Abbott RealTi*me* HIV-1

REF 6L18

51-602146/R6

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Note: Changes Highlighted

Key to Symbols Used

	Manufacturer
REF	Reference Number
LOT	Lot Number
IVD	In Vitro Diagnostic Medical Device
INTERNAL CONTROL	Internal Control
AMPLIFICATION REAGENT PACK	Amplification Reagent Pack
CAL A	Calibrator A
CAL B	Calibrator B
CONTROL –	Negative Control
CONTROL L	Low Positive Control
CONTROL H	High Positive Control
-10°C	Store at – 10°C or colder
	Use by
	Consult instructions for use
	CAUTION: Handle human sourced materials as potentially infectious. Consult instructions for use. (Infection Risk)

See **REAGENTS** section for a full explanation of symbols used in reagent component naming.

CUSTOMER SERVICE: 1-800-553-7042

INTERNATIONAL: CALL YOUR ABBOTT REPRESENTATIVE

This package insert must be read carefully prior to use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert

NAME

Abbott RealTi*me* HIV-1

INTENDED USE

The Abbott RealTi*me* 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*me* 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. 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.

SUMMARY AND EXPLANATION OF THE TEST

Human Immunodeficiency Virus (HIV) is the etiologic agent of Acquired Immunodeficiency Syndrome (AIDS).[1–3] It can be transmitted through sexual contact, exposure to infected blood or blood products, or from an infected mother to the fetus.[4] Acute HIV syndrome, characterized by flu-like symptoms, develops 3 to 5 weeks after initial infection and is associated with high levels of viremia.[5,6] Within 4 to 6 weeks of the onset of symptoms, HIV specific immune response is detectable.[7,8] After seroconversion, viral load in peripheral blood declines and most patients enter an asymptomatic phase that can last for years.[9]

Quantitative measurement of HIV levels in peripheral blood has greatly contributed to the understanding of the pathogenesis of HIV infection[10,11] and has been shown to be an essential parameter in prognosis and management of HIV infected individuals.[12–17] Decisions regarding initiation or changes in antiretroviral therapy are guided by monitoring plasma HIV RNA levels (viral load), CD4+ T cell count, and the patient's clinical condition.[17,18] The goal of antiretroviral therapy is to reduce the HIV virus in plasma to below detectable levels of available viral load tests.[17,19]

HIV RNA levels in plasma can be quantitated by nucleic acid amplification or signal amplification technologies.[20–22] The Abbott RealTi*me* HIV-1 assay uses Polymerase Chain Reaction (PCR) technology with homogenous real-time fluorescent detection. Partially double-stranded fluorescent probe design allows detection of diverse group M subtypes and group O isolates. The assay is standardized against a viral standard from the Virology Quality Assurance (VQA) Laboratory of the AIDS Clinical Trial Group,[23] and against World Health Organization (WHO) 1st International Standard for HIV-1 RNA (97/656).[24,25] The assay results can be reported in copies/mL or International Units/mL (IU/mL).

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The Abbott RealTi*me* HIV-1 assay uses RT-PCR[26] to generate amplified product from the RNA genome of HIV-1 in clinical specimens. An RNA sequence that is unrelated to the HIV-1 target sequence is introduced into each specimen at the beginning of sample preparation. This unrelated RNA sequence is simultaneously amplified by RT-PCR, and serves as an internal control (IC) to demonstrate that the process has proceeded correctly for each sample. The amount of HIV-1 target sequence that is present at each amplification cycle is measured through the use of fluorescent-labeled oligonucleotide probes on the Abbott *m*2000*rt* instrument. The probes do not generate signal unless they are specifically bound to the amplified product. The amplification cycle at which fluorescent signal is detected by the Abbott *m*2000*rt* is proportional to the log of the HIV-1 RNA concentration present in the original sample.

Sample Preparation

The purpose of sample preparation is to extract and concentrate the target RNA molecules to make the target accessible for amplification, and to remove potential inhibitors of amplification from the extract.

The Abbott *m*2000*sp* instrument prepares samples for the Abbott RealTi*me* HIV-1 assay using the Abbott *m*Sample Preparation System (4 × 24 Preps) reagents. The *m*2000*sp* uses magnetic particle technology to capture nucleic acids and washes the particles to remove unbound sample components. The bound nucleic acids are eluted and transferred to a 96 deep-well plate. The nucleic acids are then ready for amplification. The IC is taken through the entire sample preparation procedure along with the calibrators, controls, and specimens.

Reagent Preparation and Reaction Plate Assembly

The Abbott *m*2000*sp* combines the Abbott RealTi*me* HIV-1 amplification reagent components (HIV-1 Oligonucleotide Reagent, Thermostable rTth Polymerase Enzyme, and Activation Reagent). The Abbott *m*2000*sp* dispenses the resulting master mix to the Abbott 96-Well Optical