

**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 Dr., Silver Spring, MD, 20910

***HIV-1 TNA PCR, HIV-2 TNA PCR Test Specification***

<b>Test Name: HIV-1 DNA PCR / HIV-2 TNA PCR</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>HIV-1 DNA PCR: Qualitative HIV-1 TNA test for detection of HIV-1 infection in infants up to 18 months of age, and detection of HIV-1 Total Nucleic Acid in difficult to resolve infection cases.</p> <p>HIV-2 TNA PCR: Qualitative TNA test to distinguish between HIV-1 and HIV-2 infection.</p>	<p>18 ml whole blood in EDTA (lavender top) tubes</p> <p>Store at room temperature for overnight or same day delivery.</p>	<p><b>Ship ambient within 24 hours of collection.</b></p>	<p>Not FDA approved</p> <p>Intended for use in screening of infants 18 months of age or less, born to HIV-1 infected mothers; and for resolution of difficult to resolve HIV infection cases.</p>	<p>10 business days</p>
<p><u>Please note:</u></p> <ol style="list-style-type: none"> <li>Maternal antibodies may persist for the first 18 months of life, confounding diagnosis in the infant; however, maternal antibodies do not interfere with nucleic acid testing.</li> <li>This test may be used to detect HIV-1 in patients with acute infection prior to seroconversion (antibody formation), as well as in patients with agammaglobulinemia.</li> <li>It is recommended that positive results be confirmed on two separate blood samples with one or a combination of virus-specific tests.</li> <li>HIV-2 TNA PCR is a laboratory developed test designed and validated by HIV Diagnostics and Reference Laboratory in September 2019; the test is a real-time qualitative RT-PCR assay for detection of highly conserved regions within the Long Terminal Repeat (LTR) of the virus; it provides a highly sensitive assay for detection of the major HIV-2 Groups (A, B).</li> <li>The HIV-1 TNA assay is real-time qualitative RT-PCR assay for detection of highly conserved regions within the Long Terminal Repeat (LTR) of the virus; the test provides a highly sensitive assay for the detection cell free RNA and proviral DNA of HIV-1.</li> </ol>				

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