SCREEN®

SCREEN TEST COVID-19 SALIVA
COVID-19 Antigen Rapid Test
(Oral Fluid)
Package Insert

REF: SC-1286-20	English

COVID-19 Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens present in human Oral Fluid.
For professional in vitro diagnostic use only.

INTENDED USE

The COVID-19 Antigen Rapid Test (Oral Fluid) is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens in oral fluid 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 nucleocapsid protein 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 preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary for patient management. 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.

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 Rapid Test (Oral Fluid) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein antigens in human Oral Fluid specimen. SARS-CoV-2 nucleocapsid protein antibody is coated in the test line region. During testing, the specimen reacts with SARS-CoV-2 nucleocapsid protein antibody-coated particles in the test. The mixture then migrates upward on the membrane by capillary action and reacts with the SARS-CoV-2 nucleocapsid protein antibody in test line region. If the specimen contains SARS-CoV-2 Antigens, a colored line will appear in test line region as a result of this. If the specimen does not contain antigens to SARS-CoV-2, no colored line will appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains anti-SARS-CoV-2 nucleocapsid protein antibody as the capture reagent and anti-SARS-CoV-2 nucleocapsid protein 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. Do not use after expiration date.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Do not use test if pouch is damaged.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout in the collection, handling, storage, and disposal of patient samples and used kit contents.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Wash hands thoroughly after handling.
8. Please ensure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.
9. Extracted specimens for PCR tests or Viral Transport Media (VTM) specimen cannot be used for the test.
10. The used test should be discarded according to local regulations.
11. Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

The oral fluid specimen should be collected using the collection device provided with the kit. Follow the detailed Directions for Use below. No other collection devices should be used with this assay. Oral fluid collected at any time of the day may be used.
Specimens should be tested as soon as possible after collection. If Oral Fluid is not to be processed immediately, it is stable for up to 8 hours at room temperature and 24 hours at 2-8 °C.

MATERIALS

Material Provided

- Test Devices
- Collection Devices
- Buffer
- Package Insert
- Procedure card
- Biosafety bags

Materials required but not provided

- Timer
- Specimen container

DIRECTION OF USE

Allow the test device, collection device, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

Specimen Collection

Important: Before collecting oral fluid, instruct the patients not to place anything in the mouth including food, drink, gum or tobacco products for at least 10 minutes prior to collection.

Instruct the patients to deeply cough 3-5 times.

It is recommended to collect the first oral fluid after deep coughing in the morning.

① Remove the collection device and collect **oral fluid** specimen.

If there's not enough oral fluid collected, repeat the above **specimen collection** steps.

Specimen Extraction

② Mix the buffer with the collected oral fluid.

Gently shake or squeeze the tube with mixture for **10 seconds** to mix well.

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

Test Reaction

Remove the test device from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.

③ Add Extracted specimen to the Test Device, Wait for the colored line(s) to appear. **Read the result at 15 minutes**. Do not interpret the result after 20 minutes.

Refer to the **Procedure Card** for detailed information of the testing procedure.

INTERPRETATION OF RESULTS

POSITIVE:* Two colored lines appear. One colored line should be in the control region (C) and another colored line should be in the Test region (T). Positive result in the Test region indicates detection of SARS-CoV-2 antigens in the sample.

***NOTE**: The intensity of the color in the test line region (T) will vary based on the amount of SARS-CoV-2 antigen present in the sample. So any shade of color in the test region (T) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test line region (T) indicates a Negative COVID-19 Antigen test result.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line 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.

QUALITY CONTROL

Internal Quality Control

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal procedural control.

External Quality Control

Positive/negative controls are not included in this kit. However, in compliance with Good Laboratory Practice (GLP), these controls are recommended.[1]

LIMITATIONS

1. The test Procedure and the Interpretation of test Result must be followed closely when testing for the presence of SARS-CoV-2 nucleocapsid protein antigens in the human oral fluid specimens from suspected individuals. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
2. The performance of the COVID-19 Antigen Rapid Test (Oral Fluid) was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test. Extracted specimens for PCR tests or Viral Transport Media (VTM) specimen cannot be used for the test.
3. The COVID-19 Antigen Rapid Test (Oral Fluid) is for *in vitro* diagnostic use only. This test should be used for detection of SARS-CoV-2 nucleocapsid protein Antigens in human oral fluid 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 nucleocapsid protein antigens can be determined by this qualitative test.
4. The COVID-19 Antigen Rapid Test (Oral Fluid) 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.
5. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
6. 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.
7. The test will show negative results under the following conditions: The titer of the novel coronavirus antigens in the sample is lower than the minimum detection limit of the test.
8. 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.
9. Positive results of COVID-19 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.

PERFORMANCE CHARATERISTICS

Sensitivity, Specificity and Accuracy

The COVID-19 Antigen Rapid Test (Oral Fluid) has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the COVID-19 Antigen Rapid Test (Oral Fluid). Specimens were considered positive if the individuals were indicated positive result by RT-PCR. Specimens were considered negative if the individuals were indicated negative result by RT-PCR.

Oral Fluid Specimen

COVID-19 Antigen Rapid Test (Oral Fluid)	RT-PCR		Total
	Positive	Negative	

COVID-19 Antigen	Positive	91	2	93
	Negative	10	303	313
Total		101	305	406
Relative Sensitivity		90.1% (95%CI*:82.5%~95.1%)		
Relative Specificity		99.3% (95%CI*: 97.7%~99.9%)		
Accuracy		97.0% (95%CI*: 94.9%~98.5%)		

*Confidence Intervals

Specificity Testing with Various Viral Strains

The COVID-19 Antigen Rapid Test was tested with the following viral strains. No discernible line at either of the test-line regions was observed at these concentrations:

Description	Test Level
Adenovirus type 3	3.16 x 10^4 $TCID_{50}$/ml
Adenovirus type 7	1.58 x 10^5 $TCID_{50}$/ml
Human coronavirus OC43	1 x 10^6 $TCID_{50}$/ml
Human coronavirus 229E	5 x 10^5 $TCID_{50}$/ml
Human coronavirus NL63	1 x 10^6 $TCID_{50}$/ml
Human coronavirus HKU1	1 x 10^6 $TCID_{50}$/ml
MERS coronavirus Florida	1.17x10^4 $TCID_{50}$/ml
Influenza A H1N1	3.16 x 10^5 $TCID_{50}$/ml
Influenza A H3N2	1 x 10^5 $TCID_{50}$/ml
Influenza B	3.16 x 10^6 $TCID_{50}$/ml
Measles	1.58 x 10^4 $TCID_{50}$/ml
Mumps	1.58 x 10^4 $TCID_{50}$/ml
Parainfluenza virus 2	1.58 x 10^7 $TCID_{50}$/ml
Parainfluenza virus 3	1.58 x 10^8 $TCID_{50}$/ml
Respiratory syncytial virus	8.89 x 10^4 $TCID_{50}$/ml

$TCID_{50}$ = 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.

Precision

Intra-Assay&Inter-Assay

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 Rapid Test (Oral Fluid) have been tested using negative SARS-CoV-2 Antigen weak and SARS-CoV-2 Antigen Strong. Ten replicates of each level were tested each day for 3 consecutive days. The specimens were correctly identified>99% of the time.

Cross-reactivity

The following organisms were tested and all found to be negative when tested with the COVID-19 Antigen Rapid Test (Oral Fluid):

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
Neisseria subflava	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

Interfering Substances

The following substances were tested with COVID-19 Antigen Rapid Test (Oral Fluid) and no interference was observed:

Dexamethasone	0.8mg/ml
Mucin	50μg/ml
Flunisolide	6.8ng/ml
Mupirocin	12mg/ml
Oxymetazoline	0.6mg/ml
Phenylephrine	12mg/ml
Rebetol	4.5μg/ml
Relenza	282ng/ml
Tamiflu	1.1μg/ml
Tobryamycin	2.43mg/ml
Tea	33.3mg/ml
Milk	11.2%
Orange juice	100%
Mouthwash	2%
Caffeine	1mg/ml
Coca Cola	/
Toothpaste	/

BIBLIOGRAFY

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	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		

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