BALLYA®
璞雅生物

Covid 19 Antigen Rapid Test

(Immunochromatography)

(Saliva)

For in vitro diagnostic use only.

Cat. No.: CAG-19 / CAG-20

Package: 1T, 5T

PRODUCT NAME

COVID-19 Antigen Rapid Test

INTENDED USE

The test kit is used for the qualitative detection of novel coronavirus (SARS-CoV-2) antigen in sample, only for in vitro diagnostic use. The novel coronaviruses belong to the β genus.

SARS-CoV-2 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 is generally detectable in upper respiratory specimens during the acute phase of infection. Rapid diagnosis of SARS-CoV-2 infection will help healthcare professionals to treat patients and control the disease more efficiently and effectively.

PRINCIPLE

This kit is based on the principle of highly specific antibody-antigen reaction and colloidal gold labeling immunochromatographic analysis technology. The reagent contains SARS-CoV-2 monoclonal antibody prefixed in the test area (T) on the membrane and the SARS-CoV-2 monoclonal antibody coated on the label pad-colloidal gold mixture. The sample is dripped into the sample well and reacts with the SARS-CoV-2 monoclonal antibody which is bound to the pre-coated colloidal gold particles when testing. Then the mixture is chromatographed upwards with capillary effects. If it is positive, the antibody labeled by colloidal gold particles will first bind to the SARS-CoV-2 virus in the sample during chromatography. Then the conjugates are bound by the SARS-CoV-2 monoclonal antibody fixed on the membrane, and a red line appears in the test area (T). If it is negative, there's no red line in the test area (T). Whether the sample contains SARS-CoV-2 antigen or not, a red line will appear in the quality control area (C). The red line appearing in the quality control area (C) is the standard for judging whether there are enough samples and whether the chromatographic process is normal, and it also serves as the internal control standard for the reagent.

COMPONENTS

Components of the test strip in the cassette: Sample pad: contains buffered salts and detergents. Label pad: contains gold-labeled mouse anti-SARS-CoV-2 monoclonal antibody. Nitrocellulose membrane: Control area: contains Goat anti-mouse IgG polyclonal antibody and buffer. Test area: contains mouse anti-SARS-CoV-2 monoclonal antibody and buffer. Absorbent pad: made of highly absorbent paper.

MATERIALS SUPPLIED

Test Cassette
Extraction Tube
Saliva Collection Pouch
Extraction Buffer Solution
Instruction For Use

MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Gloves

WARNINGS AND PRECAUTIONS

1. This product is a single-use in vitro diagnostic reagent. Do not reuse it. Do not use it if it is expired.
2. Each component of the kit cannot be used in batches.
3. The positive result obtained by using this kit needs further confirmation by other methods.
4. Excessive temperature of the experimental environment should be avoided. The reaction temperature should be 10~30℃, and the reaction humidity should be less than 60%. The test cassette stored at low temperature should be equilibrated to room temperature before opening to avoid moisture absorption.
5. The intensity of the color of the test line is not necessarily related to the concentration of the antigen in the sample, and the result interpreted after 15 minutes is invalid.
6. It is recommended to use fresh samples, do not use repeatedly freeze-thaw samples.
7. Avoid cross-contamination of samples by using a new plastic cup and pipette dropper for each sample.
8. The components of the kit and the waste produced by the test are treated as infectious pollutants.
9. For clinical reference only, and cannot be used as a basis for confirming or excluding cases alone.

STORAGE AND SHELF LIFE AFTER FIRST OPENING

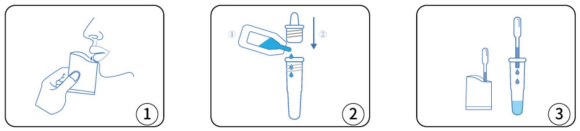
1. Store at 2℃ to 30℃ in the sealed pouch up to the expiration date (24 months).
2. Keep away from sunlight, moisture and heat.
3. DO NOT FREEZE.
4. When the humidity is below 60%, use it within 1 hour after opening. When the humidity is above 60%, use it immediately after opening. Production date, expiry date will be in the label.

SAMPLE COLLECTION

The test kit can be performed using saliva specimen. Testing should be performed immediately after specimen collection, or at most within one (1) hour after specimen collection, if stored at room temperature (15-30℃).

Collect Procedure:

1. Before collecting saliva, relax your cheeks and massage them gently with your fingers for 15-30 seconds, spit saliva gently in the collection pouch.
2. Transfer extraction buffer solution into extraction tube.
3. Transfer saliva into extraction tube
4. Shake extraction tube 10 second



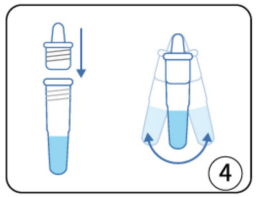
TEST PROCEDURE

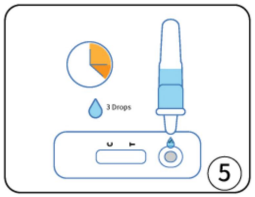
Detection operations

(1) Bring the sample, test kit and other controls to recover to room temperature prior to testing.
(2) Open a pouch containing a test cassette. Place the test cassette on a dry, horizontal work surface.
(3) Hold the dropper vertically and transfer 3 drops

of specimen to the sample well of the test cassette.

(4) Observe the results showed within 10-15 minutes, and the results showed after 15 minutes have no clinical significance.



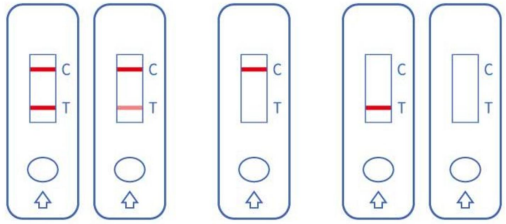


INTERPRETATION OF RESULTS

Negative : Only a red line appears in the quality control area (C), and no line appears in the test area (T).

Positive : Two red lines appear. One is in the test area (T) and the other is in the quality control area (C).

Invalid : No red line displays in the quality control area (C). This indicates that the incorrect operation or the test cassette has deteriorated or damaged. Repeat the test with a new kit. If the problem persists, stop using this lot number immediately and contact your local supplier.



***Note**: Invalid samples should be treated as infectious pollutants, and samples should be collected again.*

CONTROL PROCEDURE

The test kit has its own built-in quality control indicator. After performing the test and no line in the Control area (C) of the reaction membrane is visible, the sample has not been added correctly or the test may have deteriorated.

LIMITATIONS

1. This kit is only for the detection of SARS-CoV-2 antigen in human.
2. The accuracy of the test depends on the sample collection, handing, storage and operation procedure. Improper sample collection, improper storage of samples, unfresh samples, or repeated freeze-thaw cycles of samples will affect the test results.
3. The test cassette only provides qualitative detection of the SARS-COV-2 in the sample. If you need to detect the specific content of an indicator, please use the relevant professional instruments.
4. The test result of this kit is for clinical reference only and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests, and treatment responses.
5. Due to the limitation of the method of antigen detection reagents, its analytical sensitivity is generally lower than that of nucleic acid reagents. Therefore, the experimenters should pay more attention to the negative results and need to make a comprehensive judgment in combination with other test results. It is recommended to review the suspicious negative results by using nucleic acid detection or virus culture identification methods.
6. Analysis of the possibility of false negative results:

①Unreasonable sample collection, transportation and processing, and too low concentration of tested substances in samples may lead to false

negative results.

②Genetic variations of virus can cause changes in antigenic determinants, which can lead to false negative results. This is more likely to occur by using monoclonal antibody reagents.

③The optimal sample type and sampling time (peak virus titer) after infection have not been verified, so collecting samples fractionally, in multiple parts on the same patient may avoid false negative results.

PERFORMANCE CHARACTERISTICS

Clinical performance

A total of 301 speichel samples included 118 positive samples and 183 negative samples. All samples were compared with ABI 7500 real-time PCR detection results, with BGI Europe A/S and Real-time fluorescent RT-PCR kit for detecting SARS-COV-2.The results are as follows:

Sensitivity 97.46%, 95% confidence interval 92.19% to 99.34%, specificity 99.45%, 95% confidence interval 96.53% to 99.97%, total coincidence rate 98.46%.

Rapid Test	Nucleic Acid Test (PCR)		
	Positive(+)	Negative(-)	Total
Positive(+)	115	1	116
Negative(-)	3	182	185
Total	118	183	301
Sensitivity	937.46% (95% CI:92.19-99.34%)	/	
Specificity	/	99.45% (95% CI:96.53%-99.97%)	
Overal coincidence rate			98.46%

Interfering substances:

The kit is not affected with the substances at the following concentrations

No.	Interference substances	Concentration
1	Mucin	60mg/dL
2	Whole blood	20%(v/v)
3	Phenylephrine	2mg/mL
4	Oxymetazoline	2mg/mL
5	Sodium chloride (with preservative)	0.1%
6	Beclomethasone	20mg/mL
7	Dexamethasone	20mg/mL
8	Flunisolide	20μg/mL
9	Triamcinolone acetonide	2mg/mL
10	Budesonide 2mg/mL 23 Ceftriaxone	40μg/mL
11	Mometasone	2mg/mL
12	Fluticasone	2mg/mL
13	Zanamivir	20mg/mL
14	Peramivir	1mg/mL
15	Lopinavir	500mg/mL
16	Ritonavir	60mg/mL
17	Interferon-α	800IU/mL
18	Ribavirin	10mg/mL
19	Oseltamivir	60ng/mL
20	Arbidol	700ng/mL
21	Levofloxacin	10μg/mL
22	Azithromycin	1mg/L
23	Ceftriaxone	40μg/mL
24	Meropenem	200mg/mL
25	Tobramycin	0.6mg/mL
26	Histamine dihydrochloride	5mg/mL

Cross reactivity:

There is no cross-reaction with pathogens at the following concentrations.

No.	Phathogen	Concentration
1	HCoV-HKU1	$1.5x10^6$copies/mL
2	HCoV-OC43	$1.1x10^6$copies/mL
3	HCoV-NL63	$1.0x10^6$copies/mL
4	HCoV-229E	$3.8x10^6$copies/mL
5	Novel influenza A(h1n1) virus(2009)	$1.8x10^7$copies/mL
6	Seasonal h1n1 influenza virus	$8x10^7$copies/mL
7	Influenza A virus(h3n2)	$1.2x10^7$copies/mL

8	Influenza A virus(h5n1)	10^6copies/mL
9	Influenza A virus(h7n9)	10^6copies/mL
10	Influenza B (yamagata)	$2.8x10^7$copies/mL
11	Influenza B (victoria)	$2.0x10^7$copies/mL
12	Respiratory syncytial virus type A	10^6copies/mL
13	Respiratory syncytial virus type B	$1.2x10^6TCID_{50}$/mL
14	Parainfluenza virus type 1	10^6copies/mL
15	Parainfluenza virus type 2	10^6copies/mL
16	Parainfluenza virus type 3	10^6copies/mL
17	Rhinovirus A	10^6copies/mL
18	Rhinovirus B	10^6copies/mL
19	Rhinovirus C	10^6copies/mL
20	Adenovirus 1	10^6copies/mL
21	Adenovirus 2	10^6copies/mL
22	Adenovirus 3	10^6copies/mL
23	Adenovirus 4	10^6copies/mL
24	Adenovirus 5	10^6copies/mL
25	Adenovirus 7	10^6copies/mL
26	Adenovirus 55	10^6copies/mL
27	Human metapneumovirus	10^6copies/mL
28	Enterovirus A	10^6copies/mL
29	Enterovirus B	10^6copies/mL
30	Enterovirus C	10^6copies/mL
31	Enterovirus D	10^6copies/mL
32	EB virus	10^6copies/mL
33	Measls virus	10^6copies/mL
34	Human cytomegalovirus	10^6copies/mL
35	Rotavirus	10^6copies/mL
36	Norovirus	10^6copies/mL
37	Mumps virus	10^6copies/mL
38	Herpes zoster virus	10^6copies/mL
39	Mycoplasma pneumoniae	10^6CFU/mL

Repeatability and Reproducibility

Tests showed positive results with all positive samples and showed negative results with negative samples. There was no significant difference observed to the same sample when repeatedly testing 10 tests in the same batch. No appreciable intra and inter lot variation were observed among different tests for each lot, different lots, different operators at different test sites in different time for the same sample. The results demonstrated that the repeatability and reproducibility of SARS-CoV-2 Antigen Rapid Test are satisfactory.

INDEX OF SYMBOL

Do not re-use	IVD In vitro diagnostic medical device
Store between 4-30°C	Consult instructions for use
Caution	LOT Batch Code
Use-by date	Contains sufficient for <n> tests
Keep away from sunlight	Keep dry
Manufacturer	Do not use if package is damaged
Date of manufacture	CE Mark

EC REP Authorized representative in the European Community

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EC REP

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