

## SPECIMEN SUBMISSION GUIDELINES

HIV Diagnostics and Reference Laboratory, Diagnostics and Countermeasures Branch  
Center for Infectious Disease Research, Walter Reed Army Institute of Research  
508 Research Drive, Silver Spring, MD 20910

### *HIV-1 Phenotype (sent out to Reference Laboratory) Test Specification*

<b>Test Name: HIV-1 Phenotype</b>				
<b>Clinical Significance</b>	<b>Specimen Requirements</b>	<b>Transport/Storage Temperature</b>	<b>Test Approved For</b>	<b>Turn Around Time (After Receipt at HDRL)</b>
<p>To aid clinicians in selection of most effective antiretroviral regimens for patients who are highly resistant to antiretroviral agents due to long-term therapy.</p> <p>Sent out to Monogram BioSciences:</p>	<p>Minimum of 4 ml non-heparinized plasma from either PPT or EDTA tubes.</p> <p>Centrifuge at room temperature at 1000 – 1200 x g for 10 – 15 minutes within separation times below:</p> <p>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.</p> <p>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.</p> <p><b><u>Please note:</u></b> Patients presently on antiretroviral drug therapy should still be on their drug regimen when blood specimen collected.</p>	<p>Frozen</p> <p>Use 2 lbs. of dry ice per day of transport.</p> <p>Recommended: Ship on 6 lbs dry ice in case of shipment delay.</p>	<p>Not FDA approved</p> <p>Used to inform selection of therapeutic regimens for patients failing therapy.</p>	<p>25 business days</p>
<p><b><u>Please note:</u></b></p> <ol style="list-style-type: none"> <li>1. HIV-1 Genotype results should indicate resistance to a majority of antiretroviral drugs.</li> <li>2. <b>Patient Viral Load must be <math>\geq 500</math> copies/ml at time of test.</b> 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. <b>HDRL will not forward specimens for HIV-1 Phenotyping with Viral Loads <math>&lt; 500</math> copies/ml, or if HIV-1 genotype does not indicate antiretroviral resistance.</b></li> </ol>				

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