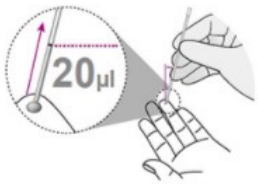
Instructions for use

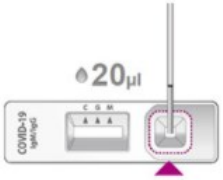
TEST PROCEDURE

Using Capillary whole blood

1 Collecting of Specimen
Using a capillary tube, collect the 20μl of capillary whole blood to the black line of the capillary tube.



2 Adding of Specimen
Add the collected capillary whole blood to the specimen well of the test device.



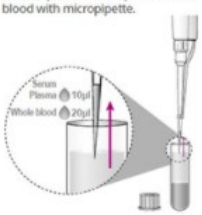
3 Dropping of buffer
Add 3 drops (90μl) of buffer vertically into the specimen well of the test device.

4 Reading Time
Read the test result at 10~15 minutes.

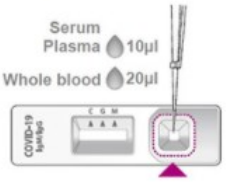
CAUTION
- Do not read test results after 15 minutes. It may give false results.

Using serum/plasma/venous whole blood

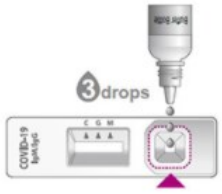
1 Collecting of Specimen
Using a micropipette, collect the 10μl of serum, plasma or 20μl of venous whole blood with micropipette.



2 Adding of Specimen
Add the collected serum, plasma or venous whole blood to the specimen well of the test device.



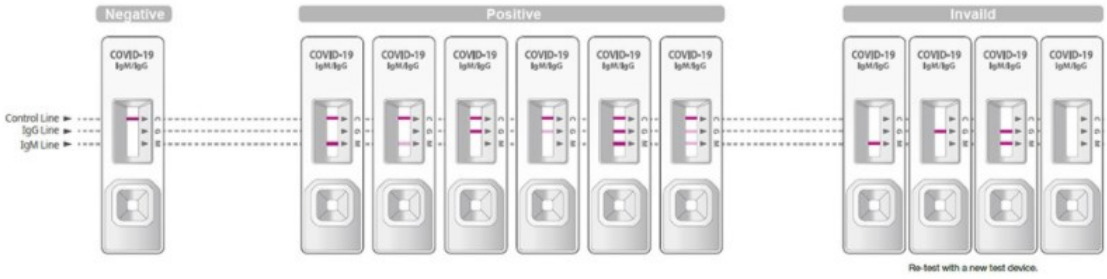
3 Dropping of buffer
Add 3 drops (90μl) of buffer vertically into the specimen well of the test device.



4 Reading Time
Read the test result at 10~15 minutes.

CAUTION
- Do not read test results after 15 minutes. It may give false results.

INTERPRETATION OF TEST RESULT



1. A colored band will appear in the top section of the result window to show that the test is working properly. This band is control line (C).
2. A colored bands will appear in the lower section of the result window. These bands are each test line of IgM/IgG (M, G).
3. Even if the control line is faint, or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted as a positive result.

*** STANDARD Q COVID-19 IgM/IgG Combo Test may cross-react with antibody against SARS-CoV-1.**
*** 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.**
*** Positive results should be considered in conjunction with the clinical history, RT-PCR results and other data available.**

PERFORMANCE CHARACTERISTICS

[Clinical evaluation]

Performance characteristic for the STANDARD Q COVID-19 IgM/IgG Combo Test for rapid detection of anti-SARS-CoV-2 antibodies was established in retrospective, multi institutes, randomized, single-blinded study conducted at trial sites in KOREA and BRAZIL during the 2020 SARS-CoV-2 pandemic situation. A total of 471 retrospective specimens were tested using the STANDARD Q COVID-19 IgM/IgG Combo Test. These specimens consisted of serum from PCR positive or negative confi rmed patients. The performance of the STANDARD Q COVID-19 IgM/IgG Combo Test were compared to a commercialized molecular assay. Although the STANDARD Q COVID-19 IgM/IgG Combo Test allows to test for IgM and IgG separately, due to the diff ering inter-patient time response to the virus, any individual with positive result for the IgM or the IgG test should be read as a positive for anti-SARS-CoV-2 antibodies. The combined test result (positive for IgM and/or IgG or negative for IgM and/or IgG) was used to calculate the total test sensitivity and specifi city.

• Test sensitivity

The seroconversion time of IgM and IgG antibodies varies from person to person, but it was estimated to be around 7 days after onset of symptom[4,5]. The STANDARD Q COVID-19 IgM/IgG Combo Test showed **94.51% of sensitivity** using specimens from patients 7 days after symptom onset (combined IgM+IgG).

Table 1. Summary of sensitivity of the STANDARD Q COVID-19 IgM/IgG Combo Test Compare to PCR confirmed specimens from **7 days after symptoms onset is 94.51%**

≥ 7 days after symptom onset		PCR		
		Positive	Negative	Total
STANDARD Q COVID-19 IgM/IgG Combo Test	Positive	155	0	155
	Negative	9	0	9
	Total	164	0	164
Sensitivity		**94.51% (155/164, 95% CI, 89.84% - 97.46%)**		

Table 2. Summary of sensitivity of the STANDARD Q COVID-19 IgM/IgG Combo Test compared to PCR confirmed specimens within less than **7 days after symptom onset is 69.05%**

< 7 days after symptom onset		PCR		
		Positive	Negative	Total
STANDARD Q COVID-19 IgM/IgG Combo Test	Positive	29	0	29
	Negative	13	0	13
	Total	42	0	42
Sensitivity		69.05% (29/42, 95% CI, 52.91% - 82.38%)		

Table 3. Summary of sensitivity of the STANDARD Q COVID-19 IgM/IgG Combo Test compared to PCR confirmed specimens between **7 days to 14 days after symptom onset is 89.39%**

7-14 days after symptom onset		PCR		
		Positive	Negative	Total
STANDARD Q COVID-19 IgM/IgG Combo Test	Positive	59	0	59
	Negative	7	0	7
	Total	66	0	66
Sensitivity		89.39% (59/66, 95% CI, 79.36% - 95.63%)		

Table 4. Summary of sensitivity of the STANDARD Q COVID-19 IgM/IgG Combo Test compared to PCR confirmed specimens from **14 days after symptom onset is 96.94%**

> 14 days after symptom onset		PCR		
		Positive	Negative	Total
STANDARD Q COVID-19 IgM/IgG Combo Test	Positive	95	0	95
	Negative	3	0	3
	Total	98	0	98
Sensitivity		96.94% (95/98, 95% CI, 91.31% - 99.36%)		

- **Test specificity**

The STANDARD Q COVID-19 IgM/IgG Combo Test showed **96.23% of specificity** (combined IgM+IgG).

Table 5. Summary of specificity of the STANDARD Q COVID-19 IgM/IgG Combo Test compared to PCR confirmed specimens is 96.23%

		PCR		
		Positive	Negative	Total
STANDARD Q COVID-19 IgM/IgG Combo Test	Positive	0	10	10
	Negative	0	265	265
	Total	0	265	265
Specificity		**96.23% (255/265, 95% CI, 93.17 - 98.18%)**		

ANALYTICAL PERFORMANCE

1. Limit of Detection: IgM-9.37 ug/ml, IgG-3.75 ug/ml
2. Cross-Reactivity: No cross-reactivity for the specimen of HIV Seroconversion panel, Japanese Encephalitis positive, Zika virus positive, Chikungunya positive, Dengue IgM positive, Salmonella typhi IgM positive, Rubella IgM, CMV IgG/IgM, Tick borne encephalitis IgM positive, West Nile Virus positive, Treponema palladium, HAV IgM positive, HAV IgG positive, HBV Ab positive, HCV Ab positive, Influenza vaccine positive, Leishmania positive, Brucella IgM positive, Chagas positive, Toxoplasma positive, Filariasis positive, Mycoplasma pneumonia IgM positive, Mycoplasma pneumonia IgG positive, Mycoplasma pneumonia IgM positive, Influenza A IgM positive, Influenza B IgM positive, Influenza A and B IgG+IgM positive and Tuberculosis positive.
3. Interference study: For Exogenous substances, there was no interference with medicines such as Zanamivir (for Influenza), Oseltamivir (for Influenza), Artemether-lumefantrine (for Malaria), Doxycycline hyclate (for Malaria), Quinine (for Malaria), Lamivudine (Retroviral medication), Ribavirin (for HCV), Daclatasvir (for HCV). Also there was no interference with Anti-inflammatory medication (Acetaminophen, Acetylsalicylic acid, Ibuprofen), Antibiotic (Erythromycin, Ciprofloxacin), Dietary substances (Caffeine, Ethanol, Biotin), Triglycerides, Cholesterol, Bilirubin(Unconjugate), Hemoglobin and Anticoagulants (EDTA, Heparin, Sodium citrate). For Edogenous substances, there was no interference with human anti-mouse antibody, whole blood of pregnant women and whole blood having elevated levels of hemoglobin, elevated levels of C-reactive protein and Elevated IgG or IgM samples.
4. Matrix Equivalency: The matrix and anticoagulant does not affect the detection of COVID-19 IgG and IgM in contrived specimens between serum, plasma(Heparin, EDTA, Sodium citrate), venous whole blood(Heparin, EDTA, Sodium citrate), and capillary whole blood(collected in EDTA-treated tubes).

LIMITATION OF TEST

1. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
2. This test detects the presence of SARS-CoV-2 IgM/IgG in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infection.
3. Test results must be considered with other clinical data available to the physician.
4. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
5. Neither the quantitative value nor the rate anti- SARS-CoV-2 IgM/IgG concentration can be determined by this qualitative test.
6. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
7. A negative result may occur if the concentration of antigen or antibody in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of SARS-CoV-2 infection, and should be confirmed by viral culture or an molecular assay or ELISA.
8. Positive test results do not rule out co-infections with other pathogens.
9. Negative test results are not intended to rule in other coronavirus infection except the SARS-CoV-1.
10. Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children.

NOTIFICATION FOR COVID-19 ANTIBODY TESTS

1. This test has not been reviewed by the FDA.
2. 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.
3. 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.
4. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E or past or present infection with SARS virus (no. 6).
5. Not for the screening of donated blood.
6. The test procedure should be conducted in ambient temperature and pressure.
7. Results of these tests should be appropriately recorded in a test report.