One Step SARS-CoV-2(COVID-19) Antigen Rapid Test
(Oral Fluid)
Package Insert

REF ICOV-803
English

One Step SARS-CoV-2(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 One Step SARS-COV-2 (COVID-19) Antigen 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 One Step SARS-COV-2 (COVID-19) Antigen Test (Oral Fluid) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein antigens in human Oral Fluid specimen. 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. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. Wash hands thoroughly after handling.
7. The used test should be discarded according to local regulations.
8. 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 STORAGE

The oral fluid specimen is collected by the absorbent wick of the device. Follow the detailed Directions for Use below.

MATERIALS

Material Provided

- Test Devices
- Package Insert
- Biosafety Bags (optional)
- Specimen containers (optional)

Materials required but not provided

- Timer

DIRECTIONS FOR USE

Allow the test device to reach room temperature (15-30°C) prior to testing.

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.

Method 1:

①Remove 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. Take off the device cap.

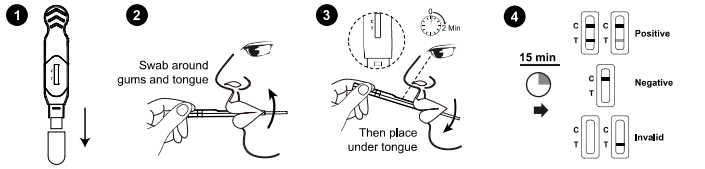
② Place the tongue against the upper and lower jaws and roots to enrich the oral fluid. Insert the absorbent wick end into the mouth, actively swab around the gums on both sides of the mouth (10-15 times) to assist saturation.

③Then put the absorbent wick under the tongue to collect oral fluid until the flow appear in the test windows (approximately 2 minutes) and then take out the device and close the device cap.

Place the test device on a flat and level surface. Then start a timer.

***NOTE**: During sample collection, the hand-held part cannot be lower than the absorbent wick. Do not move the test device during testing.

④**Read the result at 15 minutes.** Do not interpret the result after 20 minutes.



Method 2：

①Collect enough fresh oral fluid specimen (at least 0.5ml) in a single use disposable cup.

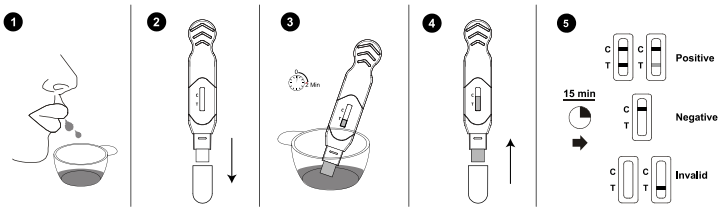
②Remove the test device from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch. Take off the device cap.

③Place the absorbent wick into the oral fluid specimens. Keep the device up right until the flow appear in the test window (approximately 2 minutes).

④Take out the device and close the device cap. Place the test device on a flat and level surface. Then start a timer.

*NOTE: Do not move the test device during testing

⑤**Read the result at 15 minutes.** Do not interpret the result after 20 minutes.



***NOTE**: After test is completed, place the used kit into the bag and dispose all the used kit according to local regulation. Do not reuse any used components of the kit. Wash hands thoroughly after test disposal.

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 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.

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 One Step SARS-COV-2 (COVID-19) Antigen 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 One Step SARS-COV-2 (COVID-19) Antigen 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 One Step SARS-COV-2 (COVID-19) Antigen 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 CHARACTERISTICS

Sensitivity, Specificity and Accuracy

The One Step SARS-CoV-2(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 One Step SARS-COV-2 (COVID-19) Antigen 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

One Step SARS-CoV-2(COVID-19) Antigen Rapid Test(Oral Fluid)		RT-PCR		Total
		Positive	Negative	
One Step SARS-CoV-2(COVID-19) Antigen Rapid Test	Positive	99	4	103
	Negative	1	1196	1197
Total		100	1200	1300
Relative Sensitivity		99.0%(95%CI*:94.55%~99.97%)		
Relative Specificity		99.7%(95%CI*:98.15%~99.91%)		
Accuracy		99.6%(95%CI*: 99.10%~99.88%)		

*Confidence Intervals

Specificity Testing with Various Viral Strains

The One Step SARS-CoV-2(COVID-19) Antigen Rapid Test (Oral Fluid) 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	1.17 x 10^4 $TCID_{50}$/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 One Step SARS-CoV-2(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 five 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 One Step SARS-COV-2 (COVID-19) Antigen 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 pyogenes	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 One Step SARS-COV-2 (COVID-19) Antigen 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	/

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

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

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