

## 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 Integrase Genotype Test Specification*

<b>Test Name: HIV-1 Integrase Genotype</b>				
Clinical Significance	Specimen Requirements	Transport/Storage Temperature	Test Approved For	Turn Around Time
<p>Intended for use in detecting genomic mutations in Integrase region of HIV-1 conferring resistance to specific types of antiretroviral drugs.</p> <p>Intended for use in conjunction with clinical presentation and other laboratory markers as an indicator of disease progression and as an assay to monitor or assess viral response to antiretroviral treatment</p> <p>The test is available for all patients who are: (1) initiating drug therapy; (2) not responding to antiretroviral drug therapy (low viral RNA level at 1,000 to 3,000 copies/ml); or (3) failing their antiretroviral regimen.</p> <p>FDA-not approved, Laboratory Developed Test using commercially available test kit from Abbott Viroseq HIV-1 Integrase Genotype.</p>	<p>Two (2) vials of non-heparinized plasma at 1 ml per tube</p> <p>Centrifuge at room temperature at 800-1600 x g for 20 minutes within separation times below:                      PPT Tubes: Centrifuge immediately or within 2 hours of collection. Store at ambient temperature for overnight delivery, or transfer to sterile 2.0 ml polypropylene screw-cap tubes at 1 ml per tube and store at -60 to -80°C.</p> <p>EDTA Plasma: Store blood at 25°C until centrifuged. Centrifuge within 4 hours of collection. Aliquot EDTA plasma to sterile 2.0 ml polypropylene screw cap tubes at 1 ml per tube. Store at -70°C.</p> <p><b>Please note:</b> Patients presently on antiretroviral drug therapy should still be on their drug regimen when specimen is collected.</p>	<p>PPT Tubes: Store spun tubes refrigerated (2-8°C) for overnight or same day delivery. If transport longer than overnight or same day, aliquot plasma, freeze at -70°C, then ship frozen. Store plasma frozen (-70°C or colder).</p> <p>EDTA Plasma: Store refrigerated (2-8°C) for overnight or same day delivery. If transport longer than overnight or same day, aliquot plasma, freeze at -70°C, then ship frozen. Store plasma frozen (-70°C or colder).</p> <p>Use 2 lbs. dry ice per day of transport.</p> <p>Recommended: Ship on 6 lbs dry ice in case of shipment delay.</p>	<p>This test was developed and its performance characteristics determined by HDRL. It has not been cleared or approved by the US Food and Drug Administration.</p>	<p>15 business days after receipt at HDRL.</p> <p>Due to low volume of tests requested, samples are batched for testing.</p>
<p><b>Please note:</b></p> <ol style="list-style-type: none"> <li>1. Viral load MUST BE <math>\geq</math> 2000 copies/ml and result must have been obtained within the past 30 days. Viroseq HIV-1 Integrase Genotype testing can be performed if viral load is between 1000 to 2000 copies /ml, but a resistance profile may not be generated.</li> <li>2. When requesting HIV-1 Integrase Genotype, requesting lab must provide most recent Viral Load result on request form at time of submission.</li> <li>3. If the patient has not had a Viral Load determination within the past 30 days, request a HIV-1 Viral Load along with the HIV-1 Integrase Genotype request.</li> <li>4. Any specimen without a Viral Load reported (or a Viral Load requested) on the request form will need resolution and may affect Turn Around Time.</li> <li>5. Duplicate specimens will be discarded.</li> <li>6. Treatment Decision should be made in consideration of all relevant clinical and laboratory findings and the prescribing information of the drug in question.</li> </ol>				

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