

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

Test Name: HIV-1 DNA PCR / HIV-2 TNA PCR				
Clinical Significance	Specimen Requirements	Transport/Storage Temperature	Test Approved For	Turn Around Time (After Receipt at HDRL)
<p>HIV-1 TNA 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.</p> <p>HIV-2 TNA PCR: Qualitative TNA test to distinguish between HIV-1 and HIV-2 infection.</p>	<p>3 ml (0.5 ml minimum) whole blood in EDTA (lavender top) tubes</p> <p>Store at room temperature for overnight or same day delivery.</p>	<p>Ship ambient within 24 hours of collection.</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/or difficult to resolve infection status cases.</p>	<p>10 business days</p>
<p><u>Please note:</u></p> <ol style="list-style-type: none"> 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. 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. It is recommended that positive results be confirmed on two separate blood samples with one or a combination of virus-specific tests. Repeatedly reactive HIV-1 EIA results with a supplemental confirmatory test are required to confirm the diagnosis HIV-1 infection. HIV-2 TNA PCR is a laboratory developed test designed and validated by HIV Diagnostics and Reference Laboratory in September 2019. The HIV-2 TNA assay is real-time qualitative RT-PCR assay for detection of highly conserved regions within the Long Term Terminal Repeat (LTR) of the virus; it provides a highly sensitive assay for all major HIV-2 Groups (A, B). 				

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