

# Human Immunodeficiency Virus 1 RNA Quantitative Real-time PCR

## *FOR MEASUREMENT OF HIV-1 VIRAL LOAD IN HIV-INFECTED PATIENTS*

### Test Highlights

This assay covers the analytic range of both quantitative PCR and ultrasensitive quantitative PCR, eliminating the need to offer two separate tests.

#### Clinical Background

- Human immunodeficiency virus types 1 and 2 (HIV-1 and HIV-2) are the causative agents of acquired immunodeficiency syndrome (AIDS).
- Most infection in the United States is caused by the HIV-1 group M viruses, which include types A–H, as well as potential circulating recombinant forms (CRFs).
- These viruses replicate using an error prone reverse transcriptase to form a double stranded DNA that can integrate into the host genome (proviral DNA). The combination of error prone replication, high viral load, and immunologic or drug selection leads to significant polymorphic variation of viral sequences, which may challenge diagnostic assays.
- Quantification of Human Immunodeficiency Virus Type 1 (HIV-1), also referred to as HIV viral-load testing, has become a standard of care for the management of HIV-1 infected patients. Plasma levels of HIV-1 RNA are used as markers of prognosis and disease progression, as a guide for determining when to initiate therapy, and for therapeutic monitoring.
- An important goal for patient management is achieving low levels of plasma HIV-1, as this correlates with a favorable clinical course. Evolving technologies for HIV-1 viral quantification have focused on more sensitive testing and the ability to quantify a broad spectrum of HIV-1 viral loads with a single assay. In addition, tests have been continuously optimized in order to accurately quantify the diversity of HIV-1 types and recombinant variants increasingly found in patient samples.

#### Epidemiology

- The Centers for Disease Control reported that at the end of 2003, approximately 1,100,000 persons in the United States were living with HIV/AIDS.
- Worldwide, UNAIDS estimates that 33,200,000 persons are living with HIV, with the highest prevalence of disease occurring in sub-Saharan Africa.
- Worldwide, there were 2,100,000 deaths from AIDS in 2007.

#### Indications for Ordering

- This test should be ordered to determine levels of HIV-1 RNA in HIV-positive patients. These levels serve as a marker of prognosis and disease progression, as a guide for determining when to initiate therapy, and for therapeutic monitoring.
- This assay is not approved for the diagnosis of HIV-1 infection.

#### Interpretation

- Because viral load may vary by orders of magnitude, results of viral-load testing are often expressed in log units, where each increase of one log corresponds to a factor of 10. Thus, a viral load of 1,000 would be three log units, and the difference between a viral load of 1,000 and 10,000 would be one log unit.
- A change in viral load of >0.5 log copies/mL (approximately three fold) exceeds assay and diurnal variations, and may be considered to represent a true biological event, whereas a change of <0.5 log copies/mL cannot be distinguished from random variability.
- Diurnal variation in stable HIV viral loads is approximately 0.4 log copies/mL. Acute intercurrent infection or immunization may also transiently increase viral load.

#### Limitations

- This test has not been evaluated with specimens containing HIV-1 groups O and N, nor HIV-2.
- Single nucleotide polymorphisms in the primer or probe regions could lead to underquantification or false negative results.

#### Methodology

- Real-Time Reverse Transcription Polymerase Chain Reaction.
- Samples are extracted for purification and concentration of nucleic acid and presented for amplification and fluorescence detection by the COBAS® AmpliPrep/COBAS® TaqMan® instrument.
- Analytic range of 1.7-7.0 log HIV-1 RNA copies/mL (48 to 10,000,000 copies/mL).
- The assay detects HIV-1 RNA and integrated HIV-1 proviral DNA.

#### Related Tests

- Human Immunodeficiency Virus 1 Antibody with Reflex to Confirmation by Western Blot ([0051154](#))
- Human Immunodeficiency Virus 1 Antibody, Confirmation ([0020284](#))
- Human Immunodeficiency Virus 1 RNA Quantitative Real-Time PCR with Reflex to Human Immunodeficiency Virus 1 Genotyping ([0051660](#))

## References

1. Joint United Nations Programme on HIV/AIDS (UNAIDS). AIDS epidemic update: December 2007. [http://data.unaids.org/pub/EPISlides/2007/2007\\_epiupdate\\_en.pdf](http://data.unaids.org/pub/EPISlides/2007/2007_epiupdate_en.pdf). (accessed June 11, 2008).
2. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. HIV/AIDS Statistics and Surveillance. <http://www.cdc.gov/hiv/topics/surveillance/basic.htm> (accessed June 11, 2008).
3. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. HIV/AIDS Surveillance Report, 2006. Vol. 18. <http://www.cdc.gov/hiv/topics/surveillance/resources/reports/2006report/pdf/2006SurveillanceReport.pdf> (accessed June 11, 2008).

## Test Information

**0055598**

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For specific collection, transport, and testing information, refer to the ARUP Web site at [www.aruplab.com](http://www.aruplab.com).

For information on test selection, ordering, and interpretation, refer to ARUP Consult® at [www.arupconsult.com](http://www.arupconsult.com).