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CoV-2 IgG

6R86

H14806R05

SARS-CoV-2 IgG

FOR USE I

ARCHITECT

Revised December 2020.

REF 6R86-20

REF 6R86-30

For use under an Emergency Use Authorization (EUA) Only
Prescription Use only.

For *In Vitro* Diagnostic Use Only.

Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

For laboratory professional use only.

NAME

SARS-CoV-2 IgG (also referred to as CoV-2 IgG)

INTENDED USE

The SARS-CoV-2 IgG assay is a chemiluminescent microparticle immunoassay (CMIA) intended for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum, serum separator tube and plasma (ACD, CPD, CPDA-1, dipotassium EDTA, tripotassium EDTA, lithium heparin, lithium heparin separator tube, sodium citrate, sodium heparin). The SARS-CoV-2 IgG assay is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The SARS-CoV-2 IgG assay should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C 263a, to perform moderate or high complexity test.

Results are for the detection of SARS CoV-2 antibodies. IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities. The sensitivity of SARS-CoV-2 IgG early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for SARS-CoV-2 IgG assay may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using a second, different IgG assay.

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

SUMMARY AND EXPLANATION OF THE TEST

The SARS-CoV-2 IgG assay is designed to detect immunoglobulin class G (IgG) antibodies to the nucleocapsid protein of SARS-CoV-2 in serum and plasma from individuals who are suspected to have had coronavirus disease (COVID-19) or in serum and plasma of subjects that may have been infected by SARS-CoV-2.

COVID-19 is defined as illness caused by a novel coronavirus now called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, formerly called 2019-nCoV).¹ On March 11, 2020, the World Health Organization (WHO) declared COVID-19 a global pandemic.²

The incubation period of COVID-19 ranges between 1 and 14 days, with the majority of cases manifesting within 3 to 5 days. The most common symptoms of COVID-19 are fever, tiredness, dry cough, and difficulty breathing. A severe acute respiratory distress syndrome (ARDS) may develop.³ Reported case fatality rates depend on geographic location,⁴ age, and comorbidities.

The causative agent of COVID-19 is a beta coronavirus and belongs to a family of viruses that may cause respiratory symptoms ranging from common cold to severe pneumonia. These viruses are common in animals worldwide and may eventually transfer to humans, as has likely happened with SARS-CoV-2.¹

The host immune system reacts to the infection by SARS-CoV-2 by producing specific antibodies. These antibodies have been reported to appear in serum or plasma of infected individuals after the detection of viral ribonucleic acid (RNA) in swabs⁵ in as early as a few days to 2 weeks after the onset of symptoms.⁶ Specific IgG antibodies to SARS-CoV-2 may be detectable in COVID-19 patients during the symptomatic phase of the disease after RNA is no longer detectable.^{5, 6} The persistence of IgG antibodies allows identification of people who have been infected in the past, and likely have recovered from the illness.⁷ It is unknown if IgG antibodies to SARS-CoV-2 confer immunity to infection. IgG detection and other serological assays will likely play an important role in research and surveillance.⁸

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

This assay is an automated, two-step immunoassay for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) technology.

Sample, SARS-CoV-2 antigen coated paramagnetic microparticles, and assay diluent are combined and incubated. The IgG antibodies to SARS-CoV-2 present in the sample bind to the SARS-CoV-2 antigen coated microparticles. The mixture is washed. Anti-human IgG acridinium-labeled conjugate is added to create a reaction mixture and incubated. Following a wash cycle, Pre-Trigger and Trigger Solutions are added.

The resulting chemiluminescent reaction is measured as a relative light unit (RLU).

The presence or absence of IgG antibodies to SARS-CoV-2 in the sample is determined by comparing the chemiluminescent RLU in the reaction to the calibrator RLU, which is calculated by the system as an Index (S/C).

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

REAGENTS

Kit Contents

SARS-CoV-2 IgG Reagent Kit 6R86

NOTE: Some kit sizes may not be available for use on all ARCHITECT i Systems. Please contact your local distributor.

Volumes (mL) listed in the following table indicate the volume per bottle.

REF	6R86-20	6R86-30
Tests per kit	100	500
Number of kits per box	1	1
Tests per box	100	500
M I	6.6 mL	27.0 mL
CONJUGATE	5.8 mL	26.2 mL
ASSAY I	7.9 mL	40.7 mL
M I Purified SARS-CoV-2 recombinant antigen coated microparticles in TRIS buffer with surfactant. Minimum concentration: 0.045% solids. Preservatives: ProClin 950 and sodium azide.		
CONJUGATE Anti-human IgG (mouse, monoclonal) acridinium-labeled conjugate in MES buffer with surfactant and protein (bovine) stabilizer. Minimum concentration: 4 ng/mL. Preservatives: ProClin 300 and antimicrobial agents.		
ASSAY I TRIS buffer and detergent. Preservatives: ProClin 950 and sodium azide.		

Warnings and 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 test has not been FDA cleared or approved; this test has been authorized 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.
- This test has been authorized only for the presence of IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens.
- This test 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials and all consumables contaminated with potentially infectious materials be considered potentially infectious and 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.⁹⁻¹²

The following warnings and precautions apply to: M I and ASSAY I	
WARNING	Contains methylisothiazolone and sodium azide.
H317	May cause an allergic skin reaction.
EUH032	Contact with acids liberates very toxic gas.
Prevention	
P261	Avoid breathing mist / vapors / spray.
P272	Contaminated work clothing should not be allowed out of the workplace.

P280	Wear protective gloves / protective clothing / eye protection.
Response	
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.
The following warnings and precautions apply to: CONJUGATE	
H402	Harmful to aquatic life.
H412	Harmful to aquatic life with long lasting effects.
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 or contact your local representative.

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

Reagent Handling

- Reagents are shipped on wet ice.
- Do not pool reagents within a kit or between kits.
- Before loading the reagent kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may have settled during shipment. For microparticle mixing instructions, refer to the PROCEDURE, Assay Procedure section of this package insert.
- **Septums MUST be used to prevent reagent evaporation and contamination and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if septums are not used according to the instructions in this package insert.**
 - To avoid contamination, wear clean gloves when placing a septum on an uncapped reagent bottle.
 - Once a septum has been placed on an open reagent bottle, do not invert the bottle as this will result in reagent leakage and may compromise assay results.
 - Over time, residual liquids may dry on the septum surface. These are typically dried salts and have no effect on assay efficacy.
- When handling conjugate vials, change gloves that have contacted human serum or plasma, since introduction of human IgG will result in a neutralized conjugate.

For a detailed discussion of reagent handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Reagent Storage

- Do not freeze.
- Protect from light.

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2 to 8°C	Until expiration date	Store in upright position.

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Onboard	System Temperature	7 days	
Opened	2 to 8°C	Until expiration date	Store in upright position. If the microparticle bottle does not remain upright (with a septum installed) while in refrigerated storage off the system, the reagent kit must be discarded.

Reagents may be stored on or off the ARCHITECT i System. If reagents are removed from the system, store them at 2 to 8°C (with septums and replacement caps) in an upright position. For reagents stored off the system, it is recommended that they be stored in their original trays and boxes to ensure they remain upright.

For information on unloading reagents, refer to the ARCHITECT System Operations Manual, Section 5.

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when a calibration error occurs or a control value is out of the specified range. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary.

For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The SARS-CoV-2 IgG assay file must be installed on the ARCHITECT i System prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.

For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.

For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

The specimen types listed below may be used with this assay.

Specimen Types	Collection Tubes
Serum	Serum Serum separator
Plasma	ACD CPD CPDA-1 Dipotassium EDTA Tripotassium EDTA Lithium heparin Lithium heparin separator Sodium heparin Sodium citrate

- Each laboratory is responsible for following their own procedures to establish the use of additional tube or collection types.
- Performance has not been established for the use of cadaveric specimens or the use of bodily fluids other than human serum/plasma.
- Liquid anticoagulants may have a dilution effect resulting in lower Index (S/C) values for individual specimens.

The instrument does not provide the capability to verify specimen types. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.

Specimen Conditions

- Do not use:
 - heat-inactivated specimens
 - pooled specimens
 - grossly hemolyzed specimens
 - specimens with obvious microbial contamination
 - specimens with fungal growth
- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.
- Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

To ensure consistency in results, recentrifuge specimens prior to testing if

- they contain fibrin, red blood cells, or other particulate matter.

NOTE: If fibrin, red blood cells, or other particulate matter are observed, mix by low speed vortex or by inverting 10 times prior to recentrifugation.

Prepare frozen specimens as follows:

- Frozen specimens must be completely thawed before mixing.
- Mix thawed specimens thoroughly by low speed vortex or by inverting 10 times.
- Visually inspect the specimens. If layering or stratification is observed, mix until specimens are visibly homogeneous.
- If specimens are not mixed thoroughly, inconsistent results may be obtained.
- Recentrifuge specimens.

Recentrifugation of Specimens

- Transfer specimens to a centrifuge tube and centrifuge.
- Transfer clarified specimen to a sample cup or secondary tube for testing. For centrifuged specimens with a lipid layer, transfer only the clarified specimen and not the lipemic material.

Specimen Storage

Specimen Type	Temperature	Maximum Storage Time
Serum/Plasma	Room temperature (15 to 30°C)	2 days
	2 to 8°C	7 days

If testing will be delayed more than 7 days, it is recommended to store frozen.

It is the responsibility of the individual laboratory to determine specific specimen stability criteria for their laboratory per their laboratory workflow.

For additional information on sample handling and processing, refer to CLSI GP44-A4.¹³ The storage information provided here is based on data maintained by the manufacturer.

Frozen specimens subjected to up to 2 freeze/thaw cycles have been evaluated.

Specimen Shipping

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

Do not exceed the storage limitations listed above.

PROCEDURE

Materials Provided

6R86 SARS-CoV-2 IgG Reagent Kit

Materials Required but not Provided

- SARS-CoV-2 IgG assay file found on www.corelaboratory.abbott
- 6R86-01 SARS-CoV-2 IgG Calibrator Kit
- 6R86-10 SARS-CoV-2 IgG Control Kit or other control material containing IgG antibodies to SARS-CoV-2
- ARCHITECT Pre-Trigger Solution
- ARCHITECT Trigger Solution
- ARCHITECT Wash Buffer
- ARCHITECT Septum

For information on materials required for operation of the instrument, refer to the ARCHITECT System Operations Manual, Section 1.

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

Assay Procedure

For a detailed description of how to run an assay, refer to the ARCHITECT System Operations Manual, Section 5.

- If using primary or aliquot tubes, refer to the ARCHITECT System Operations Manual, Section 5 to ensure sufficient specimen is present.
- Minimum sample cup volume is calculated by the system and printed on the Order List report. To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.
- When loading the reagents on the reagent carousel or reagent carrier, the conjugate must be placed in the inner ring (yellow), the microparticles must be placed in the middle ring (pink), and the assay diluent must be placed in the outer ring (green).
- Before loading the reagent kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may have settled during shipment. After the first time the microparticles have been loaded, no further mixing is required.
 - **Invert the microparticle bottle 30 times.**
 - Visually inspect the bottle to ensure microparticles are resuspended. If microparticles are still adhered to the bottle, continue to invert the bottle until the microparticles have been completely resuspended.
 - **If the microparticles do not resuspend, DO NOT USE. Contact your local Abbott representative.**
 - Once the microparticles have been resuspended, place a septum on the bottle. For instructions about placing septums on bottles, refer to the Reagent Handling section of this package insert.
- Maximum number of replicates sampled from the same sample cup: 10
 - Priority:
 - Sample volume for first test: 75 µL
 - Sample volume for each additional test from same sample cup: 25 µL
 - Routine:
 - Sample volume for first test: 150 µL
 - Sample volume for each additional test from same sample cup: 25 µL
- Refer to the SARS-CoV-2 IgG calibrator package insert
 - REF** 6R86-01 and/or SARS-CoV-2 IgG control package insert
 - REF** 6R86-10 for preparation and usage.

- For general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
- For optimal performance, it is important to perform routine maintenance as described in the ARCHITECT System Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Sample Dilution Procedures

Dilution of samples for the SARS-CoV-2 IgG assay has not been verified.

Calibration

Once a calibration is accepted and stored, it may be used for 30 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.

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

Quality Control Procedures

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

Additional controls may be tested in accordance with local, state, and/or federal regulations or accreditation requirements and your laboratory's quality control policy.

To establish statistically-based control limits, each laboratory should establish its own concentration target and ranges for new control lots at each clinically relevant control level. This can be accomplished by assaying a minimum of 20 replicates over several (3-5) days and using the reported results to establish the expected average (target) and variability about this average (range) for the laboratory. Sources of variation that should be included in this study in order to be representative of future system performance include:

- Multiple stored calibrations
- Multiple reagent lots
- Multiple calibrator lots
- Multiple processing modules (if applicable)
- Data points collected at different times of the day

Refer to published guidelines for information or general control recommendation, for example Clinical and Laboratory Standards Institute (CLSI) Guideline C24, 4th ed., or other published guidelines, for general quality control recommendations.¹⁴

- If more frequent control monitoring is required, follow the established quality control procedures for your laboratory.
- If quality control results do not meet the acceptance criteria defined by your laboratory, sample results may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Controls should be used according to the guidelines and recommendations of the control manufacturer. Concentration ranges provided in the control package insert should be used only for guidance.

For any control material in use, the laboratory should ensure that the matrix of the control material is suitable for use in the assay per the assay package insert.

Quality Control Guidance

Refer to “Basic QC Practices” by James O Westgard, Ph.D. for guidance on laboratory quality control practices.¹⁵

Verification of Assay Claims

For protocols to verify package insert claims, refer to the ARCHITECT System Operations Manual, Appendix B.

For protocols to verify package insert claims, follow CLIA recommendations or internal laboratory procedures.

RESULTS

Calculation

The ARCHITECT 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 SARS-CoV-2 IgG assay is Index (S/C).

Interpretation of Results

The cutoff is 1.40 Index (S/C).

As with all analyte determinations, the result should be used in conjunction with information available from clinical evaluation and other diagnostic procedures.

Index (S/C)	Interpretation
< 1.40	Negative
≥ 1.40	Positive

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the ARCHITECT System Operations Manual, Section 5.

LIMITATIONS OF THE PROCEDURE

- **For use under an Emergency Use Authorization only.**
- This assay is for *in vitro* diagnostic use under FDA Emergency Use Authorization only.
- This test is for clinical laboratory use only. It is not for home use.
- Results should be used in conjunction with other data; e.g., symptoms, results of other tests, and clinical impressions.
- Immunocompromised patients who have COVID-19 may have a delayed antibody response and produce levels of antibody which may not be detected as positive by the assay.
- A positive result may not indicate previous SARS-CoV-2 infection. Consider other information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Testing with a molecular diagnostic should be considered to evaluate for active infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Pedigreed specimens with direct evidence of antibodies to non-SARS-CoV-2 coronavirus (common cold) strains such as HKU1, NL63, OC43, or 229E have not been evaluated with this assay.
- Not to be used to screen units of blood for SARS-CoV-2 infection.
- Potentially interfering disease states and other cross reactants have been evaluated and are represented in the SPECIFIC PERFORMANCE CHARACTERISTICS section of this package insert.
- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits such as SARS-CoV-2 IgG that employ mouse monoclonal antibodies.^{16, 17}

- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference, and anomalous values may be observed.¹⁸
- Rheumatoid factor (RF) in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays.¹⁸

CONDITIONS OF AUTHORIZATIONS FOR THE LABORATORIES

The SARS-CoV-2 IgG Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas> or at <https://www.corelaboratory.abbott/us/en/offerings/segments/infectious-disease/sars-cov-2>.

Authorized laboratories using the SARS-CoV-2 IgG (“your product” in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

- A. Authorized laboratories* using your product will include with result reports of your product, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- B. Authorized laboratories using your product will use your product as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- C. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- D. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- E. Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Abbott Laboratories at <https://www.corelaboratory.abbott/us/en/offerings/segments/infectious-disease/sars-cov-2> any suspected occurrence of false reactive or false non-reactive results and significant deviations from the established performance characteristics of your product of which they become aware.
- F. All laboratory personnel using your product must be appropriately trained in automated immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.
- G. Abbott Laboratories, authorized distributors, and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

* The letter of authorization refers to, “Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate and high complexity tests” as “authorized laboratories.”

SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

Precision

Within-Laboratory Precision

A study was performed based on guidance from CLSI EP05-A3.¹⁹ Testing was conducted using 1 lot of the SARS-CoV-2 IgG Reagent Kit, 1 lot of the SARS-CoV-2 IgG Calibrator Kit, and 1 lot of the SARS-CoV-2 IgG Control Kit and 1 instrument. Two controls and 1 human serum panel were assayed in replicates of 3 at 2 separate times per day on 5 different days.

Sample	n	Mean (Index [S/C])	Repeatability (Within-Run)		Within-Laboratory ^a	
			SD	%CV	SD	%CV
Negative Control	30	0.04	0.003	N/A ^b	0.003	N/A ^b
Positive Control	30	3.51	0.033	0.9	0.038	1.1
Positive Panel	30	2.30	0.038	1.7	0.045	1.9

^a Includes repeatability (within-run), between-run, and between-day variability.

^b Not applicable

Analytical Specificity

Potentially Cross-Reacting Antibodies

The SARS-CoV-2 IgG assay was evaluated for potentially cross-reacting antibodies. A total of 112 specimens from 23 different categories were tested. One hundred eleven (111) specimens were negative and 1 specimen was positive by the SARS-CoV-2 IgG assay. The data are summarized in the following table.

Category	n	Positive	Negative
Antinuclear Antibody (ANA)	5	0	5
Cytomegalovirus (CMV) IgG	5	1*	4
CMV Immunoglobulin Class M (IgM)	5	0	5
Double-Stranded Deoxyribonucleic Acid (dsDNA) Antibody	5	0	5
Epstein-Barr Virus (EBV) IgG	5	0	5
EBV IgM	5	0	5
<i>Escherichia coli</i> (<i>E. coli</i>) Antibody	5	0	5
HAMA	5	0	5
Anti-Hepatitis A Virus (HAV)	5	0	5
Hepatitis B Core (HBc) IgM	4	0	4
Anti-Hepatitis C Virus (HCV)	5	0	5
Anti-Hepatitis D Virus (HDV)	5	0	5
Anti-Herpes Simplex Virus (HSV)	5	0	5
Heterophilic Antibody Positive	5	0	5
Anti-Human T-Lymphotropic Virus (HTLV) Type 1	5	0	5
Anti-HTLV Type 2	5	0	5
Monoclonal Hyper IgG	5	0	5
Polyclonal Hyper IgG	3	0	3
Anti-Respiratory Syncytial Virus (RSV)	5	0	5
RF	5	0	5
Rubella IgG	5	0	5
Toxoplasmosis IgG	5	0	5
Anti-Varicella Zoster Virus	5	0	5
Total	112	1	111

* Testing was performed on an additional 199 specimens collected prior to September 2019 from subjects who were reactive for total (IgG/IgM) antibodies to CMV. Of those 199 specimens, 1 was positive on the SARS-CoV-2 IgG assay.

Potentially Interfering Medical Conditions and Respiratory Illnesses

The SARS-CoV-2 IgG assay was evaluated for potential cross-reactivity from individuals with potentially interfering medical conditions and respiratory illnesses. A total of 65 specimens from

12 different categories were tested. Sixty-five (65) specimens were negative by the SARS-CoV-2 IgG assay. The data are summarized in the following table.

Category	n	Positive	Negative
Adenovirus	5	0	5
Autoimmune Hepatitis	5	0	5
Hepatitis B Virus (HBV)	5	0	5
Human Immunodeficiency Virus (HIV)	5	0	5
Influenza A	7	0	7
Influenza B	5	0	5
Influenza (Type Unknown)	8	0	8
Influenza Vaccine	5	0	5
Lupus	5	0	5
Picornavirus	5	0	5
Pregnant Females	5	0	5
Pregnant Females, Multiparous	5	0	5
Total	65	0	65

Interference

Potentially Interfering Endogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.²⁰ Each substance was tested at 2 levels of the analyte (high negative and low positive levels, approximately 1.25 Index and 2.75 Index) in replicates of ten. The observed interference was within ± 0.14 Index or $\pm 10\%$ at the following concentrations and therefore, the study showed no interference from these endogenous substances:

Potentially Interfering Endogenous Substance	Interferent Level
Unconjugated Bilirubin	40 mg/dL
Conjugated Bilirubin	40 mg/dL
Hemoglobin	1000 mg/dL
Triglyceride (Intralipid)	2000 mg/dL
Total Protein	15 g/dL

Potentially Interfering Exogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.²⁰ Each substance was tested at 2 levels of the analyte (approximately 1.25 Index and 2.75 Index) in replicates of ten. The observed interference was within ± 0.14 Index or $\pm 10\%$ at the following concentrations and therefore, the study showed no interference from these exogenous substances.

Potentially Interfering Exogenous Substance	Interferent Level
Acetaminophen	1030 μ mol/L
Alprazolam	0.835 μ mol/L
Ascorbic Acid	298 μ mol/L
Biotin	4250 ng/mL
Captopril	12.1 μ mol/L
Fluoxetine	4.59 μ mol/L
Guaifenesin	22.7 μ mol/L
Hydroxychloroquine	388.8 ng/mL

Clinical Performance

A study was performed to determine the clinical performance of the SARS-CoV-2 IgG assay.

To estimate the positive percent agreement (PPA), between the SARS-CoV-2 IgG assay and the PCR comparator, 122 serum and plasma specimens were collected at different times from 31 subjects who tested positive for SARS-CoV-2 by a polymerase chain reaction (PCR) method and who also presented with COVID-19 symptoms. Each specimen was tested using the SARS-CoV-2 IgG assay. The PPA and the 95% confidence interval (CI) were calculated.

To estimate the negative percent agreement (NPA), 1070 serum and plasma specimens from subjects assumed to be negative for SARS-CoV-2 were tested. Of the 1070 specimens, 997 specimens were collected prior to September 2019 (pre-COVID-19 outbreak). An additional 73 specimens were collected in 2020 from subjects who were exhibiting signs of respiratory illness but tested negative for SARS-CoV-2 by a PCR method. All 1070 specimens were tested using the SARS-CoV-2 IgG assay. The NPA and the 95% CI were calculated.

The results of both groups are presented in the following 2 tables.

Positive Agreement by Days Post-Symptom Onset

Days Post-Symptom Onset	n	Positive	Negative	PPA (95% CI)
< 3	4	0	4	0.00% (0.00, 60.24)
3 - 7	8	2	6	25.00% (3.19, 65.09)
8 - 13	22	19	3	86.36% (65.09, 97.09)
≥ 14	88 ^a	88	0	100.00% (95.89, 100.00)

^a Five specimens from 1 immunocompromised patient were excluded from the study. Refer to the LIMITATIONS OF THE PROCEDURE section of this package insert for further information. When the results from these specimens were included, the PPA at ≥ 14 days post-symptom onset was 96.77% (95% CI: 90.86, 99.33).

Negative Agreement by Category

Category	n	Positive	Negative	NPA (95% CI)
Pre-COVID-19 Outbreak	997	4	993	99.60% (98.98, 99.89)
Other Respiratory Illness	73	0	73	100.00% (95.07, 100.00)
Total	1070	4	1066	99.63% (99.05, 99.90)

Class Specificity

The anti-human IgG antibody used in the SARS-CoV-2 IgG assay demonstrates class-specific reactivity only to human IgG isotypes. No binding interactions were observed to human IgM, human IgA, or sheep (ovine) IgG.

Longitudinal Study

From the positive agreement study above, a subset of 13 subjects with 2 or more blood draws post-symptom onset were assessed longitudinally. Out of the 13 subjects, 7 presented positive results and 4 presented negative results in all the bleeds while 2 subjects showed SARS-CoV-2 IgG seroconversion as shown in the SARS-CoV-2 IgG results provided below.

Subject	Draw	Days Post-Symptom Onset	Result (Index)	Interpretation
A	1	5	0.27	Negative
	2	6	0.52	Negative
	3	7	2.12	Positive
	4	7	2.16	Positive
	5	8	4.45	Positive
B	1	9	0.41	Negative
	2	10	1.17	Negative
	3	11	2.25	Positive
	4	13	5.79	Positive

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Revised December 2020.

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■ Key to Symbols

ISO 15223 Symbols	
	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
	In Vitro Diagnostic Medical Device
	Lot Number
	List Number
	Serial number
Other Symbols	
	Assay Diluent
	Conjugate
	Contains Sodium Azide. Contact with acids liberates very toxic gas.
	Control Number
	Identifies products to be used together
	Global Trade Item Number
	Information needed for United States of America only
	Microparticles
	Product of Ireland
	Protect from light
	Reagent Lot
	For use by or on the order of a physician only (applicable to USA classification only).
	Warning: May cause an allergic reaction.

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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en

CoV-2 IgG

REF 6R86-01

H14807R06

SARS-CoV-2 IgG Calibrator Kit

FOR USE I

ARCHITECT

Revised December 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

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, serum separator tube and plasma (ACD, CPD, CPDA-1, dipotassium EDTA, tripotassium EDTA, lithium heparin, lithium heparin separator tube, sodium citrate, sodium heparin).

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

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

CONTENTS

The **CA I** contains inactivated, cell-free, human blood-derived material, reactive for anti-SARS-CoV-2 IgG.

Preservatives: sodium azide and antimicrobial agents.

Calibrator	Quantity
CA I	1 x 2.0 mL

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 the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate or high complexity tests.
- 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.¹⁻⁴
- The human-sourced materials used in the **CA I** 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: CA I	
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.

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	Until expiration date	
Opened	2 to 8°C	Up to 60 days after thaw, not to exceed expiration date	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, it may be used for 30 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.

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.












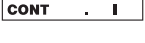


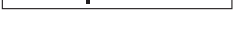

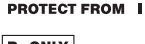


INDICATIONS OF INSTABILITY OR DETERIORATION

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.

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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
	<i>In Vitro</i> Diagnostic Medical Device
	Lot Number
	List Number
Other Symbols	
	After thaw store at
	Calibrator Or Whole Blood Calibrator
	Contains Sodium Azide. Contact with acids liberates very toxic gas.
	Identifies products to be used together
	Global Trade Item Number
	Information needed for United States of America only
	Product of Ireland
	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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Revised December 2020.

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SARS-CoV-2 IgG Control Kit

FOR USE I

ARCHITECT

Revised December 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

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

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, serum separator tube and plasma (ACD, CPD, CPDA-1, dipotassium EDTA, tripotassium EDTA, lithium heparin, lithium heparin separator tube, sodium citrate, sodium heparin).

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

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

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
- Control lot
- Reagent lot
- Calibrator lot
- Instrument

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 the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate or high complexity tests.
- 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.¹⁻⁴
- 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 - / 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.

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	Until expiration date	
Opened	2 to 8°C	Up to 60 days after thaw, not to exceed expiration date	Return to original carton to protect from light. Store tightly capped. Store in upright position.

INSTRUMENT PROCEDURE

- For routine processing, 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 priority processing, to obtain the recommended volume requirements for the controls, hold the bottle vertically, and dispense 3 drops of the negative control and 3 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.

QUALITY CONTROL PROCEDURES

The recommended control requirement for the SARS-CoV-2 IgG 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 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.
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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
IVD	<i>In Vitro</i> Diagnostic Medical Device
LOT	Lot Number
REF	List Number
Other Symbols	
AFTER THAW	After thaw store at
CONT . I	Contains Sodium Azide. Contact with acids liberates very toxic gas.
FOR USE I	Identifies products to be used together
G I	Global Trade Item Number
I	Information needed for United States of America only
PRODUCT O I	Product of Ireland
PROTECT FROM I	Protect from light
RANGE	Range
Rx ONLY	For use by or on the order of a physician only (applicable to USA classification only).
UN I	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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