SCREEN

SCREEN IFA TEST COVID-19 AG
(Nasopharyngeal Swab)
Package Insert

REF: SC-1293	English

Covid-19 Antigen Test Cassette is a fluorescence immunoassay for the qualitative detection of SARS-CoV-2 antigens present in human nasopharynx with the use of SCREEN® fluorescence Immunoassay Analyzer.
For professional in vitro diagnostic use only.

INTENDED USE

The COVID-19 Antigen Test Cassette (Nasopharyngeal Swab) is based on fluorescence immunoassay for the qualitative detection of SARS-CoV-2 antigens in nasopharyngeal swab specimens from individuals with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests.
Results are for the detection of SARS-CoV-2 Antigens. An antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.
Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary for patient management.
The COVID-19 Antigen Test Cassette is intended for use by trained clinical laboratory personnel.

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 COVID-19 Antigen Test Cassette (Nasopharyngeal Swab) is a qualitative membrane-based Fluorescence immunoassay for the detection of SARS-CoV-2 Antigen in human nasopharyngeal swab specimen. SARS-CoV-2 antibody is coated in test line region. During testing, SARS-CoV-2 antigen in the specimen reacts with SARS-CoV-2 antibody-coated by fluorescent microspheres in the test, the mixture then migrates upward on the membrane by capillary action and reacts with the SARS-CoV-2 antibody in test line region. The fluorescence immunoassay analyzer detects the fluorescence signal value of a specific area and calculates the result of the SARS-CoV-2 Antigen in the sample according to the algorithm on the ID card.

REAGENTS

The test contains anti-SARS-CoV-2 antibody as the capture reagent, anti-SARS-CoV-2 antibody as the detection reagent.

PRECAUTIONS

1. This package insert must be read completely before performing the test. Failure to follow directions in package insert may yield inaccurate test results.
2. For professional in vitro diagnostic use only.
3. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse
4. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained for each specimen obtained.
5. To obtain accurate results, do not use visually bloody or overly viscous samples.
6. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Viral Transport Media (VTM) may affect the test result; extracted specimens for PCR tests cannot be used for the test. Do not interchange or mix reagents from different lots.
8. Humidity and temperature can adversely affect results.
9. Used testing materials should be discarded in accordance with local regulations.
10. Read the entire procedure carefully prior to any testing.
11. The COVID-19 Antigen Test Cassette should only be used with the SCREEN® Analyzer by approved medical professionals

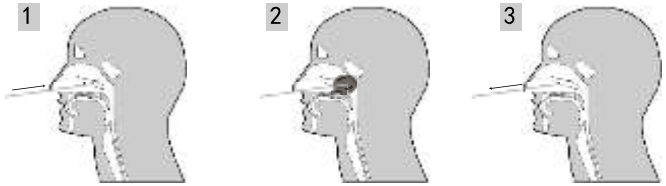
STORAGE AND STABILITY

1. The kit should be stored at 4-30 °C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. **Do not freeze.**

Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION, TRANSPORT AND STORAGE

Specimen Collection
1. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.
2. Swab over the surface of the posterior nasopharynx.
3. Withdraw the sterile swab from the nasal cavity.



Specimen transport and storage
Specimens should be tested as soon as possible after collection.
If swabs are not been processed immediately, it is highly recommended the swab sample is placed into a dry, sterile, and tightly sealed plastic tube for storage. The swab specimen in dry and sterile condition is stable for 1 hour at room temperature and 24 hours at 2-8°C.

MATERIALS

Materials Provided
- Test cassettes
- Extraction tubes and tips(Optional)
- Sterile Swabs
- Package insert
- Workstation
- Procedure Card
- Extraction Buffer
- ID Card

Materials Required But Not Provided
• Timer • Centrifuge • SCREEN® Fluorescence Immunoassay Analyzer

SPECIMEN PREPARATION

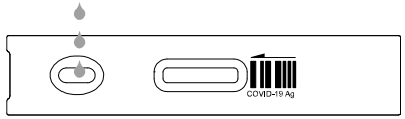
Only the extraction buffer and tubes provided in the kit is to be used for swab specimen preparation.
Please refer to the Procedure card for detailed information of Specimen Extraction.
1. Place the swab specimen in the Extraction tube with Extraction Buffer (Approx. 350µl). Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.
2. Remove the swab while squeezing the swab head against the inside of the Extraction tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.

***NOTE:** The storage of the specimen after extraction is stable for 2 hours at room temperature or 24 hours at 2-8°C.

DIRECTION FOR USE

Refer to SCREEN® Fluorescence Immunoassay Analyzer Operation Manual for the complete instructions on use of the Test. The test should be conducted in room temperature.
Allow the test, extracted specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
1. Turn on the Analyzer power. Then according to the need, select "Standard Test" or "Quick Test" mode.
2. Take out the ID card and insert it into the Analyzer ID Card Slot.
3. Remove the test cassette from the sealed foil pouch and use it within one hour. Best result will be obtained if the test is performed immediately after opening the foil pouch.
4. Invert the specimen collection tube and add 3 drops of the extracted specimen (approx.100µl) to the specimen well(S) and then start the timer.
5. There are two test modes for SCREEN® Fluorescence Immunoassay Analyzer, Standard Test mode and Quick Test mode. Please refer to the user manual of SCREEN® Fluorescence Immunoassay Analyzer for details.

"Quick Test" mode: After **10 minutes** of adding sample, Insert the test cassette into the Analyzer, click "**QUICK TEST**", fill the test information and click "**NEW TEST**" immediately. The Analyzer will automatically give the test result after a few seconds.
"**Standard Test**" mode: Insert the test cassette into the Analyzer immediately after adding specimen, click "**STANDARD TEST**", fill the test information and click "**NEW TEST**" at the same time, The Analyzer will automatically countdown **10 minutes**. After the countdown, the Analyzer will give the result at once.



INTERPRETATION OF RESULTS

Results read by SCREEN® Fluorescence Immunoassay Analyzer.
The result of tests for SARS-CoV-2 Antigens is calculated by SCREEN® Fluorescence Immunoassay Analyzer and display the result on the screen. For additional information, please refer to the user manual of SCREEN® Fluorescence Immunoassay Analyze.
NOTE: The test result of each specimen is given as Pos (+) or Neg (-) with a Value. This value is calculated by dividing the signal obtained with sample by cut-off value (S/C Ratio).
- Test results of Value ≥ 1.00 are considered positive for SARS-CoV-2 Antigen.
- Test results of Value < 1.00 are considered negative for SARS-CoV-2 Antigen.

QUALITY CONTROL

Internal Quality Control
Each COVID-19 Antigen Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test cassette was inserted and read properly by SCREEN® Fluorescence Immunoassay Analyzer. An invalid result from the internal control causes an error message on SCREEN® Fluorescence Immunoassay Analyzer indicating that the test should be repeated. An invalid result from the internal control causes an "N/A" message on SCREEN® Fluorescence Immunoassay Analyzer. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.
External Quality Control
Positive/Negative Controls are not included in this kit. However, in compliance with Good Laboratory Practice (GLP) positive/negative controls are recommended.[1]

LIMITATIONS

1. To obtain the best sensitive result, directly test patient specimens without viral transport media is required for the testing. Proper specimen collection, storage and transport are critical to the performance of this test.
2. The test Procedure and the Interpretation of test Result must be followed closely when testing for the presence of SARS-CoV-2 antigens in the human nasopharyngeal specimens from suspected individuals. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results. Viral Transport Media (VTM) may affect the test result; extracted specimens for PCR tests cannot be used for the test.
3. The performance of the COVID-19 Antigen Test (Nasopharyngeal swab) was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
4. The COVID-19 Antigen Test Cassette (Nasopharyngeal swab) is for in vitro diagnostic use only. This test should be used for detection of SARS-CoV-2 Antigens in human nasopharyngeal specimens as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests. Neither the quantitative value nor the rate of increase in the concentration of SARS-CoV-2 antigens can be determined by this qualitative test.
5. The COVID-19 Antigen Test Cassette (Nasopharyngeal Swab) will only indicate the presence of SARS-CoV-2 Antigens in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infections.
6. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
7. If the test result is negative or non-reactive and clinical symptoms persist. It is recommended to re-sample the patient a few days later and test again or test with a molecular diagnostic device to rule out infection in these individuals.
8. The test will show negative results under the following conditions: The concentration of the novel coronavirus antigens in the sample is lower than the minimum detection limit of the test. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus or with symptom onset .Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
9. Excess blood or mucin on the swab specimen may interfere with test performance and may yield a false positive result.
10. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
11. Positive results of COVID-19 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.
12. The formulation of extraction buffer in the kit may inactivate cells and virus. So the specimen in the extraction buffer is not suitable for culture.

PERFORMANCE CHARACTERISTICS

1. Precision

Within-run and Between-run precision has been determined by using three specimens of COVID-19 standard control. Three different lots of COVID-19 Antigen Test (Nasopharyngeal Swab) have been tested using negative, SARS-CoV-2 Antigen weak Positive and SARS-CoV-2 Antigen Strong Positive. Ten replicates of each level were tested each day for 3 consecutive days. The specimens were correctly identified>99% of the time.

2. Clinical Performance

The COVID-19 Antigen Test Cassette (Nasopharyngeal Swab) has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the COVID-19 Antigen Test Cassette (Nasopharyngeal Swab). Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result.

Nasopharyngeal Swab Specimen

COVID-19 Antigen Test Cassette		**RT-PCR**		Total
		Positive	Negative	
COVID-19 Antigen	Positive	43	1	44
	Negative	2	60	62
Total		45	61	106
Relative Sensitivity		95.6%(95%CI*: 84.9%~99.5%)		
Relative Specificity		98.4%(95%CI*: 91.2%~>99.9%)		
Accuracy		97.2%(95%CI*: 92.0%~99.4%)		

*Confidence Intervals

3. Cross Reactivity (Analytical Specificity)

No cross-reactivity or interference was observed with the following microorganisms when tested at these concentrations presented in the table below.

Description	**Test Level**
Adenovirus type 3	3.16 x 10^4 TCID50/ml
Adenovirus type 7	1.58 x 10^5 TCID50/ml
Human coronavirus OC43	2.45 x 10^6 LD50/ml
Influenza A H1N1	3.16 x 10^5 TCID50/ml
Influenza A H3N2	1 x 10^5 TCID50/ml
Influenza B	3.16 x 10^6 TCID50/ml
Human Rhinovirus 2	2.81 x 10^4 TCID50/ml
Human Rhinovirus 14	1.58 x 10^6 TCID50/ml
Human Rhinovirus 16	8.89 x 10^6 TCID50/ml
Measles	1.58 x 10^4 TCID50/ml
Mumps	1.58 x 10^4 TCID50/ml
Parainfluenza virus 2	1.58 x 10^7 TCID50/ml
Parainfluenza virus 3	1.58 x 10^8 TCID50/ml
Respiratory syncytial virus	8.89 x 10^4 TCID50/ml
Arcanobacterium	1.0x10^8 org/ml
Candida albicans	1.0x10^8 org/ml
Corynebacterium	1.0x10^8 org/ml
Escherichia coli	1.0x10^8 org/ml
Moraxella catarrhalis	1.0x10^8 org/ml
Neisseria lactamica	1.0x10^8 org/ml
Nesseria subllava	1.0x10^8 org/ml
Pseudomonas aeruginosa	1.0x10^8 org/ml
Staphylococcus aureus subspaureus	1.0x10^8 org/ml
Staphylococcus epidermidis	1.0x10^8 org/ml
Streptococcus pneumoniae	1.0x10^8 org/ml
Streptococcus pygenes	1.0x10^8 org/ml
Streptococcus salivarius	1.0x10^8 org/ml
Streptococcus sp group F	1.0x10^8 org/ml

TCID50 = Tissue Culture Infectious Dose is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated.

4. Endogenous Interfering Substances

Active Ingredient	**Concentration**
Mucin	2% w/v
Whole Blood	1% v/v
Sodium Chloride	5% w/v
Oxymetazoline	15%v/v
Zincum gluconium	5% w/v
peppermint	0.5% w/v
Fluconazole	5% w/v

BIBLIOGRAPHY

1. Westgard JO, Barry PL,Hunt MR, Groth T. A multi-rule Shewhart for quality control in clinical chemistry, Clinical Chemistry 1981;27:493-501.

INDEX OF SYMBOLS

	Consult Instructions for Use		Tests per kit		Authorized Representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 4-30°C		Lot Number		Catalog #
	Do not use if package is damaged		Manufacturer		

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Effective Date: 17-12-2020

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EC REP
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Kochstr.1, 47877, Willich,
Germany

Or:

Copan Italia S.p.A.
Via F. Perotti, 10
25125 Brescia -Italy
www.copangroup.com

CE 0123

Or:

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CE 0123

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