HOTLINE: Effective January 4, 2021

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	0091586	Heroin - Screen with Reflex to Confirmation/Quantitation - Urine				x								
2	0099869	Homocysteine, Total				x	x							
3	2006385	Thrombotic Risk Reflexive Panel				x	x							
5	0030133	Thrombotic Risk, Inherited Etiologies (Most Common) with Reflex to Factor V Leiden				x	x							

0091586 Heroin - Screen with Reflex to Confirmation/Quantitation - Urine HEROIN URN

Specimen Required: Collect: Random urine.
Specimen Preparation: Transfer 2 mL urine to an ARUP Standard Transport Tube. (Min: 1 mL)
Test is not performed at ARUP; separate specimens must be submitted when multiple tests are ordered.
Storage/Transport Temperature: Frozen
Unacceptable Conditions: Thawed specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 48 hours; Frozen: 3 months

0099869 Homocysteine, Total HOMOCY-QNT

Specimen Required: Collect: Green (lithium heparin), serum separator tube, or EDTA (K_2 and K_3).
Specimen Preparation: **Serum or plasma must be separated immediately after collection**. If immediate centrifugation is not possible, collected blood specimens should be kept on ice and centrifuged within one hour. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Sodium citrate.
Stability (collection to initiation of testing): Ambient: 4 days; Refrigerated: 1 month; Frozen: 10 months

Reference Interval:
Effective January 4, 2021
0-15 µmol/L, for both male and female

2006385 **Thrombotic Risk Reflexive Panel** **THROMRISKR**

Specimen Required: Patient Prep: Fasting preferred. Refer to Specimen Handling at aruplab.com for hemostasis/thrombosis specimen handling guidelines.
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 (K_2 or K_3).
Specimen Preparation: One Serum Separator Tube (SST), Green (Sodium or Lithium Heparin) or EDTA (K_2 or K_3) 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)
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) or EDTA (K_2 or K_3): Refrigerated.
Unacceptable Conditions: Specimens collected in any tube type not listed above.
Stability (collection to initiation of testing): **Light Blue (Sodium Citrate):** Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 2 weeks
Lavender Whole Blood: Ambient: 2 hours; Refrigerated: 1 week; Frozen: Unacceptable
Serum: Ambient: 2 hours; Refrigerated: 1 week; Frozen: 2 weeks
Green (Sodium or Lithium Heparin) or EDTA (K_2 or K_3): Ambient: 4 days; Refrigerated: 1 month; Frozen: 10 months

Reference Interval:

Test Number	Components	Reference Interval
	Prothrombin Time	12.0-15.5 seconds
	Dilute Russell Viper Venom Time (dRVVT)	33-44 seconds
	Dilute Russell Viper Venom (dRVVT) 1:1 Mix **(performed if dRVVT > 44 seconds)**	33-44 seconds
	Dilute Russell Viper Venom Time (dRVVT) Confirmation Test **(performed if dRVVT 1:1 Mix > 44 seconds)**	Negative
	Partial Thromboplastin Time	32-48 seconds
	Thrombin Time	14.7-19.5 seconds
	Reptilase Time	Less than 22.0 seconds
	PTT Heparin Neutralized	32-48 seconds
	Partial Thromboplastin Time 1:1 Mix **(performed if PTT > 48 seconds)**	32-48 seconds
	Platelet Neutralization Procedure **(performed if PTT 1:1 Mix > 48 seconds)**	Negative
	Hexagonal Phospholipid Neutralization	Negative
0050901	Cardiolipin Antibody, IgG	Effective August 18, 2014 0-14 GPL: Negative 15-19 GPL: Indeterminate 20-80 GPL: Low to Moderately Positive 81 GPL or above: High Positive
0050902	Cardiolipin Antibody, IgM	Effective August 18, 2014 0-12 MPL: Negative 13-19 MPL: Indeterminate 20-80 MPL: Low to Moderately Positive 81 MPL or above: High Positive
	Beta-2 Glycoprotein 1 Antibody, IgG	Effective August 18, 2014 0-20 SGU
	Beta-2 Glycoprotein 1 Antibody, IgM	Effective August 18, 2014 0-20 SMU
0098894	Protein S Free, Antigen	**Age** / **Male** / **Female** 1-89 days: 15-55% / 15-55% 90-179 days: 35-92% / 35-92% 180-364 days: 45-115% / 45-115% 1-5 years: 62-120% / 62-120% 6-9 years: 62-130% / 62-130% 10-17 years: 60-140% / 60-140% 18 years and older: 74-147% / 55-123%
0099869	Homocysteine, Total	Effective January 4, 2021 0-15 µmol/L, for both male and female
0030010	Antithrombin, Enzymatic (Activity)	**Age** / **Reference Interval** 1-4 days: 39-87% 5-29 days: 41-93% 30-89 days: 48-108% 90-179 days: 73-121% 180-364 days: 84-124% 1-5 years: 82-139% 6 years: 90-131% 7-9 years: 90-135% 10-11 years: 90-134% 12-13 years: 90-132% 14-15 years: 90-131% 16-17 years: 87-131% 18 years and older: 76-128%
0030113	Protein C, Functional	Effective November 17, 2014 **Age** / **Reference Interval** 1-4 days: 17-53% 5-29 days: 20-64% 30-89 days: 21-65% 90-179 days: 28-80% 180-364 days: 37-81% 1-6 years: 40-92%

		7-9 years: 70-142% 10-11 years: 68-143% 12-13 years: 66-162% 14-15 years: 69-170% 16-17 years: 70-171% 18 years and older: 83-168%
	APC Resistance Profile	Effective February 21, 2011 2.00 or greater **Test Number** / **Components** / **Reference Interval**: 0030127 — APC Resistance Profile — Refer to report 0097720 — Factor V Leiden (*F5*) R506Q Mutation — Refer to report
	Factor V Leiden by PCR & Fluorescence Monitoring	Negative: The sample is negative for factor V Leiden, R506Q mutation.
0056060	Prothrombin (*F2*) c.*97G>A (G20210A) Pathogenic Variant	

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 (K_2EDTA) **AND** serum separator tube, green (sodium or lithium heparin), or EDTA (K_2 or K_3).
Specimen Preparation: Serum Separator Tube, Green (sodium or lithium heparin), or EDTA (K_2 or K_3) 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 or Green (sodium or lithium heparin): Refrigerated.
Unacceptable Conditions: Specimens collected in any tube type not listed above.
Stability (collection to initiation of testing): **Light blue (sodium citrate)**: Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 2 weeks
Lavender whole blood: Ambient: 2 hours; Refrigerated: 1 week; Frozen: Unacceptable
Serum, Green (sodium or lithium heparin), or EDTA (K_2 or K_3): Ambient: 4 days; Refrigerated: 1 month; Frozen: 10 months

Reference Interval: Effective November 18, 2013

Test Number	Components	Reference Interval
0030235	Partial Thromboplastin Time	24-35 seconds
0030095	Factor VIII, Activity	**Age** / **Reference Interval**: 0-6 years: 56-191% 7-9 years: 76-199% 10-11 years: 80-209% 12-13 years: 72-198% 14-15 years: 69-237% 16-17 years: 63-221% 18 years and older: 56-191%
0099869	Homocysteine, Total	Effective January 4, 2021 0-15 µmol/L, for both male and female
0056060	Prothrombin (*F2*) c.*97G>A (G20210A) Pathogenic Variant	
0030127	APC Resistance Profile	2.0 or greater
	Factor V Leiden by PCR & Fluorescence Monitoring	Negative: The sample is negative for factor V Leiden, R506Q mutation.