MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: May 02, 2022
Effective Date: May 31, 2022

HIV-1 Genotypic Drug Resistance to Reverse Transcriptase, Protease, and Integrase Inhibitors, Plasma

Test ID: HIVDR

Useful for:

Identifying HIV-1 genotypic mutations associated with resistance to nucleotide and non-nucleoside reverse-transcriptase inhibitors, protease inhibitors, and integrase strain transfer inhibitors

Guiding initiation or change of combination antiretroviral therapy in individuals, including children, with HIV-1 infection

Methods:

Reverse Transcription Polymerase Chain Reaction (RT-PCR) followed by Targeted Next-Generation Sequencing (NGS)

Reference Values:

An interpretive report will be provided.

Specimen Requirements:

Collection Container/Tube:	Lavender top (EDTA)
Submission Container/Tube:	Plastic vial (T465)
Specimen Volume:	2.2 mL
Collection Instructions:	1. Centrifuge blood collection tube and aliquot plasma into plastic vial per collection tube manufacturer's instructions (eg, centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes). 2. Freeze aliquoted plasma for shipment.
Minimum Volume:	0.8 mL
Additional Information:	Specimens submitted for HIV-1 genotyping must contain 1,000 copies/mL or more of HIV-1 RNA.

Specimen Stability Information:

Specimen Type	Temperature	Time
Plasma EDTA	Frozen (preferred)	60 days
	Refrigerated	7 days

Necessary Information:

The following ask-at-order entry questions must be answered at the time of test ordering:

Questions	Possible Answers
HIV RNA level copies/mL <30 days =	<1,000 copies/mL 1,000 to 1,000,000 copies/mL 1,000,001 to 10,000,000 copies/mL >10,000,000 copies/mL

Note: Test requests for submitted specimens with <1,000 copies/mL or an unclear response will be cancelled.

Cautions:

Due to the complexity of the results generated, the International AIDS Society-USA Panel recommends expert interpretation of genotyping and phenotype test results for patient care management. A patient's response to antiviral therapy depends on multiple factors, including the percentage of patient's viral populations that is drug resistant, patient compliance with the prescribed drug therapy, patient access to adequate care, drug pharmacokinetics, and drug interactions. Drug resistance test results should be interpreted only in conjunction with clinical presentation and other laboratory markers when making therapeutic decisions.

Absence of resistance to a drug does not rule out the presence of reservoirs of drug-resistant virus in the infected individual.

The HIV-1 genotypic test is not a direct measure of drug resistance. Although genotypic testing can detect variants in the relevant HIV-1 genome, the significance of these variants requires careful interpretation to predict drug susceptibility. This assay's ability to amplify the target and detect genotypic mutation is poor and unreliable when the plasma HIV-1 viral load (VL) is less than 1,000 copies/mL. Specimens submitted for this test should contain greater than or equal to 1,000 copies/mL of HIV-1 RNA. Per assay manufacturer claims, the assay's ability to detect minor drug-resistant HIV-1 variants among 90% or more of HIV-1 group M strains varies depending on the VL in the tested plasma specimen; 20% or higher at VL of 1,000 copies/mL, 10% or higher at VL of 5,000 copies/mL, and 5% or higher at VL of 15,000 copies/mL.

The list of drug resistance-associated codon mutations and interpretive rules used by the Stanford HIV database are updated periodically by the Stanford HIV Database team. Therefore, the test results do not necessarily include all of the resistance-associated codon mutations described in the current medical literature.

Possible causes of treatment failure other than the development of drug resistance are poor adherence to medication regimen, drug potency, and individual variation in pharmacokinetics (eg, inadequate phosphorylation of nucleosides).

CPT Code:

0219U

Day(s) Performed: Monday through Friday **Report Available:** 3 to 10 days

Questions

Contact James Conn, Laboratory Technologist Resource Coordinator at 800-533-1710.