Lab Dept:	**Microbiology/Virology**
Test Name:	**HIV-1 GENOTYPIC DRUG RESISTANCE TO REVERSE TRANSCRIPTASE, PROTEASE, AND INTEGRASE INHIBITORS**

General Information

Lab Order Codes:	GHIVD
Synonyms:	
CPT Codes:	0219U – HIV-1 Genotypic Drug Resistance
Test Includes:	Amplification and analysis of drug-targeted HIV-1 gene sequences

Logistics

Test indications:	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.
Lab Testing Sections:	Microbiology/Virology - Sendouts
Referred to:	Mayo Medical Laboratories (MML: HIVDR)
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours
Turnaround Time:	3 – 10 days
Special Instructions:	Prior to requesting this test, patients must have a confirmed plasma HIV-1 RNA level of 1,000 copies/mL or higher within the preceding 30 days. If the patient's viral load is unknown, order HIV-1 RNA Quantification with Reflex to Genotypic Drug Resistance, which will perform viral load followed by genotype, if appropriate.

Specimen

Specimen Type:	Blood

Container:	Lavender top (EDTA) tube
Draw Volume:	6.6 mL (Minimum 2.4 mL) blood
Processed Volume:	2.2 mL (Minimum 0.8 mL) EDTA plasma
Collection:	Routine blood collection, invert tube several times to mix so no clots form. Send to Children's laboratory as soon as possible for shipping to the reference lab facility.
Special Processing:	Lab Staff: Immediately centrifuge blood (within 2 hours of collection). Immediately remove plasma from cells and transfer to a plastic screw capped tube. Store frozen and ship at frozen on dry ice. If shipment is delayed for >24 hours, freeze specimen at -70°C (up to 35 days) until shipment on dry ice.
Patient Preparation:	None
Sample Rejection:	Collected in wrong tube; specimen thawed; mislabeled or unlabeled specimens; submitted specimens with <1,000 copies/mL.

Interpretive

Reference Range:	An interpretive report will be provided.
Critical Values:	N/A
Limitations:	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 genotypic variant codons 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 drug-related mutations described in 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).

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

References:

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