specimens. Frozen specimens in glass collection tubes. <u>Stability (collection to initiation of testing):</u> Plasma: Ambient: 4 hours; Refrigerated: Unacceptable; Frozen at -20°C: 3 months; Frozen at -70°C: 6 months Whole Blood: Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month</p>		
<u>3001855</u>	BRCA1 and BRCA2-Associated HBOC Syndrome Panel, Sequencing and Deletion/Duplication	BRCA NGS
<p>Methodology: Massively Parallel Sequencing</p> <p>Specimen Required: <u>Collect:</u> Lavender or pink (EDTA) or yellow (ACD solution A or B). <u>Specimen Preparation:</u> Transport 3 mL whole blood. (Min: 2 mL) <u>Storage/Transport Temperature:</u> Refrigerated. <u>Unacceptable Conditions:</u> Serum or plasma; grossly hemolyzed or frozen specimens; saliva, buccal brush, or swab; FFPE tissue. <u>Stability (collection to initiation of testing):</u> Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable</p> <p>Interpretive Data: Refer to report.</p> <p>Note: Genes tested: <i>BRCA1</i>* (NM_007294), <i>BRCA2</i> (NM_000059) *One or more exons are not covered by deletion/duplication analysis for the indicated gene; see Additional Technical Information.</p>		
<u>0070416</u>	C-Telopeptide, Beta-Cross-Linked, Serum	CTX
<p>Specimen Required: <u>Patient Prep:</u> Fasting specimen preferred. <u>Collect:</u> Serum separator tube, Lavender (K₂ EDTA or K₃ EDTA), Pink (K₂ EDTA), or Green (lithium heparin). A morning specimen is preferred. <u>Specimen Preparation:</u> Allow serum separator tube to sit for 15-20 minutes at room temperature for proper clot formation. Centrifuge and separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL) <u>Storage/Transport Temperature:</u> CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered. <u>Unacceptable Conditions:</u> Hemolyzed specimens. <u>Stability (collection to initiation of testing):</u> After separation from cells: Ambient: 4 hours; Refrigerated: 8 hours; Frozen: 3 months</p>		
<u>0020454</u>	Hepatitis B Virus Panel, Chronic with Reflex to HBsAg Confirmation	HEPCHRONIC
<p>Methodology: Qualitative Chemiluminescent Immunoassay Performed: Sun-Sat Reported: Within 24 hours</p> <p>Specimen Required: <u>Patient Prep:</u> Refer to individual components. <u>Collect:</u> Serum separator tube (SST). <u>Specimen Preparation:</u> Separate serum from cells ASAP or within 2 hours of collection. Transfer 3.5 mL serum to an ARUP Standard Transport Tube. (Min: 2.5 mL). <u>Storage/Transport Temperature:</u> Refrigerated. <u>Unacceptable Conditions:</u> Heparinized plasma, specimens that are heat-inactivated, grossly hemolyzed, grossly icteric, grossly lipemic or specimens containing particulate material. <u>Stability (collection to initiation of testing):</u> After separation from cells: Ambient: Unacceptable; Refrigerated: 7 days; Frozen: 30 days (avoid repeated freeze/thaw cycles)</p>		

<u>0020095</u>	Hepatitis Be Virus Antibody	HBEAB
Methodology:	Qualitative Chemiluminescent Immunoassay	
Performed:	Sun-Sat	
Reported:	Within 24 hours	
Specimen Required:	<p>Collect: Serum separator tube (SST). Also acceptable: Lavender (EDTA) or Green (lithium heparin).</p> <p>Specimen Preparation: Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)</p> <p>Storage/Transport Temperature: Refrigerated.</p> <p>Unacceptable Conditions: Specimens that are heat-inactivated, grossly hemolyzed, grossly icteric, grossly lipemic specimens, or specimens containing particulate material.</p> <p>Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 7 days; Frozen: 30 days (avoid repeated freeze/thaw cycles).</p>	
Interpretive Data:	<p>This assay should not be used for blood donor screening, associated reentry protocols, or for screening human cell, tissues, and cellular and tissue-based products (HCT/P).</p>	
<u>2012141</u>	Hepatitis Be Virus Antigen and Antibody Panel	HBE PAN
Methodology:	Qualitative Chemiluminescent Immunoassay	
Performed:	Sun-Sat	
Reported:	Within 24 hours	
Specimen Required:	<p>Collect: Serum separator tube (SST). Also acceptable: Lavender (EDTA) or Green (lithium heparin).</p> <p>Specimen Preparation: Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 1.5 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1.0 mL)</p> <p>Storage/Transport Temperature: Refrigerated.</p> <p>Unacceptable Conditions: Specimens that are heat-inactivated, grossly hemolyzed, grossly icteric, grossly lipemic or specimens containing particulate material.</p> <p>Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 7 days; Frozen: 30 days (avoid repeated freeze/thaw cycles)</p>	
<u>3001784</u>	Interstitial Lung Disease Autoantibody Panel	ILD PANEL
CPT Code(s):	86235 x5; 83516 x7 ; 84182 x2; 86431 ; 86200; 86039	
<u>2007370</u>	Periodic Fever Syndromes Panel, Sequencing and Deletion/Duplication	PRFEVERPAN
CPT Code(s):	81404 ; 81479	
<u>2006385</u>	Thrombotic Risk Reflexive Panel	THROMRISKR
Specimen Required:	<p>Patient Prep: Fasting preferred. Refer to Specimen Handling at aruplab.com for hemostasis/thrombosis specimen handling guidelines.</p> <p>Collect: Four Light Blue (Sodium Citrate) AND two Lavender (EDTA) AND two Serum Separator Tubes (SST). Also acceptable in place of one of the Serum Separator Tubes (SST): Green (Sodium or Lithium Heparin) or EDTA (K₂ or K₃).</p> <p>Specimen Preparation: One Serum Separator Tube (SST), Green (Sodium or Lithium Heparin) or EDTA (K₂ or K₃) must be centrifuged and serum or plasma separated within 1 hour of collection. Transfer 1 mL centrifuged serum or plasma to ARUP Standard Transport Tube and label centrifuged tube for homocysteine testing. (Min: 0.5 mL) AND Transfer 2 mL serum into 2 ARUP Standard Transport Tubes, label as serum. (Min: 0.5 mL/tube) AND Transfer 7.5 mL platelet poor plasma prepared from the sodium citrate tubes to 5 ARUP Standard Transport Tubes, label as sodium citrate. (Min: 1 mL/tube) AND Transfer 3 mL lavender whole blood to 2 ARUP Standard Transport Tubes. (Min: 1 mL/tube)</p> <p>Storage/Transport Temperature: Light Blue (Sodium Citrate): CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.</p> <p>Lavender whole blood, serum, and green (sodium or lithium heparin) or EDTA (K2 or K3): Frozen.</p> <p>Unacceptable Conditions: Specimens collected in any tube type not listed above.</p> <p>Stability (collection to initiation of testing): Light Blue (Sodium Citrate): Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 2 weeks</p> <p>Lavender Whole Blood: Ambient: 7 days; Refrigerated: 1 week; Frozen: 1 month</p> <p>Serum: Ambient: 2 hours; Refrigerated: 1 week; Frozen: 2 weeks</p> <p>Green (Sodium or Lithium Heparin) or EDTA (K₂ or K₃): Ambient: 4 days; Refrigerated: 1 month; Frozen: 10 months</p>	

0030133

Thrombotic Risk, Inherited Etiologies (Most Common) with Reflex to Factor V Leiden

THROM COM

Specimen Required: Patient Prep: Fasting preferred. Refer to Specimen Handling at aruplab.com for hemostasis/thrombosis specimen handling guidelines.
Collect: Lt. blue (sodium citrate) **AND** lavender (EDTA) or pink (K₂EDTA) **AND** serum separator tube, green (sodium or lithium heparin), or EDTA (K₂ or K₃).
Specimen Preparation: Serum Separator Tube, Green (sodium or lithium heparin), or EDTA (K₂ or K₃) must be centrifuged and serum or plasma separated within 1 hour of collection. Transfer 1 mL centrifuged serum or plasma to ARUP Standard Transport Tube and label centrifuged tube for homocysteine testing. (Min: 0.5 mL) **AND** Transport two 2 mL aliquots platelet-poor plasma (sodium citrate) (Min: 1 mL/aliquot) **AND** Transport 5 mL whole blood (EDTA). (Min: 1 mL)
Storage/Transport Temperature: **Light blue (sodium citrate):** CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Lavender whole blood and serum, green (sodium or lithium heparin): **Frozen.**
Unacceptable Conditions: Specimens collected in any tube type not listed above and frozen specimens in glass collection tubes.
Stability (collection to initiation of testing): **Light blue (sodium citrate):** Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 2 weeks
Lavender whole blood: Ambient: 7 days; Refrigerated: 1 week; Frozen: 1 month
Serum, Green (sodium or lithium heparin), or EDTA (K₂ or K₃): Ambient: 4 days; Refrigerated: 1 month; Frozen: 10 months

2006502

Tick Identification with Reflex to Borrelia Species by PCR (Lyme Disease)

TICK ID

Methodology: Qualitative Microscopy/**Macroscopy**

Specimen Required: Collect: Full intact tick, dead
Specimen Preparation: Transport tick in 70 percent ethanol in a **sterile container.** (Min: 1 tick)
Test is not performed at ARUP; separate specimens must be submitted when multiple tests are ordered.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated
Unacceptable Conditions: Dry specimens. Preservative other than 70 percent ethanol.
Stability (collection to initiation of testing): Ambient: 2 weeks; Refrigerated: 2 weeks; Frozen: Unacceptable

HOTLINE: Effective **April 4, 2022**

**The following will be discontinued from ARUP's test menu on April 4, 2022.
Replacement test options are supplied if applicable.**

Test Number	Test Name	Refer To Replacement
2013008	Periprosthetic Joint Infection (PJI) Detection (Synovasure)	