

Created May 2020

REF 09N78-080  
53-608194/R1

### CUSTOMER SERVICE: 1-800-553-7042

### CUSTOMER SERVICE INTERNATIONAL:

### CALL YOUR ABBOTT REPRESENTATIVE

Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

### NOTICE TO USER

If a serious incident occurs in relation to this device, the incident should be reported to the manufacturer and to the appropriate competent authority of the member state in which the user and/or the patient is established. To report to the manufacturer, see the contact information provided in the technical assistance section of these instructions.

### NAME

Alinity m SARS-CoV-2 CTRL Kit

### INTENDED USE

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; refer to the assay package insert for additional information.

### INTENDED USER

The intended users for Alinity m SARS-CoV-2 are laboratory and healthcare professionals. Sites of use for the Alinity m SARS-CoV-2 assay include:

- Healthcare facilities that provide patient care
- Reference diagnostic laboratories
- Private diagnostic laboratories
- Hospital based diagnostic laboratories
- Public health sector

### REAGENTS

#### Kit Contents

Alinity m SARS-CoV-2 Negative CTRL (List No. 9N78Z) contains 1.0% ammonium sulfate and 7.9% detergent in a buffer solution.

Alinity m SARS-CoV-2 Positive CTRL (List No. 9N78W) contains non-infectious, recombinant Sindbis virus containing SARS-CoV-2 RNA sequences, 1.0% ammonium sulfate, and 7.9% detergent in a buffer solution.

Control	Quantity
Alinity m SARS-CoV-2 Negative CTRL	12 tubes x 1.3 mL
Alinity m SARS-CoV-2 Positive CTRL	12 tubes x 1.3 mL

### WARNINGS AND PRECAUTIONS

#### IVD

- For In Vitro Diagnostic Use
- Do not use beyond expiration date.

### Safety Precautions

The following safety precautions apply to:  
Alinity m SARS-CoV-2 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,<sup>1</sup> OSHA Standard on Bloodborne Pathogens,<sup>2</sup> CLSI Document M29-A4,<sup>3</sup> and other appropriate biosafety practices.<sup>4</sup> 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.<sup>1</sup>

Decontaminate and dispose of all potentially infectious materials in accordance with local, state, and federal regulations.<sup>4</sup>

The following warnings and precautions apply to:

Alinity m SARS-CoV-2 Negative CTRL and Positive CTRL.



#### ANGER 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 SARS-CoV-2 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 SARS-CoV-2 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

09N78-080 Alinity m SARS-CoV-2 CTRL Kit

### Instructions for Use

Lot-specific values for assay positive controls are available via Abbott Mail, the Abbott Molecular customer portal [www.molecular.abbott/portal](http://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 (SARS-CoV-2 NEG CTRL and SARS-CoV-2 POS CTRL).
- Lot-specific values can also be obtained from the Abbott Molecular 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 SARS-CoV-2 Negative CTRL and Alinity m SARS-CoV-2 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 SARS-CoV-2 AMP Kit package insert.

## BIBLIOGRAPHY

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

## KEY TO SYMBOLS

	Reference Number
	In Vitro Diagnostic Medical Device
	Lot Number
	In Vitro Test
	Negative Control
	Positive Control
	Corrosive
	Caution
	Consult Instructions for Use
	Temperature Limit
	Use By
	Authorized Representative in the European Community
	Manufacturer

## TECHNICAL ASSISTANCE

For technical assistance, call Abbott Molecular Technical Services at 1-800-553-7042 (within the US) or +49-6122-580 (outside the US), or visit the Abbott Molecular website at [www.molecular.abbott/portal](http://www.molecular.abbott/portal).

Abbott Molecular Inc. is the legal manufacturer of the Alinity m SARS-CoV-2 CTRL Kit.

The Alinity m SARS-CoV-2 CTRL Kit is imported into the European Union by Abbott Diagnostics GmbH, located at Max-Planck-Ring 2, 65205 Wiesbaden, Germany.

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



Abbott GmbH  
Max-Planck-Ring 2  
65205 Wiesbaden, Germany

© 2020 Abbott. All Rights Reserved.

Alinity is a trademark of Abbott. Other trademarks are property of their respective owners.

[www.molecular.abbott/portal](http://www.molecular.abbott/portal)

53-608194/R1

May 2020