SsmarTest COVID-19 Ag Detection kit

IDENTIFICATION OF THE IVD REAGENT

Proprietary Name: SsmarTest COVID-19 Ag Detection Kit

Catalogue number: SLS-005

Panel: Immunology

INTENDED USE

The SsmarTest COVID-19 Ag Detection Kit is an in vitro diagnostic medical device that measures the presence of SARS-CoV-2 nucleocapsid protein(N protein) in specimen from human respiratory tract with immunochromatography and thus assists in diagnosing COVID-19. The test results are used in conjunction with other laboratory tests.

PRINCIPLES OF THE EXAMINATION METHOD

The SsmarTest COVID-19 Ag Detection Kit is a lateral flow immunochromatographic assay for the detection of extracted N protein specific to SARS-CoV-2 in nasopharyngeal swab specimens and oropharyngeal specimen (sputum) either directly collected or collected in universal transport media(UTM media) from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of symptom onset.

Both specimens require a sample preparation step in which the sample is eluted into the extraction buffer solution. Extracted sample is added to the sample well of the test device to initiate the test. When the sample migrates in the test strip, SARS-CoV-2 viral antigens(N protein) bind to anti-SARS-CoV-2 N-protein conjugated to indicator and capture molecules(anti-SARS-CoV-2 Nprotein) in the test strip forming an immune complex. The immune complex is then captured by the test line on the nitrocellulose membrane as it migrates through the strip.

Test results are interpreted at 20 minutes. The presence of colored lines in the control line region "C" and test line region "T" indicates COVID-19 positive. The presence of one colored lines in the control line region "C" indicates COVID-19 negative. No appearance of a colored line in the control region "C" indicates an invalid test.

INGRIDENTS

1) Test device: There is a circular sample spot on the outside of the plastic device and the internal examination strips are colorless with sample pads, purple conjugated pads, white nitrocellulose membranes, and absorbent pads overlaid in turn

2) Extraction solution: colorless or aesthetic liquid

3) Nozzle cap: colorless polystyrene nozzle containing filter

4) Swab: white polystyrene swab

COMPONENTS

Components	Amount / kit	Storage
Devices coated with anti-SARS-CoV-2 N protein and anti-mouse IgG	20 devices	1-30°C
Extraction buffer solution, key components: triton X-100	0.35 ㎖ x 20 vial	
Swab	20 ea	
Nozzle cap	20 ea	

Material required but not provided

1. Pair of gloves
2. Timer
3. Container for specimen collection
4. Micropipette

REAGENT PREPARATION

Refrigerated or frozen samples and reagents should be taken to room temperature for 20 to 30 minutes before the test.

STORAGE AND SHELF LIFE AFTER FIRST OPENING

Components	Release Status	Storage method	Expiring date
Test Device Extraction solution	Before release	1 ~ 30°C	2 years from date of manufacture

WARNINGS AND PRECAUTIONS

1. Intended use
   1) Only use for in vitro diagnostic purposes.
   2) This test has been approved only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
   3) The use of disassembly, use, etc. may result in serious accidents and shall not be used for any other purpose.
   4) Disposable products are prohibited for reuse.
2. Test Device and Reagent Usage
   1) This intended for use (IFU) must be read completely before performing the test because of the follow to IFU may yield accurate test results.
   2) Immediately use after opening the test device in the pouch because this product is very sensitive to moisture, so be
   especially careful about performance degradation caused by moisture. In addition, all inspection procedures of this product shall be carried out at room temperature and moisturized kits are not used for examinations.

3) If the product is kept refrigerated, experimentation at room temperature may cause moisture in the device due to dew formation. Do not refrigerate or refrigerate as this moisture may degrade performance.

4) If any of the reagents contained in this product are on the skin or eyes, wash them with running water and consult a doctor if there is anything wrong with them.

5) Do not eat, drink, or smoke in the areas where handled to specimens or kit reagents.

6) Do not perform the test in the areas with strong air flow.

3. Specimens

1) When preparing samples, do not reuse the swab to prevent infection caused by reusing the swabs.

2) Multiple freezing and thawing samples may result in false negative or false positives.

3) The samples cannot exclude unknown pathogenic viruses or bacterial infections, so be careful with handling.

4) Use lab coat and disposable rubber gloves when handling infectious substances and wash your hands clean after handling them.

5) Samples mixed with multiple samples shall not be used as test results and shall not be inspected.

6) Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false-positive result. Avoid touching any bleeding areas of the nasopharynx when collecting specimens.

4. Results

1) This medical device is intended to be an SARS-CoV-2 screening test, so even if the presence of SARS-CoV-2 Nprotein, the clinical condition of the patient and the results of the examination should be summed.

2) The determination of a drug or other drug-addicted specimen may cause false positives.

3) Care should be taken to determine the results of false positives in special cases under the basic principles of this reagent.

5. Others

1) Comply with general laboratory precautions.

2) Do not interpret the test result before 20 minutes and after 30 minutes starting the test.

3) Inadequate or inappropriate sample collection, storage, and transport can result in incorrect results. If specimen storage is necessary, swabs can be placed into extraction buffer for up to four hours. Specimens should not be stored dry.

4) Do not use if the test device package is damaged.

5) Do not use the kit contents beyond the expiration date.

6) Do not interchange kit contents from different lots.

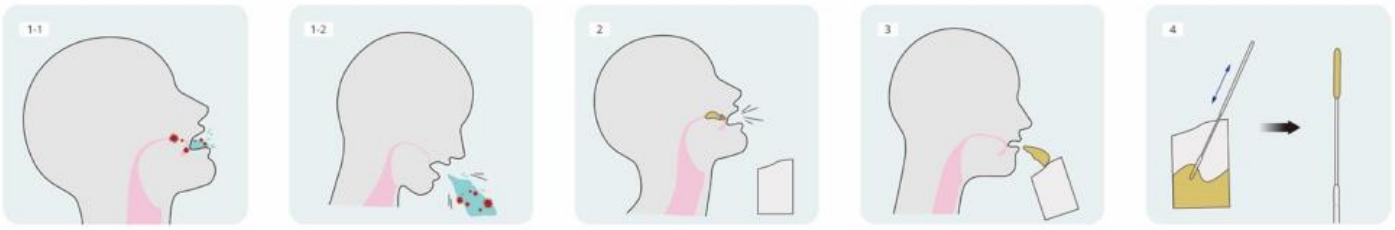
7) Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.

8) Nitrile or latex gloves should be worn when performing this test.

9) Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.

SAMPLE COLLECTION, HANDLING AND STORAGE

1. Sputum Specimen Collection Procedure



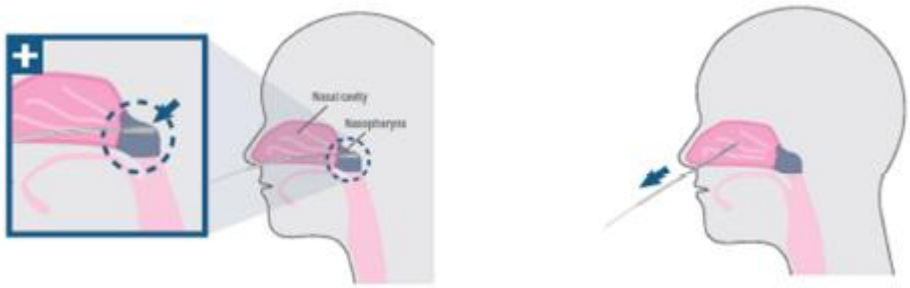
1) Rinse your mouth with water and spit out fluids. This is important to prevent the contamination by bacteria in mouth.

2) Take a deep cough and take out the sputum from your neck.

3) Prepare a container with a lid and spit out the sputum in the container.

4) Insert the swab into the container containing the specimen and plunge the swab up and down in the specimen until the swab head is saturated.

2. Nasopharyngeal Swab Sample Collection Procedure



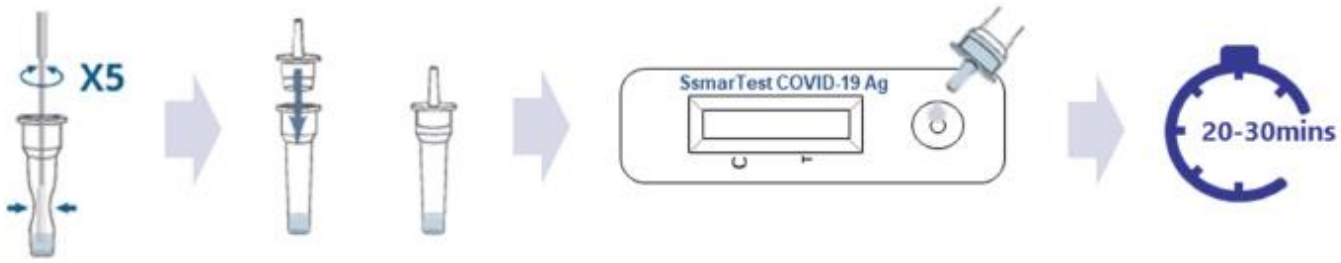
2) Place the swab into one of the patient's nostrils until it reaches the posterior nasopharynx; keep insert until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient.

3) Slowly rotate 3-5 times the swab over the surface of the posterior nasopharynx.

4) Slowly remove the swab from the nostril while rotating it.

Inadequate specimen collection, improper specimen handling and/or transport may yield false results; therefore, specimen collection requires specific training and guidance due to the importance of specimen quality to obtain accurate test results.

EXAMINATION PROCEDURE



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Direct Swab(Sputum, Nasopharyngeal swab) Test Procedure

1) Write the personal identification number of the sample on the device.
2) Peel off aluminum foil seal from the top of the extraction vial containing the extraction buffer.
3) Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.
4) Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Properly discard the swab.
5) Close the vial with the provided cap and push firmly onto the vial.
6) Mix thoroughly by flicking the bottom of the tube.
7) Invert the extraction vial and hold the sample vertically above the sample well. Squeeze the vial gently. Allow three (3) drops of sample to fall into the sample well. 2 drops of the sample are required minimum volume to initiate the test run and invalid results will be obtained if 1 drop of sample is added to the cassette
8) Read and interpret the test result at 20 minutes. The test result should not be read and interpreted after 30 minutes.

Swab in Viral Transport Media (VTM) Test Procedure

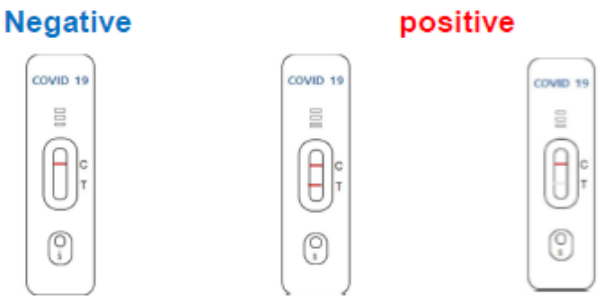
1) Mix the specimen stored in VTM by vortexing.
2) Collect 350 µl of swab specimen with a calibrated micropipette from the VTM tube.
3) Add all 350 µl of collected swab specimen from the micropipette into the extraction vial after peel off the aluminum foil seal
4) Follow Steps 5-8 of the Direct Nasopharyngeal Swab Test Procedure above.

INTERPRETATION OF RESULTS

The test results should be read and interpreted at 20 minutes after the sample application and the reading and interpretation of the results should not exceed 30 minutes. A clear red line must appear on the control line (C) in all tests. If there is no red line, re-inspection shall be performed.

1. Valid Result

1) When the C line and T line appear, it indicates SARS-CoV-2 positive. The color intensity in the test region will vary depending on the amount of SARS-CoV-2 nucleocapsid protein present in the sample. Any faint colored line(s) in the test region(s) should be considered as positive.
2) When the C line only appear, it indicates SARS-CoV-2 negative.



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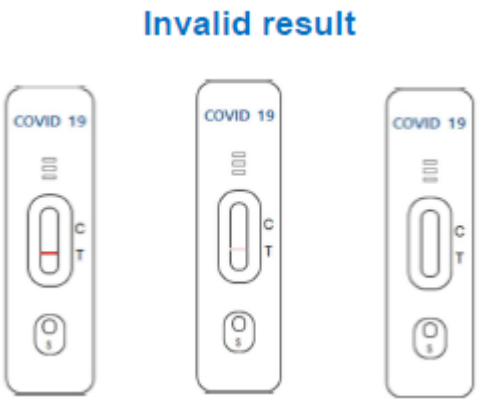
2. Invalid Result (Re-inspection)

1) Without any lines in tested samples: control line and test lines do not appear.

2) Without control line in tested samples: Only test lines (T) appear.



DISPOSAL METHOD

Sterilize and discard solid wastes used for inspection at 121°C for at least an hour. Dispose of liquid wastes used in testing in 1%

sodium hypochlorite solution for at least 1 hour.

SPECIFIC PEFORMANCE CHARACTERISTICS

1. Clinical Performance

For clinical performance analysis (correlation test) of "SsmarTest COVID-19 Ag Detection Kit", the study was conducted with the CE certified product Standard M-CoV Real-Time Detection kit (SD Bio sensor) and Standard Q COVID-10 Ag at Korea University GURO Hospital (KUMC). Total seventy-nine of human oropharyngeal (sputum) and nasopharyngeal swab samples shall be evaluated. Human oropharyngeal (sputum) and nasopharyngeal swab samples collected from DKU(Dankook University Hospital). All samples were tested using Standard M-CoV Real-Time Detection kit. Thirty-nine samples are COVID-19 positive and the rest of forty samples are COVID-19 negative. In the test of clinical evaluation, SsmarTest COVID-19 Ag Detection Kit compare to reference devices, Standard M-CoV Real-Time Detection kit and Standard Q COVID-10 Ag.

Correlation with Standard M-CoV Real-Time Detection kit

		Reference device (Standard M-CoV Real-Time Detection kit)		Total
		Positive	Negative	
SsmarTest COVID-19 Ag Detection Kit	Positive	34	0	34
	Negative	5	40	45
Total		39	40	79

Correlation with Standard Q COVID-10 Ag

		Reference device (Standard Q COVID-10 Ag)		Total
		Positive	Negative	
SsmarTest COVID-19 Ag Detection Kit	Positive	31	2	33
	Negative	3	43	46
Total		34	45	79

Clinical evaluation of COVID-19 in SsmarTest COVID-19 Ag Detections Kit was tested human oropharyngeal (sputum) and nasopharyngeal swab specimens. The accuracy was 93.67% (74/79) in the comparative test with the Ssmar test COVID-19 antigen detection kit and the standard Q-COVID19 Ag. The detailed positive percent agreement is 91.18% (31/34) and the negative percentage agreement is 93.33 % (42/45). In conclusion, the SsmarTest COVID-19 Antigen Detection Kit proved effective diagnosis for SARS-CoV-2 infection.

2. Analytical Sensitivity (Detection limit)

For the detection limit test of "SsmarTest COVID-19 Ag Detection Kit", heat-inactivated SARS-CoV-2 isolate USAWA1/2020 was spiked into negative nasal swab extract. The estimated detection limit found from the initial two-fold serial dilution test was confirmed by testing 2 lot, each 5 replicates. The confirmed detection limit was 143.75 TCID50/ml.

3. Cross reactivity

The 'Smart Test COVID 19 Ag Detection Kit' was evaluated using various viruses (14 species) and microorganisms (2 species) that potentially may have cross-reactivity. As a result of testing with specimens containing pathogens, no false negative or false positive results were found.

Virus Name					
Adenovirus	Human coronavirus OC43	Human parainfluenza virus 1	Influenza A	Human metapneumovirus (hMPV)	*Mycoplasma pneumoniae*
Rhinovirus	Human coronavirus 229E	Human parainfluenza virus 2	Influenza B	Respiratory Syncytial Virus B	*Legionella pnuemophila*
Enterovirus	Human coronavirus NL63	Human parainfluenza virus 3	Respiratory Syncytial Virus A		

4. Interference

For testing the interfering substances in the SsmarTest COVID-19 Ag Detection Kit, total eleven (11) types of potential interfering substances were prepared with a stock solution, and then diluted with the test concentration of each negative and positive sample. There was no interference such as non-specific reactions to negative specimens and there was no reduction of sensitivity by interfering substances in positive specimens

Potential Interfering Substances	Concentration	Potential Interfering Substances	Concentration
Acetaminophen	1 mg/l	Budesonide	2 mg/ml
Destromethorphan HBr	2 mg/l	Halls	5 mg/ml
Chlorpheniramine maleate	5 mg/ml	Histmamine dihydrochloride	10 mg/ml
Acetyl salicylic acid	15 mg/mll	musin	0.5 %
Phenalephrine HCL	5 mg/ml	ricola	5 mg/ml
Fluticasone	1 mg/ml		

TECHNICAL SUPPORT

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LITERATURE REFERENCES

1. https://www.who.int/emergencies/diseases/novel-coronavirus-2019
2. Coronaviridae study group of the international committee on taxonomy of viruses, The species Severe acute respiratory syndrome-related coronavirus; classifying 2019-nCoV and naming it SARS-CoV-2, Nature Microbiology, Mar 2, 2020
3. https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance

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