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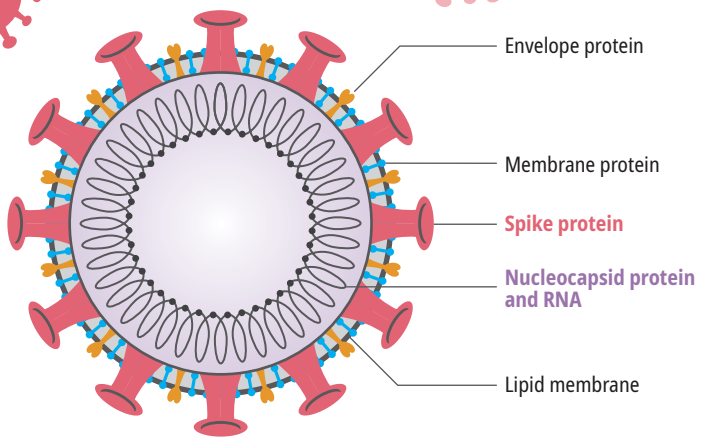
STANDARD Q

COVID-19 IgM/IgG Duo

SD BIOSENSOR

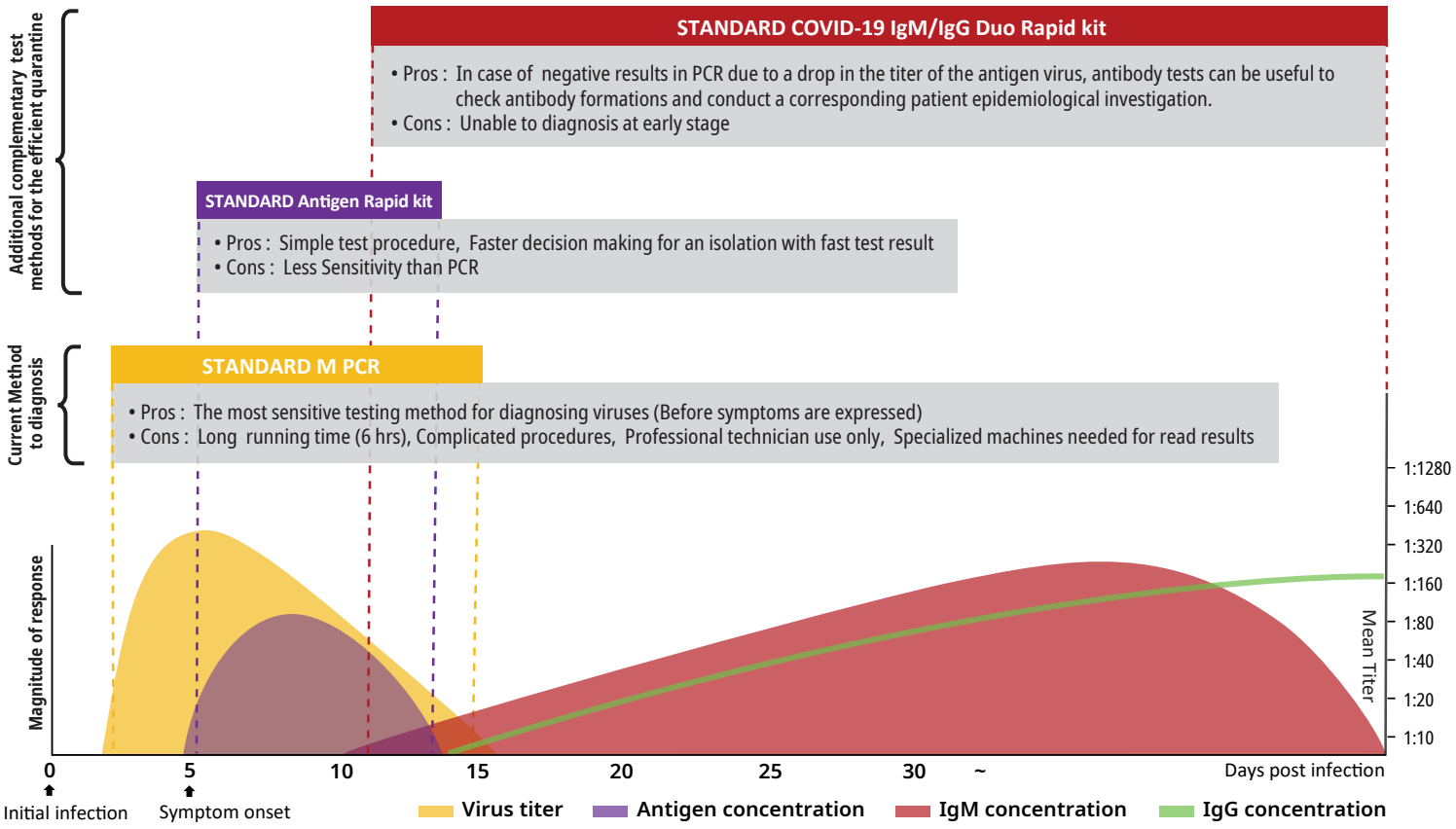


Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). The novel coronavirus now known as SARS-CoV-2 is a new strain which has not previously been identified in humans.

The core protein of SARS-CoV-2 is the N protein (Nucleocapsid protein), which is a protein component located inside the virus. It is relatively conserved among β-coronaviruses and is often used as a tool for the diagnosis of coronaviruses. ACE2, as a key receptor for SARS-CoV-2 to enter cells, is of great significance for the research of viral infection mechanism.

Reference :
1. Information from Li et al, 2020 Journal of Medical Virology. "Development and Clinical Application of a Rapid IgM-IgG Combined Antibody Test for SARS-CoV-2 Infection Diagnosis"
2. Test results from FDA Pre-EUA Submission_Q COVID-19 Ag

Epidemiology and Test Overview



Reference :
1. Chen J, Lau YF, Lamirande EW, Paddock CD, Bartlett JH, Zaki SR, Subbarao K. Cellular immune responses to severe acute respiratory syndrome coronavirus (SARS-CoV) infection in senescent BALB/c mice: CD4+ T cells are important in control of SARS-CoV infection. J Virol. 2010 Feb;84(3):1289-301. doi: 10.1128/JVI.01281-09. Epub 2009 Nov 11.
2. Hsueh PR, Huang LM, Chen PJ, Kao CL, Yang PC. Chronological evolution of IgM, IgA, IgG and neutralisation antibodies after infection with SARS-associated coronavirus. Clin Microbiol Infect. 2004 Dec;10(12):1062-6.
*It is a graph modified based on reference materials. *It is not a graph that applies to all patients. Just for reference. Please use for reference only.

STANDARD Q COVID-19 IgM/IgG Duo Test

CE

Cat. No : 09COV12B

- **Test time** : Within 15 mins
- **Specimen** : Whole blood/Serum/plasma
- **Storage temperature** : 2-30℃/36-86℉
- **Pack size** : 40T/kit (IgM 20T, IgG 20T)

Performance characteristics

STANDARD Q COVID-19 IgM/IgG Duo TEST

[Clinical evaluation]

Test were performed according to instructions for use of **'STANDARD Q COVID-19 IgM/IgG Duo Test'** with residual serum from 33 positive patients confirmed by real-time PCR (2019-nCoV Real-time PCR kit) method and 30 healthy donors at hospital in Korea. Next page for more detail data.

- **Due to the differing inter-patient time response to the virus, any individual positive result of IgM or IgG should be read as a positive result for SARS-CoV-2 and the combined positive test results are used to calculate total Duo test sensitivity.**

Combined positive test results are used to calculate total Duo test sensitivity

		PCR		Total
		Positive	Negative	
STANDARD Q COVID-19 IgM+IgG	Positive	27	1	28
	Negative	6	29	35
Total		33	30	63

Sensitivity : 81.8%, Specificity : 96.6%

- **STANDARD Q COVID-19 IgM + IgG showed 81.8% of sensitivity and 96.6% of specificity.**

- **Test results of the specimens collected after 8 days and 10 days from the date of symptom onset below.**

Test result of the specimens collected after 8 days from the date of symptom onset

		PCR		Total
		Positive	Negative	
STANDARD Q COVID-19 IgM+IgG	Positive	25	1	28
	Negative	2	29	31
Total		27	30	57

Sensitivity : 92.6%, Specificity : 96.6%

Test result of the specimens collected after 10 days from the date of symptom onset

		PCR		Total
		Positive	Negative	
STANDARD Q COVID-19 IgM+IgG	Positive	23	1	24
	Negative	1	29	30
Total		24	30	54

Sensitivity : 95.8%, Specificity : 96.6%

※ **Based on result of test with positive specimens, it was found that IgM antibody diagnosis with STANDARD Q COVID-19 IgM/IgG Duo Test was effective for diagnosis SARS-CoV-2 from the time when after about 7 days from the date of symptom onset. And STANDARD Q COVID-19 IgM/IgG Duo Test showed a high specificity in the test with negative specimens.**

[Data table]

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Positive specimens

No.	Onset of Symptom date	Date confirmed as positive by PCR	Blood collection date	Days after symptom onset	STANDARD Q COVID-19 IgM/IgG Duo Test result	
					IgM	IgG
1	Unknown	Feb. 09, 2020	Feb. 17, 2020	Unknown	Positive	Pos weak
2	Unknown	Jan. 30, 2020	Feb. 17, 2020	Unknown	Positive	Positive
3	Unknown	Feb. 02, 2020	Feb. 17, 2020	Unknown	Positive	Positive
4	Feb. 15, 2020	Feb. 23, 2020	Feb. 23, 2020	8	Pos weak	Pos weak
5	Feb. 15, 2020	Feb. 23, 2020	Feb. 27, 2020	12	Pos weak	Positive
6	Feb. 15, 2020	Feb. 23, 2020	Mar. 03, 2020	17	Pos weak	Positive
7	Feb. 06, 2020	Feb. 09, 2020	Feb. 13, 2020	7	Negative	Negative
8	Feb. 06, 2020	Feb. 09, 2020	Feb. 21, 2020	15	Pos weak	Positive
9	Feb. 06, 2020	Feb. 09, 2020	Mar. 03, 2020	26	Pos weak	Positive
10	Feb. 18, 2020	Feb. 19, 2020	Feb. 19, 2020	1	Negative	Negative
11	Feb. 18, 2020	Feb. 19, 2020	Feb. 26, 2020	8	Negative	Positive
12	Feb. 19, 2020	Feb. 19, 2020	Feb. 23, 2020	4	Negative	Negative
13	Feb. 15, 2020	Feb. 23, 2020	Feb. 23, 2020	8	Positive	Positive
14	Feb. 6, 2020	Feb. 9, 2020	Mar. 03, 2020	26	Positive	Positive
15	Jan. 30, 2020	Feb. 1, 2020	Feb. 09, 2020	10	Negative	Negative
16	Jan. 25, 2020	Feb. 1, 2020	Feb. 12, 2020	18	Positive	Positive
17	Feb. 25, 2020	Feb. 25, 2020	Mar. 03, 2020	7	Negative	Positive
18	Feb. 15, 2020	Feb. 23, 2020	Feb. 25, 2020	10	Positive	Positive
19	Feb. 6, 2020	Feb. 9, 2020	Feb. 21, 2020	15	Positive	Positive
20	Jan. 30, 2020	Feb. 1, 2020	Feb. 13, 2020	14	Positive	Positive
21	Jan. 25, 2020	Feb. 1, 2020	Feb. 09, 2020	15	Trace	Positive
22	Feb. 15, 2020	Feb. 23, 2020	Feb. 26, 2020	11	Positive	Positive
23	Feb. 6, 2020	Feb. 9, 2020	Feb. 17, 2020	11	Positive	Positive
24	Jan. 30, 2020	Feb. 1, 2020	Feb. 06, 2020	7	Negative	Negative
25	Feb. 18, 2020	Feb. 21, 2020	Feb. 26, 2020	8	Negative	Negative
26	Feb. 15, 2020	Feb. 23, 2020	Feb. 27, 2020	12	Positive	Positive
27	Feb. 6, 2020	Feb. 9, 2020	Mar. 01, 2020	24	Positive	Positive
28	Jan. 25, 2020	Feb. 1, 2020	Feb. 17, 2020	23	Positive	Positive
29	Feb. 25, 2020	Feb. 25, 2020	Mar. 02, 2020	6	Negative	Positive
30	Feb. 15, 2020	Feb. 23, 2020	Feb. 29, 2020	14	Positive	Positive
31	Feb. 22, 2020	Feb. 24, 2020	Mar. 06, 2020	13	Negative	Positive
32	Feb. 4, 2020	Feb. 4, 2020	Feb. 20, 2020	16	Negative	Positive
33	Feb. 4, 2020	Feb. 4, 2020	Feb. 20, 2020	16	Negative	Positive

Remarks

- **According to no.31, no.32, and no.33 patients data, STANDARD Q COVID-19 IgM/IgG Duo Test results showed negative in IgM test and positive in IgG test with specimens collected after about 13 days from symptom onset.**
- **This can be interpreted that RT-PCR result might come out with negative at that period.**
- **Thus, antibody test can be useful to check antibody formations and conduct a corresponding patient epidemiological investigation in case of negative results in PCR due to a drop in the titer of virus.**

Negative specimens

No.	Blood collection date	STANDARD Q COVID-19 IgM/IgG Duo Test result	
		IgM	IgG
1	Mar. 6, 2020	Negative	Negative
2	Feb. 20, 2020	Negative	Negative
3	Mar. 4, 2020	Negative	Negative
4	Mar. 5, 2020	Negative	Negative
5	Mar. 9, 2020	Negative	Negative
6	Mar. 7, 2020	Negative	Negative
7	Mar. 11, 2020	Negative	Negative
8	Mar. 5, 2020	Negative	Negative
9	Mar. 11, 2020	Negative	Negative
10	Mar. 7. 2020	Negative	Negative
11	Mar. 9, 2020	Negative	Negative
12	Mar. 6, 2020	Negative	Negative
13	Mar. 4, 2020	Negative	Negative
14	Feb. 20, 2020	Negative	Negative
15	Feb. 19, 2020	Negative	Negative

No.	Blood collection date	STANDARD Q COVID-19 IgM/IgG Duo Test result	
		IgM	IgG
16	Feb. 18, 2020	Negative	Negative
17	Feb. 25, 2020	Negative	Negative
18	Feb. 20, 2020	Negative	Negative
19	Feb. 25, 2020	Negative	Pos weak
20	Feb. 17, 2020	Negative	Negative
21	Feb. 20, 2020	Negative	Negative
22	Feb. 20, 2020	Negative	Negative
23	Feb. 20, 2020	Negative	Negative
24	Feb. 19, 2020	Negative	Negative
25	Feb. 13, 2020	Negative	Negative
26	Feb. 10, 2020	Negative	Negative
27	Feb. 10, 2020	Negative	Negative
28	Feb. 2, 2020	Negative	Negative
29	Feb. 12, 2020	Negative	Negative
30	Feb. 6, 2020	Negative	Negative

STANDARD Q COVID-19 Products

STANDARD Q
COVID-19 IgM/IgG Duo Test

- **Test time** : Within 15 mins
- **Specimen** : Whole blood/Serum/plasma
- **Storage temperature** : 2-30℃/36-86℉
- **Pack size** : 40T/kit (IgM 20T, IgG 20T)

Ordering Information

Cat. No.	Product	Storage temperature	Pack size
139-7701	STANDARD Q COVID-19 IgM/IgG Duo Test	2-30℃/36-86℉	20T/kit

MEMO

※ This test has not been reviewed by FDA.
※ 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.
※ 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).
※ Results of these tests should be appropriately recorded in a test report.

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