Abbott RealTi*me* SARS-CoV-2

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REF 09N77-095

51-608445/R6

Rx ONLY

IVD

REF 09N77-095

51-608445/R6

NOTE: Changes highlighted

For use under an Emergency Use Authorization (EUA) Only

Instructions for Use

INTRODUCTION

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

NAME

Abbott RealTi*me* SARS-CoV-2

INTENDED USE

The Abbott RealTi*me* SARS-CoV-2 assay is a real-time (rt) reverse transcriptase (RT) polymerase chain reaction (PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal swabs, self-collected at a healthcare location or collected by a healthcare provider and mid-turbinate nasal swabs, nasopharyngeal (NP) and oropharyngeal (OP) swabs, and bronchoalveolar lavage fluid (BAL) collected by a healthcare provider, from individuals suspected of COVID-19 by their healthcare provider.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The Abbott RealTi*me* SARS-CoV-2 assay is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures. The Abbott RealTi*me* SARS-CoV-2 assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION OF THE TEST

The Abbott RealTi*me* SARS-CoV-2 assay is real-time reverse transcription polymerase chain reaction (rRT-PCR) test on the Abbott *m*2000 System. The SARS-CoV-2 primer and probe sets are designed to detect RNA in respiratory specimens collected from patients who are suspected of COVID-19 by their health care provider.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The Abbott RealTi*me* SARS-CoV-2 assay consists of 2 reagent kits:

- Abbott RealTi*me* SARS-CoV-2 Amplification Reagent Kit
- Abbott RealTi*me* SARS-CoV-2 Control Kit

The Abbott RealTi*me* SARS-CoV-2 assay is a dual target assay for the RdRp and N genes.

An RNA sequence that is unrelated to the SARS-CoV-2 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 Abbott RealTi*me* SARS-CoV-2 assay detects the SARS-CoV-2 virus and IC target sequences through the use of target-specific fluorescent-labeled oligonucleotide probes. The probes do not generate a signal unless they are specifically bound to the amplified product. The two SARS-CoV-2-specific probes are labeled with the same fluorophore and the IC-specific probe is labeled with a different fluorophore, thus allowing for simultaneous detection of both SARS-CoV-2 and IC amplified products in the same reaction well.

The Abbott RealTi*me* SARS-CoV-2 assay is performed on the Abbott *m*2000 System consisting of a sample preparation unit, the Abbott *m*2000*sp*, and an amplification and detection unit, the Abbott *m*2000*rt*. Application parameters specific to the Abbott RealTi*me* SARS-CoV-2 assay are contained on an assay-specific application specification file, distributed electronically, stored on portable media and loaded onto the Abbott *m*2000*sp* and Abbott *m*2000*rt* instruments.

Sample Preparation

The Abbott *m*2000*sp* provides automated sample preparation using a magnetic microparticle-based protocol and reagents (Abbott *m*Sample Preparation System$_{DNA}$) to process respiratory specimens.

During the sample preparation protocol, SARS-CoV-2 virions are disrupted by guanidine isothiocyanate, nucleic acids are captured on the magnetic microparticles, and inhibitors and unbound sample components are removed by washing steps. The bound nucleic acids are eluted off the microparticles with buffer and transferred to a 96 deep-well plate. The nucleic acids are then ready for amplification. The Internal Control (IC) is introduced into each specimen at the beginning of the sample preparation process to demonstrate that the process was completed correctly for each specimen and control.

A positive control and a negative control are processed from the start of sample preparation for each test order to evaluate run validity.

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

The Abbott *m*Sample Preparation System$_{DNA}$ uses magnetic particle technology to capture nucleic acids and washes the particles to remove unbound sample components. The bound nucleic acids are eluted and transferred to a 96 deep-well plate. The nucleic acids are then ready for amplification. The IC is taken through the entire sample preparation procedure along with the controls and specimens.

The Abbott *m*2000*sp* automated instrument system is used to prepare samples for the Abbott RealTi*m*e SARS-CoV-2 assay. The Abbott *m*2000*sp* provides automated sample eluate transfer and reaction assembly in the Abbott 96-Well Optical Reaction Plate.

Reagent Preparation and Reaction Plate Assembly

The Abbott *m*2000*sp* combines the Abbott RealTi*m*e SARS-CoV-2 assay amplification reagent components (SARS-CoV-2 Oligonucleotide Reagent, Thermostable rTth Polymerase Enzyme, and Activation Reagent). The Abbott *m*2000*sp* dispenses the resulting master mix to the Abbott 96-Well Optical Reaction Plate along with aliquots of the nucleic acid samples prepared by the Abbott *m*2000*sp*. The plate is ready, after manual application of the optical seal, for transfer to the Abbott *m*2000*rt*.

Amplification

During the amplification reaction on the Abbott *m*2000*rt*, the target RNA is converted to cDNA by the reverse transcriptase activity of the thermostable rTth DNA polymerase. First, the SARS-CoV-2 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 the three targets (SARS-CoV-2 RdRp, SARS-CoV-2 N, and IC) takes place simultaneously in the same reaction.

The target sequences for the Abbott RealTi*m*e SARS-CoV-2 assay are in the SARS-CoV-2 RdRp and N genes of the SARS-CoV-2 genome. The selected target sequences are highly conserved and also specific to this strain of coronavirus.

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 negative human plasma.

Detection

During the read cycles of amplification on the Abbott *m*2000*rt*, the temperature is lowered further to allow fluorescent detection of amplification products as the SARS-CoV-2 and IC probes anneal to their targets (real-time fluorescence detection). The SARS-CoV-2 probes have a fluorescent moiety that is covalently linked to the 5′ end and has a quencher molecule at its 3′ end. In the absence of target sequences, the probes adopt a conformation that brings the quencher close enough to the excited fluorophore to absorb its energy before it can be fluorescently emitted. When the probe binds to its complementary sequence in the target, the fluorophore and the quencher are held apart, allowing fluorescent emission and 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 SARS-CoV-2 and IC specific probes are each labeled with a different fluorophore, thus allowing for simultaneous detection of both amplified products.

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 RealTi*m*e SARS-CoV-2 assay. Refer to the **SPECIAL PRECAUTIONS** section of this package insert.

REAGENTS

Abbott RealTi*m*e SARS-CoV-2 Amplification Reagent Kit (List No. 09N77-095)

1. Abbott RealTi*m*e SARS-CoV-2 Internal Control
   (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 non-reactive by appropriate FDA-licensed, approved, or cleared tests for antibody to HCV, antibody to HIV-1, antibody to HIV-2, HIV-1 Ag, HBsAg, and Syphilis. The material is also tested and found to be negative by appropriate FDA-licensed, approved, or cleared PCR methods for HIV RNA, HCV RNA, and HBV DNA. Preservatives: 0.1% ProClin® 300 and 0.15% ProClin 950.
2. Abbott RealTi*m*e SARS-CoV-2 Amplification Reagent Pack (List No. 9N77)
   (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 (1.0 mL) SARS-CoV-2 Amplification Reagent containing synthetic oligonucleotides (6 primers and 3 probes), and dNTPs in a buffered solution with a reference dye. Preservative: 0.10% ProClin 300 and 0.15% ProClin 950.
   - 1 bottle (0.400 mL) Activation Reagent. 30 mM manganese chloride solution. Preservatives: 0.10% ProClin 300 and 0.15% ProClin 950.

Abbott RealTi*m*e SARS-CoV-2 Control Kit (List No. 09N77-085)

1. Abbott RealTi*m*e SARS-CoV-2 Negative Control
   (8 vials, 1.3 mL per vial) Contains 1.0% ammonium sulfate and 7.9% detergent in a buffer solution.
2. Abbott RealTi*m*e SARS-CoV-2 Positive Control
   (8 vials, 1.3 mL per vial) Contains non-infectious, recombinant Sindbis virus containing SARS-CoV-2 RNA sequences, 1.0% ammonium sulfate, and 7.9% detergent in a buffer solution.

WARNINGS AND PRECAUTIONS

For In Vitro Diagnostic Use Under the FDA Emergency Use Authorization

- For use under Emergency Use Authorization.
- For Prescription Use Only.
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- This product has been authorized by FDA under EUA for use by laboratories certified under CLIA, to perform high complexity tests;
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Safety Precautions

Refer to the Abbott *m*2000*sp* and Abbott *m*2000*rt* Operations Manuals, Hazard Section, for instructions on safety precautions.

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

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 appropriate FDA-licensed, approved, or cleared tests for antibody to HCV, antibody to HIV-1, antibody to HIV-2, HIV-1 Ag, HBsAg, and Syphilis. The material is also tested and found to be negative by appropriate FDA-licensed, approved, or cleared PCR methods for HIV RNA, HCV RNA, and HBV DNA. 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,[1] OSHA Standards on Bloodborne Pathogens,[2] CLSI Document M29-A4,[3] and other appropriate biosafety practices.[4] 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 1.0% sodium hypochlorite or other suitable disinfectant.[1]
- Decontaminate and dispose of all potentially infectious materials in accordance with local, state, and federal regulations.[4]

Components of the Abbott RealTi*m*e SARS-CoV-2 Internal Control, Oligonucleotide Reagent, and Activation Reagent contain the following components:

2-Methyl-4-isothiazol-3-one:

- Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one (EC no. 247-500-7) and 2-methyl-2H-isothiazol-3-one (EC no. 220-239-6)(3:1)
- Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one (EC no. 247-500-7) and 2-methyl-4-isothiazolin-3-one (EC no. 220-239-6)(3:1)

Potassium Hydroxide

The following warnings apply:

Warning	
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H402	Harmful to aquatic life.*
H412	Harmful to aquatic life with long lasting effects.
P261	Avoid breathing mist/vapors/spray.
P264	Wash hands thoroughly after handling.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection.
P273	Avoid release to the environment,
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash before reuse.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice/attention.
P501	Dispose of contents/container in accordance with local regulations.

* Not applicable where regulation EC 1272/2008 (CLP) has been implemented.

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

Safety Data Sheets are available from your Abbott Representative.

SPECIAL PRECAUTIONS

As with any test procedure, good laboratory practice is essential to the proper performance of this assay. Due to the high sensitivity of this test, care should be taken to keep reagents and amplification mixtures free of contamination.

- For in vitro diagnostic use under Emergency Use Authorization only.
- Positive results are indicative of the presence of SARS-CoV-2 RNA.
- Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.
- All patient samples should be handled as if infectious, using good laboratory procedures as outlined in Biosafety in Microbiological and Biomedical Laboratories[1] and in the CLSI Document M29-A4.[3] Only personnel proficient in handling infectious materials and the use of the Abbott RealTi*m*e SARS-CoV-2 assay and the Abbott *m*2000 System should perform this procedure.

Handling Precautions for Specimens

- The Abbott RealTi*m*e SARS-CoV-2 assay is only for use with respiratory specimens that have been handled and stored as described in the **SPECIMEN COLLECTION, STORAGE, AND TRANSPORT TO THE TEST SITE** section.
- Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false test results. Training in specimen collection is highly recommended due to the importance of specimen quality. Refer to CLSI MM13-A[5] as an appropriate resource.
- 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

The *m*2000*sp* and the *m*2000*rt* instruments may be operated in the same location. The use of 2 dedicated areas (Sample Preparation Area and Amplification Area) within the laboratory is recommended when performing the Abbott RealTi*m*e SARS-CoV-2 assay.

The **Sample Preparation Area** is dedicated to processing samples (specimens and Abbott RealTi*m*e SARS-CoV-2 Controls) and to adding processed samples and controls to the 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 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 control, positive controls, or specimens. Refer to the Abbott *m*2000*sp* and Abbott *m*2000*rt* Operations Manuals for instrument cleaning procedures.
- If the Abbott *m*2000*sp* instrument run is aborted, dispose of all commodities and reagents according to the Abbott *m*2000*sp* Operations Manual.
- If the Abbott *m*2000*sp* 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 *m*2000*sp* Operations Manual, Hazards section, along with the gloves used to handle the plate.
- If the Abbott *m*2000*rt* 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 *m*2000*rt* 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.[4] 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 *m*2000*sp* and Abbott *m*2000*rt* Operations Manuals.

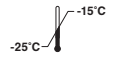
Contamination and Inhibition

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 *m*Sample Preparation System$_{DNA}$ reagents are single use only. Use new reagent troughs or vessels, reaction vessels, and newly opened reagents for every new Abbott RealTi*m*e SARS-CoV-2 assay run. At the end of each run, discard all remaining reagents from the worktable as stated in the Abbott *m*2000*sp* Operations Manual and the Abbott *m*Sample Preparation System$_{DNA}$ product information sheet.

STORAGE INSTRUCTIONS

Abbott RealTi*m*e SARS-CoV-2 Amplification Reagent Kit (List No. 09N77-095)



- Abbott RealTi*m*e SARS-CoV-2 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 RealTi*m*e SARS-CoV-2 Amplification Reagent Pack that is in use from direct contact with samples and controls.

Abbott RealTi*m*e SARS-CoV-2 Control Kit (List No. 09N77-085)

- The Abbott RealTi*m*e SARS-CoV-2 Negative and Positive Controls must be stored at −25 to −15°C.

SHIPPING CONDITIONS

- Abbott RealTi*m*e SARS-CoV-2 Amplification Reagent Kit: Ship on dry ice.
- Abbott RealTi*m*e SARS-CoV-2 Control Kit: Ship on dry ice.

If you receive reagents that are in a condition contrary to label recommendation, or that are damaged, contact your Abbott Representative.

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.

SPECIMEN COLLECTION, STORAGE, AND TRANSPORT TO THE TEST SITE

Human respiratory specimens may be used with the Abbott RealTi*m*e SARS-CoV-2 assay. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)[6] https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html or the FDA FAQs on Diagnostic Testing for SARS-CoV-2 https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2

An Abbott *m*ulti-Collect Specimen Collection Kit (List No. 09K12-01 (CE), 09K12-02 (CE), 09K12-03 or 09K12-04) or Abbott Universal Collection Kit (List No. 09N77-055) can be used for the transport of nasopharyngeal swab specimens or the collection and transport of anterior nasal, mid-turbinate nasal and oropharyngeal swab specimens from the collection site to the testing laboratory. **Neither the swab nor the transfer pipette are authorized for nasopharyngeal specimen collection.** The Transport Tube contains Specimen Transport Buffer which is used to stabilize nucleic acid until sample preparation. Transport and store transport tube at 2 to 25°C for up to 48 hours. If delivery and processing exceed 48 hours, specimens should be transported in dry ice and once in laboratory frozen at −70°C or colder.

Specimen Collection Procedure for Anterior Nasal, Mid-Turbinate Nasal and Oropharyngeal Swab Specimen Collection:

1. Discard disposable transfer pipette (if present); it is not required for anterior nasal, mid-turbinate nasal or oropharyngeal swab specimen collection.
2. Remove the sterile swab from the wrapper, taking care not to touch swab tip or lay it down on any surface. Do not pre-wet swab.
3. Collect patient specimen per CDC guidelines.[6]
4. Handle the cap and tube carefully to avoid contamination, including the outside of the transport tube and cap. If necessary, change gloves.
5. Unscrew the transport tube cap and immediately place the specimen collection swab into the transport tube so that the white tip is down.
6. Carefully break the swab at the scored line on the shaft; use care to avoid splashing of contents.
7. Recap the transport tube. Ensure the cap seals tightly. The cap must be tight or leakage may occur.
8. Label the transport tube with sample identification information, including date of collection using an adhesive label. It is recommended that each tube be placed in an individual, sealable bag prior to transport.

Specimen Transport of Nasopharyngeal Swabs:

1. Discard disposable transfer pipette (if present) and the swab; they are not authorized for nasopharyngeal swab specimen collection.
2. Collect patient specimen per CDC guidelines[6].
3. Handle the cap and tube carefully to avoid contamination, including the outside of the transport tube and cap. If necessary, change gloves.
4. Unscrew the transport tube cap and immediately place the specimen collection swab into the transport tube so that the swab tip is down.
5. If necessary, carefully break any swab shaft that protrudes out of the tube; use care to avoid splashing of contents.
6. Recap the transport tube. Ensure the cap seals tightly. The cap must be tight or leakage may occur.
7. Label the transport tube with sample identification information, including date of collection using an adhesive label. It is recommended that each tube be placed in an individual, sealable bag prior to transport.

For domestic and international shipments, specimens must be packaged, shipped, and transported according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulation. Follow shipping regulations for UN 3373 Biological Substance, Category B when sending potential SARS-CoV-2 specimens.

INSTRUMENT PROCEDURE

The Abbott RealTi*m*e SARS-CoV-2 application specification files must be installed on the Abbott *m*2000*sp* and Abbott *m*2000*rt* instruments from the Abbott RealTi*m*e SARS-CoV-2 Application Specification (List No. 09N77-010 or higher) prior to performing the assay. For a detailed description of how to perform an Abbott *m*2000*sp* instrument and Abbott *m*2000*rt* instrument protocol, refer to the Abbott *m*2000*sp* and Abbott *m*2000*rt* Operations Manuals, Operating Instructions sections.

ABBOTT REALTI*M*E SARS-COV-2 ASSAY PROCEDURE

This package insert contains instructions for running the Abbott RealTi*m*e SARS-CoV-2 assay.

Materials Provided

- Abbott RealTi*m*e SARS-CoV-2 Amplification Reagent Kit (List No. 09N77-095)

Materials Required But Not Provided

- Abbott *m*Sample Preparation System$_{DNA}$ (List No. 06K12-24)
- Abbott RealTi*m*e SARS-CoV-2 Application Specification (List No. 09N77-010 or higher)
- Abbott RealTi*m*e SARS-CoV-2 Control Kit (List No. 09N77-085)

Other Optional Materials

- Abbott *m*ulti-Collect Specimen Collection Kit (List No. 09K12-01, 09K12-02, 09K12-03 or 09K12-04)
- Abbott Universal Collection Kit (List No. 09N77-055)
  NOTE: List No. 09K12-01 and 09K12-02 are CE-marked.

Sample Preparation Area

- Abbott *m*2000*sp* Instrument (*m*2000*sp* software version 8.1 or higher)
- Abbott *m*2000*sp* Operations Manual (List No. 09K20-009 or higher)
- Abbott *m*Sample Preparation System$_{DNA}$ (List No. 06K12-24)
- Abbott RealTi*m*e SARS-CoV-2 Application Specification (List No. 09N77-010 or higher)
- 200 mL Reagent Vessels (List No. 4J71-60)
- Sample racks
- Vortex mixer
- USP Grade 190 to 200 Proof Ethanol (95 to 100% Ethanol).
  Do not use ethanol that contains denaturants.
- Calibrated precision pipettes capable of delivering 20 µL to 1000 µL
- 20 µL to 1000 µL aerosol barrier pipette tips for precision pipettes.

Other Materials

- Biological safety cabinet approved for working with infectious materials
- Amplification Reagent Pack Caps (List No. 3N20-01) (Optional)
- 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)†

See the *m*2000*sp* Operations Manual for additional materials required.

† **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.

Amplification Area

- Abbott *m*2000*rt* Instrument (*m*2000*rt* software version 8.1 or higher)
- Abbott *m*2000*rt* Operations Manual (List No. 06N03-009 or higher)
- Abbott RealTi*m*e SARS-CoV-2 Application Specification (List No. 09N77-010 or higher)
- Abbott *m*2000*rt* Optical Calibration Kit (List No. 4J71-93)

Other Materials

- Sealable plastic bags

Procedural Precautions

- Read the instructions in this package insert carefully before processing samples.
- The Abbott RealTi*m*e SARS-CoV-2 Negative Control and 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 or IC. 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 tuberculocidal disinfectant such as 1.0% sodium hypochlorite or other suitable disinfectant.
- The Abbott RealTi*m*e SARS-CoV-2 Controls must be prepared in conjunction with the specimens to be tested. The use of the Abbott RealTi*m*e SARS-CoV-2 Controls is integral to the performance of the Abbott RealTi*m*e SARS-CoV-2 assay. Refer to the **QUALITY CONTROL PROCEDURES** section of this package insert for details.

ASSAY PROTOCOL

For a detailed description of how to perform an Abbott *m*2000*sp* instrument and Abbott *m*2000*rt* instrument protocol, refer to the Abbott *m*2000*sp* and Abbott *m*2000*rt* Operations Manuals, Operating Instructions sections.

Laboratory personnel must be trained to operate the Abbott *m*2000*sp* and Abbott *m*2000*rt* instruments. The operator must have a thorough knowledge of the applications run on the instruments and must follow good laboratory practices.

Sample Preparation Area

1. Thaw assay controls and IC at 15 to 30°C or at 2 to 8°C.
   - Once thawed, assay controls and IC can be stored at 2 to 8°C for up to 24 hours before use.
   - Vortex each assay 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. **NOTE: Avoid excessive foaming.**
2. Select amplification reagent packs to be used in the run. Refer to the Abbott *m*2000*sp* Operations Manual (List No. 09K20 version 9 or higher), Operating Instructions section, for instructions pertaining to amplification reagent pack inventory management. All amplification reagent packs used in runs of greater than 24 reactions must have the same lot number. 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.

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

Sample Preparation Reagents and Internal Control Requirements				
Reagent	**1 to 24 Reactions**	**25 to 48 Reactions**	**49 to 72 Reactions**	**73 to 96 Reactions**
*m*Microparticles	1 bottle	1 bottle	1 bottle	1 bottle
*m*Lysis	1 bottle	2 bottles	3 bottles	4 bottles
*m*Wash 1	1 bottle	1 bottle	2 bottles	2 bottles
*m*Wash 2	1 bottle	1 bottle	2 bottles	2 bottles
*m*Elution Buffer	1 bottle	1 bottle	1 bottle	1 bottle
Internal Control	1 vial	2 vials	3 vials	4 vials

Abbott *m*2000*sp* Procedure

3. Gently invert the Abbott *m*Sample 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. Add USP Grade 190 to 200 Proof Ethanol (95 to 100% Ethanol) to the *m*Lysis$_{DNA}$, *m*Wash1$_{DNA}$, and *m*Wash2$_{DNA}$ bottles as indicated below. Do not use ethanol that contains denaturants.
   - Add 35 mL ethanol to each bottle of *m*Lysis$_{DNA}$ being used.
   - Add 23 mL ethanol to each bottle of *m*Wash1$_{DNA}$ being used.
   - Add 70 mL ethanol to each bottle of *m*Wash2$_{DNA}$ being used.
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 1200 µL of IC to each bottle of *m*Lysis Buffer. Mix by gently inverting the container 5 to 10 times to minimize foaming and pour the contents into the appropriate reagent vessels per the table above. When pouring in 2 bottles of the *m*Lysis$_{DNA}$ with the Ethanol and IC, fill reagent vessel no higher than the fill line where the top of the reagent label is placed. Ensure bubbles or foam are not generated in the reagent vessels; if present, remove with a sterile pipette tip, using a new tip for each reagent vessel.
6. Gently pour in remaining Abbott *m*Sample Preparation bottles into the reagent vessels per the table above except for *m*Microparticles$_{DNA}$ which will be loaded later.
   A total of 96 samples can be processed in each run. A negative control and a positive control are included in each run, therefore allowing a maximum of 94 specimens to be processed per run.
   - If the Transport Tube contained within an Abbott *m*ulti-Collect Specimen Collection Kit is used for the storage and/or transport of specimens, or if a sample has been transferred to an Abbott Transport Tube (i.e., Master Mix Tube), the minimum sample volume and associated rack requirements on the Abbott *m*2000*sp* are:

Rack	Tube	Minimum Volume
13 mm	Abbott Transport Tube	1.0 mL

   - For specimens in sample tubes other than the Abbott Transport Tube, the Abbott RealTi*m*e SARS-CoV-2 assay minimum sample volume and associated rack requirements on the Abbott *m*2000*sp* are:

Rack	Tube Diameter[a]	Minimum Volume
13 mm	11.5 - 14.0 mm	1.3 mL
16 mm	14.5 - 16.0 mm	1.5 mL

[a] Refers to sample tube outer diameter. Minimum sample volume varies with tube geometry and size. Refer to the Abbott *m*2000*sp* Operations Manual and **QUICK REFERENCE GUIDE FOR SAMPLE TUBE SIZES AND VOLUMES** for recommended sample input volume.

7. Prepare specimens for testing

   - 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, if centrifugation is needed, the following actions must be done in the order described: vortex the specimen first and follow with centrifugation of respiratory specimens. If these actions are not performed in this order, then invalid results may occur.

   - Vortex each specimen 3 times for 2 to 3 seconds.
   - If needed, centrifuge respiratory specimens only at 2000 *g* for 5 minutes before loading onto the Abbott *m*2000*sp* worktable. Aliquot each specimen into clean tubes or vials if necessary. Refer to the Abbott *m*2000*sp* Operations Manual for tube sizes.
8. Remove cap. Avoid touching the inside of the cap when opening tubes. Remove swab if present.
9. Place the positive and negative controls, if applicable, and the patient specimens into the Abbott *m*2000*sp* sample rack. If used, bar codes on tube labels must face right for scanning.
10. Place the 5 mL Reaction Vessels into the Abbott *m*2000*sp* 1 mL subsystem carrier.
11. Immediately prior to initiation of the sample extraction protocol, vigorously mix or vortex the *m*Microparticles$_{DNA}$ until they are fully resuspended and pour the *m*Microparticles$_{DNA}$ into the appropriate 200 mL reagent vessel.
12. Load the Abbott *m*Sample Preparation System$_{DNA}$ reagents and the Abbott 96 Deep-Well Plate on the Abbott *m*2000*sp* worktable as described in the Abbott *m*2000*sp* Operations Manual, Operating Instructions section.
13. From the Protocol screen, select the appropriate application file and initiate the sample extraction protocol as described in the Abbott *m*2000*sp* Operations Manual, Operating Instruction section.

    - **The application specification file m2000 SARS_CoV-2 is required for respiratory specimens.**
    - **The Abbott *m*2000*sp* Master Mix Addition protocol (step 15) must be initiated within 1 hour after completion of Sample Preparation.**

    NOTE: Change gloves before handling the amplification reagents.
14. Load the amplification reagents and the master mix tube on the Abbott *m*2000*sp* worktable after sample preparation is completed. The following table shows the number of amplification reagent packs needed based on the number of reactions.

Amplification Reagent Pack Requirements			
1 to 24 Reactions	**25 to 48 Reactions**	**49 to 72 Reactions**	**73 to 96 Reactions**
1 pack	2 packs	3 packs	4 packs

    - All amplification reagent packs used in runs of greater than 24 reactions must have the same lot number.
    - Ensure that the contents of 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.
    - **Ensure that amplification reagent packs are firmly seated on the instrument.**
15. Select the appropriate deep-well plate that matches the corresponding sample preparation extraction. Initiate the Abbott *m*2000*sp* Master Mix Addition protocol. Follow the instructions as described in the Abbott *m*2000*sp* Operations Manual, Operating Instructions section.

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

    The Abbott *m*2000*rt* protocol (step 19) must be started within 50 minutes of the initiation of the Master Mix Addition protocol (step 15).

    NOTE: If the run is aborted for any reason subsequent to step 15, a new 96-well PCR plate must be used if the Abbott *m*2000*sp* Master Mix Addition Protocol (step 15) will be repeated.

Amplification Area

16. Switch on and initialize the Abbott *m*2000*rt* instrument in the Amplification Area.

    NOTE: The Abbott *m*2000*rt* requires 15 minutes to warm-up.

    NOTE: Remove gloves before returning to the sample preparation area.
17. Seal the Abbott 96-Well Optical Reaction Plate according to the Abbott *m*2000*sp* Operations Manual, Operating Instructions section.
18. Place the sealed optical reaction plate into the Abbott Splash-Free Support Base for transfer to the Abbott *m*2000*rt* instrument. Export the completed PCR plate results to a CD (or directly to a mapped Abbott *m*2000*rt* via a network connection).

Abbott *m*2000*rt* Procedures

For a detailed description of how to perform the Abbott *m*2000*rt* SARS-CoV-2 assay protocol, refer to the Operating Instructions section in the Abbott *m*2000*rt* Operations Manual.

19. Place the Abbott 96-Well Optical Reaction Plate in the Abbott *m*2000*rt* instrument. Initiate the Abbott RealTi*m*e SARS-CoV-2 assay protocol (**m2000 SARS-CoV-2)**, as described in the Abbott *m*2000*rt* 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 *m*2000*sp* and *m*2000*rt* software is recommended. If creating the Abbott *m*2000*rt* 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 *m*2000*sp*. See Section 5 of the Abbott *m*2000*sp* Operations Manual.

POST PROCESSING PROCEDURES

1. Remove the Abbott 96 Deep-Well Plate from the worktable and dispose of according to the Abbott *m*2000*sp* Operations Manual.
2. Place the Abbott 96-Well Optical Reaction Plate in a sealable plastic bag and dispose according to the Abbott *m*2000*rt* 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 *m*2000*rt* Operations Manual.

QUALITY CONTROL PROCEDURES

Abbott *m*2000*rt* Optical Calibration

Refer to the Calibration Procedures section in the Abbott *m*2000*rt* Operations Manual for a detailed description of when and how to perform an Abbott *m*2000*rt* Optical Calibration.

Optical calibration of the Abbott *m*2000*rt* instrument is required for the accurate measurement and discrimination of dye fluorescence during the Abbott RealTi*m*e SARS-CoV-2 assay.

The following Abbott *m*2000*rt* Optical Calibration Plates are used to calibrate the Abbott *m*2000*rt* instrument for the Abbott RealTi*m*e SARS-CoV-2 assay:

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

Detection of Inhibition

A defined, consistent quantity of IC nucleic acid is introduced into each specimen and control at the beginning of sample preparation and measured on the Abbott *m*2000*rt* to demonstrate proper specimen processing and assay validity. The IC is comprised of a RNA sequence unrelated to the SARS-CoV-2 virus target sequences. An IC CN validity range is defined within the Abbott RealTi*m*e SARS-CoV-2 Assay Application File.

An error code or flag is displayed when a specimen or control fails to meet the IC specification. Refer to **INTERPRETATION OF RESULTS** section of this package insert and the Abbott *m*2000*rt* System Operations Manual for a list of error codes and flags.

Negative and Positive Controls

A negative control and a positive control are included in each test order to evaluate run validity in order to generate a valid result.

The Abbott *m*2000*rt* instrument automatically reports the control results on the Abbott *m*2000*rt* workstation. An error control flag is displayed when a control result is out of range. Refer to the Abbott *m*2000*rt* 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 the SARS-CoV-2 virus must not be detected in the negative control. SARS-CoV-2 virus 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 *m*2000*sp* instrument and the Abbott *m*2000*rt* 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/or amplification product. This includes routinely handled objects such as pipettes, the Abbott *m*2000*sp* and Abbott *m*2000*rt* 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 *m*Wash 1 buffer to a clean tube using the pipette dedicated for Internal Control use.
6. Add 20 µL of the *m*Wash 1 buffer to each microcentrifuge tube.
7. Cap the microcentrifuge tube.
8. Test this sample according to the assay procedure section of this study brochure.
   - 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 SARS-CoV-2 nucleic acid in the swab samples.
10. If SARS-CoV-2 nucleic acid is detected on equipment, follow the cleaning and decontaminating guidelines given in that equipment's operations manual.
    If SARS-CoV-2 nucleic acid is detected on surfaces, clean the contaminated areas with 1.0% 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.

INTERPRETATION OF RESULTS

The Abbott *m*2000*rt* instrument automatically reports the results and interpretations on the Abbott *m*2000*rt* workstation. An error is displayed when a result is invalid. Assay results and interpretations will look similar to the following examples:

Location	Sample ID	Sample Type	Assay	Result	Interpretation	Flags	Error Code
A1	CoV-2_NEG	Control	SARS-CoV-2	Not Detected			
A1	CoV-2_NEG	Control	SARS-CoV-2				XXXX[1]
B1	CoV-2_POS	Control	SARS-CoV-2	XX.XX CN			
B1	CoV-2_POS	Control	SARS-CoV-2				XXXX[2]
C1	Sample 1		SARS-CoV-2	XX.XX CN	Positive		
D1	Sample 2		SARS-CoV-2	Not Detected	Negative		
E1	Sample 3		SARS-CoV-2	XX.XX CN	Positive	IC[3]	
F1	Sample 4		SARS-CoV-2				XXXX[4]
G1	Sample 5		SARS-CoV-2	Not Detected	Negative	-QC, +QC[5]	
H1	Sample 6		SARS-CoV-2	XX.XX CN	Positive	-QC, +QC[5]	

[1] Error code generated due to negative control failure.

[2] Error code generated due to positive control failure

[3] Patient sample with positive amplification of target but failed internal control will produce valid result with a flag for internal control failure.

[4] Error code generated due to no amplification of target and internal control failure.

[5] Indicates a failed control, invalidating all results in the run. Users are instructed to rerun the samples starting at sample preparation.

For more information about error codes and flags, refer to the Abbott *m*2000*rt* Operations Manual.

LIMITATIONS OF THE PROCEDURE

For use under an Emergency Use Authorization only.

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet requirements to perform high complexity tests.
- Use of the Abbott RealTi*m*e SARS-CoV-2 assay is limited to personnel who have been trained in the procedures of a molecular diagnostic assay and the Abbott *m*2000 System.
- Laboratories are required to report all results to the appropriate public health authorities.
- The instruments and assay procedures reduce the risk of contamination by amplification product. However, nucleic acid contamination from the positive controls or specimens must be controlled by good laboratory practices and careful adherence to the procedures specified in this package insert.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- Optimal performance of this test requires appropriate specimen collection, storage, and transport to the test site (refer to the **SPECIMEN COLLECTION, STORAGE, AND TRANSPORT TO THE TEST SITE** section of this package insert).
- Detection of SARS-CoV-2 RNA may be affected by sample collection methods, patient factors (eg, presence of symptoms), and/or stage of infection.
- False-negative results may arise from degradation of the viral RNA during shipping/storage.
- The impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated.
- As with any molecular test, mutations within the target regions of Abbott RealTi*m*e SARS-CoV-2 assay could affect primer and/or probe binding resulting in failure to detect the presence of virus.
- Due to inherent differences between technologies, it is recommended that, prior to switching from one technology to the next, users perform method correlation studies in their laboratory to qualify technology differences. One hundred percent agreement between the results should not be expected due to aforementioned differences between technologies. Users should follow their own specific policies/procedures.
- Performance has only been established with the specimen types listed in the Intended Use. Other specimen types have not been evaluated and should not be used with this assay.
- Results should be interpreted by a trained professional in conjunction with the patient's history and clinical signs and symptoms, and epidemiological risk factors.
- Negative results do not preclude infection with the SARS-CoV-2 virus and should not be the sole basis of a patient treatment/management or public health decision. Follow up testing should be performed according to the current CDC recommendations.

CONDITIONS OF AUTHORIZATION FOR LABORATORIES

The Abbott RealTi*m*e SARS-CoV-2 assay Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

However, to assist clinical laboratories using the Abbott RealTi*m*e SARS-CoV-2 assay ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

A. Authorized laboratories[1] using your product must include with result reports of your product, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

B. Authorized laboratories using your product must use your product as outlined in the Authorized Labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

C. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.

D. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

E. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Abbott Molecular (email: molecularsupport@abbott.com; 1-800-553-7042) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

F. All laboratory personnel using your product must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

G. Abbott, authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[1] The letter of authorization refers to, "laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high complexity tests" as "authorized laboratories."

SPECIFIC PERFORMANCE CHARACTERISTICS

Limit of Detection (Analytical Sensitivity)

Limit of Detection (LOD) studies determine the lowest detectable concentration of SARS-CoV-2 at which greater than or equal to 95% of all (true positive) replicates test positive.

To determine the LOD, a recombinant virus containing SARS-CoV-2 RNA (Seracare, AccuPlex COVID-19, 1.3E+07 copies/mL as determined by digital PCR) was serially diluted in simulated nasal matrix (SNM). The initial LOD was determined by testing 4 levels at target concentrations of 900, 300, 100, and 33 copies/mL. Each panel member was tested in replicates of 3. The final LOD was confirmed by testing 4 panel members with target concentrations at 400, 300, 200, and 100 copies/mL tested in replicates of 21.

The results are summarized in **Table 1.** The lowest concentration level with observed positive rates ≥ 95% was 100 virus copies/mL.

Table 1. LOD Determination Using Recombinant Virus Containing SARS-CoV-2

Virus Copies/mL	GE/PCR[a]	Total Valid Replicates	Positive Replicates	Positive Rate (%)
400	12.5	21	21	100
300	9.4	21	21	100
200	6.2	21	21	100
100	3.1	21	20	95.2

[a] Genome equivalent per reaction (GE/PCR) was determined from calibration curve established using genomic RNA from SARS-Related Coronavirus 2, Isolate USA-WA1/2020 (BEI Resources, Catalog No. NR-52285).

FDA SARS-CoV-2 Reference Panel Testing

The evaluation of sensitivity and MERS-CoV cross-reactivity was performed on the Abbott RealTi*m*e SARS-CoV-2 assay using reference material (T1), blinded samples and a standard protocol provided by the FDA. The study included a range finding study and a confirmatory study for LOD. Blinded sample testing was used to establish specificity and to confirm the LOD. The results are summarized in **Table 2.**

Table 2. Summary of FDA SARS Reference Panel Results

Reference Materials Provided by FDA	Specimen Type	Product LOD	Cross-Reactivity
SARS-CoV-2	Nasopharyngeal Swab	2.7×10^3 NDU/mL	N/A
MERS-CoV		N/A	ND

NDU/mL = RNA NAAT detectable units/mL
N/A: Not applicable
ND Not detected

Inclusivity

Inclusivity was demonstrated by analyzing the sequences of the RdRp and N primer/probe sets for homology with 2,274,664 full-length sequences available in the GISAID database (http://www.gisaid.org) as of July 26, 2021. 2,272,192 sequences (99.9%) either have no mismatches in the assay target regions or have mismatches in one of the target regions. Among 2,472 sequences (0.1%) containing at least one mismatch in both target regions, all but 4 were predicted unlikely to impact the detection of SARS-CoV-2. Among 1,399,264 isolates with variant designation (including 987,776 Alpha, 28,244 Beta, 215,698 Delta, 51,794 Gamma, 51,361 Epsilon, 5,859 Eta, 46,224 Iota, 5,420 Kappa, 2,072 Lambda, 287 Theta and 4,529 Zeta), all were predicted unlikely to impact the detection of SARS-CoV-2. An additional analysis was also performed using 419,048 full-length SARS-CoV-2 sequences available in the NCBI database (https://www.ncbi.nlm.nih.gov/datasets/coronavirus/genomes/) as of September 3, 2021. 418,690 sequences (99.9%) either have no mismatches in the assay target regions or have mismatches in one of the target regions. Among 358 sequences (0.09%) containing at least one mismatch in both target regions, all but 3 were predicted unlikely to impact the detection of SARS-CoV-2.

Cross-reactivity

In Silico Analysis

Related pathogens, high prevalence disease agents and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimen have been evaluated in silico to identify the % homology between the selected probe/primer sequences and the sequence present in the microorganism.

The conclusion of this analysis is that there is limited opportunity for cross-reactivity to allow for false-positive reporting or affect performance of SARS-CoV-2 virus detection based upon the following:

- For many organisms, only one primer (forward or reverse) has >80% homology, making an amplified product unlikely.
- The probe is unlikely to bind for any of the hits (< 80% homology).
- Mismatches in the 3′ end of primers makes extension unlikely.
- For the N amplicon, two organisms with forward and reverse primers having >80% homology (LS483366.1, CP040804.1) have both primer binding sites on the same plus-sense strand and will not result in amplification.
- For the N amplicon, the remaining two organisms that may potentially give rise to amplicons due to both forward and reverse primers having >80% homology on opposite strands (CP000262.1, CP002888.1) have primer binding sites separated by >100,000 nucleotides in the bacterial chromosome, making amplification unlikely.

Overall, the results of this analysis predict no significant cross-reactivity or microbial interference.

Laboratory Testing

Cross reactivity performance of Abbott RealTi*m*e SARS-CoV-2 assay was evaluated by testing whole organisms or appropriate representative samples listed below in **Table 3**.

No cross-reactivity of the Abbott RealTi*m*e SARS-CoV-2 assay with the selected microorganisms was observed at the concentrations tested.

The results are summarized in **Table 3**.

Table 3. Abbott RealTi*m*e SARS-CoV-2 Cross-reactivity Summary

Microorganism	Concentration	Result (No. Positive/No. Tested)	Final Result
Human coronavirus 229E	1.00×10^5 Copies/mL	0/4	Negative
Human coronavirus OC43	1.00×10^5 Copies/mL	0/4	Negative
Human coronavirus HKU1	Clinical Isolates	0/2	Negative
Human coronavirus NL63	1.00×10^5 Copies/mL	0/4	Negative
SARS-coronavirus	25-28 (Ct range)	0/4	Negative
MERS-coronavirus	25-28 (Ct range)	0/4	Negative
Adenovirus (Ad. 71)	1.00×10^5 TCID50/mL	0/4	Negative
Human Metapneumovirus (hMPV)	Clinical Isolates	0/3	Negative
Parainfluenza virus 1	1.00×10^5 TCID50/mL	0/4	Negative
Parainfluenza virus 2	1.00×10^5 Copies/mL	0/4	Negative
Parainfluenza virus 3	5.00×10^5 TCID50/mL	0/4	Negative
Parainfluenza virus 4	Clinical Isolates	0/4	Negative
Influenza A (H1N1)	1.00×10^5 Copies/mL	0/4	Negative
Influenza A /(H3N2)	1.00×10^5 Copies/mL	0/4	Negative
Influenza B	1.00×10^5 Copies/mL	0/4	Negative
Enterovirus Type 71	1.00×10^5 TCID50/mL	0/4	Negative
Respiratory syncytial virus	1.00×10^5 Copies/mL	0/4	Negative
Rhinovirus	1.00×10^5 Copies/mL	0/4	Negative
Chlamydia pneumoniae	1.00×10^6 IFU/mL	0/4	Negative
Haemophilus influenzae	1.00×10^6 CFU/mL	0/4	Negative
Legionella pneumophila	1.00×10^6 CFU/mL	0/3	Negative
Mycobacterium tuberculosis	1.00×10^6 CFU/mL	0/4	Negative

Streptococcus pneumoniae	1.00 x 10^6 CFU/mL	0/4	Negative
Streptococcus pyogenes	1.00 x 10^6 CFU/mL	0/4	Negative
Bordetella pertussis	1.00 x 10^6 CFU/mL	0/3	Negative
Mycoplasma pneumoniae	1.00 x 10^6 CFU/mL	0/4	Negative
Pneumocystis jirovecii (PJP)	23-25 (Ct range)	0/4	Negative
Candida albicans	1.00 x 10^5 CFU/mL	0/4	Negative
Pseudomonas aeruginosa	1.00 x 10^6 CFU/mL	0/4	Negative
Staphylococcus epidermis	1.00 x 10^6 CFU/mL	0/4	Negative
S. salivarius	1.00 x 10^6 CFU/mL	0/4	Negative

Clinical Performance Evaluation

A clinical evaluation study was performed to evaluate the performance of the Abbott RealTi*m*e SARS-CoV-2 Assay using nasopharyngeal swab specimens. A total of 61 contrived positive specimens at approximately 1X to 2X LOD and 20x LOD were tested. Samples were contrived by spiking known concentrations of recombinant virus containing SARS-CoV-2 RNA sequences into negative patient specimens. In addition to the contrived positive specimens, 34 negative specimens were tested.

There were 21 total samples tested at the 1X to 2X LOD level with 20 results valid and included in the analysis. One result was invalid and excluded from the analysis. There were 40 total samples tested at 20x LOD with 40 results valid and included in the analysis. There were 34 total samples tested for the negative level with 31 results valid and included in the analysis and 3 results invalid and excluded from the analysis.

Table 4. Clinical Evaluation of the Abbott RealTi*m*e SARS-CoV-2 Assay

SARS-CoV-2 Concentration	Number Tested	Number Detected	% Detection
1X to 2X LOD[a]	20	20	100 (N=20/20)
20X LOD	40	40	100 (N=40/40)
Negative[b]	31	0	0 (N=0/31)

[a] One replicate was invalid and excluded from the analysis.

[b] Three replicates were invalid and excluded from the analysis.

	N	Agreement	95% Exact CI
PPA	60	100%	(94.0, 100.0)
NPA	31	100%	(88.8, 100.0)

PPA – Positive Percent Agreement

NPA – Negative Percent Agreement

An additional study evaluated the performance of the Abbott RealTi*m*e SARS-CoV-2 assay testing individual nasopharyngeal swab specimens (banked and acquired from a clinical lab). A total of 104 specimens were analyzed by both Abbott RealTi*m*e SARS-CoV-2 and Alinity m SARS-CoV-2 assays. Specimens acquired from the clinical lab were treated for viral inactivation at 65˚C for 30 minutes prior to analysis. The positive percent agreement (PPA) between the 2 assays was 95.9% (47/49) and the negative percent agreement (NPA) was 100% (55/55). The results are summarized in **Table 5**.

Table 5. Clinical Evaluation of the Abbott RealTi*m*e SARS-CoV-2 Assay

		Alinity m SARS-CoV-2	
		Positive	Negative
Abbott RealTi*m*e SARS-CoV-2	**Positive**	47	0
	Negative	2[a]	55

a These samples had an Alinity m SARS-CoV-2 CN >40.

	N	Agreement	95% Exact CI
PPA	49	95.9%	(86.0, 99.5)
NPA	55	100.0%	(93.5, 100.0)

BIBLIOGRAPHY

1. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009. [Also available online. *Type*> www.cdc.gov, *search*>BMBL>look up sections III and IV.]
2. US Department of Labor, Occupational Safety and Health Administration. 29 CFR Part 1910.1030. *Bloodborne Pathogens*.
3. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline—Fourth Edition*. CLSI Document M29-A4. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.
4. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva, Switzerland: World Health Organization; 2004.
5. Clinical and Laboratory Standards Institute. *Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods; Approved Guideline.* CLSI Document MM13-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2005.
6. Centers for Disease Control and Prevention (CDC). *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)*. Available online at: https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

Key to Symbols Used

For Prescription Use Only.


Caution


Warning


Manufacturer


Temperature Limitation

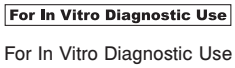

Consult Instructions For Use

In Vitro Diagnostic Medical Device

Lot Number


Use By

Reference Number



For In Vitro Diagnostic Use

In Vitro Test


Corrosive

IN VITRO DIAGNOSTIC MEDICAL DEVICE TECHNICAL ASSISTANCE

For technical assistance, call Abbott Technical Services at 1-800-553-7042, (within the US) or +49-6122-580 (outside the US), email molecularsupport@abbott.com, or visit the Abbott website at http://www.abbottmolecular.com.

Abbott Molecular Inc. is the legal manufacturer of the:

Abbott RealTi*me* SARS-CoV-2 Amplification Reagent Kit (List No. 09N77-095)

Abbott RealTi*me* SARS-CoV-2 Control Kit (List No. 09N77-085)

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

www.abbottmolecular.com
October 2021
51-608445/R6

Abbott

Abbott RealTi*me* SARS-CoV-2

Control Kit

en

REF 09N77-085

51-608446/R2

IVD **Rx ONLY**

REF 09N77-085

51-608446/R2

For use under an Emergency Use Authorization (EUA) Only.

For Prescription Use Only

NOTE: Changes Highlighted

Key to Symbols used

REF	List Number
IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
In Vitro Test	In Vitro Test
For In Vitro Diagnostic Use	For in Vitro Diagnostic Use
Rx ONLY	For Prescription Use Only.
	Expiration Date
CONTROL –	Negative Control
CONTROL +	Positive Control
	Temperature limit
	Consult instructions for use
	Warning
	Caution
	Manufacturer

Intended Use

The Abbott RealTi*me* SARS-CoV-2 controls are used to establish run validity of the Abbott RealTi*me* SARS-CoV-2 assay when used for the direct, qualitative detection of SARS-CoV-2 RNA; refer to the assay package insert for additional information.

Contents

1. CONTROL – **Abbott RealTi*me* SARS-CoV-2 Negative Control (8 vials, 1.3 mL per vial)** Contains 1.0% ammonium sulfate and 7.9% detergent in a buffer solution.
2. CONTROL + **Abbott RealTi*me* SARS-CoV-2 Positive Control (8 vials, 1.3 mL per vial)** Contains non-infectious, recombinant Sindbis virus containing SARS-CoV-2 RNA sequences, 1.0% ammonium sulfate, and 7.9% detergent in a buffer solution.

- The Abbott RealTi*me* SARS-CoV-2 controls are intended for single-use only and unused reagents should be discarded.
- The Abbott RealTi*me* SARS-CoV-2 Control Kit must only be used with the Abbott RealTi*me* SARS-CoV-2 assay (List No. 09N77-095).

Warnings and Precautions

- For In Vitro Diagnostic Use under the FDA Emergency Use Authorization
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
  - This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
  - The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- Do not use beyond expiration date.
- For Prescription Use Only.

CAUTION: This preparation contains human sourced and/or potentially infectious components. No known test method can offer complete assurance that products derived from human sources or inactivated micro-organisms 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,[1] OSHA Standards on Bloodborne Pathogens, [2] CLSI Document M29-A4,[3] and other appropriate biosafety practices. [4] 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 1.0% sodium hypochlorite or other suitable disinfectant.[1]
- Decontaminate and dispose of all potentially infectious materials in accordance with local, state and federal regulations.[4]

Components of the Abbott RealTi*me* SARS-CoV-2 Control Kit (List No. 09N77-85) contain the following components:

- Abbott RealTi*me* SARS-CoV-2 Negative Control
- Abbott RealTi*me* SARS-CoV-2 Positive Control

The following warnings apply:

Danger: Hazard-determining components of labeling:
Lithium dodecyl sulphate
Lithium hydroxide monohydrate

H318	Causes serious eye damage.
H316	Causes mild skin irritation.*
P280	Wear protective gloves / protective clothing / eye protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor physician.
P332+P313	If skin irritation occurs: Get medical advice attention.*

* Not applicable where regulation EC 1272/2008 (CLP) or OSHA Hazard Communication 29 CFR 1910.1200 (HCS) 2012 have been implemented.

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

Consult the Abbott RealTi*me* SARS-CoV-2 Package Insert.

The Abbott RealTi*me* SARS-CoV-2 Negative and Positive Controls must be stored at -25˚C to -15˚C

Shipping Conditions

Abbott RealTi*me* SARS-CoV-2 Control Kit: Ship on dry ice. If you receive reagents that are in a condition contrary to label recommendation, or that are damaged, contact your Abbott Representative.

BIBLIOGRAPHY

1. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009. [Also available online. *Type*> www.cdc.gov, *search*>BMBL>*look up* sections III and IV.]
2. US Department of Labor, Occupational Safety and Health Administration. 29 CFR Part 1910.1030. *Bloodborne Pathogens*.
3. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline—Fourth Edition*. CLSI Document M29-A4. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.
4. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva, Switzerland: World Health Organization; 2004.

CUSTOMER SERVICE:

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

For technical assistance, call Abbott Technical Services at 1-800-553-7042, email molecularsupport@abbott.com, or visit the Abbott website at http://www.abbottmolecular.com.

Abbott RealTi*me* is a trademark of Abbott Laboratories.

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

November 2021
51-608446/R2

Abbott

Abbott Universal Collection Kit

en

REF 09N77-055

51-608451/R3

REF 09N77-055

51-608451/R3

For use under an Emergency Use Authorization (EUA) Only.

For Prescription Use Only.

Rx ONLY

IVD

NOTE: Changes Highlighted

Key to Symbols	
REF	Reference Number
IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
In Vitro Test	In Vitro Test
For In Vitro Diagnostic Use	For In Vitro Diagnostic Use
Rx ONLY	For Prescription Use Only
	Use By
UNIT	Unit
TRANSPORT BUFFER	Transport Buffer
SPECIMEN COLLECTION SWAB	Specimen Collection Swab
PRODUCED BY	Produced By
	Temperature Limit
	Consult Instructions for Use
	Do Not Reuse
	Do Not Use if Package is Damaged
	Peel Open Here
	Manufacturer

CUSTOMER SERVICE: 1-800-553-7042

www.molecular.abbott

INTRODUCTION

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

NAME

Abbott Universal Collection Kit

INTENDED USE

The Abbott Universal Collection Kit is intended for the collection and transport of anterior nasal swabs, self-collected at a health care location or collected by a healthcare worker, and mid-turbinate nasal swabs and oropharyngeal (OP) swabs collected by a healthcare worker, and transport of nasopharyngeal (NP) swabs from the collection site to the testing laboratory.

SUMMARY AND EXPLANATION OF THE TEST

The Abbott Universal Collection Kit contains a Transport Tube and an individually packaged sterile Specimen Collection Swab that is placed into the Transport Tube after swab sampling. The Transport Tube contains 1.6 mL of Transport Buffer and is used to stabilize nucleic acid until sample preparation.

REAGENTS

Abbott Universal Collection Kit

Each case of Abbott Universal Collection Kit (List No. 09N77-055) contains 500 individually-wrapped Abbott Universal Collection Kits.

Each non-reusable Abbott Universal Collection Kit contains the following:

- One Transport Tube with Solid Cap containing 1.6 mL Transport Buffer (guanidine thiocyanate in Tris buffer)
- One sterile Specimen Collection Swab

Component	Quantity
Abbott Universal Collection Kit	50 individually-wrapped Abbott Universal Collection Kits per box, 10 boxes per case

Read the instructions in this package insert and associated Assay package insert carefully before processing samples.

WARNINGS AND PRECAUTIONS

For In Vitro Diagnostic Use Under the FDA Emergency Use Authorization.

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- This product is for use with a test authorized only for the detection of nucleic acid from SARS CoV-2, not for any other viruses or pathogens;
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

For Prescription Use Only.

IVD

For Use Under An Emergency Use Authorization Only.

The Abbott Universal Collection Kit is only for in vitro diagnostic use under the FDA Emergency Use Authorization.

For Prescription Use Only.

For In Vitro Diagnostic Use Only.

1. Do not use the Abbott Universal Collection Kit if the package is damaged, the seal is broken or if buffer has leaked from the tube. Discard unused, damaged, or leaking kits in accordance with local, state, and federal regulations.
2. Do not use the Abbott Universal Collection Kit beyond its expiration date.
3. Wear disposable gloves while handling specimens and wash hands thoroughly afterward. Use of protective eyewear is recommended.
4. Optimal performance of the associated assay requires adequate specimen collection and handling.
5. The swab must remain in the Transport Tube after specimen collection and for transport to testing sites. Remove solid cap prior to testing.

6. Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials in accordance with local, state, and federal regulations.[1,2]
7. This product is not classified as dangerous as defined in 29 CFR 1910.1200 (OSHA Hazard Communication Standard). Safety data sheet (SDS) for Abbott Universal Collection Kit (List No. 09N77-055) is available upon request.
8. Do not ingest or expose skin/eyes to the Abbott Universal Collection Kit Transport Buffer.

Safety Precautions

Wear disposable gloves while handling specimens and wash hands thoroughly afterward. Use of protective eyewear is recommended.

CAUTION: This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and handled with appropriate biosafety practices.[1,2]

Components of the Abbott Universal Collection Kit Transport Buffer contain the following components:

Guanidine thiocyanate

Warning

The following warnings and precautions apply to:
Guanidine thiocyanate

EUH032	Contact with acids liberates very toxic gas.
P501	Dispose of contents/container in accordance with local regulations.

Important information regarding the safe handling, transport, and disposal of this product is contained in the Safety Data Sheet. Safety Data Sheets are available from your Abbott Representative.

Shipping Conditions

	Shipment Condition
Abbott Universal Collection Kit	15 to 30°C

Storage Instructions

	Storage Temperature	Maximum Storage Time
Unopened	15 to 30°C	Until expiration date

SPECIMEN COLLECTION, STORAGE, AND TRANSPORT TO THE TEST SITE

Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)[3] https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html, or the FDA FAQs on Diagnostic Testing for SARS-CoV-2 https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2

An Abbott Universal Collection Kit (List No. 09N77-055) can be used for the transport of nasopharyngeal swab specimens or the collection and transport of nasal and oropharyngeal swab specimens from the collection site to the testing laboratory. **The swab is not authorized for nasopharyngeal specimen collection.** The Transport Tube contains 1.6 mL of Transport Buffer which is used to stabilize nucleic acid until sample preparation.

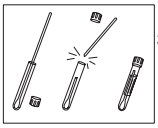
SPECIMEN COLLECTION PROCEDURES

SELF-COLLECTED NASAL SWAB SPECIMEN

Ensure that patients read and understand the Nasal Swab Collection instructions before providing them with an Abbott Universal Collection Kit. Instructions for self-collected nasal swab specimens are provided in **Appendix A.**

CLINICIAN-COLLECTED ANTERIOR NASAL SWAB SPECIMEN COLLECTION

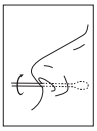
CAUTION: Do NOT expose swab to Transport Buffer prior to collection.

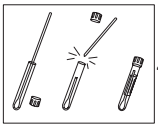


1. Remove the sterile swab from the wrapper, taking care not to touch swab tip or lay it down on any surface. Do not pre-wet swab.
2. Collect patient specimen per CDC guidelines.[3]
   - Insert the entire collection tip of the swab provided (usually ½ to ¾ of an inch, or 1 to 1.5 cm) inside the nostril.
   - Firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall at least 4 times.
   - Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present on the swab.
   - Repeat in the other nostril using the same swab.
3. Handle the cap and tube carefully to avoid contamination, including the outside of the transport tube and cap. If necessary, change gloves.
4. Unscrew the transport tube cap and immediately place the specimen collection swab into the transport tube so that the white tip is down.
5. Carefully break the swab at the scored line on the shaft; use care to avoid splashing of contents.
6. Recap the transport tube. Ensure the cap seals tightly. The cap must be tight or leakage may occur.
7. Label the transport tube with sample identification information, including date of collection using an adhesive label. It is recommended that each tube be placed in an individual, sealable bag prior to transport.

CLINICIAN-COLLECTED MID-TURBINATE NASAL SWAB SPECIMEN COLLECTION

CAUTION: Do NOT expose swab to Transport Buffer prior to collection.





1. Remove the sterile swab from the wrapper, taking care not to touch swab tip or lay it down on any surface. Do not pre-wet swab.
2. Collect patient specimen per CDC guidelines.[3]
   - Tilt patient's head back 70 degrees.
   - While gently rotating the swab, insert swab less than one inch (about 2 cm) into nostril parallel to the palate (not upwards) until resistance is met at turbinates.
   - Rotate the swab several times against nasal wall and repeat in other nostril using the same swab.
3. Handle the cap and tube carefully to avoid contamination, including the outside of the transport tube and cap. If necessary, change gloves.
4. Unscrew the transport tube cap and immediately place the specimen collection swab into the transport tube so that the white tip is down.
5. Carefully break the swab at the scored line on the shaft; use care to avoid splashing of contents.
6. Recap the transport tube. Ensure the cap seals tightly. The cap must be tight or leakage may occur.
7. Label the transport tube with sample identification information, including date of collection using an adhesive label. It is recommended that each tube be placed in an individual, sealable bag prior to transport.

CLINICIAN-COLLECTED NASOPHARNYGEAL SWAB TRANSPORT

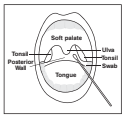
CAUTION: The Abbott Universal Collection kit supports only the following steps for transport of nasopharyngeal (NP) swabs from the collection site to the testing laboratory.

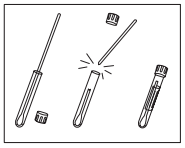
The specimen collection swab provided in this kit is not authorized for nasopharyngeal specimen collection. Follow CDC guidance for nasopharyngeal swab collection.[3]

1. Handle the cap and tube carefully to avoid contamination, including the outside of the transport tube and cap. If necessary, change gloves.
2. Unscrew the transport tube cap and immediately place the swab into the transport tube so that the swab tip is down.
3. If necessary, carefully break any swab shaft that protrudes out of the tube; use care to avoid splashing of contents.
4. Recap the transport tube. Ensure the cap seals tightly. The cap must be tight or leakage may occur.
5. Label the transport tube with sample identification information, including date of collection using an adhesive label. It is recommended that each tube be placed in an individual, sealable bag prior to transport.

CLINICIAN-COLLECTED OROPHARNYGEAL SWAB SPECIMEN COLLECTION

CAUTION: Do NOT expose swab to Transport Buffer prior to collection.





1. Remove the sterile swab from the wrapper, taking care not to touch swab tip or lay it down on any surface. Do not pre-wet swab.
2. Collect patient specimen per CDC guidelines.[3]
3. Handle the cap and tube carefully to avoid contamination, including the outside of the transport tube and cap. If necessary, change gloves.
4. Unscrew the transport tube cap and immediately place the specimen collection swab into the transport tube so that the white tip is down.
5. Carefully break the swab at the scored line on the shaft; use care to avoid splashing of contents.
6. Recap the transport tube. Ensure the cap seals tightly. The cap must be tight or leakage may occur.
7. Label the transport tube with sample identification information, including date of collection using an adhesive label. It is recommended that each tube be placed in an individual, sealable bag prior to transport.

SWAB SPECIMEN STORAGE AND TRANSPORT

- After collection, transport and store transport tube at 2 to 25°C for up to 48 hours.
- If delivery and processing exceed 48 hours, specimens should be transported in dry ice and once in laboratory frozen at −70°C or colder.

For domestic or international shipments, specimens must be packaged, shipped, and transported according to the current edition of the International Air Transport Association (ATA) Dangerous Goods Regulation. Follow shipping regulations for UN 3373 Biological Substance, Category B when sending potential SARS-CoV-2 specimens.

CONDITIONS OF AUTHORIZATION FOR LABORATORIES

The Alinity m SARS-CoV-2 assay Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd. However, to assist clinical laboratories using the Alinity m SARS-CoV-2 assay ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

A. Authorized laboratories[1] using your product will include with result reports of your product, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

B. Authorized laboratories using your product will use your product as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

C. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.

D. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

E. Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Abbott (email: molecularsupport@abbott.com; 1-800-553-7042) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

F. All laboratory personnel using your product must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

G. Abbott, authorized distributors, and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[1] The letter of authorization refers to, Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate and high complexity tests" as "authorized laboratories."

BIBLIOGRAPHY

1. Clinical and Laboratory Standards Institute (CLSI). *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. CLSI Document M29-A4. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.
2. US Environmental Protection Agency. *EPA Guide for Infectious Waste Management Publication No. EPA/530-SW-86-014*. Washington, DC: US Environmental Protection Agency. 1986:1-1–5-5, R1-R3, A1-A24.
3. Centers for Disease Control and Prevention (CDC). *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)*. Accessed April 8, 2020. https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html
4. Specimen Collection – Part 4 Obtaining a Nasal Swab. *Nursing Times.* 2008;104(20). Accessed April 8, 2020. https://cdn.ps.emap.com/wp-content/uploads/sites/3/2008/05/20080520_Specimen-collection-Part-4-Obtaining-a-nasal-swab.pdf

IN VITRO DIAGNOSTIC MEDICAL DEVICE

TECHNICAL ASSISTANCE

For technical assistance, call Abbott Technical Services at 1-800-553-7042, email molecularsupport@abbott.com, or visit the Abbott website at http://www.molecular.abbott

The Abbott Universal Collection Kit is manufactured for Abbott Molecular Inc. by MML Diagnostics Packaging, Inc., Troutdale, OR 97060 USA.

Abbott Molecular Inc. is the legal manufacturer of the Abbott Universal Collection Kit (List No. 09N77-055)

MML Diagnostics Packaging, Inc. is the legal manufacturer of the Specimen Collection Swab.

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

November 2021
51-608451/R3

Abbott

Abbott Universal Collection Kit

Appendix A: Self-Collected Nasal Swab Instructions

IVD

- **For In Vitro Diagnostic Use Only**

Your kit contains the following:

- One Transport Tube containing a liquid
- One Sterile Specimen Collection Swab

CAUTION: DO NOT touch the white tip of the swab or lay the swab down. If the white tip is touched or the swab is laid down or dropped, your results may not be accurate. You need to request a new Abbott Universal Collection Kit.

DO NOT pre-wet the collection swab with the liquid in the Transport Tube before collecting a sample.

DO NOT ingest or expose skin/eyes to the liquid in the Transport Tube.
IF exposed or concerned: Get medical advice/attention.

PRE-COLLECTION STEPS

1. Wash your hands with soap and water thoroughly before starting and after completing all steps.
2. Open the kit package. Do not open the transport tube. Set the tube aside on a clean, dry surface before beginning collection.

COLLECTION STEPS

3. Remove the swab from the wrapper with your clean hands. Hold the swab with the white tip up (Shown in Diagram 1). Do not touch the tip of the swab to anything.
4. Holding the swab with one hand, gently insert the white tip of the swab about ½ to ¾ inches (1 to 2 cm) into the opening of your nose (Shown in Diagram 2). Rotate the swab for 15 to 30 seconds. Make sure the swab touches the insides of your nose. Remove the swab from your nose being careful not to touch your skin. Do not set the swab down. Repeat in the other nostril.
5. While still holding the swab, unscrew and remove the cap from the transport tube without setting the cap down. Place the swab into the tube with the white tip down (Shown in Diagram 3 and 4). If the transport tube spills or liquid splashes out, you will need to request a new Universal Collection Kit.
6. Break off the top of the swab along the score line. (The score line is made to break easily). Try not to spill or splash any of the liquid out of the transport tube. Screw the cap back onto the transport tube tightly (Shown in Diagram 5).
7. Return the transport tube containing the swab to the healthcare provider.

Diagram 1	Diagram 2	Diagram 3	Diagram 4	Diagram 5