HIV-1 Genotypic Drug Resistance Sequencing
Test Code: 1901

Clinical and Procedure

Clinical Utility
HIV-1 Genotypic Drug Resistance Sequencing detects viral genomic mutations known to confer resistance to antiretroviral therapies and provides an estimate of susceptibility to medications including:

- Nucleoside reverse-transcriptase inhibitors (NRTI)
- Non-nucleoside reverse-transcriptase inhibitors (NNRTI)
- Protease inhibitors (PI)
- Integrase inhibitors (INI)

Susceptibility profile is determined based on the Stanford University HIV Drug Resistance Database. See the Stanford University website for a complete list of regions evaluated, associated susceptibility and references: http://hivdb.stanford.edu/pages/references.html.

Procedure
The HIV-1 Genotypic Drug Resistance assay utilizes RT-PCR amplification with primers in highly conserved viral genomic regions to amplify three fragments covering HIV-1 subtypes B, A, AE, AG, C, D, and G. These three regions include protease, a large portion of reverse-transcriptase where resistance mutations have been reported, and integrase. The fragments are purified and sequenced using sequencing primers from conserved regions of the fragments. The trimmed derived sequence is examined for resistance mutations using the curated Stanford University HIV-1 Drug Resistance Database (Soo-Yon R. et. al., 2003) and the REGA HIV-1 subtyping tool to determine the subtype (de Oliveira T. et. al. 2005 and Alcantara LCJ. et. al. 2009). The Stanford University HIV-1 Drug Resistance Database detects mutations known to confer resistance to antiretroviral therapies. Mutations are scored and these scores are converted to provide qualitative results estimating susceptibility to medications. These medications include nucleoside reverse-transcriptase inhibitors, non-nucleoside reverse-transcriptase inhibitors, protease inhibitors and integrase inhibitors. The actual quantitative score can be provided to physicians at their request. The minimum sequences that are required to generate a valid result are codons 10-93 for protease inhibitors (PI), codons 40-219 for nucleoside reverse transcriptase inhibitors (NRTI), codons 90-348 for non-nucleoside reverse transcriptase inhibitors (NNRTI), and codons 51-263 for integrase inhibitors.

Turnaround Time
4-6 business days from receipt of specimen

Specimen Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Order Code</th>
<th>CPT Code</th>
<th>NY Approved</th>
<th>Volume</th>
<th>Assay Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>plasma</td>
<td>1901</td>
<td>87901 (x1), 87906 (x1)</td>
<td>Yes</td>
<td>2 mL (min. 1 mL/ min. viral load 600 copies/mL)</td>
<td>Subtype of HIV-1 will be reported as B, A, AE, AG, C, D or G. Mutations in the protease inhibitor, reverse-transcriptase, and integrase genes will be reported as indicating the mutation detected/None. Interpretation of gene mutations and association with antiviral resistance will be reported as Susceptible, Potential low-level resistance, Low-level</td>
</tr>
</tbody>
</table>
Specimen Type | Order Code | CPT Code | NY Approved | Volume | Assay Range
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**Special Instructions**
- Collect 4-5 mL whole blood in EDTA or ACD tube.
- Centrifuge and transfer 2 mL plasma to sterile, screw top tube and freeze.
- Ship on dry ice Monday through Friday.

Subtype of HIV-1 will be reported as B, A, AE, AG, C, D or G. Mutations in the protease inhibitor, reverse-transcriptase, and integrase genes will be reported as indicating the mutation detected/None. Interpretation of gene mutations and association with antiviral resistance will be reported as Susceptible, Potential low-level resistance, Low-level resistance, Intermediate resistance, or High-level resistance.

**Shipping**
Ship Monday through Friday. Friday shipments must be labeled for Saturday delivery. All specimens must be labeled with patient’s name and collection date. A Viracor Eurofins test requisition form must accompany each specimen. Multiple tests can be run on one specimen. Ship specimens FedEx Priority Overnight® to: Viracor Eurofins, 1001 NW Technology Dr, Lee's Summit, MO 64086.

**Causes for Rejection**
HIV-1 RNA concentrations too low to allow antiviral resistance testing (see above for minimum volume and viral load), whole blood frozen, specimens beyond their acceptable length of time from collection as listed in the specimen handling, or specimen types other than those listed.

**Disclaimer**
Specimens are approved for testing in New York only when indicated in the Specimen Information field above.

The CPT codes provided are based on Viracor Eurofins’ interpretation of the American Medical Association’s Current Procedural Terminology (CPT) codes and are provided for informational purposes only. CPT coding is the sole responsibility of the billing party. Questions regarding coding should be addressed to your local Medicare carrier. Viracor Eurofins assumes no responsibility for billing errors due to reliance on the CPT codes illustrated in this material.

PCR tests are performed pursuant to a license agreement with Roche Molecular Systems, Inc.

**References**
