Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) Package Insert

A RAPID TEST FOR THE QUALITATIVE DETECTION OF NOVEL CORONAVIRUS ANTIGENS IN NASAL SWAB AND NASAL ASPIRATE SPECIMENSS.
For professional In Vitro Diagnostic Use Only.

INTENDED USE

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) is an *in vitro* diagnostic test for the qualitative detection of novel coronavirus antigens in Nasal Swab and nasal aspirate samples, using the rapid immunochromatographic method. The identification is based on the monoclonal antibodies specific for the novel coronvirus antigen. It will provide information for clinical doctors to prescribe correct medications.

SUMMARY

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) is used for the in vitro qualitative detection of novel coronavirus in the throat swabs, sputum samples of suspected pneumonia patients infected by novel coronavirus, suspected clustering cases and others needing diagnosis or differential diagnosis for novel coronavirus.

The definitions of "suspected cases" and "patients with suspected aggregated cases" and other groups are implemented with reference to the "Diagnosis and Treatment Plan for Pneumonia Infected in novel coronavirus" and "Monitoring Plan for Pneumonia Infected in novel coronavirus" and other documents (current version) issued by CDC.

The product is only used for auxiliary diagnosis of related cases and emergency reserve for in vitro diagnosis of this epidemic during the pneumonia epidemic infected by novel coronavirus (SRAS-Cov-2) since December 2019 and it cannot be used as routine in vitro diagnostic reagents in clinical practice. The kit shall comply with the relevant requirements of the "Diagnosis and Treatment Plan for Pneumonia Infected in novel coronavirus" and "Prevention and Control Plan for Pneumonia Infected in novel coronavirus" and other documents in use.

The detection results of this kit are for clinical reference only and should not be used as the sole criteria for clinical diagnosis. It is recommended to conduct a comprehensive analysis on the condition in combination with the clinical manifestations and other laboratory tests.

PRINCIPLE

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to Novel coroinavirus .

The test device is composed of the following three parts, namely sample pad, reagent pad and reaction membrane. The whole strip is fixed inside a plastic device. The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against Novel coroinavirus;the reaction membrane contains the secondary antibodies for Novel coroinavirus, and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane.

When the sample is added into the sample window,conjugates dried in the reagent pad are dissolved and migrate along with the sample. If Novel coroinavirus is present in the sample, a complex formed between the anti- Novel coroinavirus conjugate and the virus will be caught by the specific anti- Novel coroinavirus monoclonal coated on the T region. Results appear in 10 minutes in the form of a red line that develops on the strip.

Whether the sample contains the virus 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.

REAGENTS

The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against Novel coroinavirus; the reaction membrane contains the secondary antibodies for Novel coroinavirus,and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use after the expiration date.
- Ensure foil pouch containing test device is not damaged before opening for use.
- 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 bloody samples.

STORAGE AND STABILITY

Store the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) at room temperature or refrigerated (2-30°C). Do not freeze. All reagents are stable until the expiration dates marked on their outer packaging and buffer vial.

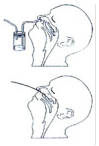
SPECIMEN COLLECTION AND PREPARATION

1. Specimen collection:

It is applicable to the diagnosis of the Novel coroinavirus from the samples of nasal swabs or nasal aspirates.Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.

1）Nasal Aspiration

Collect nasal aspirate fluids using the specific aspirator as instructed.



2）Nasal Swabbing

Completely insert the sterilized swab supplied in this kit into the nasal basin, and swab several times to collect the epidermal cells of the mucus.**It is recommended to collect sample from nasal basin for more accurate results.**

2. Specimen preparation:

Add **10 drops (about 0.3 ml)** of the sample extraction buffer into the extraction tube supplied in this kit up to the lower memory line, and put it on the tube stand.

1) Nasal Aspirate Fluids

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

2) Nasal Swabs

Insert the swab into the extraction 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 extraction tube so that liquid is expressed and reabsorbed from the swab.Remove the swab. The extracted solution will be used as test sample.

MATERIALS

Materials provided

- Test Device
- Sterilized Swab
- Extraction Tube
- Tube Stand
- Nozzle With Filter
- Sample Extraction Buffer
- Package Insert

Materials required but not provided

- Timer
- Transfer pipette

DIRECTIONS FOR USE

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

1.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.

2. Unscrew the whole cap of the specimen collection tube,

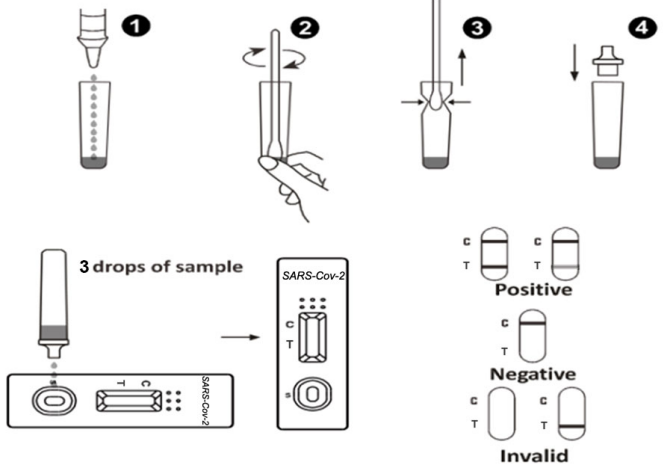
3. Add **10 drops (about 0.3 ml)** of the sample extraction buffer into the extraction tube.

4.Place the swab specimen in the Covid Ag 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.

5.Remove the swab while squeezing the swab head against the inside of Buffer 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.

6. Screw on and tighten the cap onto the specimen collection tube,then **shake the specimen collection tube vigorously** to mix the specimen and the Buffer. Place the test device on a clean and level surface. See illustration 4.

7.Add 3 drops of the solution (approx.80ul) to the sample well and then start the timer. Read the result at 10~20 minutes.Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: Two red lines appear. One red line appears in the control region(C), and one red line in the test region(T). The shade of color may vary，but it should be considered positive whenever there is even a faint line.

NEGATIVE: Only one red line appears in the control region(C), and no line in the test region(T). The negative result indicates that there are no Novel coroinavirus particles in the sample or the number of viral particles is below the detectable range.

INVALID: No red line appears in the control region(C). The test is invalid even if there is a line 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

- The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) is an acute-phase 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 Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) 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 an molecular assay or ELISA

PERFORMANCE CHARACTERISTICS

Clinical Evaluation

Clinical evaluation was performed to compare the results obtained by Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) and PCR. The results were summarized below:

Table: Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) vs. PCR

		SARS-Cov-2 Ag Rapid Test		Total Result
		+	-	
PCR	+	27	5	32
	-	0	200	200
Total Results		27	205	232

Relative sensitivity: 84.4% Relative specificity: >99%
Overall agreement: 97.8%

Cross Reaction

No cross reaction has been confirmed of the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) 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.

SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community
	Date of Manufacture		Use by date
	Do not reuse		Consult instruction foe use
LOT	Batch code	CE	Meet the requirements of EC Directive 98/79/EC

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Number: 1101381601
Version:1.1
Effective Date:2020-08-14