HOTLINE: Effective August 16, 2021

New Test **3003853** **Human Immunodeficiency Virus 1 Drug Resistance by Next Generation Sequencing** **HIV1 NGS**

Methodology: Massively Parallel Sequencing
Performed: Sunday-Saturday
Reported: 4-10 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA) or plasma preparation tube.
Specimen Preparation: Separate plasma from cells within 24 hours. Transfer 2.5 mL plasma to an ARUP Standard Transport Tube. (Min: 1.5 mL)
Storage/Transport Temperature: Frozen.
Remarks: Please submit most recent viral load and test date, if available.
Unacceptable Conditions: Serum. Heparinized specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 72 hours; Frozen: 3 months

Reference Interval: By report

Interpretive Data:

This assay predicts HIV-1 resistance to protease inhibitors, nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors and integrase inhibitors. The protease gene, integrase gene and the reverse transcriptase gene of the viral genome are sequenced using Next Generation Sequencing. Drug resistance is assigned using the Stanford hivdb database.

This test should be used in conjunction with clinical presentation and other laboratory markers. A patient's response to therapy depends on multiple factors, including patient adherence, percentage of resistant virus population, dosing, and drug pharmacology issues.

This test detects populations down to 10 percent of the total population which may account for resistance interpretation differences between methods. Some insertions or deletions may be difficult to detect using this software.

This test was developed, and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Note: This test may be unsuccessful if the plasma HIV-1 RNA viral load is less than 500 copies per mL of plasma.

CPT Code(s): 87900; 87901; 87906

New York DOH approval pending. Call for status update.

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