HIV-1 Integrase Genotyping
Test Code: 1950

Clinical and Procedure

Clinical Utility
HIV-1 Integrase Genotyping assay detects viral genomic mutations known to confer resistance to **integrase inhibitors (INI)** and provides a susceptibility estimate. The 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](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 a fragment of the integrase gene covering HIV-1 subtypes B, A, AE, AG, C, D, and G. The fragment is purified and sequenced using sequencing primers from a conserved region of the fragment. The trimmed derived sequence is examined for resistance mutations using the curated Stanford University HIV-1 Drug Resistance Database. 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 integrase inhibitor medications. The actual quantitative score can be provided to physicians at their request. A minimum sequence length, which covers codons 51-263, is required to generate a valid result. This test was developed and its performance characteristics determined by Viracor Eurofins. It has not been cleared or approved by the U.S. Food and Drug Administration.

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>1950</td>
<td>87906</td>
<td>Yes</td>
<td>2 mL (min. 1 mL with viral load of 600 copies/mL)</td>
<td>Mutations in the integrase gene will be reported as indicating the mutation detected/None. Interpretation of gene mutations and association with antiviral resistance will be provided with the report.</td>
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</table>

**Special Instructions**
- Collect 4-5 mL whole blood in EDTA or ACD tube.
- Centrifuge and transfer 2 mL plasma to a sterile, screw top tube and freeze.
- Ship on dry ice Monday through Friday.

Mutations in the integrase gene will be reported as indicating the mutation detected/None. Interpretation of gene mutations and association with antiviral resistance will be provided with the report.

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

