COVISURE™

COVID-19 IgM/IgG Rapid Test

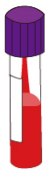
colloidal gold-based immunochromatographic assay

COVISURE™ COVID-19 IgM/IgG Rapid Test is a rapid immunochromatography test designed for the qualitative presumptive detection of specific IgM and IgG to SARS-CoV-2 in Whole Blood, Serum, or Plasma.

- COVID-19 Positive/Negative Results in 10 ~ 15 Minutes
- Works with Whole Blood, Serum, or Plasma
- Increased Screening with IgM and IgG Antibody Detection
- Ideal High-Volume Screening Device to Compliment Nucleic Acid Tests

Whole Blood Sampling Procedure

1.



Collection of Specimen
Using a micropipette, collect the 20µl of venous whole blood with micropipette.

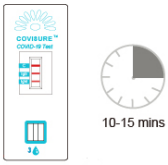
2.

Add Specimen
Add the collected venous whole blood to the Sample Well of the test device.

3.

Add Buffer
Add 3 drops of buffer vertically into the Sample Well.

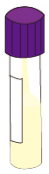
4.



Read Time
Read test result at 10-15 minutes.
Do not read test results after 15 minutes.It may give false results.

Serum/Plasma Testing Procedure

1.

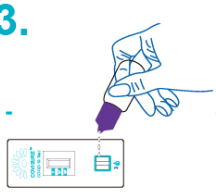


Collection of Specimen
Using a micropipette, collect the 20µl of serum or plasma with micropipette.

2.

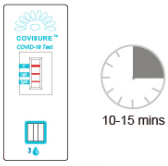
Add Specimen
Add the collected serum or plasma to the Sample Well of the test device.

3.



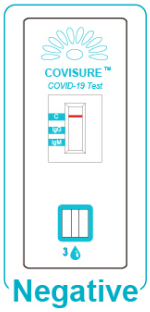
Add Buffer
Add 3 drops of buffer vertically into the Sample Well.

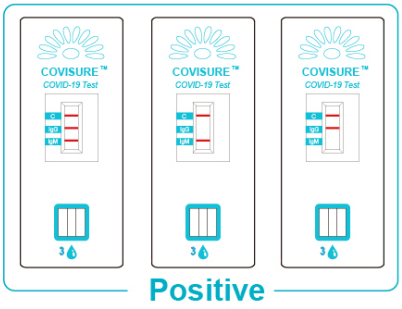
4.

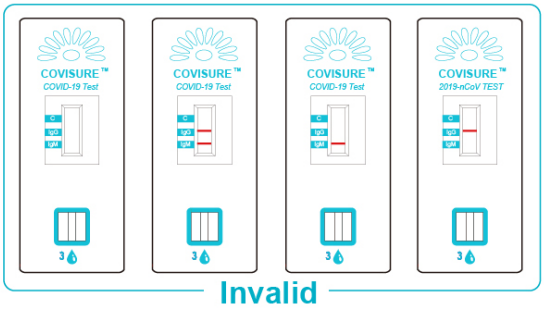


Read Time
Read test result at 10-15 minutes.
Do not read test results after 15 minutes.It may give false results.

Results







Clinical Performance

In a recent retrospective study, the COVISURE™ COVID-19 IgM/IgG Rapid Test was evaluated using 146 patient sample specimens. The samples were comprised of 46 nucleic acid test confirmed COVID-19 positive specimens as well as 100 known negative specimens collected and stored before November 1st, 2019. The following is a brief summary of the evaluation results.

Class Specific Total Positive Percentage Agreement (PPA) of IgM / IgG

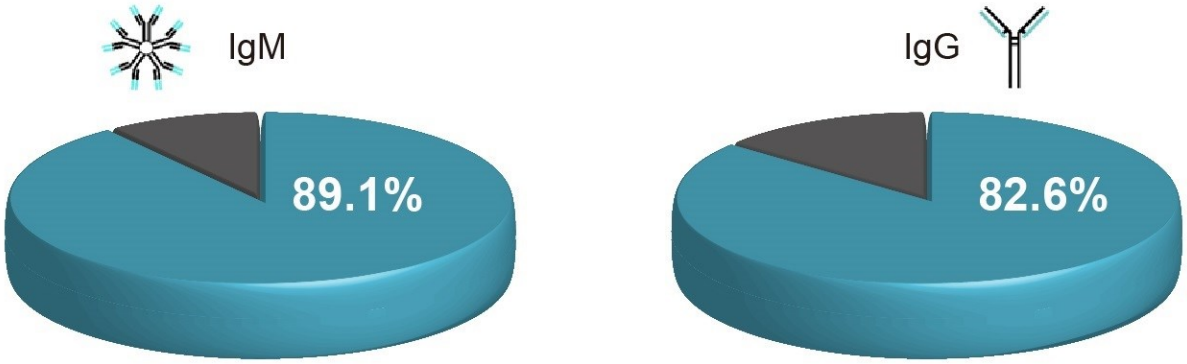
The 46 nucleic acid test confirmed positive COVID-19 clinical specimens were evaluated to calculate the class-specificity and IgM & IgG combined sensitivity / PPA of the device. The samples we collected within 4-24 days after the onset of symptoms:

IgM/IgG Clinical Sensitivity / PPA

Seroconversion Timeline Evaluation		Confirmed COVID-19 Positive Specimens
		4-24 Days
PCR Confirmed Positives		46
COVID-19 IgM/IgG Rapid Test	IgM Positive	41
	IgG Positive	38

Class Specific Clinical Sensitivity

4 ~ 24 DAYS AFTER SYMPTOM ONSET



IgM Clinical Sensitivity / IgM PPA= 41/46 = 89.1%

IgG Clinical Sensitivity / IgG PPA= 38/46 = 82.6%

The clinical class-sensitivity / PPA of clinically confirmed COVID-19 patients for all samples collected within 4-24 days after the onset of symptoms:

Clinical Application Performance

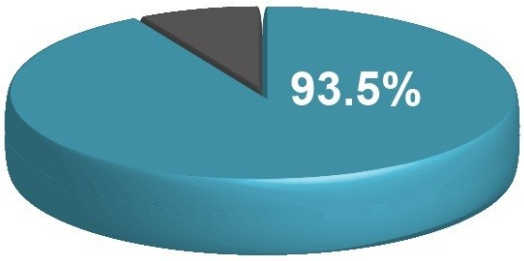
The COVISURE™ COVID-19 IgM/IgG Rapid Test is a presumptive qualitative device. Positive results of either IgM, IgG, or Both are considered a positive result. In order to calculate the combined clinical application performance of the device all results from the recent study were collected for statistical analysis. A total of 146 specimens were tested. The comparison results of the clinical application performance of the COVID-19 IgM/IgG Rapid Test with the expected results of the known negative and confirmed positive specimens was 143/146, demonstrating a relative accuracy of 97.9%

Combined IgM & IgG Clinical Application Performance

COVID-19 IgM/IgG Rapid Test		Confirmed COVID-19 Patient Specimens & Healthy Individual Specimens		
		Positive	Negative	Total
IgM/IgG	Positive	43	0	43
	Negative	3	100	103
Total		46	100	146

IgM & IgG Combined Sensitivity

4 ~ 24 DAYS AFTER SYMPTOM ONSET



- The specimens of 46 clinically confirmed COVID-19 patients with a reported timeline of 4 ~ 24 days after symptom onset were tested. The IgM/IgG antibody PPA was 43/46, demonstrating a sensitivity of 93.5%.
- The specimens of 100 healthy individuals were collected and tested. The test results of the COVID-19 IgM/IgG Rapid Test and currently approved test kits were all negative. The IgM/IgG antibody NPA was 100%.

Clinical Sensitivity	Relative Accuracy	Clinical Specificity
93.5%	97.9%	100%

Cross-Reactivity & Interference

The COVISURE™ COVID-19 IgM/IgG Rapid Test was evaluated for potential interference from antibodies against other viruses whose infection produces symptoms similar to those observed during SARS-CoV-2 infection. Five seropositive sample specimens for each cross reactant listed below to the left were evaluated for potential cross-reactivity with the device. Potentially Interfering Substances were evaluated using 3 confirmed positive and 2 confirmed negative COVID-19 serum speicmens. No cross-reactivity was observed. No interference was observed.

Cross-reactants	Sample Volume
Anti-influenza A IgG positive serum	100uL
Anti-influenza A IgM in positive serum	100uL
Anti- influenza B IgG in positive serum	100uL
Anti- influenza B IgM in positive serum	100uL
anti-HCV IgG in positive serum	100uL
anti-HCV IgM in positive serum	100uL
anti-HBV IgG in positive serum	100uL
anti-HBV IgM in positive serum	100uL
ANA in positive serum	100uL
anti-respiratory syncytial virus IgG in positive serum	100uL
anti-respiratory syncytial virus IgM in positive serum	100uL
anti-Haemophilus influenzae IgG in positive serum	100uL
anti-Haemophilus influenzae IgM in positive serum	100uL

Potentially Interfering Substance	Concentration
Mucin	14mg/g
Bilirubin	200mg/L
Cholesterol	2500mg/L
Triglyceride	2500mg
Hemoglobin	25g/L
Human Haemoglobin	30mg/g
Human Blood	200μL/g
Interferon-alpha	2mg/g
Zanamivir	2mg/g
Ribavirin	2mg/g
Oseltamivir	2mg/g
Peramivir	2mg/g
Lopinavir	2mg/g
Ritonvir:	2mg/g
Arbidol	2mg/g