



CoV-2 IgG

REF 06R8601

G90423R01

SARS-CoV-2 IgG Calibrator Kit

FOR USE WITH

ARCHITECT

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 Calibrator Kit (also referred to as CoV-2 IgG Cal)

INTENDED USE

The SARS-CoV-2 IgG Calibrator Kit is for the calibration 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 CALIBRATOR contains inactivated, cell-free, human blood-derived material, reactive for anti-SARS-CoV-2 IgG.

Preservatives: sodium azide and antimicrobial agents.

Calibrator	Quantity
CALIBRATOR	1 x 2.0 mL


STANDARDIZATION

There is currently no internationally recognized reference method or reference material for standardization. The SARS-CoV-2 IgG calibrator is 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 CALIBRATOR 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 following warnings and precautions apply to: CALIBRATOR	
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.

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.com or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

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

- Test the calibrator in replicates of 3. The calibrator should be priority loaded.
- To obtain the recommended volume requirements for the calibrator, hold the bottle vertically, and dispense 4 drops of the calibrator into the sample cup in the assigned position.
- For information on ordering calibrations, refer to the ARCHITECT System Operations Manual, Section 6.

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 ARCHITECT System Operations Manual, Section 5.

Once a calibration is accepted and stored, 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.

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 SARS-CoV-2 IgG reagent package insert and the ARCHITECT System Operations Manual.

















INDICATIONS OF INSTABILITY OR DETERIORATION

Instability or deterioration should be suspected if there are precipitates, visible signs of leakage, turbidity, if calibration does not meet the appropriate package insert and/or ARCHITECT System Operations Manual criteria, or if controls do not 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
	Consult instructions for use
	Manufacturer
	Temperature limitation
	Upper limit of temperature
	Use by/Expiration date
	Lot Number
	List Number
Other Symbols	
	After thaw store at
	Calibrator
	Contains Sodium Azide. Contact with acids liberates very toxic gas.
	Identifies products to be used together
	Product of USA
	Protect from light
	For use by or on the order of a physician only (applicable to USA classification only).
	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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