SARS-CoV-2 Antigen Test (Swab) For professional use

IVD REF COV-N002

For in vitro diagnostic use only.
For professional use only.

INTENDED USE

The SARS-CoV-2 Antigen Test is a lateral flow immunoassay that allows for the rapid, qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human swab specimens.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal (nares) swabs 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 should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. 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.

Individuals who test negative and continue to experience COVID-like symptoms should seek follow up care from their healthcare provider.

SUMMARY

COVID-19 (Corona Virus Disease) is the infectious disease caused by coronavirus SARS-CoV-2. The most common symptoms of COVID-19 are fever, dry cough, fatigue, sputum production, shortness of breath, sore throat, headache, and so on.

COVID-19 is transmitted via respiratory droplets that are exhaled by infected people via coughing, sneezing or talking. These droplets can be inhaled or ingested directly by other people or can contaminate surfaces, which can then be infectious for several days. Most estimates of the incubation period for COVID-19 range from 1 to 14 days, during which people might already be infectious without showing disease symptoms.

PRINCIPLES

The SARS-CoV-2 Antigen Test is an immunochromatographic membrane assay that uses highly sensitive antibodies to detect SARS-CoV-2 nucleocapsid protein from nasal, nasopharyngeal and oropharyngeal swab specimens. The test strip is composed by sample pad, label pad, nitrocellulose membrane and filer paper. It has anti-SARS-CoV-2 antibody as the capture reagent and anti-SARS-CoV-2 antibody as the detection reagent.

Nasal, nasopharyngeal and oropharyngeal swabs require a sample preparation step in which the sample is eluted into the extraction buffer solution. Extracted swab sample is added to the sample well of the test device to initiate the test. When the sample migrates in the test, if SARS-CoV-2 antigens exist in the sample, SARS-CoV-2 antigens bind to antibodies conjugated to detector particles in the test strip. The antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line (T) of antibodies bound on the membrane; a colored line will appear in test line region as a result of positive. If SARS-CoV-2 antigens do not exist in the sample, absence of the T line suggests a negative result.

As a procedural control, a colored line (C) will always appear in the control line region, suggests that the proper volume of specimen has been added.

MATERIALS

Materials Provided

- Test cassettes
- Sterile swabs
- Package insert
- Extraction Buffer
- Workstation

Materials Require But Not Provided

- Timer
- Gloves
- Biohazard or sharps container

WARNINGS AND PRECAUTIONS

1. Read the package insert carefully before testing.
2. For professional *in vitro* diagnostic use only.
3. Swabs, tubes and test devices are for single use.
4. Do not use beyond expiration date.
5. Do not use test kit components if the primary packaging is damaged.
6. Do not use if sterile swab packaging is damaged.
7. Do not mix components from different test kits.
8. Proper specimen collection, storage and transport are critical to the performance of this test.
9. Do not eat, drink or smoke in the area where specimens and test devices are handled.
10. Specific training or guidance is recommended if operators are not experienced with specimen collection and handling procedures.
11. Wear protective clothing, disposable gloves, and eye protection when specimens are collected.
12. Handle all specimens as if they contain infectious agents. Observe established precautions for microbiological risks throughout all procedures and standard guidelines for the appropriate disposal of specimens.
13. Humidity and temperature can adversely affect results.
14. Further specimen processing and patient management should follow local COVID-19 guidelines and regulations.
15. Used tests should be disposed according to local regulations.

STORAGE AND STABILITY

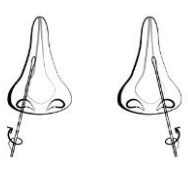
1. Kits can be stored at room temperature or refrigerated (2-30°C). **DO NOT FREEZE**.
2. Extraction Buffer and devices must be at room temperature (15-30°C) when used for testing.
3. The test device must remain in the sealed pouch until use.

SPECIMEN COLLECTION AND PREPARATION

Nasal Swab Specimen collection:

Use the nasal swab supplied in the kit.

1. Insert a sterilized swab less than one inch (about 2 cm) into a nostril, until resistance is met at the turbinates.
2. Rotate the swab 5-10 times against the nasal wall. Using the same swab repeat. The collection procedure with the second nostril.

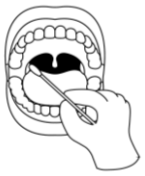


3. Withdraw the swab; avoid excess volume and high-viscous nasal discharge.

Nasopharyngeal Swab 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 5-10 times.
3. Withdraw the sterile swab from the nasal cavity and avoid excess volume and highly-viscous nasopharyngeal discharge.

Oropharyngeal Swab Specimen collection:



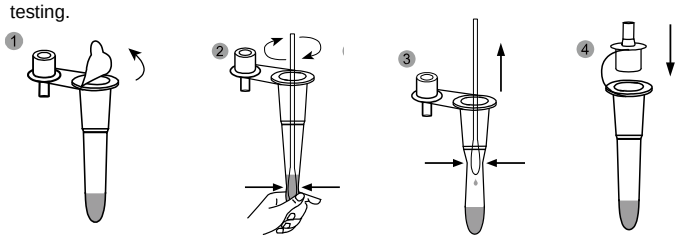
1. Remove the sterile swab from the pouch.
2. Insert the swab into the mouth and collect the specimen from the bilateral posterior pharynx, both tonsils and the uvula.
3. Withdraw the swab carefully.

Caution: If the swab stick breaks during specimen collection, repeat specimen collection with a new swab.

Specimen preparation:

Only the extraction buffer provided in the kit is to be used for swab specimen preparation.

1. Place the test extraction tube into the workstation provided. Remove the cover of the tube with extraction buffer.
2. Insert the swab specimen into the extraction tube which contains the extraction buffer. Rotate the swab for approximately **10 seconds** while pressing the head against the inside of the tube to release the antigen in the swab.
3. 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.
4. Fit the tube tip onto the extraction tube. The extracted solution will be used for testing.



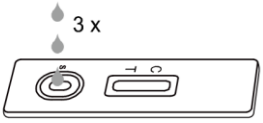
***NOTE:** The specimen after extraction should be tested as soon as possible. The storage of the specimen after extraction is stable for 24 hours at 2-8 °C.

TEST PROCEDURE

Place tests, extracted specimens to room temperature (15-30 °C) prior to testing.

Remove test device from the sealed pouch just prior to the testing and lay flat on work bench.

Invert the specimen extraction tube and add **3 drops of extracted specimen** (about 100µl) to the specimen well(S) and then start the timer.



Wait for the colored line(s) to appear. **Read the result at 15 minutes.** Do not interpret the result after 20 minutes.

RESULTS INTERPRETATION

 Positive	**POSITIVE**: **Two colored lines as control line (C) and test line (T) appear in the result area.**
 Negative	**NEGATIVE**: **One colored line as control line (C) appears in the result area**. No colored line appears in the test line region (T).
 Invalid	**INVALID: Control line fails to appear.** Results from any test which control line doesn't appear at the specified reading time must be invalid. Please review the test procedure and repeat the test with a new device. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

***NOTE**: The intensity of the color in the test line region (T) will vary based on the amount of SARS-CoV-2 antigen exist in the sample. So any shade of color in the test region (T) should be considered positive. Note that this is a qualitative test only and it cannot determine the analyte concentration in the specimen.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result. Positive/negative controls are not included in this kit. However, in compliance with

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CE IVD REF COV-N002

Good Laboratory Practice (GLP), these controls are recommended.[1]

LIMITATIONS

1. The SARS-CoV-2 Antigen Test is for professional *in-vitro* diagnostic use only. It should be used for the qualitative detection of SARS-CoV-2 viral nucleoprotein antigens in human specimens only.
2. The SARS-CoV-2 Antigen Test only detects the presence of SARS-CoV-2 viral nucleoprotein antigens in specimens and should not be used as the sole criterion for a diagnosis of COVID-19.
3. While testing, the sections 'SPECIMEN COLLECTION AND PREPARATION' and 'TEST PROCEDURE' must be followed strictly.
4. Results should be interpreted in conjunction with other clinical information available to the physician.
5. A false-negative test result may occur if the concentration of viral antigen in a sample is below the minimum detection limit of the test or if the sample was collected or transported improperly; therefore, a negative test result does not eliminate the possibility of SARS-CoV-2 infection.
6. If the test result is negative, but clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not rule out the possibility of a SARS-CoV-2 infection at any time and should be confirmed via molecular assay.
7. Positive results of COVID-19 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.
8. Test performance of frozen samples may be different with fresh samples. Specimens should be tested as soon as possible after specimen collection.

PERFORMANCE CHARACTERISTICS

Clinical Performance

RT-PCR is used as the reference method for the SARS-CoV-2 Antigen Test. The SARS-CoV-2 Antigen Test has been evaluated with 1697 nasal swab, 443 nasopharyngeal swab and 447 oropharyngeal swab specimens obtained from patients

Method		RT-PCR		Total Results
SARS-CoV-2 Antigen Test (Nasal Swab)	Results	Positive	Negative	
	Positive	605	1	606
	Negative	15	1076	1091
Total Results		620	1077	1697

Relative Sensitivity: 97.6% (95%CI*: 96.0%~98.6%)
Relative Specificity: 99.9% (95%CI*: 99.5%~100%)
Accuracy: 99.1% (95%CI*: 98.5%~99.5%)

Method		RT-PCR		Total Results
SARS-CoV-2 Antigen Test (Nasopharyngeal Swab)	Results	Positive	Negative	
	Positive	124	1	125
	Negative	3	315	318
Total Results		127	316	443

Relative Sensitivity: 97.6% (95%CI*: 93.3%~99.5%)
Relative Specificity: 99.7% (95%CI*: 98.3%~99.9%)
Accuracy: 99.1% (95%CI*: 97.7%~99.8%)

Method		RT-PCR		Total Results
SARS-CoV-2 Antigen Test (Oropharyngeal Swab)	Results	Positive	Negative	
	Positive	144	0	144
	Negative	3	300	303
Total Results		147	300	447

Relative Sensitivity: 98.0% (95%CI*: 94.2%~99.6%)
Relative Specificity: >99.9% (95%CI*: 98.8%~100.0%)
Accuracy: 99.3% (95%CI*: 98.1%~99.9%)

Analytical Sensitivity: Limit of Detection (LoD)

The SARS-CoV-2 Antigen Test can detect out SARS-CoV-2 as low as 80 $TCID_{50}$/mL.

Interfering Substances

The interfering substances below were spiked with negative, SARS-CoV-2 Antigen weak positive. No substances showed any interference with the SARS-CoV-2 Antigen Test.

Substance	Concentration
Whole Blood	20 µl/mL
Mucin	50 µg/mL
Budesonide Nasal Spray	200 µl/mL
Dexamethasone	0.8 mg/mL
Flunisolide	6.8 ng/mL
Mupirocin	12 mg/mL
Oxymetazoline	0.6 mg/mL
Phenylephrine	12 mg/mL
Rebetol	4.5 µg/mL
Relenza	282 ng/mL
Tamiflu	1.1 µg/mL
Tobryamycin	2.43 mg/mL

Cross-reactivity

The following organisms were tested at $1.0x10^8$ org/mL and all found to be negative when tested with the SARS-CoV-2 Antigen Test:

Arcanobacterium	*Pseudomonas aeruginosa*
Candida albicans	*Staphylococcus aureus subspaureus*
Corynebacterium	*Staphylococcus epidermidis*
Escherichia coli	*Streptococcus pneumoniae*
Moraxella catarrhalis	*Streptococcus pygenes*
Neisseria lactamica	*Streptococcus salivarius*
Neisseria subflava	*Streptococcus sp group F*

The SARS-CoV-2 Antigen 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
Human coronavirus 229E	$5x\ 10^5$ $TCID_{50}$/mL
Human coronavirus NL63	$1x\ 10^6$ $TCID_{50}$/mL
Human coronavirus OC43	$1 x\ 10^6$ $TCID_{50}$/mL
MERS coronavirus Florida	$1.17x10^4$ $TCID_{50}$/mL
Human coronavirus HKU1	$1x\ 10^6$ $TCID_{50}$/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
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
Adenovirus type 3	$3.16 x\ 10^4$ $TCID_{50}$/mL
Adenovirus type 7	$1.58 x\ 10^5$ $TCID_{50}$/mL
Human Rhinovirus 2	$2.81 x\ 10^4$ $TCID_{50}$/mL
Human Rhinovirus 14	$1.58 x\ 10^6$ $TCID_{50}$/mL
Human Rhinovirus 16	$8.89 x\ 10^6$ $TCID_{50}$/mL
Measles	$1.58 x\ 10^4$ $TCID_{50}$/mL
Mumps	$1.58 x\ 10^4$ $TCID_{50}$/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 SARS-CoV-2 Antigen Test 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.

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	Σ	Contains sufficient for <n> tests
IVD	*In vitro* diagnostic medical device		Use-by date
	Temperature limit	LOT	Batch code
	Do not use if package is damaged		Manufacturer
EC REP	Authorized representative in the european community		Do not re-use
REF	Catalogue number		

Hangzhou Tongzhou Biotechnology Co., Ltd.
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