AdviseDx SARS-CoV-2 IgG II Control Kit

FOR USE WITH Alinity i

en

CoV-2 IgG II

REF 06S6110

H18539R01

Created February 2021.

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 IgG II Control Kit (also referred to as CoV-2 IgG II Ctrls)

INTENDED USE

The AdviseDx SARS-CoV-2 IgG II Control Kit is for the estimation of test precision and the detection of systematic analytical deviations of the Alinity i system when used for the qualitative and semi-quantitative detection of IgG antibodies to SARS-CoV-2 in human serum (including collected using a serum separator tube) and plasma (acid citrate dextrose, sodium citrate, dipotassium EDTA, tripotassium EDTA, lithium heparin, lithium heparin in a separator tube, and sodium heparin).

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

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

CONTENTS

The CONTROL – contains negative human plasma.

The CONTROL + 1 and CONTROL + 2 contain SARS-CoV-2 IgG positive human plasma.

Preservatives: sodium azide and antimicrobial agents.

The controls are at the following target concentrations and ranges. The ranges may be used for individual replicate control specifications on the Alinity i system.

		SARS-CoV-2 IgG	
		CONC	RANGE
Control	Quantity	(AU/mL)	(AU/mL)
CONTROL –	1 x 4.0 mL	2.3	≤ 22.0
CONTROL + 1	1 x 4.0 mL	166.0	91.3 - 240.7
CONTROL + 2	1 x 4.0 mL	602.5	331.4 - 873.6

NOTE: The insert ranges for the controls are not lot specific and represent the total range of values which may be generated throughout the life of the product. It is recommended that each laboratory establish its own means and acceptable ranges which should fall within the package insert ranges. Sources of variation that can be expected include:

- Calibration
- Calibrator lot
- Control lot
- Instrument
- Reagent lot

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 but has been authorized for emergency use by FDA under an EUA for use by 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.
- 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

- **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.[1-4]
- The human-sourced materials used in CONTROL + 1 and CONTROL + 2 have been tested and found to be reactive for anti-SARS-CoV-2 IgG and nonreactive for HBsAg, HIV-1 RNA or HIV-1 Ag, anti-HIV-1/HIV-2, and anti-HCV.
- The human-sourced material used in the CONTROL – has been tested and found to be nonreactive for anti-SARS-CoV-2 IgG, HBsAg, HIV-1 RNA or HIV-1 Ag, anti-HIV-1/HIV-2, and anti-HCV.

The following warnings and precautions apply to: CONTROL + 1, CONTROL + 2, and CONTROL –	
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.

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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 30 days after thaw, not to exceed expiration date printed on the bottle	Return to original carton to protect from light. Store tightly capped. Store in upright position.

INSTRUMENT PROCEDURE

- To obtain the recommended volume requirements for the controls, hold the bottle vertically, and dispense 4 drops of the negative control and 4 drops of each positive control into each sample cup in the assigned position.
- For information on configuring control data, refer to the Alinity ci-series Operations Manual, Section 2.
- For instructions on ordering and loading controls on the instrument, refer to the Alinity ci-series Operations Manual, Section 5.
- Refer to the Alinity ci-series Operations Manual for details on performing quality control.

QUALITY CONTROL PROCEDURES

The recommended control requirement for the AdviseDx SARS-CoV-2 IgG II assay is that a single sample of each control level be tested once every 24 hours each day of use.

INDICATIONS OF INSTABILITY OR DETERIORATION

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

LIMITATIONS

Control values have not been established for assays other than the AdviseDx SARS-CoV-2 IgG II assay.

The controls are not calibrators and should not be used for assay calibration.

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
	Consult instructions for use
	Manufacturer
	Temperature limitation
	Upper limit of temperature
	Use by/Expiration date
CONTROL −	Negative Control
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
REF	List Number

Other Symbols	
AFTER THAW	After thaw store at
CN	Control Number
CONC	Concentration
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
CONTROL + 1	Positive Control 1
CONTROL + 2	Positive Control 2
PRODUCT OF IRELAND	Product of Ireland
PROTECT FROM LIGHT	Protect from light
RANGE	Range
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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