SARS-CoV-2 IgG Control Kit

FOR USE WITH
ARCHITECT

en
CoV-2 IgG
REF 06R8610
G90426R01

Created April 2020.

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.

WARNING:

This test has not been reviewed by the FDA.

NAME

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

INTENDED USE

The SARS-CoV-2 IgG Control Kit is for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT i System when used for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma.

For additional information, refer to the SARS-CoV-2 IgG reagent package insert and the ARCHITECT System Operations Manual.

CONTENTS

The CONTROL − contains human plasma.

The CONTROL + contains inactivated, cell-free, human blood-derived material, reactive for anti-SARS-CoV-2 IgG.

Preservatives: sodium azide and antimicrobial agents.

The controls are at the following ranges. The ranges may be used for individual replicate control specifications on the ARCHITECT i System.

		Anti-SARS-CoV-2 IgG RANGE
Control	**Quantity**	**(Index [S/C])**
CONTROL −	1 x 4.0 mL	≤ 0.78
CONTROL +	1 x 4.0 mL	1.65 - 8.40

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

STANDARDIZATION

There is currently no internationally recognized reference method or reference material for standardization. The SARS-CoV-2 IgG controls are traceable to internal reference standards.

PRECAUTIONS

- For *In Vitro* Use
- Rx ONLY

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 the CONTROL + 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 +	
Contains sodium azide and polyethylene glycol octylphenyl ether.	
H402	Harmful to aquatic life.
H412	Harmful to aquatic life with long lasting effects.
EUH032	Contact with acids liberates very toxic gas.
Prevention	
P273	Avoid release to the environment.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

The following warnings and precautions apply to: 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 ARCHITECT System Operations Manual, Section 8.

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PREPARATION FOR USE

- Thaw completely before use.
- 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	Call Customer Service at 1-877-4ABBOTT for the most current lot-specific information.	Customer is responsible for manually tracking expiration dating.
Opened	2 to 8°C	Call Customer Service at 1-877-4ABBOTT for the most current lot-specific information.	Customer is responsible for manually tracking expiration dating. 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 the positive control into each sample cup in the assigned position.
- For information on configuring control data, refer to the ARCHITECT System Operations Manual, Section 2.
- For instructions on ordering and loading controls on the instrument, refer to the ARCHITECT System Operations Manual, Section 5.

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 ARCHITECT System Operations Manual 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
	Consult instructions for use
	Manufacturer
	Temperature limitation
	Upper limit of temperature
	Use by/Expiration date
CONTROL −	Negative Control
CONTROL +	Positive Control
LOT	Lot Number
REF	List Number

Other Symbols	
AFTER THAW	After thaw store at
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
FOR USE WITH	Identifies products to be used together
PRODUCT OF USA	Product of USA
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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