BioTeke

SARS-CoV-2 Antigen Test Kit (colloidal gold method)

IVD CE

User Instruction Manual

PRODUCT NAME

SARS-CoV-2 Antigen Test Kit (colloidal gold method)

PACKAGE SPECIFICATION

1 Test/Kit; 3 Tests/Kit; 5 Tests/Kit; 20 Tests/Kit; 50 Tests/Kit

INTENDED USE

This kit is only used for the in vitro qualitative detection of SARS-CoV-2 antigen from human nasopharyngeal swabs specimens. SARS-CoV-2 Antigen Test Kit (colloidal gold method) is an immunochromatographic double-antibody sandwich assay intended for the qualitative detection of nucleocapsid protein antigen of SARS-CoV-2 from individuals who are suspected of COVID-19 by their healthcare provider within the first 7 days of symptom onset to suspect COVID-19 infection. This kit is suitable for the auxiliary diagnosis of COVID-19, the results are for clinical reference only and cannot be used as the sole basis for diagnosis and exclusion decision. The clinical diagnosis and treatment of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment responses. Positive test result needs to be further confirmed, negative result does not preclude SARS-CoV-2 infection. This kit is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of in vitro diagnostic procedures.

TEST PRINCIPLE

The kit is immunochromatographic and uses double-antibody sandwich method to detect SARS-CoV-2 antigen. During detection, the treated specimens are loaded into the sample wells of the test card. When the concentration of SARS-CoV-2 antigen in specimen is higher than the minimum detection limit, the viral antigen will form complexes with labeled antibodies first. Under chromatography, the complexes move forward along the nitrocellulose membrane till captured by pre-coated monoclonal antibody of SARS-CoV-2 in detection zone on nitrocellulose film (T) to form a pink/purple reaction line on the detection zone, at this point the result is positive; conversely, if there is no viral antigen or the concentration of antigen in specimen is below the minimum detection limit, no pink/purple reaction line appears in the detection zone, at this point the result is negative. Regardless of whether the sample contains viral antigens or not, a pink/purple reaction line will appear in the quality control zone (C), the pink/purple reaction line that appears in the quality control zone (C) is the criterion for determining if the chromatography process is normal.

MATERIALS PROVIDED

The test kit consists of test card, sample diluent, sample extraction tube and nasopharyngeal swab.

Components	Main Ingredients	Loading quantity (Specification)				
		1 Test/Kit	3Tests/Kit	5 Tests/Kit	20 Tests/Kit	50 Tests/Kit
Test card	Test strip containing SARS-CoV-2 monoclonal antibody, Anti-mouse IgG polyclonal antibody	1 pc	3 pcs	5 pcs	20 pcs	50 pcs
Sample diluent		0.5mL	0.5mL*3	0.5mL*5	0.5mL*20	0.5mL*50
Sample extraction tube		1 pc	3 pcs	5 pcs	20 pcs	50 pcs
Nasopharyngeal swab		1 pc	3 pcs	5 pcs	20 pcs	50 pcs

Note:

1. Test cards are sealed together with desiccant in aluminum foil pouch.

2. Do not mix use different batches of test cards and sample diluent.

STORAGE CONDITIONS AND SHELF LIFE

The test card and sample diluent should be stored at 2°C~30°C, valid for 18 months. Test cards should be used as soon as possible within 1 hour after opening the foil pouch. The bottle of sample diluent should be capped immediately after use and stored at 2°C~30°C, please use it within the validity period.

Date of manufacture and expiration: See package label for details.

SPECIMEN REQUIREMENTS

	Nasopharyngeal swab collection: Ask the patient to keep the head still to remove surface secretions from the anterior nasal foramen; Gently and slowly insert the swab through the nasal cavity to the nasopharynx, it reaches the posterior nasopharynx when resistance is encountered. Remain for several seconds to aspirate secretions; remove the swab with gentle rotation.

It is recommended that specimens be treated with the sample diluent provided with the kit as soon as possible after collection. If immediate processing is not possible, the specimen can be stored in a dry, sterilized and tightly sealed plastic tube at 2℃~8℃ for up to 8 hours, and -70 °C for long-term storage.

TEST PROCEDURE

Please read the instruction manual seriously before testing. If the reagents in kit are stored in refrigerator, please take them out and leave them at room temperature before testing. The test should be done at room temperature.

I. Specimen extraction (see Figure 1).

1. Add all of sample diluent vertically to the sample extraction tube.

2. Insert the sampled swab into the sample diluent in the sample extraction tube, squeeze the villi part of the swab in the tube through the outer wall of the tube by finger 5 times to dissolve the potential viral antigen into solution from swab as much as possible, then remove and discard the swab.

3. Cover the dropper lid on the sample extraction tube after step 2.

II. Testing procedures (see Figure 1).

1. Remove the test card by opening the aluminum foil pouch from tear notch and lay it flat.

2. Add 3 drops (approximately 80μL) of the treated specimen into the sample well of the test card.

3. Please read the chromogenic results in the detection zone between 15~20 minutes to ensure proper test performance. Do not read results after 30 minutes. Results read after 30 minutes are invalid.

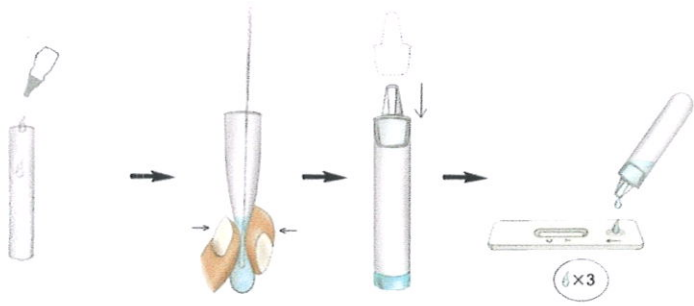


Figure 1

INTERPRETATION OF TEST RESULTS

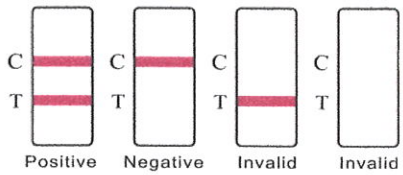


Figure 2

1. This kit contains quality control process, when the pink/purple reaction line appears in the C zone, it indicates the correct and effective operation. C line is the prerequisites to see if the test is valid. If the C line does not show color, regardless of whether the T line shows color or not, the test is invalid, and it is recommended to retest.

2. The detection results of the kit are interpreted according to the following table.

C Line	T Line	Result
Pink/purple	Pink/purple	Positive
Pink/purple	Colorless	Negative
Colorless	Whether color is visible or not	Invalid test, retest

LIMITATIONS OF THE TEST

1. The test results of this kit are only for the reference of clinicians and should not be used as the sole basis for clinical diagnosis and treatment. Clinical management of patients should be considered in the context of their symptoms/signs, medical history, other laboratory tests and response to treatment.

2. Sample collection and sample processing have a greater impact on the detection of pathogens, and a negative test result does not exclude the possibility of a viral infection.

3. Due to methodological limitations of antigen-based test, the analytical sensitivity of immunochromatographic method is generally lower than that of nucleic acid-based test. Therefore, the test provider should pay more attention to the negative results and make a comprehensive judgment based on other test results. It is suggested that the negative results in suspected patients should be checked by nucleic acid test or virus culture identification.

4. When the result of test kit is positive, it is recommended to combine the results of other methods (such as PCR and CT imaging) for further confirmation, and consult with local public health prevention institutions for treatment.

5. Analysis of the likelihood of false-negative results.

(i) Improper sample collection, transport and processing, and low viral titers in the sample may lead to false negative results.

(ii) The optimal sample type and the optimal sampling time after infection (peak viral titer) have not been validated, therefore, multiple sampling at multiple sites in the same patient may avoid false negatives.

PERFORMANCE CHARACTERISTICS

1. The width of the membrane strip of this kit is not less than 2.5 mm, and the liquid migration speed is not less than 10 mm/min.

2. Negative/positive reference coincidence rate

All the positive references are positive for the corresponding pathogens, which is consistent with the known results of the reference; all the negative references are negative for the corresponding pathogen.

3. Repeatability

Repeated testing was conducted for national or enterprise repeatable reference products for 10 times. The test results were consistent with the known results of the reference products and were uniform in color.

4. Limit of Detection (LoD)

The Limit of Detection (LoD) of SARS-CoV-2 Antigen Test Kit (colloidal gold method) is $1.75x10^2$ $TCID_{50}$/mL.

5. Analytical specificity

1) Sensitivity and Specificity

The SARS-CoV-2 Antigen Test Kit (colloidal gold method) was compared with the PCR Comparator Method.

Bioteke reagent	PCR reagent		Total
	Positive	Negative	
Positive	110	2	112
Negative	4	276	280
Total	114	278	392

Clinical sensitivity = 96.49% (95%CI: 91.26%～99.04%)

Clinical specificity = 99.28% (95%CI: 97.43%～99.91%)

Accuracy = 98.47% (95%CI: 96.70%～99.44%)

Kappa value = 0.9627

2) Cross-reactivity

There is no cross-reactivity with the following pathogens: There is no cross-reactivity with the following pathogens: Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, MERS-coronavirus, SARS-coronavirus, Human coronavirus HKU1, Respiratory adenovirus type 1, Respiratory adenovirus type 2, Respiratory adenovirus type 3, Respiratory adenovirus type 4, Respiratory adenovirus type 5, Respiratory adenovirus type 7, Respiratory adenovirus type 55, Human Metapneumovirus (hMPV), Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Influenza A virus 2009H1N1, Influenza A virus seasonal H1N1, Influenza A virus H3N2, Influenza B virus Yamagata, Influenza B virus Victoria, Enterovirus 71, Respiratory syncytial virus Rhinovirus, Haemophilus influenza, Streptococcus pneumonia, Streptococcus pyogenes, Candida albicans, Pooled human nasal wash – representative of normal respiratory microbial flora, Bordetella pertussis, Mycoplasma pneumonia, Chlamydia pneumonia, Legionella pneumophila, Staphylococcus aureus, Staphylococcus epidermidis, Mycobacterium tuberculosis, Pneumocystis jirovecii (PJP), Measles virus, Human cytomegalovirus, Rotavirus, Norovirus, Mumps virus and Varicella zoster virus.

Pathogens likely to cross react with the test kit	***Strain***	***Source/ Sample type***
Human coronavirus 229E	*ATCC VR-740, 229E*	*Virus cultures*
Human coronavirus OC43	*ATCC VR-1558, OC43*	*Virus cultures*
Human coronavirus NL63	*BELRESOURCES NR-470*	*Virus cultures*
MERS-coronavirus	*Synthesis*	*Pseudovirus*
SARS-coronavirus	*Synthesis*	*Pseudovirus*
Human coronavirus HKU1	*GZ/1804-138*	*Virus cultures*

Respiratory adenovirus type 1	*ADV1/GZ/Hecin1 608-21*	*Virus cultures*
Respiratory adenovirus type 2	*ADV1/GZ/Hecin1 609-42/2016*	*Virus cultures*
Respiratory adenovirus type 3	*ADV11/GZ/Hecin 1608-21*	*Virus cultures*
Respiratory adenovirus type 4	*ATCC VR-1572*	*Virus cultures*
Respiratory adenovirus type 5	*ADV3/GZ/1609-2*	*Virus cultures*
Respiratory adenovirus type 7	*ATCC VR-7*	*Virus cultures*
Respiratory adenovirus type 55	*ADV55/GZ/1612-129*	*Virus cultures*
Human Metapneumovirus (hMPV)	*GZ/1803-107*	*Virus cultures*
Parainfluenza virus 1	*PIV1/Guangzhou/ 0701/2011*	*Virus cultures*
Parainfluenza virus 2	*ATCC VR-92, Greer*	*Virus cultures*
Parainfluenza virus 3	*PIV3/Guangzhou/ 0902/2012*	*Virus cultures*
Parainfluenza virus 4	*ATCC VR-1378, M-25*	*Virus cultures*
Influenza A virus 2009H1N1	*A/GZ/GIRD02/2009(2009H1N1)*	*Virus cultures*
Influenza A virus seasonal H1N1	*A/PR/8/34(H1N1)*	*Virus cultures*
Influenza A virus H3N2	*A/Aichi/2/68(H3N2)*	*Virus cultures*
Influenza B virus Yamagata	*B/Guangzhou/GIRD06/09(Yamagata)*	*Virus cultures*
Influenza B virus Victoria	*B/Guangzhou/GIRD08/09(Victoria)*	*Virus cultures*
Enterovirus 71	*EV71/Guangzhou/ 0401/2011*	*Virus cultures*
Respiratory syncytial virus	*RSVA/GZ/Hecin17*	*Virus cultures*

	05-74	
Rhinovirus	*A30/GZ/1710-89*	*Virus cultures*
Haemophilus influenzae	*GIM 1.961*	*Virus cultures*
Streptococcus pneumoniae	*GIM 1.550*	*Virus cultures*
Streptococcus pyogenes	*GDM1.546*	*Virus cultures*
Candida albicans	*FSCC 129002*	*Virus cultures*
Pooled human nasal wash – representative of normal respiratory microbial flora	*Clinical specimen*	*Clinical specimen*
Bordetella pertussis	*GDM 1.952*	*Virus cultures*
Mycoplasma pneumoniae	*ATCC 15531*	*Virus cultures*
Chlamydia pneumoniae	*ATCC VR-2282, TW-183*	*Virus cultures*
Legionella pneumophila	*GIM 1.840*	*Virus cultures*
Staphylococcus aureus	*FSCC 223005*	*Virus cultures*
Staphylococcus epidermidis	*GIM 1.143*	*Virus cultures*
Mycobacterium tuberculosis	/	/
Pneumocystis jirovecii (PJP)	/	/
Measles virus	*RA27/3*	*Virus cultures*
Human cytomegalovirus	*RC256*	*Virus cultures*
Rotavirus	*ATCC VR2018*	*Virus cultures*
Norovirus	*ATCC VR-3234SD*	*Virus cultures*
Mumps virus	*Jones*	*Virus cultures*
Varicella zoster virus	*CCTCC VR-1367*	*Virus cultures*

3) Interfering substance: Human blood and mucins will not interfere with the results of the kit. The following common drugs will not interfere with the results of the kit: Oxymetazoline, Dexamethasone, Flunisolide, Sulphur, Kim Anh, Benzocaine, Zanamivir, Mupirocin, Tobramycin, Kalii Dehydrographolidi Succinas, Aspirin (enteric-coated tablets), Ibuprofen (granules), Acetaminophen (slow-release tablets) and Nimesulide Tablets.

Interfering substance	***Test***

		concentration
Mucins		1%
Human blood		5%
Nasal spray	Oxymetazoline	1.125mg/mL
Nasal corticosteroids	Dexamethasone	0.009mg/mL
	Flunisolide	0.75mg/mL
Zicam Cold Remedy Nasal Gel	Sulphur	335mg/mL
Allergic symptom relief drug	Kim Anh	4.5mg/mL
Oral anesthetic	Benzocaine	1.875mg/mL
Antiviral drug	Zanamivir,	75mg/mL
Antibiotics, nasal ointments	Mupirocin	33.5mg/mL
Systemic antibiotics	Tobramycin	0.3mg/mL
Immune system medication	Kalii Dehydrographolidi Succinas	3.8mg/mL
Antipyretic	Aspirin (enteric-coated tablets)	0.04g/L
	Ibuprofen (granules)	0.2g/L
	Acetaminophen (slow-release tablets)	450mg/mL
	Nimesulide Tablets	0.05g/L

4) Hook effect: This kit doesn't have hook effect.

PRECAUTIONS

1. This is a single-use in vitro diagnostic reagent, do not reuse, and do not use expired products.

2. All test specimens must be considered potentially infectious, and during collection, processing, storage, mixing of specimens and testing should be taken appropriate protective measures. Therefore, wear protective measures such as wearing gloves and masks should be done, and dispose of all wastes as potentially biohazardous items. (Used cotton swabs, test cards, extraction tubes, etc., should be decontaminated before disposal and tested for autoclaving.)

3. Use the swab and sample diluent provided with this reagent for sampling, and do not mix use different batches of test cards and sample diluent.

4. Use fresh specimens for testing, do not use repeated freeze-thaw samples.

5. Operate at room temperature. Test cards kept at low temperature should be restored to room temperature before opening to avoid moisture absorption.

6. Do not use reagent kits with obvious damage or test cards with damaged or expired packaging.

7. The aluminum foil pouch contains desiccant and must not be taken orally.

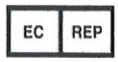
8. Improper sample collection or processing may result in false-negative results.

9. If the initial screen is a positive sample, contact your local public health agency.

10. As with the diagnostic reagents used, the final diagnosis should be made by a physician after combining the various test parameters and clinical symptoms.

11. If you have any questions or suggestions on the use of this kit, please contact the manufacturer.

SYMBOLS

	Date of manufacture		Do not use if package is damaged
	Keep away from sunlight		For *In Vitro* Diagnostic Use
	Keep dry		Consult instructions for use
	Do not re-use		Authorized representative in the European Community
	Manufacturer		Use-by date
	CE mark of conformity		Temperature limit
	Batch code		

BIOTEKE CORPORATION (WUXI) CO., LTD
4th Floor, D5&2nd Floor, D3 & 1st and 2nd Floor, D16, No.1719,
Huishan Avenue, Wuxi, Jiangsu, CN 214174.

SUNGO Europe B.V.
Olympisch Stadion 24,1076 DE Amsterdam ,Netherlands

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