SARS-CoV-2 IgG

for use with **ARCHITECT**

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 1.4 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
< 1.4	Negative
≥ 1.4	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

- Results should be used in conjunction with other data; e.g., symptoms, results of other tests, and clinical impressions.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out 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.
- Non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E, have not been evaluated with this assay. In a population of patients with non-COVID-19 respiratory illnesses, no cross-reactivity has been observed. Refer to the SPECIFIC PERFORMANCE CHARACTERISTICS section of this package insert.
- Not to be used to screen units of blood for SARS-CoV-2 infection.
- 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.
- 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.[1,6,17]
- 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]

SPECIFIC PERFORMANCE CHARACTERISTICS

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

Precision

Within-Laboratory Precision

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 were assayed in replicates of 10 on 5 different days.

			Within-Run (Repeatability)		Within-Laboratory [a]	
Sample	n	Mean (Index [S/C])	SD	%CV	SD	%CV
	50	0.04	0.002	5.9	0.002	5.9
	50	3.53	0.040	1.1	0.042	1.2

[a] Includes within-run and between-day variability.

Analytical Specificity

The SARS-CoV-2 IgG assay was evaluated for potential cross- reactivity from individuals with other medical conditions. A total of 182 specimens from 36 different categories were tested. One hundred eighty-one (181) specimens were negative and 1 specimen was positive by the SARS-CoV-2 IgG assay. The data are summarized in the following table. Bold indicates other respiratory illness categories.

Category	n	Positive	Negative
Adenovirus	**5**	**0**	**5**
Antinuclear Antibody (ANA)	5	0	5
Autoimmune Hepatitis Cytomegalovirus	5	0	5
(CMV) IgG	5	1	4
CMV Immunoglobulin Class M (IgM)	5	0	5
Double-Stranded Deoxyribonucleic Acid	5	0	5
(dsDNA) Antibody			
Epstein-Barr Virus (EBV) IgG	5	0	5
EBV IgM	5	0	5
Escherichia coli (E. coli) Antibody	5	0	5
HAMA	5	0	5
Hemodialysis Patients	5	0	5
Hepatitis A Virus (HAV)	5	0	5
Hepatitis B Core (HBC) IgM	4	0	4
Hepatitis B Virus (HBV)	5	0	5
Hepatitis C Virus (HGV)	5	0	5
Hepatitis D Virus (HDV)	5	0	5
Herpes Simplex Virus (HSV)	5	0	5
Heterophilic Antibody Positive	5	0	5
Human Immunodeficiency Virus (HIV)	5	0	5
Human T-Lymphotrophic Virus (HTLV)	5	0	5
Type 1 HTLV Type 2	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
Monoclonal Hyper IgG	5	0	5
Picornavirus	5	0	5
Polyclonal Hyper IgG	3	0	3
Pregnant Females	5	0	5
Pregnant Females, Multiparous	5	0	5
Respiratory Syncytial Virus (RSV)	**5**	**0**	**5**
RF	5	0	5
Rubella IgG	5	0	5
Toxoplasmosis IgG	5	0	5
Varicella Zoster Virus	5	0	5
Total	**182**	**1**	**181**

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), 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.

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