December 6, 2024

Abbott Molecular
Stacy Ferguson
Director Regulatory Affairs
1300 E Touhy Ave
Des Plaines, Illinois 60018

Re: K241580
Trade/Device Name: Alinity m SARS-CoV-2
Regulation Number: 21 CFR 866.3981
Regulation Name: Device To Detect And Identify Nucleic Acid Targets In Respiratory Specimens From Microbial Agents That Cause The SARS-Cov-2 Respiratory Infection And Other Microbial Agents When In A Multi-Target Test
Regulatory Class: Class II
Product Code: QQX
Dated: May 31, 2024
Received: June 3, 2024

Dear Stacy Ferguson:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Anna M. Mielech -S

Anna Mielech, Ph.D.
Deputy Branch Chief (Acting)
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241580

Device Name
Alinity m SARS-CoV-2

Indications for Use *(Describe)*

Alinity m SARS-CoV-2 is a real-time *in vitro* reverse transcription polymerase chain reaction (RT-PCR) assay for use with the automated Alinity m System for the qualitative detection of nucleic acid from SARS-CoV-2 from patients with signs and symptoms of COVID-19 in nasopharyngeal (NP) swab and anterior nasal swab (ANS) specimens.

Results are for the detection and identification of SARS-CoV-2 RNA. Alinity m SARS-CoV-2 assay is intended for use as an aid in the diagnosis of COVID-19 if used in conjunction with other clinical, epidemiologic, and laboratory findings. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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1.0 510(k) Summary

This 510(k) summary is being submitted in accordance with the requirement of 21 CFR Section 807.92(c).

1.1 Submitter

Applicants Name and Address:	Abbott Molecular Inc. 1300 E. Touhy Ave Des Plaines, IL 60018
Contact Person:	Stacy Ferguson Director Regulatory Affairs Abbott Molecular, Inc. 1300 E. Touhy Avenue Des Plaines, IL 60018 Phone: 224-361-7449 Fax: 224-361-7269
Date Prepared:	December 4, 2024

1.2 Device Information

Trade Name	Regulation Name	Product Code	Regulation Number	Class
Alinity m SARS-CoV-2	Respiratory Specimen Nucleic Acid SARS-CoV-2 Test	QQX	21 CFR 866.3981	II

1.3 Predicate Device

Predicate Device	510(k)	Date Cleared
Roche cobas® SARS-CoV-2 Qualitative for use on the cobas 6800/8800 Systems	K213804	October 22, 2022

1.4 Indication(s) for Use

1.4.1 Alinity m SARS-CoV-2 AMP Kit (List No. 09N78-096)

Alinity m SARS-CoV-2 is a real-time *in vitro* reverse transcription polymerase chain reaction (RT-PCR) assay for use with the automated Alinity m System for the qualitative detection of nucleic acid from SARS-CoV-2 from patients with signs and symptoms of COVID-19 in nasopharyngeal (NP) swab and anterior nasal (ANS) swab specimens.

Results are for the detection and identification of SARS-CoV-2 RNA. Alinity m SARS-CoV-2 assay is intended for use as an aid in the diagnosis of COVID-19 if used in conjunction with other clinical, epidemiologic, and laboratory findings. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.

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

1.5 Device Description

Alinity m SARS-CoV-2 is a real-time *in vitro* reverse transcription polymerase chain reaction (RT-PCR) assay for use with the automated Alinity m System for the qualitative detection of nucleic acid from SARS-CoV-2 in specimens collected from patients with signs and symptoms of COVID-19.

The steps of the Alinity m SARS-CoV-2 assay consist of sample preparation, RT-PCR assembly, amplification/detection, and result reporting. All stages of the Alinity m SARS-CoV-2 assay procedure are executed automatically by the Alinity m System. No intermediate processing or transfer steps are performed by the user. The Alinity m System is designed to be a random-access analyzer that can perform the Alinity m SARS-CoV-2 assay in parallel with other Alinity m assays on the same instrument.

The Alinity m SARS-CoV-2 assay requires two separate assay specific kits as follows:

- **Alinity m SARS-CoV-2 AMP Kit; 09N78-096** is comprised of 2 types of multi-well trays: Alinity m SARS-CoV-2 AMP TRAY 1 and Alinity m SARS-CoV-2 ACT TRAY 2. The intended storage condition for the Alinity m SARS-CoV-2 AMP Kit is –15°C to –25°C.
- **Alinity m SARS-CoV-2 CTRL Kit**; **09N78-086** consists of negative controls and positive controls, each supplied as liquid in single-use tubes. The Alinity m SARS-CoV-2 controls are used for validity determination of the Alinity m SARS-CoV-2 assay on the automated Alinity m System. These controls are intended to be used with the Alinity m SARS-CoV-2 assay. The intended storage condition for the Alinity m SARS-CoV-2 Control Kit is –15°C to –25°C.

The Alinity m SARS-CoV-2 assay may utilize the following for collection and transport of anterior nasal swab specimens:

- **Abbott Universal Collection Kit; 09N92-030** consists of one Transport Tube with a solid cap containing 1.65 mL Specimen Transport Buffer and one sterile Specimen Collection Swab. The Abbott Universal Collection Kit is intended for the collection and transport of anterior nasal swabs for testing with the Alinity m SARS-CoV-2 assay. The collected specimens are intended to be tested on the automated Alinity m

System. The intended storage condition for the Abbott Universal Collection Kit is 15°C to 30°C.

- **Abbott Universal Collection Kit II; 09N92-040** consists of one Transport Tube with a pierceable cap containing 1.65 mL Specimen Transport Buffer, one sterile Specimen Collection Swab, and one absorbent pad. The Abbott Universal Collection Kit II is intended for the collection and transport of anterior nasal swabs for testing with the Alinity m SARS-CoV-2 assay. The collected specimens are intended to be tested on the automated Alinity m System; The intended storage condition for the Abbott Universal Collection Kit is 15°C to 30°C.

SARS-CoV-2 RNA from specimens is extracted automatically on-board the Alinity m System using the Alinity m Sample Prep Kit 2, Alinity m Lysis Solution, and Alinity m Diluent Solution. The Alinity m System employs magnetic microparticle technology to facilitate nucleic acid capture, wash and elution. The resulting purified nucleic acids are then combined with the liquid unit-dose activation reagent, liquid unit-dose amplification reagents, and Alinity m Vapor Barrier Solution, and transferred by the instrument to an amplification/detection module for reverse transcription, PCR amplification, and real-time fluorescence detection.

Assay controls are tested to help ensure that instrument and reagent performance remain satisfactory. During each control event, a negative control and a positive control are processed through sample preparation and RT- PCR procedures that are identical to those used for specimens. Assay controls are used to demonstrate proper sample processing and assay validity. Each Alinity m SARS-CoV-2 CTRL kit contains 12 vials (1.3 mL fill volume) of Negative Control and 12 vials (1.3 mL fill volume) of Positive Control.

The Alinity m SARS-CoV-2 amplification reagents include primers and probes that amplify and detect an exogenous internal control (containing an armored RNA sequence). Amplification and detection of the internal control demonstrates proper sample processing. The internal control is used to demonstrate assay validity.

Patient results are automatically reported on the Alinity m instrument. The Alinity m SARS-CoV-2 application parameters will be contained in an assay application specification file.

The Alinity m SARS-CoV-2 assay also utilizes the following:

- Alinity m SARS-CoV-2 Assay Application Specification File, List No. 09N78-05A

  The Alinity m SARS-CoV-2 application specification file is intended for use with the Alinity m SARS-CoV-2 assay on the automated Alinity m System to allow for processing of assay controls and patient samples.

- Alinity m System and System Software, List No. 08N53-002
- Alinity m Sample Prep Kit 2, List No. 09N12-001
- Alinity m Tubes and Caps, List No. 09N49:
  - Alinity m Transport Tubes Pierceable Capped, List No. 09N49-010
  - Alinity m Transport Tube, List No. 09N49-011
  - Alinity m Pierceable Cap, List No. 09N49-012
  - Alinity m Aliquot Tube, List No. 09N49-013
- Alinity m System Solutions, List No. 09N20
- Alinity m Lysis Solution, List No. 09N20-001
- Alinity m Diluent Solution, List No. 09N20-003
- Alinity m Vapor Barrier Solution, List No. 09N20-004

1.6 Similarities and Differences to Predicate Devices

1.6.1 Alinity m SARS-CoV-2

The legally marketed predicate device chosen for the current submission is the Roche cobas SARS-CoV-2 Qualitative for use on the cobas 6800/8800 Systems assay. The Alinity m SARS-CoV-2 assay is substantially equivalent to the predicate device intended for the qualitative detection of SARS-CoV-2. The primary similarities between Alinity m SARS-CoV-2 assay and the predicate device are presented in **Table 1.** The primary differences between Alinity m SARS-CoV-2 and the predicate device are shown in **Table 2**. Both the Alinity m SARS-CoV-2 assay and the predicate have the same intended use. Any technological differences that exist between Alinity m SARS-CoV-2 assay and the predicate device do not raise new types of safety or effectiveness questions.

Table 1. Similarities Between Alinity m SARS-CoV-2 Assay and Predicate Device		
Feature	**Current Submission**	**Predicate Device**
Device Trade Name	**Alinity m SARS-CoV-2 Assay (K241580)**	**Roche cobas® SARS-CoV-2 Qualitative for use on the cobas 6800/8800 Systems (K213804)**
Regulation Number and Product Code	21 CFR 866.3981; QQX	21 CFR 866.3981; QQX
Device Class	II	II
Technology/Detection	Real-Time Reverse Transcription- Polymerase Chain Reaction (RT-PCR)	Real-Time Reverse Transcription- Polymerase Chain Reaction (RT-PCR)
Intended Use/ Indications For Use	Alinity m SARS-CoV-2 is a real-time *in vitro* reverse transcription polymerase chain reaction (RT-PCR) assay for use with the automated Alinity m System for the qualitative detection of nucleic acid from SARS-CoV-2 from patients with signs and symptoms of COVID-19 in nasopharyngeal (NP) swab and anterior nasal (ANS) swab specimens. Results are for the detection and identification of SARS-CoV-2 RNA. Alinity m SARS-CoV-2 assay is intended for use as an aid in the diagnosis of COVID-19 if used in conjunction with other clinical, epidemiologic, and laboratory findings. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status.	cobas SARS-CoV-2 Qualitative for use on the cobas 6800/8800 Systems is a real- time RT-PCR test intended for the qualitative detection of nucleic acids from SARS- CoV-2 in nasal and nasopharyngeal specimens collected from symptomatic individuals suspected of COVID-19 by their healthcare provider. Results are for the detection of SARS-CoV-2 RNA. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other pathogens. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Results are meant to be used in conjunction with clinical observations, patient history, recent exposures and epidemiological information, and laboratory data, in accordance with the guidelines provided by the relevant public health authorities. cobas SARS-

Table 1. Similarities Between Alinity m SARS-CoV-2 Assay and Predicate Device		
Feature	**Current Submission**	**Predicate Device**
Device Trade Name	**Alinity m SARS-CoV-2 Assay (K241580)**	**Roche cobas® SARS-CoV-2 Qualitative for use on the cobas 6800/8800 Systems (K213804)**
	Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.	CoV-2 is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and on the use of the cobas 6800/8800 Systems.
Conditions for use	For prescription use	For prescription use
Assay Type	Qualitative	Qualitative
Specimen Types	• Nasopharyngeal swab • Anterior Nasal swab	• Nasopharyngeal swab • Nasal swab
Assay Targets	SARS-CoV-2 RNA	SARS-CoV-2 RNA
Assay Steps	All steps of the Alinity SARS-CoV-2 assay procedure are executed automatically by the Alinity m System. No intermediate processing or transfer steps are performed by the user.	All steps of the cobas® SARS-CoV-2 qualitative assay procedure are executed automatically by the cobas® 6800/8800 Systems. No intermediate processing or transfer steps are performed by the user.
Principles of the Procedure	Alinity m SARS-CoV-2 is a real-time *in vitro* reverse transcription polymerase chain reaction (RT-PCR) assay for use with the automated Alinity m System for the qualitative detection of	cobas® SARS-CoV-2 is based on fully automated sample preparation (nucleic acid extraction and purification) followed by PCR amplification and detection. The cobas® 6800/8800 Systems consist of the sample supply module, the transfer module, the processing module, and the analytic module. Automated data

Table 1. Similarities Between Alinity m SARS-CoV-2 Assay and Predicate Device		
Feature	**Current Submission**	**Predicate Device**
Device Trade Name	**Alinity m SARS-CoV-2 Assay (K241580)**	**Roche cobas® SARS-CoV-2 Qualitative for use on the cobas 6800/8800 Systems (K213804)**
	nucleic acid from SARS-CoV-2 in NP swab and ANS specimens. The steps of the Alinity m SARS-CoV-2 assay consist of sample preparation, RT-PCR assembly, amplification/detection, and result reporting. All stages of the Alinity m SARS-CoV-2 assay procedure are executed automatically by the Alinity m System. No intermediate processing or transfer steps are performed by the user. The Alinity m System is designed to be a random-access analyzer that can perform the Alinity m SARS-CoV-2 assay in parallel with other Alinity m assays on the same instrument. SARS-CoV-2 RNA from specimens are extracted automatically on-board the Alinity m System using the Alinity m Sample Prep Kit 2, Alinity m Lysis Solution, and Alinity m Diluent Solution. The Alinity m System employs magnetic microparticle technology to facilitate nucleic acid capture, wash and elution. The resulting purified nucleic acids are then combined with the liquid unit-dose activation reagent, liquid unit-dose amplification reagents, and	management is performed by the cobas® 6800/8800 software, which assigns test results for all tests. Results can be reviewed directly on the system screen, and printed as a report. Nucleic acid from patient samples and added internal control RNA (RNA IC) molecules are simultaneously extracted. Nucleic acid is released by addition of proteinase and lysis reagent to the sample. The released nucleic acid binds to the silica surface of the added magnetic glass particles. Unbound substances and impurities, such as denatured protein, cellular debris and potential PCR inhibitors, are removed with subsequent wash steps and purified nucleic acid is eluted from the magnetic glass particles with elution buffer at elevated temperature. External controls (positive and negative) are processed in the same way with each cobas® SARS-CoV- 2 run. Selective amplification of target nucleic acid from the sample is achieved by the use of target-specific forward and reverse primers for ORF1 a/b non-structural region that is unique to SARS-CoV-2. Additionally, a conserved region in the structural protein envelope E-gene were chosen for pan-Sarbecovirus detection. The pan-Sarbecovirus detection sets will also detect SARS-CoV-2 virus. Selective amplification of RNA Internal Control is achieved by the use of non- competitive sequence specific forward and reverse primers which have no homology with the coronavirus genome. A thermostable DNA polymerase enzyme is used for amplification.

Table 1. Similarities Between Alinity m SARS-CoV-2 Assay and Predicate Device		
Feature	**Current Submission**	**Predicate Device**
Device Trade Name	**Alinity m SARS-CoV-2 Assay (K241580)**	**Roche cobas® SARS-CoV-2 Qualitative for use on the cobas 6800/8800 Systems (K213804)**
	Alinity m Vapor Barrier Solution, and transferred by the instrument to an amplification/detection module for reverse transcription, PCR amplification, and real- time fluorescence detection.	The cobas® SARS-CoV-2 master mix contains detection probes which are specific for the coronavirus type SARS-CoV-2, members of the Sarbecovirus subgenus, and the RNA Internal Control nucleic acid. The coronavirus and RNA Internal Control detection probes are each labeled with unique fluorescent dyes that act as a reporter. Each probe also has a second dye which acts as a quencher. When not bound to the target sequence, the fluorescent signals of the intact probes are suppressed by the quencher dye. During the PCR amplification step, hybridization of the probes to the specific single-stranded DNA template results in cleavage of the probe by the 5' to 3' exonuclease activity of the DNA polymerase resulting in separation of the reporter and quencher dyes and the generation of a fluorescent signal. With each PCR cycle, increasing amounts of cleaved probes are generated and the cumulative signal of the reporter dye increases concomitantly. Each reporter dye is measured at defined wavelengths, which enables simultaneous detection and discrimination of the amplified coronavirus target and the RNA Internal Control. The master mix includes deoxyuridine triphosphate (dUTP), instead of deoxythimidine triphosphate (dTTP), which is incorporated into the newly synthesized DNA (amplicon). Any contaminating amplicons from previous PCR runs are destroyed by the AmpErase enzyme [uracil-N-glycosylase], which is included in the PCR mix, when heated in the first thermal cycling step. However, newly

Table 1. Similarities Between Alinity m SARS-CoV-2 Assay and Predicate Device		
Feature	**Current Submission**	**Predicate Device**
Device Trade Name	**Alinity m SARS-CoV-2 Assay (K241580)**	**Roche cobas® SARS-CoV-2 Qualitative for use on the cobas 6800/8800 Systems (K213804)**
		formed amplicons are not destroyed since the AmpErase enzyme is inactivated once exposed to temperatures above 55°C.
Instrumentation System Components	Alinity m System: High-throughput, fully integrated laboratory automation system which utilize real-time PCR technology	cobas® 6800/8800 Systems: High-throughput, fully integrated laboratory automation systems which utilize real- time PCR technology
Sample Preparation Instrument Components	Automated liquid handling and robotic manipulation platform.	Automated liquid handling and robotic manipulation platform
Amplification and Detection Instrument Components	The Amp-Detect units of the Alinity m System are comprised of PCR thermal cycler/fluorescence reader modules that automate the steps for real-time PCR.	The Analytic Modules of the cobas® 6800/8800 Systems are used for amplification and detection of nucleic acid using real-time PCR, which is carried out by employing fluorescence spectroscopy.
Sample Extraction Technology	• Non-specific nucleic acid capture with magnetic microparticles • Magnetic microparticles are washed to remove unbound sample components including potential inhibitors. • The bound nucleic acids are eluted and transferred to the lyophilized master mix.	• Nucleic acid capture with magnetic glass particles • Magnetic glass particles are washed to remove unbound substances and impurities, such as denatured protein, cellular debris and potential PCR inhibitors. • The purified nucleic acids are eluted from the glass particles with elution buffer.

Table 1. Similarities Between Alinity m SARS-CoV-2 Assay and Predicate Device		
Feature	**Current Submission**	**Predicate Device**
Device Trade Name	**Alinity m SARS-CoV-2 Assay (K241580)**	**Roche cobas® SARS-CoV-2 Qualitative for use on the cobas 6800/8800 Systems (K213804)**
	An internal control (IC) is taken through the entire sample preparation and real-time PCR procedure along with the specimens, calibrators, and controls to demonstrate proper sample processing and IC validity.	An internal control (ie, DNA-QS) is taken through the sample preparation procedure along with the specimens for monitoring the sample preparation and PCR amplification process.
Amplification Controls	Assay specific IC. The IC primer/probe set amplifies and detects an exogenous RNA sequence unrelated to the SARS-CoV-2 target sequences	Selective amplification of RNA Internal Control is achieved by the use of non- competitive sequence specific forward and reverse primers which have no homology with the coronavirus genome.
Detection Procedure	• Optical detection of stimulated fluorescence. The fluorescence reader monitors real-time fluorescence during every PCR amplification cycle.	• Optical detection of stimulated fluorescence. The Analytic Module monitors real-time fluorescence during every PCR amplification cycle.
Detection Chemistry	• Fluorescence labeled, single stranded, target-specific probes. • Detection of the DNA amplicon is achieved using nucleic acid (DNA:DNA) hybridization. • Probes labeled with different fluorophores allowing SARS-CoV-2 to be distinguished from the IC amplicons.	Paired reporter and quencher fluorescence labeled probes (TaqMan Technology) using fluorescence resonance energy transfer (FRET)
Assay Controls	• Internal Control (IC) • Negative Control • Positive Control	• Sample processing Control (IC) • Negative control • Positive control

Table 2. *Differences* Between Alinity m SARS-CoV-2 Assay and Predicate Device		
Feature	**Current Submission**	**Predicate Device**
	Alinity m SARS-CoV-2 Assay (K241580)	**Roche cobas® SARS-CoV-2 Qualitative (K213804)**
Specimen Collection and Transport	Nasopharyngeal samples must be collected in viral transport media. Nasal specimens must be collected in viral transport medium, universal transport media, or *Abbott Universal Collection Kit, or Abbott Universal Collection Kit II*.	Nasopharyngeal swab and nasal swab, specimens collected in viral transport medium or *universal transport media*. Nasal swab specimens may also be collected in *cobas® PCR Media Uni Swab Sample Kit, cobas® PCR Media Dual Swab Sample Kit, cobas® PCR Media Kit (and 100 tube PCR Media Kit), or 0.9% Physiological Saline.*
Results Reporting	• Not Detected, Negative • *xx.xx CN*, Positive	• *Target 1 and Target 2 Positive, Detected* • *Target 1 Positive and Target 2 Negative, Detected* • *Target 1 Negative and Target 2 Positive, Presumptive Positive* • *Target 1 and 2 Negative, Not Detected*
Instrument System	• Alinity m System	• Cobas 6800/8800 Systems

1.7 Performance Data

The following performance data were provided in support of the substantial equivalence determination.

1.7.1 Specific Performance Characteristics – Analytical Studies

1.7.1.1 Limit of Detection (Analytical Sensitivity) Using Cultured Gamma-Irradiated Virus in Nasopharyngeal Swab Clinical Matrix

LoD in clinical Nasopharyngeal (NP) swab matrix was evaluated by testing dilutions of cultured gamma-irradiated SARS-CoV-2 virus (USA-WA1/2020; BEI Catalog NR-52287, Lot 70033322) prepared in pooled SARS-CoV-2 negative clinical NP swab specimens collected in UTM. The initial LoD was determined by testing 3 target levels at 0.0180, 0.0090, and 0.0045 $TCID_{50}$/mL, each in replicates of 4. LoD was confirmed by testing the 3 target levels, each in replicates of 21. The results are summarized in **Table 3**. The LoD for NP swab specimens was determined to be 0.009 $TCID_{50}$/mL [or 55 Genome Equivalents (GE)/mL].

Table 3. Limit of Detection Using Cultured Gamma-Irradiated SARS-CoV-2 Virus in Nasopharyngeal Swab Clinical Matrix

Concentration		Number of Replicates		
$TCID_{50}$/mL[a]	GE[b]/mL	Valid	Positive	Positive Rate (%)
0.0180	109	21	20	95.2
0.0090	55	21	21	100.0
0.0045	27	21	7	33.3

[a] $TCID_{50}$/mL = Median Tissue Culture Infectious Dose/mL.

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

1.7.1.2 Limit of Detection (Analytical Sensitivity) Using Cultured Gamma-Irradiated Virus in Nasal Swab Clinical Matrix

LoD in clinical nasal swab matrix was evaluated by testing dilutions of cultured gamma-irradiated SARS-CoV-2 virus (USA-WA1/2020; BEI Catalog NR-52287, Lot 70033322) prepared in pooled SARS-CoV-2 negative clinical nasal swab specimens collected in UTM. The initial LoD was determined by testing 3 target levels at 0.0180, 0.0090, and 0.0045 $TCID_{50}$/mL, each in replicates of 3. LoD was confirmed by testing the 3 target levels, each in replicates of 21. The results are summarized in **Table 4**. The LoD of 0.0180 $TCID_{50}$/mL [or 10^9 GE/mL] was determined for nasal swab specimens.

Table 4. Limit of Detection Using Cultured Gamma-Irradiated SARS-CoV-2 Virus in Nasal Swab Clinical Matrix

Concentration		Number Of Replicates		
$TCID_{50}$/mL	**GE[a]/mL**	**Valid**	**Positive**	**Positive Rate (%)**
0.0180	109	21	21	100.0
0.0090	55	21	17	81.0
0.0045	27	21	9	42.9

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

1.7.1.3 Limit of Detection Using Cultured Gamma-Irradiated Virus in Universal Collection Kit Swab Clinical Matrix

LoD in clinical nasal swab matrix was evaluated by testing dilutions of cultured gamma-irradiated SARS-CoV-2 virus (USA-WA1/2020; BEI Catalog NR-52287, Lot 70039068) prepared in pooled SARS-CoV-2 negative clinical Universal Collection Kit (UCK) nasal swab specimens. The initial LoD was determined by testing 4 target levels at 109.0, 55.0, 27.0, and 13.5 GE/mL, each in replicates of 3. LoD was confirmed by testing 3 target levels (109.0, 55.0, and 27.0 GE/mL), each in replicates of 20. The results are summarized in **Table 5**. The LoD of 55 GE/mL was determined for UCK swab specimens.

Table 5. Limit of Detection Using Cultured Gamma-Irradiated SARS-CoV-2 Virus in Nasal Swab Matrix

Concentration	Number Of Replicates		
GE[a]/mL	Valid	Positive	Positive Rate (%)
109	20	20	100.0
55	20	20	100.0
27	20	4	20.0

[a] Based on the information provided in the Certificate of Analysis from the vendor, 1 $TCID_{50}$ is equal to 273 genome equivalents (GE) by ddPCR.

1.7.1.4 Detection of SARS-CoV-2 in WHO International Standard

Detection of SARS-CoV-2 by Alinity m SARS-CoV-2 was evaluated by testing World Health Organization (WHO) 1st International Standard for SARS-CoV-2 (NIBSC code: 20/146) at 8 concentration levels (125, 100, 75, 50, 25, 10, 5, and 1 IU/mL), prepared in simulated nasal matrix (SNM). Each concentration level was tested in a total of 24 replicates. The results are summarized in **Table 6**.

Table 6. Detection of SARS-CoV-2 Virus in WHO International Standard

Concentration	**Number of Replicates**		
IU/mL	**Valid**	**Positive**	**Positive Rate (%)**
125	24	24	100.0
100	24	24	100.0
75	24	21	87.5
50	24	20	83.3
25	24	16	66.7
10	24	7	29.2
5	24	1	4.2
1	24	0	0.0

1.7.1.5 Precision

Alinity m SARS-CoV-2 assay within-laboratory precision was evaluated using a 3-member panel composed of 2 positive panel members and 1 negative panel member in simulated nasal matrix (SNM). The 2 positive panels consisted of one moderate positive panel member containing gamma irradiated SARS-CoV-2 virus at approximately 5X LoD and one low positive panel at approximately 2X LoD. Negative SNM was used as a negative panel member. The SARS-CoV-2 positive panel members were prepared by diluting cultured gamma-irradiated SARS-CoV-2 virus (USA-WA1/2020; BEI Catalog No. NR-52287, Lot 70033322) in SNM. Each panel member was tested in 4 replicates in a run, 2 runs each day for 5 days, on 3 Alinity m Systems with 3 Alinity m SARS-CoV-2 AMP Kit lots by 3 operators, for a total of 120 replicates for each panel member. The results, representative of the precision of Alinity m SARS-CoV-2, are summarized in **Table 7**. The positive percent agreement was 99.2% for low positive and 100.0% for moderate positive. The negative percent agreement was 100.0%.

Table 7. Precision

Panel Member	N[a]	N[b]	Agreement (n/N)	Mean CN	Within-Run Component		Between-Run Component		Between-Day Component		Within-Laboratory[c]		Between-Instrument/ Lot/Operator Component[d]		Total[e]	
					SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
Moderate Positive (5x LoD)	120	120	100.0%	34.49	0.808	2.3	0.000	0.0	0.368	1.1	0.888	2.6	0.000	0.0	0.888	2.6
Low Positive (2x LoD)	119	118	99.2%	36.15	0.966	2.7	0.000	0.0	0.311	0.9	1.015	2.8	0.181	0.5	1.031	2.9
Negative	119	119	100.0%	-	-	-	-	-	-	-	-	-	-	-	-	-

[a] Total number of valid replicates.

[b] Replicates with positive result interpretation for positive panels and negative result interpretation for negative panel. Number of replicates used in the Mean and SD calculation for the positive panel members.

[c] Within-laboratory includes Within-Run, Between-Run, and Between-Day Components.

[d] Alinity m System, Alinity m SARS-CoV-2 AMP Kit lot, and Operator are confounded, and the confounding effect is represented by Instrument/Lot/Operator.

[e] Total includes Within-Run, Between-Run, Between-Day, and Between-Instrument/Lot/Operator Components.

1.7.1.6 Precision in Universal Collection Kits Sample Matrix

Alinity m SARS-CoV-2 assay within-laboratory precision was evaluated using a 3-member panel composed of 2 positive panel members and 1 negative panel member in simulated Universal Collection Kits sample matrix. The 2 positive panels consisted of one moderate positive panel member containing gamma irradiated SARS-CoV-2 virus at approximately 5X LoD and one low positive panel at approximately 2X LoD. Negative SNM was used as a negative panel member. The SARS-CoV-2 positive panel members were prepared by diluting cultured gamma-irradiated SARS-CoV-2 virus (USA-WA1/2020; BEI Catalog No. NR-52287, Lot 70039068) in simulated Universal Collection Kit sample matrix. Each panel member was tested in 3 replicates in a run, 2 runs each day for 5 days, on 3 Alinity m Systems with 3 Alinity m SARS-CoV-2 AMP Kit lots by 3 operators, for a total of 90 replicates for each panel member. The results, representative of the precision of Alinity m SARS-CoV-2, are summarized in **Table 8**.

The positive percent agreement was 100.0% and the negative percent agreement was 100.0%.

Table 8. Precision in Simulated Universal Collection Kits Sample Matrix

Panel Member	N[a]	N[b]	Agreement (n/N)	Mean CN	Within-Run Component		Between-Run Component		Between-Day Component		Within-Laboratory[c]		Between-Instrument/ Lot/Operator Component[d]		Total[e]	
					SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
Moderate Positive (5x LoD)	90	90	100.0%	33.85	0.525	1.6	0.000	0.0	0.000	0.0	0.525	1.6	0.128	0.4	0.541	1.6
Low Positive (2x LoD)	90	90	100.0%	35.38	0.681	1.9	0.000	0.0	0.000	0.0	0.681	1.9	0.085	0.2	0.686	1.9
Negative	90	90	100.0%	-	-	-	-	-	-	-	-	-	-	-	-	-

[a] Total number of valid replicates.

[b] Replicates with positive result interpretation for positive panels and negative result interpretation for negative panel. Number of replicates used in the Mean and SD calculation for the positive panel members.

[c] Within-laboratory includes Within-Run, Between-Run, and Between-Day Components.

[d] Alinity m System, Alinity m SARS-CoV-2 AMP Kit lot, and Operator are confounded, and the confounding effect is represented by Instrument/Lot/Operator.

[e] Total includes Within-Run, Between-Run, Between-Day, and Between-Instrument/Lot/Operator Components.

1.7.1.7 Reproducibility

Reproducibility of the Alinity m SARS-CoV-2 assay was evaluated at 3 external clinical testing sites by testing a 3-member panel prepared with SNM. The 2 positive panels consisted of one moderate positive panel member containing gamma irradiated SARS-CoV-2 virus (USA-WA1/2020; BEI Catalog NR-52287, Lot 70033322) at approximately 5X LoD and one low positive panel at approximately 2X LoD. Negative SNM was used as a negative panel member. A total of 3 Alinity m SARS-CoV-2 AMP Kit lots were used. Each of the 3 external sites tested 2 Alinity m SARS-CoV-2 AMP Kit lots, on 5 non-consecutive days for each lot. Four replicates of each panel member were tested on each of 5 days. Each of the 3 external sites used different lots of Alinity m SARS-CoV-2 CTRL Kits and Alinity m Sample Prep Kit 2. The reproducibility results are summarized in **Table 9**.

Table 9. Reproducibility

Panel Member	N[a]	N[b]	Agreement (n/N)	Mean CN	Within-Run Component		Between-Run Component		Between-Day Component		Within-Laboratory[c]		Between-Site/Instrument Component		Total[d]	
					SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	%CV
Moderate Positive (5x LoD)	120	120	100.0%	34.27	0.62	1.8	0.00	0.0	0.54	1.6	0.535	1.6	0.00	0.0	0.82	2.4
Low Positive (2x LoD)	119	119	100.0%	35.78	0.74	2.1	0.38	1.1	0.28	0.8	0.681	1.9	0.17	0.5	0.89	2.5
Negative	119	119	100.0%	-	-	-	-	-	-	-	-	-				

[a] Total number of valid replicates.

[b] Replicates with positive result interpretation for positive panels and negative result interpretation for negative panel. Number of replicates used in the Mean and SD calculation for the positive panel members.

[c] Within-laboratory includes Within-Run, Between-Run, and Between-Day Components.

[d] Total includes Within-Run, Between-Run, Between-Day, and Between-Instrument Components.

1.7.1.8 Analytical Specificity: Potentially Interfering Substances

The effects of potentially interfering substances that may be encountered in respiratory specimens on Alinity m SARS-CoV-2 performance were evaluated by testing both SARS-CoV-2 negative panel and SARS-CoV-2 positive panel (targeted to 3X LoD) in the presence of the substances (**Table 10**). No interference in the performance of Alinity m SARS-CoV-2 was observed for the tested substances at concentrations listed in **Table 10**.

Table 10. Potentially Interfering Endogenous and Exogenous Substances

Substance	Active Ingredient(s)	Tested Concentration
Analgesic Ointment – Vicks® VapoRub™	Camphor-synthetic, eucalyptus oil and menthol ointment	1% (w/v)
Antibacterial, Systemic (Tobramycin)	Tobramycin	4 µg/mL
Antibiotic, Nasal Ointment - Bactroban®	Mupirocin	5 mg/mL
Anti-Viral Drug - Relenza™	Zanamivir	5 mg/mL
Anti-Viral Drug - Tamiflu®	Oseltamivir	3.3 mg/mL
Anti-Viral Drug - Veklury®	Remdesivir	27.0 µM
Blood (human)[a]	N/A	10% (v/v)
Chloroseptic Sore Throat Spray	Phenol	5% (v/v)
Corticosteroid - Dexamethasone	Dexamethasone	0.2 mg/mL
Cough Syrup (Wal-Tussin)	Dextromethorphan and guaifenesin	5% (v/v)
FluMist©[b]	Live intranasal influenza virus	10% (v/v)
Human Genomic DNA	N/A	0.02 mg/mL
Leukocytes	Leukocytes	1.1E6 cells/mL
Liposomal-NUMB250 Spray	Lidocaine and Phenylephrine	2.68 mg/mL
Mucin - Bovine	Purified bovine mucin protein	5 mg/mL
Mucin – Porcine[c]	Purified porcine mucin protein	5 mg/mL
Nasal Corticosteroid - Budesonide	Budesonide	2% (v/v)
Nasal Corticosteroid - Flunisolide	Flunisolide	2% (v/v)

Table 10. Potentially Interfering Endogenous and Exogenous Substances

Nasal Corticosteroid - Mometasone	Mometasone	2% (v/v)
Nasal Corticosteroid - QVAR®	Beclomethasone	2% (v/v)
Nasal Corticosteroid - Triamcinolone	Triamcinolone	2% (v/v)
Nasal Corticosteroid - Flonase® Sensimist™	Fluticasone Furoate	10% (v/v)
Nasal Decongestant - Phenylephrine	Phenylephrine	2% (v/v)
Nasal Gel /Homeopathic Allergy Relief Medicine - Zicam®[c]	Galphimia glauca, Histaminum hydrochloricum, Luffa operculata, Sulfur	10% (v/v)
Nasal Spray-Afrin®	Oxymetazoline	15% (v/v)
Nicotine Product	Nicotine	0.05 mg/mL
Oral rinse- Listerine® Cool Mint®	Ethanol, essential oil	10% (v/v)
Saline nasal mist	Sodium chloride	2% (v/v)
Saliva (Human)	N/A	10% (v/v)
Throat Lozenges, Oral Anesthetic and Analgesic - Cepacol®	Benzocaine, Menthol	5 mg/mL
Throat Lozenge – Cold Eeze®	Zincuum Gluconicum	2.5% (w/v)
Tobacco product	Nicotine	0.1% (w/v)
Toothpaste	Fluoride	1% (w/v)
Vaseline®	Petroleum Jelly	1% (w/v)

[a] One replicate was valid and not detected. Per protocol, the sample was retested in triplicate and all retest samples were valid and detected.
[b]FluMist was not tested for negative panel due to material availability.
[c] One replicate was a “no test” (instrument error) and per protocol, the sample was retested in triplicate and all retest samples were valid and detected.

1.7.1.9 Analytical Specificity: Potential Cross-reactivity and Microbial Interference

A panel of potential cross-reacting microorganisms (viruses, bacteria, and fungi) that are phylogenetically related to the analyte of the assay or that are commonly found in respiratory tract and pooled human nasal wash were tested with Alinity m SARS-CoV-2 to assess cross-reactivity and microbial interference. The microorganisms, except where noted otherwise in **Table 11**, were tested at 10^5 Units/mL for viruses and fungi and 10^6 Units/mL for bacteria, 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, viral lysate, or viral RNA.

To assess potential cross-reactivity, each microorganism was tested in SARS-CoV-2 negative samples. No cross-reactivity was observed in the presence of the tested microorganisms (**Table 11**) at the concentrations tested.

To assess potential microbial interference, microorganisms were added to positive samples containing SARS-CoV-2 targeted to 3X LoD. No interference in the performance of Alinity m SARS-CoV-2 was observed for the tested microorganisms (**Table 11**) at the concentrations tested.

Table 11. Potential Cross-Reactants

Bacteria		**Viruses**	
Bordetella pertussis	*Neisseria elongata*	Adenovirus Type 5[b]	MERS-coronavirus[d]
Chlamydia pneumoniae	*Neisseria meningitidis*	Bocavirus DNA	Mumps Virus
Chlamydophila psittaci	*Pseudomonas aeruginosa*	Cytomegalovirus (CMV)[b]	Parainfluenza virus 1[b]
Corynebacterium diphtheriae	*Staphylococcus epidermis*	Enterovirus EV68[b]	Parainfluenza virus 2[b]
Coxiella burnetti	*Staphylococcus aureus*	Epstein-Barr Virus (EBV)[b]	Parainfluenza virus 3[b]
Escherichia coli	*Streptococcus pneumoniae*	Human coronavirus 229E[c]	Parainfluenza virus 4[b]
Haemophilus influenzae	*Streptococcus salivarius*	Human coronavirus HKU1[d]	Parechovirus Type 3[b]
Lactobacillus gasseri	*Streptococcus pyogenes*	Human coronavirus NL63[c]	Respiratory syncytial virus Type A[c]
Lactobacillus (plantarum 17-5*)*	**Fungi**	Human coronavirus OC43[b]	Respiratory syncytial virus Type B[c]
Legionella pneumophila	*Aspergillus fumigatus*	Human Metapneumovirus (hMPV)	Rhinovirus[c]
Legionella longbeachae, Long Beach 4	*Candida albicans*	Influenza A (H1N1)[c]	SARS-coronavirus[d]
Moraxella catarrhalis	*Pneumocystis jirovecii* (PJP) (2% and 100%)[a]	Influenza A (H3N2)[c]	
Mycoplasma pneumoniae	**Other**	Influenza B[c]	
Mycobacterium tuberculosis	Pooled Human Nasal Wash (10%)	Measles[b]	

[a] The concentration provided by the vendor is expressed in Ct Range, 23 to 25. This sample was tested neat (100%) and as a 50-fold dilution (2%).

[b] Viral lysate

[c] Viral particles

[d] Viral RNA

1.7.1.10 Inclusivity

The inclusivity of Alinity m SARS-CoV-2 assay for the detection of SARS-CoV-2 was evaluated by testing 7 isolates of SARS-CoV-2 from 6 different geographical regions. SARS-CoV-2 isolates tested in this study were different from the inactivated virus tested in the Limit of Detection studies. Each individual virus isolate (inactivated virus or purified RNA) was tested in negative NP swab matrix in 5 replicates. The Alinity m SARS-CoV-2 assay detected all replicates of all isolates at the concentrations tested (Refer to **Table 12**). Additional *in silico* analysis of the RdRp and N primer/probe sets for homology with SARS-CoV-2 genomic sequences was performed and showed that more than 99.999% of the sequences available in the GISAID as of October 11, 2023 and NCBI as of October 10, 2023 databases are predicted to be detected by the Alinity m SARS-CoV-2 assay.

Table 12. Inclusivity

SARS-CoV-2 Isolate	Concentration[a]	Positive Rate (Number Positive/Total Valid)
USA-AZ1/2020	165 GE/mL	100% (5/5)
USA-CA3/2020	165 GE/mL	100% (5/5)
Hong Kong/VM20001061/2020	165 GE/mL	100% (5/5)
USA-IL1/2020	165 GE/mL	100% (5/5)
Italy-INMI1	165 GE/mL	100% (5/5)
USA/CA_CDC_5574/2020 (B.1.1.7)	0.027 $TCID_{50}$/mL	100% (5/5)
hCoV-19/South Africa/KRISP-K005325/2020 (B.1.351)	0.027 $TCID_{50}$/mL	100% (5/5)

[a] GE/mL = Genome Equivalent/mL or $TCID_{50}$/mL = Median Tissue Culture Infectious Dose/mL.

1.7.1.11 Carryover

The carryover rate for Alinity m SARS-CoV-2 was determined by analyzing 361 replicates of negative samples processed from alternating positions with high positive samples containing SARS-CoV-2 target at 2,000,000,000 Copies/mL, across a total of 15 runs. SARS-CoV-2 RNA was not detected in any of the negative samples, resulting in an overall carryover rate of 0.0% (95% CI: 0.0% to 1.1%).

1.7.2 Clinical Performance

The performance of the Alinity m SARS-CoV-2 assay was evaluated in 2 prospective clinical studies that tested prospective clinical specimens collected in viral transport media (UVT or UTM) and in Abbott Universal Collection Kit (UCK) from individuals presenting with signs and symptoms of a respiratory tract infection and/or COVID-19. Study 1 tested nasopharyngeal swab (NPS) specimens, collected by a healthcare provider (HCP), in UVT. Study 2 tested anterior self-collected anterior nasal swab (ANS) specimens by the subject under HCP supervision, in the UCK and UVT.

In both studies, the Alinity m SARS-CoV-2 results were compared to a composite comparator (CC) established using a minimum of two and up to three highly sensitive EUA SARS-CoV-2 molecular assays. A specimen was categorized as CC positive if a minimum of 2 comparator positive results were reported. A specimen was categorized as CC negative if a minimum of 2 comparator negative results were reported. A specimen was categorized as CC indeterminate if a CC could not be determined due to missing results from the comparator assays.

1.7.2.1 Study 1

NPS specimens were prospectively collected by the HCP at 8 geographically distributed locations in the US from January to February 2021. One NPS UVT specimen was collected from each subject for both Alinity m SARS-CoV-2 and comparator testing. A

total of 627 UVT NPS specimens from symptomatic subjects were tested by Alinity m SARS-CoV-2.

Valid Alinity m SARS-CoV-2 results were obtained for 611 specimens, of which 535 specimens had CC and were included in the analysis, while 76 specimens did not have CC.

1.7.2.2 Study 2

Anterior NS specimens were prospectively collected at 8 geographically distributed locations in the US from September 2021 to January 2022. Each subject self-collected 2 anterior NS specimens, one in UCK and another in UVT under HCP supervision, where the collection order (first specimen collected in UVT or UCK) alternated between two nostrils. ANS UCK specimens were tested by Alinity m SARS-CoV-2 only, whereas ANS UVT specimens were used for both Alinity m SARS-CoV-2 and comparator testing. A total of 792 ANS UCK specimens and 787 ANS UVT specimens from symptomatic subjects were available for testing by Alinity m SARS-CoV-2, of which 785 ANS UCK and 778 ANS UVT specimens had valid Alinity m SARS-CoV-2 results. Of the 785 ANS UCK specimens with valid results, 766 specimens had CC and were included in the analysis, while 19 specimens did not have CC. Of the 778 NS UVT specimens with valid results, 759 specimens had CC and were included in the analysis, while 19 specimens did not have CC. The analysis of the Alinity m SARS-CoV-2 results for the paired UCK and UVT specimens included 778 pairs.

For specimens in UVT, Alinity m SARS-CoV-2 yielded a positive percent agreement (PPA) with CC of 96.3% for NPS, and 100.0% for self-collected (under HCP supervision) ANS specimens; and a negative percent agreement (NPA) with CC of 95.2% for NPS, and 99.7% for ANS specimens. For the self-collected (under HCP supervision) ANS specimens in UCK, Alinity m SARS-CoV-2 yielded a PPA of 97.9% and an NPA of 97.9% when compared to CC. (**Table 13**).

Table 13. Clinical Performance of the Alinity m SARS-CoV-2 Assay Versus Composite Comparator

Specimen Type[a]	N	TP	FN	TN	FP	PPA (%) (95% CI)	NPA (%) (95% CI)
Nasopharyngeal Swab HCP-collected	535	154	6	357	18	96.3 (92.1,98.3)	95.2 (92.5,96.9)
Self-Collected[b]							
Anterior Nasal Swab (UVT)	759	96	0	661	2	100.0 (96.2,100.0)	99.7 (98.9,99.9)
Anterior Nasal Swab (UCK)	766	94	2	656	14	97.9 (92.7-99.4)	97.9 (96.5-98.8)

TP = true positive; FN = false negative; TN = true negative; FP = false positive

[a] HCP-collected nasopharyngeal swab data were from study 1. HCP-collected nasal swab data were from study 2. Self-collected nasal swab data were from study 3.

[b] Nasal swab specimens self-collected on-site with healthcare provider instructions.

2.0 Conclusion Drawn from the Studies

The analytical and clinical study results demonstrate that the Alinity m SARS-CoV-2 assay on the Alinity m System performs comparably to the predicate device in detecting SARS-CoV-2 and supports a substantial equivalence decision.