Created September 2020.

For use under an Emergency Use Authorization (EUA) Only

Prescription Use only.

For *In Vitro* Diagnostic Use Only.

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

For laboratory professional use only.

NAME

AdviseDx SARS-CoV-2 IgM Calibrator Kit (also referred to as CoV-2 IgM Cal or SARS-CoV-2 IgM Cal)

INTENDED USE

The AdviseDx SARS-CoV-2 IgM Calibrator Kit is for the calibration of the Alinity i system when used for the qualitative detection of IgM antibodies to SARS-CoV-2 in human serum, serum separator tube, and plasma (dipotassium EDTA, tripotassium EDTA, lithium heparin, lithium heparin separator tube, sodium heparin).

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For additional information, refer to the AdviseDx SARS-CoV-2 IgM reagent package insert and the Alinity ci-series Operations Manual.

The AdviseDx SARS-CoV-2 IgM assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

CONTENTS

The CALIBRATOR contains inactivated, cell-free, human blood-derived material, reactive for anti-SARS-CoV-2 IgM.

Preservatives: sodium azide and antimicrobial agents.

Calibrator	Quantity
CALIBRATOR	1 x 2.0 mL

MATERIALS REQUIRED BUT NOT PROVIDED

- 04R1001 Alinity ci-series Calibrator/Control Replacement Caps

STANDARDIZATION

There is currently no internationally recognized reference method or reference material for standardization.

PRECAUTIONS

For Use Under An Emergency Use Authorization Only.

This assay is only for *in vitro* diagnostic use under the FDA Emergency Use Authorization.

- IVD
- For *In Vitro* Diagnostic Use
- Rx ONLY
- This product has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by laboratories certified under CLIA, that meet requirements to perform moderate or high complexity tests.
- This product has been authorized only for the presence of IgM antibodies against SARS-CoV-2, not for any other viruses or pathogens;
- This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Safety Precautions

- **CAUTION:** This product contains human-sourced and/or potentially infectious components. Refer to the CONTENTS section of this package insert. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human-sourced materials should be considered potentially infectious. It is recommended that this product, human specimens, and all consumables contaminated with potentially infectious materials be handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate regional, national, and institutional biosafety practices should be used for materials that contain, are suspected of containing, or are contaminated with infectious agents.[1], [2], [3], [4]

· The human-sourced materials used in the CALIBRATOR have been tested and found to be reactive for anti-SARS-CoV-2 IgM and nonreactive for HBsAg, HIV-1 RNA or HIV-1 Ag, anti-HIV-1/HIV-2, and anti-HCV.

The following warnings and precautions apply to: CALIBRATOR	
Contains sodium azide.	
EUH032	Contact with acids liberates very toxic gas.
P501	Dispose of contents / container in accordance with local regulations.

Follow local chemical disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.

For the most current hazard information, see the product Safety Data Sheet.

Safety Data Sheets are available at www.corelaboratory.abbott or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the Alinity ci-series Operations Manual, Section 8.

PREPARATION FOR USE

· Thaw completely at room temperature (15 to 30°C).

· Prior to each use, mix by gentle inversion.

STORAGE

· This product is shipped on dry ice.

· Protect from light.

· Do not use past expiration date.

	Storage Temperature	**Maximum Storage Time**	**Additional Storage Instructions**
Unopened	-20°C or colder	Until expiration date	
Opened	2 to 8°C	Up to 45 days after thaw, not to exceed expiration date	Return to original carton to protect from light. Store tightly capped with

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
		printed on the bottle	new replacement cap. Store in upright position.

The system will track In-use Stability, which is the time the calibrator is outside of refrigerated storage while on the analyzer. The analyzer will not allow the use of the calibrator if the In-use Stability has been exceeded. Maximum In-use Stability can be found in the Assay Parameter Report. For additional information on calibrator In-use Stability, refer to the Alinity ci-series Operations Manual, Section 5.

For additional information on printing assay parameters, refer to the Alinity ci-series Operations Manual, Section 5.

INSTRUMENT PROCEDURE

- Test the calibrator in replicates of 3.
- The Calibrator vial is placed directly on the instrument and automatically processed using the barcode on the calibrator vial.
- Calibrator lots may be configured using the bar code label on the calibrator carton.
- The Alinity i system calculates the calibrator mean chemiluminescent signal from 3 calibrator replicates and stores the result. Results are reported by dividing the sample result by the stored calibrator result. The default result unit for the AdviseDx SARS-CoV-2 IgM assay is Index (S/C). The cutoff is 1.00 Index (S/C).
- The acceptable calibration is stored by the Alinity i analyzer for use with any reagent kit of that lot. The calibration should be used in conjunction with control ranges to determine the validity of the calibration.
- For information on configuring calibrator data, refer to the Alinity ci-series Operations Manual, Section 2.
- For instructions on ordering and loading calibrators on the instrument, refer to the Alinity ci-series Operations Manual, Section 5.

QUALITY CONTROL PROCEDURES

A single sample of each control level must be tested to evaluate the assay calibration. Ensure that assay control values are within the ranges specified in the respective control package insert.

For information on ordering controls, refer to the Alinity ci-series Operations Manual, Section 5.

Once a calibration is accepted and stored, it may be used for 10 days. During this time, all

subsequent samples may be tested without further calibration unless:

- A reagent kit with a new lot number is used.
- Daily quality control results are outside of quality control limits used to monitor and control system performance.

To track the 10 day calibration stability, edit the assay calibration interval from 720 hours to 240 hours, in the assay settings before running the AdviseDx SARS-CoV-2 IgM assay. Refer to the Alinity ci-series Operations Manual, Section 2.

This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

For additional information, refer to the AdviseDx SARS-CoV-2 IgM reagent package insert and the Alinity ci-series Operations Manual.

INDICATIONS OF INSTABILITY OR DETERIORATION

Instability or deterioration should be suspected if there are precipitates, visible signs of leakage, if calibration does not meet the appropriate package insert and/or Alinity ci-series Operations Manual criteria, or if controls do not meet the appropriate criteria.

NOTE: The AdviseDx SARS-CoV-2 IgM calibrator may present a cloudy or turbid appearance following thaw. This is not necessarily a sign of deterioration if the controls meet the appropriate criteria.

BIBLIOGRAPHY

1. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
2. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009.
3. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
4. 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.

Key to Symbols

ISO 15223 Symbols	
	Caution

ISO 15223 Symbols	
	Consult instructions for use
	Manufacturer
	Temperature limitation
	Upper limit of temperature
	Use by/Expiration date
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
REF	List Number
SN	Serial number

Other Symbols	
AFTER THAW	After thaw store at
CALIBRATOR	Calibrator Or Whole Blood Calibrator
CN	Control Number
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
FOR USE WITH	Identifies products to be used together
INFORMATION FOR USA ONLY	Information needed for United States of America only
PRODUCT OF IRELAND	Product of Ireland
PROTECT FROM LIGHT	Protect from light
Rx ONLY	For use by or on the order of a physician only (applicable to USA classification only).
UNTIL FIRST USE	Until first use store at

Note for number formatting:

· A space is used as thousands separator (example: 10 000 specimens).

· A period is used to separate the integer part from the fractional part of a number written in decimal form (example: 3.12%).

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Customer Service: Contact your local representative or find country-specific contact information on www.corelaboratory.abbott

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