

| <b>HIV-1 RNA Viral Load</b>              |  |
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| <b>Test description</b>                  | The Aptima HIV-1 Quant Dx assay is for the detection and quantitation of human immunodeficiency virus type 1 (HIV-1).  |
| <b>Test uses</b>                         | For use as an aid in diagnosis of HIV-1 infection using appropriate HIV testing algorithms. The presence of HIV-1 nucleic acid in the plasma or serum of individuals without antibodies to HIV-1 is indicative of acute or primary infection.<br>The Aptima HIV-1 Quant Dx is also intended for use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in monitoring the effects of antiretroviral treatment, as measured by changes in plasma HIV-1 RNA levels.   |
| <b>Test department</b>                   | Virology<br>Phone: (860) 920-6662, FAX (860) 920-6661  |
| <b>Methodology</b>                       | Aptima HIV-1 Quant assay detects and quantitates HIV-1 RNA groups M, N, and O over the range of 30 to 10,000,000 copies/mL.  |
| <b>Availability</b>                      | Weekly as needed   |
| <b>Specimen requirements</b>             | <b>Quantitative (Viral Load Monitoring):</b> 1.5 mL <b>plasma only</b> collected in tubes containing EDTA or Acid Citrate Dextrose (ACD) anticoagulants, or in Plasma Preparation Tubes (PPTs)<br><b>Qualitative (HIV-1 Diagnosis):</b> 1.5 mL <b>plasma</b> as listed above or 1.5 mL <b>serum</b> .  |
| <b>Collection kit/container</b>          | To obtain collection kit, refer to Collection Kit Ordering Information   |
| <b>Collection instructions</b>           | Standard venipuncture  |
| <b>Specimen handling &amp; transport</b> | Whole blood can be stored at 2°C to 30°C and must be centrifuged within 24 hours of collection.<br><b>Plasma:</b> Centrifuged specimen can be stored in the PPT or primary collection tube at 2°C to 8°C for up to 3 days. Plasma transferred to a secondary tube can be stored at 2°C to 8°C for up to 5 days, or at -20°C or colder for up to 90 days.<br><b>Serum:</b> Centrifuged specimen can be stored in the SST or serum tube at 2°C to 8°C for up to 5 days. Serum transferred to a secondary tube can be stored at 2°C to 8°C for up to 5 days, or at -20°C or colder for up to 90 days.<br>Transport to laboratory with ice packs.  |
| <b>Unacceptable conditions</b>           | Unlabeled specimens<br>Specimens that have leaked or containers that have broken in transit<br>Specimens not handled, stored, or transported as described above  |
| <b>Requisition form</b>                  | Clinical Test Requisition OL-9B (select or write in: <b>HIV-1 RNA Viral Load</b> )   |
| <b>Required information</b>              | Name and address of submitter. Two patient identifiers (ie.name, DOB, Acc.#, MRN), Town of residence (city, state, zip), specimen source/type, date collected, test(s) requested. Please ensure information on the requisition matches that on the specimen.   |
| <b>Limitations</b>                       | <ul style="list-style-type: none"> <li>* Reliable results are dependent on adequate specimen collection, transport, storage and processing.</li> <li>* This assay has been validated for use as a quantitative assay with only plasma.</li> <li>* This assay has been validated for use as a qualitative assay with plasma and serum.</li> <li>* Though rare, mutations within the highly conserved regions of the viral genome covered by the primers and/or probes in the Aptima HIV-1 Quant Dx assay may result in underquantification of or failure to detect the virus.</li> <li>* This assay is not intended to be used as a donor screening test for HIV-1.</li> <li>* Performance of this test has not been evaluated for use in pregnant women or in a pediatric population.</li> </ul> |

Revision: 1/2/2024