CE
IVD

COVID-19

S1 Covid-19 Rapid Antigen Test Kit
Saliva/Sputum/Stool/NP swab/OP swab

Instructions For Use (IFU)

Model No: ERCSSO5320 | 1 test/box | 25 tests/box
Version: 1.56

Specimens: Saliva/Sputum/Stool/NP swab/OP swab
Effective Date: 2020-12

For prescription use only. For in vitro diagnostic use only.

INTENDED USE

This product is suitable for the qualitative detection of novel coronavirus in Saliva/Sputum/Stool/NP Swab/OP Swab samples. It provides an aid in the diagnosis of infection with novel coronavirus.

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

The S1 Covid-19 Rapid Antigen Test Kit by Sensing Self is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2 in nasopharyngeal swab (NP swab)/ oropharyngeal swab (OP swab)/Saliva/Stool/Sputum sample. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2.

The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen presents in the sample, a complex formed between the anti-SARS-2 conjugate and the virus will be captured by the specific anti-SARS-2 monoclonal antibodies coated on the test line region (T). Absence of the T line suggests a negative result. To serve as a procedural control a red line will always appear in the control line region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

STORAGE AND STABILITY

1. Store as packaged in the hermetic bag at the temperature (2-30℃ or 38-86℉) and avoid direct sunshine. The kit is stable within the expiration date printed on the labelling.

2. Once open the hermetic bag, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.

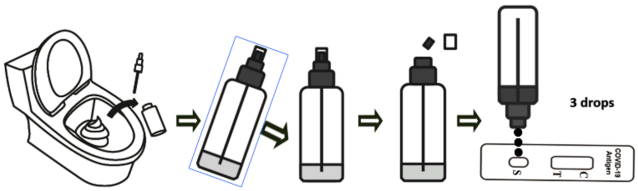
3. The lot number and the expiration date are printed on the labels.

COMPOSITION

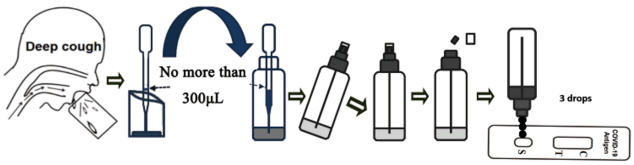
1. Disposable test card
2. Disposable sample extraction tube
3. Pipette
4. Disposable paper cup

TEST PROCEDURE

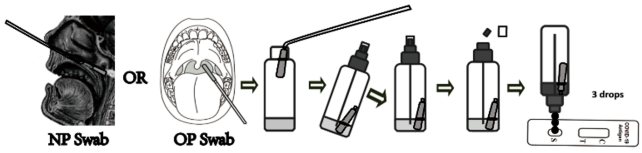
Stool Sample:



Saliva/Sputum Sample:



NP/OP Swab Sample:



1. **Stool Sample:** Unscrew the sampling bottle, Use the sampling rod to pick up about 30mg fresh stool samples at 6 different points or locations (equivalent to the size of a match head). Put them into the tube, tighten the sample extraction tube, shake and mix completely for at least 15 seconds.

2. **Saliva/Sputum Sample:** It is best to use the first mouthful of saliva/sputum after wake up (after waking up, the first thing is to open your eyes and the second thing is to take a good sample). Cough deeply, make the noise of “Kruuua" from the throat to clear sputum/oropharyngeal saliva from deep throat into a paper bag repeat 3~4 times to collect enough sample. Unscrew the sampling bottle, use a pipette to suck up to 300μL (1/4~1/3 pipette) of fresh saliva/sputum sample from the paper bag into the test tube, shake and mix well for at least 15 seconds.

3. **NP/OP Swab Sample:** It is best to collect sample after waking up. open the cap of disposable sample extraction tube, use pipette to absorb half of the liquid in Extraction and discard. Use the NP/OP swab provided in the kit to wipe the back wall of the nasopharyngeal cavity deep in the nasal cavity (NP swab), or swab over the lateral and posterior walls of pharynx, as well as the intratonsillar cleft (OP swab). Cut off the tip of the cotton swab which inserted in the tube and close the extraction tube, shake and mix well for at least 15 seconds.

4. Take the test card from the packaging bag, place it on a table, cut off the protrusion of the collection tube, and add 3 drops of the sample into the sample hole vertically.

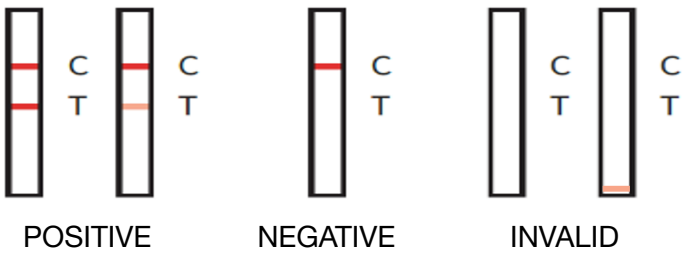
5. Wait for the appearance of the red stripe on T line, read the result in 15 minutes, and judge it invalid after 20 minutes.

RESULTS OF INTERPRETATION

Positive(+): Both of T and C lines are appeared in 3-15minutes.

Negative(-): C line is appeared while no T line appeared in 15 minutes after the sample added.

Invalid: If the C line does not appear, it indicates that the test result is **invalid**, and should retest using another test card.
Incorrect sample addition: Will cause premature precipitation, making the line appear at the very bottom of the reading window.



NOTES

1. The S1 Covid-19 Rapid Antigen Test Kit is applicable to specimens like NP swab/OP swab/Saliva/Sputum/Stool sample. Blood, serum, plasma, urine and other samples may cause abnormal results.
2. It is best to use the first mouthful of saliva/sputum after waking up.
3. Cough deeply to cough up saliva. Please cough deeply at least three times to expel the mucus-like saliva deep in your throat.
4. Please make sure that a **proper amount of sample is collected** for testing. Too much or too little sample may cause deviations in results. **No more than 300 µL (1/3 pipette) Saliva/Sputum should be transferred to the Extraction tube.**
5. For positive judgement, it can be confirmed as soon as both T and C line appeared. That may be in 3-15 minutes after the sample added. For negative judgement, please wait for 15 minutes after the sample added, C line is appeared while no T line appeared. The result is invalid after 30 minutes after sample added.
6. The test card is a disposable product. Please dispose properly after use.
7. This test device is disposable, please use within the validity period. After use, the test reagent, sample and other waste should be treated in accordance with the relevant national regulations.
8. If part of the test paper in the strip is out of the test window, do not use. The test result is invalid and should replace with another new kit.
9. Incorrect sample addition will cause premature precipitation of the antibody-antigen complex, making the line appear at the bottom of the reading window and the C line will be sharply weakened. At this time, the Detection Kit should be replaced, and the samples should be added correctly again.

INDEX OF SYMBOLS

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by	2	Do not reuse
30°C 2°C	Store between 2-30°C	LOT	Lot Number	REF	Catalogue number

Sensing Self Pte. Ltd.
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ask@sensingself.me

EC REP

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kamil.Krajnak@venari.sk

ISO 13485:2016

CE IVD

Performance Characteristics:

1. Clinical Performance:

Compared with the novel coronavirus (SARS-COV-2) real-time multiplex RT-PCR kit, the positive coincidence rate (Sensitivity), negative coincidence rate (Specificity), total coincidence/agreement rate of the S1 Covid-19 Rapid Antigen Test Kit are presented in table below.

S1 Covid-19 Rapid Antigen Test Kit				
Saliva Sample		Gold Standard Reagent		Total Results
Test reagent	Results	Positive	Negative	
	Positive	81	0	81
	Negative	8	65	73
Total Results		89	65	154

Saliva samples: The S1 Covid-19 Rapid Antigen Test Kit showed 91.0% sensitivity and 100% specificity in saliva samples.

Clinical sensitivity (%) = [81 / (81 + 8)] ×100% = 91.0%

Clinical specificity (%) = [65/ (0+ 65)] ×100% = 100%

Total agreement rate (%) = [(81 +65) / (81 + 8+ 0+ 65)] ×100% = 94.8%

S1 Covid-19 Rapid Antigen Test Kit				
Sputum Sample		Gold Standard Reagent		Total Results
Test reagent	Results	Positive	Negative	
	Positive	63	0	63
	Negative	4	65	69
Total Results		67	65	132

Sputum samples: The S1 Covid-19 Rapid Antigen Test Kit showed 94.0% sensitivity and 100% specificity in sputum samples.

Clinical sensitivity (%) = [63/ (63+ 4)] ×100% =94.0

Clinical specificity (%) = [65/ (0+ 65)] ×100% = 100%

Total agreement rate (%) = [(63 +65) / (63+ 4+ 0+ 65)] ×100% = 96.9%

S1 Covid-19 Rapid Antigen Test Kit				
Stool Sample		Gold Standard Reagent		Total Results
Test reagent	Results	Positive	Negative	
	Positive	80	0	80
	Negative	3	65	68
Total Results		83	65	148

Stool samples: The S1 Covid-19 Rapid Antigen Test Kit showed 96.3% sensitivity and 100% specificity in stool samples.

Clinical sensitivity (%) = [80/ (80+ 3)] ×100% = 96.3%

Clinical specificity (%) = [65/ (0+ 65)] ×100% = 100%

Total agreement rate (%) = [(80 +65) / (80 +3+ 0+ 65)] ×100% = 98.0%

S1 Covid-19 Rapid Antigen Test Kit				
NP Swab		Gold Standard Reagent		Total Results
Test reagent	Results	Positive	Negative	
	Positive	67	0	67
	Negative	7	65	72
Total Results		74	65	139

NP Swab samples: The S1 Covid-19 Rapid Antigen Test Kit showed 90.5% sensitivity and 100% specificity in NP Swab samples.

Clinical sensitivity (%) = [67/ (67+ 7)] ×100% = 90.5%

Clinical specificity (%) = [65/ (0+ 65)] ×100% = 100%

Total agreement rate (%) = [(67+65) / (67 +7+ 0+ 65)] ×100% = 95.0%

S1 Covid-19 Rapid Antigen Test Kit				
OP Swab		Gold Standard Reagent		Total Results
Test reagent	Results	Positive	Negative	
	Positive	64	0	64
	Negative	6	65	71
Total Results		70	65	135

OP Swab samples: The S1 Covid-19 Rapid Antigen Test Kit showed 91.4% sensitivity and 100% specificity in OP Swab samples.

Clinical sensitivity (%) = [64/ (64+ 6)] ×100% = 91.4%

Clinical specificity (%) = [65/ (0+ 65)] ×100% = 100%

Total agreement rate (%) = [(64+65) / (64 +6+ 0+ 65)] ×100% = 95.5%

2. Cross-reactivity:

Cross-reactivity of S1 Covid-19 Rapid Antigen Test Kit was evaluated with Positive saliva/sputum/stool/NP Swab/OP Swab specimens of different respiratory diseases.

No false positivity or false negativity was found with the following:

Sample ID	Concentration ($TCID_{50}$/mL)	Saliva Sample			Sputum Sample			Stool Sample		
		201001	201002	201003	201001	201002	201003	201001	201002	201003
HKU1	5×10^5	-	-	-	-	-	-	-	-	-
OC43	5×10^5	-	-	-	-	-	-	-	-	-
NL63	4.5×10^5	-	-	-	-	-	-	-	-	-
229E	5×10^5	-	-	-	-	-	-	-	-	-
Influenza A H1N1	3×10^5	-	-	-	-	-	-	-	-	-
Seasonal Influenza H1N1	2×10^5	-	-	-	-	-	-	-	-	-

Influenza A H3N2	3×10^5	-	-	-	-	-	-	-	-	-
Influenza A H5N1	3×10^5	-	-	-	-	-	-	-	-	-
Influenza A H7N9	3×10^5	-	-	-	-	-	-	-	-	-
Influenza B	5×10^5	-	-	-	-	-	-	-	-	-
Syncytial virus	4×10^5	-	-	-	-	-	-	-	-	-
Rhinovirus A	2.5×10^5	-	-	-	-	-	-	-	-	-
Rhinovirus B	2.5×10^5	-	-	-	-	-	-	-	-	-
Rhinovirus C	2.5×10^5	-	-	-	-	-	-	-	-	-
Adenovirus type 1	5×10^5	-	-	-	-	-	-	-	-	-
Adenovirus type 2	5×10^5	-	-	-	-	-	-	-	-	-
Adenovirus type 3	5×10^5	-	-	-	-	-	-	-	-	-
Adenovirus type 4	3.5×10^5	-	-	-	-	-	-	-	-	-
Adenovirus 5	5×10^5	-	-	-	-	-	-	-	-	-
Adenovirus type 7	3.5×10^5	-	-	-	-	-	-	-	-	-
Adenovirus 55	4×10^5	-	-	-	-	-	-	-	-	-
Enterovirus A	4×10^5	-	-	-	-	-	-	-	-	-
Enterovirus B	4×10^5	-	-	-	-	-	-	-	-	-
Enterovirus C	4×10^5	-	-	-	-	-	-	-	-	-
Enterovirus D	4×10^5	-	-	-	-	-	-	-	-	-
Epstein-Barr virus	2.5×10^5	-	-	-	-	-	-	-	-	-
Measles virus	3×10^5	-	-	-	-	-	-	-	-	-
Human cytomegalovirus	3×10^5	-	-	-	-	-	-	-	-	-
Rotavirus	5×10^5	-	-	-	-	-	-	-	-	-
Norovirus	5×10^5	-	-	-	-	-	-	-	-	-
Mumps virus	5×10^5	-	-	-	-	-	-	-	-	-
Varicella-zoster virus	5×10^5	-	-	-	-	-	-	-	-	-
Mycoplasma pneumoniae	6×104 cells/ mL	-	-	-	-	-	-	-	-	-

S1 Covid-19 Rapid Test Kit shows good reliability in the cross-reactive study.

3. Potentially Interfering Substances (Endogenous/exogenous material):

No false negative or false positive results were observed with these potential interference substances.

Sample	Concentration	Saliva Sample			Sputum Sample			Stool Sample		
		201001	201002	201003	201001	201002	201003	201001	201002	201003
Purified Mucin	100μg/mL	-	-	-	-	-	-	-	-	-
Bilirubin	200μM	-	-	-	-	-	-	-	-	-

Blood lipids	10%(v/v)	-	-	-	-	-	-	-	-	-
Hemoglobin	10mg/mL	-	-	-	-	-	-	-	-	-
Rheumatoid factor	10mg/mL	-	-	-	-	-	-	-	-	-
Antinuclear antibody	10mg/mL	-	-	-	-	-	-	-	-	-
Antimitochondrial antibody	20mg/mL	-	-	-	-	-	-	-	-	-
HAMA	10mg/mL	-	-	-	-	-	-	-	-	-
Total IgG	20mg/mL	-	-	-	-	-	-	-	-	-
Total IgM	20mg/mL	-	-	-	-	-	-	-	-	-
Hematocrit	20mg/mL	-	-	-	-	-	-	-	-	-
alpha-interferon	10mg/mL	-	-	-	-	-	-	-	-	-
Zanamivir	1mg/mL	-	-	-	-	-	-	-	-	-
Ribavirin	1mg/mL	-	-	-	-	-	-	-	-	-
Oseltamivir	1mg/mL	-	-	-	-	-	-	-	-	-
Paramivir	1mg/mL	-	-	-	-	-	-	-	-	-
Lopinavir	100μg/mL	-	-	-	-	-	-	-	-	-
Ritonavir	20mg/mL	-	-	-	-	-	-	-	-	-
Abidol	25mg/mL	-	-	-	-	-	-	-	-	-
Levofloxacin	1mg/mL	-	-	-	-	-	-	-	-	-
Azithromycin	5mM	-	-	-	-	-	-	-	-	-
Ceftriaxone	20mg/mL	-	-	-	-	-	-	-	-	-
Meropenem	20mg/mL	-	-	-	-	-	-	-	-	-
Tobramycin	1.51mM	-	-	-	-	-	-	-	-	-
Histamine hydrochloride	5mg/mL	-	-	-	-	-	-	-	-	-
Benfurin	5mM	-	-	-	-	-	-	-	-	-
Oxymetazoline	500μg/mL	-	-	-	-	-	-	-	-	-
Sodium chloride	20mg/mL	-	-	-	-	-	-	-	-	-
Beclomethasone	35mM	-	-	-	-	-	-	-	-	-
Dexamethasone	11mg/mL	-	-	-	-	-	-	-	-	-
Flunisolone	20mg/mL	-	-	-	-	-	-	-	-	-
Triamcinolone	2.54mM	-	-	-	-	-	-	-	-	-
Budesonide	20mg/mL	-	-	-	-	-	-	-	-	-
Momisson	20mg/mL	-	-	-	-	-	-	-	-	-
Fluticasone	5mg/mL	-	-	-	-	-	-	-	-	-

S1 Covid-19 Rapid Test Kit shows good reliability in the interference study.