

HOTLINE: Effective July 1, 2019

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	2010647	Hepatitis C Virus (HCV) NS3/4A Protease Inhibitor Resistance, GenoSure				x								
2	2007578	High Molecular Weight Kininogen (HMWK), Activity				x								
2	2004331	HIV GenoSure MG				x								
2	0092399	HIV PhenoSense GT				x								
4	2011283	HIV-1 Co-Receptor Tropism by Next Generation Sequencing (DEEPGEN)												x
4	2011279	HIV-1 Genotyping and Tropism by Next Generation Sequencing (DEEPGEN)												x

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3	0092050	Human Immunodeficiency Virus (HIV) Phenotype Comprehensive				X								
3	2010808	Human Immunodeficiency Virus Type 1 (HIV-1) Drug Resistance (PhenoSense GT Plus Integrase)				X								
3	0099289	Organic Acids, Plasma				X						X		
3	0093370	Trofile Co-Receptor Tropism				X								

2010647

Hepatitis C Virus (HCV) NS3/4A Protease Inhibitor Resistance, GenoSure

HCV NS3

Specimen Required: Collect: Lavender (K₂ or K₃EDTA), Plasma Preparation Tube (PPT), or Serum Separator Tube (SST).
Specimen Preparation: Separate from cells within 6 hours of collection. Transfer 3 mL plasma or serum to an ARUP Standard Transport Tube and freeze immediately. (Min: 2 mL)
Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 2 weeks

2007578

High Molecular Weight Kininogen (HMWK), Activity

HIGH MOLE

Specimen Required: Patient Prep: Do not draw from an arm with a heparin lock or heparinized catheter.
Collect: Light Blue (Sodium Citrate).
Specimen Preparation: Transfer 2 mL plasma to an ARUP Standard Transport Tube. (Min: 1 mL)
Storage/Transport Temperature: Frozen.
Stability (collection to initiation of testing): Ambient: 4 hours; Refrigerated: Unacceptable; Frozen: 2 weeks

2004331

HIV GenoSure MG

GENOSURE

Specimen Required: Collect: Lavender (EDTA) or plasma preparation tube (PPT).
Specimen Preparation: Separate plasma from cells within 6 hours of collection. Transfer 3 mL plasma to an ARUP Standard Transport Tube and freeze immediately. (Min: 3 mL)
Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Remarks: Provide patient's most recent viral load and viral load collection date. Procedure should be used for patients with documented HIV-1 infection and viral loads greater than 500 copies/mL.
Unacceptable Conditions: Thawed specimens.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 2 weeks

0092399

HIV PhenoSense GT

HIVPHENO GT

Specimen Required: Collect: Lavender (EDTA) or Plasma Preparation Tube (PPT).
Specimen Preparation: Separate from cells within 6 hours of collection. Transfer 3 mL plasma to an ARUP Standard Transport Tube and freeze immediately. (Min: 1 mL)
Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.
Remarks: Provide patient's most recent viral load and viral load collection date.
Unacceptable Conditions: Thawed specimens.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 2 weeks

0092050

Human Immunodeficiency Virus (HIV) Phenotype Comprehensive

HIV COMPRE

Specimen Required: Collect: Lavender (EDTA) or plasma preparation tube (PPT).

Specimen Preparation: Separate plasma from cells within 6 hours of collection. Transfer 3 mL plasma to an ARUP Standard Transport Tube and freeze immediately. (Min: 3 mL)

Storage/Transport Temperature: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**

Remarks: Provide patient's most recent viral load and viral load collection date. Procedure should be used for patients with documented HIV-1 infection and viral loads greater than 500 copies/mL.

Unacceptable Conditions: Thawed specimens.

Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: Unacceptable; **Frozen: 2 weeks**

2010808

Human Immunodeficiency Virus Type 1 (HIV-1) Drug Resistance (PhenoSense GT Plus Integrase)

PHENO PLUS

Specimen Required: Collect: Lavender (EDTA) or plasma preparation tube (PPT).

Specimen Preparation: Separate plasma from cells within 6 hours of collection. Transfer 5 mL plasma to an ARUP Standard Transport Tube and freeze immediately. (Min: 3 mL)

Storage/Transport Temperature: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**

Remarks: Provide patient's most recent viral load and viral load collection date.

Unacceptable Conditions: Thawed specimens.

Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: Unacceptable; **Frozen: 2 weeks**

0099289

Organic Acids, Plasma

ORG AC P

Specimen Required: Collect: Green (Sodium or Lithium Heparin).

Specimen Preparation: **Separate from** cells within one hour of collection. Transfer 3 mL plasma to an ARUP Standard Transport Tube. (Min: 1 mL)

Storage/Transport Temperature: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**

Remarks: **Clinical information is needed for appropriate interpretation.** Additional required information includes age, gender, diet (e.g. TPN therapy), drug therapy, and family history. **Biochemical Genetics Patient History Form is available on the ARUP Web site at <http://www.aruplab.com/patienthistory> or by contacting ARUP Client Services.**

Unacceptable Conditions:

Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: **5 months**

HOTLINE NOTE: There is a unit of measure change associated with this test.

Change the unit of measure for component 0081044, Lactic Acid, Plasma from nmol/mL to **umol/L**.

Change the unit of measure for component 0081045, Pyruvic Acid, Plasma from nmol/mL to **umol/L**.

Change the unit of measure for component 0081046, Succinic Acid, Plasma from nmol/mL to **umol/L**.

Change the unit of measure for component 0081047, 3-OH-Butyric Acid, Plasma from nmol/mL to **umol/L**.

Change the unit of measure for component 0081048, Acetoacetic Acid, Plasma from nmol/mL to **umol/L**.

Change the unit of measure for component 0081049, 2-Keto-3-methylvaleric Acid, Plasma from nmol/mL to **umol/L**.

Change the unit of measure for component 0081050, 2-Ketoisocaproic Acid, Plasma from nmol/mL to **umol/L**.

Change the unit of measure for component 0081051, 2-Ketoisovaleric Acid, Plasma from nmol/mL to **umol/L**.

Change the unit of measure for component 3001293, Glutaric Acid, Plasma from nmol/mL to **umol/L**.

0093370

Trofile Co-Receptor Tropism

TROFILE

Specimen Required: Collect: Lavender (EDTA) or plasma preparation tube (PPT).

Specimen Preparation: Separate plasma from cells within 6 hours of collection. Transfer 3 mL plasma to an ARUP Standard Transport Tube and freeze immediately. (Min: 3 mL)

Storage/Transport Temperature: **CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.**

Remarks: Provide patient's most recent viral load and viral load collection date. Procedure should be used for patients with documented HIV-1 infection and viral loads greater than 1000 copies/mL.

Unacceptable Conditions: Thawed specimens.

Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: Unacceptable; **Frozen: 2 weeks**

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**The following will be discontinued from ARUP's test menu on July 1, 2019.
Replacement test options are supplied if applicable.**

Test Number	Test Name	Refer To Replacement
2011283	HIV-1 Co-Receptor Tropism by Next Generation Sequencing (DEEPGEN)	
2011279	HIV-1 Genotyping and Tropism by Next Generation Sequencing (DEEPGEN)	