GenoSure PRIme®
A COMPREHENSIVE RESISTANCE PROFILE IN A SINGLE TEST
To Aid in First-line Therapy Decisions

• The Department of Health and Human Services guidelines for antiretroviral use in patients with HIV-1 recommend genotypic testing as the preferred resistance testing in treatment-naive patients.¹
• GenoSure PRIme is the first assay to provide genotypic resistance information on all DHHS-preferred first-line treatment options, including those containing integrase inhibitors.
• Recent studies have demonstrated the transmission of drug-resistant viruses in up to 16% of treatment-naïve patients.¹
• Testing for integrase strand transfer inhibitors (INI) may be warranted² and should be obtained if there is a concern for resistance to this class of drugs.¹

Consider GenoSure PRIme for baseline resistance testing and detection of transmitted drug resistance.

To Aid in Therapy Decisions for Treatment-experienced Patients

• The DHHS guidelines recommend genotypic testing as the preferred resistance test for patients experiencing virologic failure while on first- or second-line antiretroviral therapy.¹
• In patients failing integrase inhibitor-based regimens, genotypic testing for integrase inhibitor resistance should be considered.¹
• Genotypic testing using GenoSure PRIme provides an assessment of viral susceptibility to every commercially available PI, NRTI, NNRTI, and INI in a single assay.

Consider GenoSure PRIme when contemplating changes to your patient’s course of therapy.

Features of GenoSure PRIme

• GenoSure PRIme is the first HIV-1 genotype to provide susceptibility information for four drug classes in a single report: NRTIs, NNRTIs, PIs, and INIs.
• GenoSure PRIme evaluates the HIV-1 polymerase (pol) region including the complete protease and integrase coding regions and amino acids 1-400 of reverse transcriptase.
• GenoSure PRIme uses Monogram’s proprietary database of more than 100,000 matched HIV-1 genotype-phenotype results.
A single assay providing a comprehensive picture of resistance to PIs, NRTIs, NNRTIs, and INIs.

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Drug Resistance Associated Mutations Detected</th>
<th>Drug</th>
<th>Assessment</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abacavir</td>
<td>Ziagen</td>
<td>L74V, T118I, M184V</td>
<td>ABC</td>
<td>Resistant</td>
<td></td>
</tr>
<tr>
<td>Didanosine</td>
<td>Videx</td>
<td>L74V, T118I, M184V</td>
<td>ddI</td>
<td>Resistant</td>
<td></td>
</tr>
<tr>
<td>Emtricitabine</td>
<td>Emtriva</td>
<td>M184V</td>
<td>FTC</td>
<td>Resistant</td>
<td></td>
</tr>
<tr>
<td>Lamivudine</td>
<td>Epivir</td>
<td>M184V</td>
<td>3TC</td>
<td>Resistant</td>
<td></td>
</tr>
<tr>
<td>Stavudine</td>
<td>Zirena</td>
<td>T97A, Y143R</td>
<td>TDF</td>
<td>Sensitive</td>
<td></td>
</tr>
<tr>
<td>Tenofovir</td>
<td>Viread</td>
<td>T97A</td>
<td>TFV</td>
<td>Sensitive</td>
<td></td>
</tr>
<tr>
<td>Zidovudine</td>
<td>Retrovir</td>
<td>None</td>
<td>TVDR</td>
<td>Sensitive</td>
<td></td>
</tr>
</tbody>
</table>

**Prescriptions**

- A comprehensive summary of all mutations observed in each region is provided. This may be useful for tracking longitudinal changes and development of novel resistance mutations.
- Lists key resistance-associated mutations.
- Provides an assessment of susceptibility: sensitive, resistant, or resistance possible.

**Summary of Mutations Observed**

1. Assessment for this drug was derived considering the sensitizing effect of L74V and M184V.
2. Assessment for this drug was derived considering the sensitizing effect of M184V.

For more information or to order this test, please visit www.MonogramNY.com or call Customer Service at 800-777-0177 between the hours of 6:30am to 5:00pm ET Monday through Friday.
Summary

For Treatment-naïve Patients
DHHS panel recommendations include more than 20 drug combinations as initial treatment options for treatment-naïve patients.¹ These include members of the PI, NRTI, NNRTI, and INI classes of antiretrovirals.

For Treatment-experienced Patients
The management of patients on antiretroviral therapy is complex. As many as 20% of patients on antiretroviral therapy experience treatment failure due to drug resistance.³

GenoSure PRIme provides a complete picture of resistance to PIs, NRTIs, NNRTIs, and INIs to aid in selecting the optimal therapy for each patient.

### Test Name HIV-1 GenoSure PRIme

<table>
<thead>
<tr>
<th>Test Name</th>
<th>LabCorp Test Number</th>
<th>Specimen Collection</th>
<th>Limitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>GenoSure PRIme</td>
<td>551700</td>
<td>5 mL plasma in an EDTA or PPT tube, shipped frozen</td>
<td>This procedure may not be successful when the HIV viral load is &lt;500 copies/mL. If there is insufficient virus to produce results, HIV-1 RNA Quantitation will be performed to confirm viral load, resulting in a separate CPT code.</td>
</tr>
</tbody>
</table>

For full test information, visit LabCorp's online test menu at [www.LabCorp.com/testmenu](http://www.LabCorp.com/testmenu).

GenoSure PRIme is also available as a reflex from a quantitative viral load.

**HIV-1, quantitative, real-time PCR (Graphical) With reflex to HIV-1 GenoSure PRIme** .......... 550630

**HIV-1, quantitative, real-time PCR (Nongraphic) With reflex to HIV-1 GenoSure PRIme** ....... 550655

References

