Babio SARS-CoV-2 Antigen Rapid Detection Kit

(Colloidal Gold Method) – Nasal swab

Instructions for Use-Self Test

IFU-03，Ver.03

1T/box catalog number：011521

5T/box catalog number：011522

How to use

INTENDED USE

Babio SARS-CoV-2 Antigen Rapid Detection Kit (Colloidal Gold Method) is a lateral flow immunoassay intended for the qualitative detection of nucleoprotein from SARS-CoV-2 nasal swab. It is used by laymen as a test and provides a preliminary test result to aid in the diagnosis of infection with individuals suspected of COVID-19.

Results from antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status. The diagnosis should be confirmed in combination with clinical symptoms or other conventional testing methods.

SUMMARY AND EXPLANATION OF THE TEST

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.

Antigen detection is a common method for the diagnosis of infection with novel coronavirus. This test is an immunological diagnostic test used for detection of SARS-CoV-2 nucleoprotein antigen based on the colloidal gold-immunochromatography assay. This method is rapid and convenient to use and requires few equipment. It can be performed within 15-20 minutes by laymen.

TEST PRINCIPLE

This kit adopts colloidal gold-immunochromatography assay.

The test card contains:

1. Colloidal gold-labeled mouse nucleoprotein monoclonal antibody and quality control antibody complex.

2. Nitrocellulose membranes immobilized with test lines (T line） and one quality control line (C line).

When an appropriate amount of sample is added to the sample well of the test card, the sample will move forward along the test card under capillary action. If the sample contains an antigen of SARS-CoV-2, the antigen will bind to the colloidal gold-labeled SARS-CoV-2 antibody, and the immune complex will be captured by the monoclonal anti-human antibody immobilized on the nitrocellulose membrane to form a burgundy line, showing that the sample is positive for antigen.

REAGENTS AND MATERIALS PROVIDED

Materials Provided:

Component Name	1T/box	5T/box
Disposable Test Card	1	5
Desiccant	1	5
Nasal swab	1	5
Sample Diluent	500 μl	500 μl *5
Drop Bottle	1	5
Biosafety bag(25cmX18cm)	1	5
Manual	1	1

Specification： 1T/box, 5T/box

WARNINGS AND PRECAUTIONS

1. For personal or family testing
2. Read the package insert in its entirety prior to performing the test. Failure to follow the package insert instructions may result in an invalid test result.
3. Wash hands thoroughly after handling specimen.
4. Do not use it if the tube/pouch is damaged or broken.
5. Test is for single use only. Do not re-use under any circumstances.
6. Humidity and temperature can adversely affect results.
7. Follow storage recommendations listed on the product labels. Storage and handling outside of these conditions may adversely affect product.
8. Do not use product after indicated expiration date.

SHELF LIFE AND STORAGE

1. The original packaging should be stored in a dry place at 2-30°C and protected from light.
2. The shelf life of the test kit is 2 years from date of manufacture. Refer to the product labels for stated expiration date.
3. The original packaging can be transported at 2-37°C for 20 days.
4. After opening the inner package, the test card will become invalid due to moisture absorption, please use it within 1 hour.

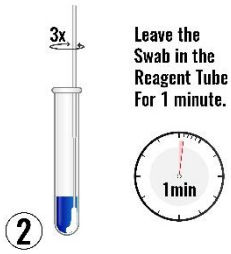
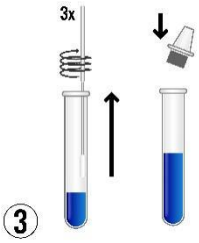
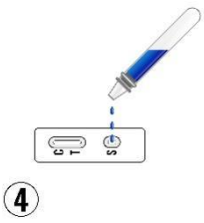
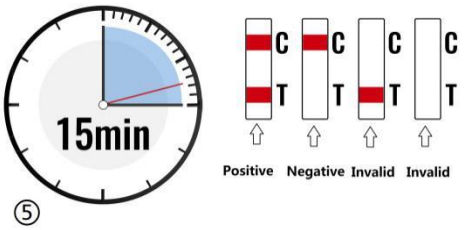
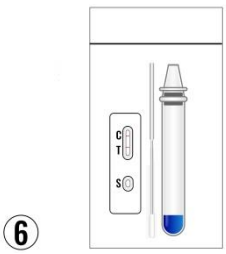
SPECIMEN COLLECTION AND HANDLING

This test performed using human nasal swab. Samples can be collected using components provided with the test and should be tested immediately. Please see diagram in Test Procedure section.

TEST PROCEDURE

(Please scan QR code provided for video demonstration and fill in a mandatory form)

1. Open the packaging box, take out the inner package and let it equilibrate to room temperature.
2. Remove the test card from sealed pouch and use within 1 hour after opening.
3. Place the test card on a clean and level surface.
4. For all the test methods, disinfect and collect the disposable parts into the biosafety bag after test.

 ① Specimen from SARS-CoV-2 nasal swabs. Put the swab into nasal slowly，rotate it 2-3 times around the inner side of nasal，then move it out slowly. Repeat for the second nasal cavity.	 ②Place the patient swab sample into the Tube. Roll the swab at least 3 times while pressing the head against the bottom and side of the Tube.	 ③Roll the Swab head against the inside of the Tube as you remove it. Dispose of the used Swab in your biohazard waste. Put the lid on the dropper bottle.
 ④Drop 60-100ul sample (2-3 drops) into the test card. NOTE: Do not pour sample from the Tube.	 ⑤Read the result at 15 minutes. It must be repeated if the result is invalid	 ⑥Put all test items in the Biosafety bag

INSTRUCTION FOR DISPOSAL

(Please scan QR code provided for video demonstration and fill in a mandatory form)

1. Put the tube, swab and test card into the box.
2. Disinfect and collect all the components into the biohazard bag(25cmX18cm).

QUALITY CONTROL

1. The test card includes an internal procedural control. This control confirms that sufficient specimen volume and technique have been applied.
2. Control standards are not provided with this kit.
3. It is recommended to follow good laboratory practice including adding positive and negative controls in order to verify proper test performance.

INTERPRETATION OF ASSAY RESULT

(Please scan QR code provided to report result in MySejahtera Application)

1. NEGATIVE:

If only the quality control line C appears, and the test lines T are not burgundy, it indicates that no antigen is detected, and the result is negative. Due to the limitation of detection sensitivity, negative results may be caused by antigen concentrations lower than the analytical sensitivity of the product.

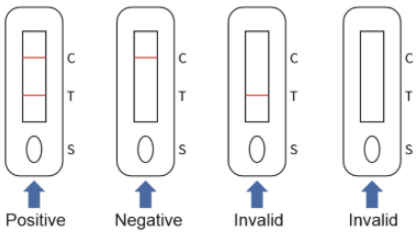
2. POSITIVE:

If both the quality control line C and the test line T appear, it indicates that antigen is detected. Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made.

3. INVALID:

If the quality control line C is not displayed, the test result is invalid regardless of whether there is a burgundy test line, and it should be tested again. Repeat the test using remaining sample or new sample, if results are not clear.

If the test repeated fail to produce a result, discontinue using the kit and contact the manufacture.



Reporting Test Results

(Please scan QR code provided to report result in MySejahtera Application)

a) All test results of the COVID-19 Self-Test Kit whether positive, negative or invalid must be reported by self-reporting into the MySejahtera application.

b) Users are responsible for reporting the actual results and not falsifying the results to prevent the implications of infection to others.

If the test result is POSITIVE: -

a) Positive results must be reported to MySejahtera (subject to the Prevention and Control of Infectious Diseases Act 1988 [Act 342]).

b) Individuals are requested to go in person to a private health facility, COVID-19 Assessment Center (CAC) or a nearby health clinic for health assessment and further action. These individuals are required to wear face masks when leaving the house and avoid riding public transport.

If the test result is NEGATIVE: -

a) If you have symptoms, go to a private health facility or health clinic for a health assessment.

b) If the individual concerned is a contact to the COVID 19 case, the individual must continue to undergo compulsory quarantine until the end of the quarantine period.

If the test results are INVALID, the test needs to be repeated.

PERFORMANCE CHARACTERISTICS

1. Performance

Contingency table 2X2, which lists the number of true positives, false positives, true negatives, false negatives and the prevalence

Method		RT-PCR test		Total
SARS-CoV-2 Antigen Rapid Detection Kit		Positive	Negative	
	Positive	160	0	160
	Negative	6	331	337
Total		166	331	497

Relative sensitivity: (95% CI: 95.21% -97.55%) 96.38%

Relative specificity: (95% CI *: 100% -100%) 100%

Random rate: (95% CI *: 98.12% -99.46%) 98.79%

2. Interference study

It was found that substances listed in the table below did not affect test performance

Possible cross reactant	Test Concentration
Influenza A H1N1 antigen	$1{,}0\times10^5$ TCID $_{50}$/mL
Influenza A H3N2 antigen	$1{,}0\times10^5$ TCID $_{50}$/mL
Influenza B antigen	$1{,}0\times10^5$ TCID $_{50}$/mL
Adenovirus antigen	$1{,}0\times10^5$ TCID $_{50}$/mL
Mycoplasma antigen	$1{,}0\times10^5$ TCID $_{50}$/mL
Respiratory Syncytial Virus A.	$1{,}0\times10^5$ PFU/mL
Staphylococcus aureus	$1{,}0\times10^6$ org/mL
Streptococcus pneumonia	$1{,}0\times10^6$ Zellen/mL

3. Cross reactivity

Pathogens	Concentration
Human coronavirus 229E	$1{,}0\times10^6$ pfu / ml
Human coronavirus OC43	$1{,}0\times10^6$ pfu / ml
Human coronavirus NL63	$1{,}0\times10^6$ pfu / ml
MERS coronavirus	$1{,}0\times10^6$ pfu / ml
Respiratory syncytial virus	$1{,}0\times10^6$ pfu / ml
Adenovirus	$1{,}0\times10^6$ pfu / ml
Influenza A H1N1	$1{,}0\times10^6$ pfu / ml
Influenza B	$1{,}0\times10^6$ pfu / ml

The cross-reactivity of the Babio SARS-CoV-2 Antigen Rapid Detection Kit with a total of 8 viruses was investigated. None of the microorganisms tested in the following table gave a positive result at the stated concentration.

LIMITATIONS OF TEST

1. This product is for qualitative assessment of SARS-CoV-2 antigen only.

2. Results from antigens testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status. The diagnosis should be confirmed in combination with clinical symptoms or other conventional testing methods.

3. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

4. A negative or non-reactive result can occur if the quantity of antigen for the SARS-CoV-2 virus present in the specimen is below the detection limit of the assay.

5.This test can detect SARS-CoV-2 no matter the virus is viable or non-viable. Test performance depends on the amount of virus (antigen) in the sample ， but it does not necessarily correlate to SARS-CoV-2 antigen titer in the specimen.

6.A negative test result may occur if the level of antigen is below the detection limit or if the sample was collected or transported improperly.

7.Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.

8. If the test result is positive, self-isolation should be done; if the test result is negative, protection should also be done to minimize going out

REFERENCES

1. Chaolin Huang, Yeming Wang, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. The Lancet.2020;VOL395:497-506.
2. Zhu N, Zhang D, Wang W, Li X, Yang B, Song J, et al. A Novel Coronavirus from Patients with Pneumonia in China, 2019. 24 January 2020. New England Journal of Medicine.
3. Lamarre A, Talbot PJ. Effect of pH and temperature on the infectivity of human coronavirus 229E. Canadian Journal of Microbiology. 1989;35(10):972-4.
4. Wang C, Horby PW, Hayden FG, Gao GF. A novel coronavirus outbreak of global health concern. The Lancet. 24 January 2020.

Symbols

	Manufacturer		Date of manufacture
EC REP	Authorised Representative in the European community		Use by
	Caution	LOT	Batch code
	Do not reuse		Keep dry
	Do not use if package is damaged	Σ	Total number of tests
	instructions for use	IVD	in vitro diagnostic
CE	CE mark		Temperature limit

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