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REF 09N79-080
53-608212/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 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.

INTENDED USER

The intended users for Alinity m Resp-4-Plex are laboratory and healthcare professionals.

REAGENTS**Kit Contents**

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

Alinity m Resp-4-Plex Positive Control (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 Control	12 tubes x 1.3 mL
Alinity m Resp-4-Plex Positive Control	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 Resp-4-Plex Positive Control



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 Control and Positive Control

**DANGER Hazard-determining components of labeling:**

Lithium dodecyl sulphate
Lithium hydroxide monohydrate

H318 Causes serious eye damage.

H316 Causes mild skin irritation.^a

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.^a

^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 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

09N79-080 Alinity m Resp-4-Plex 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, 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 Molecular customer portal or provided by your Abbott Representative and imported to the Alinity m System via 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 Control and Alinity m Resp-4-Plex Positive Control 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.

BIBLIOGRAPHY

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

KEY TO SYMBOLS

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

TECHNICAL ASSISTANCE

For technical assistance, call Abbott Molecular 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 Molecular website at www.molecular.abbott/portal.

Abbott Molecular Inc. is the legal manufacturer of the Alinity m Resp-4-Plex CTRL Kit.

The Alinity m Resp-4-Plex CTRL Kit is imported into the European Union by Abbott Diagnostics GmbH, located at Max-Planck-Ring 2, 65205 Wiesbaden, Germany.



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