RightSign®

COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) Package Insert

REF INCP-C81	English

A rapid test for the qualitative detection of COVID-19 Antigen in a Nasopharyngeal swab.
For professional in vitro diagnostic use only.

【INTENDED USE】

The COVID-19 Antigen Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of COVID-19 Antigen in Nasopharyngeal swab. The identification is based on monoclonal antibodies specific to the Nucleocapsid（N）protein of SARS-CoV-2. It is intended to aid in the rapid differential diagnosis of COVID-19 infection.

【SUMMARY】

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. Currently, patients infected by the novel coronavirus are the main source of other people getting infected; asymptomatic and symptomatic infected people can both be an infectious source. Based on the current epidemiological investigations, 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 Cassette (Nasopharyngeal Swab) is a qualitative, lateral flow immunoassay for the detection of the N protein of SARS-CoV-2 in Nasopharyngeal swabs. In this test, antibodies specific to the N protein of SARS-CoV-2 are separately coated on the test line regions of the test cassette. During testing, the extracted specimen reacts with the antibodies to N protein of SARS-CoV-2 that are coated onto particles. The mixture migrates up the membrane to react with the antibodies to N protein of SARS-CoV-2 on the membrane and generate one colored line in the test region. The presence of this colored line in the test region indicates a positive result. To serve as a procedural control, a coloured line will always appear in the control region if the test has performed properly.

【REAGENTS】

The test cassette contains anti-SARS-CoV-2 Nucleocapsid protein antibody gold colloid particles conjugate and anti-SARS-CoV-2 Nucleocapsid protein antibody coated onto the membrane.

【PRECAUTIONS】

Please read all the information in this package insert before performing the test.

1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. The test should remain in the sealed pouch until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. Used tests should be discarded according to the local regulations.
5. Avoid using bloody samples.
6. Wear gloves, or sterilize hands with alcohol gel before and after handling the samples, avoid touching the reagent membrane and sample well.

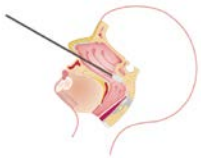
【STORAGE AND STABILITY】

Store as packaged at room temperature, or refrigerated (2-30℃). 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】

Use a nasopharyngeal swab, insert swab through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. The swab should reach depth equal to the distance from the nostrils to the outer opening of the ear. Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions. Slowly remove the swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the swab is saturated with fluid from the first collection. If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

Specimen Collection Instruction



【MATERIALS】

Materials provided

Test cassettes	Exaction Buffer	Extraction Tubes	Dropper tips
Sterile Swabs	Package Insert	Workstation	

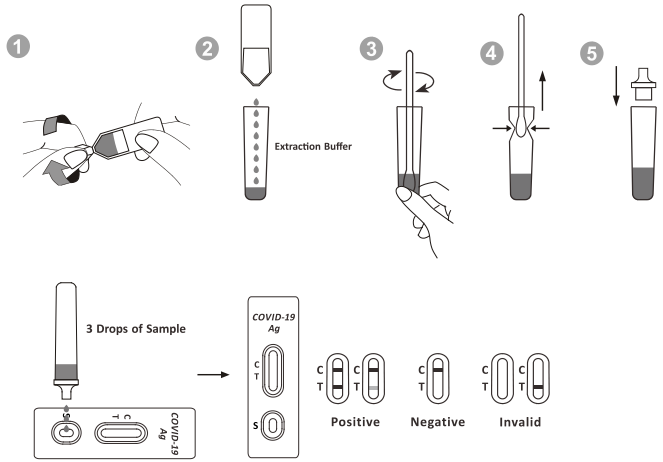
Materials required but not provided

Timer, Sterilization Gloves

【DIRECTIONS FOR USE】

Allow the test, specimen, and extraction buffer to equilibrate to room temperature (15-30℃) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Place the extraction tube in the workstation. Turn the hand over and add **all** extraction buffer (approx. 300µl) to the extraction tube. See illustration 1&2.
3. Place the swab specimen in the extraction tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab. See illustration 3.
4. 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. See illustration 4.
5. Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface. See illustration 5
6. Add 3 drops of the solution (approx.80µL) to the sample well and then start the timer. Read the result at 10 minutes. Do not interpret the result after 20minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T). A positive result indicates that SARS-CoV-2 was detected in the specimen.

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of COVID-19 Antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). A negative result indicates that COVID-19 Antigen is not present in the specimen, or is present below the detectable level of the test.

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】

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms adequate membrane wicking.

Control solutions are not provided in this kit. It is however recommended where possible, for positive and negative controls to be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) is for use only by individuals who have been given appropriate training for in vitro diagnostic use. Neither the quantitative value nor the rate of increase in SARS-CoV-2 virus concentration can be determined by this qualitative test.
2. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
3. The COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) will only indicate the presence of SARS-CoV-2 in the specimen from both viable and non-viable SARS-CoV-2 coronavirus strains.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. A negative result obtained from this kit should be confirmed by PCR. A negative result should be interpreted in line with national/regional guidance. A negative result may be obtained if the concentration of the SARS-CoV-2 virus present in the swab is not adequate or is below the detectable level of the test.
6. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result.
7. A positive result for SARS-CoV-2 does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.
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 may be due to current infection with acute non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43 or 229E.
10. Results from antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
11. The extraction buffer has the ability to kill the virus, but it cannot inactivate 100% of the virus. The method of inactivating the virus should be referred to as recommended by WHO/CDC, or according to local regulations.

【PERFORMANCE CHARACTERISTICS】

Sensitivity, Specificity and Accuracy

The COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) has been evaluated with specimens obtained from different clinical sites where the specimens were collected with Nasal Swabs. The Nasopharyngeal Swabs were randomized and blind tested by operators following the instructions for use. RT-PCR was used as the reference method for the COVID-19 Antigen Rapid Test Cassette. Specimens were considered positive if PCR indicated a positive result.

For Nasopharyngeal Swab:

Method	RT-PCR	Total

COVID-19 Antigen Rapid Test Cassette	Results	Positive	Negative	Results
	Positive	112	3	115
	Negative	5	360	365
Total Results		117	363	480

Relative Sensitivity: 95.7% (95%CI*:90.3%-98.6%)*
Relative Specificity: 99.2% (95%CI*:97.6%-99.8%)*
Relative accuracy: 98.3% (95%CI*:96.7%-99.3%)*
* Confidence Intervals

Detection Limit

The LOD for the COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) was established using limiting dilutions of an inactivated viral sample. The control (ZeptoMetrix, 0810587CFHI) was supplied at a concentration of 1.15 x 10^7TCID$_{50}$/mL. The Estimated LOD is 1000 TCID$_{50}$/mL.

Cross Reactivity

The COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab)has been tested for Influenza A virus, Influenza B virus, Adenovirus, Coxsackie virus, Parainfluenza Virus Type1, Parainfluenza Virus Type2, Parainfluenza Virus Type3, Parainfluenza Virus Type4a, Enterovirus, Mumps virus, Respiratory syncytial virus, Rhinovirus, Bordetella pertussis, Haemophilus parainfluenzae, Staphylococcus aureus, Streptococcus agalactiae, Neisseria meningitides, Streptococcus sp. group A, Streptococcus sp. group B, Streptococcus sp. group C, Candida albicans, Human Metapneumovirus (hMPV), Legionella pneumophila, Mycobacterium tuberculosis, Mycoplasma pneumoniae, Pneumocystis jirovecii(PJP)-S cerevisiae Recombinant, Pseudomonas aeruginosa, Staphylococcus epidermis, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus salivarius, Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, MERS-coronavirus positive specimens. The results showed no cross reactivity.

【BIBLIOGRAPHY】

1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164.
2. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019;17:181-192.
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016;24:490-502.

Index of Symbols

	Consult Instruction for use		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
Hangzhou Biotest Biotech Co., Ltd.
17#, Futai Road, Zhongtai Street,
Yuhang District, Hangzhou, P. R. China

EC REP
Shanghai International
Holding Corp. GmbH (Europe)
Eiffestrasse 80,
20537 Hamburg, Germany

Number:
Effective date: