Alinity m

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REF 09N79-096
53-608211/R6

Resp-4-Plex AMP Kit

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REF 09N79-096
53-608211/R6

NOTE: Changes highlighted

For Use Under an Emergency Use Authorization (EUA) Only.
For Prescription Use Only.

Rx ONLY

IVD

CUSTOMER SERVICE: 1-800-553-7042
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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

Alinity m Resp-4-Plex AMP Kit

INTENDED USE

The Alinity m Resp-4-Plex assay is a multiplex real-time reverse transcription (RT) polymerase chain reaction (PCR) test intended for the simultaneous qualitative detection and differentiation of RNA from SARS-CoV-2, influenza A virus (flu A), influenza B virus (flu B), and/or Respiratory Syncytial Virus (RSV) in anterior nasal or nasopharyngeal swab specimens collected by a healthcare provider (HCP), or in anterior nasal swab specimens that are self-collected at a healthcare location, from individuals suspected by their HCP of respiratory viral infection consistent with COVID-19. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2, influenza, and RSV can be similar. 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 moderate or high complexity tests.

Results are for the identification and differentiation of RNA from influenza A, influenza B, RSV, and SARS-CoV-2. The Alinity m Resp-4-Plex assay is not intended to detect influenza C virus. RNA from influenza A, influenza B, RSV, and SARS-CoV-2 is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of active infection but do not rule out bacterial infection or co-infection with other pathogens not detected by the test. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

Negative results do not preclude influenza A, influenza B, RSV, or 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.

Testing with the Alinity m Resp-4-Plex assay is intended for use by trained operators who are proficient in performing tests using the Alinity m system and in vitro diagnostic procedures. The Alinity m Resp-4-Plex assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION OF THE TEST

The Alinity m Resp-4-Plex assay is a multiplex real-time reverse transcription (RT) polymerase chain reaction (PCR) test for use with the automated Alinity m System for the qualitative detection and differentiation of RNA from flu A, flu B, RSV, and SARS-CoV-2 in respiratory specimens from individuals suspected of a respiratory viral infection consistent with COVID-19.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The Alinity m Resp-4-Plex assay consists of 2 reagent kits:

- Alinity m Resp-4-Plex AMP Kit
- Alinity m Resp-4-Plex CTRL Kit

The Alinity m Resp-4-Plex assay detects flu A, flu B, RSV, SARS-CoV-2, and internal control (IC) target sequences through the use of target-specific fluorescent-labeled oligonucleotide probes. The probes do not generate a detectable signal unless they are specifically bound to the amplified product. The 2 SARS-CoV-2-specific probes are labeled with the same fluorophore and the flu A, flu B, RSV, and IC-specific probes are each labeled with distinct fluorophores, thus allowing for simultaneous detection and differentiation of amplified products of all 4 viruses and IC in a single reaction vessel.

An RNA sequence that is unrelated to the flu A, flu B, RSV, and SARS-CoV-2 sequences is introduced into each sample at the beginning of sample preparation. This unrelated RNA sequence is simultaneously amplified by RT-PCR and serves as an IC to demonstrate that the process has proceeded correctly for each sample.

The Alinity m Resp-4-Plex assay is to be used with the Alinity m System, which performs sample preparation, RT-PCR assembly, amplification, detection, result analysis and reporting. All testing steps of the Alinity m Resp-4-Plex assay procedure are executed automatically by the Alinity m System.

The Alinity m System is a continuous random access analyzer that can perform the Alinity m Resp-4-Plex assay in parallel with other Alinity m assays on the same instrument.

Application parameters specific to Alinity m Resp-4-Plex assay are contained in an assay-specific application specification file, which is distributed electronically and loaded onto the Alinity m System.

Sample Preparation

The Alinity m System provides automated sample preparation using the Alinity m Sample Prep Kit 2, Alinity m Lysis Solution, and Alinity m Diluent Solution. The purpose of sample preparation is to extract and concentrate the target RNA molecules to make the target accessible for amplification, and to remove potential inhibitors of amplification from the extract. The Alinity m System employs magnetic microparticle technology to facilitate nucleic acid capture, wash, and elution. 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 sample.

During the sample preparation protocol, flu A, flu B, RSV, and/or SARS-CoV-2 virions are disrupted by lysis reagent, nucleic acids are captured on the magnetic microparticles, and inhibitors and unbound sample components are removed by washing steps within the Integrated Reaction Unit (IRU).

The resulting purified RNA is combined with liquid unit-dose Alinity m Resp-4-Plex activation reagent and liquid unit-dose Alinity m Resp-4-Plex amplification/detection reagent and transferred into a reaction vessel. Alinity m Vapor Barrier Solution is then added to the reaction vessel which is then transferred to an amplification/detection unit for reverse transcription, PCR amplification, and real-time fluorescence detection.

A positive control and a negative control are processed in the same manner and tested at least once every 24 hours to help confirm that instrument and reagent performance remain satisfactory.

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Amplification

During the amplification reaction, the target RNA is converted to cDNA by the reverse transcriptase. The flu A, flu B, RSV, and 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 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 exponential amplification of target sequences. Amplification of the 6 targets (flu A, flu B, RSV, SARS-CoV-2 RdRp gene, SARS-CoV-2 N gene, and IC) takes place simultaneously in the same reaction mixture.

The target sequences for the Alinity m Resp-4-Plex assay are:

- the RdRp and N genes of the SARS-CoV-2 genome
- the Matrix gene of the flu A genome
- the Nonstructural 1 gene of the flu B genome
- the Matrix gene of the RSV genome

The selected target sequences are highly conserved and also specific to the target viruses.

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. A gene from the pumpkin plant was selected for the IC so that it is not competitive with any microorganism or human sequence of interest that may be in the specimen.

Detection

Fluorescent detection of amplification products occurs as the flu A, flu B, RSV, SARS-CoV-2, and IC probes anneal to their targets (real-time fluorescence detection). The probes have a fluorescent moiety that is covalently linked to the 5′ end and have a quencher molecule at the 3′ end. In the absence of target sequences, probe fluorescence is quenched. In the presence of target sequences, hybridization to complementary sequences separates the fluorophore and the quencher and allows fluorescent emission and detection.

The Alinity m Resp-4-Plex assay detects the flu A, flu B, RSV, SARS-CoV-2 and IC target sequences through the use of target-specific fluorescent-labeled oligonucleotide probes. The probes do not generate a detectable signal unless they are specifically bound to the amplified product. The 2 SARS-CoV-2-specific probes are labeled with the same fluorophore and the flu A, flu B, RSV, and IC-specific probes are each labeled with distinct fluorophores, thus allowing for simultaneous detection and differentiation of all 4 viruses and IC amplified products in a single reaction vessel.

PREVENTION OF NUCLEIC ACID CONTAMINATION

The possibility of nucleic acid contamination on the Alinity m System is minimized because:

- Aerosol barrier pipette tips are used for all pipetting. The pipette tips are discarded after use.
- PCR amplification and detection are carried out automatically in a sealed reaction vessel.
- Disposal of the reaction vessel into the waste container is performed automatically by the Alinity m System.

For additional information on system and assay technology, refer to the Alinity m System Operations Manual, Section 3.

REAGENTS

Alinity m Resp-4-Plex AMP Kit (List No. 09N79-096)

- Alinity m Resp-4-Plex AMP Kit (List No. 09N79-096) is comprised of 2 types of multi-well trays: Alinity m Resp-4-Plex AMP TRAY 1 and Alinity m Resp-4-Plex ACT TRAY 2.
- Each Alinity m Resp-4-Plex AMP TRAY 1 (individually packed in a foil pouch) contains 48 unit-dose liquid amplification reagent wells and 48 unit-dose liquid IC wells. One well of each is used per test. Amplification reagent wells consist of synthetic oligonucleotides, DNA polymerase, reverse transcriptase, dNTPs and 0.15 % ProClin® 950 in a buffered solution. Internal control (IC) wells consist of noninfectious Armored RNA® with unrelated IC sequences in negative human plasma. Negative human plasma was tested and found to be nonreactive for HBsAg, HIV-1 antigen, Syphilis, HIV-1 RNA, HCV RNA, HBV DNA, antibody to HCV, antibody to HIV-1, and antibody to HIV-2. Preservative: 0.15% ProClin 950.
- Each Alinity m Resp-4-Plex ACT TRAY 2 (individually packed in a foil pouch) contains 48 unit-dose liquid activation reagent wells. One reagent well is used per test. Activation reagent wells consist of magnesium chloride and tetramethylammonium chloride. Preservative: 0.15% ProClin 950.

	Quantity
▽Σ	192 tests
Alinity m Resp-4-Plex AMP TRAY 1	4 trays / 48 tests each
Alinity m Resp-4-Plex ACT TRAY 2	4 trays / 48 tests each

WARNINGS AND PRECAUTIONS

IVD

- **For In Vitro Diagnostic Use Under the FDA Emergency Use Authorization.**
- For use under an Emergency Use Authorization.
- Do not use beyond expiration date.
- For Prescription Use 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 moderate or high complexity tests;
- This product has been authorized by FDA under an EUA for use by authorized laboratories certified under CLIA to perform moderate or high complexity tests.
- This product has been authorized only for the detection and differentiation of nucleic acid from influenza A, influenza B, Respiratory Syncytial Virus and 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 the authorization is revoked sooner.
- Quality control requirements must be performed in conformance with local, state, and/or federal regulations or accreditation requirements and your laboratory's standard quality control procedures.

Safety Precautions

The following warnings and precautions apply to:
Alinity m Resp-4-Plex AMP TRAY 1.

WARNING	Contains 2-Methyl-4-isothiazolin-3-one
H317	May cause an allergic skin reaction.
Prevention	
P261	Avoid breathing mist / vapors / spray
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
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 it before reuse.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

 **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-1 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]

The following warnings and precautions apply to:
Alinity m Resp-4-Plex ACT TRAY 2.

DANGER	Contains Tetramethylammonium chloride, and 2-Methyl-4-isothiazolin-3-one
H302	Harmful if swallowed.
H316	Causes mild skin irritation.[a]
H317	May cause an allergic skin reaction.
H370	Causes damage to organs.
H412	Harmful to aquatic life with long lasting effects.
Prevention	
P260	Do not breathe mist / vapors / spray.
P264	Wash hands thoroughly after handling.
P272	Contaminated work clothing should not be allowed out of the workplace.
P273	Avoid release to the environment.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P302+P352	IF ON SKIN: Wash with plenty of water.
P308+P311	IF exposed or concerned: Call a POISON CENTER / doctor.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

[a] Not applicable where regulation EC 1272/2008 (CLP) or OSHA Hazard Communication 29 CFR 1910.1200 (HCS) 2012 have 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.

For a detailed discussion of safety precautions during system operation, refer to the Alinity m System Operations Manual, Section 7 and Section 8.

Reagent Shipment

	Shipment Condition
Alinity m Resp-4-Plex AMP Kit	On dry ice

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

Reagent Storage

In order to minimize damage to foil pouches, it is recommended that the Alinity m Resp-4-Plex AMP TRAY 1 (AMP TRAY 1) and Alinity m Resp-4-Plex ACT TRAY 2 (ACT TRAY 2) are stored in the original kit packaging. Thaw reagent trays and open the foil pouch for the reagent trays just prior to loading on the Alinity m System. Onboard storage time begins when reagents are thawed and immediately loaded on the Alinity m System.

	Storage Temperature	Maximum Storage Time
Unopened	−25 to −15°C	Until expiration date
Onboard	System Temperature	96 hours (not to exceed expiration date)

Reagent Handling

- Do not use reagents that have been damaged.
- IMPORTANT: Immediately prior to use on the Alinity m System, thaw amplification reagents at 15 to 30°C or at 2 to 8°C. Onboard storage time begins immediately after thaw. See ASSAY PROCEDURE section for additional instructions.
- Minimize contact with the surface of reagent trays during handling.
- Up to 2 lots of assay trays (AMP TRAY 1 and ACT TRAY 2) can be loaded on each Alinity m Assay Tray Carrier, as long as the AMP TRAY 1 and ACT TRAY 2 from the same AMP kit lot are included together as a set.
- The Alinity m System will track the onboard storage time of AMP TRAY 1 and ACT TRAY 2 while on the Alinity m System. The Alinity m System will not allow the use of AMP TRAY 1 and ACT TRAY 2 if the maximum onboard storage time has been exceeded.
  IMPORTANT: The maximal allowable onboard storage for the Alinity m Resp-4-Plex AMP TRAY 1 and ACT TRAY 2 is 96 hours from thaw/onboarding.
- For a detailed discussion of reagent handling precautions during system operation, refer to the Alinity m System Operations Manual, Section 8.

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 flu A, flu B, RSV, and/or SARS-CoV-2 RNA.
- Laboratories within the United States and its territories are required to report all SARS-CoV-2 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 Alinity m Resp-4-Plex assay and the Alinity m System should perform this procedure.
- Always follow best laboratory practices to monitor for potential contamination and unexpected positive results.

Handling Precautions for Specimens

- The Alinity m Resp-4-Plex assay is only for use with anterior nasal and nasopharyngeal swab 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 nucleic acid amplification.
- 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 small amount of amplification product. Measures to reduce the risk of contamination in the laboratory include physically separating the activities involved in the handling of contaminated waste in compliance with good laboratory practices.

INDICATION OF INSTABILITY OR DETERIORATION OF REAGENTS

- Deterioration of the reagents may be indicated when a control error occurs or controls are repeatedly out of the specified ranges.
- Reagents are shipped on dry ice and are stored at −25 to −15°C upon arrival. If reagents arrive in a condition contrary to this recommendation or are damaged, immediately contact your Abbott Representative.
- For troubleshooting information, refer to the Alinity m System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The Alinity m Resp-4-Plex application specification file must be installed on the Alinity m System prior to performing the assay.

For a detailed description of system operating instructions, refer to the Alinity m System Operations Manual, Section 5.

SPECIMEN COLLECTION, STORAGE, AND TRANSPORT TO THE TEST SITE

Human anterior nasal and nasopharyngeal swab specimens can be used with the Alinity m Resp-4-Plex assay on the Alinity m System. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing for Patients with Suspected Novel Influenza A (H1N1) Virus Infection[6] (https://www.cdc.gov/h1n1flu/specimencollection.htm), CDC Influenza Specimen Collection guidelines (https://www.cdc.gov/flu/pdf/professionals/flu-specimen-collection-poster.pdf) and the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)[7] (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-testing-sars-cov-2).

An Abbott Universal Collection Kit (List No. 09N77-055) can be used for the collection and transport of anterior nasal swab specimens and the transport of nasopharyngeal swab specimens from the collection site to the testing laboratory. The Transport Tube contains Specimen Transport Buffer which is used to stabilize nucleic acid until sample testing. 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 on dry ice and once in laboratory frozen at −70°C or colder for a maximum of 7 days prior to testing. When this transport tube is loaded on the sample rack of the instrument the swab can be kept in the tube if the solid cap is replaced with a pierceable cap list number 09N49-012.

Specimens in VTM (and its equivalents) can be stored at 5°C ± 3°C for a maximum of 80 hours prior to testing, or stored at −70°C or colder for a maximum of 7 days (with a maximum of 2 freeze/thaws) prior to testing. Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical, diagnostic, or biological specimens.

For domestic and international shipments, specimens must be packaged, 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.

Preparation for Analysis

Frozen specimen is thawed at 15 to 30°C or at 2 to 8°C.

Prior to processing, each specimen is vortexed 3 times for 2 to 3 seconds.

If needed, centrifuge specimens at 2000 *g* for 5 minutes before loading on the Alinity m System. Specimen can be transferred into an Alinity m Transport Tube or an Alinity m Aliquot Tube and/or recapped with an Alinity m Pierceable Cap before loading onto the Alinity m System.

IMPORTANT: Except where pierceable caps are used, swab and cap should be removed from the specimens before loading onto the Alinity m System.

Primary collection tubes may be used directly, if they meet the requirements listed in the tube type table in the Assay Procedure section below. All specimen tubes must be labeled with specimen ID barcodes or must be identified with a specimen ID, rack ID, and position in the rack. Refer to the Assay Procedure section of this package insert for tube sizes and requirements for minimum sample volume and use of caps. Avoid touching the inside of the cap when opening tubes.

PROCEDURE

Materials Provided

- Alinity m Resp-4-Plex AMP Kit (List No. 09N79-096)

Materials Required But Not Provided

- 08N53-002 Alinity m System with software version 1.5.2 or higher
- 09N79-086 Alinity m Resp-4-Plex CTRL Kit
- 09N12-001 Alinity m Sample Prep Kit 2
- 09N20-001 Alinity m Lysis Solution
- 09N20-003 Alinity m Diluent Solution
- 09N20-004 Alinity m Vapor Barrier Solution
- 09N79-05E (v5.0 or higher) Alinity m Resp-4-Plex Application Specification File
- Vortex mixer
- Centrifuge capable of 2000 *g*
- Plate adapter for 384 well plates (eg, Eppendorf Catalog No. 022638955)
- Centrifuge with swing plate rotor capable of accommodating the plate adapter and capable of ≥ 100 *g*

For information on materials required for operation of the Alinity m System, refer to the Alinity m System Operations Manual, Section 1.

Other Optional Materials

- 09N77-055 Abbott Universal Collection Kit
- 09N49-010 Alinity m Transport Tube Pierceable Capped
- 09N49-011 Alinity m Transport Tube
- 09N49-012 Alinity m Pierceable Cap
- 09N49-013 Alinity m Aliquot Tube
- Viral transport medium (UVT/UTM)
- Sealable plastic bags

Procedural Precautions

- Read the instructions in this package insert carefully before processing samples.
- Use aerosol barrier pipette tips or disposable pipettes only 1 time when pipetting specimens. 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.
- Work area and instrument platforms must be considered potential sources of contamination.
- Ensure the Alinity m Resp-4-Plex AMP TRAY 1 and ACT TRAY 2 are centrifuged prior to loading on the Alinity m System per instructions in Assay Procedure section.
- Monitoring procedures for the presence of amplification target contamination can be found in the Alinity m System Operations Manual, Section 9.
- 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.
- To prevent contamination, change to new gloves before handling the Alinity m Sample Prep Kit 2, assay trays, system solutions, Integrated Reaction Unit (IRU) sleeves, and pipette tips. Also change to new gloves whenever they are contaminated by a specimen, a control, or a reagent. Always use powder-free gloves.
- The use of the Alinity m Resp-4-Plex CTRL Kit is integral to the performance of the Alinity m Resp-4-Plex assay. Refer to the QUALITY CONTROL PROCEDURES section of this package insert for details. Refer to the Alinity m Resp-4-Plex CTRL Kit package insert for preparation and usage.
- The Alinity m Resp-4-Plex control reagents are contained in single-use tubes with solid caps. Remove caps from the tube prior to use. Discard tubes after use.

ASSAY PROCEDURE

Thaw AMP TRAY 1 and ACT TRAY 2 at 15 to 30°C or at 2 to 8°C immediately prior to use.

Prior to loading on the Alinity m System, the AMP TRAY 1 and ACT TRAY 2 must be centrifuged as follows:

1. Load the trays onto the plate adapter (eg, Eppendorf Catalog No. 022638955).
2. Load the plate adapter (with the trays) on a swing plate centrifuge capable of accommodating the plate adapter. Spin at 100 to 800 *g* for 1 to 5 minutes to ensure reagents remain at the bottom of the well and to remove potential bubbles.
3. Immediately following centrifugation, carefully transfer the trays to the Alinity m Assay Tray Carriers. Take care to minimize disturbance to the trays. Load the tray carriers per the Alinity m System Operations Manual, Section 5.
4. If disturbance occurs during the transfer that could potentially introduce bubbles or displace reagents from the bottom of the wells (eg, dropping, bumping, inversion of the trays), re-centrifuge the trays.
5. Proceed with **Reagent and sample management** per the Alinity m System Operations Manual, Section 5.

For a detailed description of how to run an assay, refer to the Alinity m System Operations Manual, Section 5. Prior to testing specimens, check the control status. If control testing is required, refer to the **QUALITY CONTROL PROCEDURES** section. Controls may be tested separately or with specimens.

One PCR reaction can detect 1 or more pathogens with the Alinity m Resp-4-Plex assay. Therefore, only 1 patient specimen aliquot is required for detection of the selected assay(s).

To create a test order, select COV2_4PEUA for SARS-CoV-2 and any combination of the other 3 test target names to match the requested tests for each patient specimen. Refer to the following table.

Assay Name	Test Target
FLUA_4PEUA	Flu A
FLUB_4PEUA	Flu B
RSV_4PEUA	RSV
COV2_4PEUA	SARS-CoV-2

The testing results will be reported only for those test targets selected for the specimen in the test order.

A test result, for a test target that was not originally selected in the test order, may still be obtained without repeat testing, within a user-configured period of time. Refer to Alinity m System Operations Manual, Section 5 Operating Procedures, Stored Result Retrieval subsection.

The Alinity m System will track the onboard storage time of AMP TRAY 1, ACT TRAY 2, controls, and specimens while on the Alinity m System. The Alinity m System will not allow the use of AMP TRAY 1, ACT TRAY 2, controls, or process specimens that have exceeded the allowable onboard storage time setting by the system.

IMPORTANT: The maximal allowable onboard storage for Alinity m Resp-4-Plex AMP TRAY 1 and ACT TRAY 2 is 96 hours from thaw/onboarding.

Specimen tubes need to meet the requirements below for sample volumes and use of caps when loaded on the Alinity m System.

Tube Type[a]	List No.	Minimum Volume Required	Maximum Volume	Cap Requirement on Instrument
Alinity m Aliquot Tube	09N49-013	0.8 mL	3.5 mL	Uncapped[b]
Alinity m Transport Tube	09N49-011	1.0 mL	3.5 mL	Uncapped[b]
Alinity m Transport Tube Pierceable Capped	09N49-010	1.0 mL	3.5 mL	Uncapped[b]/Capped[c]
Alinity m Transport Tube where Pierceable Cap (09N49-012) is added	09N49-011, 09N49-012	1.0 mL	3.5 mL	Capped[c]
Abbott Universal Collection Kit	09N77-055	1.0 mL	3.5 mL	Uncapped[b]
Abbott Universal Collection Tube where Pierceable Cap (09N49-012) is added	09N77-055, 09N49-012	1.0 mL	3.5 mL	Capped[c]
Tube with 11.5 – 14.0 mm diameter		1.3 mL	2.5 mL	Uncapped[b]
Tube with 14.5 – 16.0 mm diameter		1.4 mL	3.5 mL	Uncapped[b]

[a] Refer to the Alinity m System Operations Manual, Section 4, for sample tube specifications and requirements and Section 5 for sample rack loading instructions.

[b] Avoid touching the inside of the cap when opening the tubes.

[c] Avoid touching inside of the cap when replacing or adding a new cap. Avoid touching the septum when handling the sample tubes.

Place the uncapped positive and negative controls, if applicable, and patient specimens into the sample rack. If used, bar codes on tube labels must face the correct orientation for scanning.

When loading Alinity m Transport Tubes with pierceable caps onto the Alinity m System, the Sample Rack Retention Bar is required. Clean the retention bar after each use per the instructions in the Alinity m Systems Operations Manual Section 9.

QUALITY CONTROL PROCEDURES

Detection of Inhibition

A defined, consistent quantity of IC is introduced into each specimen and control at the beginning of sample preparation and measured on the Alinity m System to demonstrate proper specimen processing and assay validity.

A Message Code is displayed for the control when the IC Cycle Number (CN) value exceeds the established range.

A Flag or Message Code is displayed for the sample when the IC Cycle Number (CN) value falls outside of the established range:

- For Positive Specimens: If the IC CN is out of range, and any analyte(s) (flu A, flu B, RSV or SARS-CoV-2) in that specimen is detected, the specimen will yield a Positive interpretation for the detected analyte(s). An IC Flag will be reported next to the detected analyte(s).
- For Negative Specimens: If the IC CN is out of range and any of the analyte(s) (flu A, flu B, RSV or SARS-CoV-2) in that specimen is not detected, no result will be reported for that analyte(s) and a Message Code will be generated.
- For Negative and Positive Controls: If the IC CN is out of range, a Message Code will be generated for all the analytes in the Controls.
- Note that for a specimen, each analyte test is treated independently. For example, a specimen may be reported Positive for flu A with an IC flag, but may get a Message Code indicating IC failure for each of the other 3 analytes if they are not detected.

Refer to the Alinity m System Operations Manual, Section 5 for an explanation of the Flags.

Refer to the Alinity m System Operations Manual, Section 10 for an explanation of the corrective actions for Message Codes.

Negative and Positive Controls

A set of Alinity m Resp-4-Plex Negative Control (CTRL-) and Positive Control (CTRL+) are required to be tested at least once every 24 hours, to monitor the performance of the assay and Alinity m System. Valid results for all control levels must be obtained before specimen results are reported.

Additional controls may be tested in accordance with local, state, and/or federal regulations or accreditation requirements and your laboratory's quality control policy.

A Flag is displayed for specimens when a control result is invalid. If the controls for a given target analyte (flu A, flu B, RSV, or SARS-CoV-2) are invalid, all of the specimens for that target analyte processed in parallel with an invalid assay control must be retested. If control results are invalid, refer to the Alinity m System Operations Manual, Section 5 for a description of quality control flags, and Section 10 for troubleshooting information.

The presence of flu A, flu B, RSV, or SARS-CoV-2 must not be detected in the negative control. Flu A, flu B, RSV, or SARS-CoV-2 detected in the negative control is indicative of contamination by other samples or by amplified product. If contamination is suspected, clean the Alinity m System and repeat sample processing for controls and specimens following the Procedural Precautions in this package insert. Cleaning and monitoring procedures for the presence of amplification target contamination can be found in the Alinity m System Operations Manual, Section 9.

If negative controls are persistently reactive, contact your Abbott Representative at www.molecular.abbott/portal.

INTERPRETATION OF RESULTS

The Alinity m System will report a Result and an Interpretation for each specimen. If applicable, message codes or flags will also be displayed. A clinical interpretation can be performed by the user, based on the Result, according to the table below:

SID	Assay	Result	Interpretation	Flags	Result Codes
Resp-4-Plex POS CTRL	FLUA_4PEUA				9198[a]
Resp-4-Plex POS CTRL	FLUB_4PEUA	XX.XX CN			
Resp-4-Plex POS CTRL	RSV_4PEUA	XX.XX CN			
Resp-4-Plex POS CTRL	COV2_4PEUA	XX.XX CN			
Resp-4-Plex NEG CTRL	FLUA_4PEUA	Not Detected			
Resp-4-Plex NEG CTRL	FLUB_4PEUA				9193[b]
Resp-4-Plex NEG CTRL	RSV_4PEUA	Not Detected			
Resp-4-Plex NEG CTRL	COV2_4PEUA	Not Detected			
Sample 1	FLUA_4PEUA	Not Detected	Flu A Negative	FPC[c]	
Sample 1	FLUB_4PEUA	Not Detected	Flu B Negative	FNC[c]	
Sample 1	RSV_4PEUA	Not Detected	RSV Negative		
Sample 1	COV2_4PEUA	Not Detected	SARS-CoV-2 Negative		
Sample 2	FLUA_4PEUA				9186[d]
Sample 2	FLUB_4PEUA				9186[d]
Sample 2	RSV_4PEUA	XX.XX CN	RSV Positive	IC[e]	
Sample 2	COV2_4PEUA				9186[d]
Sample 3	FLUA_4PEUA	XX.XX CN	Flu A Positive	FPC[c], IC[e]	
Sample 3	FLUB_4PEUA				9186[d]
Sample 3	RSV_4PEUA				9186[d]
Sample 3	COV2_4PEUA				9186[d]
Resp-4-Plex POS CTRL	FLUA_4PEUA	XX.XX CN			
Resp-4-Plex POS CTRL	FLUB_4PEUA	XX.XX CN			
Resp-4-Plex POS CTRL	RSV_4PEUA	XX.XX CN			
Resp-4-Plex POS CTRL	COV2_4PEUA	XX.XX CN			
Resp-4-Plex NEG CTRL	FLUA_4PEUA	Not Detected			
Resp-4-Plex NEG CTRL	FLUB_4PEUA	Not Detected			
Resp-4-Plex NEG CTRL	RSV_4PEUA	Not Detected			
Resp-4-Plex NEG CTRL	COV2_4PEUA	Not Detected			
Sample 4	FLUA_4PEUA	XX.XX CN	Flu A Positive		
Sample 4	FLUB_4PEUA	Not Detected	Flu B Negative		
Sample 4	RSV_4PEUA	Not Detected	RSV Negative		
Sample 4	COV2_4PEUA	Not Detected	SARS-CoV-2 Negative		
Sample 5	FLUA_4PEUA	XX.XX CN	Flu A Positive		
Sample 5	FLUB_4PEUA	Not Detected	Flu B Negative		
Sample 5	RSV_4PEUA	Not Detected	RSV Negative		
Sample 5	COV2_4PEUA	XX.XX CN	SARS-CoV-2 Positive		
Sample 6	FLUA_4PEUA	Not Detected	Flu A Negative		
Sample 6	FLUB_4PEUA	XX.XX CN	Flu B Positive		
Sample 6	RSV_4PEUA	Not Detected	RSV Negative		
Sample 6	COV2_4PEUA	Not Detected	SARS-CoV-2 Negative		

[a] Error code generated due to positive control failure.
[b] Error code generated due to negative control failure.
[c] Indicates failed control. All of the specimens processed in parallel with an invalid assay control must be retested.
[d] Error code generated due to no amplification of target and internal control failure. Specimen must be retested.
[e] Patient sample with positive amplification of target but failed internal control will produce valid result with a flag for internal control failure.

Flags, Results Codes, and Message Codes

Some results may contain information in the Flags and Codes fields. For a description of the flags and result codes that may appear in these fields, refer to the Alinity m System Operations Manual, Section 5. For a description of message codes refer to the Alinity m System Operations Manual, Section 10.

LIMITATIONS OF THE PROCEDURE

For use under an Emergency Use Authorization only.

- The use of this assay as an in vitro diagnostic under the FDA Emergency Use Authorization (EUA) is limited to laboratories that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C § 263a, that meet requirements to perform moderate or high complexity tests.
- Use of the Alinity m Resp-4-Plex assay is limited to personnel who have been trained in the procedures of a molecular diagnostic assay and the Alinity m System.
- Laboratories are required to report all SARS-CoV-2 results to the appropriate public health authorities.
- The instrument and assay procedures reduce the risk of contamination by amplification product. However, nucleic acid contamination from positive controls or specimens must be controlled by good laboratory practices and careful adherence to the procedures specified in this package insert.
- 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 flu A, flu B, RSV, or SARS-CoV-2 RNA may be affected by sample collection methods, patient factors (eg, presence of symptoms), and/or stage of infection.
- Recent patient exposure to FluMist® or other attenuated influenza vaccines may cause inaccurate positive results for flu A and flu B due to the presence of attenuated viruses.
- Interference was observed for RSV when evaluated with FluMist. Recent patient exposure to FluMist or other attenuated influenza vaccines may cause inaccurate false negative RSV results.
- Interference was observed for flu A, flu B, RSV, and SARS-CoV-2 when evaluated with high concentrations of Pneumocystis jirovecii (PJP). There is a risk of false negative for flu A, B, RSV, and SARS-CoV-2 results under certain co-infection circumstances with Pneumocystis jirovecii (PJP).
- False-negative results may arise from degradation of the viral RNA during storage and transport of the specimens.
- As with any molecular test, mutations within the target regions of Alinity m Resp-4-Plex assay could affect primer and/or probe binding resulting in failure to detect the presence of virus.
- The clinical performance has not been established in 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.
- Results should be interpreted by a trained professional in conjunction with the patient's history and clinical signs and symptoms, and epidemiological risk factors.
- The Alinity m Resp-4-Plex assay was validated with nasopharyngeal swabs. Anterior nasal swabs (self-collected under healthcare provider (HCP) supervision or HCP-collected) are also considered acceptable specimen types, but performance has not been established. Specimen types other than nasopharyngeal and anterior nasal swabs should not be tested with this assay.
- Negative results do not preclude infection with the flu A, flu B, RSV, or SARS-CoV-2 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.
- Self-collected under supervision of or healthcare provider collected anterior nasal swabs are additional acceptable upper respiratory specimens that can be tested with the Alinity m Resp-4-Plex assay; however, performance with this specimen type has not been validated.
- Influenza was validated in the clinical study by testing archived, selected specimens only. If an influenza result is inconsistent with clinical presentation and/or other clinical and epidemiological information, FDA-cleared Influenza NAATs are available for confirmation if clinically indicated.
- A positive result indicates the detection of nucleic acid from the relevant virus. Nucleic acid may persist even after the virus is no longer viable.

CONDITIONS OF AUTHORIZATION FOR LABORATORIES

The Alinity m Resp-4-Plex 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/vitro-diagnostics-euas.

However, to assist clinical laboratories using the Alinity m Resp-4-Plex assay ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

A. Authorized laboratories[a] using your product must include with test 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[a] 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[a] 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[a] 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[a] 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 (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 distributor(s), and authorized laboratories[a] 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.

[a] 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 moderate or 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, flu A, flu B, and RSV, at which greater than or equal to 95% of replicates test positive.

The LoD was determined by testing dilutions of 7 cultured viruses, including 1 SARS-CoV-2 strain, 2 flu A strains (H1N1 and H3N2), 2 flu B strains (Victoria and Yamagata lineages), and 2 RSV strains (RSV A and RSV B), spiked in pooled negative clinical nasopharyngeal swab specimens. For each virus, the preliminary LoD was determined by testing a minimum of 3 levels, each in 3 replicates. The final LoD was confirmed by testing 3 to 4 panel members with target concentrations bracketing the preliminary LoD, each panel member in replicates of 21. LoD is defined as the lowest concentration at which greater than or equal to 95% of all replicates tested positive, as summarized in **Table 1.**

Table 1. Limit of Detection

Virus	Strain	LoD
SARS-CoV-2	Isolate USA-WA1/2020, gamma irradiated (Cat No NR-52287 Lot 70033322[a])	0.005 $TCID_{50}$/mL (30 GE/mL)[b]
Flu A	A/Brisbane/59/2007 (H1N1) (Cat No 0810244CF Lot 323919)	0.002 $TCID_{50}$/mL
	A/Switzerland/9715293/13 (H3N2) (Cat No 0810511CF Lot 322440)	0.015 $TCID_{50}$/mL
Flu B	B/Brisbane/33/08 (Victoria lineage) (Cat No 0810253CF Lot 316752)	0.020 $TCID_{50}$/mL
	B/Massachusetts/2/12 (Yamagata lineage) (Cat No 0810239CF Lot 324519)	0.050 $TCID_{50}$/mL
RSV	RSVA/Long/MD/56 (Cat No VR-26PQ Lot 70024412)	0.300 $TCID_{50}$/mL
	RSVB/WestVirginia/14617/85 (Cat No VR-1400 Lot 70013461)	0.100 $TCID_{50}$/mL

[a] Based on the information provided in the Certificate of Analysis from the vendor, 1 $TCID_{50}$/mL is equal to 6,071 genome equivalents (GE) by ddPCR.

[b] GE/mL = Genome Equivalent/mL.

Inclusivity

The inclusivity of Alinity m Resp-4-Plex assay for the detection of SARS-CoV-2, flu A, flu B, and RSV was evaluated by testing 6 isolates of SARS-CoV-2, 20 strains of flu A virus (including H1N1, H3N2, H5N1, and H7N2), 9 strains of flu B virus (including Victoria and Yamagata lineages), and 6 strains of RSV (including RSV A and B). Each individual virus isolate or strain (cultured virus or viral RNA) was tested in simulated nasal matrix, in a minimum of 3 replicates. The Alinity m Resp-4-Plex assay detected all replicates of all strains at the concentrations tested (see **Table 2**). Viral strains present at concentrations below those tested may not be detected.

Table 2. Inclusivity

Viral Target	Strain	Catalog Number	Lot Number	Test Concentration
SARS-CoV-2	SARS-CoV-2/USA-IL1/2020	NR-52503	70035254	100 GE/mL[a]
	SARS-CoV-2/Germany/BavPat1/2020	NR-52502	70036181	100 GE/mL[a]
	SARS-CoV-2/USA-AZ1/2020	NR-52505	70035256	100 GE/mL[a]
	SARS-CoV-2/USA-CA3/2020	NR-52507	70035258	100 GE/mL[a]
	SARS-CoV-2/Italy-INMI1	NR-52498	70035261	100 GE/mL[a]
	SARS-CoV-2/Hong Kong/VM20001061/2020	NR-52388	70034679	100 GE/mL[a]
Flu A	A/NewCaledonia/20/1999 (H1N1)	0810036CF	324516	0.006 $TCID_{50}$/mL
	A/Brisbane/59/2007 (H1N1)	0810244CF	323919	0.006 $TCID_{50}$/mL
	A/Brisbane/2/2018 (H1N1pdm)[e]	0810585CFHI	325433	0.006 $TCID_{50}$/mL
	A/Michigan/45/2015 (H1N1pdm) [e]	0810538CFHI	325503	0.006 $TCID_{50}$/mL
	A/HongKong/8/1968 (H3N2)	0810250CF	323534	0.045 $TCID_{50}$/mL
	A/Perth/16/2009 (H3N2)	0810251CF	313219	0.045 $TCID_{50}$/mL
	A/Wisconsin/67/2005 (H3N2)	0810252CF	324078	0.045 $TCID_{50}$/mL
	A/California/07/2009 (H1N1)	ATCC-VR-1894	70014833	10 $CEID_{50}$/mL
	A/FortMonmouth/1/1947 (H1N1)	ATCC-VR-1754	59523491	10 $CEID_{50}$/mL
	A/NewJersey/8/1976 (H1N1)	ATCC-VR-897	58810588	10 $CEID_{50}$/mL
	A/Victoria/3/1975 (H3N2)	ATCC-VR-822	61834480	10 $CEID_{50}$/mL
	A/Brisbane/10/2007 (H3N2)	0810138CF	324694	0.03 $TCID_{50}$/mL
	A/Singapore/INFIMH-16-0019/2016 (H3N2)	0810574CF	322550	0.045 $TCID_{50}$/mL
	A/Kansas/14/2017 (H3N2)	0810586CF	324822	0.045 $TCID_{50}$/mL
	A/PuertoRico/8/1934 (H1N1)	ATCC-VR-1469	70020665	0.067 PFU/mL
	A/Aichi/2/1968 (H3N2)	NR-9534	58007006	0.0108 pg/µL
	A/Vietnam/1203/2004 (H5N1)	NR-12148	VNV1F009A	9.0 x 10^{-5} mcg/mL[c]
	A/equine/Prague/1/1956 (HA) x A/Aichi/2/1968 (NA) x A/Puerto Rico/8/1934 (H7N2), Reassortant X-33, NA Deficient Influenza A virus (H7N2)	NR-10082	58406990	12.5 pg/µL
	CVV:A/H1N1/Guangdong_Maonan/1536/2019 (H1N1)[b]	NA[b]	3001293900	5.12 x 10^{-5} HA[d]
	CVV:A/H3N2/HongKong/2671/2019 (H3N2)[b]	NA[b]	3001292400	2.56 x10^{-4} HA[d]
Flu B	B/Brisbane/60/2008 (Victoria lineage)	0810254CF	313375	0.006 $TCID_{50}$/mL
	B/Malaysia/2506/04 (Victoria lineage)	0810258CF	324158	0.006 $TCID_{50}$/mL
	B/Colorado/6/17 (Victoria lineage)	0810573CF	325651	0.02 $TCID_{50}$/mL
	B/Alabama/2/17 (Victoria lineage)	0810572CF	325540	0.02 $TCID_{50}$/mL
	B/Lee/40	0810257CF	315896	0.06 $TCID_{50}$/mL
	B/Allen/1945	ATCC-VR-102	70021278	1 $CEID_{50}$/mL
	B/GL/1739/1954 (Yamagata lineage)	ATCC-VR-103	64295716	10 $CEID_{50}$/mL
	CVV: B/Washington/02/2019-like virus (Victoria lineage)[b]	NA[b]	3026019537	5.12 x 10^{-5} HA[d]
	CVV: B/Phuket/3073/2013-like virus (Yamagata lineage)[b]	NA[b]	2014768619	6.4 x 10^{-5} HA[d]
RSV	RSVA/2/Australia/61	VR-1540	70021273	0.9 PFU/mL
	RSVB/Washington/18537	VR-1580PQ	70025292	0.3 $TCID_{50}$/mL
	RSVB/3/2015 Isolate 2	0810480CF	322742 (sublot 538033)	0.1 $TCID_{50}$/mL
	RSVA/ 1/2015 Isolate 1	0810466CF	318843	0.09 $TCID_{50}$/mL
	RSVA/ 12/2014 Isolate 12	0810462CF	318841	0.9 $TCID_{50}$/mL
	RSVA/ 2014 Isolate 341	0810290CF	315911	0.09 $TCID_{50}$/mL

[a] GE/mL = Genome Equivalent/mL.

[b] CVV = Candidate Vaccine Virus, catalog number is not applicable.

[c] Inactivated H5N1 influenza Vaccine (non-adjuvanted). Unit of measurement is based on hemagglutinin antigen concentration.

[d] HA = Hemagglutination titer, indicates Hemagglutinin levels.

[e] Heat Inactivated

In addition, *in silico* analyses were performed in which the sequence of each of the Alinity m Resp-4-Plex analyte primers and probes was analyzed for homology with sequences available in GISAID and/or NCBI Virus Sequences for Discovery (GenBank) databases. A total of 67,426 full-length target gene sequences (consisting of 27,550 H1 strains, 39,162 H3 strains, and 714 H7 strains) available in the GISAID database as of May 20, 2020 were analyzed for flu A inclusivity. A total of 20,917 full-length target gene sequences (consisting of 10,934 Victoria strains, 9,967 Yamagata strains, and 16 unclassified strains) available in the GISAID database as of May 22, 2020 were analyzed for flu B inclusivity. A total of 460 full-length sequences (consisting of 316 RSV A strains and 144 RSV B strains) available in the NCBI database as of August 3, 2020 were analyzed for RSV inclusivity.

Inclusivity was demonstrated by analyzing the sequences of the RdRp and N primer/probe sets for homology with 8,634,788 full-length sequences available in the GISAID database (http://www.gisaid.org) as of March 16, 2022. 8,585,868 sequences (99.4%) either have no mismatches in the assay target regions or have mismatches in one of the target regions. Among 48,920 sequences (0.6%) containing at least one mismatch in both target regions, 48,857 were predicted unlikely to impact the detection of SARS-CoV-2. Among 7,565,966 isolates with variant designation (including 1,139,842

Alpha, 40,183 Beta, 4,086,797 Delta, 116,655 Gamma, 2,033,303 Omicron, 64,677 Epsilon, 7,480 Eta, 41,807 Iota, 7,173 Kappa, 7,420 Lambda, 14,876 Mu, 618 Theta, and 5,135 Zeta), 7,519,355 sequences (99.4%) either have no mismatches in the assay target regions or have mismatches in only one of the target regions and are therefore predicted to be detected.

An additional analysis was also performed using 989,930 full-length SARS-CoV-2 sequences available in the NCBI database (https://www.ncbi.nlm.nih.gov/datasets/coronavirus/genomes/) as of April 14, 2022. 987,119 sequences (99.7%) either have no mismatches in the assay target regions or have mismatches in only one of the target regions and are therefore predicted to be detected. Among 2,811 sequences (0.3%) containing at least one mismatch in both target regions, 2,806 were predicted unlikely to impact the detection of SARS-CoV-2.

Overall, the results of these *in silico* analyses and inclusivity testing predict that sequence heterogeneity in Alinity m Resp-4-Plex primer/probe target regions do not impact the detection of SARS-CoV-2, flu A, flu B, and RSV.

Precision

Alinity m Resp-4-Plex assay within-laboratory precision was evaluated using a 3-member panel: 2 positive panels composed of each assay analyte SARS-CoV-2, flu A, flu B, and RSV at 2 target concentrations in simulated nasal matrix, as well as a negative panel member in simulated nasal matrix. Each panel member was tested with a target of minimum 3 replicates in a run, 2 runs on each of 5 days, on 3 Alinity m instruments, for a total of minimum 90 replicates of each panel (see **Table 3**).

Table 3. Precision

Target Concentration	Analyte	N[a]	n[b]	Agreement[c]	Mean (CN)	Within-Run Component		Between-Run Component		Between-Day Component		Within-Lab Component.[d]		Between-Inst. Component		Total[e]	
						SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
1-2X LoD	Flu A[f]	91	91	100.0%	34.40	0.45	1.3	0.09	0.3	0.12	0.4	0.47	1.4	0.05	0.1	0.47	1.4
	Flu B[g]	93	93	100.0%	31.63	0.25	0.8	0.11	0.3	0.00	0.0	0.27	0.8	0.15	0.5	0.31	1.0
	RSV[h]	92	92	100.0%	32.50	0.24	0.7	0.26	0.8	0.00	0.0	0.35	1.1	0.18	0.6	0.40	1.2
	SARS-CoV-2[i]	93	93	100.0%	33.73	0.36	1.1	0.23	0.7	0.00	0.0	0.43	1.3	0.14	0.4	0.45	1.3
5X LoD	Flu A[f]	91	91	100.0%	32.97	0.30	0.9	0.14	0.4	0.00	0.0	0.33	1.0	0.14	0.4	0.36	1.1
	Flu B[g]	91	91	100.0%	30.44	0.28	0.9	0.00	0.0	0.08	0.2	0.29	1.0	0.24	0.8	0.38	1.2
	RSV[h]	90	90	100.0%	31.47	0.30	1.0	0.06	0.2	0.00	0.0	0.31	1.0	0.15	0.5	0.34	1.1
	SARS-CoV-2[i]	91	91	100.0%	32.24	0.31	1.0	0.08	0.3	0.01	0.0	0.33	1.0	0.17	0.5	0.37	1.1
Negative	Flu A	90	90	100.0%	-	-	-	-	-	-	-	-	-	-	-	-	-
	Flu B	90	90	100.0%	-	-	-	-	-	-	-	-	-	-	-	-	-
	RSV	90	90	100.0%	-	-	-	-	-	-	-	-	-	-	-	-	-
	SARS-CoV-2	90	90	100.0%	-	-	-	-	-	-	-	-	-	-	-	-	-

[a] N: Total number of valid replicates.

[b] n: Replicates with detected analyte for positive panels, not detected for negative panel.

[c] Agreement = n/N.

[d] Within-laboratory Includes Within-Run, Between-Run and Between-Day Components.

[e] Total includes Within-Run, Between-Run, Between-Day and Between-Inst. Components.

[f] Strain Flu A/Brisbane/59/2007(H1N1), Catalog 0810244CF, lot 323919 (2x LoD=0.004 $TCID_{50}$/mL, 5xLoD=0.010 $TCID_{50}$/mL).

[g] Strain B/Brisbane/33/08 (Victoria lineage), Catalog 0810253CF, lot 325127 (2x LoD=0.040 $TCID_{50}$/mL, 5xLoD=0.100 $TCID_{50}$/mL).

[h] Strain RSVB/WestVirginia/14617/85, Catalog VR-1400, lot 70038817 (2x LoD=0.200 $TCID_{50}$/mL, 5xLoD=0.500 $TCID_{50}$/mL).

[i] Strain USA-WA1/2020, Catalog NR-52287, lot 70039068 (2x LoD=61 GE/mL, 5xLoD=152 GE/mL).

Lot-to-Lot Reproducibility

Alinity m Resp-4-Plex assay lot-to-lot reproducibility was evaluated using a positive panel member composed of SARS-CoV-2, flu A, flu B, and RSV in simulated nasal matrix, as well as a negative panel member (simulated nasal matrix). Both panel members were tested using 3 amplification reagent lots with a minimum of 4 replicates per lot (see **Table 4**).

Table 4. Lot-to-Lot Reproducibility

Panel Target Concentration	N[a]	n[b]	Agreement (%)	Mean CN	Within Lot Component		Between Lot Component		Total[c]	
					SD	% CV	SD	% CV	SD	% CV
SARS-CoV-2 (0.015 $TCID_{50}$/mL)	21	21	100%	31.98	0.155	0.5	0.186	0.6	0.242	0.8
Flu A (0.045 $TCID_{50}$/mL)	21	21	100%	31.25	0.405	1.3	0.353	1.1	0.537	1.7
Flu B (0.06 $TCID_{50}$/mL)	21	21	100%	31.82	0.235	0.7	0.041	0.1	0.238	0.7
RSV (0.30 $TCID_{50}$/mL)	21	21	100%	34.88	0.662	1.9	0.184	0.5	0.687	2.0
Negative	21	0	100%	--	--	--	--	--	--	--

a Number of valid replicates.

b Number of positive replicates for SARS-CoV-2, flu A, flu B, and RSV panel members and number of negative replicates for the negative panel member.

c Total includes Within Lot Component and Between Lot Component.

Analytical Specificity and Microbial Interference

A total of 55 potential cross-reacting microorganisms (viruses, bacteria, and fungi) that are phylogenetically related to the analytes of the assay or that are commonly found in respiratory tract and pooled human nasal wash were tested with Alinity m Resp-4-Plex to assess analytical specificity and microbial interference. The microorganisms were tested at 10^5 Units/mL for viruses and 10^6 Units/mL for bacteria and fungi, where these concentrations were available. The unit of measure was specific to each microorganism. Bacteria and fungi were tested as whole microorganisms. Viruses were tested as viral particles or viral lysate unless noted otherwise.

To assess potential cross-reactivity, each microorganism was tested in analyte (flu A, flu B, RSV and SARS-CoV-2) negative samples comprised of simulated nasal matrix. No cross-reactivity was observed in the presence of these potential cross-reactants (see **Table 5**).

To assess potential microbial interference, microorganisms were spiked into analyte positive samples containing 1 strain each for flu A [A/Switzerland/9715293/13 (H3N2)], flu B [B/Brisbane/33/08 (Victoria lineage)], RSV (RSVB/WestVirginia/14617/85), and SARS-CoV-2 (USA-WA1/2020) targeted to final concentration of 3X LoD. No interference was observed for any of the analyte (flu A, flu B, RSV and SARS-CoV-2) positive samples in the presence of these microorganisms, except when undiluted *Pneumocystis jirovecii* (PJP) was tested. With a 1:50 dilution of the PJP culture, no interference was observed (see **Table 5**).

Table 5. Potential Cross-Reactants

Potential Cross-Reactant	Test Concentration	Potential Cross-Reactant	Test Concentration
Adenovirus type 1	1.00E+05 $TCID_{50}$/mL	*Legionella pneumophila*	1.00E+06 CFU/mL
Adenovirus Type 5	1.00E+05 $TCID_{50}$/mL	Measles	1.00E+05 $TCID_{50}$/mL
Adenovirus type 7A	1.00E+05 $TCID_{50}$/mL	MERS-coronavirus[b]	1.00E+05 Copies/mL
Bordetella pertussis	1.00E+06 CFU/mL	Moraxella catarrhalis	1.00E+06 CFU/mL
Candida albicans	1.00E+06 CFU/mL	Mumps	1.00E+05 $TCID_{50}$/mL
Chlamydia pneumoniae	1.00E+06 IFU/mL	*Mycobacterium tuberculosis*	1.00E+06 CFU/mL
Corynebacterium diptheriae	1.00E+06 CFU/mL	*Mycoplasma pneumoniae*	1.00E+06 CFU/mL
Coxsackievirus	1.00E+05 $TCID_{50}$/mL	*Neisseria elongata*	1.00E+06 CFU/mL
Cutibacterium acnes[a]	1.00E+06 CFU/mL	*Neisseria meningitidis*	1.00E+06 CFU/mL
Cytomegalovirus	1.00E+05 IU/mL	Parainfluenza virus 1	1.00E+05 $TCID_{50}$/mL
EBV	1.00E+05 Copies/mL	Parainfluenza virus 2[b]	1.00E+05 Copies/mL
Echovirus	1.00E+05 $TCID_{50}$/mL	Parainfluenza virus 3	1.00E+05 $TCID_{50}$/mL
Enterococcus faecalis	1.00E+06 CFU/mL	Parainfluenza virus 4	1.00E+05 $TCID_{50}$/mL
Enterovirus (EV68)	1.00E+05 $TCID_{50}$/mL	*Pneumocystis jirovecii* (PJP)	N/A[f]
Escherichia coli	1.00E+06 CFU/mL	Pooled Human Nasal Wash	N/A[g]
Haemophilus influenzae	1.00E+06 CFU/mL	*Proteus mirabilis*	1.00E+06 CFU/mL
Herpes Simplex virus	1.00E+05 $TCID_{50}$/mL	*Pseudomonas aeruginosa*	1.00E+06 CFU/mL
Human coronavirus 229E	1.00E+05 Copies/mL	Rhinovirus	1.00E+05 Copies/mL
Human coronavirus HKU1[b]	1.00E+05 Copies/mL	RSV A[e]	1.00E+05 Copies/mL
Human coronavirus NL63	1.00E+05 Copies/mL	RSV B[e]	1.00E+05 Copies/mL
Human coronavirus OC43[b]	1.00E+05 Copies/mL	SARS-coronavirus[b]	1.00E+05 Copies/mL
Human Metapneumovirus[b]	1.00E+05 Copies/mL	*Staphylococcus aureus*	1.00E+06 CFU/mL
Influenza A (H1N1)[c]	1.00E+05 Copies /mL	*Staphylococcus epidermis*	1.00E+06 CFU/mL
Influenza A (H3N2)[c]	1.00E+05 Copies /mL	*Streptococcus pneumoniae*	1.00E+06 CFU/mL
Influenza B[d]	1.00E+05 Copies /mL	*Streptococcus pyogenes*	1.00E+06 CFU/mL
Influenza C	1.00E+05 $CEID_{50}$/mL	*Streptococcus salivarius*	1.00E+06 CFU/mL
Klebsiella pneumoniae	1.00E+06 CFU/mL	Varicella-zoster virus	1.00E+05 Copies/mL
Lactobacillus	1.00E+06 CFU/mL		

[a] Also known as *Propionibacterium acnes*.

[b] Tested as viral RNA.

[c] Only the cross-reactivity of the non-flu A signals were evaluated.

[d] Only the cross-reactivity of the non-flu B signals were evaluated.

[e] Only the cross-reactivity of the non-RSV signals were evaluated.

f Concentration not available. Certificate of Analysis for the undiluted PJP culture expressed concentration in Ct Range of 23 to 25.

[g] Concentration not available; individual nasal wash samples were pooled and tested neat.

On-Panel Cross-Reactivity

The cross-reactivity of each signal channel of the Alinity m Resp-4-Plex assay for on-panel viruses was evaluated by testing representative strains, at 10^5 Units/mL. No cross reactivity was observed for on-panel viruses (see **Table 6**).

Table 6. On-Panel Cross Reactivity

Viral Target	Strain	Test Concentration	Results (minimum n = 3 replicates)[b]			
			SARS-CoV-2	Flu A	Flu B	RSV
SARS-CoV-2	Isolate USA-IL1/2020	10^5 GE/mL[a]	positive	negative	negative	negative
Flu A	A/Denver/1/57 (H1N1)	10^5 $CEID_{50}$/mL	negative	positive	negative	negative
	A/PortChalmers/1/1972 (H3N2)	10^5 $CEID_{50}$/mL	negative	positive	negative	negative
Flu B	B/GL/1739/1954 (Yamagata)	10^5 $CEID_{50}$/mL	negative	negative	positive	negative
	B/Malaysia/2506/04 (Victoria)	10^5 $TCID_{50}$/mL	negative	negative	positive	negative
RSV	RSVA/Long/MD/56	10^5 $TCID_{50}$/mL	negative	negative	negative	positive
	RSVB/WestVirginia/14617/85	10^5 $TCID_{50}$/mL	negative	negative	negative	positive

[a] GE/mL = Genome Equivalent/mL

[b] All replicates had the same result for each viral target.

Co-Infection (Competitive Interference)

To assess potential competitive interference between SARS-CoV-2, flu A, flu B, and RSV, samples containing low concentrations (≤ 3X LoD) of 3 analyte targets were mixed with a high concentration 10^5 $TCID_{50}$/mL of the fourth analyte target and tested in 20 or more replicates. None of the analyte targets present at the high concentration interfered with the detection of low levels of the other 3 analyte targets.

Fresh versus Frozen Specimen Comparison

The performance of Alinity m Resp-4-Plex with fresh and frozen specimens was evaluated for equivalency by testing individual flu A, flu B, RSV and SARS-CoV-2 strains spiked, at two different concentrations representing low positives (3X LoD) and moderate positives (5X LoD), in pooled negative nasopharyngeal clinical swab specimens collected in viral transport medium (VTM). Individual nasopharyngeal swab specimens were prescreened with Alinity m Resp-4-Plex to be negative for flu A, flu B, RSV and SARS-CoV-2 prior to being pooled. In addition to positive samples, negative samples consisted of pooled negative nasopharyngeal clinical swab specimens collected in VTM were also tested.

The influenza, RSV and SARS-CoV-2 viruses selected for this study included one flu A strain (Flu A H3N2/Switzerland/9715293/13), one flu B strain (Flu B Brisbane/33/08), one RSV strain (RSVB/West Virginia/14617/85) and one SARS-CoV-2 strain (USA-WA1/2020). A minimum of 40 replicates of 3X LoD samples, 10 replicates of 5X LoD samples, and 10 replicates of negative samples were tested for each storage condition. Two sample storage conditions were evaluated, including fresh and after two freeze-thaw cycles. For each freeze-thaw cycle, samples were placed at -70°C or colder for a minimum of 24 hours, after which they were thawed at 5°C ± 3°C for a minimum of 2 hours prior to Alinity m Resp-4-Plex testing. All positive and negative sample replicates were correctly identified using Alinity m Resp-4-Plex for both storage conditions.

Specimen Stability

A stability study was conducted to establish transport and storage claims for nasopharyngeal swab specimens collected in VTM to be analyzed with Alinity m Resp-4-Plex. Samples tested in the study consisted of one flu A strain (Flu A H3N2/Switzerland/9715293/13), one flu B strain (Flu B Brisbane/33/08), and one RSV strain (RSVB/West Virginia/14617/85) that were spiked in pooled negative clinical nasopharyngeal swab specimens to an analyte concentration of approximately 3X LoD.

Positive samples were stored at 5°C ± 3°C and -70°C or colder and five replicates were tested at different time points. All specimens tested at each storage temperature/condition were correctly identified using Alinity m Resp-4-Plex. The study data supports the recommended specimen storage condition (5°C ± 3°C for a maximum of 80 hours and -70°C or colder for a maximum of 7 days).

Use of Simulated Nasal Matrix

In comparing simulated nasal matrix (SNM) to natural clinical matrix, it was found that all replicates, prepared near the LoD for each on-panel analyte, in either natural clinical matrix or SNM, tested positive for all on-panel analytes.

Interfering Substances

Potentially interfering substances that may be encountered in respiratory specimens were evaluated by testing 1 strain of SARS-CoV-2 (USA-WA1/2020), and 2 strains each of flu A [A/Switzerland/9715293/13 (H3N2) and A/Brisbane/59/2007 (H1N1)], flu B [B/Brisbane/33/08 (Victoria lineage) and B/Massachusetts/02/2012 (Yamagata lineage)], and RSV [RSVB/WestVirginia/14617/85 and RSVA/Long/MD/56 (RSV A)] at a target concentration of 3X LoD. No interference resulting in a negative result (except for RSVA/Long/MD/56, where one of the six replicates was not detected in the presence of FluMist) was observed in the presence of any of the substances at the concentrations shown in **Table 7**.

Table 7. Potentially Interfering Endogenous and Exogenous Substances

Substance	Active Ingredient(s)	Tested Concentration
Blood	Blood (human)	10% (v/v)
Throat Lozenges, Oral Anesthetic and Analgesic - Cepacol®	Benzocaine, Menthol	0.63 mg/mL
Mucin	Purified mucin protein	1060 ug/mL
Antibiotic, Nasal Ointment - Bactroban®	Mupirocin	5 mg/mL
Nasal Spray-Afrin®	Oxymetazoline	5% (v/v)
Anti-Viral Drug - Relenza	Zanamivir	3.3 mg/mL
Anti-Viral Drug - Remdesivir	Remdesivir	13.26 µg/mL
Antibacterial, systemic	Tobramycin	4 µg/mL
Nasal Gel /Homeopathic Allergy Relief Medicine - Zicam®	Galphimia glauca, Histaminum hydrochloricum, Luffa operculata, Sulfur	5% (v/v)
FluMist©	Live intranasal influenza virus	6.7% (v/v)
Nasal Corticosteroid-Flonase® Sensimist	Fluticasone Furoate	5% (v/v)
BD Universal viral transport (UVT) medium with swab	Transport medium	100% (v/v)

Carryover

The carryover rate for Alinity m Resp-4-Plex assay using application specification version 5.0 was determined by testing alternating replicates of SARS-CoV-2 high positive samples and SARS-CoV-2 negative samples across multiple runs. The high positive samples were prepared by diluting SARS-CoV-2 synthetic target (plasmid DNA) in Simulated Nasal Matrix targeting final concentration of 2.0E+09 copies/mL. SARS-CoV-2 negative Simulated Nasal Matrix served as negative sample. Out of the 360 negative valid samples, 0 samples were positive ("detected") for SARS-CoV-2. The sample carryover rate was 0.0% (0/360, 95% CI: 0.0% to 1.1%).

Clinical Performance Evaluation

The performance of Alinity m Resp-4-Plex was evaluated by testing individual banked clinical nasopharyngeal (NP) swab specimens in viral transport medium.

A total of 114 specimens were analyzed for SARS-CoV-2 detection by both Alinity m Resp-4-Plex and a comparator EUA SARS-CoV-2 assay. The positive percent agreement (PPA) between the 2 assays was 100% (55/55) and the negative percent agreement (NPA) was 96.6% (57/59).

An additional 22 specimens were analyzed for SARS-CoV-2 detection by both Alinity m Resp-4-Plex and a different comparator EUA SARS-CoV-2 assay. These specimens all had Ct values within 3 Cts of the mean Ct at the LoD for the comparator. The positive percent agreement (PPA) between the two assays was 100% (22/22).

A total of 239 specimens were analyzed for flu A detection by both Alinity m Resp-4-Plex and a comparator FDA-cleared assay for flu A, flu B, and RSV. The positive percent agreement (PPA) between the 2 assays was 100% (63/63) and the negative percent agreement (NPA) was 100% (176/176).

A total of 239 specimens were analyzed for flu B detection by both Alinity m Resp-4-Plex and a comparator FDA-cleared assay for flu A, flu B, and RSV. The positive percent agreement (PPA) between the 2 assays was 100% (63/63) and the negative percent agreement (NPA) was 99.4% (175/176).

A total of 240 specimens were analyzed for RSV detection by both Alinity m Resp-4-Plex and a comparator FDA-cleared assay for flu A, flu B, and RSV. The positive percent agreement (PPA) between the 2 assays was 100% (64/64) and the negative percent agreement (NPA) was 100% (176/176).

The results are summarized in **Table 8** through **Table 12.**

Table 8. SARS-CoV-2 Detection			
		Comparator Assays for SARS-CoV-2	
		Positive	Negative
Alinity m Resp-4-Plex	Positive	77	2[a]
	Negative	0	57

[a] These specimens had an Alinity m Resp-4-Plex CN > 39.0.

Table 9. Flu A Detection			
		Comparator Assay for Flu A, Flu B, and RSV	
		Positive	Negative
Alinity m Resp-4-Plex	Positive	63	0
	Negative	0	176

Table 10. Flu B Detection			
		Comparator Assay for Flu A, Flu B, and RSV	
		Positive	Negative
Alinity m Resp-4-Plex	Positive	63	1[a]
	Negative	0	175

[a] One specimen that was RSV positive and flu A and flu B negative by the comparator was negative for flu A and positive for both RSV (CN = 22.55) and flu B (CN = 36.89) using Alinity m Resp-4-Plex assay.

Table 11. RSV Detection			
		Comparator Assay for Flu A, Flu B, and RSV	
		Positive	Negative
Alinity m Resp-4-Plex	Positive	64	0
	Negative	0	176

Table 12. Agreement between Alinity m Resp-4-Plex and Comparators				
	PPA		NPA	
Viral Target	**Estimate (%) (95% Exact CI)**	**n/N**	**Estimate (%) (95% Exact CI)**	**n/N**
SARS-CoV-2	100 (95.3, 100)	77/77	96.6 (88.3, 99.6)	57/59
Flu A	100 (94.3, 100)	63/63	100 (97.9, 100)	176/176
Flu B	100 (94.3, 100)	63/63	99.4 (96.9, 100)	175/176
RSV	100 (94.4, 100)	64/64	100 (97.9, 100)	176/176

PPA – Positive Percent Agreement / NPA – Negative Percent Agreement

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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
AMP TRAY	AMP Tray
ACT TRAY	ACT Tray
Rx ONLY	For Prescription Use Only
	Warning
	Systemic Health Effects
	Caution
	Consult Instructions for Use
	Temperature Limitation
	Contains sufficient for <*n*> tests
	Use By
	Manufacturer

TECHNICAL ASSISTANCE

For technical assistance, call Abbott Technical Services at 1-800-553-7042 in the US and from outside the US at +49-6122-580, email molecularsupport@abbott.com, or visit the Abbott website at www.molecular.abbott.

Abbott Molecular Inc. is the legal manufacturer of the Alinity m Resp-4-Plex AMP Kit (List No. 09N79-096)

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

53-608211/R6

Abbott

Alinity m

en

REF 09N79-086
53-608214/R4

Resp-4-Plex CTRL Kit

Revised January 2022

REF 09N79-086
53-608214/R4

NOTE: Changes Highlighted

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

Rx ONLY
IVD

CUSTOMER SERVICE: 1-800-553-7042
CUSTOMER SERVICE INTERNATIONAL:
CALL YOUR ABBOTT REPRESENTATIVE

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

Alinity m Resp-4-Plex CTRL Kit

INTENDED USE

The Alinity m Resp-4-Plex controls are used for validity determination of the Alinity m Resp-4-Plex assay on the automated Alinity m System. These controls are intended to be used with the Alinity m Resp-4-Plex assay; refer to the assay package insert for additional information.

REAGENTS

Kit Contents

Alinity m Resp-4-Plex Negative CTRL (List No. 9N79Z) contains 1.0% ammonium sulfate and 7.9% detergent in a buffer solution.

Alinity m Resp-4-Plex Positive CTRL (List No. 9N79W) contains non-infectious, recombinant Sindbis viruses containing influenza A virus, influenza B virus, Respiratory Syncytial Virus, and SARS-CoV-2 RNA sequences, 1.0% ammonium sulfate, and 7.9% detergent in a buffer solution.

Control	Quantity
Alinity m Resp-4-Plex Negative CTRL	12 tubes x 1.3 mL
Alinity m Resp-4-Plex Positive CTRL	12 tubes x 1.3 mL

WARNINGS AND PRECAUTIONS

IVD

- **For In Vitro Diagnostic Use under the FDA Emergency Use Authorization**
- Do not use beyond expiration date
- 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 only for the detection and differentiation of nucleic acid from influenza A, influenza B, Respiratory Syncytial Virus and 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

The following safety precautions apply to:
Alinity m Resp-4-Plex Positive CTRL.

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 microorganisms will not transmit infection. These reagents and human specimens should be handled as if infectious using safe laboratory procedures, such as those outlined in Biosafety in Microbiological and Biomedical Laboratories,[1] OSHA Standard 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]

The following warnings and precautions apply to:

Alinity m Resp-4-Plex Negative CTRL and Positive CTRL.

DANGER	**Hazard-determining components of labeling:**
	Lithium dodecyl sulphate
	Lithium hydroxide monohydrate
H318	Causes serious eye damage.
H316	Causes mild skin irritation.*
Prevention	
P280	Wear protective gloves / protective clothing / eye protection.
Response	
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.

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.

For a detailed discussion of safety precautions during system operation, refer to the Alinity m System Operations Manual; Section 7 and Section 8.

Reagent Shipment

	Shipment Condition
Alinity m Resp-4-Plex CTRL Kit	On dry ice

Reagent Storage

	Storage Temperature	Maximum Storage Time
Unopened	–25 to –15°C	Until expiration date
Onboard	System Temperature	Discard after 4 hours

Reagent Handling

- Alinity m Resp-4-Plex control reagents are contained in single-use tubes.
- Remove cap from the tube. Avoid touching the inside of the cap when opening tubes.
- The Alinity m System will track onboard storage of the Alinity m assay controls. Onboard storage time begins when control tubes are loaded on the Alinity m System. The Alinity m System will not allow the use of Alinity m assay controls that have exceeded the maximum onboard storage time.
- For a detailed discussion of handling controls during system operations, refer to the Alinity m System Operations Manual, Section 5.

Indications of Reagent Deterioration

- Deterioration of the reagents may be indicated when a control error occurs or controls are repeatedly out of the specified ranges.
- Reagents are shipped on dry ice and are stored at −25 to −15°C upon arrival. If you receive reagents that are in a condition contrary to this recommendation, or that are damaged, immediately contact your Abbott Representative.
- For troubleshooting information, refer to the Alinity m System Operations Manual, Section 10.

PROCEDURE

Materials Provided

09N79-086 Alinity m Resp-4-Plex CTRL Kit

Instructions for Use

Lot-specific values for assay positive controls are available via Abbott Mail, the Abbott customer portal www.molecular.abbott/portal, and from your Abbott Representative.

When a control test order is created:

- Lot-specific values can be automatically imported to the Alinity m System via Abbott Mail upon scanning the control tube barcodes (Resp-4-Plex NEG CTRL and Resp-4-Plex POS CTRL).
- Lot-specific values can also be obtained from the Abbott customer portal or provided by your Abbott Representative and imported to the Alinity m System via a USB drive.

For instructions on creating a test order and loading controls on the Alinity m System, refer to the Alinity m System Operations Manual, Section 5.

The Alinity m Resp-4-Plex Negative CTRL and Alinity m Resp-4-Plex Positive CTRL tubes are intended for single-use only.

- Thaw assay controls at 15 to 30°C or at 2 to 8°C.
- Once thawed, assay controls can be stored at 2 to 8°C for up to 24 hours before use.
- This product may be used immediately after removal from 2 to 8°C storage.
- Prior to loading onto the Alinity m System, vortex each assay control 3 times for 2 to 3 seconds. Ensure that the contents of each tube are at the bottom after vortexing by tapping the tubes on the bench to bring liquid to the bottom of the tube. **NOTE: Avoid excessive foaming.**
- Remove cap from the tube. Avoid touching the inside of the cap when opening tubes.
- Load the assay controls onto the Alinity m Universal Sample Rack.

QUALITY CONTROL PROCEDURES

Refer to the **QUALITY CONTROL PROCEDURES** section of the Alinity m Resp-4-Plex AMP Kit package insert.

CONDITIONS OF AUTHORIZATION FOR LABORATORIES

The Alinity m Resp-4-Plex 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 Alinity m Resp-4-Plex assay ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

A. Authorized laboratories[a] using your product must include with test 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 (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 distributor(s), 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.

[a] 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 or high complexity tests" as "authorized laboratories."

Alinity m

Resp-4-Plex Application Specification File

en

IVD Rx ONLY

REF 09N79-05E

53-608353/R2

Created May 2022

NOTE: Changes Highlighted

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

For Prescription Use Only.

For detailed instructions or assay related information please refer to the corresponding Alinity m Resp-4-Plex AMP Kit (List No. 09N79-096) package insert.

INTENDED USE

The Alinity m Resp-4-Plex application specification is intended for use with the Alinity m Resp-4-Plex assay on the automated Alinity m System to allow for processing of assay controls and patient samples.

Assay Specific Information	
Application Name	**Version**
R4Plex-05E	5.00

Specimen Type	
Host Code	**Screen (Manual Order)**
PAI	Per Assay Insert

Host Configuration	
Assay Name	**Assay Number**
FLUA_4PEUA	3916
FLUB_4PEUA	3917
RSV_4PEUA	3918
COV2_4PEUA	3919

WARNING 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 and differentiation of nucleic acid from influenza A, influenza B, Respiratory Syncytial Virus and 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.
- For Prescription Use Only

The following are important facts to know about this application specification:

- **For In Vitro Diagnostic Use**
- The installation of the application specification file is to be performed by Abbott Field Service.
- Upon installation by an Abbott Field Service Representative, the Alinity m Resp-4-Plex application specification can be used for processing assay results. The Abbott Field Service Representative will ensure the application is properly installed and ready for processing assay results.
- Prior to processing results, refer to section 2 (Configure screen, Assay tab) of the Alinity m System Operations Manual for options for configuring your application specification. Refer to section 5 of the Alinity m System Operations Manual for ordering tests (Specimen, and control orders) and reviewing results (Results screen).
- This application specification contains unique information for communicating with middleware or laboratory information systems. The unique identifiers for the assay in this application specification are 3916, 3917, 3918, and 3919. Use these numbers when working with your middleware or laboratory information system provider.
- In the event that you experience error conditions during processing this application specification, refer to the Alinity m System Operations Manual for the corrective action associated with the specific message code identified.

KEY TO SYMBOLS

REF	Reference Number
IVD	In Vitro Diagnostic Medical Device
Rx ONLY	For Prescription Use Only
	Manufacturer

TECHNICAL ASSISTANCE

For Technical Assistance call Abbott Technical Services at 1-800-553-7042 (within the US) or +49-6122-580 (outside the US), or visit the Abbott website at www.molecular.abbott.

Abbott Molecular Inc. is the legal manufacturer of the Alinity m Resp-4-Plex Application Specification File.

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

53-608353/R2

(01)00884999050464(240)09N79-05E(8012)5.00

Abbott

Abbott Universal Collection Kit

en

REF 09N77-055

51-608451/R4

REF 09N77-055

51-608451/R4

NOTE: Changes Highlighted

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

For Prescription Use Only.

Rx ONLY

IVD

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 swab specimens that are self-collected at a healthcare location or collected by a healthcare provider (HCP), collection and transport of mid-turbinate nasal and oropharyngeal swab specimens collected by an HCP, and transport of nasopharyngeal swab specimens collected by an HCP, for testing with the Abbott RealTime SARS-CoV-2 and Alinity m SARS-CoV-2 assays.

The Abbott Universal Collection Kit is also intended for the collection and transport of anterior nasal swab specimens that are self-collected at a healthcare location or collected by a healthcare provider (HCP) and transport of nasopharyngeal swab specimens collected by an HCP, from individuals suspected by their HCP of respiratory viral infection consistent with COVID-19 for testing with the Alinity m Resp-4-Plex assay.

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;
- When used with the Alinity m SARS-CoV-2 or Abbott RealTime SARS-CoV-2 assays, 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.
- When used with the Alinity m Resp-4-Plex assay, this product is for use with a test authorized only for the detection and differentiation of nucleic acid from SARS-CoV-2, influenza A, influenza B, and/or Respiratory Syncytial Virus, 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 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.

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.

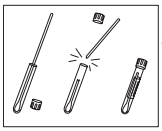
SPECIMEN COLLECTION PROCEDURES

SELF-COLLECTED ANTERIOR 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

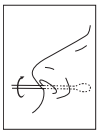
CAUTION: Do NOT expose swab to Transport Buffer prior to collection.

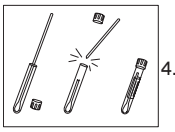


1. Remove the sterile swab from the wrapper, taking care not to touch swab tip or lay it down on any surface. Do not pre-wet swab.
2. Collect patient specimen per CDC guidelines.[3]
   - Insert the entire collection tip of the swab provided (usually ½ to ¾ of an inch, or 1 to 1.5 cm) inside the nostril.
   - 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 NASOPHARYNGEAL SWAB TRANSPORT

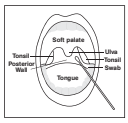
CAUTION: The Abbott Universal Collection kit supports only the following steps for transport of nasopharyngeal (NP) swabs from the collection site to the testing laboratory.

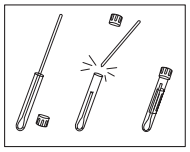
The specimen collection swab provided in this kit is not authorized for nasopharyngeal specimen collection. Follow CDC guidance for nasopharyngeal swab collection.[3]

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 OROPHARYNGEAL 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 a maximum of 7 days prior to testing.

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, the Alinity m Resp-4-Plex assay Letter of Authorization, along with the authorized Fact Sheets for Healthcare Providers, the authorized Fact Sheets 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 and the Alinity m Resp-4-Plex 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."

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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 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

June 2022
51-608451/R4

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