

Georgia Esoteric & Molecular Labs, LLC

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HIV-1 Drug Resistance Genotyping Analysis

Test Ordering Code:	1081
CPT Codes:	87901
Specimen:	Plasma samples collected in EDTA anticoagulant tube (lavender top, vacutainer PPT). Remove EDTA plasma from cells within 30 minutes and PPT samples within 2 hours of collection and store it in at least -20° C freezer, preferably in -70° C. Samples will be picked up by GEM Labs as scheduled.
Turnaround Time:	7-15 business days
Clinical Significance:	At the beginning of the diagnosis of HIV-1 infection, this test can establish a specific patient viral strain profile to assess any drug resistant HIV-1 strains. Throughout the whole therapy with anti-retroviral drugs, this test is used to monitor the emergence of drug resistant variants, and guide the treatment by replacing non-responding drugs with sensitive ones.
Indications for Testing:	Drug therapy failure (with increased viral load) Before initial drug therapy
Methodology:	Reverse transcription polymerase chain reaction (RT-PCR), DNA sequencing with FDA approved in vitro diagnostic reagents, and software from Abbott. The sequence of the entire protease gene and two-thirds of the reverse transcriptase gene of the patient sample is compared to a known reference strain, HXB-2, to identify mutations. The relative impacts of these mutations are interpreted as probabilities of resistance to commonly prescribed antiretroviral drugs based on a proprietary algorithm.
Reporting of Results:	Negative: The patient does not have any known drug resistant mutations Positive: List of drugs and drug resistant mutations
Intended Use:	Detection of HIV-1 subtype B viral drug resistance strains in samples with a viral load range from 2000 to 750,000 copies /mL
References:	ViroSeq™ HIV-1 Genotyping System v2.0 Operator's manual