We introduce our high quality products

You can find our company's products through
the searching of product name, product code or product category.

STANDARD Q COVID-19 IgM/IgG Duo

This kit is a rapid immunochromatography test designed for the qualitative presumptive detection of specific IgM and IgG to 2019 novel coronavirus (nCoV) in humoral fluid.

CE

STANDARD Q COVID-19 IgM/IgG Duo Test Kit is a rapid immunochromatography test designed for the qualitative presumptive detection of specific IgM and IgG to SARS-CoV-2 in humoral fluid.

- Rapid testing for SARS-CoV-2 antibodies within 10 minutes
- Just 10ul of specimen : Whole blood, serum , plasma
- Suitable for Point of Care Testing. No need for extra equipment

Contact	E-mail
Europe / Africa	covid-emea@sdbiosensor.com
Asia	covid-asia@sdbiosensor.com
America	covid-latam@sdbiosensor.com

Information

Specification

Ordering information

Instructions for use

TEST PROCEDURE - Be sure to test both STANDARD Q COVID-19 IgM and IgG simultaneously.

The test procedures for both COVID-19 IgM and IgG are the same.

Using Capillary whole blood

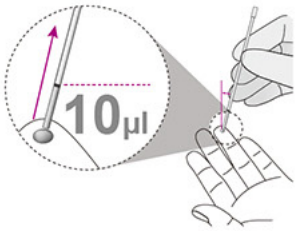
1 **Collecting of Specimen** Using a capillary tube, collect the 10ul of

2 **Adding of Specimen** Add the collected capillary whole blood to

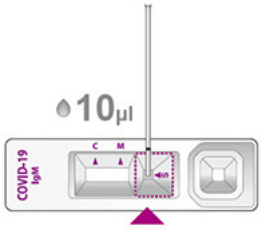
3 **Dropping of buffer** Add 3 drops (90μl) of buffer vertically into

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

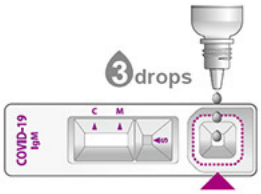
capillary whole blood to the black line of the capillary tube.



the specimen well of the test device.



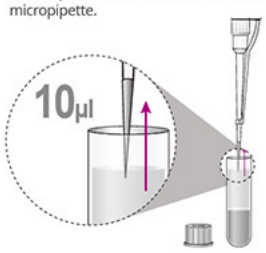
the buffer well of the test device.



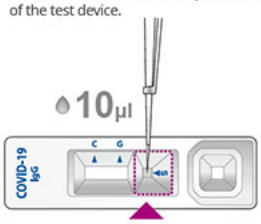
CAUTION • Do not read test results after 15 minutes. It may give false results.

Using serum/plasma/venous whole blood

1 Collecting of Specimen
Using a micropipette, collect the 10μl of serum, plasma or 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.

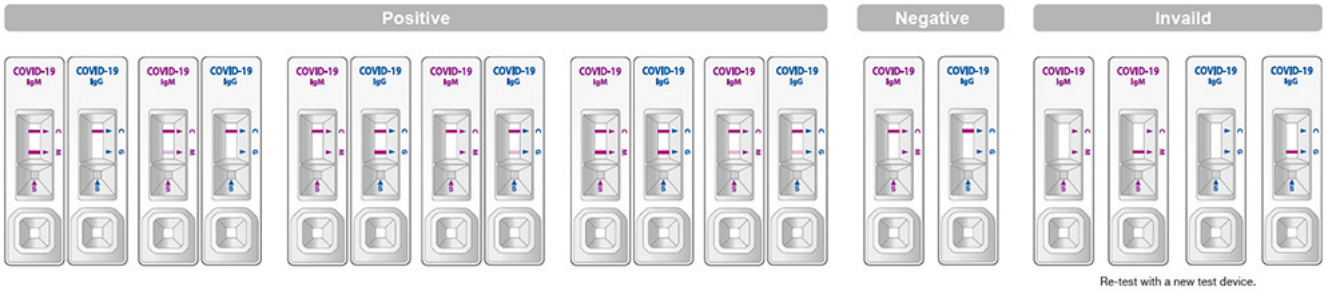


3 Dropping of buffer
Add 3 drops (90μl) of buffer vertically into the buffer well of the test device.

4 Reading Time
Read 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 band will appear in the lower section of the result window. These bands are 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 Duo 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]

Across three clinical studies, 239 positive serum samples collected from individuals who tested positive with a RT-PCR method for SARS-CoV-2 infection. The day of collection relative to the onset of illness was recorded. Minus the three samples excluded, 236 positive serum samples were included in the analysis. These samples, along with 205 negative serum samples from healthy donors were coded and tested together with the STANDARD Q COVID-19 IgM/IgG Duo Test.

	SARS-CoV-2 positive patients	SARS-CoV-2 negative patients
Study 1	33*	30
Study 2	30	75
Study 3	176	100
Total	**239**	**205**

*Although 33 samples were collected, three samples for Study 1 were excluded from the summary of the first clinical study due to absence of clear date of symptom onset.

Test were performed according to instruction for use of STANDARD Q COVID-19 IgM/IgG DUO Test. SARS-CoV-2 status was confirmed by real-time PCR (PowerchekTM 2019-nCoV Real-time PCR kit, Emergency Use Approved) method for all patients (positive and negative). Of the 236 positive samples, two hundred and eleven (211) tested positive with IgG or IgM or both. Of the 205 negative samples, one hundred ninety-seven (197) were tested negative. Results are stratified by the day of collection relative to the onset of illness.

Sensitivity analysis (PPA) – analysis of samples positive for SARS-CoV-2

Sensitivity		STANDARD COVID-19 IgM/IgG Duo Test		
		IgM +	IgG +	IgM+ or IgG+
	0-7 days	60.3% (38/63)	61.9% (39/63)	71.4% (45/63)

Time post symptom onset	0-7 days	[95% CI: 48.0%-71.5%]	[95% CI: 49.6%-72.9%]	[95% CI: 59.3%-81.1%]
	8-14 days	87.5% (56/64) [95% CI: 77.2%-93.5%]	84.4% (54/64) [95% CI: 73.6%-91.3%]	90.6% (58/64) [95% CI: 80.7%-96.5%]
	15-21 days	92.3% (48/52) [95% CI: 81.3%-97.0%]	96.2% (50/52) [95% CI: 73.6%-91.3%]	98.1% (51/52) [95% CI: 79.1%-94.6%]
	22+ days	98.3% (56/57) [95% CI: 90.7%-99.7%]	96.5% (55/57) [95% CI: 88.1%-99.3%]	100% (57/57) [95% CI: 93.7%-100%]

Specificity analysis (NPA) – analysis of samples negative for SARS-CoV-2

Specificity	STANDARD COVID-19 IgM/IgG Duo Test		
	IgM -	IgG -	IgM - or IgG -
RT-PCR SARS-CoV-2 negative samples	99.5% (204/205) [95% CI: 97.3%-99.9%]	96.6% (198/205) [95% CI: 93.1%-98.3%]	96.1% (197/205) [95% CI: 92.5%-98.3%]

LIMITATION OF TEST

1. The Assay Procedure and the Interpretation of Assay Result must be followed closely when testing for the presence of SARS-CoV-2 virus specific antibodies in the serum, plasma or whole blood specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
2. The STANDARD Q COVID-19 IgM/IgG Duo Test is limited to the qualitative detection of antibodies specific for the SARS-CoV-2 virus. The intensity of the test line does not necessarily correlate to SARS-CoV-2 antibody titer in the specimen. Neither the quantitative value nor the rate anti- SARS-CoV-2 IgM/IgG concentration can be determined by this qualitative test.
3. A negative or non-reactive result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limit of the assay, or the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody detected by the test.
4. 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.
5. Test results must be considered with other clinical data available to the physician.
6. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
7. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
8. If symptoms persist and the result from the STANDARD Q COVID-19 IgM/IgG Duo Test is negative or non-reactive, it is recommended to re-sample the patient a few days later or test with an alternative test device.

EXTERNAL QUALITY CONTROL

1. Positive and negative controls are optional contents (Cat No. 10COVC20) and these controls can be provided as a means on additional quality control to demonstrate a positive or negative reaction.
2. Quality controls should be treated and tested the same as patient specimens.
3. It is recommended that positive and negative controls be run:
   - Once for each new lot,
   - Once for each untrained operator,
   - Once for each new shipments of test kits,
   - As required by test procedures in this instructions and in accordance with local, state and federal regulations of accreditation requirements.

NOTIFICATION FOR COVID-19 ANTIBODY TESTS

1. 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.
2. 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.
3. 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).
4. Not for the screening of donated blood.
5. The test procedure should be conducted in ambient temperature and pressure.
6. Results of these tests should be appropriately recorded in a test report.

SD BIOSENSOR

SD BIOSENSOR **Site Map**

SD BIOSENSOR

Address : C-4&5 Floor, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC of KOREA
Tel : +82-31-300-0400, Email : sales@sdbiosensor.com, Website : www.sdbiosensor.com 관리자