Abbott *RealTime* HIV-1

The Abbott RealTi*m*e HIV-1 assay is an *in vitro* reverse transcription-polymerase chain reaction (RT-PCR) assay for the quantitation of Human Immunodeficiency Virus type 1 (HIV-1) on the automated *m*2000 System in human plasma from HIV-1 infected individuals over the range of 40 to 10,000,000 copies/mL. The Abbott RealTi*m*e HIV-1 assay is intended for use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in assessing viral response to antiretroviral treatment as measured by changes in plasma HIV-1 RNA levels.

Development Philosophy

Today's clinical molecular diagnostics laboratory must have confidence in the quality of the HIV-1 patient results. As a result of our real-time PCR development philosophy, Abbott RealTi*m*e HIV-1 is engineered to tolerate the genetic diversity of HIV-1 Subtypes.

HIV-1 diversity can be attributed to:

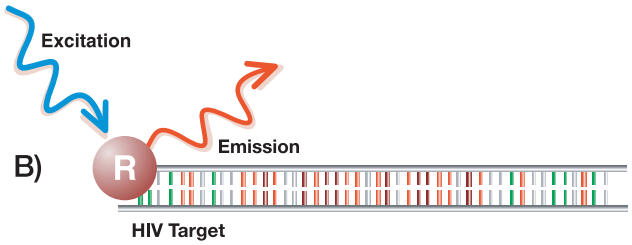
- Error-prone reverse transcriptase enzyme
- Recombination of subtypes
- Cross-species transmission

Accurate quantitation is dependent upon a combination of:

- Primer design
- Probe design
- Cycling conditions

Partially Double Stranded Probe Design

In the absence of target, the probe hybridizes to the quencher oligonucleotide, preventing fluorescent signal generation.



In the presence of target, the probe prefers to hybridize with the target sequence, disassociating from the quencher oligonucleotide and allowing fluorescent detection.

Abbott RealTi*m*e HIV-1 Performance

Sensitivity	40 copies/mL for 1.0 mL input, 75 copies/mL for 0.5 mL input, 150 copies/mL for 0.2 mL input
Linear Range	40 copies/mL (1.6 log copies/mL) to 10 million copies/mL (7.0 log copies/mL)
Precision	Inter-assay standard deviation (SD) of ≤0.25 log copies/mL
Specificity	100%[†]
Specimen Type	Plasma (ACD-A and EDTA)
HIV-1 Subtype Detection	Group M subtypes A–H, Group O and Group N
Standardization	Virology Quality Assurance (VQA) Laboratory of the AIDS Clinical Trial Group and against World Health Organization (WHO) 1st International Standard for HIV-1 RNA (97/656)
Internal Control	Added to lysis buffer during extraction and detected at all levels

This assay is not intended to be used as a donor screening test for HIV-1 or as a diagnostic test to confirm the presence of HIV-1 infection.

[†] The specificity of the RealTi*m*e HIV-1 assay was evaluated at three external sites by testing 514 HIV-1 seronegative plasma specimens from volunteer blood donors. HIV-1 RNA was not detected for all 514 specimens and the RealTi*m*e HIV-1 assay specificity was estimated to be 100% (514/514), (95% CI 99.28 to 100%).

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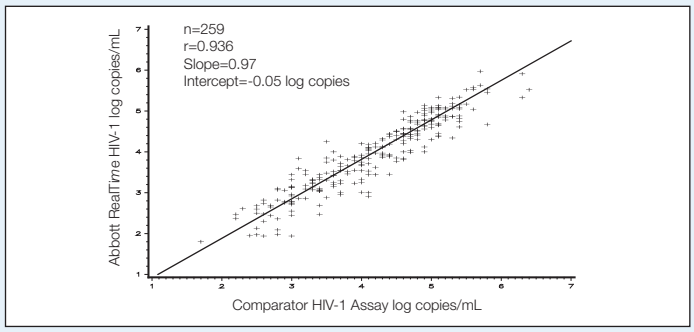
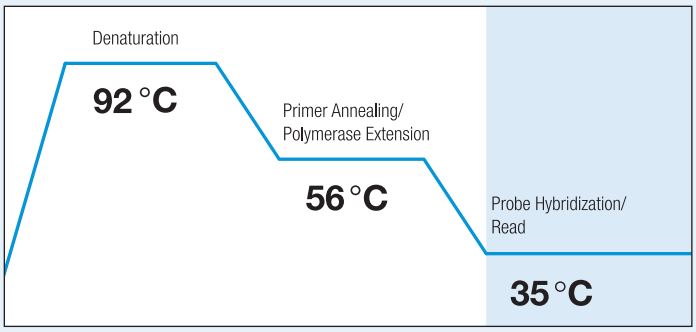
Correlation to Comparator Assay



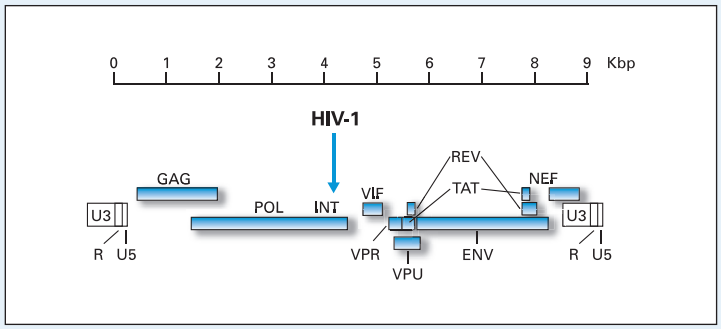
A total of 301 specimens collected from HIV-1 infected patients were tested with the RealTime HIV-1 assay at three external sites and with the comparator method at a central laboratory site. The results from a total of 259 specimens that fell within the common assay dynamic range were analyzed by the Passing-Bablok linear regression method.

Cycling Conditions: Low Temperature Read Cycles



The cycling conditions for Abbott RealTime HIV-1 encompass a low temperature read cycle. This read cycle allows the probe to tolerate mismatches more effectively than a probe required to bind during the extension phase.

Primers and Probe are Targeted to the Integrase Region of the Polymerase Gene



The integrase region of the polymerase gene is a conserved region of the HIV-1 genome.

Detection of HIV-1 Subtypes and Groups

Group/Subtypes	n	RealTime Detected	Comparator 1 Detected	Comparator 2 Detected
M/Subtype A	10	10	10 (1)	10 (1)
M/Subtype B	10	10	10 (0)	10 (0)
M/Subtype C	10	10	10 (0)	10 (0)
M/Subtype D	10	10	10 (0)	10 (0)
M/Subtype AE	10	10	10 (0)	10 (0)
M/Subtype F	10	10	10 (0)	10 (0)
M/Subtype AG	10	10	10 (3)	10 (1)
M/Subtype G	10	10	10 (2)	10 (1)
Group O	10	10	0 (NA)	7 (7)

A total of 90 clinical specimens, ten of each Group M subtype (A, B, C, D, CRF01-AE, F, CRF02-AG, G) and of Group O, were tested with the RealTime HIV-1 assay and by two other approved HIV-1 quantitative assays referred to as Comparator 1 (FDA-approved version used) and Comparator 2 (CE-marked version used). The numbers in parentheses are the number of specimens that had lower quantitation values by more than 1.00 log copies/mL when compared to RealTime HIV-1 assay.

Ordering Information

Product	List Number	Configuration
Abbott RealTime HIV-1 Amplification Reagent Kit	6L18-90	96 Assays (4 packs x 24 assays)
Abbott RealTime HIV-1 Control Kit	6L18-80	8 Low Positive, 8 High Positive, 8 Negative
Abbott RealTime HIV-1 Calibrator Kit	6L18-70	12 Cal A, 12 Cal B (4 Complete Calibration Sets)
Abbott RealTime HIV-1 Application CD-ROM	6L83	1 each

For additional information please visit www.abbottmolecular.com
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