MONTEBIO

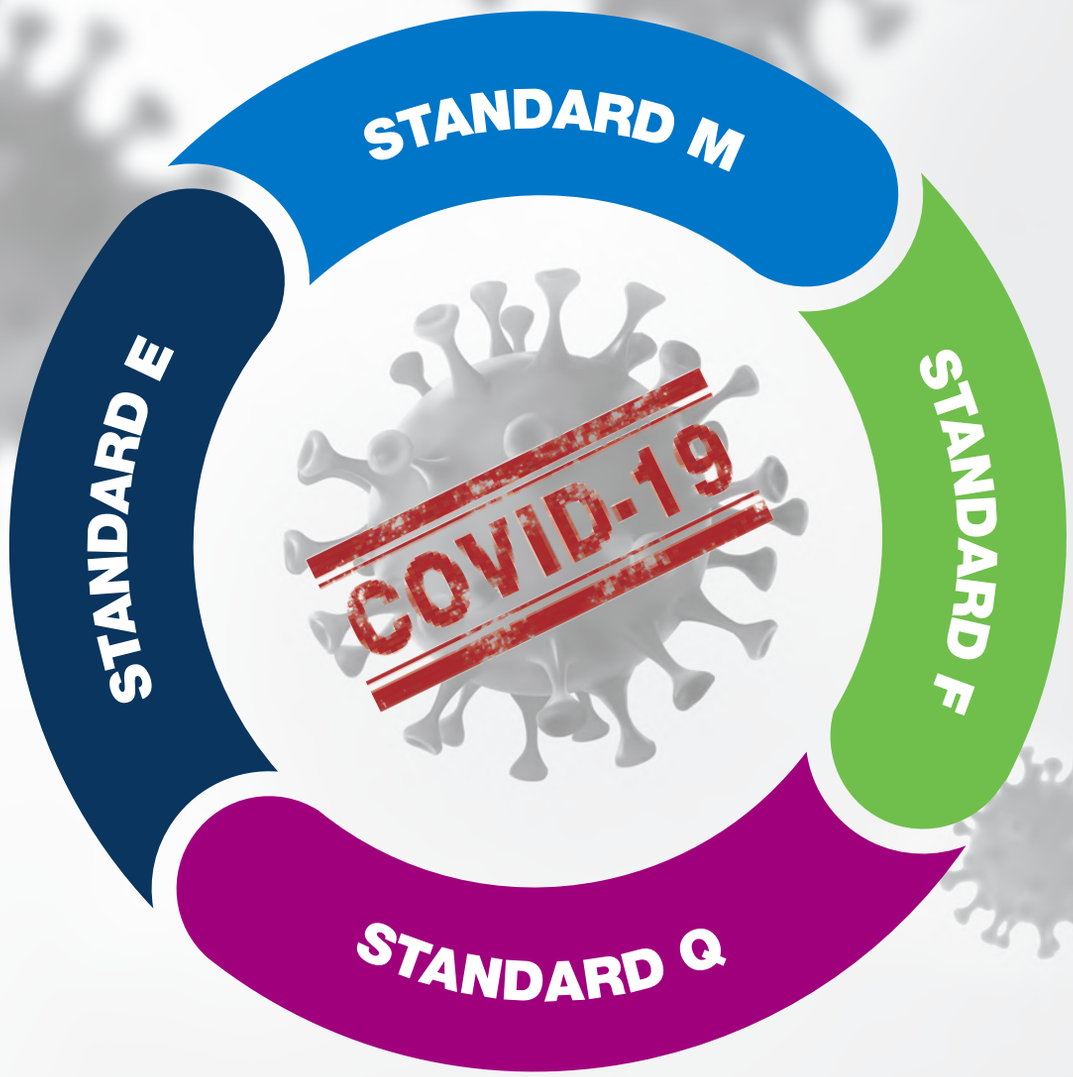
DIAGNÓSTICO & INVESTIGACIÓN

STANDARD M - MOLECULAR DETECTION
STANDARD F - FLUORESCENT IMMUNOASSAY
STANDARD Q - RDT SERIES
STANDARD E - ELISA SERIES

COVID-19
TOTAL SOLUTION

MADE IN KOREA

SD BIOSENSOR



STANDARD M

- STANDARD™ M nCoV Real-Time Detection kit

STANDARD F

- STANDARD™ F COVID-19 Ag FIA
- STANDARD™ F COVID-19 IgM/IgG Combo Test

STANDARD Q

- STANDARD™ Q COVID-19 Ag Test
- STANDARD™ Q COVID-19 IgM/IgG Combo Test
- STANDARD™ Q COVID-19 Ag/Ab Total Test

STANDARD E

- STANDARD™ E COVID-19 Total Ab ELISA

TABLE OF CONTENTS

STANDARD M

Molecular diagnostics

- Complete bundle for SARS-CoV-2 RT-PCR
- One-Step, One-Tube reaction in 90 mins
- Reliable clinical performance
- Optimized primer/probe design for the early SARS-CoV-2 detection

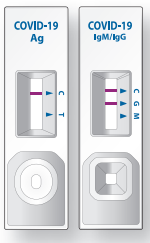
STANDARD F

Fluorescent immunoassay

- Improved sensitivity through FIA method
- Maximized usability & connectivity
- 6 other respiratory markers for classification

STANDARD Q

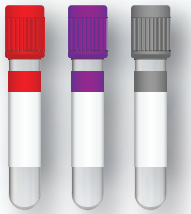
RDT Series



- Point of care without any instruments
- Extend diagnostic scope of infection status not only acute phase but convalescent phase
- Fastest results among the STANDARD brands
  (Ag : within 30 min, Ab : within 15 min)

STANDARD E

ELISA Series



- Suitable for population antibody screening
- Superior sensitivity & specificity

STANDARD M nCoV Real-Time Detection kit

CE · KFDA EUA APPROVED · FDA EUA APPROVED

Background

STANDARD M nCoV Real-Time Detection kit is a real-time RT-PCR assay intended for the *in vitro* qualitative detection of Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA in human nasopharyngeal swab, oropharyngeal swab and sputum specimens. This provides highly sensitive and specific results, which is essential to make an appropriate diagnostic decision.

Specimen type

- Nasopharyngeal swab in VTM
- Oropharyngeal swab in VTM
- Sputum

Compatible Instruments

- CFX96™ Dx System (Bio-Rad)
- Applied Biosystems 7500 Real-Time PCR Instrument System (Thermo Fisher Scientific)
- Applied Biosystems 7500 Fast Real-Time PCR Instrument System (Thermo Fisher Scientific)
- LightCycler 480 II (Roche)

Advantage

- **Providing complete bundle for SARS-CoV-2 RT-PCR**
- **One-Step, One-Tube RT-PCR assay**
- **1.5 hour TAT (after extraction)**
- **Optimized primer/probe design for the early SARS-CoV-2 detection**
  ORF1ab (RdRp) gene, E gene
- **Limit of detection (LoD): 5 copies/reaction**
- **Distributed to more than 30 countries**
  About 1 Million tests has been deployed and used cumulatively

Performance Characteristics

Clinical Evaluation

- Korean hospital (YoungNam Univ. Hospital)
- Sensitivity - 100%, Specificity - 100%

		KCDC EUA RT-PCR Assay		
		Positive	Negative	Total
STANDARD M nCoV Real-Time Detection kit	Positive	101	0	101
	Negative	0	111	111
	Total	101	111	212
Sensitivity		**100% (101/101, 95% CI: 96.41% - 100%)**		
Specificity		**100% (111/111, 95% CI: 96.73% - 100%)**		

Ordering Information

Cat. No.	Product	Storage temperature	Tests/kit	Kit/carton	Carton size (W/D/H)
11NCO10	STANDARD M nCoV Real-Time Detection kit	-25~ -15°C/-13~ 5°F	96	160	764 x 590 x 515 mm
11SPN10	STANDARD M SPIN-X Viral RNA Extraction Kit	15 - 35°C/59 - 95°F	100	12	420 x 410 x 350 mm
UTNFS-3B-2	Viral Collection, Preservation and Transport Medium Kit (Nasopharyngeal Swab + Oropharyngeal Swab) + 2ml UTM Tube	4~25°C/40~77°F	50	10	540 x 460 x 387 mm

STANDARD F

COVID-19 Ag FIA

CE

Background

STANDARD F COVID-19 Ag FIA is the fluorescent immunoassay for the qualitative detection of specific nucleoprotein antigens to SARS-CoV-2 present in human nasopharynx. STANDARD F COVID-19 Ag FIA should be used with the STANDARD F Analyzers manufactured by SD BIOSENSOR. This test is for *in vitro* professional diagnostic use and intended as an aid to early diagnosis of SARS-CoV-2 infection in patient with clinical symptoms with SARS-CoV-2 infection.

Specimen type

- Nasopharyngeal swab

Compatible Instruments

- STANDARD F2400
- STANDARD F200
- STANDARD F100

Advantage of Antigen Test

- **Improved sensitivity through FIA method**
- **Providing additional information through Cut-off Index value**
- **Convenient data management via LIS/HIS connectivity**
- **Ready-to-use & room temperature storage condition**

Performance Characteristics

Clinical Evaluation

- Sensitivity - 100%, Specificity - 100%

Specimen	Concentration	Result analysis
Positive Nasopharyngeal swab specimen	1x Limit of Detection: $7.81 \times 10^{1.2}$ $TCID_{50}$/ml	**100% Sensitivity (30/30)**
	2x Limit of Detection: $1.56 \times 10^{2.2}$ $TCID_{50}$/ml	
	4x Limit of Detection: $3.13 \times 10^{2.2}$ $TCID_{50}$/ml	
Negative Nasopharyngeal swab specimen	N/A	**100% Specificity (30/30)**

Interpretation of Test Results

Result	COI (Cutoff index) value	SARS-COV-2 Ag
Positive	COI ≥ 1.0	Positive for SARS-COV-2 Ag
Negative	COI < 1.0	Negative for SARS-COV-2 Ag
Invalid	COI value is not displayed	Retest should be performed with a new test device and a new patient's specimen.

STANDARD F

COVID-19 IgM/IgG Combo FIA

CE

Background

STANDARD F COVID-19 IgM/IgG Combo FIA is the fluorescent immunoassay for the qualitative detection of specific antibodies to SARS-CoV-2 present in human serum and whole blood. STANDARD F COVID-19 IgM/IgG Combo FIA should be used with the STANDARD F Analyzers manufactured by SD BIOSENSOR. This test is for *in vitro* professional diagnostic use and intended as an aid to diagnosis of SARS-CoV-2 infection in convalescent phase of patient with clinical symptoms with SARS-CoV-2 infection.

Specimen type

- EDTA Whole blood
- Capillary blood
- Serum

Compatible Instruments

- STANDARD F2400
- STANDARD F200
- STANDARD F100

Advantage of Antibody Test

- Total Antibody test (IgM, IgA, and IgG)
- Superior sensitivity & specificity
- Suitable method for population antibody screening

Performance Characteristics

Clinical Evaluation

- Sensitivity - 94.41%, Specificity - 90.62%

≥ 7 days after symptom onset		PCR		
		Positive	Negative	Total
STANDARD F COVID-19 IgM/IgG Combo FIA	Positive	135	0	135
	Negative	8	0	8
	Total	143	0	143
Sensitivity		94.41% (135/143, 95% CI, 89.27% - 97.55%)		

		PCR		
		Positive	Negative	Total
STANDARD F COVID-19 IgM/IgG Combo FIA	Positive	0	15	15
	Negative	0	145	145
	Total	0	160	160
Specificity		90.62% (145/160, 95% CI, 85.01% - 94.66%)		

Interpretation of Test Results

Result	COI (Cutoff index) value	SARS-COV-2 Ag
Positive	COI ≥ 1.0	Positive result for Anti-SARS-CoV-2 IgM and/or IgG
Negative	COI < 1.0	Negative result for Anti-SARS-CoV-2 IgM and/or IgG
Invalid	COI value is not displayed	Retest should be performed

Ordering Information

Cat. No.	Product	Storage temperature	Tests/kit	Kit/carton	Carton size (W/D/H)
10COV30D	STANDARD F COVID-19 Ag FIA	2-30°C/36-86°F	25	30	560 x 520 x 390 mm
10COV50G	STANDARD F COVID-19 IgM/IgG Combo FIA	2-30°C/36-86°F	40	40	585 x 515 x 390 mm
10COVC10	STANDARD COVID-19 Ag Control	2-30°C/36-86°F	40	40	585 x 515 x 390 mm
10COVC20	STANDARD COVID-19 IgM/IgG Control	2-30°C/36-86°F	40	40	585 x 515 x 390 mm

STANDARD Q
COVID-19 Ag Test

CE

Background

STANDARD Q COVID-19 Ag Test is test device that can quickly and easily diagnose SARS-CoV-2 structural antigen at the point-of-care.

Specimen type

- Nasopharyngeal swab

Advantage of Antibody Test

- **Efficient :** It requires minimal training and no need any equipment for the testing.
- **Dependable :** It can provide clear result within 30 minutes, with built-in procedural controls.
- **Point-of-care :** It can provide rapid results for use at the COVID-19 screening center.

Performance Characteristics

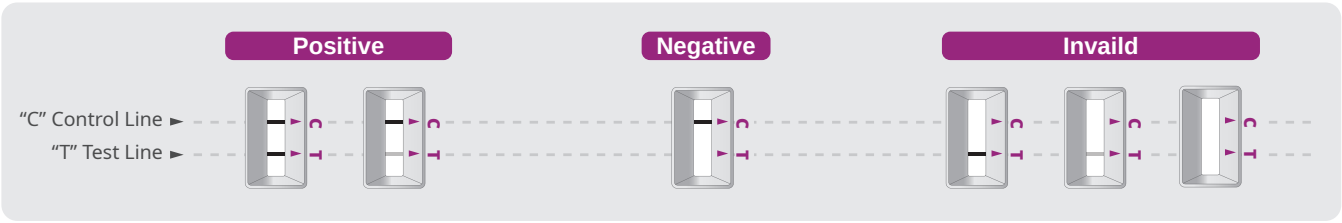
Clinical Evaluation

- Sensitivity - 84.38% , Specificity - 100%

		PCR		
		Positive	Negative	Total
STANDARD Q COVID-19 Ag Test	Positive	27	0	27
	Negative	5	0	5
	Total	32	0	32
Sensitivity		84.38% (27/32, 95% CI, 67.21% - 94.72%)		

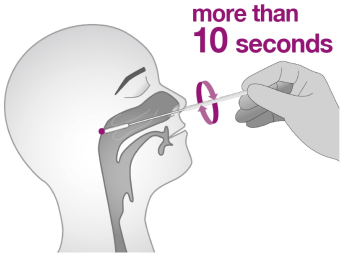
		PCR		
		Positive	Negative	Total
STANDARD Q COVID-19 Ag Test	Positive	0	0	0
	Negative	0	170	170
	Total	0	170	170
Specificity		100.00% (170/170, 95% CI, 97.85% - 100%)		

Interpretation of Test Results

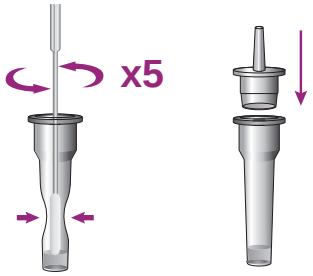


Procedure

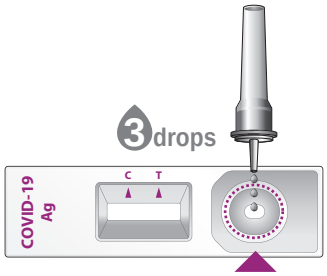
1 **Collecting of specimen**
from the patient's nasopharynx



2 **Mix the specimen**
with extraction buffer



3 **Apply the specimen**
Get result within 30 minutes



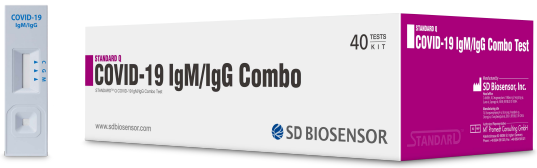
STANDARD Q

COVID-19 IgM/IgG Combo Test

CE

Background

STANDARD Q COVID-19 IgM/IgG Combo Test is intended to diagnose the SARS-CoV-2 specific IgM and IgG antibody at simultaneously. STANDARD Q COVID-19 antibody test can be used as a complementary test for SARS-CoV-2 diagnose. The PCR plus antibody test or antigen test plus antibody test can be increased positive rate than the sole PCR or antigen test only.



Specimen type

- Whole blood(Capillary, Venous), Plasma, Serum

Advantage of Antibody Test

- **Efficient :** It requires minimal training and no need any equipment for the testing.
- **Dependable :** It can provide clear result within 15 minutes, with built-in procedural controls.
- **Point-of-care :** It can provide rapid results for use at the COVID-19 screening center.

Performance Characteristics

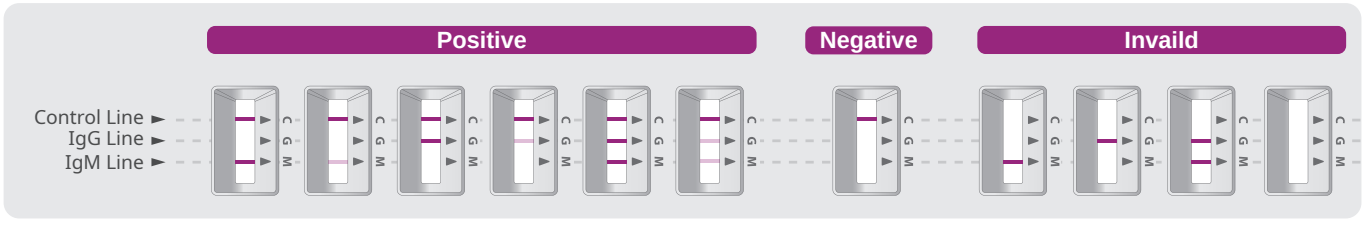
Clinical Evaluation

- Sensitivity - 93.90%, Specificity - 95.74%

≥ 7 days after symptom onset		PCR		
		Positive	Negative	Total
STANDARD Q COVID-19 IgM/IgG Combo Test	Positive	154	0	154
	Negative	10	0	10
	Total	164	0	164
Sensitivity		93.90% (154/164, 95% CI, 89.07% - 97.04%)		

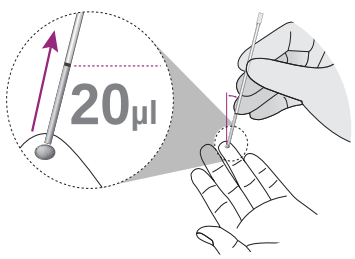
		PCR		
		Positive	Negative	Total
STANDARD Q COVID-19 IgM/IgG Combo Test	Positive	0	10	10
	Negative	0	225	225
	Total	0	235	235
Specificity		95.74% (225/235, 95% CI, 92.31% - 97.94%)		

Interpretation of Test Results

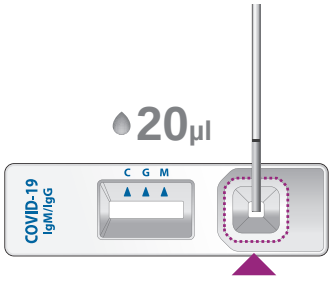


Procedure

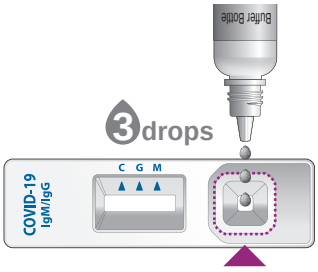
1 **Collecting of specimen**
using a capillary tube



2 **Apply the specimen**



3 **Apply the buffer**
Get result within 15 minutes



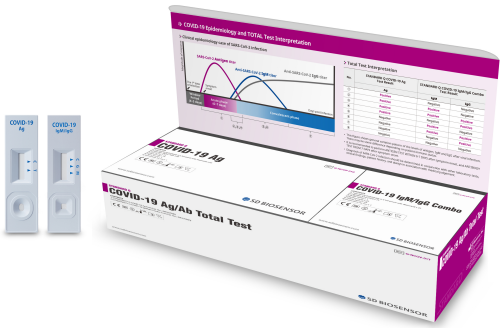
STANDARD Q

COVID-19 Ag/Ab Total Test

CE

Background

STANDARD Q COVID-19 Ag/Ab Total Test is intended to SARS-CoV-2 antigen and antibody test at simultaneously. Performing antigen and antibody tests at the same time, you can diagnosis SARS-CoV-2 infection extensively from acute to convalescent phase.

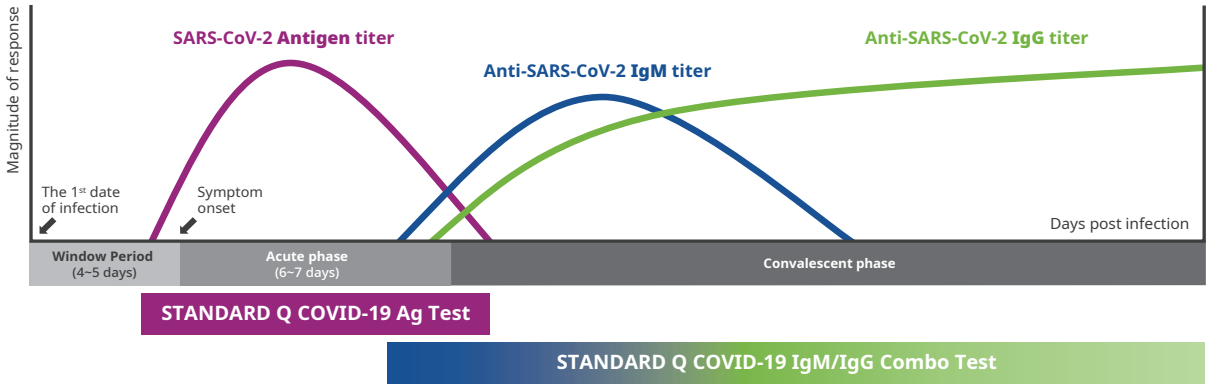


Specimen type

- STANDARD Q COVID-19 Ag Test : Nasopharyngeal swab
- STANDARD Q COVID-19 IgM/IgG Combo Test : Whole blood (Venous, Capillary), Serum, Plasma

Cover acute to convalescent phase of SARS-CoV-2 infection with COVID-19 Ag/Ab Total Test

The STANDARD Q COVID-19 Ag Test helps to identify COVID-19 within less than 6 days after symptom onset.
The STANDARD Q COVID-19 IgM/IgG Test helps to identify COVID-19 infection from 7 days after symptom onset.



This figure shows general variation pattern of the levels of antigen, IgM and IgG after viral infection. There may be some difference depending on patient immune status.

Performance Characteristics

STANDARD Q COVID-19 Ag Test

		PCR		
		Positive	Negative	Total
STANDARD Q COVID-19 Ag Test	Positive	27	0	27
	Negative	5	0	5
	Total	32	0	32
Sensitivity		84.38% (27/32, 95% CI, 67.21% - 94.72%)		

		PCR		
		Positive	Negative	Total
STANDARD Q COVID-19 Ag Test	Positive	0	0	0
	Negative	0	170	170
	Total	0	170	170
Specificity		100.00% (170/170, 95% CI, 97.85% - 100%)		

STANDARD Q COVID-19 IgM/IgG Combo Test

≥ 7 days after symptom onset		PCR		
		Positive	Negative	Total
STANDARD Q COVID-19 IgM/IgG Combo Test	Positive	154	0	154
	Negative	10	0	10
	Total	164	0	164
Sensitivity		93.90% (154/164, 95% CI, 89.07% - 97.04%)		

		PCR		
		Positive	Negative	Total
STANDARD Q COVID-19 IgM/IgG Combo Test	Positive	0	10	10
	Negative	0	225	225
	Total	0	235	235
Specificity		95.74% (225/235, 95% CI, 92.31% - 97.94%)		

Ordering Information

Cat. No.	Product	Storage temperature	Tests/kit	Kit/carton	Carton size (W/D/H)
09COV60D	STANDARD Q COVID-19 Ag/Ab Total Test	2-30°C/36-86°F	25	20	630 x 430 x 400 mm
09COV30D	STANDARD Q COVID-19 Ag Test	2-30°C/36-86°F	25	30	550 x 460 x 390 mm
09COV50G	STANDARD Q COVID-19 IgM/IgG Combo Test	2-30°C/36-86°F	40	40	515 x 515 x 370 mm
10COVC10	STANDARD COVID-19 Ag Control	2-30°C/36-86°F	10	20	155 x 390 x 110 mm
10COVC20	STANDARD COVID-19 IgM/IgG Control	2-30°C/36-86°F	10	20	215 x 390 x 110 mm

STANDARD E
COVID-19 Total Ab ELISA

CE

Background

STANDARD E COVID-19 Total Ab ELISA is an enzyme linked immunosorbent assay for the detection of IgM/IgA/IgG antibodies to SARS-CoV-2 in human serum. This test is intended for professional use as an aid to diagnosis of SARS-CoV-2 virus infection. Diagnosis of SARS-CoV-2 infection needs a comprehensive judgment in conjunction with clinical presentation and testing with other diagnostic methods such as RT-PCR, CT-Scan, and antibody test. This test kit is for *in vitro* use only.

Specimen type

- Serum

Compatible Instruments

- Manual operation
- Commercially available automation ELISA units

Advantage of Antibody Test

- Total Antibody test (IgM, IgA, and IgG)
- Superior sensitivity & specificity
- Suitable method for population antibody screening

Interpretation of Test Results

1. Calculate the mean absorbance of the triplicates of the negative control and add 0.25. This is the Cut-off value.
   * Cut-off value = Mean absorbance of Negative control + 0.25
2. Interpretation of Results

O.D value of sample	Result
O.D value of sample < Cut-off value	Negative
O.D value of sample ≥ Cut-off value	Positive

Performance Characteristics

Clinical Evaluation

Tests were performed according to instruction for use of 'STANDARD E COVID-19 Total Ab ELISA' with serum specimens from 48 positive patients confirmed by real-time PCR method and 50 negative patients confirmed by real-time PCR method.

Sensitivity & Specificity

Sensitivity (8 days after symptom onset)	Specificity
100% (29/29)	98% (49/50)

Sensitivity

Day between onset of symptoms and sample collection	N	STANDARD E COVID-19 Total Ab ELISA	Sensitivity
		Positive	
0 - 3 days	4	(0/4)	0%
4 - 7 days	15	(8/15)	53%
8 - 12 days	13	(13/13)	100%
13- 20 days	7	(7/7)	100%
21- 40 days	9	(9/9)	100%
Sensitivity (Total)	**48**	**(37/48)**	**77%**

Specificity

PCR Negative samples	N	STANDARD E COVID-19 Total Ab ELISA	Specificity
		Negative	
PCR Negative	50	(49/50)	98%

Ordering Information

Cat. No.	Product	Storage temperature	Wells/kit	Kit/carton	Carton size (W/D/H)
07COV10	STANDARD E COVID-19 Total Ab ELISA	2-8°C/36-46°F	96	-	-

SD BIOSENSOR

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SD BIOSENSOR

STANDARD™

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