IVD CE

COVID-19 Ag Rapid Test Device

For professional *in vitro* diagnostic use only.

Intended Use

COVID-19 Ag Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of specific antigens to SARS-CoV-2 present in human naso-pharynx. This test is for professional used only, as an aid to early diagnosis of SARS-CoV-2 infection in patient.

The result of this test should not be the sole basis for the diagnosis; confirmatory testing is required.

Summary

Coronavirus is a single-stranded positive-sense RNA virus with an envelope of about 80 to 120 nm in diameter. Its genetic material is the largest of all RNA viruses and is an important pathogen of many domestic animals, pets, and human diseases. It can cause a variety of acute and chronic diseases. Common signs of a person infected with a coronavirus include respiratory symptoms, fever, cough, shortness of breath, and dyspnea. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure, and even death. The 2019 new coronavirus, or "SARS-CoV-2 (COVID-19)" named by the World Health Organization can cause pneumonia epidemic.

The detection results of this kit are for clinical reference only. The result of this test should not be the sole basis for the diagnosis; confirmatory testing is required.

Principle

The COVID-19 Ag Rapid Test Device uses double antibody sandwich immunoassay. The NC membrane pre-immobilized with monoclonal antibodies against SARS-CoV-2 antigen and anti-mouse polyclonal antibodies, and the colloidal-gold conjugated with monoclonal antibodies specific to SARS-CoV-2 antigen.

If SARS-CoV-2 antigen present in the sample, a complex formed between the anti-SARS-CoV-2 conjugate and the antigen will be caught by the specific anti- SARS-CoV-2 monoclonal coated on the T region. Results appear in 10 to 20 minutes in the form of a red line that develops on the strip.

Whether the sample contains the SARS-CoV-2 antigen or not, the solution continues to migrate to encounter another reagent (an anti-mouse IgG antibody) that binds the remaining conjugates, thereby producing a red line on the region C.

Kit Content

1). Test device (individually packed in a foil pouch.
2). Extraction buffer vial.
3). Sterile swab.
4). Instruction for use.

Precautions

• For *in vitro* diagnostic use only.
• Do not re-use the test device.
• Do not use after the expiration date.
• Do not use the test kit if the pouch is damaged or the seal is broken.
• Perform test at room temperature 15 to 30°C.
•Wear gloves when hanging the samples, avoid touching the reagent membrane and sample window.
• All samples and used accessories should be treated as infectious and discarded according to local regulations.
• Avoid using blood samples.

Storage and Stability

Store the COVID-19 Ag Rapid Test Device at 2-30℃. Do not freeze. All reagents are stable until the expiration dates marked on their outer packaging and buffer vial.

Materials

Materials Provided

1. Test Device 2. Sterilized Swab
3. Sample Collection Tube 4. Nozzle With Filter
5. Sample Extraction Buffer 6. Package Insert

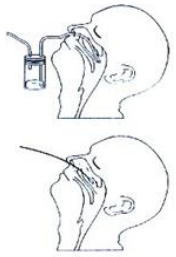
Materials Required but not Provided

1. Timer 2. Transfer pipette

Specimen Collection and Precaution

1. Specimen Collection:

It is applicable to the detection of the specific antigens to SARS-CoV-2 present in samples from human naso-pharynx.



Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may generate a false-negative result.

1）Nasal Aspiration

Collect nasal aspirate fluids using the specific aspirator as instructed.

2）Nasal Swabbing

Insert a sterile swab into the nostril of the patient, swab over the surface of the posterior nasopharynx. Withdraw the sterile swab from the nasal cavity.

2. Specimen Preparation:

1) Nasal Aspirate Fluids

Add **10 drops (about 0.3 ml)** of the nasal aspirate fluids into the sample collection tube which contains **10 drops (about 0.3 ml)** of the extraction buffer and mix well to be used as test sample.

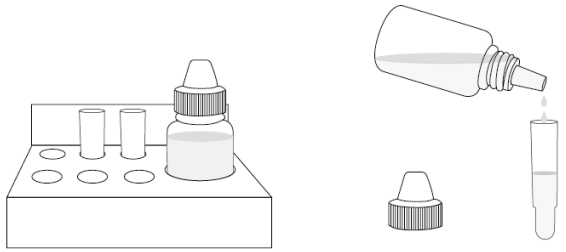
2) Nasal Swabs

Insert the swab into the sample collection tube which contains **10 drops (about 0.3 ml)** of the extraction buffer. Rotate the swab inside the tube using a circular motion to roll the side of the collection tube so that liquid is expressed and reabsorbed from the swab. Remove the swab and cover the tube with the nozzle lid. The extracted solution will be used as test sample.

Test Procedure

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

- Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
- Put the test device on a clean and level surface.
- Shake the swab specimen in the collection tube to well mix.
- Transfer 3 drops (~90µl) of the sample from the nozzle to the sample well of the test device and make sure a colored liquid appearing in the detection window in 30 seconds.
- Start the timer. Read the result at 10~20 minutes. Do not interpret the result after 20 minutes.



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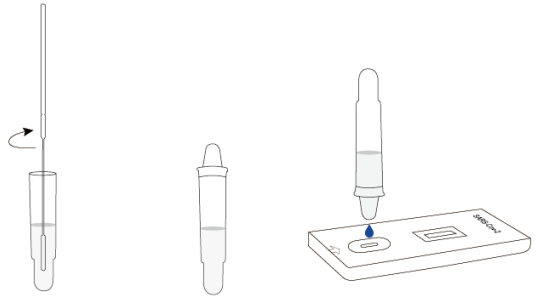

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Interpretation of Results

NEGATIVE:

Only one red band appears in the control region (C), and no band in the test region (T). The negative result indicates that there are no Novel coronavirus particles in the sample or the number of viral

particles is below the detectable range.

POSITIVE:

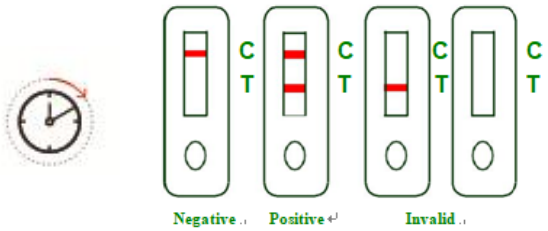
Two red bands appear. One red band appears in the control region (C), and one red band in the test region (T).

The shade of color may vary，but it should be considered positive whenever there is even a faint band.

INVALID:

No red band appears in the control region (C). The test is invalid even if there is a band on test region (T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device.

At 10~20 minutes



Do not interpret the result after 20 minutes.

Limitations

• The COVID-19 Ag Rapid Test Device is an initial screening test for qualitative detection. Sample collected may contain antigen titles below the reagent's sensitivity threshold, so a negative test result does not exclude infection with novel coronavirus.

• The COVID-19 Ag Rapid Test Device detects viable and non-viable novel coronavirus antigen. Test performance depends on antigen load in the sample and may not correlate with cell culture performed on the same sample. A positive test does not rule out the possibility that other pathogens may be present. Therefore, the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.

• A negative test result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if a poor quality specimen is obtained.

• Performance of the test has not been established for monitoring antiviral treatment of novel coronavirus.

• Positive test results do not rule out co-infections with other pathogens.

• Negative test results are not intended to rule in other coronavirus infection except the SARS-Cov-1.

• Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children list.

• A negative result may occur if the concentration of antigen or antibody in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of SARS-Cov-2 infection, and should be confirmed by viral culture or a molecular assay or ELISA.

Performance Characteristics

Clinical Evaluation

Clinical evaluation was performed to compare the results obtained by COVID -19 Ag Rapid Test Device and PCR. The results were summarized below:

Table: COVID Ag Rapid Test Device vs. PCR

		COVID Ag Rapid Test Device		Total Result
		+	-	
PCR	+	34	1	35
	-	0	200	200
Total Results		34	201	235

Relative sensitivity: 97.1%

Relative specificity: >99%

Overall agreement: 99.6%

Cross Reaction

No cross reaction has been confirmed of the COVID-19 Ag Rapid Test Device with the following pathogens:

①Bacteria

Acinetobacter baumannii, Bordetella pertussis, Branhamella catarrhalis, Candida albicans, Candida glabrata, Cardiobacterium hominis,Eikenella corrodens,Enterococcus faecalis, Enterococcus gallinarum.Escherichia coil, Group C streptococcus, Group G streptococcus, Haemophilus aphrophilus, Haemophilus influenzae, Haemophilus paraphrophilus, Klebsiella pneumoniae, Neisseria gonorrhoeae Peptococcus asaccharolyticus, Peptostreptococcus anaerobius, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus epidermidis, Streptococcus agalactiae(group B), Streptococcus mutans, Streptococcus pneumoniae, Streptococcus pyogenes(group A), Veillonella parvula

②Virus

Influenza A,Influenza B, Adenovirus Type 1～8, 11, 19, 37, Coxsackie virus Type A16, B1～5, Cytomegalovirus, Echovirus Type 3, 6, 9, 11, 14, 18, 30, Enterovirus Type 71, HSV-1,Mumps virus, Tyep I simple herpes virus Parainfluenza virus Type 1～3, Poliovirus Type 1～3, Respiratory syncytial virus, Rhinovirus Type 1A, 13, 14, Type I simple herpes virus.

③Mycoplasma etc.

No cross reaction with Chlamydia pneumoniae, Chlamydia psittaci, Chlamydia trachomatis, Mycoplasma pneumoniae.

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Symbols

Symbol	Meaning
	Consult instruction for use
IVD	In-Vitro Diagnostic Medical Device
	Manufacturer
LOT	Batch code
	Caution, consult accompanying documents
	Keep away from sunlight
	Do not reuse
	Temperature Limitation
	Use by date
	Production Date
	Contains sufficient for <n>test
EC REP	Authorized representative in the European Community
CE	Meet the requirements of EC Directive 98/79/EC