WHO Prequalification of Diagnostics Programme
PUBLIC REPORT

Product: Abbott RealTime HIV-1 (m2000sp)
Number: PQDx 0145-027-00

Abstract

Abbott RealTime HIV-1 (m2000sp) assay with product code 2G31 (which includes 2G31-80 and 2G31-70 and 2G31-90 or 2G31-010,) manufactured by Abbott Molecular Inc., 1300 East Touhy Avenue, Des Plaines, IL 60018, United States of America, CE-marked regulatory version, was accepted for the WHO list of prequalified diagnostics and was listed on 17 October 2011. This public report was amended on 23 June 2016, and subsequently on 30 June 2016. This version of the product is intended to be used in conjunction with the following instruments/reagents: 9K14-02, 9K15-01, 2G31-66, 1L68-09 (or higher), 04J70-24 and 4J71-93.

Intended use:
Abbott RealTime HIV-1 (m2000sp) assay is an in vitro reverse transcription-polymerase chain reaction (RT-PCR) assay for the quantitation of Human Immunodeficiency Virus type 1 (HIV-1) in human plasma only (for 2G31-90) and in human plasma and whole blood spotted on cards as dried blood spots (for 2G31-010) from HIV-1 infected individuals. Abbott RealTime HIV-1 (m2000sp) assay is intended for use in conjunction with clinical presentation and other laboratory markers as an indicator of disease prognosis and for use as an aid in assessing viral response to antiretroviral treatment as measured by changes in HIV-1 RNA levels. This assay is not intended to be used as a screening test for HIV-1 or as a diagnostic test to confirm the presence of HIV-1 infection.

Assay principle:
Abbott RealTime HIV-1 (m2000sp) assay uses RT-PCR 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 m2000rt 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 m2000rt is proportional to the log of the HIV-1 RNA concentration present in the original sample.
In order to perform the assay, the following components are required:

<table>
<thead>
<tr>
<th>Component</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Instrumentation</strong></td>
<td><strong>Abbott m2000sp Instrument (9K14-02)</strong>&lt;br&gt;<strong>Abbott m2000rt Instrument (9K15-01)</strong></td>
</tr>
<tr>
<td><strong>Reagents</strong></td>
<td><strong>m Sample Preparation System RNA (4 X 24 Preps) (04J70-24) for plasma and DBS processing.</strong>&lt;br&gt;<strong>Abbott mSample Preparation System DBS Buffer Kit (List No. 09N02-001) for DBS processing only.</strong>&lt;br&gt;<strong>Abbott RealTime HIV-1 2G31 list which includes the following kits:</strong>&lt;br&gt;• <strong>Abbott RealTime HIV-1 Control Kit (2G31-80) and&lt;br&gt;Abbott RealTime HIV-1 Calibrator Kit (2G31-70) and&lt;br&gt;Abbott RealTime HIV-1 Amplification Reagent Kit (2G31-010)-plasma and DBS or&lt;br&gt;Abbott RealTime HIV-1 Amplification Reagent Kit (2G31-90)-plasma</strong>&lt;br&gt;<strong>Abbott m2000rt Optical Calibration kit (4J71-93)</strong></td>
</tr>
<tr>
<td><strong>Software</strong></td>
<td><strong>Abbott RealTime HIV-1 m2000 ROW System Combined Application CD-ROM 1L68-09 or higher</strong>&lt;br&gt;<strong>Optional Abbott RealTime HIV-1 UNG Protocol (2G31-66)</strong></td>
</tr>
<tr>
<td><strong>Consumables</strong></td>
<td><strong>Disposable Tips (DiTis), 1000 µL (4J7110)</strong>&lt;br&gt;<strong>Disposable Tips (DiTis), 200 µL (4J7117)</strong>&lt;br&gt;<strong>Biohazard Bags (4J7145)</strong>&lt;br&gt;<strong>5 mL Reaction Vessels (4J7120)</strong>&lt;br&gt;<strong>200 ml Reagent Vessels (4J7160)</strong>&lt;br&gt;<strong>96 Deep Well Plates (4J7130)</strong>&lt;br&gt;<strong>96-Well Optical Reaction Plates (4J7170)</strong>&lt;br&gt;<strong>Optical Adhesive Covers (4J7175)</strong>&lt;br&gt;<strong>Master Mix Tube (4J7180)</strong>&lt;br&gt;<strong>Adhesive Cover Applicator (9K3201)</strong>&lt;br&gt;<strong>Splash-Free Support Base (9K3101)</strong>&lt;br&gt;<strong>13 mm Sample Racks (4J7282)</strong>&lt;br&gt;<strong>m2000 System 13mm DBS PoSt Set (09N03-001) for (DBS processing only)</strong></td>
</tr>
</tbody>
</table>

**Storage:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Storage temperature</th>
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<tbody>
<tr>
<td><strong>Abbott RealTime HIV-1 Calibrator A and Calibrator B</strong></td>
<td>-10°C or colder</td>
</tr>
<tr>
<td><strong>Abbott RealTime HIV-1 Negative, Low Positive, and High Positive Controls</strong></td>
<td>-10°C or colder</td>
</tr>
<tr>
<td><strong>Abbott RealTime HIV-1 Amplification Reagent Pack</strong></td>
<td>-10°C or colder when not in use</td>
</tr>
</tbody>
</table>
(2G31-90) OR
Abbott RealTime HIV-1 Amplification Reagent Kit (02G31-010) -15 to -25 °C
Abbott mSample Preparation System RNA (4X24 Preps) 15-30°C
Abbott mSample Preparation System DBS Buffer Kit 15-30°C

Maximum shelf-life upon manufacture:

<table>
<thead>
<tr>
<th>Component</th>
<th>Shelf life</th>
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<tr>
<td>Abbott RealTime HIV-1 Amplification Reagent Kit (02G31-010)</td>
<td>18 months</td>
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<tr>
<td>Abbott RealTime HIV-1 Amplification Reagent Kit (2G31-90 and 02G31-010)</td>
<td>18 months</td>
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<tr>
<td>Abbott RealTime HIV-1 Internal Control 2G31Y</td>
<td>18 months</td>
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<tr>
<td>Thermostable rTth Polymerase Enzyme 56685 Per control date on vendor certificate of analysis</td>
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<tr>
<td>HIV-1 Oligonucleotide Reagent 2G31L</td>
<td>18 months</td>
</tr>
<tr>
<td>Activation Reagent 93591</td>
<td>18 months</td>
</tr>
<tr>
<td>Abbott RealTime HIV-1 Control Kit (2G31-80)</td>
<td>18 months</td>
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<tr>
<td>Abbott RealTime HIV-1 Calibrator Kit (2G31-70)</td>
<td>18 months</td>
</tr>
<tr>
<td>Abbott mSample Preparation System RNA Kit 04J70-24</td>
<td>18 months</td>
</tr>
<tr>
<td>Abbott mSample Preparation System DBS Buffer Kit</td>
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Limitations:
This assay is not intended to be used as a screening test for HIV-1 or as a diagnostic test to confirm the presence of HIV-1 infection.

Summary of prequalification status for Abbott RealTime HIV-1 (m2000sp)

<table>
<thead>
<tr>
<th>Initial acceptance</th>
<th>Outcome</th>
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<tr>
<td>Amended PQ</td>
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<tr>
<td>Date</td>
<td>18 June 2016</td>
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<td>Status on PQ list</td>
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<tr>
<td>Date</td>
<td>17 October 2011</td>
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<tr>
<td>Dossier assessment</td>
<td>MR</td>
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<tr>
<td>Date</td>
<td>28 September 2011</td>
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<tr>
<td>Inspection status</td>
<td>MR</td>
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<tr>
<td>Date</td>
<td>29 September 2011</td>
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<tr>
<td>Laboratory evaluation</td>
<td>MR</td>
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<tr>
<td>Date</td>
<td>FT for plasma/30 June 2015 (DBS)</td>
</tr>
</tbody>
</table>

MR: Meets Requirements,  NA: Not Applicable,  FT: Fast-tracked

Abbott RealTime HIV-1 (m2000sp) was accepted for the WHO list of prequalified diagnostics on the basis of data submitted and publicly available information.
Background information

Abbott Molecular Inc. submitted an application for prequalification of Abbott RealTime HIV-1 (m2000sp). Based on the established prioritization criteria, Abbott RealTime HIV-1 (m2000sp) was given priority for prequalification.

Product dossier assessment

In 2011, Abbott Molecular Inc. submitted a product dossier for Abbott RealTime HIV-1 (m2000sp) as per the ‘Instructions for compilation of a product dossier’ (PQDx_018 v1). The information submitted in the product dossier was reviewed in accordance with the ‘Internal report on the screening and assessment of a product dossier’ (PQDx_009 v2) by WHO staff and external experts (assessors) appointed by WHO. Based on the product dossier screening and assessment findings, a recommendation was made to accept the product dossier for Abbott RealTime HIV-1 (m2000sp) for prequalification.

Commitments for prequalification: N/A

Manufacturing site inspection

An inspection was conducted at the site of manufacture (1300 East Touhy Avenue, 60018 Des Plaines, IL, USA) of Abbott RealTime HIV-1 (m2000sp) on 29 June to 1 July 2011 as described in ‘Information for manufacturers on WHO prequalification inspection procedures for the sites of manufacture of diagnostics (PQDx_014 v1)’.

The inspection found that the manufacturer had a well-established quality management system and manufacturing practices in place that would ensure the manufacture of a product of consistent quality. The manufacturer’s responses to the nonconformities noted at the time of the inspection were accepted on 29 September 2011.

Commitments for prequalification:

1. Risk management files will be updated to include risk analysis for end users in resource limited and environmentally challenging regions to which the product is distributed. This will apply to the Abbott RealTime HIV-1 (m2000sp) product as well as to the related products.
2. Abbott Molecular Inc. has committed to work towards improving communication (e.g. customer feedback mechanisms, tailored training, labeling) for users in resource limited regions where communication may be problematic.

Laboratory evaluation

Given the regulatory version of the product submitted for prequalification and the quality of the data submitted as part of the product dossier to support the claims for its intended use, Abbott RealTime HIV-1 (m2000sp) assay has been found eligible to undergo the WHO
fast track procedure. Subsequently, the product will not be required to undergo a laboratory evaluation for its use with human plasma.

**Performance evaluation using dried blood spots (DBS)**

At the time of the evaluation, the recommended protocol required a single DBS with a volume of 70 µl of specimen per DBS.

In this limited performance evaluation on a panel of 323 specimens, we found an initial bias (95% CI) of -0.42 log copies/mL ([−0.52] - [-0.32]) compared to the reference results for samples >1,000 copies/mL. The upward and downward misclassification rates around the threshold of 1,000 copies/mL were 10.3% and 24.0% respectively. The upward and downward misclassification rates around the threshold of 5,000 copies/mL were 2.1% and 22.0% respectively. The sensitivity (95% CI) was 76.0% (68.1%-82.5%) and the specificity (95% CI) was 89.7% (82.7%-94.2%) compared to the reference results at a threshold of 1,000 copies/mL. At 5,000 copies/mL, sensitivity and specificity were 78.0% (67.3%-86.1%) and 97.9% (94.3%-99.3%) respectively. In this study, the invalid rate was 1.1%.

Limitations of the evaluation:
The reference method used to compare results obtained from DBS specimens was plasma, for which a viral load result was obtained using the Roche Cobas AmpliPrep/Cobas TaqMan HIV-1 Version 2.0, which is the standard assay in the evaluating site. This may have contributed to an increase in bias and misclassification rate (Sollis 2014) (Amendola 2014). Discrepant results will not be retested on plasma using the Abbott platform given that the protocol used in the evaluation has now been made obsolete. It was thus considered that any additional testing was superfluous.

The evaluation was conducted using the standard protocol provided by the manufacturer at the time. The manufacturer has since, developed a new protocol and added DBS as an additional specimen type. The new instructions for use including DBS testing can be found in the labelling section.

**Change notification**

In 2016, Abbott Molecular Inc. submitted a change notification related to a change in specimen types to include dried blood spot specimens as an additional specimen type, changes to software, changes to storage temperature claims and changes to labelling, introducing a new product code: 2G31-010. This change notification was assessed and product was found to meet WHO prequalification requirements.
Labelling

1. Labels
2. Instructions for use
1. Labels

**Abbott RealTime Amplification Reagent Pack (2G31)**
HIV-1 Amplification Reagent Kit (List No. 02G31-010)

Abbott RealTime HIV-1 Amplification Reagent Kit

- 96 tubes (4 x 1.2mL)
- Internal Control: H317, P280, P272, P292-P296, P333-P393, P362-P364, P361

Abbott RealTime HIV-1 Amplification Reagent Kit

- Store at -25°C to -15°C

Abbott Molecular Inc.
1900 East Touhy Avenue
Des Plaines, IL 60018 USA

Abbott GmbH & Co. KG
Mannheim/Saarbrücken Zentrum
85204 Westhafen, Germany
+49-0-22-55-080

Colors: BLACK
PMS 299
PMS 185
Labeling: 802
Abbott RealTime HIV-1 Calibrator Kit (List No. 2G31-70)

### Abbott RealTime HIV-1 Calibrator Kit

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ablation</strong></td>
<td>Ablation guide for Ablation procedures</td>
</tr>
<tr>
<td><strong>Calibrator</strong></td>
<td>Calibrator guide for Calibrator procedures</td>
</tr>
</tbody>
</table>

### Calibrator Kit

- **Calibrator**
- **Ablation**
- **Preparation**

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**Abbott RealTime HIV-1 Calibrator Kit (List No. 2G31-70)**

- **Ablation**
- **Calibrator**
- **Preparation**

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**Abbott RealTime HIV-1 Calibrator Kit (List No. 2G31-70)**

- **Ablation**
- **Calibrator**
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- **Ablation**
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**Abbott RealTime HIV-1 Calibrator Kit (List No. 2G31-70)**

- **Ablation**
- **Calibrator**
- **Preparation**

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**Abbott RealTime HIV-1 Calibrator Kit (List No. 2G31-70)**

- **Ablation**
- **Calibrator**
- **Preparation**

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Label for Abbott RealTime HIV-1 Calibrator A (List No. 2G31A)

Label for the Abbott RealTime HIV-1 Calibrator B (List No. 2G31B)
Abbott RealTime HIV-1 High Positive Control (List No. 2G31X)

Abbott RealTime HIV-1 Low Positive Control (List No. 2G31W)
Abbott RealTime HIV-1 Negative Control (List No. 2G31Z)
Abbott RealTime HIV-1 Amplification Reagent Kit (List No. 2G31-90)

Amplification Reagent Kit
(4x24 Tests)

Abbott RealTime
HIV-1

Abbott Molecular Inc.
1800 East Touhy Avenue
Des Plaines, IL 60018 USA

Abbott GmbH & Co. KG
Isen Platz 2
69256 Heidelberg, Germany

Abbott RealTime HIV-1 Amplification Reagent Kit (List No. 2G31-90)
Abbott RealTime HIV-1 Internal Control (List No. 2G31Y)

Labels for the Abbott mDBS Buffer (List No. 09N02-001)
Labels for the Abbott mSample Preparation System (List No. 4J70-24)
INTENDED USE
The Abbott RealTime 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) in human plasma from HIV-1 infected individuals. The Abbott RealTime HIV-1 assay is intended for use in conjunction with clinical presentation and other laboratory markers as an indicator of 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 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). Acute HIV syndrome, characterized by flu-like symptoms, develops 3 to 5 weeks after initial infection and is associated with high levels of viremia. Within 4 to 6 weeks of the onset of symptoms, HIV specific immune response is detectable. After seroconversion, viral load in peripheral blood declines and most patients enter an asymptomatic phase that can last for years. Quantitative measurement of HIV levels in peripheral blood has greatly contributed to the understanding of the pathogenesis of HIV infection and has been shown to be an essential parameter in prognosis and management of HIV infected individuals. 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. The goal of antiretroviral therapy is to reduce the HIV virus in plasma to below detectable levels of available viral load tests.

HIV RNA levels in plasma can be quantitated by nucleic acid amplification or signal amplification technologies. The Abbott RealTime 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, and against World Health Organization (WHO) 1st International Standard for HIV-1 RNA. The assay results can be reported in copies/mL or International Units/mL (IU/mL).

BIOLOGICAL PRINCIPLES OF THE PROCEDURE
The Abbott RealTime HIV-1 assay consists of 3 reagent kits:
- Abbott RealTime HIV-1 Amplification Reagent Kit
- Abbott RealTime HIV-1 Control Kit
- Abbott RealTime HIV-1 Calibrator Kit

The Abbott RealTime HIV-1 assay uses RT-PCR 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 m2000rt 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 m2000rt is proportional to the log of the HIV-1 RNA concentration present in the original sample.

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

CUSTOMER SERVICE
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 RealTime HIV-1
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 mSample Preparation System (4 × 24 Preps) 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 output tubes or 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.

Two automated instrument systems, the Abbott m2000sp or the Abbott m1000 System can be used to prepare samples for the Abbott RealTime HIV-1 assay. The Abbott m2000sp provides automated sample elute transfer and reaction assembly in the Abbott 96-Well Optical Reaction Plate, while the Abbott m1000 System requires manual sample elute transfer and reaction assembly.

Alternatively, samples can be prepared manually using the Abbott mSample Preparation System, followed by manual reaction assembly.

Reagent Preparation and Reaction Plate Assembly
The Abbott m2000sp combines the Abbott RealTime HIV-1 amplification reagent components (HIV-1 Oligonucleotide Reagent, Thermostable rTth Polymerase Enzyme, and Activation Reagent). The Abbott m2000sp dispenses the resulting master mix to the Abbott 96-Well Optical Reaction Plate along with aliquots of the nucleic acid samples prepared by the Abbott m2000sp. The plate is ready, after manual application of the optical seal, for transfer to the Abbott m2000rt.

Abbott m1000 System users and manual sample preparation method users manually combine the Abbott RealTime HIV-1 amplification reagent components to create the amplification master mix and transfer aliquots of the master mix and sample eluates to the reaction plate. The plate is ready, after manual application of the optical seal and centrifugation, for transfer to the Abbott m2000rt.

Amplification
During the amplification reaction on the Abbott m2000rt, the target RNA is converted to cDNA by the reverse transcriptase activity of the thermostable rTth DNA polymerase. First, the HIV-1 and IC reverse primers anneal to their respective targets and are extended during a prolonged incubation period. After a denaturation step, in which the temperature of the reaction is raised above the melting point of the double-stranded cDNA:RNA product, a second primer anneals to the cDNA strand and is extended by the DNA polymerase activity of the rTth enzyme to create a double-stranded DNA product.

During each round of thermal cycling, amplification products dissociate to single strands at high temperature allowing primer annealing and extension as the temperature is lowered. Exponential amplification of the product is achieved through repeated cycling between high and low temperatures, resulting in a billion-fold or greater amplification of target sequences. Amplification of both targets (HIV-1 and IC) takes place simultaneously in the same reaction.

The target sequence for the Abbott RealTime HIV-1 assay is in the pol integrase region of the HIV-1 genome. This region is highly conserved. The primers are designed to hybridize to the pol integrase region with the fewest possible mismatches among various subtypes.

The IC target sequence is derived from the hydroxypruvrate reductase gene from the pumpkin plant, Cucurbita pepo, and is delivered in an Armored RNA® particle that has been diluted in negative human plasma.

Detection
During the read cycles of amplification on the Abbott m2000rt, the temperature is lowered further to allow fluorescent detection of amplification products as the HIV-1 and IC probes anneal to their targets (real-time fluorescence detection). The HIV-1 probe has a fluorescent moiety that is covalently linked to the 5’ end. A short oligonucleotide (quencher oligonucleotide) is complementary to the 5’ end of the HIV-1 probe and has a quencher molecule at its 3’ end. In the absence of HIV-1 target, the HIV-1 probe fluorescence is quenched through hybridization to the quencher oligonucleotide. In the presence of the HIV-1 target sequence, the HIV-1 probe preferentially hybridizes to the target sequence, dissociating from the quencher oligonucleotide, allowing fluorescent detection.

The IC probe is a single-stranded DNA oligonucleotide with a fluorophore at the 5’ end and a quencher at the 3’ end. In the absence of IC target sequences, probe fluorescence is quenched. In the presence of IC target sequences, probe hybridization to complementary sequences separates the fluorophore and the quencher and allows fluorescent emission and detection.

The HIV-1 and IC specific probes are each labeled with a different fluorophore, thus allowing for simultaneous detection of both amplified products at each cycle. The amplification cycle at which a fluorescent signal is detected by the Abbott m2000rt is proportional to the log of the HIV-1 RNA concentration present in the original sample.

PREVENTION OF NUCLEIC ACID CONTAMINATION
The possibility of nucleic acid contamination is minimized because:

- Reverse transcription, PCR amplification, and oligonucleotide hybridization occur in a sealed Abbott 96-Well Optical Reaction Plate.
- Detection is carried out automatically without the need to open the Abbott 96-Well Optical Reaction Plate.
- Pipettes with aerosol barrier tips or disposable transfer pipettes are used for all pipetting. The disposable pipettes or pipette tips are discarded after use.
- Separate, dedicated areas are used to perform the Abbott RealTime HIV-1 assay. Refer to the SPECIAL PRECAUTIONS section of this package insert.

REAGENTS

Abbott RealTime HIV-1 Amplification Reagent Kit (List No. 2G31-90)

1. INTERNAL CONTROL Abbott RealTime HIV-1 Internal Control (List No. 2G31Y) (4 vials, 1.2 mL per vial)

- < 0.01% noninfected Armored RNA with internal control sequences in negative human plasma. Negative human plasma tested and found to be nonreactive for HBsAg, HIV RNA, HCV RNA, HBV DNA, anti-HIV-1/HIV-2, and anti-HCV. Preservatives: 0.1% ProClin® 300 and 0.15% ProClin 950.

2. AMPLIFICATION REAGENT PACK Abbott RealTime HIV-1 Amplification Reagent Pack (List No. 2G31) (4 packs, 24 tests/pack)

- 1 bottle (0.141 mL) Thermostable rTth Polymerase Enzyme (2.9 to 3.5 Units/µL) in buffered solution.
- 1 bottle (1.10 mL) HIV-1 Oligonucleotide Reagent. < 0.1% synthetic oligonucleotides (4 primers, 2 probes, and 1 quencher oligonucleotide), and < 0.3% dNTPs in a buffered solution with a reference dye. Preservatives: 0.1% ProClin 300 and 0.15% ProClin 950.
- 1 bottle (0.40 mL) Activation Reagent. 30 mM manganese chloride solution. Preservatives: 0.1% ProClin 300 and 0.15% ProClin 950.

Abbott RealTime HIV-1 Control Kit (List No. 2G31-80)

1. CONTROL A Abbott RealTime HIV-1 Negative Control (List No. 2G31Z) (8 vials, 1.8 mL per vial) Negative human plasma tested and found to be nonreactive for HBsAg, HIV RNA, HCV RNA, HBV DNA, anti-HIV-1/HIV-2, and anti-HCV. Preservatives: 0.1% ProClin 300 and 0.15% ProClin 950.

2. CONTROL B Abbott RealTime HIV-1 Low Positive Control (List No. 2G31W) (8 vials, 1.8 mL per vial) Noninfected Armored RNA with HIV-1 sequences in negative human plasma. Negative human plasma tested and found to be nonreactive for HBsAg, HIV RNA, HCV RNA, HBV DNA, anti-HIV-1/HIV-2, and anti-HCV. Preservatives: 0.1% ProClin 300 and 0.15% ProClin 950.

3. CONTROL H Abbott RealTime HIV-1 High Positive Control (List No. 2G31X) (8 vials, 1.8 mL per vial) Noninfected Armored RNA with HIV-1 sequences in negative human plasma. Negative human plasma tested and found to be nonreactive for HBsAg, HIV RNA, HCV RNA, HBV DNA, anti-HIV-1/HIV-2, and anti-HCV. Preservatives: 0.1% ProClin 300 and 0.15% ProClin 950.

Abbott RealTime HIV-1 Calibrator Kit (List No. 2G31-70)

1. CAL A Abbott RealTime HIV-1 Calibrator A (List No. 2G31A) (12 vials, 1.8 mL per vial) Noninfected Armored RNA with HIV-1 sequences in negative human plasma. Negative human plasma tested and found to be nonreactive for HBsAg, HIV RNA, HCV RNA, HBV DNA, anti-HIV-1/HIV-2, and anti-HCV. Preservatives: 0.1% ProClin 300 and 0.15% ProClin 950.

2. CAL B Abbott RealTime HIV-1 Calibrator B (List No. 2G31B) (12 vials, 1.8 mL per vial) Noninfected Armored RNA with HIV-1 sequences in negative human plasma. Negative human plasma tested and found to be nonreactive for HBsAg, HIV RNA, HCV RNA, HBV DNA, anti-HIV-1/HIV-2, and anti-HCV. Preservatives: 0.1% ProClin 300 and 0.15% ProClin 950.
WARNINGS AND PRECAUTIONS

IVD

For In Vitro Diagnostic Use

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

Safety Precautions

Refer to the Abbott m1000 Operating Manual, Safety Section, the Manual Sample Preparation for Abbott RealTime RNA Assays Procedure, Handling Precaution Section, or Abbott m2000sp and Abbott m2000rt Operations Manuals, Hazard Section, for instructions on safety precautions.

CAUTION: This preparation contains human sourced and/or potentially infectious components. Components sourced from human blood have been tested and found to be nonreactive by FDA-licensed tests for antibody to HCV, antibody to HIV-1, antibody to HIV-2, and HBsAg. The material is also tested and found to be negative by FDA-licensed PCR methods for HIV-1 RNA and HCV RNA. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. These reagents and human specimens should be handled as if infectious using safe laboratory procedures, such as those outlined in Biosafety in Microbiological and Biomedical Laboratories,28 OSHA Standards on Bloodborne Pathogens,29 CLSI Document M29-A3,30 and other appropriate biosafety practices.31 Therefore all human sourced materials should be considered infectious.

These precautions include, but are not limited to, the following:

• Wear gloves when handling specimens or reagents.
• Do not pipette by mouth.
• Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in areas where these materials are handled.
• Clean and disinfect spills of specimens by including the use of a disinfectant that can be used on the reaction plate. Laboratory coats, pipettes, pipette tips, and vortexers used in the Reagent Preparation Area must remain in this area and not be moved to either the Sample Preparation Area or the Amplification Area.

Work Areas

Use 3 dedicated areas within the laboratory for performing the Abbott RealTime HIV-1 assay with the Abbott m1000 System or manual sample preparation using the Abbott mSample Preparation System and Abbott m2000rt:

• The Reagent Preparation Area is dedicated to combining the Abbott RealTime HIV-1 amplification reagent components to create the amplification master mix and transferring aliquots of the master mix to the reaction plate. Laboratory coats, pipettes, pipette tips, and vortexers used in the Reagent Preparation Area must remain in this area and not be moved to either the Sample Preparation Area or the Amplification Area.
• The Sample Preparation Area is dedicated to processing samples (specimens, Abbott RealTime HIV-1 Controls, and Calibrators), and to adding processed samples, controls, and calibrators to the Abbott 96-Well Optical Reaction Plate. All reagents used in the Sample Preparation Area should remain in this dedicated area at all times. Laboratory coats, pipettes, pipette tips, and vortexers used in the Sample Preparation Area must remain in this area and not be moved to either the Reagent Preparation Area or the Amplification Area. Do not bring amplification product into the Sample Preparation Area.
• The Amplification Area is dedicated to the amplification and detection of amplified product. Laboratory coats and equipment used in the Amplification Area must remain in this area and not be moved to either the Reagent Preparation Area or the Sample Preparation Area.

Only 2 dedicated areas, Sample Preparation Area and Amplification Area, are recommended when the Abbott m2000sp and Abbott m2000rt are used.

Components contained within a kit are intended to be used together. Do not mix components from different kit lots. For example, do not use the negative control from control kit lot X with the positive controls from control kit lot Y. Do not use kits or reagents after the dates shown on kit labels.

Work area and instrument platforms must be considered potential sources of contamination. Change gloves after contact with potential contaminants (specimens, eluates, and/or amplified product) before handling unopened reagents, negative control, positive controls, and instruments. Refer to the Abbott m1000 Operating Manual or the Abbott m2000sp and Abbott m2000rt Operations Manuals for instrument cleaning procedures.

If the Abbott m1000 System or Abbott m2000sp instrument run is aborted, dispose of all commodities and reagents according to the Abbott m1000 Operating Manual or the Abbott m2000sp Operations Manual. If the Abbott m2000sp master mix addition protocol is aborted, seal the Abbott 96-Well Optical Reaction Plate in a sealable plastic bag and dispose according to the Abbott m2000sp Operations Manual, Hazards section, along with the gloves used to handle the plate. If the Abbott m2000rt instrument run is interrupted or aborted, seal the Abbott 96-Well Optical Reaction Plate in a sealable plastic bag and dispose according to the Abbott m2000rt Operations Manual along with the gloves used to handle the plate.

Decontaminate and dispose of all potentially biohazardous materials in accordance with local, state, and federal regulations.31 All materials should be handled in a manner that minimizes the chance of potential contamination of the work area.

NOTE: Autoclaving the sealed Reaction Plate will not degrade the amplified product and may contribute to the release of the amplified product by opening the sealed plate. The laboratory area can become contaminated with amplified product if the waste materials are not carefully handled and contained.

Aerosol Containment

To reduce the risk of nucleic acid contamination due to aerosols formed during manual pipetting, aerosol barrier pipette tips must be used for all manual pipetting. The pipette tips must be used only 1 time. Clean and disinfect spills of specimens and reagents as stated in the Abbott m1000 Operating Manual or the Abbott m2000sp and Abbott m2000rt Operations Manuals.

Amplification technologies such as PCR are sensitive to accidental introduction of product from previous amplification reactions. Incorrect results could occur if either the clinical specimen or the Abbott RealTime reagents used in the amplification step become contaminated by accidental introduction of even a few molecules of amplification product. Measures to reduce the risk of contamination in the laboratory include physically separating the activities involved in performing PCR in compliance with good laboratory practices.

Special Precautions

Handling Precautions

The Abbott RealTime HIV-1 assay is only for use with plasma specimens that have been handled and stored in capped tubes as described in the SPECIMEN COLLECTION, STORAGE, AND TRANSPORT TO THE TEST SITE section.

During preparation of samples, compliance with good laboratory practices is essential to minimize the risk of cross-contamination between samples and the inadvertent introduction of ribonucleases (RNases) into samples during and after the extraction procedure. Proper aseptic technique should always be used when working with RNA.
Contamination and Inhibition

The following precautions should be observed to minimize the risks of RNase contamination, cross-contamination between samples, and inhibition:

- Wear appropriate personal protective equipment at all times.
- Use powder-free gloves.
- Change gloves after having contact with potential contaminants (such as specimens, eluates, and/or amplified product).
- To reduce the risk of nucleic acid contamination due to aerosols formed during pipetting, pipettes with aerosol barrier tips must be used for all pipetting. The length of the tip should be sufficient to prevent contamination of the pipette barrel. While pipetting, care should be taken to avoid touching the pipette barrel to the inside of the sample tube or container. The use of extended aerosol barrier pipette tips is recommended.
- Change aerosol barrier pipette tips between ALL manual liquid transfers.

- The Abbott mSample Preparation System (4 × 24 Preps) reagents are single use only. Use new reagent vials or vessels, reaction vessels, and newly opened reagents for every new Abbott RealTime HIV-1 assay run. At the end of each run, discard all remaining reagents from the worktable as stated in the Abbott m1000 Operating Manual or the Abbott m2000sp Operations Manual and the Abbott mSample Preparation System (4 × 24 Preps) product information sheet.

STORAGE INSTRUCTIONS

Abbott RealTime HIV-1 Amplification Reagent Kit (List No. 2G31-90)

The Abbott RealTime HIV-1 Amplification Reagent Pack and Internal Control vials must be stored at −10°C or colder when not in use. Care must be taken to separate the Abbott RealTime HIV-1 Amplification Reagent Pack that is in use from direct contact with samples, calibrators and controls.

Abbott RealTime HIV-1 Control Kit (List No. 2G31-80)

The Abbott RealTime HIV-1 Negative and Positive Controls must be stored at −10°C or colder.

Abbott RealTime HIV-1 Calibrator Kit (List No. 2G31-70)

The Abbott RealTime HIV-1 Calibrator A and Calibrator B must be stored at −10°C or colder.

SHIPPING CONDITIONS

- Abbott RealTime HIV-1 Amplification Reagent Kit: Ship on dry ice.
- Abbott RealTime HIV-1 Control Kit: Ship on dry ice.
- Abbott RealTime HIV-1 Calibrator Kit: Ship on dry ice.

INDICATION OF INSTABILITY OR DETERIORATION OF REAGENTS

When a positive or negative control value is out of the expected range, it may indicate deterioration of the reagents. Associated test results are invalid and samples must be retested. Assay recalibration may be necessary.

INSTRUMENT PROCEDURE

The nucleic acid testing (NAT) software must be installed on the Abbott m1000 System prior to performing the assay. For detailed information on NAT software installation, refer to the Abbott m1000 Operating Manual, Putting into Operation section.

The Abbott RealTime HIV-1 application files must be installed on the Abbott m2000sp and Abbott m2000rt systems from the Abbott RealTime HIV-1 m2000 ROW System Combined Application CD-ROM prior to performing the assay. For detailed information on application file installation, refer to the Abbott m2000sp and Abbott m2000rt Operations Manuals, Operating Instructions section.

SPECIMEN COLLECTION, STORAGE, AND TRANSPORT TO THE TEST SITE

Specimen Collection and Storage

Human plasma (ACD-A and EDTA) specimens may be used with the Abbott RealTime HIV-1 assay. Follow the manufacturer’s instructions for processing plasma collection tubes.

Freshly drawn specimens (whole blood) may be held at 15 to 30°C for up to 6 hours or at 2 to 8°C for up to 24 hours, prior to centrifugation. Separate plasma from cells by centrifugation.

After centrifugation, plasma may be removed from cells. Plasma specimens may be stored at 15 to 30°C for up to 24 hours or at 2 to 8°C for up to 5 days.

If longer storage is required, plasma specimens must be kept at −70°C or lower.32,33 Multiple freeze-thaw cycles should be avoided. If frozen, thaw plasma specimens at 15 to 30°C or at 2 to 8°C. Once thawed, if plasma specimens are not being processed immediately, they can be stored at 2 to 8°C for up to 6 hours.

NOTE: Plasma specimens should not be frozen in non-gel blood collection tubes.

Specimen Transport

Ship specimens according to the recommended storage temperature and time listed in the Specimen Collection and Storage section above. For domestic and international shipments, specimens should be packaged and labeled in compliance with applicable state, federal, and international regulations covering the transport of clinical, diagnostic, or biological specimens.

ABBOTT REALTIME HIV-1 ASSAY PROCEDURE

This Abbott RealTime HIV-1 package insert contains 2 assay protocols:

- Samples prepared for amplification using the Abbott m1000 System or the manual sample preparation method follow ASSAY PROTOCOL I.
- Samples prepared for amplification using the Abbott m2000sp instrument follow ASSAY PROTOCOL II.

The Abbott RealTime HIV-1 assay provides up to 4 sample volume options (0.2 mL, 0.5 mL, 0.6 mL, and 1.0 mL). (See assay protocol step 6 and INTERPRETATION OF RESULTS section).

Materials Provided

- Abbott RealTime HIV-1 Amplification Reagent Kit (List No. 2G31-90)

Materials Required But Not Provided

- Abbott RealTime HIV-1 Calibrator Kit (List No. 2G31-70)
- Abbott RealTime HIV-1 Control Kit (List No. 2G31-80)

For manual sample preparation method refer to the Materials and Equipment Required Section of the Manual Sample Preparation for Abbott RealTime RNA Assays Procedure (List No. 06L73).

For Abbott m1000 System Sample Preparation Area

- Abbott m1000 System
- Abbott mSample Preparation System (4 × 24 Preps) (List No. 04J70-24)
- Reaction Vessels
- Calibrated precision pipettes capable of delivering 20 to 1000 µL
- 20 µL to 1000 µL aerosol barrier pipette tips for precision pipettes
- 11.6 to 16 mm Sample Tubes
- 200 µL and 1000 µL disposable tips
- Abbott 96 Deep-Well Plate (List No. 04J71-30)
- Vortex Mixer
- Abbott Optical Adhesive Covers (List No. 04J71-75)
- Abbott Adhesive Cover Applicators
- Abbott Splash-Free Support Base (List No. 09K31-01)
- Reagent Vessels
- 1.5 mL Output Tubes
- Centrifuge capable of 5000g

For Abbott m2000sp Instrument Sample Preparation Area

- Abbott m2000sp instrument
- Abbott mSample Preparation System (4 × 24 Preps) (List No. 04J70-24)
- 5 mL Reaction Vessels
- Calibrated precision pipettes capable of delivering 20 to 1000 µL
- 20 µL to 1000 µL aerosol barrier pipette tips for precision pipettes
- 11.5 to 16 mm Sample Tubes
- 200 µL and 1000 µL disposable tips
- Abbott Optical Adhesive Covers (List No. 04J71-75)
- Abbott Adhesive Cover Applicators
- Abbott Splash-Free Support Base (List No. 09K31-01)
- Master Mix Vial
- 200 mL Reagent Vessels
- Abbott 96-Deep-Well Plate (List No. 04J71-30)
- Abbott RealTime HIV-1 m2000 ROW System Combined Application CD-ROM (List No. 1L68)
- Abbott 96-Well Optical Reaction Plate (List No. 04J71-70)
- Centrifuge capable of 2000g
For Abbott m1000 System
Reagent Preparation Area
• StrataCooler® 96 Benchtop Cooler
• Abbott 96-Well Optical Reaction Plate (List No. 04J71-70)
• Calibrated precision pipettes capable of delivering 20 to 1000 µL
• 20 µL to 1000 µL aerosol barrier pipette tips for precision pipettes
• Single-use RNase/DNase-free tube or container
• Vortex Mixer

For Abbott m2000rt Instrument
Amplification Area
• Abbott m2000rt instrument
• Abbott RealTime HIV-1 m2000 ROW System Combined Application CD-ROM (List No. 1L68)
• Abbott m2000rt Optical Calibration Kit (List No. 04J71-93)

Laboratory for the Presence of Contamination Control Procedures
1. Thaw assay controls and IC at 15 to 30°C or at 2 to 8°C. Thaw laboratory practices.
   • Sealed plastic bags
   • 1.7 mL molecular biology grade microfuge tubes (Dot Statistical, Inc. or equivalent)
   • Cotton Tip Applicators (Puritan or equivalent)
   • RNase-free water (Eppendorf or equivalent)

Other Materials
• Biological safety cabinet approved for working with infectious materials
• Sealable plastic bags

NOTE: These 3 items are used in the procedure for Monitoring the Laboratory for the Presence of Contamination. Refer to the QUALITY CONTROL PROCEDURES section of this package insert.

Procedural Precautions
Read the instructions in this package insert carefully before processing samples.

The Abbott RealTime HIV-1 Calibrators, Internal Control, Negative Control, Low Positive Control, and High Positive Control vials are intended for single-use only and should be discarded after use.

Use aerosol barrier pipette tips or disposable pipettes only one time when pipetting specimens, IC, or amplification reagents. To prevent contamination to the pipette barrel while pipetting, care should be taken to avoid touching the pipette barrel to the inside of the sample tube or container. The use of extended aerosol barrier pipette tips is recommended.

Monitoring procedures for the presence of amplification product can be found in the QUALITY CONTROL PROCEDURES section in this package insert.

To reduce the risk of nucleic acid contamination, clean and disinfect spills of specimens by including the use of a tuberculosis disinfectant such as 1.0% sodium hypochlorite or other suitable disinfectant.

The Abbott RealTime HIV-1 Calibrators and Controls must be prepared in conjunction with the specimens to be tested. The use of the Abbott RealTime HIV-1 Controls and Calibrators is integral to the performance of the Abbott RealTime HIV-1 assay. Refer to the QUALITY CONTROL PROCEDURES section of this package insert for details.

ASSAY PROTOCOL I: ABBOTT m1000 SYSTEM OR THE MANUAL SAMPLE PREPARATION METHOD AND ABBOTT m2000rt INSTRUMENT


Laboratory personnel must be trained to operate the Abbott m1000 System and the Abbott m2000rt instrument. The operator must have a thorough knowledge of the software applications and must follow good laboratory practices.

1. Thaw assay controls and IC at 15 to 30°C or at 2 to 8°C. Thaw calibrators at 15 to 30°C or at 2 to 8°C only if performing a calibration run; see QUALITY CONTROL PROCEDURES section of this package insert.
   • Once thawed, assay controls, IC, and calibrators can be stored at 2 to 8°C for up to 24 hours before use.
   • Vortex each assay calibrator and each control 3 times for 2 to 3 seconds before use. Ensure that the contents of each vial are at the bottom after vortexing by tapping the vials on the bench to bring liquid to the bottom of the vial.
2. Thaw amplification reagents at 15 to 30°C or at 2 to 8°C and store at 2 to 8°C until required for the amplification master mix procedure.

• Once thawed, the amplification reagents can be stored at 2 to 8°C for up to 24 hours if not used immediately.

NOTE: Use 1 bottle of mLysis Buffer, 1 vial of IC, and 1 Abbott RealTime HIV-1 Amplification Reagent Pack to support up to 24 reactions. Use a second set of reagents to support 25 to 48 reactions. A maximum of 48 reactions can be performed per run using an Abbott m1000 instrument.

Sample Preparation Area
For sample preparation using the Abbott m1000 System, follow steps 3 through 10. For the manual sample preparation method refer to the Extraction Protocol Section of the Manual Sample Preparation for Abbott RealTime RNA Assays Procedure (List No. 06L73).

3. Gently invert the Abbott mSample Preparation bottles to ensure a homogeneous solution. If crystals are observed in any of the reagent bottles upon opening, allow the reagent to equilibrate at room temperature until the crystals disappear. Do not use the reagents until the crystals have dissolved.
4. Vortex each IC 3 times for 2 to 3 seconds before use.
5. Use a calibrated precision PIPETTE DEDICATED FOR INTERNAL CONTROL USE ONLY to add 500 µL of IC to each bottle of mLysis Buffer. Mix by gently inverting the container 5 to 10 times to minimize foaming.
6. A total of 48 samples can be processed in each run. A negative control, a low positive control, and a high positive control are included in each run, therefore allowing a maximum of 45 specimens to be processed per run.
   • The Abbott RealTime HIV-1 assay minimum sample volume and associated rack requirements on the Abbott m1000 System are:

<table>
<thead>
<tr>
<th>Rack</th>
<th>Tube Diametera</th>
<th>Minimum Sample Volume</th>
<th>Assay Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>13 mm</td>
<td>11.6 mm - 14.0 mm</td>
<td>0.2 mL</td>
<td>0.5 mL</td>
</tr>
<tr>
<td>16 mm</td>
<td>15.0 mm - 16.0 mm</td>
<td>1.0 mL</td>
<td>1.3 mL</td>
</tr>
</tbody>
</table>

a Refers to sample tube outer diameter

• If frozen, thaw specimens at 15 to 30°C or at 2 to 8°C. Once thawed, specimens can be stored at 2 to 8°C for up to 6 hours if not processed immediately.

NOTE: For every stored specimen, the following actions must be done in the order described: vortex the specimen first and follow with centrifugation. If these actions are not performed in this order, then invalid results may occur.
   • Vortex each specimen 3 times for 2 to 3 seconds.
   • Centrifuge specimens at 2000g for 5 minutes before loading onto the Abbott m1000 worktable. Aliquot each specimen into clean tubes or vials if necessary. Refer to the Abbott m1000 Operating Manual for tube sizes. Avoid touching the inside of the cap when opening tubes.
7. Place the calibrators (if applicable), low and high positive controls, the negative control, and the patient specimens into the Abbott m1000 sample rack. Follow directions for performing a user-defined protocol, as described in the Abbott m1000 Operating Manual, Operation section.
8. Place the Reaction Vessels into the Abbott m1000 1 mL subsystem carrier.
9. Load the Abbott mSample Preparation System reagents and the 1.5 mL Output Tubes on the Abbott m1000 System worktable as described in the Abbott m1000 Operating Manual, Operation section.
10. Initiate the Abbott m1000 protocol as described in the Abbott m1000 Operating Manual, Operation section. From the Protocol screen, select the appropriate application file corresponding to the sample volume being tested.
   • The assembly of the amplification master mix and sample eluates into the Abbott 96-Well Optical Reaction Plate (step 17) must be initiated within 1 hour after completion of Sample Preparation.

Amplification Area

11. Switch on and initialize the Abbott m2000rt instrument.

NOTE: The Abbott m2000rt instrument requires 15 minutes to warm up.
12. Create the Abbott m2000rt test order. Refer to the Operating Instructions section of the Abbott m2000rt Operations Manual. From the Protocol screen, select the appropriate application file corresponding to the sample volume being tested.

- Enter calibrator (needed if a calibration curve has not been stored on the Abbott m2000rt) and control lot specific values in the test order for accurate calibration and control evaluation. Lot-specific values are specified in each Abbott RealTime HIV-1 Calibrator and Control Kit Card.

Reagent Preparation Area
All reagent preparation must take place in the dedicated Reagent Preparation Area. Refer to the Handling Precautions section of this package insert before preparing reagents.

NOTE: Change gloved hands before handling the amplification reagents.

13. Prepare the amplification master mix.

- Each Amplification Reagent Pack supports up to 24 reactions.
- Prior to opening the amplification reagents, ensure that the contents of the vials are at the bottom by tapping the vials in an upright position on the bench to bring the liquid to the bottom of the vials.
- Prepare the master mix by using a PIPETTE DEDICATED FOR REAGENT USE ONLY to add 271 µL of the HIV-1 Activation Reagent (Reagent 1) and 949 µL of the HIV-1 Oligonucleotide Reagent (Reagent 2) together in the Thermostable rTth DNA Polymerase Enzyme bottle (Reagent 3).
- If performing 25 to 48 reactions, prepare a second amplification master mix with a second Amplification Reagent Pack.
- The Abbott m2000rt protocol (step 20) must be initiated within 40 minutes of the addition of Activation Reagent into the first rTth Enzyme Reagent bottle (step 13).

14. Pipette the contents of the master mix from the enzyme bottle(s) into a single-use RNase/DNase-free tube and vortex to mix.

15. Place an Abbott 96-Well Optical Reaction Plate in a StrataCooler 96 stored as indicated in the StrataCooler 96 instruction manual. Using a DEDICATED PIPETTE, dispense 50 µL aliquots of the amplification master mix into the Abbott 96-Well Optical Reaction Plate. A calibrated repeat pipettor may be used. Visually verify that 50 µL has been dispensed into each well.

16. Transfer the Abbott 96-Well Optical Reaction Plate on the StrataCooler 96 to the Sample Preparation Area.

Sample Preparation Area
17. In the Sample Preparation Area, transfer 50 µL of sample eluate to the Abbott 96-Well Optical Reaction Plate on the StrataCooler 96. Use a separate pipette tip for each sample eluate transfer. During the transfer of each sample, mix the reaction by pipetting up and down 3 to 5 times. Visually verify that 100 µL has been dispensed into each well.


19. Remove the Abbott 96-Well Optical Reaction Plate from the StrataCooler 96 and place in the Abbott Splash-Free Support Base. Centrifuge the Abbott 96-Well Optical Reaction Plate in the Abbott Splash-Free Support Base at 5,000g for 5 minutes. Transfer to the Amplification Area.

NOTE: Do not transfer the StrataCooler 96 to the Amplification Area.

Amplification Area
20. Place the Abbott 96-Well Optical Reaction Plate in the Abbott m2000rt instrument. From the Protocol screen, select the appropriate application file corresponding to the sample volume being tested. Initiate the Abbott RealTime HIV-1 protocol, as described in the Abbott m2000rt Operations Manual, Operating Instructions section.

POST PROCESSING PROCEDURES
1. Clean the StrataCooler 96 as described in the StrataCooler 96 instruction manual and return to the Reagent Preparation Area.
2. Remove the 1.5 mL Output Tubes from the worktable and dispose of according to the Abbott m1000 Operating Manual.
3. Place the Abbott 96-Well Optical Reaction Plate in a sealable plastic bag and dispose of according to the Abbott m2000rt Operations Manual along with the gloves used to handle the plate.
5. For manual sample preparation method users, refer to the Clean Up Section of the Manual Sample Preparation for Abbott RealTime RNA Assays Procedure (List No. 06L73).

ASSAY PROTOCOL II: ABBOTT m2000sp INSTRUMENT AND ABBOTT m2000rt INSTRUMENT
For a detailed description of how to perform an Abbott m2000sp instrument and Abbott m2000rt instrument protocol, refer to the Abbott m2000sp and Abbott m2000rt Operations Manuals, Operating Instructions sections. The 96-sample capability requires Abbott m2000sp Software Version 2.0 or higher. Please follow Abbott m2000sp Operations Manual (List 09K20-02) and addendum or addenda.

Laboratory personnel must be trained to operate the Abbott m2000sp and Abbott m2000rt instruments. The operator must have a thorough knowledge of the applications run on the instruments and must follow good laboratory practices.
1. Thaw assay controls and IC at 15 to 30°C or at 2 to 8°C. Thaw calibrators at 15 to 30°C or at 2 to 8°C only if performing a calibration run; see QUALITY CONTROL PROCEDURES section of this package insert.
- Once thawed, assay controls, IC, and calibrators can be stored at 2 to 8°C for up to 24 hours before use.
- Vortex each assay control and each control 3 times for 2 to 3 seconds before use. Ensure that the contents of each vial are at the bottom after vortexing by tapping the vials on the bench to bring liquid to the bottom of the vial.
2. Thaw amplification reagents at 15 to 30°C or at 2 to 8°C and store at 2 to 8°C until required for the amplification master mix procedure.
- Once thawed, the amplification reagents can be stored at 2 to 8°C for up to 24 hours if not used immediately.

NOTE: Use 1 bottle of mLYsis Buffer, 1 vial of IC, and 1 Abbott RealTime HIV-1 Amplification Reagent Pack to support up to 24 reactions. Use a second set of reagents to support 25 to 48 reactions, a third set of reagents to support 49 to 72 reactions, and a fourth set of reagents to support 73 to 96 reactions WITH THE EXCEPTION OF mMICROPARTICLES. USE ONLY 2 BOTTLES OF mMICROPARTICLES WHEN PROCESSING 25 TO 96 SAMPLES.
3. Gently invert the Abbott mSample Preparation bottles to ensure a homogeneous solution. If crystals are observed in any of the reagent bottles upon opening, allow the reagent to equilibrate at room temperature until the crystals disappear. Do not use the reagents until the crystals have dissolved.
4. Vortex each IC 3 times for 2 to 3 seconds before use.
5. Use a calibrated precision PIPETTE DEDICATED FOR INTERNAL CONTROL USE ONLY to add 500 µL of IC to each bottle of mLYsis Buffer. Mix by gently inverting the container 5 to 10 times to minimize foaming.
6. A total of 96 samples can be processed in each run, with the exception of the 1.0 ml Assay Application. A negative control, a low positive control, and a high positive control are included in each run, therefore allowing a maximum of 93 specimens to be processed per run. For the 1.0 ml Assay Application, a total of 48 samples can be processed in each run, allowing a maximum of 45 specimens to be processed per run.
- The Abbott RealTime HIV-1 assay minimum sample volume and associated rack requirements on the Abbott m2000sp are:

<table>
<thead>
<tr>
<th>Rack Diameter</th>
<th>Minimum Sample Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>13 mm 11.5 - 14.0 mm</td>
<td>0.4 - 0.8 mL</td>
</tr>
<tr>
<td>13 mm 11.5 - 14.0 mm</td>
<td>0.7 - 1.2 mL</td>
</tr>
<tr>
<td>14 mm 15.0 - 18.0 mm</td>
<td>1.2 - 1.7 mL</td>
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</tbody>
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NOTE: Use 1 bottle of mLYsis Buffer, 1 vial of IC, and 1 Abbott RealTime HIV-1 Amplification Reagent Pack to support up to 24 reactions. Use a second set of reagents to support 25 to 48 reactions, a third set of reagents to support 49 to 72 reactions, and a fourth set of reagents to support 73 to 96 reactions WITH THE EXCEPTION OF mMICROPARTICLES. USE ONLY 2 BOTTLES OF mMICROPARTICLES WHEN PROCESSING 25 TO 96 SAMPLES.

Abbott RealTime HIV-1 Assay Application

<table>
<thead>
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<td>14 mm 15.0 - 18.0 mm</td>
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</tr>
</tbody>
</table>

* Refers to sample tube outer diameter. Minimum sample volume varies with tube geometry and size. Refer to the Abbott m2000sp Operations Manual and QUICK REFERENCE GUIDE FOR SAMPLE TUBE SIZES AND VOLUMES for recommended sample input volume.

- If frozen, thaw specimens at 15 to 30°C or at 2 to 8°C. Once thawed, specimens can be stored at 2 to 8°C for up to 6 hours if not processed immediately.

NOTE: For every stored specimen, the following actions must be done in the order described: vortex the specimen first and follow with centrifugation. If these actions are not performed in this order, then invalid results may occur.
1. Place the sealed optical reaction plate into the Abbott Splash-Free Support Base for transfer to the Abbott m2000rt instrument.

2. Place the Abbott 96-Well Optical Reaction Plate in a sealable plastic bag and dispose according to the Abbott m2000rt Operations Manual.


POST PROCESSING PROCEDURES

1. Remove the Abbott 96-Well Deep-Well Plate from the worktable and dispose of according to the Abbott m2000sp Operations Manual.

2. Place the Abbott 96-Well Optical Reaction Plate in a sealable plastic bag and dispose according to the Abbott m2000rt Operations Manual along with the gloves used to handle the plate.

QUALITY CONTROL PROCEDURES

Abbott m2000rt Optical Calibration


Optical calibration of the Abbott m2000rt instrument is required for the accurate measurement and discrimination of dye fluorescence during the Abbott RealTime HIV-1 assay. The following Abbott m2000rt Optical Calibration Plates are used to calibrate the Abbott m2000rt instrument for the Abbott RealTime HIV-1 assay:

- FAM™ Plate (Carboxyfluorescein)
- ROX™ Plate (Carboxy-X-rhodamine)
- VIC® Plate (Proprietary dye)

Assay Calibration

For a detailed description of how to perform an assay calibration refer to the Abbott m2000sp and Abbott m2000rt Operations Manuals, Operating Instructions sections.

A calibration curve is required to quantitate the HIV-1 RNA concentration of specimens and controls. Two assay calibrators are run in replicates of 3 to generate a calibration curve (HIV-1 concentration versus the threshold cycle [CT] at which a reactive level of fluorescent signal is detected). The calibration curve slope and intercept are calculated and stored on the instrument. The concentration of HIV-1 RNA in a sample is calculated from the stored calibration curve. Results are automatically reported on the Abbott m2000rt workstation.

Follow the procedure for sample extraction, master mix addition, amplification and detection protocols as stated in the Abbott m1000 Operating Manual or Abbott m2000sp Operations Manual, and the Abbott m2000rt Operations Manual.

Once an Abbott RealTime HIV-1 calibration is accepted and stored, it may be used for 6 months. During this time, all subsequent samples may be tested without further calibration unless:

- An Abbott RealTime HIV-1 Amplification Reagent Kit with a new lot number is used.
- An Abbott mSample Preparation System (4 × 24 Preps) with a new lot number is used.
- An Abbott RealTime HIV-1 application file for a different sample volume is used.
- A new Abbott RealTime HIV-1 application specification file is installed.
• Pure Dye optical re-calibration of the Abbott RealTime HIV-1 assay-specific dyes (FAM, VIC, or ROX) is performed per the Calibration Procedures section of the Abbott m2000rt Operations Manual.

Detection of Inhibition
An IC threshold cycle [CT] assay validity parameter is established during a calibration run. A defined, consistent quantity of IC is introduced into each specimen, calibrator, and control at the beginning of sample preparation and measured on the Abbott m2000rt instrument to demonstrate proper specimen processing and assay validity. The IC is comprised of an RNA sequence unrelated to the HIV-1 target sequence. The median amplification cycle at which the IC target sequence fluorescent signal is detected in calibration samples establishes an IC CT validity range to be met by all subsequent processed specimens. An error control flag is displayed when a specimen or control fails to meet this specification. Refer to the Abbott m2000rt Operations Manual for an explanation of the corrective actions for the error control flag. Specimens whose IC CT value exceeds the established range must be retested starting with sample preparation.

Negative and Positive Controls
A negative control, a low-positive control, and a high-positive control are included in each test order to evaluate run validity. The lot-specific values for the low-positive control and high-positive control are specified on each Abbott RealTime HIV-1 Control Kit Card and must be entered into the assay test order when a run is performed. An error control flag is displayed when a control result is out of range. Refer to the Abbott m2000rt Operations Manual for an explanation of the corrective actions for the error control flag. If negative or positive controls are out of range, all of the specimens and controls from that run must be reprocessed, beginning with sample preparation. The presence of HIV-1 must not be detected in the negative control. HIV-1 detected in the negative control is indicative of contamination by other samples or by amplified product introduced during sample processing and assay validity. The IC is comprised of an RNA sequence unrelated to the HIV-1 target sequence.

Monitoring the Laboratory for the Presence of Contamination
It is recommended that this test be done at least once a month to monitor laboratory surfaces and equipment for contamination by other samples or by amplified product introduced during sample processing and assay validity. The IC is comprised of an RNA sequence unrelated to the HIV-1 target sequence. The median amplification cycle at which the IC target sequence fluorescent signal is detected in calibration samples establishes an IC CT validity range to be met by all subsequent processed specimens. An error control flag is displayed when a specimen or control fails to meet this specification. Refer to the Abbott m2000rt Operations Manual for an explanation of the corrective actions for the error control flag. Specimens whose IC CT value exceeds the established range must be retested starting with sample preparation.

Negative and Positive Controls
A negative control, a low-positive control, and a high-positive control are included in each test order to evaluate run validity. The lot-specific values for the low-positive control and high-positive control are specified on each Abbott RealTime HIV-1 Control Kit Card and must be entered into the assay test order when a run is performed. An error control flag is displayed when a control result is out of range. Refer to the Abbott m2000rt Operations Manual for an explanation of the corrective actions for the error control flag. If negative or positive controls are out of range, all of the specimens and controls from that run must be reprocessed, beginning with sample preparation. The presence of HIV-1 must not be detected in the negative control. HIV-1 detected in the negative control is indicative of contamination by other samples or by amplified product introduced during sample processing and assay validity. The IC is comprised of an RNA sequence unrelated to the HIV-1 target sequence.

Monitoring the Laboratory for the Presence of Contamination
It is recommended that this test be done at least once a month to monitor laboratory surfaces and equipment for contamination by other samples or by amplified product introduced during sample processing and assay validity. The IC is comprised of an RNA sequence unrelated to the HIV-1 target sequence. The median amplification cycle at which the IC target sequence fluorescent signal is detected in calibration samples establishes an IC CT validity range to be met by all subsequent processed specimens. An error control flag is displayed when a specimen or control fails to meet this specification. Refer to the Abbott m2000rt Operations Manual for an explanation of the corrective actions for the error control flag. Specimens whose IC CT value exceeds the established range must be retested starting with sample preparation.

Negative and Positive Controls
A negative control, a low-positive control, and a high-positive control are included in each test order to evaluate run validity. The lot-specific values for the low-positive control and high-positive control are specified on each Abbott RealTime HIV-1 Control Kit Card and must be entered into the assay test order when a run is performed. An error control flag is displayed when a control result is out of range. Refer to the Abbott m2000rt Operations Manual for an explanation of the corrective actions for the error control flag. If negative or positive controls are out of range, all of the specimens and controls from that run must be reprocessed, beginning with sample preparation. The presence of HIV-1 must not be detected in the negative control. HIV-1 detected in the negative control is indicative of contamination by other samples or by amplified product introduced during sample processing and assay validity. The IC is comprised of an RNA sequence unrelated to the HIV-1 target sequence.
The LOD was determined by testing dilutions of a viral standard from the Virology Quality Assurance (VQA) Laboratory of the AIDS Clinical Trials Group. Dilutions were made in HIV-1 negative human plasma. Testing was performed with 3 lots of amplification reagents on 3 Abbott m2000 Systems. The results, representative of the analytical sensitivity performance of the Abbott RealTime HIV-1 assay, are summarized in Table 1.

<table>
<thead>
<tr>
<th>Conc. (Copies/mL)</th>
<th>Number Tested</th>
<th>Number Detected</th>
<th>Percent Detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>57</td>
<td>57</td>
<td>100</td>
</tr>
<tr>
<td>75</td>
<td>57</td>
<td>57</td>
<td>100</td>
</tr>
<tr>
<td>60</td>
<td>57</td>
<td>57</td>
<td>100</td>
</tr>
<tr>
<td>50</td>
<td>57</td>
<td>57</td>
<td>100</td>
</tr>
<tr>
<td>40</td>
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<td>57</td>
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</tr>
<tr>
<td>20</td>
<td>57</td>
<td>50</td>
<td>88</td>
</tr>
<tr>
<td>10</td>
<td>56a</td>
<td>38</td>
<td>68</td>
</tr>
<tr>
<td>5</td>
<td>57</td>
<td>30</td>
<td>53</td>
</tr>
</tbody>
</table>

a One replicate generated an invalid replicate error message and was deleted from the data analysis.

Probit analysis of the data determined that the concentration of HIV-1 RNA detected with 95% probability was 25 copies/mL (95% CI 20 to 33).

Limit of Detection, 0.6 mL Sample Volume

The LOD of the Abbott RealTime HIV-1 assay is 40 copies/mL with the 0.6 mL sample volume procedure. The LOD for the 0.6 mL sample volume procedure was determined as described for the 1.0 mL sample volume procedure. The results, representative of the analytical sensitivity performance of the Abbott RealTime HIV-1 assay, are summarized in Table 2.

<table>
<thead>
<tr>
<th>Conc. (Copies/mL)</th>
<th>Number Tested</th>
<th>Number Detected</th>
<th>Percent Detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>57</td>
<td>57</td>
<td>100</td>
</tr>
<tr>
<td>75</td>
<td>57</td>
<td>57</td>
<td>100</td>
</tr>
<tr>
<td>60</td>
<td>57</td>
<td>57</td>
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</tr>
<tr>
<td>50</td>
<td>57</td>
<td>57</td>
<td>100</td>
</tr>
<tr>
<td>40</td>
<td>57</td>
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<td>10</td>
<td>57</td>
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</tr>
<tr>
<td>5</td>
<td>57</td>
<td>13</td>
<td>23</td>
</tr>
</tbody>
</table>

Probit analysis of the data determined that the concentration of HIV-1 RNA detected with 95% probability was 39 copies/mL (95% CI 33 to 49).

Limit of Detection, 0.5 mL Sample Volume

The LOD of the Abbott RealTime HIV-1 assay is 75 copies/mL with the 0.5 mL sample volume procedure. The LOD for the 0.5 mL sample volume procedure was determined as described for the 1.0 mL sample volume procedure. The results, representative of the analytical sensitivity performance of the Abbott RealTime HIV-1 assay, are summarized in Table 3.

<table>
<thead>
<tr>
<th>Conc. (Copies/mL)</th>
<th>Number Tested</th>
<th>Number Detected</th>
<th>Percent Detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>57</td>
<td>57</td>
<td>100</td>
</tr>
<tr>
<td>75</td>
<td>57</td>
<td>57</td>
<td>100</td>
</tr>
<tr>
<td>60</td>
<td>57</td>
<td>57</td>
<td>100</td>
</tr>
<tr>
<td>50</td>
<td>57</td>
<td>54</td>
<td>95</td>
</tr>
<tr>
<td>40</td>
<td>57</td>
<td>54</td>
<td>95</td>
</tr>
<tr>
<td>30</td>
<td>57</td>
<td>47</td>
<td>82</td>
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<tr>
<td>20</td>
<td>57</td>
<td>46</td>
<td>81</td>
</tr>
<tr>
<td>10</td>
<td>57</td>
<td>26</td>
<td>46</td>
</tr>
<tr>
<td>5</td>
<td>57</td>
<td>21</td>
<td>37</td>
</tr>
</tbody>
</table>

a One replicate generated an invalid replicate error message and was deleted from the data analysis.

Probit analysis of the data determined that the concentration of HIV-1 RNA detected with 95% probability was 65 copies/mL (95% CI 51 to 88).

Limit of Detection, 0.2 mL Sample Volume

The LOD of the Abbott RealTime HIV-1 assay is 150 copies/mL with the 0.2 mL sample volume procedure. The LOD for the 0.2 mL sample volume procedure was determined as described for the 1.0 mL sample volume procedure. The results, representative of the analytical sensitivity performance of the Abbott RealTime HIV-1 assay, are summarized in Table 4.

<table>
<thead>
<tr>
<th>Conc. (Copies/mL)</th>
<th>Number Tested</th>
<th>Number Detected</th>
<th>Percent Detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>250</td>
<td>57</td>
<td>57</td>
<td>100</td>
</tr>
<tr>
<td>200</td>
<td>57</td>
<td>57</td>
<td>98</td>
</tr>
<tr>
<td>150</td>
<td>57</td>
<td>57</td>
<td>98</td>
</tr>
<tr>
<td>100</td>
<td>57</td>
<td>57</td>
<td>95</td>
</tr>
<tr>
<td>75</td>
<td>57</td>
<td>47</td>
<td>82</td>
</tr>
<tr>
<td>60</td>
<td>57</td>
<td>38</td>
<td>67</td>
</tr>
<tr>
<td>50</td>
<td>57</td>
<td>39</td>
<td>68</td>
</tr>
<tr>
<td>40</td>
<td>54a</td>
<td>30</td>
<td>56</td>
</tr>
<tr>
<td>30</td>
<td>52a</td>
<td>19</td>
<td>37</td>
</tr>
</tbody>
</table>

a Eight replicates were invalid due to an instrument error and were deleted from the data analysis.

Probit analysis of the data determined that the concentration of HIV-1 RNA detected with 95% probability was 119 copies/mL (95% CI 102 to 150).

Linear Range

The upper limit of quantitation (ULQ) for the Abbott RealTime HIV-1 assay is 10 million copies/mL, and the lower limit of quantitation is equivalent to the LOD (40 copies/mL for the 1.0 mL and 0.6 mL sample volume procedure, 75 copies/mL for the 0.5 mL sample volume procedure, and 150 copies/mL for the 0.2 mL sample volume procedure).

A 9-member panel prepared by diluting armored HIV-1 RNA from 7.44 log copies/mL to 1.16 log copies/mL in HIV-1 negative human plasma was tested. Linearity analysis was performed following the NCCLS EP6-A guideline. The results, representative of the Abbott RealTime HIV-1 assay linearity, are shown in Figure 1.

The Abbott RealTime HIV-1 assay was shown to be linear across the range tested (n = 99, r = 0.999, slope = 0.93, and intercept = 0.26).

Precision

The precision of the Abbott RealTime HIV-1 assay was evaluated for the 1.0 mL sample volume procedure using the Abbott m1000 and Abbott m2000sp sample preparation systems and the manual sample preparation method. The Abbott RealTime HIV-1 assay is designed to achieve an inter-assay standard deviation (SD) of less than or equal to 0.25 log copies of HIV-1 RNA per mL for samples containing HIV-1 concentrations from 500 to 5 million copies/mL. The Abbott RealTime HIV-1 assay is designed to achieve an inter-assay standard deviation (SD) of less than or equal to 0.25 log copies of HIV-1 RNA per mL for samples containing HIV-1 concentrations from 500 to 5 million copies/mL. A 7-member panel containing armored HIV-1 RNA (panel members 1 through 3) and armored HIV-1 RNA (panel members 4 through 7) in HIV-1 negative human plasma was prepared by diluting an HIV-1 viral stock (panel members 1 through 3) and armored HIV-1 RNA (panel members 4 through 7) in HIV-1 negative human plasma. For the precision studies with the Abbott RealTime HIV-1 assay, the panel members were tested in replicates.
of 5 in a total of 15 runs on 3 instrument systems, with 3 lots of amplification reagents. For the precision study using the manual sample preparation method, panel members were tested in replicates of 2 for the first run on each instrument and replicates of 3 for each subsequent run for a total of 15 runs on 3 Abbott m2000rt instruments with 3 lots of amplification reagents. Precision analysis was performed following the NCCLS EP10-A2 guideline. Within-run, between-run, and inter-assay amplification reagents. Precision analysis was performed following the 2000 run for a total of 15 runs on 3 Abbott instruments with 3 lots of the first run on each instrument and replicates of 3 for each subsequent preparation method, panel members were tested in replicates of 2 for the precision study using the manual sample of 5 in a total of 15 runs on 3 instrument systems, with 3 lots of HIV-1 RNA was not detected in 2 replicates. a Inter-assay contains within-run and between-run components.
b HIV-1 RNA was not detected in 1 replicate.
c One replicate was inhibited and deleted from the data analysis.

d HIV-1 RNA was not detected in 3 replicates.

e HIV-1 RNA was not detected in 1 replicate.

Table 5. 
Precision with the Abbott m1000 System

<table>
<thead>
<tr>
<th>Panel Member</th>
<th>Conc. Mean (copies/mL)</th>
<th>Conc. Mean (log copies/mL)</th>
<th>Within-Run SD Component</th>
<th>Between-Run SD Component</th>
<th>Inter-Assay SD Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>75</td>
<td>57</td>
<td>1.75</td>
<td>0.21</td>
<td>0.00</td>
</tr>
<tr>
<td>2</td>
<td>75</td>
<td>573</td>
<td>2.76</td>
<td>0.08</td>
<td>0.00</td>
</tr>
<tr>
<td>3</td>
<td>75</td>
<td>5,000</td>
<td>3.70</td>
<td>0.05</td>
<td>0.02</td>
</tr>
<tr>
<td>4</td>
<td>75b,c</td>
<td>35,751</td>
<td>4.55</td>
<td>0.03</td>
<td>0.01</td>
</tr>
<tr>
<td>5</td>
<td>75</td>
<td>315,065</td>
<td>5.50</td>
<td>0.07</td>
<td>0.03</td>
</tr>
<tr>
<td>6</td>
<td>75b</td>
<td>2,947,538</td>
<td>6.47</td>
<td>0.05</td>
<td>0.04</td>
</tr>
<tr>
<td>7</td>
<td>75</td>
<td>5,347,285</td>
<td>6.73</td>
<td>0.04</td>
<td>0.05</td>
</tr>
</tbody>
</table>

a Inter-assay contains within-run and between-run components.
b Two replicates were inhibited and deleted from the data analysis.
c HIV-1 RNA was not detected in 1 replicate.

Table 6. 
Precision with the Abbott m2000 System

<table>
<thead>
<tr>
<th>Panel Member</th>
<th>Conc. Mean (copies/mL)</th>
<th>Conc. Mean (log copies/mL)</th>
<th>Within-Run SD Component</th>
<th>Between-Run SD Component</th>
<th>Inter-Assay SD Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>74b</td>
<td>72</td>
<td>1.86</td>
<td>0.18</td>
<td>0.07</td>
</tr>
<tr>
<td>2</td>
<td>75</td>
<td>652</td>
<td>2.81</td>
<td>0.08</td>
<td>0.01</td>
</tr>
<tr>
<td>3</td>
<td>75</td>
<td>5,417</td>
<td>3.73</td>
<td>0.04</td>
<td>0.02</td>
</tr>
<tr>
<td>4</td>
<td>75</td>
<td>39,458</td>
<td>4.60</td>
<td>0.04</td>
<td>0.03</td>
</tr>
<tr>
<td>5</td>
<td>74c</td>
<td>358,597</td>
<td>5.55</td>
<td>0.03</td>
<td>0.02</td>
</tr>
<tr>
<td>6</td>
<td>75</td>
<td>3,102,654</td>
<td>6.49</td>
<td>0.03</td>
<td>0.02</td>
</tr>
<tr>
<td>7</td>
<td>75</td>
<td>5,953,879</td>
<td>6.77</td>
<td>0.04</td>
<td>0.04</td>
</tr>
</tbody>
</table>

a Inter-assay contains within-run and between-run components.
b HIV-1 RNA was not detected in 1 replicate.
c One replicate was inhibited and deleted from the data analysis.

Table 7. 
Precision with Manual Sample Preparation Method

<table>
<thead>
<tr>
<th>Panel Member</th>
<th>Conc. Mean (copies/mL)</th>
<th>Conc. Mean (log copies/mL)</th>
<th>Within-Run SD Component</th>
<th>Between-Run SD Component</th>
<th>Inter-Assay SD Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>49b</td>
<td>46</td>
<td>1.66</td>
<td>0.21</td>
<td>0.07</td>
</tr>
<tr>
<td>2</td>
<td>41c</td>
<td>471</td>
<td>2.67</td>
<td>0.11</td>
<td>0.09</td>
</tr>
<tr>
<td>3</td>
<td>42</td>
<td>4,474</td>
<td>3.65</td>
<td>0.05</td>
<td>0.10</td>
</tr>
<tr>
<td>4</td>
<td>42</td>
<td>34,503</td>
<td>4.54</td>
<td>0.02</td>
<td>0.06</td>
</tr>
<tr>
<td>5</td>
<td>42</td>
<td>362,283</td>
<td>5.56</td>
<td>0.04</td>
<td>0.08</td>
</tr>
<tr>
<td>6</td>
<td>42</td>
<td>3,597,099</td>
<td>6.56</td>
<td>0.03</td>
<td>0.04</td>
</tr>
<tr>
<td>7</td>
<td>42</td>
<td>6,552,825</td>
<td>6.82</td>
<td>0.05</td>
<td>0.05</td>
</tr>
</tbody>
</table>

a Inter-assay contains within-run and between-run components.
b HIV-1 RNA was not detected in 2 replicates.
c One replicate was inhibited and deleted from the data analysis.

Potentially Interfering Substances

The susceptibility of the Abbott RealTime HIV-1 assay to interference by elevated levels of endogenous substances and by drugs commonly prescribed to HIV-1 infected individuals was evaluated. HIV-1 negative samples and samples containing 10,000 copies/mL of HIV-1 RNA were tested. No interference in the performance of the Abbott RealTime HIV-1 assay was observed in the presence of the following substances for all positive and negative samples tested:

- Hemoglobin: 500 mg/dL
- Triglycerides: 3000 mg/dL
- Bilirubin: 20 mg/dL
- Protein: 9 g/dL

Drugs at concentrations in excess of the peak plasma or serum levels were tested in 5 pools. No interference in the performance of the Abbott RealTime HIV-1 assay was observed in the presence of the following drug pools for all positive and negative samples tested:

<table>
<thead>
<tr>
<th>Drug Pool</th>
<th>Drugs Tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Zidovudine, Saquinavir, Ritonavir, Clarithromycin, Interferon 2a, Interferon 2b</td>
</tr>
<tr>
<td>2</td>
<td>Abacavir sulfate, Amprenavir, Peginterferon 2a, Peginterferon 2b, Ribavirin</td>
</tr>
<tr>
<td>3</td>
<td>Tenofovir disoproxil fumarate, Lamivudine, Indinavir sulfate, Ganciclovir, Valganciclovir hydrochloride, Acyclovir</td>
</tr>
<tr>
<td>4</td>
<td>Stavudine, Efavirenz, Lopinavir, Enfuvirtide, Ciprofloxacin</td>
</tr>
<tr>
<td>5</td>
<td>Zalcitabine, Nevirapine, Nelfinavir, Azithromycin, Valacyclovir</td>
</tr>
</tbody>
</table>

Specificity

The target specificity of the Abbott RealTime HIV-1 assay is greater than or equal to 99.5% after resolution. The specificity of the Abbott RealTime HIV-1 assay was evaluated by testing 187 HIV-1 seronegative plasma specimens. The specimens were tested on 3 Abbott m2000 instrument systems with 3 lots of amplification reagents. HIV-1 RNA was not detected, resulting in 100% (187/187) specificity (95% CI 98.05 to 100.00) in this representative study.

The specificity of the assay was further evaluated by testing 70 specimens that had been either obtained from individuals diagnosed or screened for an autoimmune disorder or serologically characterized as positive for the following markers: systemic lupus erythematosus (SLE), anti-nuclear antibodies (ANA), rheumatoid factor (RF), HBsAg, anti-HIV-2. HIV-1 RNA was not detected in any of the specimens tested. The results demonstrated that the presence of an autoimmune disorder or serologic markers for autoimmune disease or viral pathogens other than HIV-1 did not affect the Abbott RealTime HIV-1 assay.

Cross-Reactivity

The following viruses and microorganisms were evaluated for potential cross-reactivity in the Abbott RealTime HIV-1 assay. Purified nucleic acid or viral lysate from each microorganism or virus was added to HIV-1 RNA negative samples and samples that contained 10,000 copies/mL HIV-1 RNA.

- Human Immunodeficiency virus 2
- Vaccinia virus
- Human T-lymphotropic virus 1
- BK human polomyavirus
- Hepatitis C virus
- Human papilloma virus 16
- Hepatitis B virus
- Human papilloma virus 18
- Epstein-Barr virus
- Neisseria gonorrhoeae
- Herpes simplex virus 1
- Chlamydia trachomatis
- Herpes simplex virus 2
- Candida albicans
- Cytomegalovirus
- Staphylococcus aureus
- Human herpesvirus 6B
- Staphylococcus epidermidis
- Human herpesvirus 8
- Mycobacterium gordonae
- Varicella-zoster virus
- Mycobacterium smegmatis

No interference in the performance of the Abbott RealTime HIV-1 assay was observed in the presence of the potential cross-reactants for all positive and negative samples tested.

Detection of HIV-1 Subtypes and Groups

The performance of the Abbott RealTime HIV-1 assay with HIV-1 subtypes/groups was evaluated by analysis of purified RNA transcripts from Group M (subtypes A, B, C, D, CRF01-AE, F, CRF02-AG, G, and H), Group O, and Group N, and by testing 10 clinical specimens of each Group M subtype (A, B, C, D, CRF01-AE, F, CRF02-AG, G, and H) and 10 specimens from Group O.
RNA transcripts of Group M (subtypes A, B, C, D, CRF01-AE, F, CRF02-AG, G, and H), Group O, and Group N with concentrations targeted to approximately 6.0 log copies/mL, 4.7 log copies/mL, 3.0 log copies/mL, and 1.7 log copies/mL were tested. Three replicates were tested at each concentration for each transcript. The results, representative of the dilution linearity for the 11 subtypes/groups tested, are shown in Figure 2.

**Figure 2.**

The results showed that all subtypes and groups tested were detected, and dilution linearity was demonstrated for all groups and subtypes tested (correlation coefficients ranged from 0.997 to 1.000).

A total of 90 clinical specimens, 10 of each Group M subtype (A, B, C, D, CRF01-AE, F, CRF02-AG, G) and Group O, were tested with the Abbott RealTime HIV-1 assay and by 2 other HIV-1 quantitative assays referred to as Comparator 1 and Comparator 2. The results are summarized in Table 8.

**Table 8.**

<table>
<thead>
<tr>
<th>Group/Subtype</th>
<th>n</th>
<th>RealTime Detected</th>
<th>Comparator 1 Detected</th>
<th>Comparator 2 Detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>M/Subtype A</td>
<td>10</td>
<td>10</td>
<td>10 (1)</td>
<td>10 (1)</td>
</tr>
<tr>
<td>M/Subtype B</td>
<td>10</td>
<td>10</td>
<td>10 (1)</td>
<td>10 (1)</td>
</tr>
<tr>
<td>M/Subtype C</td>
<td>10</td>
<td>10</td>
<td>10 (1)</td>
<td>10 (1)</td>
</tr>
<tr>
<td>M/Subtype D</td>
<td>10</td>
<td>10</td>
<td>10 (1)</td>
<td>10 (1)</td>
</tr>
<tr>
<td>M/Subtype AE</td>
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<td>10 (1)</td>
<td>10 (1)</td>
</tr>
<tr>
<td>M/Subtype F</td>
<td>10</td>
<td>10</td>
<td>10 (1)</td>
<td>10 (1)</td>
</tr>
<tr>
<td>M/Subtype AG</td>
<td>10</td>
<td>10</td>
<td>10 (1)</td>
<td>10 (1)</td>
</tr>
<tr>
<td>M/Subtype G</td>
<td>10</td>
<td>10</td>
<td>10 (1)</td>
<td>10 (1)</td>
</tr>
<tr>
<td>Group O</td>
<td>10</td>
<td>10</td>
<td>0 (NA)</td>
<td>7 (7)</td>
</tr>
</tbody>
</table>

* 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 Abbott RealTime HIV-1 assay.

- The Abbott RealTime HIV-1 assay detected all subtypes and groups tested.
- Comparator 1 detected all Group M subtypes tested and did not detect the 10 Group O samples.
- Comparator 2 detected all Group M subtypes tested and 7 out of 10 Group O samples.
- There were no specimens that had Abbott RealTime assay quantitation values lower than Comparator 1 or Comparator 2 values by more than 1.00 log copies/mL.
- There were 6 Group M samples that had lower quantitation values with Comparator 1 by more than 1.00 log copies/mL when compared to Abbott RealTime HIV-1 assay.
- There were 3 Group M samples and 7 Group O samples that had lower quantitation values with Comparator 2 by more than 1.00 log copies/mL when compared to Abbott RealTime HIV-1 assay.

**Correlation**

Method comparison analysis was performed following NCCLS EP9-A2. Specimens from 141 HIV-1 infected patients were tested with the Abbott RealTime HIV-1 assay and a comparator assay. The correlation plot is shown in Figure 3.

**Figure 3.**

y=0.93x + 0.15  
r=0.958  
n=141

Specimens from 79 HIV-1 infected patients (a subset of the 141 tested) were tested with the Abbott LCx HIV RNA Quantitative assay. The correlation plot is shown in Figure 4.

**Figure 4.**

y=0.94x + 0.05  
r=0.967  
n=79

**BIBLIOGRAPHY**


**The PURCHASE OF THIS PRODUCT ALLOWS THE PURCHASER TO USE IT FOR AMPLIFICATION OF NUCLEIC ACID SEQUENCES AND FOR DETECTION OF NUCLEIC ACID SEQUENCES FOR HUMAN IN VITRO DIAGNOSTICS. NO GENERAL PATENT OR OTHER LICENSE OF ANY KIND OTHER THAN THIS SPECIFIC RIGHT OF USE FROM PURCHASE IS GRANTED HEREBY. THIS PROVISION DOES NOT PROHIBIT THE RESALE OF THIS PRODUCT.**

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Abbott Molecular Inc. is the legal manufacturer of the: Abbott RealTime HIV-1 Amplification Reagent Kit (List No. 2G31-90) Abbott RealTime HIV-1 Control Kit (List No. 2G31-80) Abbott RealTime HIV-1 Calibrator Kit (List No. 2G31-70).
The Abbott RealTime 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) in whole blood spotted on cards as dried blood spots (DBS) (i.e. obtained via venipuncture or capillary blood) or human plasma from HIV-1 infected individuals. The Abbott RealTime HIV-1 is intended for use in conjunction with clinical presentation and other laboratory markers as an indicator of disease progression and for use as an aid in assessing viral response to antiretroviral treatment as measured by changes in DBS or plasma HIV-1 RNA levels. This assay is not intended to be used as a 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). It can be transmitted through sexual contact, exposure to infected blood or blood products, or from an infected mother to the fetus. Acute HIV syndrome, characterized by flu-like symptoms, develops 3 to 5 weeks after initial infection and is associated with high levels of viremia. Within 4 to 6 weeks of the onset of symptoms, HIV specific immune response is detectable. After seroconversion, viral load in peripheral blood declines and most patients enter an asymptomatic phase that can last for years. Quantitative measurement of HIV levels in peripheral blood has greatly contributed to the understanding of the pathogenesis of HIV infection and has been shown to be an essential parameter in prognosis and management of HIV infected individuals. Decisions regarding initiation or changes in antiretroviral therapy are guided by monitoring plasma or DBS HIV RNA levels (viral load), CD4+ T cell count, and the patient’s clinical condition. The goal of antiretroviral therapy is to reduce the HIV virus in plasma and DBS to below detectable levels of available viral load tests.

HIV RNA levels in plasma or DBS can be quantitated by nucleic acid amplification or signal amplification technologies. The Abbott RealTime HIV-1 assay uses Polymerase Chain Reaction (PCR) technology with homogeneous 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, and against World Health Organization (WHO) International Standard for HIV-1 RNA (97/656). The assay results can be reported in copies/mL or International Units/mL (IU/mL) or their log base 10 equivalents.

**BIOLOGICAL PRINCIPLES OF THE PROCEDURE**

The Abbott RealTime HIV-1 assay consists of 3 reagent kits:
- Abbott RealTime HIV-1 Amplification Reagent Kit
- Abbott RealTime HIV-1 Control Kit
- Abbott RealTime HIV-1 Calibrator Kit

The Abbott RealTime HIV-1 assay uses RT-PCR 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 m2000rt 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 m2000rt 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 mSample Preparation System (4 × 24 Preps) 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 output tubes or 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.

Two automated instrument systems, the Abbott m2000sp or the Abbott m1000 System can be used to prepare samples for the Abbott RealTime HIV-1 assay. The Abbott m2000sp provides automated sample eluate transfer and reaction assembly in the Abbott 96-Well Optical Reaction Plate, while the Abbott m1000 System requires manual sample eluate transfer and reaction assembly.

Alternatively, samples can be prepared manually using the Abbott mSample Preparation System, followed by manual reaction assembly.

Reagent Preparation and Reaction Plate Assembly
The Abbott m2000sp combines the Abbott RealTime HIV-1 amplification reagent components (HIV-1 Oligonucleotide Reagent, Thermostable rTth Polymerase Enzyme, and Activation Reagent). The Abbott m2000sp dispenses the resulting master mix to the Abbott 96-Well Optical Reaction Plate along with aliquots of the nucleic acid samples prepared by the Abbott m2000sp. The plate is ready, after manual application of the optical seal, for transfer to the Abbott m2000rt.

Abbott m1000 System users and manual sample preparation method users manually combine the Abbott RealTime HIV-1 amplification reagent components to create the amplification master mix and transfer aliquots of the master mix and sample eluates to the reaction plate. The plate is ready, after manual application of the optical seal and centrifugation, for transfer to the Abbott m2000rt.

Amplification
During the amplification reaction on the Abbott m2000rt, the target RNA is converted to cDNA by the reverse transcriptase activity of the thermostable rTth DNA polymerase. First, the HIV-1 and IC reverse primers anneal to their respective targets and are extended during a prolonged incubation period. After a denaturation step, in which the temperature of the reaction is raised above the melting point of the double-stranded cDNA/RNA product, a second primer anneals to the cDNA strand and is extended by the DNA polymerase activity of the rTth enzyme to create a double-stranded DNA product.

During each round of thermal cycling, amplification products dissociate to single strands at high temperatures allowing primer annealing and extension as the temperature is lowered. Exponential amplification of the product is achieved through repeated cycling between high and low temperatures, resulting in a billion-fold or greater amplification of target sequences. Amplification of both targets (HIV-1 and IC) takes place simultaneously in the same reaction.

The target sequence for the Abbott RealTime HIV-1 assay is in the pol integrase region of the HIV-1 genome. This region is highly conserved.28 The primers are designed to hybridize to the pol integrase region with the fewest possible mismatches among various subtypes. The IC target sequence is derived from the hydroxyypyruvate reductase gene from the pumpkin plant, Cucurbita pepo, and is delivered in an armored RNA® particle that has been diluted in negative human plasma.

Detection
During the read cycles of amplification on the Abbott m2000rt, the temperature is lowered further to allow fluorescent detection of amplification products as the HIV-1 and IC probes anneal to their targets (real-time fluorescence detection). The HIV-1 probe has a fluorescent moiety that is covalently linked to the 5′ end. A short oligonucleotide (quencher oligonucleotide) is complementary to the 5′ end of the HIV-1 probe and has a quencher molecule at its 3′ end. In the absence of HIV-1 target, the HIV-1 probe fluorescence is quenched through hybridization to the quencher oligonucleotide. In the presence of the HIV-1 target sequence, the HIV-1 probe preferentially hybridizes to the target sequence, dissociating from the quencher oligonucleotide, allowing fluorescent detection.

The IC probe is a single-stranded DNA oligonucleotide with a fluorophore at the 5′ end and a quencher at the 3′ end. In the absence of IC target sequences, probe fluorescence is quenched. In the presence of IC target sequences, probe hybridization to complementary sequences separates the fluorophore and the quencher and allows fluorescent emission and detection.

The HIV-1 and IC specific probes are each labeled with a different fluorophore, thus allowing for simultaneous detection of both amplified products at each cycle. The amplification cycle at which fluorescent signal is detected by the Abbott m2000rt is proportional to the log of the HIV-1 RNA concentration present in the original sample.

Optional Amplification Reagent Extended Use Feature
An overview of this feature is provided in Appendix 1 of this package insert.

The optional amplification reagent extended use feature allows amplification reagent packs containing prepared master mix to be stored at –25 to –15°C, capped and protected from light, for up to 7 days before a second use. The internal control (IC) may be used again within 14 days if the vial remains capped at –25 to –15°C until the second use. The amplification reagent extended use feature applies only to samples prepared using the m2000sp system. Amplification reagent packs and IC can be used a total of 2 times. Throughout this manual, amplification reagent packs and IC that have not yet been used will be referred to as new amplification reagent packs and IC (ie, initial use). Amplification reagent packs that have been used once and contain prepared master mix will be referred to as partial amplification reagent packs. IC vials that have been used once will be referred to as partial vials of IC.

PREVENTION OF NUCLEIC ACID CONTAMINATION
The possibility of nucleic acid contamination is minimized because:
- Reverse transcription, PCR amplification, and oligonucleotide hybridization occur in a sealed Abbott 96-Well Optical Reaction Plate.
- Detection is carried out automatically without the need to open the Abbott 96-Well Optical Reaction Plate.

Pipettes with aerosol barrier tips or disposable transfer pipettes are used for all pipetting. The disposable pipettes or pipette tips are discarded after use.

Separate, dedicated areas are used to perform the Abbott RealTime HIV-1 assay. Refer to the SPECIAL PRECAUTIONS section of this package insert.

REAGENTS
Abbott RealTime HIV-1 Amplification Reagent Kit (List No. 02G31-010)

1. INTERNAL CONTROL Abbott RealTime HIV-1 Internal Control (List No. 2G31Y00002) (4 vials, 1.2 mL per vial)
   - < 0.01% noninfectious Armored RNA with internal control sequences in negative human plasma. Negative human plasma tested and found to be nonreactive for HBsAg, HIV RNA, HCV RNA, HBV DNA, anti-HIV-1/HIV-2, and anti-HCV. Preservatives: 0.1% ProClin® 300 and 0.15% ProClin 950.

2. AMPLIFICATION REAGENT PACK Abbott RealTime HIV-1 Amplification Reagent Pack (List No. 2G31) (4 packs, 24 tests/pack)
   - 1 bottle (0.141 mL) Thermostable rTth Polymerase Enzyme (2.9 to 3.5 Units/µL) in buffered solution.
   - 1 bottle (1.10 mL) HIV-1 Oligonucleotide Reagent, < 0.1% synthetic oligonucleotides (4 primers, 2 probes, and 1 quencher oligonucleotide), and < 0.3% dNTPs in a buffered solution with a reference dye. Preservatives: 0.1% ProClin 300 and 0.15% ProClin 950.
   - 1 bottle (0.40 mL) Activation Reagent, 30 mM manganese chloride solution. Preservatives: 0.1% ProClin 300 and 0.15% ProClin 950.

NOTE: To use the amplification reagent extended use feature, reagent packs with a 6-digit serial number above the barcodes must be used.

Abbott RealTime HIV-1 Control Kit (List No. 2G31-80)

1. CONTROL Abbott RealTime HIV-1 Negative Control (List No. 2G31Z) (8 vials, 1.8 mL per vial) Negative human plasma tested and found to be nonreactive for HBsAg, HIV RNA, HCV RNA, HBV DNA, anti-HIV-1/HIV-2, and anti-HCV. Preservatives: 0.1% ProClin 300 and 0.15% ProClin 950.

2. CONTROL Abbott RealTime HIV-1 Low Positive Control (List No. 2G31W) (8 vials, 1.8 mL per vial) Noninfectious Armored RNA with HIV-1 sequences in negative human plasma. Negative human plasma tested and found to be nonreactive for HBsAg, HIV RNA, HCV RNA, HBV DNA, anti-HIV-1/HIV-2, and anti-HCV. Preservatives: 0.1% ProClin 300 and 0.15% ProClin 950.
3. **CONTROL** (Abbott RealTime HIV-1 High Positive Control
(List No. 2G31X) (8 vials, 1.8 mL per vial). Noninfectious Armored RNA with HIV-1 sequences in negative human plasma. Negative human plasma tested and found to be nonreactive for HBsAg, HIV RNA, HCV RNA, HBV DNA, anti-HIV-1/HIV-2, and anti-HCV. Preservatives: 0.1% ProClin 300 and 0.15% ProClin 950.

**Abbott RealTime HIV-1 Calibrator Kit (List No. 2G31-70)**

1. **CAL A** Abbott RealTime HIV-1 Calibrator A (List No. 2G31A) (12 vials, 1.8 mL per vial). Noninfectious Armored RNA with HIV-1 sequences in negative human plasma. Negative human plasma tested and found to be nonreactive for HBsAg, HIV RNA, HCV RNA, HBV DNA, anti-HIV-1/HIV-2, and anti-HCV. Preservatives: 0.1% ProClin 300 and 0.15% ProClin 950.

2. **CAL B** Abbott RealTime HIV-1 Calibrator B (List No. 2G31B) (12 vials, 1.8 mL per vial). Noninfectious Armored RNA with HIV-1 sequences in negative human plasma. Negative human plasma tested and found to be nonreactive for HBsAg, HIV RNA, HCV RNA, HBV DNA, anti-HIV-1/HIV-2, and anti-HCV. Preservatives: 0.1% ProClin 300 and 0.15% ProClin 950.

**WARNINGS AND PRECAUTIONS**

**IVD**

**For In Vitro Diagnostic Use**

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

**Safety Precautions**

Refer to the Abbott m1000 Operating Manual, Safety Section, the Manual Sample Preparation for Abbott RealTime RNA Assays Procedure, Handling Preparation Section, or Abbott m2000sp and Abbott m2000rt Operations Manuals, Hazard Section, for instructions on safety precautions.

⚠️ **CAUTION**: This preparation contains human sourced and/or potentially infectious components. Components sourced from human blood have been tested and found to be nonreactive by FDA-licensed tests for antibody to HCV, antibody to HIV-1, antibody to HIV-2, and HBsAg. The material is also tested and found to be negative by FDA-licensed PCR methods for HIV-1 RNA and HCV RNA. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. These reagents and human specimens should be handled as if infectious using laboratory safety procedures, such as those outlined in Biosafety in Microbiological and Biomedical Laboratories.29 CLSI Document M29-A3,30 and other appropriate biosafety practices.32 Therefore all human sourced materials should be considered infectious.

These precautions include, but are not limited to, the following:

- Wear gloves when handling specimens or reagents.
- Do not pipette by mouth.
- Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in areas where these materials are handled.
- Clean and disinfect spills of specimens by including the use of a tuberculocidal disinfectant such as 1% sodium hypochlorite or other suitable disinfectant.29
- Decontaminate and dispose of all potentially infectious materials in accordance with local, state, and federal regulations.29
- Components of the Abbott RealTime HIV-1 Calibrator Kit (2G31-70) and Abbott RealTime HIV-1 Control Kit (2G31-80), and the HIV-1 Oligonucleotide Reagent, HIV-1 Internal Control and Activation Reagent contain the following components:
  - 2-Methyl-2H-isothiazol-3-one (EC no. 220-239-6)
  - Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one (EC no. 220-239-6) (3:1)
  - Reaction mass of: 2-methyl-4-isothiazolin-3-one (EC no. 220-239-6) (3:1)

The following warnings apply:

- **Warning**
  - H317 May cause an allergic skin reaction.
  - P261 Avoid breathing mist/vapours/spray.
  - P272 Contaminated work clothing should not be allowed out of the workplace.
  - P280 Wear protective gloves/protective clothing/eye protection.
  - P302+P352 IF ON SKIN: Wash with plenty of water.
  - P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
  - P382+P364 Take off contaminated clothing and wash before reuse.
  - P501 Dispose of contents/container in accordance with local regulations.

**SPECIAL PRECAUTIONS**

**Handling Precautions for Plasma Specimens**

The Abbott RealTime HIV-1 assay is only for use with plasma specimens that have been handled and stored in capped tubes as described in the SPECIMEN COLLECTION, STORAGE, AND TRANSPORT TO THE TEST SITE section.

**Handling Precautions for DBS Specimens**

The Abbott RealTime HIV-1 assay is only for use with whole blood or DBS specimens that have been handled and stored as described in the SPECIMEN COLLECTION, STORAGE, AND TRANSPORT TO THE TEST SITE section.

During preparation of samples, compliance with good laboratory practices is essential to minimize the risk of cross-contamination between samples and the inadvertent introduction of ribonucleases (RNases) into samples during and after the extraction procedure. Proper aseptic technique should always be used when working with RNA. Amplification technologies such as PCR are sensitive to accidental introduction of product from previous amplification reactions. Incorrect results could occur if either the clinical specimen or the reagents used become contaminated by accidental introduction of even a few molecules of amplification product. Measures to reduce the risk of contamination in the laboratory include physically separating the activities involved in performing PCR in compliance with good laboratory practices.

**Work Areas**

Use 3 dedicated areas within the laboratory for performing the Abbott RealTime HIV-1 assay with the Abbott m1000 System or manual sample preparation using the Abbott mSample Preparation System and Abbott m2000rt:

- **The Reagent Preparation Area** is dedicated to combining the Abbott RealTime HIV-1 amplification reagent components to create the amplification master mix and transferring aliquots of the master mix to the reaction plate. Laboratory coats, pipettes, pipette tips, and vortexers used in the Reagent Preparation Area must remain in this area and not be moved to either the Sample Preparation Area or the Amplification Area.

- **The Sample Preparation Area** is dedicated to processing samples (specimens, Abbott RealTime HIV-1 Controls, and Calibrators), and to adding processed samples, controls, and calibrators to the Abbott 96-Well Optical Reaction Plate. All reagents used in the Sample Preparation Area should remain in this dedicated area at all times. Laboratory coats, pipettes, pipette tips, and vortexers used in the Sample Preparation Area must remain in this area and not be moved to either the Reagent Preparation Area or the Sample Preparation Area.

- **The Amplification Area** is dedicated to the amplification and detection of amplified product. Laboratory coats and equipment used in the Amplification Area must remain in this area and not be moved to either the Reagent Preparation Area or the Sample Preparation Area.

Only 2 dedicated areas, Sample Preparation Area and Amplification Area, are recommended when the Abbott m2000sp and Abbott m2000rt are used.

Components contained within a kit are intended to be used together. Do not mix components from different kit lots. For example, do not use the negative control from control kit lot X with the positive controls from control kit lot Y.
Do not use kits or reagents after the expiration dates shown on kit labels. Work area and instrument platforms must be considered potential sources of contamination. Change gloves after contact with potential contaminants (specimens, eluates, and/or amplified product) before handling unopened reagents, negative controls, positive controls, calibrators, or specimens. Refer to the Abbott m2000sp and Abbott m2000rt Operations Manuals for instrument cleaning procedures. If the Abbott m1000 System or Abbott m2000sp instrument run is aborted, dispose of all commodities and reagents according to the Abbott m1000 Operating Manual or the Abbott m2000sp Operations Manual.

NOTE: New amplification reagents may be saved, stored, and used a second time, as described in this manual. If the Abbott m2000sp master mix addition protocol is aborted, seal the Abbott 96-Well Optical Reaction Plate in a sealable plastic bag and dispose according to the Abbott m2000sp Operations Manual, Hazards section, along with the gloves used to handle the plate. If the Abbott m2000rt instrument run is interrupted or aborted, seal the Abbott 96-Well Optical Reaction Plate in a sealable plastic bag and dispose according to the Abbott m2000rt Operations Manual along with the used gloves used to handle the plate. Decontaminate and dispose of all potentially biohazardous materials in accordance with local, state, and federal regulations. All materials should be handled in a manner that minimizes the chance of potential contamination of the work area.

NOTE: Autoclaving the sealed Reaction Plate will not degrade the contamination of the work area. Should be handled in a manner that minimizes the chance of potential contamination of the work area.

Aerosol Containment
To reduce the risk of nucleic acid contamination due to aerosols formed during manual pipetting, aerosol barrier pipette tips must be used for all manual pipetting. The pipette tips must be used only 1 time. Clean and disinfect spills of specimens and reagents as stated in the Abbott m1000 Operating Manual or the Abbott m2000sp and Abbott m2000rt Operations Manuals.

Contamination and Inhibition
The following precautions should be observed to minimize the risks of RNase contamination, cross-contamination between samples, and inhibition:

- Wear appropriate personal protective equipment at all times.
- Use powder-free gloves.
- Change gloves after having contact with potential contaminants (such as specimens, eluates, and/or amplified product).
- To reduce the risk of nucleic acid contamination due to aerosols formed during pipetting, pipettes with aerosol barrier tips must be used for all pipetting. The length of the tip should be sufficient to prevent contamination of the pipette barrel. While pipetting, care should be taken to avoid touching the pipette barrel to the inside of the sample tube or container. The use of extended aerosol barrier pipette tips is recommended.
- Change aerosol barrier pipette tips between ALL manual liquid transfers.
- The Abbott mSample Preparation System (4 × 24 Preps) reagents are single use only. Use new reagent troughs or vessels, reaction vessels, and newly opened reagents for every new Abbott RealTime HIV-1 assay run. At the end of each run, discard all remaining reagents from the worktable as stated in the Abbott m1000 Operating Manual or the Abbott m2000sp Operations Manual and the Abbott mSample Preparation System (4 × 24 Preps) product information sheet.
- Follow instructions in this manual to recap and store amplification reagents that are to be used a second time.

Contamination From External dU-Containing Amplified Product
Laboratories that use or have used HIV-1 amplification assays that include post-PCR processing of the amplified product may be contaminated by dU-containing amplified product. Such contamination may cause inaccurate results in the Abbott RealTime HIV-1 assay. Refer to the Monitoring the Laboratory for the Presence of Contamination section of the package insert. When negative controls are persistently reactive or where contamination with dU-containing HIV-1 amplified product is likely to have occurred, it is recommended that the laboratory use the uracil-N-glycosylase (UNG) (List No. 08LB7-02) contamination control procedure if decontamination of the laboratory is unsuccessful. Refer to Appendix 2 for the optional UNG Procedure.

STORAGE INSTRUCTIONS
Abbott RealTime HIV-1 Amplification Reagent Kit (List No. 02G31-010)

- New and Partial Abbott RealTime HIV-1 Amplification Reagent Packs and Internal Control (IC) vials must be stored at –25 to –15°C when not in use. Care must be taken to separate the Abbott RealTime HIV-1 Amplification Reagent Pack that is in use from direct contact with samples, calibrators, and controls.
- Partial amplification reagent packs and IC must be stored at –25 to –15°C, capped, upright, and protected from light, following initial use. If stored this way, partial amplification reagent packs with prepared master mix may be used a second time within 7 days of initial use. IC may also be used a second time within 14 days of being thawed, if stored capped at –25 to –15°C.
- After 2 uses, discard partial amplification reagent packs and IC.

Abbott RealTime HIV-1 Control Kit (List No. 2G31-80)

- The Abbott RealTime HIV-1 Negative and Positive Controls must be stored at –10°C or colder.

Abbott RealTime HIV-1 Calibrator Kit (List No. 2G31-70)

- The Abbott RealTime HIV-1 Calibrator A and Calibrator B must be stored at –10°C or colder.

SHIPPING CONDITIONS

- Abbott RealTime HIV-1 Amplification Reagent Kit: Ship on dry ice.
- Abbott RealTime HIV-1 Control Kit: Ship on dry ice.
- Abbott RealTime HIV-1 Calibrator Kit: Ship on dry ice.

INDICATION OF INSTABILITY OR DETERIORATION OF REAGENTS
When a positive or negative control value is out of the expected range, it may indicate deterioration of the reagents. Associated test results are invalid and samples must be retested. Assay recalibration may be necessary.

INSTRUMENT PROCEDURE
The nucleic acid testing (NAT) software must be installed on the Abbott m1000 System prior to performing the assay. For detailed information on NAT software installation, refer to the Abbott m1000 Operating Manual, Putting into Operation section. The Abbott RealTime HIV-1 application files with the extended use feature enabled must be installed on the Abbott m2000sp and Abbott m2000rt systems from the Abbott RealTime HIV-1 m2000 ROW System Combined Application CD-ROM (List No. 1L68-013 or higher) prior to performing the assay. For detailed information on application file installation, refer to the Abbott m2000sp and Abbott m2000rt Operations Manuals, Operating Instructions section.
### SPECIMEN COLLECTION, STORAGE, AND TRANSPORT TO THE TEST SITE

**Specimen Collection and Storage**

Freshly drawn whole blood (ACD-A and EDTA) may be held at 15 to 30°C for up to 24 hours or at 2 to 8°C for up to 48 hours prior to processing.

Human plasma (ACD-A and EDTA) specimens may be used with the Abbott RealTime HIV-1 assay. Follow the manufacturer’s instructions for processing plasma collection tubes.

To prepare EDTA and ACD-A plasma specimens, follow the manufacturer’s instructions for processing plasma collection tubes. After plasma preparation, plasma may be stored at 15 to 30°C for up to 24 hours or at 2 to 8°C for up to 5 days. If longer storage is required, plasma specimens must be kept at −70°C or colder.33,34 Multiple freeze-thaw cycles should be avoided. If frozen, thaw plasma specimens at 15 to 30°C or at 2 to 8°C. Once thawed, if plasma specimens are not being processed immediately, they can be stored at 2 to 8°C for up to 6 hours.

**NOTE:** Plasma specimens should not be frozen in non-gel blood collection tubes.

- To prepare DBS, use finger prick or EDTA whole blood (not ACD whole blood). Before spotting, mix the blood using a pipette. Spot the blood onto the one-half-inch (12 millimeter) circles on perforated Munktell paper card (or equivalent such as Whatman 903 and Ahlstrom 226), ensuring that the entire circle is covered. It is recommended that at least 70 µL of blood (approximately 3 to 5 blood drops) be used for each circle to ensure full coverage.
- Air dry the card at ambient temperature.
- Package each card in a sealable plastic bag with 2 to 3 desiccant packs. The bags can be stored under ambient conditions for up to 8 weeks. Under conditions of high humidity (85%), the cards can be stored under ambient temperature for up to 2 weeks. Alternatively, cards can be stored at 2 to 8°C or −10°C or colder for up to 12 weeks.

**Specimen Transport**

Ship specimens according to the recommended storage temperature and time listed in the Specimen Collection and Storage section above. For domestic and international shipments, specimens should be packaged and labeled in compliance with applicable state, federal, and international regulations covering the transport of clinical, diagnostic, or biological specimens.

### ABBOTT REALTIME HIV-1 ASSAY PROCEDURE

This Abbott RealTime HIV-1 package insert contains 3 assay protocols:

- Plasma samples prepared for amplification using the Abbott m1000 System or the manual sample preparation method follow ASSAY PROTOCOL I.
- Plasma samples prepared for amplification using the Abbott m2000sp instrument follow ASSAY PROTOCOL II.

The Abbott RealTime HIV-1 assay provides 4 sample volume options (0.2 mL, 0.5 mL, 0.6 mL, and 1.0 mL). (See assay protocol II step 6 and RESULTS FOR PLASMA SPECIMENS section.)

- DBS samples prepared for amplification using the Abbott m2000sp instrument follow ASSAY PROTOCOL III.

### Materials Provided

- Abbott RealTime HIV-1 Amplification Reagent Kit (List No. 02G31-010)

### Materials Required But Not Provided

- Abbott RealTime HIV-1 Calibrator Kit (List No. 2G31-70)
- Abbott RealTime HIV-1 Control Kit (List No. 2G31-80)
- Abbott mSample Preparation System DBS Buffer Kit (List No. 09N02-001) (if using DBS Sample Type)

For manual sample preparation method refer to the Materials and Equipment Required Section of the Manual Sample Preparation for Abbott RealTime RNA Assays Procedure (List No. 06L73).

### Additional materials required if using DBS Sample Type:

- 1.4 mL Micro Vial 15 mm Caps (List No. 3N20-01) optional
- Centrifuge capable of 2000g
- Abbott RealTime HIV-1 m2000 ROW System Combined Application CD-ROM (List No. 1L68-013 or higher)

### For Abbott m1000 System

#### Sample Preparation Area

- m1000 System
- mSample Preparation System (4 × 24 Preps) (List No. 04J70-24)
- Reaction Vessels

#### Reagent Preparation Area

- StrataCooler® 96 Benchtop Cooler or Eppendorf PCR Cooler
- Abbott 96-Well Optical Reaction Plate (List No. 04J71-70)
- Calibrated precision pipettes capable of delivering 20 to 1000 µL
- 20 µL to 1000 µL aerosol barrier pipette tips for precision pipettes
- Single-use RNase/DNase-free tube or container
- Vortex Mixer

### For Abbott m2000sp Instrument

#### Sample Preparation Area

- m2000sp with software version 6.0 or higher
- mSample Preparation System (4 × 24 Preps) (List No. 04J70-24)
- 5 mL Reaction Vessels

#### Amplification Area

- Abbott RealTime HIV-1 m2000 ROW System Combined Application CD-ROM (List No. 1L68-013 or higher)
- Abbott m2000rt Optical Calibration Kit (List No. 04J71-93)
Other Materials
- Biological safety cabinet approved for working with infectious materials
- Sealable plastic bags
- RNase-free water (Eppendorf or equivalent)†
- 1.7 mL molecular biology grade microcentrifuge tubes (Dot Scientific, Inc. or equivalent)†
- Cotton Tip Applicators (Puritan or equivalent)†
- 1.7 mL molecular biology grade microcentrifuge tubes (Dot Scientific, Inc. or equivalent)†
- RNase-free water (Eppendorf or equivalent)†
- Other materials

†Note: These 3 items are used in the procedure for Monitoring the Laboratory for the Presence of Contamination. Refer to the QUALITY CONTROL PROCEDURES section of this package insert.

Procedural Precautions
- Read the instructions in this package insert carefully before processing samples.
- Amplification reagents and internal control (IC) may be used up to 2 times, as described in this package insert. The Abbott RealTime HIV-1 Calibrators, Negative Control, Low Positive Control, and High Positive Control vials are intended for single-use only and should be discarded after use.
- Use aerosol barrier pipette tips or disposable pipettes only one time when pipetting specimens, IC, or amplification reagents. To prevent contamination to the pipette barrel while pipetting, care should be taken to avoid touching the pipette barrel to the inside of the sample tube or container. The use of extended aerosol barrier pipette tips is recommended.
- Monitoring procedures for the presence of amplification product can be found in the QUALITY CONTROL PROCEDURES section of this package insert.
- To reduce the risk of nucleic acid contamination, clean and disinfect spills of specimens by including the use of a tuberculocidal disinfectant.
- The Abbott RealTime HIV-1 Calibrators and Controls must be prepared in conjunction with the specimens to be tested. The use of the Abbott RealTime HIV-1 Controls and Calibrators is integral to the performance of the Abbott RealTime HIV-1 assay. Refer to the QUALITY CONTROL PROCEDURES section of this package insert for details.
- IMPORTANT: Amplification reagents that will be used a second time must be stored at –25 to –15°C within 50 minutes of the initiation of the master mix addition protocol.

ASSAY PROTOCOL I: ABBOTT m1000 SYSTEM OR THE MANUAL SAMPLE PREPARATION METHOD AND ABBOTT m2000rt INSTRUMENT


Laboratory personnel must be trained to operate the Abbott m1000 System and the Abbott m2000rt instrument. The operator must have a thorough knowledge of the software applications and must follow good laboratory practices.

For plasma samples prepared for amplification using the Abbott m1000 System or the manual sample preparation method and using the optional UNG procedure, refer to Appendix 2.

1. Thaw assay controls and IC at 15 to 30°C or at 2 to 8°C. Thaw calibrators at 15 to 30°C or at 2 to 8°C only if performing a calibration run; see QUALITY CONTROL PROCEDURES section of this package insert.
   - Once thawed, assay controls, IC, and calibrators can be stored at 2 to 8°C for up to 24 hours before use.
   - Vortex each assay calibrator and each control 3 times for 2 to 3 seconds before use. Ensure that the contents of each vial are at the bottom after vortexing by tapping the vials on the bench to bring liquid to the bottom of the vial.
2. Thaw amplification reagents at 15 to 30°C or at 2 to 8°C and store at 2 to 8°C until required for the amplification master mix procedure.
   - Once thawed, the amplification reagents can be stored at 2 to 8°C for up to 24 hours if not used immediately.

NOTE: Use 1 set of sample preparation reagent bottles, 1 vial of IC, and 1 Abbott RealTime HIV-1 Amplification Reagent Pack to support up to 24 reactions. Use a second set of reagents to support 25 to 48 reactions. A maximum of 48 reactions can be performed per run using an Abbott m1000 instrument.

Sample Preparation Area

For sample preparation using the Abbott m1000 System, follow steps 3 through 10. For the manual sample preparation method refer to the Extraction Protocol Section of the Manual Sample Preparation for Abbott RealTime RNA Assays Procedure (List No. 06L73).

3. Gently invert the Abbott mSample Preparation bottles to ensure a homogeneous solution. If crystals are observed in any of the reagent bottles upon opening, allow the reagent to equilibrate at room temperature until the crystals disappear. Do not use the reagents until the crystals have dissolved.

4. Vortex each IC 3 times for 2 to 3 seconds before use.

5. Use a calibrated precision Pipette Dedicated for Internal Control Use Only to add 500 µL of IC to each bottle of mLysis Buffer. Mix by gently inverting the container 5 to 10 times to minimize foaming.

6. A total of 48 samples can be processed in each run. A negative control, a low positive control, and a high positive control are included in each run, therefore allowing a maximum of 45 specimens to be processed per run.
   - The Abbott RealTime HIV-1 assay minimum sample volume and associated rack requirements on the Abbott m1000 System are:

   ![Sample Volume Table]

<table>
<thead>
<tr>
<th>Rack</th>
<th>Tube Diameter</th>
<th>Minimum Sample Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>13 mm</td>
<td>11.6 mm - 14.0 mm</td>
<td>0.2 mL, 0.5 mL, 1.0 mL</td>
</tr>
<tr>
<td>16 mm</td>
<td>15.0 mm - 16.0 mm</td>
<td>0.7 mL, 1.0 mL, 1.5 mL</td>
</tr>
<tr>
<td>1.7 mL</td>
<td>1.0 mL</td>
<td>1.3 mL, 1.8 mL</td>
</tr>
</tbody>
</table>
   
   a Refers to sample tube outer diameter
   
   If frozen, thaw specimens at 15 to 30°C or at 2 to 8°C. Once thawed, specimens can be stored at 2 to 8°C for up to 6 hours if not processed immediately.

NOTE: For every stored specimen, the following actions must be done in the order described: vortex the specimen first and follow centrifugation. If these actions are not performed in this order, then invalid results may occur.

   - Vortex each specimen 3 times for 2 to 3 seconds.
   - Centrifuge specimens at 2000g for 5 minutes before loading onto the Abbott m1000 worktable. Aliquot each specimen into clean tubes or vials if necessary. Refer to the Abbott m1000 Operating Manual for tube sizes. Avoid touching the inside of the cap when opening tubes.

7. Place the calibrators (if applicable), low and high positive controls, the negative control, and the patient specimens into the Abbott m1000 sample rack. Follow directions for performing a user-defined protocol, as described in the Abbott m1000 Operating Manual, Operation section.

8. Place the Reaction Vessels into the Abbott m1000 1 mL subsystem carrier.

9. Load the Abbott mSample Preparation System reagents and the 1.5 mL Output Tubes on the Abbott m1000 System worktable as described in the Abbott m1000 Operating Manual, Operation section.

10. Initiate the Abbott m1000 protocol as described in the Abbott m1000 Operating Manual, Operation section. From the Protocol screen, select the appropriate application file corresponding to the sample volume being tested.
   - The assembly of the amplification master mix and sample eluates into the Abbott 96-Well Optical Reaction Plate (step 17) must be initiated within 1 hour after completion of Sample Preparation.

Amplification Area

11. Switch on and initialize the Abbott m2000rt instrument.

NOTE: The Abbott m2000rt instrument requires 15 minutes to warm up.
12. Create the Abbott m2000rt test order. Refer to the Operating Instructions section of the Abbott m2000rt Operations Manual. From the Protocol screen, select the appropriate application file corresponding to the sample volume being tested.
   - Enter calibrator (needed if a calibration curve has not been stored on the Abbott m2000rt) and control lot specific values in the test order for accurate calibration of the control evaluation. Lot-specific values are specified in each Abbott RealTime HIV-1 Calibrator and Control Card Kit.

Reagent Preparation Area

All reagent preparation must take place in the dedicated Reagent Preparation Area. Refer to the Handling Precautions section of this package insert before preparing reagents.

NOTE: Change gloves before handling the amplification reagents.

13. Prepare the amplification master mix.
   - Each Amplification Reagent Pack supports up to 24 reactions.
   - Prior to opening the amplification reagents, ensure that the contents of the vials are at the bottom by tapping the vials in an upright position on the bench 5 to 10 times to bring the liquid to the bottom of the vials.
   - Prepare the master mix by using a PIPETTE DEDICATED FOR REAGENT USE ONLY to add 177 µL of the HIV-1 Activation Reagent (Reagent 1) and 549 µL of the HIV-1 Oligonucleotide Reagent (Reagent 2) together in the Thermostable rTth DNA Polymerase Enzyme bottle (Reagent 3).
   - If performing 25 to 48 reactions, prepare a second amplification master mix with a second Amplification Reagent Pack.
   - The Abbott m2000rt protocol (step 20) must be initiated within 40 minutes of the addition of Activation Reagent into the first rTth Enzyme Reagent bottle (step 13).

14. Pipette the contents of the master mix from the enzyme bottle(s) into a single-use RNase/DNase-free tube and vortex to mix.

15. Place an Abbott 96-Well Optical Reaction Plate in a StrataCooler 96 or Eppendorf PCR Cooler stored as indicated in the instruction manual and return to the Reagent Preparation Area. A calibrated repeat pipettor may be used. Visually verify that 50 µL has been dispensed into each well.

16. Transfer the Abbott 96-Well Optical Reaction Plate to the StrataCooler 96 or Eppendorf PCR Cooler to the Sample Preparation Area.

Sample Preparation Area

17. In the Sample Preparation Area, transfer 50 µL of sample eluate to the Abbott 96-Well Optical Reaction Plate on the StrataCooler 96 or Eppendorf PCR Cooler stored as indicated in the instruction manual. Using a DEDICATED PIPETTE, dispense 50 µL aliquots of the amplification master mix into the Abbott 96-Well Optical Reaction Plate. A calibrated repeat pipettor may be used. Visually verify that 50 µL has been dispensed into each well.


19. Remove the Abbott 96-Well Optical Reaction Plate from the StrataCooler 96 or Eppendorf PCR Cooler and place in the Abbott Splash-Free Support Base. Centrifuge the Abbott 96-Well Optical Reaction Plate in the Abbott Splash-Free Support Base at 5,000g for 5 minutes. Transfer to the Amplification Area.

NOTE: Do not transfer the StrataCooler 96 or Eppendorf PCR Cooler to the Amplification Area.

Amplification Area

20. Place the Abbott 96-Well Optical Reaction Plate in the Abbott m2000rt instrument. From the Protocol screen, select the appropriate application file corresponding to the sample volume being tested. Initiate the Abbott RealTime HIV-1 protocol, as described in the Abbott m2000rt Operations Manual, Operating Instructions section.

POST PROCESSING PROCEDURES FOR PROTOCOL I

1. Clean the StrataCooler 96 or Eppendorf PCR Cooler as described in the instruction manual and return to the Reagent Preparation Area.

2. Remove the 1.5 mL Output Tubes from the worktable and dispose of according to the Abbott m1000 Operating Manual.

3. Place the Abbott 96-Well Optical Reaction Plate in a sealable plastic bag and dispose of according to the Abbott m2000rt Operations Manual along with the gloves used to handle the plate.


5. For manual sample preparation method users, refer to the Clean Up Section of the Manual Sample Preparation for Abbott RealTime RNA Assays Procedure (List No. OSL73).

ASSAY PROTOCOL II: PLASMA SAMPLES USING THE ABBOTT m2000sp AND THE ABBOTT m2000rt INSTRUMENTS


Laboratory personnel must be trained to operate the Abbott m2000sp and Abbott m2000rt instruments. The operator must have a thorough knowledge of the applications run on the instruments and must follow good laboratory practices.

For plasma Samples prepared for amplification using the Abbott m2000sp instrument and using the optional UNG procedure, refer to Appendix 2.

1. Thaw assay controls and IC at 15 to 30°C or at 2 to 8°C. Thaw calibrators at 15 to 30°C or at 2 to 8°C only if performing a calibration run; see QUALITY CONTROL PROCEDURES section of this package insert.

   - Once thawed, assay controls, IC, and calibrators can be stored at 2 to 8°C for up to 24 hours before use.
   - Vortex each assay calibrator and each control 3 times for 2 to 3 seconds before use. Ensure that the contents of each vial are at the bottom after vortexing by tapping the vials on the bench to bring liquid to the bottom of the vial.

2. Select new and/or partial amplification reagent packs to be used in the run. Refer to the Abbott m2000sp Operations Manual (List No. 9K20 version 6 or higher), Operating Instructions section, for instructions pertaining to amplification reagent pack inventory management. Amplification reagent packs must have the same lot number. Thaw new amplification reagents at 15 to 30°C or at 2 to 8°C and store at 2 to 8°C until required for the amplification master mix procedure. Once thawed, the new amplification reagents can be stored at 2 to 8°C for up to 24 hours if not used immediately.

NOTE: Partial amplification reagent packs being used a second time should NOT be stored at 2 to 8°C before use. They should be kept at −25 to −15°C until needed for master mix addition. Once removed from the freezer, cumulative room temperature exposure should not exceed 25 minutes, including instances where packs are removed from storage, but not used. If 25 minutes is exceeded, discard the partial amplification reagent packs.

The following table shows the number of sample preparation reagents and internal control vials needed based on the number of reactions.

<table>
<thead>
<tr>
<th>Sample Preparation Reagents and Internal Control Vials Needed Based on Number of Reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagent</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>mMicroparticles</td>
</tr>
<tr>
<td>mLysis</td>
</tr>
<tr>
<td>mWash 1</td>
</tr>
<tr>
<td>mWash 2</td>
</tr>
<tr>
<td>mElution Buffer</td>
</tr>
<tr>
<td>Internal Control</td>
</tr>
<tr>
<td>vial or vial or vial or vial or vial or vials or vials or vials or vials</td>
</tr>
</tbody>
</table>

α A combination of new and partial vials of Internal Control may be used.

3. Gently invert the Abbott mSample Preparation bottles to ensure a homogeneous solution. If crystals are observed in any of the reagent bottles upon opening, allow the reagent to equilibrate at room temperature until the crystals disappear. Do not use the reagents until the crystals have dissolved.
4. Vortex each IC 3 times for 2 to 3 seconds before use.
5. Use a calibrated precision pipette dedicated for internal control use only to add 500 µL of IC to each bottle of mLysis Buffer. Mix by gently inverting the container 5 to 10 times to minimize foaming. Partial vials of IC can be recapped and stored at –25 to –15°C for a second use.
6. A total of 96 samples can be processed in each run, with the exception of the 1.0 mL Assay Application. A negative control, a low positive control, and a high positive control are included in each run, therefore allowing a maximum of 93 specimens to be processed per run. For the 1.0 mL Assay Application, a total of 48 samples can be processed in each run, allowing a maximum of 45 specimens to be processed per run.

The Abbott RealTime HIV-1 assay minimum sample volume and associated rack requirements on the Abbott m2000sp are:

<table>
<thead>
<tr>
<th>Rack</th>
<th>Tube Diameter</th>
<th>Minimum Sample Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>13mm</td>
<td>1.15 - 1.40 mm</td>
<td>0.4 - 0.8 mL</td>
</tr>
<tr>
<td></td>
<td>1.8 - 2.1 mL</td>
<td>0.8 - 1.3 mL</td>
</tr>
<tr>
<td>16mm</td>
<td>1.45 - 1.60 mm</td>
<td>0.4 - 1.0 mL</td>
</tr>
<tr>
<td></td>
<td>1.8 - 1.4 mL</td>
<td>0.9 - 1.5 mL</td>
</tr>
<tr>
<td></td>
<td>1.3 - 1.9 mL</td>
<td>1.0 mL</td>
</tr>
</tbody>
</table>


- If frozen, thaw specimens at 15 to 30°C or at 2 to 8°C. Once thawed, specimens can be stored at 2 to 8°C for up to 6 hours if not processed immediately.
  
  **NOTE:** For every stored specimen, the following actions must be done in the order described: vortex the specimen first and follow with centrifugation. If these actions are not performed in this order, then invalid results may occur.

- Vortex each specimen 3 times for 2 to 3 seconds.
- Centrifuge specimens at 2000g for 5 minutes before loading onto the Abbott m2000sp worktable. Aliquot each specimen into clean tubes or vials if necessary. Refer to the Abbott m2000sp Operations Manual for tube sizes. Avoid touching the inside of the cap when opening tubes.
- Place the low and high positive controls, the negative control, the calibrators, if applicable, and the patient specimens into the Abbott m2000sp sample rack. If used, bar codes on tube labels must face right for scanning.
- Place the 5 mL Reaction Vessels into the Abbott m2000sp 1 mL subsystem carrier.
- Load the Abbott mSample Preparation System reagents and the Abbott 96 Deep-Well Plate on the Abbott m2000sp worktable as described in the Abbott m2000sp Operations Manual, Operating Instructions section.
- From the Protocol screen, select the appropriate application file corresponding to the sample volume being tested. Initiate the sample extraction protocol as described in the Abbott m2000sp Operations Manual, Operating Instruction section.
- Enter calibrator (needed if a calibration curve has not been stored on the Abbott m2000sp) and control lot specific values in the Sample Extraction: Worktable Setup, Calibrator and Control fields. Lot-specific values are specified in each Abbott RealTime HIV-1 Calibrator and Control Kit Card.
- The Abbott m2000sp Master Mix Addition protocol (step 12) must be initiated within 1 hour after completion of Sample Preparation.

**NOTE:** Change gloves before handling the amplification reagents.

11. Load the amplification reagents and the master mix tube (if needed) on the Abbott m2000sp worktable after sample preparation is completed. The following table shows the number of amplification reagent packs needed based on the number of reactions.

| Reactions | Amplification Reagent Pack Requirements
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 24</td>
<td>1 if new; 2 if new; 3 if new; 4 new</td>
</tr>
<tr>
<td>25 to 48</td>
<td>up to 4 with partial packs</td>
</tr>
<tr>
<td>49 to 72</td>
<td>up to 4 with partial packs</td>
</tr>
<tr>
<td>73 to 96</td>
<td>up to 4 with partial packs</td>
</tr>
</tbody>
</table>

**IMPORTANT:** Partial amplification reagent packs should be stored at –25 to –15°C until immediately before the second use. Confirm that master mix is thawed before placing partial pack(s) on the Abbott m2000sp worktable. Once removed from –25 to –15°C storage, partial amplification reagent packs being used a second time must be used within 25 minutes or discarded. This applies to cumulative room temperature exposure, including instances where packs are removed from storage, but not used:

- Ensure that the contents of new amplification reagent packs are at the bottom of the vials prior to opening the amplification reagents by tapping the vials in an upright position on the bench 5 to 10 times.
- Do not tap partial amplification reagent packs being used a second time. Tapping may result in loss of master mix volume in the cap.
- Remove caps. If a new amplification reagent pack will be stored for a second use, the vials will need to be recapped for storage. If planning to reuse the original caps to recap the reagent vials, save the original caps. If planning to use fresh caps to recap the reagent vials, original caps may be discarded.
- Partial amplification reagent packs are loaded to the left of new amplification reagent packs on the Abbott m2000sp worktable.
- Ensure that amplification reagent packs are firmly seated on the instrument.

12. Select the appropriate deep-well plate that matches the corresponding sample preparation extraction. Initiate the Abbott m2000sp Master Mix Addition protocol. Follow the instructions as described in the Abbott m2000sp Operations Manual, Operating Instructions section.

**NOTE:** The operator should not manually fill any empty/unfilled wells in the Abbott 96-Well Optical Reaction Plate.

- After sample extraction is complete, the Abbott m2000sp automatically fills any empty wells in the Abbott 96-Well Optical Reaction Plate when there are greater than 48 samples processed within a run. Plate fill is not performed for runs containing 48 samples or fewer.
- If prompted by the instrument, Reagent Carrier 2 should remain in place, minimally containing the reagent vessel for mElution Buffer (Reagent Carrier 2, location 6). If this reagent vessel has been unloaded, place a new reagent vessel with the mElution Buffer label into Reagent Carrier 2, location 6. System fluid will be added to the reagent vessel and used to fill empty wells. Once this process is complete, the system will continue with the master mix addition.

**NOTE:** System instructions for use of the automated plate-filling feature are found in the Abbott m2000sp Operations Manual (List No. 9K20 version 6 or higher), section 5, Operating Instructions, Sample Extraction—Closed Mode.

- The Abbott m2000sp protocol (step 16) must be started within 50 minutes of the initiation of the Master Mix Addition protocol (step 12).

**NOTE:** If the run is aborted for any reason subsequent to step 12, a new 96-well PCR plate must be used if the Abbott m2000sp Master Mix Addition Protocol (step 12) will be repeated.
13. Switch on and initialize the Abbott m2000rt instrument in the Amplification Area.
   NOTE: The Abbott m2000rt requires 15 minutes to warm-up.
   NOTE: Remove gloves before returning to the sample preparation area.
14. Seal the Abbott 96-Well Optical Reaction Plate after the Abbott m2000sp instrument has completed addition of samples and master mix according to the Abbott m2000sp Operations Manual, Operating Instructions section.
15. Place the sealed optical reaction plate into the Abbott Splash-Free Support Base for transfer to the Abbott m2000rt instrument.
16. Place the Abbott 96-Well Optical Reaction Plate in the Abbott m2000rt instrument. From the Protocol screen, select the appropriate application file corresponding to the sample volume being tested. Initiate the Abbott RealTime HIV-1 protocol, as described in the Abbott m2000rt Operations Manual, Operating Instructions section.
   NOTE: Test order transfer through the use of CD-ROM or network connection with export and import features of the m2000sp and m2000rt software is recommended. If creating the Abbott m2000rt test order manually, enter sample IDs in the corresponding PCR tray locations according to the "Wells for Selected Plate" grid, found on the detail screen of the "PCR Plate Results" on the Abbott m2000sp. See Section 5 of the Abbott m2000sp Operations Manual.
17. If a prepared partial amplification reagent pack is to be used a second time, cap the 3 reagent vials with the saved caps or new caps (List No. SN20-01) and promptly store the reagents at −25 to −15°C, protected from light, and in an upright position. Discard any amplification reagent packs that are exhausted or have been used twice.

IMPORTANT: Amplification reagents that will be used a second time must be stored at −25 to −15°C within 50 minutes of the initiation of the master mix addition protocol.

ASSAY PROTOCOL III: DBS SAMPLES USING THE ABBOTT m2000sp AND THE ABBOTT m2000rt INSTRUMENTS


A total of 96 samples can be processed in each run. A negative control, a low positive control, and a high positive control are included in each run, therefore allowing a maximum of 93 DBS specimens to be processed per run when calibrators are not included. Process Calibrators and Controls directly as liquid samples; step 1 through step 5 are for DBS only. Do not process plasma specimens on any run where DBS protocol is used. For each DBS sample, a single Abbott Master Mix Tube should be used for the entire sample processing procedure. Ensure DBS samples are labeled throughout processing.

For DBS Samples prepared for amplification using the Abbott m2000sp instrument and using the optional UNG procedure follow, refer to Appendix 2.
1. Fill the Abbott Master Mix Tube with 1.3 mL of mDBS buffer from the Abbott mSample Preparation system DBS Buffer Kit (List No. 09N02-001).
   NOTE: Do not use mLysis Buffer or any other reagents for this step.
2. Hold perforated DBS paper card above the Abbott Master Mix Tube.
3. Push the DBS circle out of the card using a clean pipette tip, one DBS circle per Master Mix Tube. Each DBS should be approximately one-half-inch (12 millimeters) in diameter. USE A NEW PIPETTE TIP FOR EACH DBS SAMPLE TO PREVENT CROSS CONTAMINATION.
4. Ensure that the DBS circle is fully submerged in the mLysis Buffer by tapping the tube or using the pipette tip to push the DBS into the buffer.
   NOTE: If a pipette tip is used to push the DBS into the buffer, ensure that the pipette tip does not cause DBS buffer volume loss due to liquid containment in the tip and/or absorption of the buffer by the tip filter.
5. Manually shake or swirl the sample tubes and then place them in a heat block set at 55°C. Do not vortex the samples. Incubate for 30 minutes (± 2 minutes) at 55°C.
6. Meanwhile, thaw assay controls and internal control (IC) at 15 to 30°C or at 2 to 8°C. Thaw calibrators at 15 to 30°C or at 2 to 8°C only if performing a calibration run.
   NOTE: Once thawed, assay controls, IC, and calibrators can be stored at 2 to 8°C for up to 24 hours before use.
7. Vortex each assay calibrator and each control 3 times for 2 to 3 seconds before use. Ensure that the contents of each vial are at the bottom by tapping the vials on the bench to bring liquid to the bottom of the vial. Ensure bubbles or foam is not generated; if present, remove with a sterile pipette tip, using a new tip for each vial.
8. Thaw amplification reagents at 15 to 30°C or at 2 to 8°C and store at 2 to 8°C until required for the amplification master mix procedure.
9. Select new and/or partial amplification reagent packs to be used in the run. Refer to the Abbott m2000sp Operations Manual (List No. 9K20 version 6 or higher), Operating Instructions section, for instructions pertaining to amplification pack inventory management. Amplification reagent packs must have the same lot number.
   Thaw new amplification reagents at 15 to 30°C or at 2 to 8°C and store at 2 to 8°C until required for the amplification master mix procedure. Once thawed, the new amplification reagents can be stored at 2 to 8°C for up to 24 hours if not used immediately.
   NOTE: Partial amplification reagent packs being used a second time should NOT be stored at 2 to 8°C before use. They should be kept at −25 to −15°C until needed for master mix addition. Once removed from the freezer, cumulative room temperature exposure should not exceed 25 minutes, including instances where packs are removed from storage, but not used. If 25 minutes is exceeded, discard the partial amplification reagent packs.

The following table shows the number of sample preparation reagents and internal control vials needed based on the number of reactions.

<table>
<thead>
<tr>
<th>Sample Preparation Reagents and Internal Control Requirements</th>
<th>1 to 24 Reactions</th>
<th>25 to 48 Reactions</th>
<th>49 to 72 Reactions</th>
<th>73 to 96 Reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>mLipocaricles</td>
<td>1 bottle</td>
<td>2 bottles</td>
<td>2 bottles</td>
<td>2 bottles</td>
</tr>
<tr>
<td>mLysis</td>
<td>1 bottle</td>
<td>2 bottles</td>
<td>3 bottles</td>
<td>4 bottles</td>
</tr>
<tr>
<td>mWash 1</td>
<td>1 bottle</td>
<td>2 bottles</td>
<td>3 bottles</td>
<td>4 bottles</td>
</tr>
<tr>
<td>mWash 2</td>
<td>1 bottle</td>
<td>2 bottles</td>
<td>3 bottles</td>
<td>4 bottles</td>
</tr>
<tr>
<td>mLBuffer</td>
<td>1 bottle</td>
<td>2 bottles</td>
<td>3 bottles</td>
<td>4 bottles</td>
</tr>
<tr>
<td>Internal Control*</td>
<td>1 new vial</td>
<td>1 new vial</td>
<td>2 new vials</td>
<td>2 new vials</td>
</tr>
</tbody>
</table>
| * A combination of new and partial vials of Internal Control may be used.
   10. Gently invert the Abbott mSample Preparation bottles to ensure a homogeneous solution. If crystals are observed in any of the reagent bottles upon opening, allow the reagent to equilibrate at room temperature until the crystals disappear. Do not use the reagents until the crystals have dissolved.
   11. Vortex each IC 3 times for 2 to 3 seconds before use.
   12. Use a calibrated precision pipette DEDICATED FOR INTERNAL CONTROL USE ONLY to add 750 µL of IC to each bottle of mLysis Buffer. Mix by gently inverting the container 5 to 10 times to minimize foaming.
   13. Place the low and high positive controls, the negative control, and the calibrators, if applicable, into the Abbott m2000sp sample racks.
   14. After the incubation is complete, manually shake or swirl the DBS sample tubes and then place them into the Abbott m2000sp sample racks.
   NOTE: Ensure that the Abbott m2000sp sample racks have been calibrated specifically for the Abbott RealTime HIV-1 DBS procedure.
15. Load the sample racks carefully to avoid splashing. If used, bar
codes on tube labels must face right for scanning. Ensure that each
tube is placed securely in the sample rack so that the bottom of the
tube reaches the inside bottom of the rack.
16. Load filled sample racks onto the Abbott m2000sp in consecutive
sample rack positions, with the first rack farthest to the right on the
worktable, and any additional rack progressively to the left of the
first rack.
17. Place the 5 mL Reaction Vessels into the Abbott m2000sp 1
subsystem carrier.
18. Load the Abbott mSample Preparation System reagents and the
Abbott 96 Deep-Well Plate on the Abbott m2000sp worktable as
described in the Abbott m2000sp Operations Manual, Operating
Instructions section.
19. From the Protocol screen, select the HIV-1 DBS viral load application
file. Initialize the sample extraction protocol as described in the Abbott
m2000sp Operations Manual, Operating Instruction section.
20. Enter calibrator (needed if a calibration curve has not been stored
on the Abbott m2000sp) and control lot specific values in the
Sample Extraction: Worktable Setup, Calibrator and Control fields.
Lot specific values are specified in each Abbott RealTime HIV-1
Calibrator and Control Kit Card.
21. The Abbott m2000sp Master Mix Addition protocol (step 23) must be
initiated within 1 hour after completion of Sample Preparation.
NOTE: Change gloves before handling the amplification reagents.
22. Load the amplification reagents and the master mix tube (if needed)
on the Abbott m2000sp worktable after sample preparation is
completed. The following table shows the number of amplification
reactant packs needed based on the number of reactions.
If only 1 amplification reactant pack is being used, no master mix
tube is required.

<table>
<thead>
<tr>
<th>Amplification Reactant Pack Requirements*</th>
<th>1 to 24 Reactions</th>
<th>25 to 48 Reactions</th>
<th>49 to 72 Reactions</th>
<th>73 to 96 Reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 if new;</td>
<td>1 up to 4 with</td>
<td>3 up to 4 with</td>
<td>4 new</td>
<td>partial packs</td>
</tr>
<tr>
<td>2 if new;</td>
<td>up to 4 with</td>
<td></td>
<td>up to 4 with</td>
<td>partial packs</td>
</tr>
<tr>
<td>3 if new;</td>
<td>up to 4 with</td>
<td></td>
<td>up to 4 with</td>
<td>partial packs</td>
</tr>
<tr>
<td>4 new</td>
<td>up to 4 with</td>
<td></td>
<td>up to 4 with</td>
<td>partial packs</td>
</tr>
<tr>
<td>1 to 4 new, partial packs</td>
<td>partial packs</td>
<td>partial packs</td>
<td>partial packs</td>
<td></td>
</tr>
</tbody>
</table>

* Refer to the Abbott m2000sp Operations Manual (List No. 9K20 version 6 or
higher) for instructions on inventory management to determine the maximum
number of reactions that can be tested with the partial packs selected.
• Partial amplification reactant packs can only be used on the same
Abbott m2000sp instrument used for the reactant pack’s initial
preparation. Using an amplification reactant pack for a second
time on a different instrument will result in an error, which may
delay the run.
• Partial and new amplification reactant packs may be
used together.
IMPORTANT: Partial amplification reactant packs should be stored
at –25 to –15°C until immediately before the second use.
Confirm that master mix is thawed before placing partial
pack(s) on the Abbott m2000sp worktable. Once removed
from –25 to –15°C storage, partial amplification reactant packs
being used a second time must be used within 25 minutes
or discarded. This applies to cumulative room temperature
exposure, including instances where packs are removed from
storage, but not used.
• Ensure that the contents of new amplification reactant packs
are at the bottom of the vials prior to opening the amplification
reactants by tapping the vials in an upright position on the
bench 5 to 10 times.
• Do not tap partial amplification reactant packs being used a
second time. Tapping may result in loss of master mix volume in
the cap.
• Remove caps. If a new amplification reactant pack will be stored
for a second use, the vials will need to be recapped for storage.
If planning to re-use the original caps to recap the reactant vials,
save the original caps. If planning to use fresh caps to recap the
reactant vials, original caps may be discarded.
• Partial amplification reactant packs are loaded to the left of new
amplification reactant packs on the Abbott m2000sp worktable.
• Ensure that amplification reactant packs are firmly seated on the
instrument.
23. Select the appropriate deep-well plate that matches the
corresponding sample preparation extraction. Initiate the Abbott
m2000sp Master Mix Addition protocol. Follow the instructions as
described in the Abbott m2000sp Operations Manual, Operating
Instructions section.
NOTE: The operator should not manually fill any empty/unfilled
wells in the Abbott 96-Well Optical Reaction Plate.
• After sample extraction is complete, the Abbott m2000sp
automatically fills any empty wells in the Abbott 96-Well Optical
Reaction Plate with mElution buffer when there are greater than
48 samples processed within a run. Plate fill is not performed for
runs containing 48 samples or fewer.
• If prompted by the instrument, Reagent Carrier 2 should remain
in place, minimally containing the reagent vessel for mElution
Buffer (Reagent Carrier 2, location 6). If this reagent vessel has
been unloaded, place a new reagent vessel with the mElution
Buffer label into Reagent Carrier 2, location 6. System fluid will
be added to the reagent vessel and used to fill empty wells. Once
this process is complete, the system will continue with the master
mix addition.
NOTE: System instructions for use of the automated plate-filling
feature are found in the Abbott m2000sp Operations
Manual (List No. 9K20 version 6 or higher), section 5,
Operating Instructions, Sample Extraction-Closed Mode.
• The Abbott m2000rt protocol (step 27) must be started within 50
minutes of the initiation of the Master Mix Addition protocol
(step 23).
NOTE: If the run is aborted for any reason subsequent to step 23,
a new Abbott 96-Well Optical Reaction Plate must be used
if the Abbott m2000sp Master Mix Addition Protocol (step
23) will be repeated.
24. Switch on and initialize the Abbott m2000rt instrument in the
Amplification Area.
NOTE: The Abbott m2000rt requires 15 minutes to warm-up.
NOTE: Remove gloves before returning to the sample preparation
area.
25. Seal the Abbott 96-Well Optical Reaction Plate after the Abbott
m2000sp instrument has completed addition of samples and master
mix according to the Abbott m2000sp Operations Manual, Operating
Instructions section.
26. Place the sealed optical reaction plate into the Abbott Splash-Free
Support Base for transfer to the Abbott m2000rt instrument.
27. Place the Abbott 96-Well Optical Reaction Plate in the Abbott
m2000rt instrument. From the Protocol screen, select the HIV-1 DBS
viral load application file. Initialize the protocol as described in the
NOTE: Test order transfer through the use of CD-ROM or network
connection with export and import features of the m2000sp
and m2000rt software is recommended. If creating the
Abbott m2000rt test order manually, enter sample IDs in the
corresponding PCR tray locations according to the “Wells for
Selected Plate” grid, found on the detail screen of the “PCR
Plate Results” on the Abbott m2000sp. See Section 5 of the
28. If a prepared partial amplification reactant pack is to be used a
second time, cap the 3 reagent vials with the saved caps or new
caps (List No. 3N20-01) and promptly store the reagents at –25 to
–15°C, protected from light, and in an upright position. Discard any
amplification reactant packs that are exhausted or have been used
twice.
IMPORTANT: Amplification reagents that will be used a second time
must be stored at –25 to –15°C within 50 minutes of the
initiation of the master mix addition protocol.
POST PROCESSING PROCEDURES FOR PROTOCOL II
AND III
1. Remove the Abbott 96 Deep-Well Plate from the worktable and
dispose of according to the Abbott m2000sp Operations Manual.
2. Place the Abbott 96-Well Optical Reaction Plate in a sealable
plastic bag and dispose according to the Abbott m2000rt Operations
Manual along with the gloves used to handle the plate.
3. Clean the Abbott Splash-Free Support Base before next use,
according to the Abbott m2000rt Operations Manual.
QUA Li Ty Con t ro l Pro c ed u res

Abbott m2000rt Optical Calibration


Optical calibration of the Abbott m2000rt instrument is required for the accurate measurement and discrimination of dye fluorescence during the Abbott RealTime HIV-1 assay.

The following Abbott m2000rt Optical Calibration Plates are used to calibrate the Abbott m2000rt instrument for the Abbott RealTime HIV-1 assay:

- FAM™ Plate (Carboxyfluorescein)
- ROX™ Plate (Carboxy-X-rhodamine)
- VIC™ Plate (Proprietary dye)

Assay Calibration

For a detailed description of how to perform an assay calibration refer to the Abbott m2000sp and Abbott m2000rt Operations Manuals, Operating Instructions sections.

A calibration curve is required to quantitate the HIV-1 RNA concentration of specimens and controls. Two assay calibrators are run in replicates of 3 to generate a calibration curve (logarithm of HIV-1 concentration versus the threshold cycle [Ct] at which a reactive level of fluorescent signal is detected). The calibration curve slope and intercept are calculated and stored on the instrument. The concentration of HIV-1 RNA in a sample is calculated from the stored calibration curve. Results are automatically reported on the Abbott m2000rt workstation.


Once an Abbott RealTime HIV-1 calibration is accepted and stored, it may be used for 6 months. During this time, all subsequent samples may be tested without further calibration unless:

- An Abbott RealTime HIV-1 Amplification Reagent Kit with a new lot number is used.
- An Abbott mSample Preparation System (4 × 24 Preps) with a new lot number is used.
- An Abbott RealTime HIV-1 application file for a different sample volume is used.
- A new Abbott RealTime HIV-1 application specification file is installed.
- Pure Dye optical re-calibration of the Abbott RealTime HIV-1 assay-specific dyes (FAM, VIC, or ROX) is performed per the Calibration Procedures section of the Abbott m2000rt Operations Manual.

Detection of Inhibition

An IC threshold cycle [Ct] assay validity parameter is established during a calibration run. A defined, consistent quantity of IC is introduced into each specimen, calibrator, and control at the beginning of sample preparation and measured on the Abbott m2000rt instrument to demonstrate proper specimen processing and assay validity. The IC is comprised of an RNA sequence unrelated to the HIV-1 target sequence.

The median amplification cycle at which the IC target sequence fluorescent signal is detected in calibration samples establishes an IC Ct validity range to be met by all subsequent processed specimens.

An error control flag is displayed when a specimen or control fails to meet this specification. Refer to the Abbott m2000rt Operations Manual for an explanation of the corrective actions for the error control flag. Specimens whose IC Ct value exceeds the established range must be retested starting with sample preparation.

Negative and Positive Controls

A negative control, a low-positive control, and a high-positive control are included in each test order to evaluate run validity. The lot-specific values for the low-positive control and high-positive control are specified on each Abbott RealTime HIV-1 Control Kit Card and must be entered into the assay test order when a run is performed.

An error control flag is displayed when a control result is out of range. Refer to the Abbott m2000rt Operations Manual for an explanation of the corrective actions for the error control flag. If negative or positive controls are out of range, all of the specimens and controls from that run must be reprocessed, beginning with sample preparation.

The presence of HIV-1 must not be detected in the negative control. HIV-1 detected in the negative control is indicative of contamination by other samples or by amplified product introduced during sample preparation or during preparation of the Abbott 96-Well Optical Reaction Plate. To avoid contamination, clean the Abbott m1000 System or Abbott m2000sp instrument and the Abbott m2000rt instrument and repeat sample processing for controls and specimens following the Procedural Precautions. If negative controls are persistently reactive, contact your Abbott representative.

Monitoring the Laboratory for the Presence of Contamination

It is recommended that this test be done at least once a month to monitor laboratory surfaces and equipment for contamination by amplification product. It is very important to test all areas that may have been exposed to processed specimens, controls, and calibrators, and/or amplification product. This includes routinely handled objects such as pipettes, the Abbott m2000sp and Abbott m2000rt function keys, laboratory bench surfaces, microcentrifuges, and centrifuge adaptors.

1. Add 0.8 mL RNase-free water to a 1.7 mL molecular biology grade microcentrifuge tube.
2. Saturate the cotton tip of an applicator (Puritan or equivalent) in the RNase-free water from the microcentrifuge tube.
3. Using the saturated cotton tip of the applicator, wipe the area to be monitored using a sweeping motion. Place the applicator into the microcentrifuge tube.
4. Swirl the cotton tip in RNase-free water 10 times, and then press the applicator along the inside of the tube so that the liquid drains back into the solution at the bottom of the microcentrifuge tube. Discard the applicator.
5. Pipette 0.5 mL of mWash 1 buffer to a clean tube using the pipette dedicated for Internal Control use.
6. Add 20 µL of the mWash 1 buffer to each microcentrifuge tube.
7. Cap the microcentrifuge tube.
8. Test this sample according to the assay procedure section of this package insert.

- Transfer liquid from the microcentrifuge tube to a 5 mL Reaction Vessel.
- Bring the volume to 1.5 mL with RNase-free water.
9. The presence of contamination is indicated by the detection of HIV-1 nucleic acid in the swab samples.
10. If HIV-1 nucleic acid is detected on equipment, follow the cleaning and decontaminating guidelines given in that equipment’s operations manual. If HIV-1 nucleic acid is detected on surfaces, clean the contaminated areas with 1.0% (v/v) sodium hypochlorite solution, followed by 70% ethanol or water.

NOTE: Chlorine solutions may pit equipment and metal. Use sufficient amounts or repeated applications of 70% ethanol or water until chlorine residue is no longer visible.

11. Repeat testing of the contaminated area by following steps 1 through 10.

RESULTS FOR PLASMA SPECIMENS

Calculation

The concentration of viral HIV-1 RNA in a sample or control is calculated from the stored calibration curve. The Abbott m2000rt instrument automatically reports the results on the Abbott m2000rt workstation.

Assay results can be reported in copies/mL, log [copies/mL], International Units (IU)/mL, or log [IU/mL]: (1 IU = 0.58 copies, 1 copy = 1.74 IU).
The instruments and assay procedures reduce the risk of contamination by amplification product. However, nucleic acid contamination from the calibrators, positive controls, or specimens must be controlled by good laboratory practices and careful adherence to the procedures specified in this package insert.

As with any diagnostic test, results from the Abbott RealTime HIV-1 assay should be interpreted in conjunction with other clinical and laboratory findings. A specimen with a result of “Not Detected” cannot be presumed to be negative for HIV-1 RNA.

RESULTS FOR DBS SPECIMENS
The reported sample concentration result from the m2000rt DBS protocol run represents the HIV-1 viral concentration in the plasma of the whole blood specimen from which the DBS specimen is obtained. The Abbott m2000rt instrument automatically reports the results on the Abbott m2000rt workstation. Assay results can be reported in copies/mL, log [copies/mL], International Units (IU)/mL, or log [IU/mL]; (1 IU = 0.58 copies/mL).

Interpretation of Results

<table>
<thead>
<tr>
<th>Sample Volume</th>
<th>Result</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0 mL</td>
<td>Not Detected</td>
<td>Target not detected</td>
</tr>
<tr>
<td></td>
<td>&lt; 1.60 Log [Copies/mL]</td>
<td>Detected</td>
</tr>
<tr>
<td></td>
<td>1.60 to 7.00 Log [Copies/mL]</td>
<td>Detected</td>
</tr>
<tr>
<td></td>
<td>&gt; 7.00 Log [Copies/mL]</td>
<td>&gt; ULQd</td>
</tr>
<tr>
<td>0.6 mL</td>
<td>Not Detected</td>
<td>Target not detected</td>
</tr>
<tr>
<td></td>
<td>&lt; 1.60 Log [Copies/mL]</td>
<td>Detected</td>
</tr>
<tr>
<td></td>
<td>1.60 to 7.00 Log [Copies/mL]</td>
<td>Detected</td>
</tr>
<tr>
<td></td>
<td>&gt; 7.00 Log [Copies/mL]</td>
<td>&gt; ULQd</td>
</tr>
<tr>
<td>0.5 mL</td>
<td>Not Detected</td>
<td>Target not detected</td>
</tr>
<tr>
<td></td>
<td>&lt; 1.88 Log [Copies/mL]</td>
<td>Detected</td>
</tr>
<tr>
<td></td>
<td>1.88 to 7.00 Log [Copies/mL]</td>
<td>Detected</td>
</tr>
<tr>
<td></td>
<td>&gt; 7.00 Log [Copies/mL]</td>
<td>&gt; ULQ</td>
</tr>
<tr>
<td>0.2 mL</td>
<td>Not Detected</td>
<td>Target not detected</td>
</tr>
<tr>
<td></td>
<td>&lt; 2.18 Log [Copies/mL]</td>
<td>Detected</td>
</tr>
<tr>
<td></td>
<td>2.18 to 7.00 Log [Copies/mL]</td>
<td>Detected</td>
</tr>
<tr>
<td></td>
<td>&gt; 7.00 Log [Copies/mL]</td>
<td>&gt; ULQ</td>
</tr>
</tbody>
</table>

a 40 Copies/mL
b 75 Copies/mL
c 150 Copies/mL
d ULQ = upper limit of quantitation

SPECIFIC PERFORMANCE CHARACTERISTICS FOR PLASMA SPECIMENS
The performance characteristics were determined using the Abbott RealTime HIV-1 assay with Abbott m2000sp sample preparation and 1.0 mL sample volume, unless otherwise specified.

Limit of Detection (LOD)
The limit of detection is defined as the HIV-1 RNA concentration detected with a probability of 95% or greater.

Limit of Detection, 1.0 mL Sample Volume
The LOD of the Abbott RealTime HIV-1 assay is 40 copies/mL with the 1.0 mL sample volume procedure.

The LOD was determined by testing dilutions of a viral standard from the Virology Quality Assurance (VQA) Laboratory of the AIDS Clinical Trial Group. Dilutions were made in HIV-1 negative human plasma. Testing was performed with 3 lots of amplification reagents on 3 Abbott m2000 Systems. The results, representative of the analytical sensitivity performance of the Abbott RealTime HIV-1 assay, are summarized in Table 1.

<table>
<thead>
<tr>
<th>Conc. (Copies/mL)</th>
<th>Number Tested</th>
<th>Number Detected</th>
<th>Percent Detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>57</td>
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<td>100</td>
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<td>57</td>
<td>68</td>
</tr>
<tr>
<td>5</td>
<td>57</td>
<td>57</td>
<td>53</td>
</tr>
</tbody>
</table>

The LOD of the Abbott RealTime HIV-1 assay is 40 copies/mL with the 0.6 mL sample volume procedure.

The LOD for the 0.6 mL sample volume procedure was determined as described for the 1.0 mL sample volume procedure. The results, representative of the analytical sensitivity performance of the Abbott RealTime HIV-1 assay, are summarized in Table 2.

<table>
<thead>
<tr>
<th>Conc. (Copies/mL)</th>
<th>Number Tested</th>
<th>Number Detected</th>
<th>Percent Detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>57</td>
<td>57</td>
<td>100</td>
</tr>
<tr>
<td>75</td>
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<tr>
<td>5</td>
<td>57</td>
<td>13</td>
<td>23</td>
</tr>
</tbody>
</table>

The LOD of the Abbott RealTime HIV-1 assay is 75 copies/mL with the 0.5 mL sample volume procedure.

The LOD for the 0.5 mL sample volume procedure was determined as described for the 1.0 mL sample volume procedure. The results, representative of the analytical sensitivity performance of the Abbott RealTime HIV-1 assay, are summarized in Table 3.

<table>
<thead>
<tr>
<th>Conc. (Copies/mL)</th>
<th>Number Tested</th>
<th>Number Detected</th>
<th>Percent Detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>57</td>
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<tr>
<td>5</td>
<td>57</td>
<td>13</td>
<td>23</td>
</tr>
</tbody>
</table>

Probit analysis of the data determined that the concentration of HIV-1 RNA detected with 95% probability was 25 copies/mL (95% CI 20 to 33).

Probit analysis of the data determined that the concentration of HIV-1 RNA detected with 95% probability was 39 copies/mL (95% CI 33 to 49).
Table 3.

<table>
<thead>
<tr>
<th>Conc. (Copies/mL)</th>
<th>Number Tested</th>
<th>Number Detected</th>
<th>Percent Detected</th>
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</thead>
<tbody>
<tr>
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</tr>
<tr>
<td>5</td>
<td>57</td>
<td>21</td>
<td>37</td>
</tr>
</tbody>
</table>

a One replicate generated an invalid replicate error message and was deleted from the data analysis.

Probit analysis of the data determined that the concentration of HIV-1 RNA detected with 95% probability was 65 copies/mL (95% CI 51 to 88).

Limit of Detection, 0.2 mL Sample Volume

The LOD of the Abbott RealTime HIV-1 assay is 150 copies/mL with the 0.2 mL sample volume procedure.

The LOD for the 0.2 mL sample volume procedure was determined as described for the 1.0 mL sample volume procedure. The results, representative of the analytical sensitivity performance of the Abbott RealTime HIV-1 assay, are summarized in Table 4.

Table 4.

<table>
<thead>
<tr>
<th>Conc. (Copies/mL)</th>
<th>Number Tested</th>
<th>Number Detected</th>
<th>Percent Detected</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
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<tr>
<td>40</td>
<td>54a</td>
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<td>56</td>
</tr>
<tr>
<td>30</td>
<td>52a</td>
<td>19</td>
<td>37</td>
</tr>
</tbody>
</table>

a Eight replicates were invalid due to an instrument error and were deleted from the data analysis.

Probit analysis of the data determined that the concentration of HIV-1 RNA detected with 95% probability was 119 copies/mL (95% CI 102 to 150).

Linear Range

The upper limit of quantitation (ULQ) for the Abbott RealTime HIV-1 assay is 10 million copies/mL, and the lower limit of quantitation is equivalent to the LOD (40 copies/mL for the 1.0 mL and 0.8 mL sample volume procedure, 75 copies/mL for the 0.5 mL sample volume procedure, and 150 copies/mL for the 0.2 mL sample volume procedure).

A 9-member panel prepared by diluting armored HIV-1 RNA from 7.44 log copies/mL to 1.16 log copies/mL in HIV-1 negative human plasma was tested. Linearity analysis was performed following the NCCLS EP6-A guideline.36 The results, representative of the Abbott RealTime HIV-1 assay linearity, are shown in Figure 1.

Table 5.

<table>
<thead>
<tr>
<th>Panel</th>
<th>n</th>
<th>Conc. Mean (copies/mL)</th>
<th>Conc. Mean (log copies/mL)</th>
<th>Within-Run SD Component</th>
<th>Between-Run SD Component</th>
<th>Inter-Assay SDa</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>75</td>
<td>57</td>
<td>1.75</td>
<td>0.21</td>
<td>0.00</td>
<td>0.21</td>
</tr>
<tr>
<td>2</td>
<td>75</td>
<td>573</td>
<td>2.76</td>
<td>0.08</td>
<td>0.00</td>
<td>0.08</td>
</tr>
<tr>
<td>3</td>
<td>75</td>
<td>5,000</td>
<td>3.70</td>
<td>0.05</td>
<td>0.02</td>
<td>0.06</td>
</tr>
<tr>
<td>4</td>
<td>75</td>
<td>35,751</td>
<td>4.55</td>
<td>0.03</td>
<td>0.01</td>
<td>0.04</td>
</tr>
<tr>
<td>5</td>
<td>75</td>
<td>315,065</td>
<td>5.50</td>
<td>0.07</td>
<td>0.03</td>
<td>0.07</td>
</tr>
<tr>
<td>6</td>
<td>74</td>
<td>2,947,538</td>
<td>6.47</td>
<td>0.05</td>
<td>0.04</td>
<td>0.07</td>
</tr>
<tr>
<td>7</td>
<td>75</td>
<td>5,347,285</td>
<td>6.73</td>
<td>0.04</td>
<td>0.05</td>
<td>0.07</td>
</tr>
</tbody>
</table>

a Inter-assay contains within-run and between-run components.

b Two replicates were inhibited and were deleted from the data analysis.

c HIV-1 RNA was not detected in 1 replicate.

The Abbott RealTime HIV-1 assay was shown to be linear across the range tested (n = 99, r = 0.999, slope = 0.93, and intercept = 0.26).

Precision

The precision of the Abbott RealTime HIV-1 assay was evaluated for the 1.0 mL sample volume procedure using the Abbott m1000 and Abbott m2000sp sample preparation systems and the manual sample preparation method. The Abbott RealTime HIV-1 assay is designed to achieve an inter-assay standard deviation (SD) of less than or equal to 0.25 log copies of HIV-1 RNA per mL for samples containing HIV-1 concentrations from 500 to 5 million copies/mL. A 7-member HIV-1 RNA panel was prepared by diluting an HIV-1 viral stock (panel members 1 through 3) and armored HIV-1 RNA (panel members 4 through 7) in negative human plasma. For the precision studies with the Abbott m1000 and the Abbott m2000sp, the panel members were tested in replicates of 5 in a total of 15 runs on 3 instrument systems, with 3 lots of amplification reagents. For the precision study using the manual sample preparation method, panel members were tested in replicates of 2 for the first run on each instrument and replicates of 3 for each subsequent run for a total of 15 runs on 3 Abbott m2000rt instruments with 3 lots of amplification reagents. Precision analysis was performed following the NCCLS EP10-A2 guideline.36 Within-run, between-run, and inter-assay (within-run and between-run) standard deviations were determined. The results, representative of the precision of the Abbott RealTime HIV-1 assay, are summarized in Tables 5, 6, and 7.
Drugs Tested RealTime HIV-1 assay was observed in the presence of the following substances for all positive samples and samples containing 10,000 copies/mL HIV-1 RNA were tested. Three replicates were tested at approximately 6.0 log copies/mL, 4.7 log copies/mL, 3.0 log copies/mL, and 1.7 log copies/mL were tested. Three replicates were tested at each concentration for each transcript. The results, representative of the dilution linearity for the 11 subtypes/groups tested, are shown in Figure 2.

The specificity of the assay was further evaluated by testing 70 specimens that had been either obtained from individuals diagnosed or screened for an autoimmune disorder or serologically characterized as positive for the following markers: systemic lupus erythematosus (SLE), anti-nuclear antibodies (ANA), rheumatoid factor (RF), HBsAg, anti-HTLV-I/II, anti-HCV, and anti-HIV-2. HIV-1 RNA was not detected in any of the specimens tested. The results demonstrated that the presence of an autoimmune disorder or serologic markers for autoimmune disease or viral pathogens other than HIV-1 did not affect the Abbott RealTime HIV-1 assay.

### Cross-Reactivity

The following viruses and microorganisms were evaluated for potential cross-reactivity in the Abbott RealTime HIV-1 assay. Purified nucleic acid or viral lysate from each microorganism or virus was added to HIV-1 RNA.

<table>
<thead>
<tr>
<th>Virus/Microorganism</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Varicella-zoster virus</td>
<td>Negative</td>
</tr>
<tr>
<td>Mycobacterium smegmatis</td>
<td>Negative</td>
</tr>
<tr>
<td>Mycobacterium gordonae</td>
<td>Negative</td>
</tr>
<tr>
<td>Human herpesvirus 8</td>
<td>Negative</td>
</tr>
<tr>
<td>Staphylococcus epidermidis</td>
<td>Negative</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>Negative</td>
</tr>
<tr>
<td>Cytomegalovirus</td>
<td>Negative</td>
</tr>
<tr>
<td>Human herpesvirus 6B</td>
<td>Negative</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>Negative</td>
</tr>
<tr>
<td>Chlamydia trachomatis</td>
<td>Negative</td>
</tr>
<tr>
<td>Candida albicans</td>
<td>Negative</td>
</tr>
<tr>
<td>Human Immunodeficiency virus 2</td>
<td>Negative</td>
</tr>
<tr>
<td>Vaccinia virus</td>
<td>Negative</td>
</tr>
<tr>
<td>Human T-lymphotropic virus 1</td>
<td>Negative</td>
</tr>
<tr>
<td>BK human polyomavirus</td>
<td>Negative</td>
</tr>
<tr>
<td>Hepatitis C virus</td>
<td>Negative</td>
</tr>
<tr>
<td>Human papilloma virus 16</td>
<td>Negative</td>
</tr>
<tr>
<td>Hepatitis B virus</td>
<td>Negative</td>
</tr>
<tr>
<td>Human papilloma virus 18</td>
<td>Negative</td>
</tr>
<tr>
<td>Epstein-Barr virus</td>
<td>Negative</td>
</tr>
<tr>
<td>Neisseria gonorrhoeae</td>
<td>Negative</td>
</tr>
<tr>
<td>Herpes simplex virus 1</td>
<td>Negative</td>
</tr>
<tr>
<td>Chlamydia trachomatis</td>
<td>Negative</td>
</tr>
<tr>
<td>Herpes simplex virus 2</td>
<td>Negative</td>
</tr>
<tr>
<td>Candida albicans</td>
<td>Negative</td>
</tr>
<tr>
<td>Varicella-zoster virus</td>
<td>Negative</td>
</tr>
<tr>
<td>Mycobacterium smegmatis</td>
<td>Negative</td>
</tr>
</tbody>
</table>

No interference in the performance of the Abbott RealTime HIV-1 assay was observed in the presence of the potential cross-reactants for all positive and negative samples tested.

### Detection of HIV-1 Subtypes and Groups

The performance of the Abbott RealTime HIV-1 assay with HIV-1 subtypes/groups was evaluated by analysis of purified RNA transcripts from Group M (subtypes A, B, C, D, CRF01-AE, F, CRF02-AG, G, and H), Group O, and Group N, and by testing 10 clinical specimens of each Group M subtype (A, B, C, D, CRF01-AE, F, CRF02-AG, and G), and 10 specimens from Group O.

RNA transcripts of Group M (subtypes A, B, C, D, CRF01-AE, F, CRF02-AG, and G) and 10 specimens from Group O were screened for an autoimmune disorder or serologically characterized as positive for the following markers: systemic lupus erythematosus (SLE), anti-nuclear antibodies (ANA), rheumatoid factor (RF), HBsAg, anti-HTLV-I/II, anti-HCV, and anti-HIV-2.

**Table 6.** Precision with the Abbott m2000 System

<table>
<thead>
<tr>
<th>Panel Member</th>
<th>n</th>
<th>Conc. Mean (copies/mL)</th>
<th>Conc. Mean (log copies/mL)</th>
<th>Within-Run SD Component</th>
<th>Between-Run SD Component</th>
<th>Inter-Assay SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>74</td>
<td>72</td>
<td>1.86</td>
<td>0.18</td>
<td>0.07</td>
<td>0.19</td>
</tr>
<tr>
<td>2</td>
<td>75</td>
<td>652</td>
<td>2.81</td>
<td>0.08</td>
<td>0.00</td>
<td>0.08</td>
</tr>
<tr>
<td>3</td>
<td>75</td>
<td>5,417</td>
<td>3.73</td>
<td>0.04</td>
<td>0.02</td>
<td>0.05</td>
</tr>
<tr>
<td>4</td>
<td>74</td>
<td>39,468</td>
<td>4.60</td>
<td>0.04</td>
<td>0.03</td>
<td>0.05</td>
</tr>
<tr>
<td>5</td>
<td>74</td>
<td>358,587</td>
<td>5.55</td>
<td>0.03</td>
<td>0.03</td>
<td>0.04</td>
</tr>
<tr>
<td>6</td>
<td>75</td>
<td>3,102,654</td>
<td>6.49</td>
<td>0.03</td>
<td>0.02</td>
<td>0.04</td>
</tr>
<tr>
<td>7</td>
<td>75</td>
<td>5,953,879</td>
<td>6.77</td>
<td>0.04</td>
<td>0.04</td>
<td>0.05</td>
</tr>
</tbody>
</table>

* Inter-assay contains within-run and between-run components.

**Table 7.** Precision with Manual Sample Preparation Method

<table>
<thead>
<tr>
<th>Panel Member</th>
<th>n</th>
<th>Conc. Mean (copies/mL)</th>
<th>Conc. Mean (log copies/mL)</th>
<th>Within-Run SD Component</th>
<th>Between-Run SD Component</th>
<th>Inter-Assay SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>40</td>
<td>40</td>
<td>1.66</td>
<td>0.21</td>
<td>0.07</td>
<td>0.22</td>
</tr>
<tr>
<td>2</td>
<td>41</td>
<td>471</td>
<td>2.67</td>
<td>0.11</td>
<td>0.09</td>
<td>0.14</td>
</tr>
<tr>
<td>3</td>
<td>42</td>
<td>4,474</td>
<td>3.65</td>
<td>0.05</td>
<td>0.10</td>
<td>0.11</td>
</tr>
<tr>
<td>4</td>
<td>42</td>
<td>34,503</td>
<td>4.54</td>
<td>0.02</td>
<td>0.06</td>
<td>0.07</td>
</tr>
<tr>
<td>5</td>
<td>42</td>
<td>362,283</td>
<td>5.56</td>
<td>0.04</td>
<td>0.08</td>
<td>0.09</td>
</tr>
<tr>
<td>6</td>
<td>42</td>
<td>3,597,099</td>
<td>6.56</td>
<td>0.03</td>
<td>0.04</td>
<td>0.05</td>
</tr>
<tr>
<td>7</td>
<td>42</td>
<td>5,953,879</td>
<td>6.77</td>
<td>0.05</td>
<td>0.05</td>
<td>0.07</td>
</tr>
</tbody>
</table>

* Inter-assay contains within-run and between-run components.

The specificity of the Abbott RealTime HIV-1 assay was evaluated by testing 187 HIV-1 seronegative plasma specimens. The specimens were tested on 3 Abbott m2000 instrument systems with 3 lots of amplification reagents. HIV-1 RNA was not detected, resulting in 100% (187/187) specificity (95% CI 98.05 to 100.00) in this representative study.

**Table 8.** Specificity of the Abbott RealTime HIV-1 assay

<table>
<thead>
<tr>
<th>Drug Pool</th>
<th>Drugs Tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Zidovudine, Saquinavir, Ritonavir, Clarithromycin, Interferon 2a, Interferon 2b</td>
</tr>
<tr>
<td>2</td>
<td>Abacavir sulfate, Amprenavir, Peginterferon 2a, Peginterferon 2b, Ritonavir</td>
</tr>
<tr>
<td>3</td>
<td>Tenofovir disoproxil fumarate, Lamivudine, Indinavir sulfate, Ganciclovir, Valganciclovir, Hydrochloride, Acyclovir</td>
</tr>
<tr>
<td>4</td>
<td>Stavudine, Efavirenz, Lopinavir, Enfuvirtide, Ciprofloxacin</td>
</tr>
<tr>
<td>5</td>
<td>Zalcitabine, Nevirapine, Nelfinavir, Azithromycin, Valacyclovir</td>
</tr>
</tbody>
</table>

The SUSCEPTIBILITY of the Abbott RealTime HIV-1 assay to interference was evaluated by elevated levels of endogenous substances and by drugs commonly prescribed to HIV-1 infected individuals was evaluated. HIV-1 negative samples and samples containing 10,000 copies/mL of HIV-1 RNA were tested.

No interference in the performance of the Abbott RealTime HIV-1 assay was observed in the presence of the following substances for all positive and negative samples tested:

- Hemoglobin 500 mg/dL
- Triglycerides 3000 mg/dL
- Bilirubin 20 mg/dL
- Protein 9 g/dL

Drugs at concentrations in excess of the peak plasma or serum levels were tested in 5 pools. No interference in the performance of the Abbott RealTime HIV-1 assay was observed in the presence of the following drug pools for all positive and negative samples tested:

**Drug Pool | Drugs Tested**
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Zidovudine, Saquinavir, Ritonavir, Clarithromycin, Interferon 2a, Interferon 2b</td>
<td></td>
</tr>
<tr>
<td>2 Abacavir sulfate, Amprenavir, Peginterferon 2a, Peginterferon 2b, Ritonavir</td>
<td></td>
</tr>
<tr>
<td>3 Tenofovir disoproxil fumarate, Lamivudine, Indinavir sulfate, Ganciclovir, Valganciclovir, Hydrochloride, Acyclovir</td>
<td></td>
</tr>
<tr>
<td>4 Stavudine, Efavirenz, Lopinavir, Enfuvirtide, Ciprofloxacin</td>
<td></td>
</tr>
<tr>
<td>5 Zalcitabine, Nevirapine, Nelfinavir, Azithromycin, Valacyclovir</td>
<td></td>
</tr>
</tbody>
</table>

**Specificity**

The target specificity of the Abbott RealTime HIV-1 assay is greater than or equal to 99.5% after resolution.

The specificity of the Abbott RealTime HIV-1 assay was evaluated by testing 187 HIV-1 seronegative plasma specimens. The specimens were tested on 3 Abbott m2000 instrument systems with 3 lots of amplification reagents. HIV-1 RNA was not detected, resulting in 100% (187/187) specificity (95% CI 98.05 to 100.00) in this representative study.

**Table 9.** Specificity of the Abbott RealTime HIV-1 assay

<table>
<thead>
<tr>
<th>Component</th>
<th>Within-Run SD</th>
<th>Between-Run SD</th>
<th>Inter-Assay SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>AG, G, and H</td>
<td>0.11</td>
<td>0.09</td>
<td>0.14</td>
</tr>
<tr>
<td>Group M</td>
<td>0.08</td>
<td>0.07</td>
<td>0.09</td>
</tr>
<tr>
<td>Group O</td>
<td>0.07</td>
<td>0.06</td>
<td>0.08</td>
</tr>
</tbody>
</table>

**Table 10.** Specificity of the Abbott RealTime HIV-1 assay

**Figure 2.**
The results showed that all subtypes and groups tested were detected, and dilution linearity was demonstrated for all groups and subtypes tested (correlation coefficients ranged from 0.997 to 1.000).

A total of 90 clinical specimens, 10 of each Group M subtype (A, B, C, D, CRF01-AE, F, CRF02-AG, G) and Group O, were tested with the Abbott RealTime HIV-1 assay and by 2 other HIV-1 quantitative assays referred to as Comparator 1 and Comparator 2. The results are summarized in Table 8.

### Table 8.

<table>
<thead>
<tr>
<th>Group/Subtype</th>
<th>n</th>
<th>RealTime Detected</th>
<th>Comparator 1 Detected</th>
<th>Comparator 2 Detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>M/Subtype A</td>
<td>10</td>
<td>10</td>
<td>10 (1)</td>
<td>10 (1)</td>
</tr>
<tr>
<td>M/Subtype B</td>
<td>10</td>
<td>10</td>
<td>10 (0)</td>
<td>10 (0)</td>
</tr>
<tr>
<td>M/Subtype C</td>
<td>10</td>
<td>10</td>
<td>10 (0)</td>
<td>10 (0)</td>
</tr>
<tr>
<td>M/Subtype D</td>
<td>10</td>
<td>10</td>
<td>10 (0)</td>
<td>10 (0)</td>
</tr>
<tr>
<td>M/Subtype AE</td>
<td>10</td>
<td>10</td>
<td>10 (0)</td>
<td>10 (0)</td>
</tr>
<tr>
<td>M/Subtype F</td>
<td>10</td>
<td>10</td>
<td>10 (0)</td>
<td>10 (0)</td>
</tr>
<tr>
<td>M/Subtype AG</td>
<td>10</td>
<td>10</td>
<td>10 (3)</td>
<td>10 (1)</td>
</tr>
<tr>
<td>M/Subtype G</td>
<td>10</td>
<td>10</td>
<td>10 (2)</td>
<td>10 (1)</td>
</tr>
<tr>
<td>Group O</td>
<td>10</td>
<td>10</td>
<td>0 (NA)</td>
<td>7 (7)</td>
</tr>
</tbody>
</table>

* 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 Abbott RealTime HIV-1 assay.

- The Abbott RealTime HIV-1 assay detected all subtypes and groups tested.
- Comparator 1 detected all Group M subtypes tested and did not detect the 10 Group O samples.
- Comparator 2 detected all Group M subtypes tested and 7 out of 10 Group O samples.
- There were no samples that had Abbott RealTime assay quantitation values lower than Comparator 1 or Comparator 2 values by more than 1.00 log copies/mL.
- There were 6 Group M samples that had lower quantitation values with Comparator 1 by more than 1.00 log copies/mL when compared to Abbott RealTime HIV-1 assay.
- There were 3 Group M samples and 7 Group O samples that had lower quantitation values with Comparator 2 by more than 1.00 log copies/mL when compared to Abbott RealTime HIV-1 assay.

**Correlation**

Method comparison analysis was performed following NCCLS EP9-A2.37 Specimens from 141 HIV-1 infected patients were tested with the Abbott RealTime HIV-1 assay and a comparator assay. The correlation plot is shown in Figure 3.

### Figure 3.

![Correlation plot](image)

Specific performance characteristics for DBS specimens

**Limit of Detection**

The LOD of the Abbott RealTime HIV-1 assay is 839 copies/mL with the DBS sample type.

The limit of detection was determined by analysis of an HIV-1 viral dilution series from the VQA (Virology Quality Assurance laboratory) standard. Twenty-eight samples at each concentration level were tested across 4 runs using 4 lots of amplification reagents. The detection rate for each dilution panel member was summarized across the four lots of reagents. The results, representative of the analytical sensitivity performance of the Abbott RealTime HIV-1 assay, are summarized in Table 9.

### Table 9.

<table>
<thead>
<tr>
<th>Conc. (Copies/mL)</th>
<th>Number Tested</th>
<th>Number Detected</th>
<th>Percent Detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>3000</td>
<td>27</td>
<td>27</td>
<td>100</td>
</tr>
<tr>
<td>1000</td>
<td>28</td>
<td>27</td>
<td>96</td>
</tr>
<tr>
<td>500</td>
<td>28</td>
<td>24</td>
<td>86</td>
</tr>
<tr>
<td>250</td>
<td>28</td>
<td>10</td>
<td>36</td>
</tr>
<tr>
<td>125</td>
<td>28</td>
<td>4</td>
<td>14</td>
</tr>
</tbody>
</table>

* One replicate was invalid and was excluded from the analysis.

Probit analysis of the data determined that the concentration of HIV-1 RNA detected with 95% probability was 839 copies/mL (95% CI 624 to 1387 copies/mL).

**Linear Range**

The upper limit of quantitation (ULQ) for the Abbott RealTime HIV-1 assay is 10 million copies/mL and the lower limit of quantitation is equivalent to the LOD (839 copies/mL) for the DBS claim.

A dilution series of HIV-1 Armored RNA covering the range from 500 copies/mL to 10,000,000 copies/mL in HIV-1 sero-negative blood was tested. The results, representative of the Abbott RealTime HIV-1 assay linearity, are shown in Figure 5.
The Abbott RealTime HIV-1 assay was shown to be linear across the range tested \((n = 92, r = 0.995, \text{slope} = 1.08, \text{and intercept} = -0.32)\).

**Precision**

Precision was evaluated by testing HIV-1 panel members targeted to cover the range from 500 Copies/mL to 5,000,000 Copies/mL. Three lots of amplification reagents were run on the three pairs of m2000 instrument systems (each lot of reagent assigned to its own instrument pair), once a day for five days. Within-run, between-run, and inter-assay (within-run and between-run) standard deviations (SD) were determined. The results, representative of the precision of the Abbott RealTime HIV-1 assay, are summarized in Table 10.

**Specificity**

The target specificity of the Abbott RealTime HIV-1 assay is greater than or equal to 99.5% after resolution.

Specificity was determined by testing 120 HIV-1 sero-negative specimens, 60 specimens with each of two lots of amplification reagents. All 120 HIV-1 sero-negative specimens gave results of “Not Detected” for a specificity of 100% (120/120).

**Correlation**

HIV-1 RNA quantitation was compared between the Abbott RealTime HIV-1 assay using dried blood spots and the CE-marked comparator assay, Abbott RealTime HIV-1 RNA quantitative assay using human plasma. A total of 313 specimens collected from South Africa, Ivory Coast, and Uganda were included in the analysis. These HIV-1 infected patients were tested at Abbott Molecular \((N=247)\) and at one external site in South Africa \((N=66)\). For each HIV-1 infected patient dried blood spots prepared from venous blood and capillary blood (finger prick) were tested. The results from specimens that fell within the common assay dynamic range were analyzed by the least squares linear regression method (DBS finger prick versus plasma \(N=150\), DBS venous versus plasma \(N=150\), and DBS finger prick versus DBS venous \(N=146\)). The correlation coefficient for HIV-1 viral load in plasma versus DBS finger prick was 0.887, the slope was 0.84 (95% CI 0.77 to 0.91), and the intercept was 0.58 log copies/mL (95% CI 0.26 to 0.90) (Figure 6). The correlation coefficient for HIV-1 viral load in plasma versus DBS venous blood was 0.902, the slope was 0.83 (95% CI 0.78 to 0.89), and the intercept was 0.66 log copies/mL (95% CI 0.37 to 0.95) (Figure 7). The correlation coefficient for HIV-1 viral load in DBS finger prick versus DBS venous blood was 0.947, the slope was 1.00 (95% CI 0.94 to 1.05), and the intercept was –0.03 log copies/mL (95% CI –0.28 to 0.21) (Figure 8). Additionally, Bland-Altman plots for these same comparisons are presented in Figure 9, Figure 10, and Figure 11.
Figure 9. DBS Finger Prick Versus Plasma

![Graph showing DBS Finger Prick Versus Plasma](image)

Figure 10. DBS Venous Versus Plasma

![Graph showing DBS Venous Versus Plasma](image)

Figure 11. DBS Finger Prick Versus DBS Venous

![Graph showing DBS Finger Prick Versus DBS Venous](image)

### Bibliography


APPENDIX 1. OVERVIEW OF THE ABBOTT REALTIME HIV-1 AMPLIFICATION REAGENT EXTENDED USE FEATURE

The amplification reagent extended use feature allows for the use of an amplification reagent pack and internal control (IC) a total of 2 times. Amplification reagent packs that have not yet been used to prepare master mix are referred to as new amplification reagent packs. Amplification reagent packs that have been used once and contain prepared master mix are referred to as partial amplification reagent packs. Refer to the instructions provided in this manual for additional details.

### Storage Conditions (Amplification Reagent Pack and Internal Control Vials)

<table>
<thead>
<tr>
<th>Pack Type</th>
<th>Storage Temperature</th>
<th>Storage Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Packs</td>
<td>-25 to -15°C</td>
<td>Until date shown on label</td>
</tr>
<tr>
<td>New IC</td>
<td>-25 to -15°C</td>
<td>Until date shown on label</td>
</tr>
<tr>
<td>Partial Packs</td>
<td>-25 to -15°C (protected from light)</td>
<td>Up to 7 days after initial use</td>
</tr>
<tr>
<td>Partial IC</td>
<td>-25 to -15°C</td>
<td>Up to 14 days after initial use</td>
</tr>
</tbody>
</table>

**New Pack(s)**

- Remove new pack(s) from freezer (-25 to -15°C).
- Thaw at 2 to 8°C or 16 to 30°C.
- Once thawed, store at 2 to 8°C for ≤24 hours, prior to use.
- Select combination of new and/or partial packs required for run.
- Load pack(s): Firmly seat all packs; partial packs to left.
- Load master mix tube if using more than 1 pack.
- Start master mix protocol. Master mix protocol complete.
- Recap partial pack(s) after first use.
- Store partial pack(s) at -25 to -15°C, upright and protected from light.
- Initialize Abbott m2000rt.

**Partial Pack(s)**

- Remove partial pack(s) from freezer (-25 to -15°C). Confirm that master mix is thawed before use.
- Load master mix tube if using more than 1 pack.
- Start Abbott m2000rt protocol.
- Discard empty packs and partial packs after second use.
- Recap partial pack(s) after first use.
- Transfer PCR plate to Abbott m2000rt.
- Seal PCR plate.

- ≤50 minutes
- ≤25 minutes

**Guidelines:**
- Amplification reagent packs eligible for extended use must have a 6-digit serial number above the barcode.
- Partial amplification reagent packs can only be used a second time on the same instrument as the initial use. Using them on a different instrument will generate a processing error, which may delay the run.
- Partial and new amplification reagent packs may be used together. All amplification reagent packs used on the instrument for a run must have the same lot number.
APPENDIX 2. OPTIONAL UNG PROCEDURE FOR PROTOCOLS I, II, AND III

The uracil-N-glycosylase (UNG) procedure is to be used in conjunction with the Abbott RealTime HIV-1 assay as an optional contamination control for customer laboratories that are currently using or have previously used amplification technologies that incorporate uracil into the amplification product.

REAGENTS

Uracil-N-glycosylase (UNG), List No. 06L87-02 (1 tube, 112 µL, 1U/µL)

Description

Uracil DNA glycosylase (uracil-N-glycosylase) removes uracil residues from the sugar moiety of single- and double-stranded DNA without destroying the phosphodiester backbone, preventing its use as a hybridization target or as a template for DNA polymerases. Uracil DNA glycosylase will not remove uracil from RNA.

Active Ingredients

- Uracil-N-glycosylase (UNG; < 0.1%)
- Tween 20 (< 0.1%)

Storage and Handling

The product is shipped on dry ice.

-15°C Store at -25°C to -15°C.

UNG Limited License

This product is sold under licensing arrangements between Celera Corporation and Invitrogen Corporation. The purchase price of this product includes limited, nontransferable rights under US Patents 5,035,996; 5,683,896; 5,945,313; and 6,287,823 and foreign equivalents owned by Invitrogen Corporation to use only this amount of the product to practice the claims in said patents solely for activities of the purchaser. Further information on purchasing licenses under the above patents may be obtained by contacting Licensing Department, Invitrogen Corporation, 1600 Faraday Avenue, Carlsbad, CA 92008.

OPTIONAL UNG PROCEDURE FOR ASSAY PROTOCOL I: USING ABBOTT m1000 SYSTEM OR THE MANUAL SAMPLE PREPARATION METHOD AND ABBOTT m2000rt INSTRUMENT

NOTE: The step numbering from Protocol I is maintained. Starting from Step 11, execute the following:

Amplification Area

11. Switch on and initialize the Abbott m2000rt instrument.

NOTE: The Abbott m2000rt Instrument requires 15 minutes to warm up.

12. Create the Abbott m2000rt test order. Refer to the Operating Instructions section of the Abbott m2000rt Operations Manual. From the Protocol screen, select the appropriate application file corresponding to the sample volume being tested.

- Enter calibrator (needed if a calibration curve has not been stored on the Abbott m2000rt) and control lot-specific values in the test order for accurate calibration and control evaluation. Lot-specific values are specified in each Abbott RealTime HIV-1 Calibrator and Control Kit Card.

Reagent Preparation Area

All reagent preparation must take place in the dedicated Reagent Preparation Area. Refer to the Handling Precautions section of the package insert before preparing reagents.

NOTE: Change gloves before handling the amplification reagents.

13. Prepare the amplification master mix.

- Each Amplification Reagent Pack supports up to 24 reactions.
- Prior to opening the amplification reagents, ensure that the contents of the vials are at the bottom by tapping the vials in an upright position 5 to 10 times on the bench to bring the liquid to the bottom of the vials.
- Use a PIPETTE DEDICATED FOR REAGENT USE ONLY to add 27 µL of UNG to the Thermostable rTth Polymerase Enzyme bottle (Reagent 3).
- Prepare the master mix by using a PIPETTE DEDICATED FOR REAGENT USE ONLY to add 271 µL of the Activation Reagent (Reagent 1) and 949 µL of the HIV-1 Oligonucleotide Reagent (Reagent 2) together in the Thermostable rTth Polymerase Enzyme bottle (Reagent 3).

If performing 25 to 48 reactions, prepare a second amplification master mix with a second Amplification Reagent Pack.

NOTE: The Abbott m2000rt protocol (step 20) must be initiated within 50 minutes of the addition of Activation Reagent into the first rTth Enzyme Reagent bottle (step 13). This 50 minutes includes 10 minutes incubation at room temperature (step 19, below).

14. Pipette the contents of the master mix from the enzyme bottle(s) into a single-use RNase/DNase-free tube and vortex to mix.

15. Place an Abbott 96-Well Optical Reaction Plate in a StrataCooler 96 or Eppendorf PCR Cooler stored as indicated in the instruction manual. Using a DEDICATED PIPETTE, dispense 50-µL aliquots of the amplification master mix into the Abbott 96-Well Optical Reaction Plate. A calibrated repeat pipettor may be used. Visually verify that 50 µL has been dispensed into each well.

16. Transfer the Abbott 96-Well Optical Reaction Plate on the StrataCooler 96 or Eppendorf PCR Cooler to the Sample Preparation Area.

Sample Preparation Area

17. In the Sample Preparation Area, transfer 50 µL of sample eluate to the Abbott 96-Well Optical Reaction Plate on the StrataCooler 96 or Eppendorf PCR Cooler. Use a separate pipette tip for each sample eluate transfer. During the transfer of each sample, mix the reaction by pipetting up and down 3 to 5 times. Visually verify that 100 µL has been dispensed into each well.


19. Remove the Abbott 96-Well Optical Reaction Plate from the StrataCooler 96 or Eppendorf PCR Cooler to the Abbott Splash-Free Support Base. Centrifuge the Abbott 96-Well Optical Reaction Plate in the Abbott Splash-Free Support Base at 5000g for 5 minutes. Incubate at room temperature (15 to 30°C) for 10 minutes. Centrifugation may take place during the 10-minute room temperature incubation. Following room temperature incubation, transfer the Abbott 96-Well Optical Reaction Plate on the Abbott Splash-Free Support Base to the Amplification Area.

NOTE: Do not transfer the StrataCooler 96 or Eppendorf PCR Cooler to the Amplification Area.

Amplification Area

20. Place the Abbott 96-Well Optical Reaction Plate in the Abbott m2000rt Instrument. From the Protocol screen, select the appropriate application file corresponding to the sample volume being tested.

ASSAY PROTOCOL II: OPTIONAL UNG PROCEDURE WITH PLASMA SAMPLES PREPARED FOR AMPLIFICATION USING THE ABBOTT m2000sp

NOTE: The step numbering from Protocol II is maintained. Starting from Step 11, execute the following:

The Abbott m2000sp Master Mix Addition protocol (step 12) must be initiated within 1 hour after completion of Sample Preparation.

NOTE: Change gloves before handling the amplification reagents.

11. Load the amplification reagents and the master mix tube (if needed) on the Abbott m2000sp worktable after sample preparation is completed. The following table shows the number of amplification reagent packs needed based on the number of reactions.

If only 1 amplification reagent pack is being used, no master mix tube is required.

<table>
<thead>
<tr>
<th>Amplification Reagent Pack Requirements</th>
<th>1 to 24 Reactions</th>
<th>25 to 48 Reactions</th>
<th>49 to 72 Reactions</th>
<th>73 to 96 Reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 if new;</td>
<td>2 if new;</td>
<td>3 if new;</td>
<td>4 new;</td>
<td></td>
</tr>
<tr>
<td>up to 4 with partial packs</td>
<td>up to 4 with partial packs</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Refer to the Abbott m2000sp Operations Manual (List No. 9200-06 or higher) for instructions on inventory management to determine the maximum number of reactions that can be tested with the partial packs selected.
• Partial amplification reagent packs can only be used on the same Abbott m2000sp instrument used for the reagent pack’s initial preparation. Using an amplification reagent pack for a second time on a different instrument will result in an error, which may delay the run.

• Partial and new amplification reagent packs may be used together.

IMPORTANT: Partial amplification reagent packs should be stored at –25 to –15°C until immediately before the second use. Confirm that master mix is thawed before placing partial pack(s) on the Abbott m2000sp worktable. Once removed from –25 to –15°C, partial amplification reagent packs being used a second time must be used within 25 minutes or discarded. This applies to cumulative room temperature exposure, including instances where packs are removed from storage, but not used.

• Ensure that the contents of new amplification reagent packs are at the bottom of the vials prior to opening the amplification reagents by tapping the vials in an upright position on the bench 5 to 10 times.

• Do not tap partial amplification reagent packs being used a second time. Tapping may result in loss of master mix volume in the cap.

• Remove caps. If a new amplification reagent pack will be stored for a second use, the vials will need to be recapped for storage. If planning to reuse the original caps to recap the reagent vials, save the original caps. If planning to use fresh caps to recap the reagent vials, original caps may be discarded.

• Use a PIPETTE DEDICATED FOR REAGENT USE ONLY to add specified volume of 1 U/µL UNG (List No. 06L87-02) to the reagent vial in position 3 of each amplification reagent packs.

• Use the table below to determine the volume of UNG to add to each amplification reagent pack. The reagent vial in position 3 of each new and partial amplification reagent packs.

<table>
<thead>
<tr>
<th>Tests Remaining in the Pack</th>
<th>Add This Volume of UNG (µL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>6</td>
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<td>3</td>
<td>7</td>
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<td>7</td>
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<td>12</td>
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<td>14</td>
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<td>20</td>
<td>23</td>
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<td>21</td>
<td>24</td>
</tr>
<tr>
<td>22</td>
<td>25</td>
</tr>
<tr>
<td>23</td>
<td>26</td>
</tr>
<tr>
<td>24 (new pack)</td>
<td>27</td>
</tr>
</tbody>
</table>

12. Select the appropriate deep well plate that matches the corresponding sample preparation extraction. Initiate the Abbott m2000sp Master Mix Addition protocol. Follow the instructions as described in the Abbott m2000sp Operations Manual, Operating Instructions section.

NOTE: The operator should not manually fill any empty/unfilled wells in the Abbott 96-Well Optical Reaction Plate.

• After sample extraction is complete, the Abbott m2000sp automatically fills any empty wells in the Abbott 96-Well Optical Reaction Plate when there are greater than 48 samples processed within a run. Plate fill is not performed for runs containing 48 samples or fewer.

• If prompted by the instrument, Reagent Carrier 2 should remain in place, minimally containing the reagent vessel for mElution Buffer (Reagent Carrier 2, location 6). If this reagent vessel has been unloaded, place a new reagent vessel with the mElution Buffer label into Reagent Carrier 2, location 6. System fluid will be added to the reagent vessel and used to fill empty wells. Once this process is complete, the system will continue with the master mix addition.

NOTE: System instructions for use of the automated plate-filling feature are found in the Abbott m2000sp Operations Manual (List No. 9K20 version 6 or higher), section 5, Operating Instructions, Sample Extraction – Closed Mode.

• The Abbott m2000rt protocol (step 16) must be started within 50 minutes of the initiation of the Master Mix Addition protocol (step 12).

NOTE: If the run is aborted for any reason subsequent to step 12, a new 96-well Optical Reaction Plate must be used if the Abbott m2000sp Master Mix Addition Protocol (step 12) will be repeated.

13. Switch on and initialize the Abbott m2000rt instrument in the amplification area.

NOTE: The Abbott m2000rt requires 15 minutes to warm-up.

NOTE: Remove gloves before returning to the sample preparation area.

14. Seal the Abbott 96-Well Optical Reaction Plate after the Abbott m2000sp instrument has completed addition of samples and master mix according to the Abbott m2000sp Operations Manual, Operating Instructions section.

15. Keep the sealed optical reaction plate to the Abbott Splash-Free Support Base and incubate at room temperature (15 to 30°C) for 10 minutes. Following room temperature incubation, transfer the Abbott 96-Well Optical Reaction Plate on the Abbott Splash-Free Support Base to the Abbott m2000rt instrument.
16. Place the Abbott 96-Well Optical Reaction Plate in the Abbott m2000rt instrument. From the Protocol screen, select the appropriate application file corresponding to the sample volume being tested. Initiate the Abbott RealTime HIV-1 protocol as described in the Abbott m2000rt Operations Manual, Operating Instructions section.

**NOTE:** Test order transfer through the use of CD-ROM or network connection with export and import features of the m2000sp and m2000rt software is recommended. If creating the Abbott m2000rt test order manually, enter sample IDs in the corresponding PCR tray locations according to the “Wells for Selected Plate” grid, found on the detail screen of the “PCR Plate Results” on the Abbott m2000sp. See Section 5 of the Abbott m2000sp Operations Manual.

17. If a prepared partial amplification reagent pack is to be used a second time, the 3 reagent vials with the saved caps or new caps (List No. SN20-01) and promptly store the reagents at −25 to −15°C, protected from light, and in an upright position. Discard any amplification reagent packs that are exhausted or have been used twice.

**IMPORTANT:** Amplification reagents that will be used a second time must be stored at −25 to −15°C within 50 minutes of the initiation of the master mix addition protocol.

### ASSAY PROTOCOL III: OPTIONAL UNG PROCEDURE WITH DBS SAMPLES PREPARED FOR AMPLIFICATION USING THE ABBOTT m2000sp

**NOTE:** The step numbering from Protocol III is maintained. Starting from Step 22, execute the following:

The Abbott m2000sp Master Mix Addition protocol (step 23) must be initiated within 1 hour after completion of Sample Preparation.

**NOTE:** Change gloves before handling the amplification reagents.

22. Load the amplification reagents and the master mix tube (if needed) on the Abbott m2000sp worktable after sample preparation is completed. The following table shows the number of amplification reagent packs needed based on the number of reactions.

If only 1 amplification reagent pack is being used, no master mix tube is required.

**Amplification Reagent Pack Requirements**

<table>
<thead>
<tr>
<th>Reactions</th>
<th>1 to 24</th>
<th>25 to 48</th>
<th>49 to 72</th>
<th>73 to 96</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 if new;</td>
<td>up 4 with</td>
<td>partial packs</td>
<td>up 4 with</td>
<td>partial packs</td>
</tr>
<tr>
<td>2 if new;</td>
<td>up 4 with</td>
<td>partial packs</td>
<td>up 4 with</td>
<td>partial packs</td>
</tr>
<tr>
<td>3 if new;</td>
<td>up 4 with</td>
<td>partial packs</td>
<td>up 4 with</td>
<td>partial packs</td>
</tr>
<tr>
<td>4 new</td>
<td>up 4 with</td>
<td>partial packs</td>
<td>up 4 with</td>
<td>partial packs</td>
</tr>
</tbody>
</table>

*a*Refer to the Abbott m2000sp Operations Manual (List No. 9K20 version 6 or higher) for instructions on inventory management to determine the maximum number of reactions that can be tested with the partial packs selected.

- Partial amplification reagent packs can only be used on the same Abbott m2000sp instrument used for the reagent pack’s initial preparation. Using an amplification reagent pack for a second time on a different instrument will result in an error, which may delay the run.
- Partial and new amplification reagent packs may be used together.

**IMPORTANT:** Partial amplification reagent packs should be stored at −25 to −15°C until immediately before the second use. Confirm that master mix is thawed before placing partial pack(s) on the Abbott m2000sp worktable. Once removed from −25 to −15°C, partial amplification reagent packs being used a second time must be used within 25 minutes or discarded. This applies to cumulative room temperature exposure, including instances where packs are removed from storage, but not used.

- Ensure that the contents of new amplification reagent packs are at the bottom of the vials prior to opening the amplification reagents by tapping the vials in an upright position on the bench 5 to 10 times.
- Do not tap partial amplification reagent packs being used a second time. Tapping may result in loss of master mix volume in the cap.
- Remove caps. If a new amplification reagent pack will be stored for a second use, the vials will need to be recapped for storage. If planning to reuse the original caps to recap the reagent vials, save the original caps. If planning to use fresh caps to recap the reagent vials, original caps may be discarded.
- Use a PIPETTE DEDICATED FOR REAGENT USE ONLY to add specified volume of 1 U/µL UNG (List No. 06L87-02) to the reagent vial in position 3 of new and partial amplification reagent packs.
- Use the table below to determine the volume of UNG to add to the reagent vial in position 3 of new and partial amplification reagent packs. The reagent vial in position 3 of a new reagent pack contains the Thermostable rTth polymerase enzyme. The reagent vial in position 3 of a partial reagent pack contains master mix.

**NOTE:** The volume of UNG added to the reagent vial in position 3 depends upon the number of tests remaining in the reagent pack, and not the number of samples being run. Refer to the Abbott m2000sp Operations Manual for instructions pertaining to amplification reagent pack inventory management and how to determine the number of tests remaining in a reagent pack.

- Manually mix by pipetting gently up and down for all partial packs. Do not mix new packs.
- Partial amplification packs are loaded to the left of new amplification reagent packs on the Abbott m2000sp worktable.
- Ensure that amplification reagent packs are firmly seated on the instrument.

<table>
<thead>
<tr>
<th>Volume of UNG to Add to the Reagent Vial in Position 3 of Each Amplification Reagent Pack</th>
<th>Tests Remaining in the Pack</th>
<th>Add This Volume of UNG (µL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 24 Reactions</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>25 to 48 Reactions</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>49 to 72 Reactions</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>73 to 96 Reactions</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>1 if new; up 4 with</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>2 if new; up 4 with</td>
<td>6</td>
<td>10</td>
</tr>
<tr>
<td>3 if new; up 4 with</td>
<td>7</td>
<td>11</td>
</tr>
<tr>
<td>4 new; up 4 with up 4 with</td>
<td>8</td>
<td>12</td>
</tr>
<tr>
<td>partial packs</td>
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<td>25</td>
</tr>
<tr>
<td>partial packs</td>
<td>23</td>
<td>26</td>
</tr>
<tr>
<td>partial packs</td>
<td>24 (new pack)</td>
<td>27</td>
</tr>
</tbody>
</table>

23. Select the appropriate deep well plate that matches the corresponding sample preparation extraction. Initiate the Abbott m2000sp Master Mix Addition protocol. Follow the instructions as described in the Abbott m2000sp Operations Manual, Operating Instructions section.

**NOTE:** The operator should not manually fill any empty/unfilled wells in the Abbott 96-Well Optical Reaction Plate.

- After sample extraction is complete, the Abbott m2000sp automatically fills any empty wells in the Abbott 96-Well Optical Reaction Plate with mLution buffer when there are greater than 48 samples processed within a run. Plate fill is not performed for runs containing 48 samples or fewer.
- If prompted by the instrument, Reagent Carrier 2 should remain in place, minimally containing the reagent vessel for mLution Buffer (Reagent Carrier 2, location 6). If this reagent vessel has been unloaded, place a new reagent vessel with the mLution Buffer label into Reagent Carrier 2, location 6. System fluid will be added to the reagent vessel and used to fill empty wells. Once this process is complete, the system will continue with the master mix addition.
NOTE: System instructions for use of the automated plate-filling feature are found in the Abbott m2000sp Operations Manual (List No. 9K20 version 6 or higher), section 5, Operating Instructions, Sample Extraction – Closed Mode.

- The Abbott m2000rt protocol (step 27) must be started within 50 minutes of the initiation of the Master Mix Addition protocol (step 23).

NOTE: If the run is aborted for any reason subsequent to step 23, a new 96-well Optical Reaction Plate must be used if the Abbott m2000sp Master Mix Addition Protocol (step 23) will be repeated.

24. Switch on and initialize the Abbott m2000rt instrument in the amplification area.

NOTE: The Abbott m2000rt requires 15 minutes to warm-up.

NOTE: Remove gloves before returning to the sample preparation area.

25. Seal the Abbott 96-Well Optical Reaction Plate after the Abbott m2000sp instrument has completed addition of samples and master mix according to the Abbott m2000sp Operations Manual, Operating Instructions section.

26. Keep the sealed optical reaction plate to the Abbott Splash-Free Support Base and incubate at room temperature (15 to 30°C) for 10 minutes. Following room temperature incubation, transfer the Abbott 96-Well Optical Reaction Plate on the Abbott Splash-Free Support Base to the Abbott m2000rt instrument.


NOTE: Test order transfer through the use of CD-ROM or network connection with export and import features of the m2000sp and m2000rt software is recommended. If creating the Abbott m2000rt test order manually, enter sample IDs in the corresponding PCR tray locations according to the “Wells for Selected plate” grid, found on the detail screen of the “PCR Plate Results” on the Abbott m2000sp. See Section 5 of the Abbott m2000sp Operations Manual.

28. If a prepared partial amplification reagent pack is to be used a second time, cap the 3 reagent vials with the saved caps or new caps (List No. 3N20-01) and promptly store the reagents at –25 to –15°C, protected from light, and in an upright position. Discard any amplification reagent packs that are exhausted or have been used twice.

IMPORTANT: Amplification reagents that will be used a second time must be stored at –25 to –15°C within 50 minutes of the initiation of the master mix addition protocol.
Abbott mSample Preparation System DBS Buffer Kit

Key to Symbols used

<table>
<thead>
<tr>
<th>REF</th>
<th>Reference Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOT</td>
<td>Lot Number</td>
</tr>
<tr>
<td>PART</td>
<td>Part Number</td>
</tr>
<tr>
<td>IVD</td>
<td>In Vitro Test</td>
</tr>
</tbody>
</table>

In Vitro Test

mDBS buffer

Contains sufficient for <n> tests

Use By

Temperature Limit

Consult instructions for use

Refer to WARNINGS AND PRECAUTIONS

Authorized Representative in the European Community

Manufacturer

Abbott mDBS Buffer

Warning

Hazard-determining components of labeling:
Guanidinium thiocyanate

H302+H332 Harmful if swallowed or if inhaled.

H412 Harmful to aquatic life with long lasting effects.

P261 Avoid breathing mist/vapours/spray.

P264 Wash hands thoroughly after handling.

P280 Wear protective gloves / protective clothing / eye protection.

P271 Use only outdoors or in a well-ventilated area.

P273 Avoid release to the environment.

P301+P312 IF SWALLOWED: Call a POISON CENTER / doctor if you feel unwell.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P330 Rinse mouth.

P501 Dispose of contents / container in accordance with local regulations.

Safety Data Sheet Statement: Important information regarding the safe handling, transport, and disposal of this product is contained in the Safety Data Sheet.

STORAGE INSTRUCTIONS

Store at 15°C to 30°C

SHIPPING CONDITIONS

The product is shipped at ambient temperature.

If assay reagents are received in a condition contrary to the label recommendation, or are damaged, contact Abbott Customer Service.

PROCEDURE

Consult assay-specific package insert and/or assay-specific instructions for use manual.

QUALITY CONTROL PROCESSES

Consult assay-specific package insert and/or assay-specific instructions for use manual.

RESULTS, INTERPRETATION OF RESULTS, AND LIMITATIONS OF THE PROCEDURE

Consult assay-specific package insert and/or assay-specific instructions for use manual.

TECHNICAL ASSISTANCE

For technical assistance, call Abbott Molecular Technical Services at +49-6122-580, email molecularsupport@abbott.com, or visit the Abbott Molecular Web site at http://www.abbottmolecular.com.

Abbott Molecular Inc.
1300 East Touhy Avenue
Des Plaines, IL 60018 USA

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www.abbottmolecular.com

July 2015

51-608281/R2

9PIMD1695rev01
**Abbott mSample Preparation System DBS Buffer Kit**

**Erläuterung der verwendeten Symbole**

<table>
<thead>
<tr>
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<th>mDBS buffer</th>
<th>EC/REP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Abbott mDBS Buffer**

Gefahr

Gefahr bestimmende Komponenten der Produktkennzeichnung: Guanidiniumthiocyanat

H302+H332 Gesundheitsschädlich bei Verschlucken oder Einatmen.

H412 Schädlich für Wasserorganismen, mit langfristiger Wirkung.

P261 Einatmen von Nebel / Dampf / Aerosol vermeiden.

P264 Nach Gebrauch Hände gründlich waschen.

P260 Schutzhandschuhe / Schutzkleidung / Augenschutz tragen.

Lagerung

Lagerung bei 15 bis 30 °C

Transportbedingungen

Das Produkt wird bei Raumtemperatur versandt.

Verwendbar bis

Temperaturbegrenzung

Gebrauchsanweisung beachten

Siehe VORSICHTSMASSNAHMEN

Bevollmächtigter in der Europäischen Gemeinschaft

Hersteller

**KUNDENDIENST**

BEI FRAGEN WENDEN SIE SICH BITTE AN IHREN ABBOTT KUNDENDIENST.

GESETZLICH GESCHÜTZTER NAME

Abbott mSample Preparation System DBS Buffer Kit

**VERWENDUNGSZWECK**


**ZUSAMMENFASSUNG UND ERLÄUTERUNG DES TESTS**

Biologische Grundlagen des Verfahrens

Assayspezifische Packungsbeilage und/oder assayspezifische Gebrauchsanweisung beachten.

**REAGENTZIEN**

mDBS buffer (Best.-Nr. 9N02A)

mDBS-Puffer mit 41,4 % Guanidiniumthiocyanat, 5 % Tween 20, 0,5 % Kaliumacetat und 0,5 % Essigsäure

(4 Fläschchen, je 46 ml)

**VORSICHTSMASSNAHMEN**

**IVD** in-vitro-Diagnostikum

Zur Verwendung als In-vitro-Diagnostikum

Assayspezifische Packungsbeilage und/oder assayspezifische Gebrauchsanweisung beachten.

mDBS Buffer enthält Guanidiniumthiocyanat.

**ANGABEN ZUM SICHERHEITSDATENBLATT**

Wichtige Hinweise zum sicheren Umgang, Transport sowie zur Entsorgung dieses Produktes enthält das Sicherheitsdatenblatt.

**LAGERUNG**

Lagerung bei 15 bis 30 °C

**TRANSPORTBEDINGUNGEN**

Das Produkt wird bei Raumtemperatur versandt.

**KUNDENDIENST**

Bei Fragen wenden Sie sich bitte an Ihren Abbott Kundendienst unter +49-6122-580, senden Sie eine E-Mail an moleculesupport@abbott.com oder besuchen Sie die Internetseite von Abbott Molecular (http://www.abbottmolecular.com).

Abbott Molecular Inc.
1300 East Touhy Avenue
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65205 Wiesbaden, Germany
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Fiche de données de sécurité

Des informations importantes sur la manipulation, le transport et l'élimination en toute sécurité de ce produit sont contenues dans la fiche de données de sécurité.

CONDITIONS DE CONSERVATION

Conservé entre 15 et 30 °C

CONDITIONS D'EXPÉDITION

Le produit est expédié à température ambiante.

En cas de réception de réactifs endommagés ou dont l'état ne correspond pas aux recommandations figurant sur les étiquettes, contacter le Service Clients Abbott.

PROCEédURE

Consulter la notice spécifique du test et/ou les instructions d'utilisation spécifiques du test.

PROCéDURES DU CONTRÔLE DE QUALITé

Consulter la notice spécifique du test et/ou les instructions d'utilisation spécifiques du test.

RÉSULTATS, INTERPRÉTATION DES RÉSULTATS ET LIMITES DE LA MÉTHODE

Consulter la notice spécifique du test et/ou les instructions d'utilisation spécifiques du test.

ASSISTANCE TECHNIQUE

Pour obtenir une assistance technique, appeler le Service Clients Abbott Molecular au +49-6122-580, écrire à molecularsupport@abbott.com ou consulter le site Internet d'Abbott Molecular à l'adresse suivante : http://www.abbottmolecular.com.
Abbott mSample Preparation System DBS Buffer Kit

Símbolos utilizados
- REF: Número de referencia
- LOT: Número de lote
- PART: Número de componente
- IVD: Producto sanitario para diagnóstico in vitro
- mDBS buffer: Prueba in vitro
- Tampón mDBS: Contenido suficiente para <n> pruebas
- Fecha de caducidad
- Límite de temperatura
- Consulte las instrucciones de uso
- Consulte el apartado ADVERTENCIAS Y PRECAUCIONES
- Repartidor autorizado de la Unión Europea
- Fabricante

ATENCIÓN AL CLIENTE EN EE. UU.: 1-800-553-7042
ATENCIÓN AL CLIENTE: PÓNGASE EN CONTACTO CON EL CENTRO DE ASISTENCIA TÉCNICA DE ABBOTT
NOMBRE REGISTRADO
Abbott mSample Preparation System DBS Buffer Kit

FINALIDAD DE USO
Abbott mSample Preparation System DBS Buffer Kit se utiliza para eluir el ácido nucleico de gotas de sangre seca. Este equipo debe utilizarse conjuntamente con los ensayos Abbott.

RESUMEN Y EXPLICACIÓN DEL ENSAYO
Principios biológicos del procedimiento
Consulte las instrucciones de uso específicas del ensayo correspondiente o las instrucciones del manual de uso específico del ensayo.

REACTIVOS
mDBS buffer (Número de referencia 9N02A)
Tampón mDBS con 41,4% de tiocianato de guanidina, 5% de Tween 20, 0,5% de acetato de potasio y 0,5% de ácido acético (4 frascos, 46 ml cada uno)

ADVERTENCIAS Y PRECAUCIONES
- IVD: Producto sanitario para diagnóstico in vitro
- Para uso en diagnóstico in vitro
Consulte las instrucciones de uso específicas del ensayo correspondiente o las instrucciones del manual de uso específico del ensayo. El tampón mDBS contiene tiocianato de guanidina.

Tampón Abbott mDBS
Atención
Componentes peligrosos a indicar en el etiquetado:
tiocianato de guanidina
H302+H332 Nocivo en caso de ingestión o inhalación.
H412 Nocivo para los organismos acuáticos, con efectos nocivos duraderos.
P261 Evitar respirar la niebla/vapores/aerosol.
P264 Lavarse las manos concienzudamente tras la manipulación.
P280 Llevar guantes/prendas/gafas de protección.
P271 Utilizar únicamente en exteriores o en un lugar bien ventilado.
P273 Evitar su liberación al medioambiente.
P301+P330 EN CASO DE INGESTIÓN: llamar a un CENTRO DE INFORMACIÓN TOXICOLÓGICA/médico si se encuentra mal.
P304+P340 EN CASO DE INHALACIÓN: transportar a la víctima al exterior y mantenerla en reposo en una posición confortable para respirar.
P330 Enjuagarse la boca.
P501 Eliminar el contenido/recipient de acuerdo con las normativas vigentes.

Declaración sobre las fichas de datos de seguridad: las fichas de datos de seguridad contienen información importante relativa al manejo, el transporte y la eliminación seguros de este producto.

INSTRUCCIONES DE ALMACENAMIENTO
- Almacénese entre 15 °C y 30 °C

CONDICIONES PARA EL TRANSPORTE
El producto se transporta a temperatura ambiente. Si recibe algún reactivo del ensayo que no cumpla con las recomendaciones de la etiqueta o está dañado, póngase en contacto con el Servicio de Asistencia Técnica de Abbott.

PROCEDIMIENTO
Consulte las instrucciones de uso específicas del ensayo correspondiente o las instrucciones del manual de uso específico del ensayo.

PROCEDIMIENTOS DE CONTROL DE CALIDAD
Consulte las instrucciones de uso específicas del ensayo correspondiente o las instrucciones del manual de uso específico del ensayo.

RESULTADOS, INTERPRETACIÓN DE RESULTADOS Y LIMITACIONES DEL PROCEDIMIENTO
Consulte las instrucciones de uso específicas del ensayo correspondiente o las instrucciones del manual de uso específico del ensayo.

ASISTENCIA TÉCNICA
Si requiere asistencia técnica, póngase en contacto con el Centro de Asistencia Técnica de Abbott Molecular (+49-6122-580), envíe un correo a moleculesupport@abbott.com o consulte la página web de Abbott Molecular: http://www.abbottmolecular.com.

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Abbott \textit{m}Sample Preparation System DBS Buffer Kit

Attenzione

Componenti che determinano la classificazione di rischio:

Guanidina tiocianato
H302+H332 Nocivo se ingerito.
H412 Nocivo per gli organismi acquatici con effetti di lunga durata.

P261 Evitare di respirare la nebbia/i vapori/aerosol.
P264 Lavare accuratamente le mani dopo l’uso.
P280 Indossare guanti/indumenti protettivi/Proteggere gli occhi.
P271 Utilizzare soltanto all’aperto o in luogo ben ventilato.
P273 Non disperdere nell’ambiente.
P301+P312 IN CASO DI INGESTIONE: contattare un CENTRO ANTIVELENI/un medico in caso di malessere.
P304+P340 IN CASO DI INALAZIONE: trasportare l’infortunato all’aria aperta e mantenerlo a riposo in posizione che favorisca la respirazione.
P330 Sciacquare la bocca.
P501 Smaltire il contenuto/recipiente in conformità alla regolamentazione locale.

Informazione sulle schede di sicurezza dei materiali: informazioni importanti in merito al trattamento, al trasporto e allo smaltimento secondo le norme di sicurezza sono disponibili nelle schede di sicurezza dei materiali.

NORME PER LA CONSERVAZIONE

\[+15-30^\circ C\] Conservare a 15-30°C

CONDIZIONI PER LA SPEDIZIONE

Il prodotto viene spedito a temperatura ambiente. Qualora i reagenti del dosaggio ricevuti non si presentino in condizioni conformi a quanto raccomandato sull’etichetta, o siano danneggiati, rivolgersi al Servizio Clienti Abbott.

PROCEDURA

Consultare il foglietto illustrativo e/o il manuale specifico per il dosaggio.

PROCEDURE DI CONTROLLO DI QUALITÀ

Consultare il foglietto illustrativo e/o il manuale specifico per il dosaggio.

RISULTATI, INTERPRETAZIONE DEI RISULTATI E LIMITI DEL METODO

Consultare il foglietto illustrativo e/o il manuale specifico per il dosaggio.

ASSISTENZA TECNICA

Per ricevere assistenza tecnica rivolgersi al Servizio Clienti Abbott Molecular al numero di telefono +49-6122-580 o all’indirizzo e-mail molecularsupport@abbott.com o visitare il sito Abbott Molecular all’indirizzo http://www.abbottmolecular.com.

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Legenda dos símbolos utilizados

- REF Número de referência
- LOT Número de lote
- PART Número de produto
- IVD Dispositivo médico para diagnóstico in vitro
- In Vitro Test Teste in vitro
- mDBS buffer Tampão mDBS

informação relativa à ficha de dados de segurança: a ficha de dados de segurança contém informação importante relativa ao manuseamento, transporte e eliminação em segurança deste produto.

condições de conservação

Conservar a uma temperatura entre 15°C e 30°C

Condições de transporte

O produto é transportado à temperatura ambiente.

No caso de receber reagentes de ensaio que não estejam nas condições descritas nos rótulos ou que estejam danificados, contactar o Serviço ao Cliente Abbott.

Procedimento

Consultar as instruções de utilização específicas do ensaio e/ou o manual com instruções de utilização específicas do ensaio.

Procedimentos de controlo de qualidade

Consultar as instruções de utilização específicas do ensaio e/ou o manual com instruções de utilização específicas do ensaio.

Resultados, interpretação de resultados e limitações do procedimento

Consultar as instruções de utilização específicas do ensaio e/ou o manual com instruções de utilização específicas do ensaio.

Assistência técnica

Para assistência técnica, contactar o Serviço de Assistência Técnica Abbott Molecular através do número de telefone 800 849 228, do endereço de correio eletrónico molecularsupport@abbott.com ou consultar http://www.abbottmolecular.com.

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Symbolforklaring

REF
Bestillingsnummer

LOT
Lotnummer

PART
Artikelnummer

IVD
Medicinsk udstyr til in vitro-diagnostik

mDBS-buffer
Indeholder tilstrækkeligt til <n> test

Udløbsdato

Temperaturbegrænsning

Se brugsanvisningen

Se VIGTIGE FORHOLDSREGLER

EC REP
Repræsentant i EU

Fabrikant

FOR YDERLIGERE OPLYSNINGER KONTAKTES ABBOTT KUNDESERVICE

BESKYTTET PRODUKTNAVN
Abbott mSample Preparation System DBS Buffer Kit

ANVENDELSE
Abbott mSample Preparation System DBS Buffer Kit anvendes til eluering af nukleinsyre fra tørrede blodpletter. Dette sæt er beregnet til anvendelse sammen Abbott-analysen.

RESUME OG ANALYSEFORKLARING

Analysprincip
Se den analysespecifikke brugsanvisning og/eller brugermanual for yderligere oplysninger.

REAGENSE

mDBS-buffer (bestillingsnr. 9N02A)
mDBS-buffer med 41,4% guanidiniumthiocyanat, 5% Tween 20, 0,5% kaliumacetat og 0,5% eddikesyre (4 flasker a 46 ml)

VIGTIGE FORHOLDSREGLER

IVD
Medicinsk udstyr til in vitro-diagnostik

Til in vitro-diagnostisk brug

Se den analysespecifikke brugsanvisning og/eller brugermanual for yderligere oplysninger.

mDBS-buffer indeholder guanidinthiocyanat.

Abbott mDBS-buffer

Advarsel
Farebestemmende komponenter:
Guanidinthiocyanat
H302+H332 Farlig ved indtagelse eller indånding.
H412 Skadelig for vandlevende organismer, med langvarige virkninger.
P261 Undgå indånding af tåge/damp/spray.
P264 Vask hænderne grundigt efter brug.
P280 Bør beskyttelseshansker/beskyttelsestøj/ øjenbeskyttelse.
P271 Brug kun udendørs eller i et rum med god uduftning.
P273 Undgå udledning til miljøet.
P301+P312 I TILFÆLDE AF INDTAGELSE: I tilfælde af ubehag, ring til en GIFTINFORMATION/læge.
P330 Skyl munden.
P501 Indholdet/beholderen bortskaffes i overensstemmelse med lokale regler.

Erklæring om sikkerhedsdatablad: Sikkerhedsdatabladet indeholder vigtige oplysninger om sikker håndtering, transport og bortskaffelse af dette produkt.

OPBEVARINGSANVISNINGER

Opbevares ved 15 °C til 30 °C

15°C

KOLO

Opbevares ved 15 °C til 30 °C

FORSENDELSE
Dette produkt forsendes ved stuetemperatur.

Hvis de leverede reagenser ikke overholder specifikationerne på etiketterne eller er beskadiget, kontaktes Abbotts kundeservice.

PROCEDURE
Se den analysespecifikke brugsanvisning og/eller brugermanual for yderligere oplysninger.

PROCEDURER FOR KVALITETSKONTROL
Se den analysespecifikke brugsanvisning og/eller brugermanual for yderligere oplysninger.

RESULTATER, FORTOLKNING AF RESULTATER OG PROCEDUREBEGRÆNSNINGER
Se den analysespecifikke brugsanvisning og/eller brugermanual for yderligere oplysninger.

TEKNISK HJÆLP
Ring til Abbott Moleculars kundeservice på 39770000, send en e-mail til molecularsupport@abbott.com, eller besøg Abbott Moleculars websted på http://www.abbottmolecular.com for teknisk hjælp.

Abbott mDBS-buffer

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Abbott mSample Preparation System DBS Buffer Kit

**Používané symboly**

- REF: Katalogové číslo
- LOT: Číslo šárky
- PART: Číslo produktu
- IVD: Diagnostické zdravotnické prostředky in vitro
- In Vitro Test
- mDBS buffer
- Pufr mDBS
- Datum expirace
- Teplotní omezení
- Viz návod k použití
- Viz VAROVÁNÍ A BEZPEČNOSTNÍ OPATŘENÍ
- Zplovomocněný zástupce v zemích Evropského společenství

**ZÁKAZNICKÝ SERVIS:**
KONTAKTUJTE ZÁSTUPCE FIRMY ABBOTT

**OBDODNÍ ČÁST** Abbott mSample Preparation System DBS Buffer Kit

**POUŽITÍ**

Abbott mSample Preparation System DBS Buffer Kit se používá k eluci nukleové kyseliny ze zaschlých kapek krve. Tato sada je určena k použití s metodami Abbott.

**SHRNUTÍ A VYSVĚTLENÍ TESTU**

Biologické principy postupu

Viz příbalový leták a/nebo pokyny pro použití příslušné metody.

**REAGENCIE**

- mDBS buffer (kat. č. 9N02A)
  Pufr mDBS s 41,4% guanidinium thiokyanátem, 5% Tween 20, 0,5% octanem draselným a 0,5% kyselinou octovou (4 lahvičky, 46 ml na lahvičku)

**VAROVÁNÍ A BEZPEČNOSTNÍ OPATŘENÍ**

IVD: Diagnostické zdravotnické prostředky in vitro

Pro diagnostické účely in vitro

Viz příbalový leták a/nebo pokyny pro použití příslušné metody.

Pufr mDBS obsahuje guanidinium thiokyanát.

**Pufr Abbott mDBS Buffer**

**VAROVÁNÍ**

Složka určující označení nebezpečnosti:
- Guanidinium thiokyanát H302+H332 Zdraví škodlivý při požití a při vdechování.
- P261 Zamezte vdechování mlhy / par / aerosolů.
- P264 Po manipulaci si důkladně omyjte ruce.
- P280 Používejte ochranné rukavice / ochranný oděv / ochranné brýle.
- P271 Používejte pouze venku nebo v dobře větraných prostorách.
- P273 Zabraňte uvolnění do životního prostředí.
- P301+P312 PŘI POŽITÍ: Necítíte-li se dobře, volejte TOXIKOLOGICKÉ INFORMAČNÍ STŘEDISKO / lékaře.
- P304+P340 PŘI VDECHNUTÍ: Přeneste osobu na čerstvý vzduch a ponechte ji v poloze usnadňující dýchání.
- P330 Vypláchněte ústa.
- P301+P312 PŘI POŽITÍ: Necítíte-li se dobře, volejte TOXIKOLOGICKÉ INFORMAČNÍ STŘEDISKO / lékaře.

**Informace v bezpečnostních listech:** V bezpečnostním listu jsou uvedeny důležité informace týkající se bezpečného zacházení, přepravy a likvidace tohoto produktu.

**PODÍMKY SKLADOVÁNÍ**

- Skladujte při teplotě 15 – 30 °C

**PŘEPRAVNÍ PODMÍNKY**

Tento produkt je přepravován při teplotě okolí.

Pokud vám budou reagencie pro metodu dodány poškozené nebo ve stavu, který neodpovídá doporučením uvedeným v příbalovém letáku nebo na obalovém štítku, obraťte se na zákaznický servis firmy Abbott.

**POSTUP**

Viz příbalový leták a/nebo pokyny pro použití příslušné metody.

**POSTUPY KONTROLY KVALITY**

Viz příbalový leták a/nebo pokyny pro použití příslušné metody.

**VÝSLEDKY, INTERPRETACE VÝSLEDKŮ A OMEZENÍ METODY**

Viz příbalový leták a/nebo pokyny pro použití příslušné metody.

**TECHNICKÁ PODPORA**

Pro technickou podporu se obraťte na zástupce divize Abbott Molecular, použijte e-mail: molecularsupport@abbott.com nebo navštivte webovou stránku firmy Abbott Molecular http://www.abbottmolecular.com.

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Abbott mSample Preparation System DBS Buffer Kit

Symbolförklaring

REF
Lotnummer

PART
Artikelnummer

IVD
Medicintechnisk produkt för in vitro-diagnostik

mDBS buffer

Innehåller tillräckligt för <n> analyser

Sista förbrukningsdag

Temperaturbegränsning

Läs tillhörande dokumentation

Se SÄKERHETSFÖRESKRIFTER

Auktoriserad representant inom Europeiska gemenskapen

Tillverkare

KONTAKTA ABBOTTS REPRESENTANT FÖR YTTERLIGARE PRODUKTINFORMATION

VARUMÄRKE
Abbott mSample Preparation System DBS Buffer Kit

ANVÄNDNINGSOMRÅDE
Abbott mSample Preparation System DBS Buffer Kit används för att eluera nukleinsyra från DBS (torkat blod). Denna förpackning ska användas tillsammans med Abbotts analyser.

SAMMANFATTNING OCH FÖRKLARING AV ANALYSEN
Analysmetodens biologiska principer
Se den analysspecifika bruksanvisningen och/eller den analysspecifika användarmanualen.

REAGENS
mDBS buffer (Listnr 9N02A)
mDBS Buffer med 41,4 % guanidiniumtiocyanat, 5 % Tween 20, 0,5 % kaliumacetat och 0,5 % ättiksyra
(4 flaskor, 46 mL per flaska)

SÄKERHETSFÖRESKRIFTER
IVD Medicintechnisk produkt för in vitro-diagnostik
För diagnostisk användning in vitro
Se de analysspecifika bruksanvisningen och/eller den analysspecifika användarmanualen.
mDBS Buffer innehåller guanidiniumtiocyanat.

Abbott mDBS Buffer

Varning
Riskavgörande komponenter i produkten:
Guanidiniumtiocyanat
H302+H332 Skadligt vid förtäring eller inandning.
H412 Skadliga långtidseffekter för vattenlevande organismer.
P261 Undvik att inandas dimma/ångor/sprej.
P264 Tvätta händerna grundligt efter användning.
P280 Använd skyddshandskar/skyddskläder/ögonskydd.
P271 Används endast utomhus eller i väl ventilerade utrymmen.
P273 Undvik utsläpp till miljön.
P301+P312 VID FÖRTÄRING: Vid obehag, kontakta GIFTINFORMATIONSCENTRALEN/läkare.
P330 Skölj munnen.
P501 Hantera innehållet/behållaren i enlighet med lokala bestämmelser för avfall.

Upptäck om säkerhetsdatablad: Viktig information om säker hantering, transport och kassering av denna produkt finns i säkerhetsdatabladet.

FÖRVARING

15 °C till 30 °C

TRANSPORT
Produkten transporteras i rumstemperatur.
Kontakta Abbotts kundservice om reagensen inte uppfyller de specifika tioner som anges på etiketten eller är skadade vid framkomsten.

METODBESKRIVNING
Se den analysspecifika bruksanvisningen och/eller den analysspecifika användarmanualen.

KVALITETSKONTROLL
Se den analysspecifika bruksanvisningen och/eller den analysspecifika användarmanualen.

RESULTAT, TOLKNING AV RESULTAT OCH ANALYSMETODENS BEGRÄNSNINGAR
Se den analysspecifika bruksanvisningen och/eller den analysspecifika användarmanualen.

TEKNIK HJÄLP

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Πίνακας συμβόλων

κωδικός προϊόντος
αριθμός παρτίδας
κωδικός παραγγελίας
In vitro διαγνωστικό ιατροτεχνολογικό προϊόν
Εξέταση in vitro
Διάλυμα mDBS
Περιέχει επαρκή ποσότητα για <n> εξετάσεις
Ημερομηνία λήξης
Όρια θερμοκρασίας
Λόγοι θερμοκρασίας
Συμβουλευτείτε τις οδηγίες χρήσης
Ανατρέξτε στις ΠΡΟΕΙΔΟΠΟΙΗΣΕΙΣ ΚΑΙ ΠΡΟΦΥΛΑΞΕΙΣ
Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κανονική
Κατασκευαστής

ΕΞΥΠΗΡΕΤΗΣΗ ΠΕΛΑΤΩΝ
ΑΠΕΥΘΥΝΟΙΤΕ ΣΤΟΝ ΥΠΕΥΘΥΝΟ ΠΩΛΗΣΕΩΝ ΤΗΣ ABBOTT
ΚΑΤΟΧΥΡΩΜΕΝΗ ΟΝΟΜΑΣΙΑ
Διαγωνιστικό σύνολο Abbott mSample Preparation System DBS Buffer Kit

ΣΚΟΠΟΣ ΧΡΗΣΗΣ
Το διαγνωστικό σύνολο Abbott mSample Preparation System DS Buffer Kit χρησιμοποιείται στην έκλογη ηνίακου αόξιος από αποζημιωμένες κηλίδες αίματος. Το διαγωνιστικό σύνολο αυτό προορίζεται για χρήση με τις εξετάσεις της Abbott.

ΠΕΡΙΛΗΨΗ ΚΑΙ ΕΠΕΞΗΓΗΣΗ ΤΗΣ ΕΞΕΤΑΣΗΣ
ΒΙΟΛΟΓΙΚΕΣ ΑΡΧΕΣ ΤΗΣ ΔΙΑΙΔΙΚΑΣΙΑΣ
Συμβουλευτείτε το συνοδευτικό φυλλάδιο ή/και τις οδηγίες χρήσης της αντίστοιχης εξετάσης.

ΑΝΤΙΔΡΑΣΤΗΡΙΑ
mDBS buffer (κωδ. προϊόντος 9N02A)
Διάλυμα mDBS Buffer με 41,4% θειοκυανική γουανιδίνη, 5% Tween 20, 0,5% οξέο καλό και 0,5% οξέο αξο (4 φιάλες, 46 mL ανα φιάλες)

ΠΡΟΕΙΔΟΠΟΙΗΣΕΙΣ ΚΑΙ ΠΡΟΦΥΛΑΞΕΙΣ
In vitro διαγωνιστικό ιατροτεχνολογικό προϊόν
Για διαγωνιστική χρήση in vitro
Συμβουλευτείτε το συνοδευτικό φυλλάδιο ή/και τις οδηγίες χρήσης της αντίστοιχης εξετάσης.

Προσοχή
Συμβουλευτείτε το συνοδευτικό φυλλάδιο ή/και τις οδηγίες χρήσης της αντίστοιχης εξετάσης.

Δήλωση για Δελτία δεδομένων ασφαλείας: Σημαντικές πληροφορίες σχετικά με τον ασφαλή χειρισμό, τη μεταφορά και τη διάθεση του προϊόντος αυτού περιέχονται στα δελτία δεδομένων ασφαλείας.

ΟΔΗΓΙΕΣ ΑΠΟΘΗΚΕΥΣΗΣ
30°C Αποθήκευση στους 15°C έως 30°C

ΣΥΝΘΕΤΙΚΕΣ ΑΠΟΣΤΟΛΕΣ
Το προϊόν αποστέλλεται σε συνθήκες περιβάλλοντος. Εάν παραλάβете αντιδραστήρια σε κατάσταση διαφορετική από αυτή που αναγράφεται στην ετικέτα ή που έχουν υποστεί ζημιά, απευθυνθείτε στο Τμήμα εξυπηρέτησης πελατών της Abbott.

ΔΙΑΙΔΙΚΑΣΙΑ
Συμβουλευτείτε το συνοδευτικό φυλλάδιο ή/και τις οδηγίες χρήσης της αντίστοιχης εξετάσης.

ΔΙΑΙΔΙΚΑΣΙΕΣ ΕΛΕΓΧΟΥ ΠΟΙΟΤΗΤΑΣ
Συμβουλευτείτε το συνοδευτικό φυλλάδιο ή/και τις οδηγίες χρήσης της αντίστοιχης εξετάσης.

ΑΠΟΤΕΛΕΣΜΑΤΑ, ΕΡΜΗΝΕΙΑ ΑΠΟΤΕΛΕΣΜΑΤΩΝ ΚΑΙ ΠΕΡΙΟΡΙΣΜΟΙ ΤΗΣ ΔΙΑΙΔΙΚΑΣΙΑΣ
Συμβουλευτείτε το συνοδευτικό φυλλάδιο ή/και τις οδηγίες χρήσης της αντίστοιχης εξετάσης.

ΤΕΧΝΙΚΗ ΥΠΟΣΤΗΡΙΣΗ
Για τεχνική υποστήριξη, καλέστε στο Τμήμα τεχνικής υποστήριξης της Abbott Molecular της περιοχής σας, επικοινωνώντας με το +49-6122-280, στείλτε μήνυμα στην ηλεκτρονική διεύθυνση molecularsupport@abbott.com ή επικοινωνήστε τον ιστότοπο της Abbott Molecular http://www.abbottmolecular.com

Abbott Molecular Inc.,
1300 East Touhy Avenue
Des Plaines, IL 60018 USA
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Ιούλιος 2015
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Abbott Molecular & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden, Germany
+ 49-6122-580
Bufor Abbott mDBS Buffer

Uwaga
Składniki warunkujące stopień zagrożenia umieszczone na etykietce:
- tiocyjanian guanidyny H302+H332 Działa szkodliwie po połknięciu lub w następstwie wdychania.
- H412 Działa szkodliwie na organizmy wodne, powodując długotrwałe skutki.
- P261 Unikać wdychania mgły / pary / rozpylanej cieczy.
- P264 Dokładnie umyć ręce po użyciu.
- P280 Stosować rękawice ochronne / odzież ochronną / ochronę oczu.
- P271 Stosować wyłącznie na zewnątrz lub w dobrze wentylowanym pomieszczeniu.
- P273 Unikać uwolnienia do środowiska.
- P301+P330 W PRZYPADKU POŁKNIĘCIA: W przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUĆ lub z lekarzem.
- P304+P340 W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: Wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania.
- P330 Wypłukać usta.
- P501 Zawartość / pojemnik usuwać zgodnie z miejscowymi przepisami.

Oświadczenie dotyczące karty charakterystyki: Wąskie informacje dotyczące bezpiecznego obchodzenia się z produktem, jego transportem i utylizacją podane są w karcie charakterystyki.

ZASADY PRZECZOWYWAŃIA
Przechowywać w temp. 15 °C do 30 °C.

WARUNKI TRANSPORTOWANIA
Produkt ten jest transportowany w temperaturze otoczenia. Jeśli stan dostarczonych odczynników jest inny niż zalecany na etykietce bądź odczynniki są uszkodzone, należy skontaktować się z przedstawicielem firmy Abbott.

PROCEDURA
Sprawdź w ulotce i/lub instrukcji używania danego testu.

PROCEDURY KONTROLI JAKOŚCI
Sprawdź w ulotce i/lub instrukcji używania danego testu.

WYNIKI, INTERPRETACJA WYNIKÓW ORAZ OGRANICZENIA PROCEDURY
Sprawdź w ulotce i/lub instrukcji używania danego testu.

POMOC TECHNICZNA
W przypadku problemów technicznych prosimy o kontakt z przedstawicielem firmy Abbott Molecular w Polsce pod numerem telefonu: (+48) 22 319 12 00, kontakt e-mailowy na adres molecularsupport@abbott.com lub o odwiedzenie strony internetowej firmy Abbott Molecular pod adresem http://www.abbottmolecular.com.


OBSŁUGA KLIENTĂ:
PROSIMY O KONTAKT Z PRZEDSTAWIECIELM FIRMY ABBOTT.

NAZWA ZASTRZEŽONA
Abbott mSample Preparation System DBS Buffer Kit

PRZECZOWYWAŃ
Zestaw Abbott mSample Preparation System DBS Buffer Kit służy do elucji kwasów nukleinowych z próbek w postaci suchej kropli krwi. Zestaw ten jest przeznaczony do użycia w połączeniu z testami firmy Abbott.

WPROWADZENIE
Zasada metody
Sprawdź w ulotce i/lub instrukcji używania danego testu.

ODCZYNNIKI
mDBS buffer (nr kat. 9N02A)
Bufor mDBS zawierający 41,4% tiocyjanian guanidyny, 5% Tween 20, 0,5% octan potasu oraz 0,5% kwas octowy (4 buteleczki, 46 ml w buteleczce)

OSTRZEŻENIA I ŚRODKI OSTRZEGOWE
IVD Wyrób medyczny do diagnostyki in vitro
Do diagnostyki in vitro
Sprawdź w ulotce i/lub instrukcji używania danego testu.
Bufor mDBS Buffer zawiera tiocyjanian guanidyny.

Bufor Abbott mDBS Buffer

Uwaga
Składniki warunkujące stopień zagrożenia umieszczone na etykietce:
- tiocyjanian guanidyny H302+H332 Działa szkodliwie po połknięciu lub w następstwie wdychania.
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WARUNKI TRANSPORTOWANIA
Produkt ten jest transportowany w temperaturze otoczenia. Jeśli stan dostarczonych odczynników jest inny niż zalecany na etykietce bądź odczynniki są uszkodzone, należy skontaktować się z przedstawicielem firmy Abbott.

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PROCEDURY KONTROLI JAKOŚCI
Sprawdź w ulotce i/lub instrukcji używania danego testu.

WYNIKI, INTERPRETACJA WYNIKÓW ORAZ OGRANICZENIA PROCEDURY
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NAZWA ZASTRZEŽONA
Abbott mSample Preparation System DBS Buffer Kit

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Abbott mSample Preparation System DBS Buffer Kit

Jelmagyarázat

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Tárolási hőmérsékleti tartomány
Olvasza el a használati utasításokat
Lásd a FIGYELMEZTETÉSEK ÉS ÖVINTÉZKEDESEK cím alatt
Meghatalmazott képviselő az Európai Közösségben
Gyártó

ABBOTT GmbH & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden, Germany

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Július 2015.
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Veszély!
A termékre vonatkozó nyomtatványokban közlendő veszélyességi osztályba való tartozást meghatározó összetevők:
Guanidinium-tiocianát

H302+H332 Lenyelve vagy belélegezve ártalmas.
P261 Kerülje a köd/gőzök/permet belélegzését.
P264 A használatot követően a kezeket alaposan kell mosni.
P280 Védőkesztyű / védőruha / szemvédő használata kötelező.
P271 Kizárólag szabadban vagy jól szellőző helyiségben használható.
P273 Kerülni kell az anyagnak a környezetbe való kijutását.
P301+P312 LENYELÉS ESETÉN: Rosszullét esetén forduljon TOXIKOLÓGIAI KÖZPONTHOZ / orvoshoz.
P304+P340 BELÉLEGZÉS ESETÉN: Az érintett személyt friss levegőre kell vinni, és olyan nyugalmi helyzetet kell hoztatni, hogy könnyen tudjon lélegezni.
P330 A szájat ki kell öblíteni.

Biztonsági adatlapra vonatkozó információ: Az e termék biztonságos kezelésére, szállítására és ártalmatlanítására vonatkozó fontos információkat a Biztonsági adatlap tartalmazza.

Szállítási feltételek
Az Abbott mSample Preparation System DBS Buffer Kit a beszárított věrőlökóból történő nukleinsav-eluálásra szolgál. Ez a készlet az Abbott teszteihez használható.

A teszt összefoglalása és magyarázata
Az eljárás biológiai elvei
Lásd az adott tesztre vonatkozó terméksmertető nyomtatványt és/vagy az adott tesztre vonatkozó használati utasításokat tartalmazó kézikönyvet!

REGENSEK

mDBS buffer (Listaszám: 9N02A)
mDBS puffer 41,4% guanidinium-tiocianáttal, 5% Tween 20-szállal, 0,5% kálium-acetáttal és 0,5% ecetsavval.
(4 palack, palackonként 46 ml)

FIGYELMEZTETÉSEK ÉS ÖVINTÉZKEDESEK

In vitro diagnosztikai orvostechnikai eszköz
In vitro diagnosztikai alkalmazásra

Lásd az adott tesztre vonatkozó terméksmertető nyomtatványt és/vagy az adott tesztre vonatkozó használati utasításokat tartalmazó kézikönyvet!

Az mDBS puffer guanidinium-tiocianáttal tartalmaz.

Abbott mDBS Buffer

Veszély!
A termékre vonatkozó nyomtatványokban közlendő veszélyességi osztályba való tartozást meghatározó összetevők:
Guanidinium-tiocianát

H302+H332 Lenyelve vagy belélegezve ártalmas.
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TÁROLÁSI UTASÍTÁSOK

15°C és 30°C közti hőmérsékleten tárolandó.

SZÁLLÍTÁSI FELTÉTELEK
A terméket környezeti hőmérsékleten szállítjuk.

Amennyiben olyan tesztet kap, amely állapota nem felel meg a terméksmertető nyomtatványban vagy a címkén található meghatározásoknak, vagy ha a termék sérült, lépjen érintkezésbe az Abbott területi képviselővel!

ELJÁRÁS
Lásd az adott tesztre vonatkozó terméksmertető nyomtatványt és/vagy az adott tesztre vonatkozó használati utasításokat tartalmazó kézikönyvet!

MÍNŐSÉG-ELLENÖRZÉSI ELJÁRÁSOK
Lásd az adott tesztre vonatkozó terméksmertető nyomtatványt és/vagy az adott tesztre vonatkozó használati utasításokat tartalmazó kézikönyvet!

EREDMÉNYEK, EREDMÉNYEK ÉRTELMEZÉSE ÉS AZ ELJÁRÁS KORLÁTAI
Lásd az adott tesztre vonatkozó terméksmertető nyomtatványt és/vagy az adott tesztre vonatkozó használati utasításokat tartalmazó kézikönyvet!

TECHNIKAI SEGÍTSÉGYŰJTÉS
Technikai segítségért, kérjük, lépjen érintkezésbe az Abbott Molecular Technical Services-vel (+49-6122-580, email: molecularsupport@abbott.com) vagy látogasson el az Abbott Molecular honlapjára: http://www.abbottmolecular.com.

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65205 Wiesbaden, Germany
+ 49-6122-580
**Abbott mSample Preparation System DBS Buffer Kit**

(Abbott mSample Preparasyon Sistemi DBS Tampon Kiti)

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**MÜŞTERİ DESTEK SERVİSİ: ABBOTT TEMSİLÇİNİZİ ARAYIN**

**TESCİLLİ ADI** Abbott mSample Preparation System DBS Buffer Kit

**KULLANIM AMACI** Abbott mSample Preparation System DBS Tampon Kit kurumuş kan noktalardan nükleik asidi ayrırmak için kullanılır. Bu kit Abbott tetkiklerine beraber kullanılacaktır.

**TESTİN ÖZETI VE AÇIKLAMASI**

Prosedürü Biyolojik İlkeleri

Tetkike özgü prospektüse ve/veya tetkike özgü kullanım talimatlarına bakınız.

**REAKTİFLER**

mDBS buffer (Liste No. 9N02A)
mDBS Buffer; 41.4 Guanidinyum Tiosiyanat, 0.5 Tween 20, 0.5 Potasyum Asetat ve 0.5 Asetik Asit içerir (4 şişe, her şişede 46 mL)

**UYARILAR VE ÖNLEMLER**

İn Vitro Test In Vitro Diagnostik Medikal Cihaz

Tetkike özgü prospektüse ve/veya tetkike özgü kullanım talimatlarına bakınız.

mDBS Buffer Guanidinyum tiosiyanat içerir.

**Abbott mDBS Buffer**

Uyarı

Etiketin tehlike belirten bileşenleri:

Guanidinyum tiosiyanat

H302+H332 Yutulması veya solunması halinde zararlıdır.

H412 Suda yaşayan canlılar için zararlı, su çevresine uzun vadede olumsuz etkilerde bulunabilir.

P261 Çişe/buhar/püskürme hallerini solumaya dikkat edin.

P264 Temas sonrası ellerinizi iyice yıkayınız.

P280 Koruyucu eldiven / koruyucu giysi / koruyucu gözlük kullanın.

P271 Yalnızca açık havada veya iyi havalandırılmış alanda kullanın.

P273 Çevreye salınmasını önleyiniz.

P301+ P312 YUTULMASI HALİNDE: Rahatsızlık hissediyorsanız, bir ZEHİR DANIŞMA MERKEZİ veya doktor ile iletişime geçin.

P304+P340 SOLUNMASI HALİNDE: Mağdur kişiyi temiz havaya çıkarın ve rahatça nefes almasını sağlayın.

P330 Ağzınızı çalkalayın.

P501 İçerikleri / kapları yerel yönetmeliklere göre atın.

Güvenlik Bilgi Formları Açıklaması: Bu ürünün emniyetli biçimde ele alınması, nakledilmesi ve imha edilmesi ile ilgili önemli bilgiler Güvenlik Bilgi Formunda bulunmaktadır.

**SAKLAMA TALIMATLARI**

15°C ila 30°C de saklayın

**NAKLİYE KOŞULLARI**

Ürün 15°C'de sicaklığındaki nakledilir.

Aldığınız reaktifi etiketteki tavsiyelere uygun olmayan bir tarzda veya hasarlı olarak gelirse, Abbott Müşteri Destek Servisi ile iletişim kurun.

**PROSEDÜR**

Tetkike özgü prospektüse ve/veya tetkike özgü kullanım talimatlarına bakınız.

**KALİTE KONTROL PROSEDÜRLERİ**

Tetkike özgü prospektüse ve/veya tetkike özgü kullanım talimatlarına bakınız.

**SONUÇLAR, SONUÇLARIN YORUMLANMASI VE PROSEDÜRÜN SINIRLAMALARI**

Tetkikin prospektüsüne ve/veya tetkike özel kullanım talimatlarına bakınız.

**TEKNİK DESTEK**


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Temmuz 2015
51-608281/R2
9PIMD1695rev01
Abbott mSample Preparation System DBS Buffer Kit

Symbolforklaring

- **REF** Bestillingsnummer
- **LOT** Lotnummer
- **PART** Delenummer
- **IVD** Medisinsk utstyr for *in vitro*-diagnostikk
- **In Vitro Test** *In vitro*-test
- **mDBS buffer** mDBS-buffer
- **Σ** Inneholder tilstrekkelig for <n> tester
- **✉** Utleopardato
- **🌡️** Temperaturogrenser
- **📖** Se pakningsvedlegg
- **⚠️** Se VIKTIGE FORHOLDSREGLER
- **EC REP** Autorisert representant i EU
- **镤** Produsent

**KUNDESERVICE:**
**KONTAKT ABBOTT KUNDESERVICE**
** PROPRIETÆRT NAVN** Abbott mSample Preparation System DBS Buffer Kit

**BRUKSAMRÅDE**
Abbott mSample Preparation System DBS Buffer Kit brukes til å eluere nukleinsyre fra tørkede blodutstryk. Denne pakken skal brukes sammen med Abbott-analyser.

**SAMMENDRAK OG ANALYSFORKLARING**
Fremgangsmåte
Se det analysespesifikk pakningsvedlegget og/eller den analyse-spesifikk håndboken.

**REAGENGER**
- **mDBS buffer** (bestillingsnr. 9N02A)
  mDBS Buffer med 41,4 % guanidintiocyanat, 5 % Tween 20, 0,5 % kaliumacetat og 0,5 % eddiksyre (4 flasker, 46 ml per flaske)

**VIKTIGE FORHOLDSREGLER**
- **IVD** Medisinsk utstyr for *in vitro*-diagnostikk
  Til bruk ved *in vitro*-diagnostikk
  Se det analysespesifikk pakningsvedlegget og/eller den analyse-spesifikk håndboken.
- **mDBS Buffer** inneholder guanidintiocyanat.

**Abbott mDBS Buffer**

**Advarsel**
Komponenter som avgjør faremerking i produkt-dokumentasjonen:
- Guanidintiocyanat
  - H302: Farlig ved svelging eller innånding.
  - H332: Farlig ved svelging eller nedreizing.
- H412: Skadelig, med langtidsvirkning, for liv i vann.
- P261: Unngå innånding av tåke/damp/aerosoler.
- P280: Vask hendene grundig etter bruk.
- P271: Brukes bare utendørs eller i et godt ventiler område.
- P273: Unngå utslipp til miljøet.
- P330: Skyll munnen.
- P501: Kast innhold/beholder i samsvar med lokale bestemmelser.

**Erklæring om sikkerhetsdatablad:** Sikkerhetsdatabladet inneholder viktig informasjon om hvordan produktet trygt skal håndteres, transporteres og uskadeliggjøres.

**OPPBEVARING**
15°C til 30°C Oppbevares ved 15 °C til 30 °C

**FORSENDELSE**
Produktet sendes ved romtemperatur.
Hvis de mottatte analysereagensene er i en tilstand som ikke stemmer overens med produktmeringen, eller hvis de er skadet, ta kontakt med Abbott kundeservice.

**PROSEDYRE**
Se det analysespesifikk pakningsvedlegget og/eller den analyse-spesifikk håndboken.

**PROSEDYRER FOR KVALITETSKONTROLL**
Se det analysespesifikk pakningsvedlegget og/eller den analyse-spesifikk håndboken.

**RESULTATER, TOLKNING AV RESULTATER OG PROSEDYRENS BEGRENSNINGER**
Se det analysespesifikk pakningsvedlegget og/eller den analyse-spesifikk håndboken.

**TEKNISK STØTTE**
Teknisk støtte fås ved å kontakte Abbott Molecular kundeservice, ved å sende e-post til molecularsupport@abbott.com eller ved å gå til nettstedet for Abbott Molecular på http://www.abbottmolecular.com.

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