**SPECIMEN SUBMISSION GUIDELINES**

HIV Diagnostics and Reference Laboratory
US Military HIV Research Program, Walter Reed Army Institute of Research
9100 Brookville Road, BLDG 508, Silver Spring, MD 20910

**HIV-1 Phenotype (sent out to Monogram Biosciences) Test Specification**

<table>
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<tr>
<th>Clinical Significance</th>
<th>Specimen Requirements</th>
<th>Transport/Storage Temperature</th>
<th>Test Approved For</th>
<th>Turn Around Time (After Receipt at HDRL)</th>
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</thead>
<tbody>
<tr>
<td>To aid clinicians in selection of most effective antiretroviral regimens for patients who are highly resistant to antiretroviral agents due to long-term therapy. Sent out to Monogram BioSciences reference lab.</td>
<td>Minimum of 4 ml non-heparinized plasma from either PPT or EDTA tubes. Centrifuge at room temperature at 1000 – 1200 x g for 10 – 15 minutes within separation times below: PPT Tubes: Centrifuge immediately or within 2 hours of collection. Separate plasma. Aliquot into sterile 2 ml polypropylene screw-cap tubes at 1 ml per tube. Store frozen at -20 to -80°C until shipped. EDTA Plasma: Centrifuge within 4 hours of collection. Separate plasma. Aliquot into sterile 2 ml polypropylene screw cap tubes at 1 ml per tube. Store frozen at -20 to -80°C until shipped.</td>
<td>Frozen Use 2 lbs. of dry ice per day of transport. Recommended: Ship on 6 lbs dry ice in case of shipment delay.</td>
<td>Non FDA approved Used to inform selection of therapeutic regimens for patients failing therapy.</td>
<td>25 business days</td>
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</tbody>
</table>

**Please note:**

1. HIV-1 Genotype results should indicate resistance to a majority of antiretroviral drugs.
2. **Patient Viral Load must be ≥ 500 copies/ml at time of test.** If Viral Load results are not current within the past 30 days, request an HIV-1 Viral Load on the test request form in addition to the HIV-1 Phenotype request. HDRL will not forward specimens for HIV-1 Phenotyping with Viral Loads < 500 copies/ml, or if HIV-1 genotype does not indicate antiretroviral resistance.

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