**USEFUL FOR**

- Virologic detection of HIV-1 infection in infants <18 months of age (an age group for which serologic tests are unreliable) born to HIV-1-infected mothers
- Early detection of acute HIV-1 infection in children and adults who may be receiving combination antiretroviral prophylaxis or pre-emptive treatment
- Determining eradication of HIV-1 in individuals receiving combination highly active antiretroviral therapies

**CLINICAL INFORMATION**

Human immunodeficiency virus (HIV)-1 infection is usually confirmed by detection of HIV-1-specific antibodies in serum. However, serologic testing may not reliably identify HIV-1 infection in neonates with passively acquired maternal HIV-1 antibodies or with incompletely developed immune systems, individuals with early HIV-1 infection (<30 days from infection), or individuals with “indeterminate” HIV-1 antibody results by supplemental serologic assays. In these situations, detection of HIV-1 nucleic acids (RNA or proviral DNA) by PCR can provide definitive, early evidence of HIV-1 infection (approximately 10 to 14 days after infection), when results of routine diagnostic assays may be inconclusive.

Upon entry into human cells (including peripheral blood mononuclear cells), the HIV-1 RNA is converted into complementary DNA (cDNA) by reverse transcription. These linear cDNA strands are then integrated into the host cell genome, thus representing the proviral form of HIV-1. mRNA, transcribed from the proviral DNA, is used to synthesize the proteins required to make new viral particles. These proteins and viral RNA are packaged in the host’s cytoplasm and released from the cell, completing the life cycle of the virus.

HIV-1 DNA and/or RNA tests are recommended at 14 to 21 days, 1 to 2 months, and 4 to 6 months after birth, in infants born to HIV-1-infected mothers. Breastfeeding infants should be tested at baseline (1 to 2 days), 4 to 6 weeks, 3 months, and 4 to 6 months after birth. Two consecutive positive HIV-1 virologic test results (HIV-1 DNA and/or RNA) are necessary for confirming the diagnosis of HIV-1 infection in infants <18 months of age.
INTERPRETATION

A “Detected” result is consistent with HIV infection (see Cautions section). Per CDC and USPHS recommendations, a second specimen should be collected from any patient with first-time detectable HIV-1 DNA or RNA result and tested to verify the diagnosis of HIV-1 infection.

An “Undetected” result indicates that neither HIV-1 DNA nor RNA is detected in the specimen (see Cautions). Repeat testing in 1 to 2 months is recommended for those at risk of HIV-1 infection. The lower limits of detection (based on 95% detection rate) of this assay in plasma are 311 copies/mL for HIV-1 DNA and 75 copies/mL for HIV-1 RNA.

An “Inconclusive” result indicates that the absence or presence of HIV-1 DNA or RNA could not be determined with certainty after repeat testing of the clinical specimens in the laboratory, possibly due to PCR inhibition. Submission of a new specimen for testing is recommended.

CLINICAL REFERENCE