



COVID-19 Antigen Detection Kit (Colloidal Gold)

Instructions for Use

[PRODUCT NAME]

COVID-19 Antigenic Detection Kit (Colloidal Gold)

[PACKING SPECIFICATION]

1. Model: Model A, Model B, Model C
2. Packing: 25 Tests/Kit, 5 Tests/Kit, 1 Test/Kit

[INTENDED USE]

This kit is intended for the qualitative detection of the new coronavirus antigen (COVID-19) in human oropharyngeal swabs, nasopharyngeal swabs, nasal swabs, and saliva samples.

[TEST PRINCIPLES]

This kit uses the double antibody sandwich method to qualitatively detect the new coronavirus antigen in human oropharyngeal swabs, nasopharyngeal swabs, nasal swabs, and saliva samples. The kit uses colloidal gold to label the *monoclonal anti-human coronavirus antibody 1* (MCA1). Then *monoclonal coronavirus antibody 2* (MCA2) and *polyclonal goat-anti-mouse IgG* are coated in a nitrocellulose membrane. In a positive sample, it binds virus antigen with MCA1 (which is labeled with colloidal gold). Then the antigenic is chromatographed to the detection area, after which it binds to it for coated MCA2 to form a double antibody sandwich complex, which gives a red color. Both MCA1 and MCA2 bind to the N protein of SARS-CoV-2. The other colloidal gold labeled antibodies bind to the polyclonal goat-anti-mouse IgG antibodies that also generate a red color on the quality control line. In the case of negative samples, a red colour will therefore only be observed on the control line.

[HOOFDSAMENSTELLING]

Composition	Packaging (Model A)			Packaging (Model B)	Packaging (Model C)	
Detection Card	25 Tests	5 Tests	1 Test	25 Tests	25 Tests	1 Test
Extraction Buffer	25 Bottles	5 Bottles	1 Bottle	1 Bottle	25 Bottles	1 Bottle
Extraction Tube	/	/	/	25 Pieces	/	/
Sampling Swab (Nasal)	25 Tests	5 Tests	1 Test	25 Tests	/	/
Negative control (optional)	1 Piece	/	/	1 Piece	/	/
Positive control (optional)	1 Piece	/	/	1 Piece	/	/
Instructions for Use	1 Set	1 Set	1 Set	1 Set	1 Set	1 Set
Workstation	/	/	/	1 Piece	/	/
Saliva collector	/	/	/	/	25 Pieces	1 Piece
Dropper	/	/	/	/	25 Pieces	1 Piece

[STORAGE CONDITIONS & SHELF LIFE]

The original packaging is stored in a dark spot at 4-30°C, valid for 24 months; the test card should be used within one hour of opening the aluminum packaging.

[SAMPLE REQUIREMENT]

1. Oropharyngeal swab sample: Use a special swab to gently wipe the posterior pharynx wall and tonsils on both sides, do not touch the tongue; quickly immerse the swab head in the extraction buffer.
2. Nasopharyngeal swab sample: Insert the swab into the nasal cavity with the most secretions. Turn gently and push it into the nasal cavity until you feel resistance, then press the swab against the wall of the nose three times, remove the head from the swab; quickly immerse the head of the swab in the extraction buffer.
3. Nasal smear: Insert the swab into the nasal cavity with the most secretions. Turn gently and push it into the nasal cavity until you feel resistance, then press the swab against the wall of the nose three times, remove the head from the swab; quickly immerse the head of the swab in the extraction buffer.
4. Saliva sample: Take the saliva collector from the test kit. Spit in the funnel until the saliva volume is 2 mL (excluding air bubbles). Hold the tube vertically and unscrew the funnel from the tube and discard it. Take the cap (blue color) and turn it firmly on the tube. Shake the tube upside down 12 times to mix the saliva with the extraction buffer.
5. Transfer of samples (for swab samples only):
 - (1) If the extraction buffer is packed separately (Model A), insert the swab directly into the buffer.
 - (2) If the buffer is packed in 1 bottle (Model B), add 8~10 drops of extraction buffer to the tube, then insert the swab into the buffer.
6. When the swab is inserted into the solution, press the head of the swab against the wall of the tube to push out the trapped liquid. Repeat this several times. When this is done, remove the head of the swab while trying to leave as much solution as possible in the tube.
7. Dispose of the swab/saliva collector safely.
8. After collection, the samples should be processed as soon as possible with the virus sampling solution supplied by this kit. Complete the test within 10 minutes.



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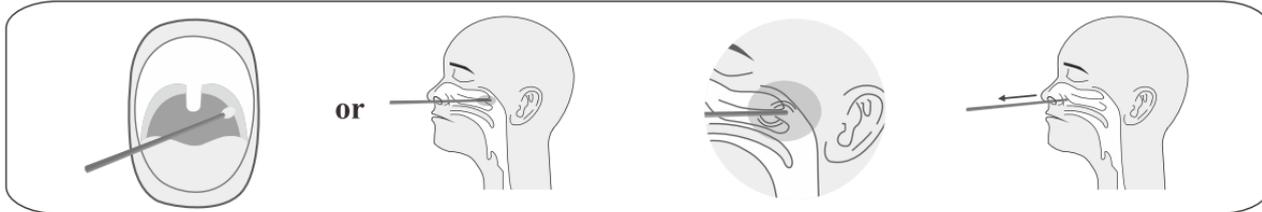
[TEST METHOD]

Please read the instructions carefully before testing. The test must be carried out at room temperature. For the sampling method, we refer you to [sample requirement].

1. Open the aluminium packaging, take the cassette and place it on the table.
2. Add 60 μL (about 2 drops) of the sample (the extraction buffer) into the sample well of the cassette.
3. The results can be observed within 10-15 minutes, if necessary, extend this time to 20 minutes.

[OPERATION PROCESS & RESULT INTERPRETATION]

Swab specimen detection procedures:

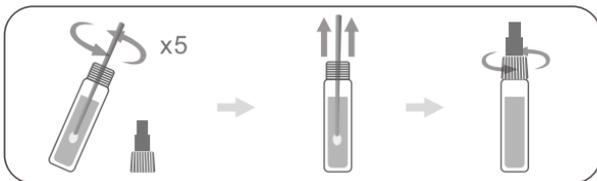


1. Collection nasopharyngeal swabs:

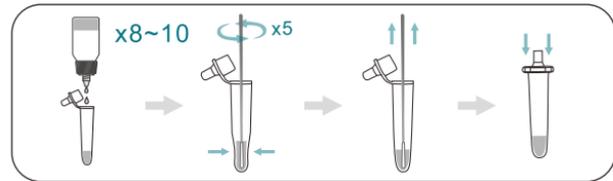
Stick the swab into the nostril and go deep into the back wall of the nasopharynx through the lower nasal cavity. If you experience resistance, gently lift the nasopharyngeal swab until it feels like you are touching the wall. After the swab reaches the nasal cavity, wait 15 seconds, then rotate 3 turns. Rotate slowly to remove the swab.

Collection of nasal swabs: gently turn the swab and push it into the nasal cavity, press the swab against the nasal wall three times, then remove it.

Collection of oropharyngeal swabs: collect at the back wall of the pharynx or both sides of the tonsils; do not touch the tongue.

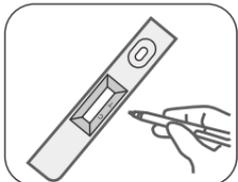


OR

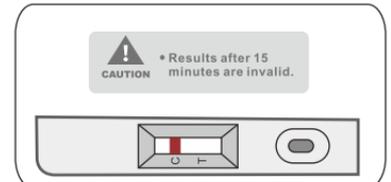
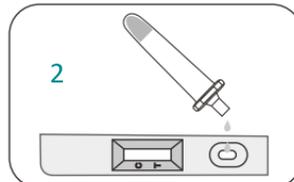
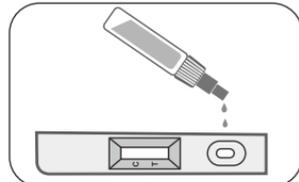


2. Insert the swab into the extraction buffer. Stir the swab at least 5 times and squeeze it to make the sample overflow. Remove the swab and turn the cap on the tube.

Add 8~10 drops of buffer into the extraction tube. Stir the swab at least 5 times and squeeze it to overflow the sample. Remove the swab and press the cap on.



OR

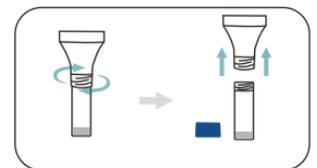
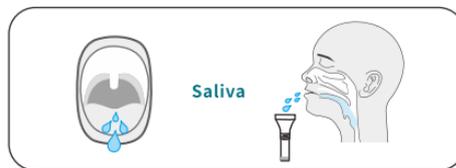
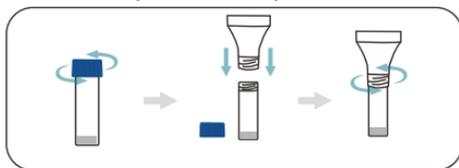


3. Open the foil pouch, take the testcard and make a mark.

4. Add 60 μL (about 2 drops) of the sample into the sample well.

5. Read the results within 10 to 15 minutes.

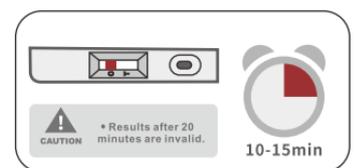
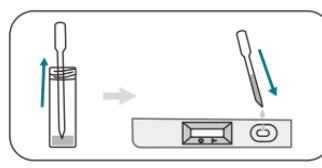
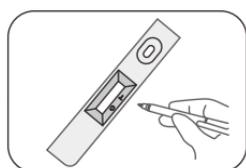
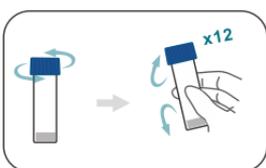
Saliva sample detection procedures:



1. Take out the saliva collector from the test kit. Screw the collection funnel on to the tube.

2. Spit into the funnel until the volume is about 2 mL (excluding air bubbles).

3. Hold the tube vertically and unscrew the funnel. Throw away the funnel.



4. Take the blue tube cap and screw it on the tube tightly. Shake the tube upside down 12 times to mix the saliva with the extraction solution.

5. Open the foil pouch, take out the test card and make a mark.

6. Add 2 drops of the sample (60 μL) vertically into the sample well of the test cassette.

7. Read the results within 10 to 15 minutes.



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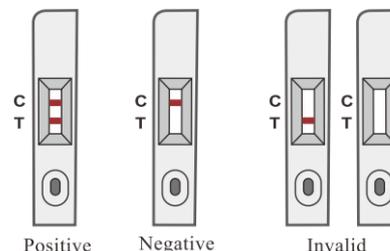
Instructions for Use

[INTERPRETATION OF THE TEST RESULTS]

Positive result: a red precipitation line appears in the control area (C) and in the detection area (T).

Negative result: a red precipitation line appears in the control area (C). No red line appears in the detection area (T).

Invalid result: no red precipitation line can be seen in both control (C) and detection (T) area, or there is only a line visible in the detection area (T).



[QUALITY CONTROL]

1. Open the quality control packaging and remove the negative control (negative swab) and positive control (positive swab).

Model A: insert the negative/positive swab into the extraction buffer, stir the swab at least 5 times and squeeze the swab to fully release the quality control substance. Remove the swab and tighten the cap.

Model B: open the extraction buffer and insert 8~10 drops (about 400-500 µL) into an extraction tube. Stick the negative/positive swab into the extraction buffer, stir the swab at least 5 times and squeeze the swab to completely overflow the control. Take out the swab and druk the cap on it.

2. Take two test cards and add 60 µL (about 2 drops) of the negative as positive control respectively into the sample well.

3. View the results between 10 and 15 minutes.

4. The negative control should show a negative result; the positive control should show a positive result.

5. If the results of the quality checks are abnormal, the measurement should be repeated once in order to prevent quality control from failing as a result of the failure of the individual test cards.

[PERFORMANCE ATTRIBUTES]

COVID-19 Antigen Detection Kit (Colloidal Gold)	Positive	Negative	Total Specimen
Positive	122	1	123
Negative	4	128	132
Total Samples PCR	126	129	255
Sensitivity	96,83%		
95% Confidence Interval	93,88% - 98,38%		
Specificity	99,22%		
95% Confidence Interval	97,20% - 99,79%		
Accuracy	98,04%		

[ANALYTICAL PERFORMANCE]

Cross-reaction: for the 100ng/mL canine coronavirus, feline coronavirus and porcine coronavirus recombinant antigenic samples; 25µg/mL rubella virus (RV), measles virus (MV), norovirus (NV), Epstein-Barr virus (EB-VCA-Ag3), human cytomegalovirus (HCMV-Ag11) recombinant antigenic samples; 5µg/mL influenza A virus (FluA-NP), influenza B virus (FluB-NP) recombinant antigen samples; 50µg/mL human respiratory syncytial virus (hRSV), human respiratory syncytial virus (hRSV-2), enterovirus 71 (EV71- 1) recombinant antigen samples; 10µg/mL rotavirus (RV-VP6), 20µg/mL adenovirus(VP-15-01) and 10µg/mL human coronavirus (229E, OC43, NL64 and MERS) recombinant antigenic samples, all test results are negative.

Recombinant Antigen Specimen	Code	Concentration	Result
Canine coronavirus positive sample	/	100 ng/mL	Negative
Feline coronavirus positive sample	/	100 ng/mL	Negative
Porcine coronavirus positive sample	/	100 ng/mL	Negative
Human respiratory syncytial virus	hRSV	50 µg/mL	Negative
Human respiratory syncytial virus	hRSV-2	50 µg/mL	Negative
Human rubella virus	RV	25 µg/mL	Negative
Human measles virus	MV	25 µg/mL	Negative
Human influenza A virus	FluA-NP	5 µg/mL	Negative
Human influenza B virus	FluB-NP	5 µg/mL	Negative



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Human norovirus	NV	25 µg/mL	Negative
Human enterovirus 71	EV71-1	50 µg/mL	Negative
Human Epstein-Barr virus	EB-VCA-Ag3	25 µg/mL	Negative
Human cytomegalovirus	HCMV-Ag11	25 µg/mL	Negative
Rotavirus	RV-VP6	10 µg/mL	Negative
Adenovirus	VP-15-01	20 µg/mL	Negative
Human Coronavirus	229E	10 µg/mL	Negative
Human Coronavirus	OC43	10 µg/mL	Negative
Human Coronavirus	NL63	10 µg/mL	Negative
Human Coronavirus	Seas	10 µg/mL	Negative

[LIMITATIONS OF THE TEST METHOD]

1. This kit is only used to detect in saliva and respiratory secretions of nasopharyngeal, oropharyngeal- and nasal swabs.
2. The accuracy of the test depends on the sample collection process. Improper sampling, unsuitable sample storage, sample thawing or repeated freeze-thaw of the sample may affect the results.
3. The presence of medicines in the collected samples, for example a high concentration of over-the-counter drugs and prescription drugs (nasal sprays), may interfere with the results. If suspicious results come out, take the test again.
4. This reagent is generally used in the acute infection period of the coronavirus, which means, samples taken within 7 days after the onset of symptoms in suspicious people.

[REFERENCE]

The reference value of this kit is negative.

[NOTES]

1. This kit is only intended for in vitro diagnostics.
2. This product is a one-time in vitro diagnostic reagent. Please do not reuse it. Do not use expired products.
3. If no lines are visible in the control area (C) and the test area (T), it means that the test card is invalid. Please retest.
4. When taking samples, use the swab and virus sampling solution supplied with this kit. Do not mix different batches of test cassettes and virus sampling solutions.
5. The new coronavirus belongs to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. At the moment, the patients infected with the new coronavirus are the main source of infection; asymptotically infected individuals can also be a source of infection. Based on current epidemiological studies, the incubation period ranges from 1 to 14 days, most often 3 to 7 days. The most common symptoms include fever, fatigue and a dry cough. In a few cases, nasal congestion, runny nose, sore throat, myalgia and diarrhea have also been observed.
6. Incorrect sample collection, storage and stale samples will affect the results.
7. Patients treated with antiviral medications will have a large decrease in viral load, resulting in false negative results.
8. A negative does not completely rule out the possibility of infection with the new coronavirus. If the result is negative but there are clinical symptoms, it is recommended to use other clinical methods for testing.

[LABEL EXPLANATION]



Never re-use



Store at 4-30°C



Refer to the instruction of use



In-vitro diagnostic medical devices

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Before production date see box

[Date of publication or revision]

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