New Coronavirus (COVID-19) Antigen Rapid Test (swab) Package Insert

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

INTENDED USE

New Coronavirus (COVID-19) Antigen Rapid (swab) is an *in vitro* diagnostic test for the qualitative detection of novel coronavirus antigens in Nasopharyngeal swab and Oropharyngeal swab, using the rapid immunochromatographic method. The identification is based on the monoclonal antibodies specific for the New Coronavirus antigen. It will provide information for clinical doctors to prescribe correct medications.

SUMMARY

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

New Coronavirus (COVID-19) Antigen Rapid (swab) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to New Coronavirus.
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 New Coronavirus; the reaction membrane contains the secondary antibodies for New Coronavirus, and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane.
When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If New Coronavirus is present in the sample, a complex formed between the anti-New Coronavirus conjugate and the virus will be caught by the specific anti-New Coronavirus monoclonal coated on the T region.
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 New Coronavirus; the reaction membrane contains the secondary antibodies for New Coronavirus, and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane.

PRECAUTIONS

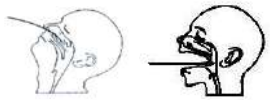
- For *in vitro* diagnostic use only.
- Do not use after the expiration date.
- Ensure foil pouch containing test device is not damaged before opening for use.
- Perform test at room temperature 15 to 30°C.
- Wear gloves when hanging the samples, avoid touching the reagent membrane and sample well.
- All samples and used accessories should be treated as infectious and discarded according to local regulations.
- Avoid using bloody samples.

STORAGE AND STABILITY

Store New Coronavirus (COVID-19) Antigen Rapid (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

It is applicable to the diagnosis of the New Coronavirus from the samples of Nasopharyngeal swab. Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.



For nasopharyngeal swab 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.
For oropharyngeal swab completely insert the sterilized swab supplied in this kit into the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.
It is recommended to collect sample from Nasopharyngeal for more accurate results.

MATERIALS

Materials provided

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

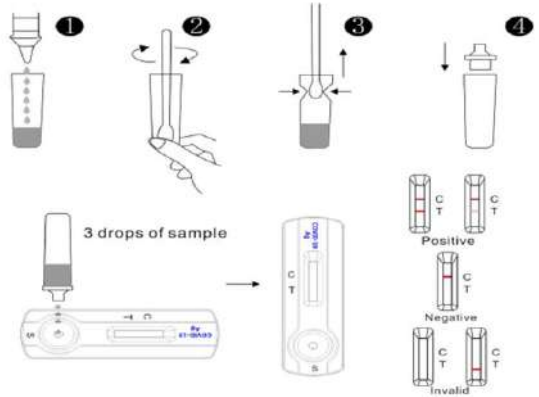
Materials required but not provided

- Timer

DIRECTIONS FOR USE

Allow the test, test sample and buffer to equilibrate to room temperature (15-30°C) prior to testing. Please refer to procedure card in this kit.

1. Remove the test device from the sealed foil pouch and use it within 0.5 hour. Best results will be obtained if the assay is performed immediately after opening the foil pouch
2. 1). Put the buffer vial in an upright position.
   2). Gently tap on the upper half of the vial, ensure all buffer has flown to the bottom.
   3). Twist the vial neck until it breaks.
   4). Place the vial above the Extraction Tube, upside down. Squeeze the vial hard until every drop of buffer has been transferred to the Extraction Tube. See illustration 1.
3. Place the swab specimen in the Extraction Tube. Rotate the swab for approximately 8 seconds while pressing the head against the inside of the tube to release the antigen in the swab. See illustration 2.
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 3.
5. Fit the dropper tip on top of the extraction tube. Place the test device on a clean and level surface. See illustration 4.
6. Add three drops of the solution (approx. 80uL) to the sample well and then start the timer. Read the result at 15 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 New Coronavirus 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

- New Coronavirus (COVID-19) Antigen Rapid (swab) is an acute-phase screening test for qualitative detection. Sample collected may contain antigen concentration below the reagent's sensitivity threshold, so a negative test result does not exclude infection with novel coronavirus
- New Coronavirus (COVID-19) Antigen Rapid (swab) detects viable and non-viable New 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 poor quality specimen is obtained
- Performance of the test has not been established for monitoring antiviral treatment of New 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 COVID-19.
- 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 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 COVID-19 infection, and should be confirmed by viral culture or PCR.

PERFORMANCE CHARACTERISTICS

Clinical Evaluation

Clinical evaluation was performed to compare the results obtained by Novel Coronavirus (COVID-19) Antigen Rapid Test Cassette (swab) and PCR. The results were summarized below:

Table: New Coronavirus (COVID-19) Antigen Rapid Test Cassette (swab) vs. PCR

Method		RT-PCR		Total Results
New Coronavirus (COVID-19) Antigen Rapid (Swab)	Results	Positive	Negative	
	Positive	28	2	30
	Negative	3	106	109
Total Results		31	108	139

Clinical sensitivity = 28/31=90.32%
Clinical specificity = 106/108=98.1%
Accuracy: (28+106)/139*100%=96.4%

Limit of Detection (LoD)

Stock COVID-19 Concentration	$1 X 10^6$ $TCID_{50}$/mL				
Dilution	1/100	1/200	1/400	1/800	1/1600
Concentration in Dilution tested ($TCID_{50}$/ml)	$1X10^4$	$5X10^3$	$2.5X\ 10^3$	$1.25X10^3$	$6.25X10^2$
Call rates of 20 replicates near cut-off	100 (20/20)	100 (20/20)	100 (20/20)	95 (19/20)	10 (2/20)
Limit of detection (LoD) per Virus Strain	$1.25 X 10^3$ $TCID_{50}$/mL				

Cross Reaction

The test results are below the corresponding concentration of the substances in the table below, which has no effect on the negative and positive test results of this reagent, and there is no cross-reaction.

Virus/Bacteria/Parasite	Strain	Concentration
Adenovirus	Type 1	$1.5 x 10^6 TCID_{50}$/mL
	Type 3	$7.5 x 10^6 TCID_{50}$/mL
	Type 5	$4.5 x 10^6 TCID_{50}$/mL
Influenza A	H1N1 Denver	$3.0 x 10^8 TCID_{50}$/mL
	H1N1 WS/33	$2.0 x 10^8 TCID_{50}$/mL
	H1N1 A/Mal/302/54	$1.5 x 10^8 TCID_{50}$/mL
	H1N1 New Caledonia	$7.6 x 10^8 TCID_{50}$/mL
	H3N2 A/Hong Kong/8/68	$4.6 x 10^8 TCID_{50}$/mL
Influenza B	Nevada/03/2011	$1.5 x 10^8 TCID_{50}$/mL
	B/Lee/40	$8.5 x 10^8 TCID_{50}$/mL
	B/Taiwan/2/62	$4.0 x 10^8 TCID_{50}$/mL
Respiratory syncytial virus	N/A	$2.5 x 10^6 TCID_{50}$/mL
Mycobacterium tuberculosis	K	$1 x 10^5$PFU/mL
	Erdman	$1 x 10^5$PFU/mL
	HN878	$1 x 10^5$PFU/mL
	CDC1551	$1 x 10^5$PFU/mL
	H37Rv	$1 x 10^5$PFU/mL
Mycoplasma pneumoniae	Mutant 22	$1 x 10^5$PFU/ml
	FH strain of Eaton Agent [NCTC 10119]	$1 x 10^5$PFU/ml
	36M129-B7	$1 x 10^5$PFU/ml

Interfering Substances Reaction

When tested using New Coronavirus (COVID-19) Antigen Rapid (swab), there was no interference between the device reagents and the potential interference substances listed in below table that would create false positive or negative results for COVID-19 antigen.

Substance	Concentration
Mucin	100μg/mL
Whole Blood	5% (v/v)
Oxymetazoline Hydrochloride Spray	100μg/mL
Carbazochrome Tablets	2.5mg/mL
Sulfur	5% (w/v)
Physiological Seawater Nasal Sprayer	100μL
Beclometasone	50μg/mL
Menthol	17.5mg/mL
Canker-Rid	10μL
Dexamethasone Acetate	0.15 mg/mL
Budesonide	10μL
Mometasone Furoate	5uL
Ambroxol	3mg/mL
Mupirocin	0.8mg/mL
Ibuprofen	0.1g/mL
azelastine	1 mg/mL

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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