

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 DNA PCR, HIV-2 DNA PCR Test Specification

Test Name: HIV-1 DNA PCR / HIV-2 DNA PCR				
Clinical Significance	Specimen Requirements	Transport/Storage Temperature	Test Approved For	Turn Around Time (After Receipt at HDRL)
<p>HIV-1 DNA PCR: Qualitative HIV-1 DNA test for detection of HIV-1 infection in infants up to 18 months of age, and detection of HIV-1 proviral DNA.</p> <p>HIV-2 DNA PCR: Qualitative DNA 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 (15-30°C) for overnight or same day delivery.</p>	<p>Ship ambient within 24 hours of collection.</p>	<p>Not FDA approved</p> <p>HIV-1 DNA PCR intended for use in screening of infants 18 months of age or less, born to HIV-1 infected mothers.</p> <p>HIV-2 DNA PCR intended use for follow-up evaluation of negative results on confirmatory HIV-1 RNA testing, when clinically indicated.</p>	<p>10 business days</p>
<p><u>Please note:</u></p> <ol style="list-style-type: none"> 1. Maternal antibodies may persist for the first 18 months of life, confounding diagnosis in the infant; however, maternal antibodies do not interfere in the HIV-1 DNA test. 2. 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. 3. 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 supplemental confirmatory test are required to confirm the diagnosis HIV-1 infection. 4. HIV-2 DNA PCR is a highly sensitive and specific method to detect the presence of HIV-2 proviral DNA in specimens. 5. The diagnosis of HIV-2 infection should not rely solely upon the result of a PCR assay. A negative PCR result indicates the absence of HIV-2 proviral DNA at detectable levels in the sample and does not exclude diagnosis of disease. 				

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