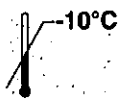
Abbott RealTime HCV

REF 1N30-90
51-608374/R1
Rx Only

Customer Service: 1-800-553-7042

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.

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

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

NAME

Abbott RealTime HCV

INTENDED USE

The Abbott RealTime HCV assay is an in vitro reverse transcription-polymerase chain reaction (RT-PCR) assay for use with the Abbott *m*Sample Preparation System reagents and with the Abbott *m*2000*sp* and *m*2000*rt* instruments

for the quantitation of hepatitis C viral (HCV) RNA in human serum or plasma (EDTA) from HCV-infected individuals. Specimens containing HCV genotypes 1 - 6 have been validated for quantitation in the assay.

The Abbott RealTi*me* HCV assay is intended for use as an aid in the management of HCV-infected patients undergoing antiviral therapy. The assay measures HCV RNA levels at baseline and during treatment and can be utilized to predict sustained and non-sustained virological response to HCV therapy. The results from the RealTi*me* HCV assay must be interpreted within the context of all relevant clinical and laboratory findings.

Assay performance characteristics have been established for individuals treated with peginterferon alfa-2a or 2b plus ribavirin. No information is available on the assay's predictive value when other therapies are used. Assay performance for determining the state of HCV infection has not been established.

The Abbott RealTi*me* HCV assay is not for screening blood, plasma, serum or tissue donors for HCV, or to be used as a diagnostic test to confirm the presence of HCV infection.

SUMMARY AND EXPLANATION OF THE TEST

HCV is a single-stranded RNA virus, with a genome of 9,500 nucleotides.[1] HCV is a leading cause of liver disease in the United States, infecting an estimated 3.2 million people.[2] HCV has been transmitted primarily through intravenous drug use and through blood products. Sensitive serological tests for HCV antibodies have greatly reduced the incidence of new infections from donated blood. About 75-85% of HCV-infected individuals develop chronic hepatitis, with up to 20% of chronically infected individuals developing cirrhosis. In patients with cirrhosis, the incidence of hepatocellular carcinoma is 1-4% per year.[3,4]

Quantitation of HCV RNA has been instrumental in understanding the effectiveness of antiviral response to interferon monotherapy, interferon plus ribavirin combination therapy, and peginterferon plus ribavirin combination therapy.[5-9] Current guidelines for the management and treatment of HCV recommend quantitative testing for HCV RNA before the start of antiviral therapy, during therapy, and after the conclusion of treatment. The objective of treatment is a sustained virologic response (SVR), defined as the absence of HCV RNA detectable by a sensitive test 24 weeks after the end of treatment.[10] SVR is almost always preceded by an early virologic response (EVR), defined as a two-log or greater decrease in HCV viral load after 12 weeks of therapy. Failure to achieve EVR has a high negative predictive value for SVR.[3,4]

A rapid viral response (RVR), undetectable levels of HCV RNA after 4 weeks of therapy, has a high positive predictive value for SVR.[11] Determining viral kinetics during therapy has more recently been used to individualize treatment duration. Current guidelines[10] recommend considering extended therapy for patients with genotype 1 infection who have delayed virus clearance (HCV viral load reaches undetectable levels between weeks 12 and 24).[12-14]

HCV RNA in serum or plasma can be quantitated using nucleic acid amplification or signal amplification technologies.[15] The Abbott RealTi*me* HCV assay uses RT-PCR technology combined with homogeneous real time fluorescent detection for the quantitation of HCV RNA. The selection of a conserved region of the HCV genome provides for the detection of genotypes 1, 2, 3, 4, 5, and 6. The assay is standardized against the Second WHO International Standard for Hepatitis C Virus RNA (NIBSC Code 96/798)[16] and results are reported in International Units/mL (IU/mL).

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The Abbott RealTi*me* HCV assay consists of three reagent kits:

- Abbott RealTi*me* HCV Amplification Reagent Kit
- Abbott RealTi*me* HCV Control Kit
- Abbott RealTi*me* HCV Calibrator Kit

The Abbott RealTi*me* HCV assay uses RT-PCR[17] to generate amplified product from the RNA genome of HCV in clinical specimens. In addition, an RNA sequence that is unrelated to the HCV 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 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 the HCV-specific fluorescent signal is detected by the Abbott *m2000rt* is proportional to the log of the HCV 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 them accessible for amplification, and to remove potential inhibitors of amplification from the extract. The Abbott *m2000sp* is an automated sample preparation system designed to use magnetic microparticle processes for the purification of nucleic acids from samples. The Abbott *m2000sp* instrument along with the Abbott *m*Sample Preparation System (4 X 24 Preps) processes plasma or serum samples for nucleic acid amplification. Multiple samples can be processed at once. The IC is taken through the entire sample preparation procedure along with the calibrators, controls, and specimens. After capture of nucleic acids onto magnetic microparticles, the microparticles are washed to remove unbound sample components. Next, the bound nucleic acids are eluted from the microparticles and the eluates are transferred to the Abbott 96 Deep-Well Plate.

Amplification Master Mix

The Abbott *m2000sp* instrument automates the assembly of the amplification master mix (HCV Oligonucleotide Reagent, Thermostable rTth Polymerase Enzyme, and Activation Reagent) and then transfers aliquots of the master mix to the Abbott 96-Well Optical Reaction Plate. Nucleic acid samples from the Abbott 96 Deep-Well Plate are then transferred into the Abbott 96-Well Optical Reaction Plate by the Abbott *m2000sp*. The plate is sealed by the user with an Abbott Optical Adhesive Cover and placed into the Abbott *m2000rt* instrument for PCR amplification and fluorescence detection.

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 HCV 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 (HCV and IC) takes place simultaneously in the same reaction.

The target sequence for the Abbott RealTi*m*e HCV assay is in the 5′*utr* region of the HCV genome. This region is specific for HCV and is highly conserved.[18] The primers are designed to hybridize to the 5′*utr* region with the fewest possible mismatches among HCV genotypes 1, 2, 3, 4, 5, and 6.

The IC target sequence is derived from the hydroxypyruvate reductase gene from the pumpkin plant, *Cucurbita pepo* and is delivered in an Armored RNA® particle that has been diluted in HCV-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 HCV and IC probes anneal to their targets (real-time fluorescence detection). The HCV and IC probes are single-stranded DNA oligonucleotides consisting of a probe sequence with a fluorescent moiety that is covalently linked to the 5′end of the probe and a quenching

moiety that is covalently linked to the 3′ end of the probe.

In the absence of the HCV or IC target sequences, probe fluorescence is quenched. In the presence of HCV or IC target sequences, probe hybridization to complementary sequences separates the fluorophore and the quencher and allows fluorescent emission and detection. The HCV and IC 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 the HCV probe fluorescent signal is detected by the Abbott *m2000rt* is proportional to the log of the HCV RNA concentration present in the original sample.

Quantitation

A calibration curve is required to quantitate the HCV RNA concentration of specimens and controls. Two assay calibrators are run in replicates of three to generate a calibration curve. The calibration curve slope and intercept are calculated from the assigned HCV RNA concentration and the median observed threshold cycle for each calibrator and are stored on the instrument. The concentration of HCV RNA in specimens and controls is calculated from the stored calibration curve, and the results are automatically reported on the Abbott *m2000rt* workstation. The Abbott RealTi*me* HCV Negative Control, Low Positive Control, and High Positive Control must be included in each run to verify run validity. The Abbott *m2000rt* verifies that the controls are within the assigned ranges.

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 96-Well Optical Reaction Plate.
- Detection is carried out automatically without the need to open the 96-Well Optical Reaction Plate.
- Aerosol barrier pipette tips are used for all pipetting. The pipette tips are discarded after use.
- Separate dedicated areas are used to perform the Abbott RealTi*me* HCV assay. Refer to the SPECIAL PRECAUTIONS section of this package insert.

REAGENTS

Abbott RealTi*me* HCV Amplification Reagent Kit (List No. 1N30-90)

1. **INTERNAL CONTROL Abbott RealTi*me* HCV Internal Control (List No. 4J86Y)**
   (4 vials, 1.2 mL per vial)
   - Less than 0.01% noninfectious Armored RNA with internal control sequences in negative human plasma. Negative human plasma 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. Preservatives: 0.1% ProClin® 300 and 0.15% ProClin 950.

2. **AMPLIFICATION REAGENT PACK Abbott RealTi*me* HCV Amplification Reagent Pack (List No. 1N30)**
   Four packs of single-use reagents, 24 tests/pack. Discard after use.
   Each pack contains:
   - 1 bottle (0.141 mL) Thermostable rTth Polymerase Enzyme (2.9 to 3.5 Units/µL) in buffered solution.
   - 1 bottle (1.10 mL) HCV Oligonucleotide Reagent. Less than 0.1% synthetic oligonucleotides (4 primers and 2 probes) and less than 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 RealTi*me* HCV Control Kit (List No. 1N30-80)

1. **CONTROL − Abbott RealTi*me* HCV Negative Control (List No. 4J86Z)**
   (8 vials, 1.8 mL per vial)
   - Negative human plasma 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. Preservatives: 0.1% ProClin 300 and 0.15% ProClin 950.

2. CONTROL L **Abbott RealTi*me* HCV Low Positive Control (List No. 4J86W)**
(8 vials, 1.3 mL per vial)
   - Noninfectious Armored RNA with HCV sequences in negative human plasma. Negative human plasma 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. Preservatives: 0.1% ProClin 300 and 0.15% ProClin 950.

3. CONTROL H **Abbott RealTi*me* HCV High Positive Control (List No. 4J86X)**
(8 vials, 1.3 mL per vial)
   - Noninfectious Armored RNA with HCV sequences in negative human plasma. Negative human plasma 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. Preservatives: 0.1% ProClin 300 and 0.15% ProClin 950.

Abbott RealTi*me* HCV Calibrator Kit (List No. 1N30-70)

1. CAL A **Abbott RealTi*me* HCV Calibrator A (List No. 4J86A)**
(12 vials, 1.3 mL per vial)
   - Noninfectious Armored RNA with HCV sequences in negative human plasma. Negative human plasma 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. Preservatives: 0.1% ProClin 300 and 0.15% ProClin 950.

2. CAL B **Abbott RealTi*me* HCV Calibrator B (List No.4J86B)**
(12 vials, 1.3 mL per vial)
   - Noninfectious Armored RNA with HCV sequences in negative human plasma. Negative human plasma 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. Preservatives: 0.1% ProClin 300 and 0.15% ProClin 950.

NOTE: Control and calibrator lots can be used interchangeably with amplification reagent kit lots. If a new amplification reagent kit lot is used, then a new calibration curve must be generated.

WARNINGS AND PRECAUTIONS

IVD In Vitro Diagnostic Medical Device

For In Vitro Diagnostic Use.

The Abbott RealTi*me* HCV assay is not for screening blood, plasma, serum or tissue donors for HCV, or to be used as a diagnostic test to confirm the presence of HCV infection.

The Abbott RealTi*me* HCV reagents are intended to be used only on the Abbott *m*2000 System consisting of the Abbott *m*2000*sp* for sample processing and the Abbott *m*2000*rt* for amplification and detection.

Only use Uracil-N-glycosylase (UNG) List No. 1N30-66 when performing the Uracil-N-Glycosylase protocol.

Do not use expired reagents.

NOTE: The Abbott m2000sp Master Mix Addition protocol must be initiated within 60 minutes after completion of Sample Preparation.

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. Do not import the test order onto the Abbott *m2000rt*.

The appropriate PCR plate must be selected when samples are loaded into the Abbott *m2000rt* instrument.

NOTE: The Abbott m2000rt protocol must be started within 50 minutes of the initiation of the Master Mix Addition protocol.

If the Abbott *m2000rt* instrument run is not initiated within 50 minutes, or 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.

Safety Precautions

Refer to the Abbott *m2000sp* Operations Manual, Hazards Section and the Abbott *m2000rt* Operations Manual, Hazards Section for instructions on safety precautions.

⚠ **CAUTION**: The Calibrator Kit, Control Kit, and Internal Control contain human sourced and/or potentially infectious components. For a specific listing, refer to the **REAGENTS** section of this package insert. 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,[19] OSHA Standard on Bloodborne Pathogens,[20] CLSI Document M29-A3,[22] and other appropriate biosafety practices.[21,22] Therefore, all human sourced materials should be considered potentially 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 using a tuberculocidal disinfectant such as 1.0% sodium hypochlorite or other suitable disinfectant.[23,24]
- Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials in accordance with local, state, and federal regulations.[25,26]

The Abbott RealTi*m*e HCV Calibrator Kit, Control Kit, Internal Control, HCV Oligonucleotide Reagent, and Activation Reagent contain a mixture of 5-chloro-2- methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one which are components of ProClin. The following are the appropriate Risk (R) and Safety (S) phrases:

R43 May cause sensitization by skin contact.
S24 Avoid contact with skin.
S35 This material and its container must be disposed of in a safe way.
S37 Wear suitable gloves.
S46 If swallowed, seek medical advice immediately and show this container or label.

Special Precautions

Handling Precautions

The Abbott RealTi*m*e HCV assay is only for use with human serum and plasma (EDTA) 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.
Amplification reactions 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 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 and complying with good laboratory practices.

Work Areas
Use two dedicated areas within the laboratory for performing the Abbott RealTime HCV assay.

- The **Sample Preparation Area** is dedicated to processing samples (specimens, Abbott RealTime HCV 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 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 the **Sample Preparation Area.**

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 beyond expiration date.

Work areas and instrument platforms must be considered potential sources of contamination. Change gloves after contact with potential contaminants (such as specimens, eluates, and/or amplified product) before handling unopened reagents, negative control, positive controls, calibrators, or specimens. Refer to the Abbott *m2000sp* and *m2000rt* Operations Manuals for instructions on instrument cleaning procedures.

If the Abbott *m2000sp* instrument run is aborted, dispose of all commodities and reagents according to 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 specimens, reagents, and other potentially biohazardous materials in accordance with local, state, and federal regulations.[25,26] All materials should be handled in a manner that minimizes the chance of potential contamination of the work area. **Note: Autoclaving the sealed Abbott 96 well Optical 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 before and after processing.**

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 one time. Clean and disinfect spills of specimens and reagents as stated in 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 sample and IC reagent 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 surface 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.
- Clean and disinfect spills of specimens and reagents as stated in the Abbott *m*2000*sp* and the Abbott *m*2000*rt* Operations Manuals, Hazards section.
- Replace any empty or partially used 200 µL and 1000 µL disposable tip trays with full trays before every run.
- The Abbott *m*Sample Preparation System reagents are single use only. Use new reagent vessels, reaction vessels, and newly opened reagents for every new Abbott RealTi*m*e HCV assay run. At the end of each run, discard all remaining reagents from the Abbott *m*2000*sp* worktable as stated in the Abbott *m*2000*sp* Operations Manual and the Abbott *m*Sample Preparation System (4 X 24 Preps) product information sheet.

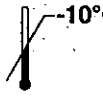
Contamination From External dU-Containing Amplified Product

Laboratories that use or have used HCV 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 RealTi*m*e HCV assay. Refer to the Monitoring the Laboratory for the Presence of Amplified Product section of this package insert.

When negative controls are persistently reactive or where contamination with dU containing HCV amplified product is likely to have occurred, it is recommended that the laboratory use the Uracil-N-Glycosylase (UNG) (List No. 01N30-66) contamination control procedure if decontamination of the laboratory is unsuccessful.

STORAGE INSTRUCTIONS

Abbott RealTi*m*e HCV Amplification Reagent Kit (List No. 1N30-90)

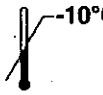


The Abbott RealTi*m*e HCV Amplification Reagent Pack and Internal Control vials must be stored at -10°C or colder when not in use. Care must be taken to separate the Abbott RealTi*m*e HCV Amplification Reagent Pack that is in use from direct contact with samples, calibrators and controls.

Abbott RealTi*m*e HCV Control Kit (List No. 1N30-80)

The Abbott RealTi*m*e HCV Negative and Positive Controls must be stored at -10°C or colder.

Abbott RealTi*m*e HCV Calibrator Kit (List No. 1N30-70)



The Abbott RealTi*m*e HCV Calibrator A and Calibrator B must be stored at -10°C or colder.

SHIPPING CONDITIONS

- Abbott RealTi*m*e HCV Amplification Reagent Kit: Ship on dry ice.
- Abbott RealTi*m*e HCV Control Kit: Ship on dry ice.
- Abbott RealTi*m*e HCV Calibrator Kit: Ship on dry ice.

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

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. Refer to the **QUALITY CONTROL PROCEDURES: Assay Calibration** section of this package insert for details.