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REF: VC012104

2019-nCoV Antigen Rapid Test
(Colloidal Gold)

CE IVD

FOR IN VITRO DIAGNOSTIC USE

This instruction for use (IFU) must be read carefully prior to use. Instruction for use must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions for use.

PACKING SPECIFICATION

25 Tests/ Kit

INTENDED USE

This product is used for in vitro qualitative detection of the antigen of novel coronavirus in human throat swabs or nasal swabs.

The novel coronaviruses belong to the β genus. 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 OF THE PROCEDURE

This kit by immune chromatography test, the sample will be under the capillary action to move forward along the test card, if the sample contains new crown of antigen, the antigens will with colloidal gold labeling will be coronavirus monoclonal antigen, the immune complex will be membrane fixed will be coronavirus monoclonal antibody capture, form the purple line, display will be coronavirus antigen positive; If the line does not show color, the negative result will be displayed. The test card also contains a quality control line C, which shall appear in magenta regardless of whether there is a detection line.

REAGENTS AND MATERIALS SUPPLIED

1. Main components:

1) nasopharyngeal swab or throat swab
2) antigen extraction tube
3) antigen extract R1
4) test card

2. Ingredients of the Test device

2019- nCoV antibody	Coated in the Test region on NC membrane
Goat anti Chicken IgY polyclonal antibody	Coated in the control region on NC membrane
2019- nCoV antibody, Chicken IgY, Colloidal gold conjugate	Coated in the conjugate pad
Other test device supports	/

3. Ingredients of the sample extraction solution

• Phosphate solution

Note: The components in different batches of the kit cannot be mixed.

MATERIALS REQUIRED BUT NOT PROVIDED

• Timer
• Pipette

STORAGE AND STABILITY

1. The kit is stored at 2-30℃ and is valid for 24 months
2. The test card should be in aluminum foil bag after opening, to the specified environment (temperature 2℃~35℃, humidity 40%~60%) used within 15 minutes.
3. The buffer should be used immediately after dropping into the dropper.
4. MFD date and EXP date: marked on the label.

SPECIMEN REQUIEMENTS

1. Throat swab:
   Have the patient's head slightly tilted back, mouth open, and "ah" sound, exposing both sides of the pharyngeal tonsils. Use a hand swab to gently wipe the pharyngeal tonsils on both sides of the patient for at least 3 times, and then wipe them on the posterior pharyngeal wall for at least 3 times. Place the swab specimen into the pre-added extract tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigens in the swab.
2. Nose swab:
   Allow the patient's head to relax naturally, and slowly rotate the swab against the nostril wall into the nostril of the patient to the nasal palate, and then slowly rotate it out while wiping. Wipe the other nostril with the same swab, using the same method; Place the swab specimen into the pre-added extract tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigens in the swab.
3. Nasopharyngeal swabs:
   Place the nasal swab into the sampling tube where the pharyngeal swab has been collected. In this way, there is a pharyngeal swab and a nasal swab in a sampling tube, so-called nasopharyngeal swab tube. Place the swab specimen in the extraction tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigen in the swab.
4. The samples should be used as soon as possible after collected (within half an hour).
5. Samples should not be inactivated.

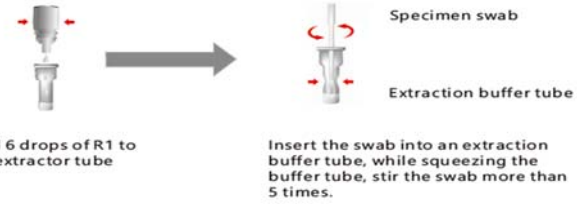
TEST PROCEDURE

Do not open the pouch until you are ready to perform a test, and the single-use test is suggested to be used under low environment humidity (RH≤70%) within 1 hour.

1. Allow all kit components and specimens to reach room temperature between 18°C~26°C prior to testing.
2. Remove the test card from the foil pouch and place on a clean dry surface.
3. Identify the test card for each specimen.

Sample processing:

1. Open the package and take out the test card.
2. Place the extraction tube on the workbench. The swab extractor bottle (R1) is pressed vertically downward to allow the solution to drip freely into the extractor tube without touching the edge of the tube. Add 6 drops(around 200 μl) of R1 to the extractor tube.
3. Put the swab specimen into the extraction tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigen in the swab. Squeeze the swab over the head to remove the swab so as to remove as much liquid as possible from the swab. Dispose of swabs according to biohazard waste disposal method.
4. Press the nozzle cap tightly onto the tube, put two drops(around 65 μl) into the sample hole of the test card, and start the timer.
5. Read the results in 20 minutes: a strong positive result can be reported within 20 minutes, but a negative result must be reported after 20 minutes, and the result after 30 minutes is no longer valid.



Add 6 drops of R1 to the extractor tube

Insert the swab into an extraction buffer tube, while squeezing the buffer tube, stir the swab more than 5 times.

Remove the swab while squeezing the side of the tube to extract the liquid from the swab

Press the nozzle cap tightly onto the tube

Add 2 drops of extracted specimen to the specimen well of the test device

Read the test results in 20-30 minutes.

Discard used test tubes and Test device in suitable biohazards waste container
Caution: Use a clean pipette or tip for every sample to avoid cross-contamination.

INTERPRETATION OF TEST RESULTS

Positive: if both the quality control line C and the detection line appear, novel coronavirus antigen has been detected.

Negative: if there is only a quality control line C, the detection line is colorless, indicating that novel coronavirus antigen has not been detected and the result is negative.

Invalid: if the quality control line C is not observed, it will be invalid regardless of whether there is detection line (as shown in the figure below), and the test shall be conducted again.

Positive Negative Invalid

Note: The band in the test area (T) can show the color depth. However, within the specified observation time, regardless of the color of the ribbon, even a very weak ribbon should be judged as a positive result.

LIMITATIONS

1. The result of the product should not be taken as a confirmed diagnosis, for clinical reference only. Judgement should be made along with RT-PCR results, clinical symptoms, epidemic condition and further clinical data.
2. In the early stage of infection, the test result may be negative because the low 2019- nCoV antigen level or antigen has not yet appeared in the sample.
3. Due to the limitation of the detection method, the negative result cannot exclude the possibility of infection. The positive result should not be taken as a confirmed diagnosis. Judgement should be made along with clinical symptoms and further diagnosis methods.
4. This reagent can only qualitatively detect 2019-nCoV antigens in human nasopharyngeal swab, oropharyngeal swab. It cannot determine the certain antigen content in the samples.
5. The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample transportation and storage or freezing and thawing of the sample will affect the test results.
6. It is optimum when eluting swabs with the matched samples extraction solution. Using other diluents may result in wrong results.
7. The solution and test card must be equilibrated to room temperature (18℃~26℃) before used, otherwise the results may be incorrect.
8. Sensitivity maybe decrease if the sample did not test directly. Please test the sample as soon as possible.
9. Cross reactions maybe exist due to the N protein in SARS has a high homology with the new coronavirus (2019-nCoV). However, the interpretation of the results is not affected during seasons without SARS infection.
10. Analysis the possibility of false negative results:

1) Inappropriate sample collection, using other non-matching solution, sample transfer time is too long (more than half an hour), the volume of solution added when eluted the swab are too much, non- standardized elution operation, low virus titer in the sample, these may all lead to false negative results.
2) Mutations in viral genes may lead to changes in antigen epitope, leading to false negative results.

11. Analysis the possibility of false positive results:

1) Inappropriate sample collection, using other non-matching solutions, non-standardized elution operation, these may all lead to false positive results.
2) Cross-contamination of samples may lead to false positive results.
3) False negative result from nucleic acid.

12. Analysis the possibility of invalid result:

1) If the sample volume is not enough, the chromatography cannot be carried out successfully.
2) The test card would invalid if the package was broken. The packaging status must be carefully checked before use.

PERFORMANCE CHARACTERISTIC

1. Limit of Detection

The LOD for 2019-nCoV Antigen Rapid Test was established using dilutions of an inactivated virus culture. The starting material was supplied at a concentration of 3.84 x 10^5 $TCID_{50}$/mL. Studies were designed to estimate the LOD of the assay using nasal swab specimens, the starting material was spiked into a volume of pooled human nasal matrix obtained from healthy donors and confirmed negative for 2019-nCoV to obtain a series of different concentrations.

2019-nCoV Titer	3.84x$10^5$$TCID_{50}$/mL								
Dilution	1/100	1/200	1/400	1/800	1/1600	1/3200	1/6400	1/12800	1/25600
Concentration in Dilution tested (TCID50/mL)	3.84x 10^3	1.92x 10^3	9.6x 10^2	4.8x 10^2	2.4x 10^2	1.2x 10^2	6x 10	3x 10	1.5x 10
Detection rates of 5 replicates	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	80% (4/5)
Detection rates of 20 replicates near cut-off	NA	NA	NA	NA	NA	100% (20/20)	100% (20/20)	95% (19/20)	75% (15/20)
Lowest Concentration with Uniform	30 $TCID_{50}$/mL								

Positivity per Analyte	
Limit of detection(LoD) per inactivated Virus Culture	30 $TCID_{50}$/mL

2. Clinical study

2019-nCoV Antigen Rapid Test	PCR Test		Total
	Positive	Negative	
Positive	74	2	76
Negative	6	238	244
Total	80	240	320

Analysis of coincidence rate of 2019-nCoV Antigen rapid test and PCR Test in nasal samples:

Positive coincidence rate (Sensitivity):

74/ (74+6) × 100% = 92.5%

Negative coincidence rate (Specificity):

238 / (2+238) × 100% = 99.16%

Total coincidence rate (Accuracy):

(74+238) / (74+6+2+238) × 100% = 97.5%

3. Cross reaction testing

Cross-reaction is mainly used to verify the influence of common respiratory pathogens on the detection performance of reagents. According to the guidelines published by the Medical Device Technology Evaluation Center of the National Medical Products Administration, we selected the following respiratory pathogens for cross-reactivity tests: influenza A virus H1N1, influenza B virus, Mycoplasma pneumoniae, Rhinovirus A, Rotavirus, Large intestine Escherichia, respiratory syncytial virus, adenovirus, etc. are used as a batch (HR200401) test card for sample testing.

The concentration of bacterial samples is set to 10^6 cfu/ml or higher, and the concentration of virus samples is set to 10^5 pfu/ml or higher. The test results are shown in the table below.

Cross reaction

Pathogen	Concentration	Testing results
HKU1	10^5 pfu/mL	-
OC43	10^5 pfu/mL	-
NL63	10^5 pfu/mL	-
229E	10^5 pfu/mL	-
MERS-coronavirus	10^5 pfu/mL	-
Human Metapneumovirus	10^5 pfu/mL	-
Influenza A virus H1N1	10^5 pfu/mL	-
Influenza A virus H3N2	10^5 pfu/mL	-
Influenza A virus H5N1	10^5 pfu/mL	-

Influenza A virus H7N9	10^5 pfu/mL	-
Influenza B virus	10^5 pfu/mL	-
Mycoplasma pneumoniae	10^5 cfu/mL	-
Rhinovirus A	10^5 pfu/mL	-
Rhinovirus B	10^5 pfu/mL	-
Rhinovirus C	10^5 pfu/mL	-
Adenovirus 1	10^5 pfu/mL	-
Adenovirus 2	10^5 pfu/mL	-
Adenovirus 3	10^5 pfu/mL	-
Adenovirus 4	10^5 pfu/mL	-
Adenovirus 5	10^5 pfu/mL	-
Adenovirus 7	10^5 pfu/mL	-
Adenovirus 55	10^5 pfu/mL	-
Enterovirus A	10^5 pfu/mL	-
Enterovirus B	10^5 pfu/mL	-
Enterovirus C	10^5 pfu/mL	-
Enterovirus D	10^5 pfu/mL	-
EB Virus	10^5 pfu/mL	-
Measles virus	10^5 pfu/mL	-
Human cytomegalovirus	10^5 pfu/mL	-
Rotavirus	10^5 pfu/mL	-
Norovirus	10^5 pfu/mL	-
Mumps virus	10^5 pfu/mL	-
Varicella-zoster virus	10^5 pfu/mL	-
Respiratory syncytial virus	10^5 pfu/mL	-
Mycoplasma pneumoniae	10^5 pfu/mL	-
Escherichia Coli	10^5 pfu/mL	-
20 samples of normal people		All negative

Experiments have confirmed that the concentration of microorganisms or viruses set above has no effect on the detection performance of the new coronavirus (2019-nCoV) antigen detection kit (colloidal gold method)。

4. Interference testing

Some clinically commonly used substances may affect product performance. The design adds the following substances to negative and weakly positive samples to detect the impact on the test results (see the table below).

Materials	Concentration	Negative sample	Weak positive samples
Mucin	200 mg/ml	-	+
Hemoglobin	10 mg/ml	-	+
Histamine Hydrochloride	4.0mg/L	-	+
Human albumin	60 mg/ml	-	+
α- interferon	2 ng/ml	-	+
Lopinavir	2 μg/ml	-	+
Tobramycin	10 mg/L	-	+
Ribavirin	40 mg/L	-	+
Tramadol	12 μg/ml	-	+
Azithromycin	5 μg/ml	-	+
Meropenem	10 mg/ml	-	+
Oseltamivir	1000 ng/ml	-	+
Benzocaine	1.5 mg/ml	-	+
Peramivir	20 μg/ml	-	+

Experiments have confirmed that the above-mentioned clinically commonly used substances have no effect on the detection performance of the new coronavirus antigen detection kit. However, high concentrations of hemoglobin have an effect on the elimination of the background, suggesting that the hemolyzed sample has an effect on the elimination of the background of the product, so it can affect the result observation of weakly positive samples.

5.HOOK effect

Determination of Hook effect

Use the new coronavirus antigen strong positive sample to carry out the gradient dilution and start the detection from low concentration to high concentration. Each gradient is repeated 3 to 5 copies. The concentration when the color depth becomes lighter as the concentration increases is used as the new coronavirus minimum concentration of antigen when the hook effect occurs.

Specimen	1:2	1:4	1:8	1:16	1:32	1:64
Detection intensity	+++	+++	+++	++	>+	+
Detection times	5 times	5 times	5 times	5 times	5 times	5 times

The new coronavirus (2019-nCoV) antigen detection kit detects the positive samples of the new coronavirus antigen antibody without obvious hook or prozone effect

Prozone effect verification

Take 5 strong positive samples of the new coronavirus antigen for verification

Specimen	1:2	1:4	1:8	1:16	1:32	1:64
Specimen 1	+++	+++	+++	++	>+	+
Specimen 2	+++	+++	+++	++	>+	+
Specimen 3	+++	+++	+++	++	++	+
Specimen 4	+++	+++	+++	++	>+	+
Specimen 5	+++	+++	+++	++	++	+

Repeat the verification with 5 strong positive samples, and there is no obvious prozone effect.

PRECAUTIONS

1. The reagent is a disposable diagnostic reagent in vitro, which is only used for the detection of human nasopharyngeal swab, or oropharyngeal swab. The operation should be carried out strictly according to the instructions. Do not use expired and damaged products.
2. The kit should be sealed and kept away from moisture. Reagents or samples stored at low temperature should be balanced to room temperature before they can be used.
3. Reagents should be used as soon as possible after removal from aluminum foil bags, so as to avoid exposure to air for too long and affecting test results due to dampness.
4. Do not use samples that have been placed for too long or contaminated.
5. Please operate in accordance with the laboratory testing procedures for infectious diseases. Waste after use should be treated in accordance with infectious substances and should not be discarded at will.
6. Incorrect operation may affect the accuracy of the results, such as insufficient sample mixing, insufficient amount, inaccurate detection time, etc.
7. Components in different batch should not be mixed.
8. Recommend to use "fresh specimen" for testing, if testing not available in same day, specimen collected by swab should keep in minus 20 degree centigrade for storage and transfer in dry condition.
9. There should be appropriate biosafety assurance procedures for those substances containing and suspected sources of infection. The following are relevant considerations:

1) Handle samples and reagents with gloves;
2) Do not suck samples with your mouth;
3) Do not smoke, eat, drink, cosmetic or handle contact lenses while handling these items;
4) Disinfect the spilled sample or reagent with disinfectant;
5) Disinfect and treat all samples, reagents and potential pollutants in accordance with relevant local regulations;
6) Each component of the reagent remains stable until the expiry date under proper handling and storage conditions. Do not use the expired reagent kit.

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INSTRUCTIONS OF SYMBOL

	Consult instruction for use		Keep dry
	Store between	LOT	Batch number
	For single use	IVD	In vitro diagnostic medical device
	Manufacturer		Date of manufacture
	Expire date		Contains sufficient for <n> tests
EC REP	European representative	CE	CE Mark

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