
Lab Dept: Microbiology/Virology

Test Name: HIV-1 ULTRASENSITIVE GENOTYPIC DRUG RESISTANCE MUTATION ANALYSIS

General Information

Lab Order Codes: GHIVS

Synonyms: HIV -1 Resistance; HIV-1 Genotyping for Drug Resistance

CPT Codes: 87901 – Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV 1, reverse transcriptase and protease

Test Includes: Amplification and analysis of drug-targeted HIV-1 gene sequences.

Logistics

Test Indications: Identification of HIV-1 genotypic mutations associated with resistance to nucleotide reverse-transcriptase inhibitors, non-nucleotide reverse-transcriptase inhibitors, and protease.

Guiding initiation or change of drug combinations for the treatment of HIV-1 RNA.

Lab Testing Sections: Microbiology/Virology – Sendout

Referred to: Mayo Medical Laboratories (MML: HIVPR)

Phone Numbers: MIN Lab: 612-813-6280

STP Lab: 651-220-6550

Test Availability: Daily, 24 hours

Turnaround Time: 2 days, performed Monday - Thursday

Special Instructions: Plasma specimens submitted for this test should contain > or =500 copies per/mL of HIV-1 RNA.

Specimen

Specimen Type: Blood

Container: Lavender top (EDTA) tube

Draw Volume: 6.6 mL (Minimum 3.6 mL) blood

Processed Volume:	2.2 mL (Minimum: 1.2 mL) EDTA plasma
Collection:	Routine venipuncture, 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 6 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 with dry ice.
Patient Preparation:	None
Sample Rejection:	Collected in wrong tube; specimen thawed; mislabeled or unlabeled specimens

Interpretive

Reference Range: Not applicable

Interpretation: Detectable HIV-1 genotypic mutations conferring resistance to an antiviral drug are reported as amino acid codon changes (eg, M194V) resulting from mutations in the viral nucleotide sequence.

Susceptible indicates that the genotypic mutations present in patient's HIV-1 strain have not been associated with resistance to the specific drug in question.

Resistant indicates that genotypic mutations detected have been associated with maximum reduction in susceptibility to the specific drug.

Possibly resistant indicates that genotypic mutations detected have been associated with 1 or both of the following outcomes:

- Diminished virologic response in some, but not all, patients having virus with these mutations.
- Intermediate decrease in susceptibility of the virus to the specific drug.

Insufficient evidence indicates that there is adequate direct or indirect evidence to determine susceptibility of the virus to the specific drug on the basis of the genotypic mutations present, according to the opinion of the consensus panel of leading experts in the field of HIV-1 resistance.

Unable to genotype indicates that the sequence data obtained are of poor quality to determine the presence or absence of genotypic resistant mutations in the patient's HIV-1 strain. Possible causes of such poor sequence data include low HIV-1 viral load (eg, <500 copies/mL) and polymorphisms in the region of the sequencing primers interfering with primer bonding and subsequent sequencing reactions.

Critical Values: N/A

Limitations:

The HIV-1 genotypic drug resistance test is not a direct measure of drug resistance. Although this test can detect mutations in the relevant HIV-1 genome sequences, the significance of these mutations requires careful interpretation to predict drug susceptibility. This assay's ability to amplify the target and detect genotypic mutations is poor and unreliable when plasma HIV-1 vira load is <500 copies/mL. Specimens submitted for this test should contain > or =500 copies/mL of HIV-1 RNA.

Methodology:

Reverse transcription-polymerase chain reaction (RT-PCR), and DNA sequencing

References:

[Mayo Medical Laboratories](#) June 2015

Updates:

6/25/2015: Method update, specimen volume update, test code update.