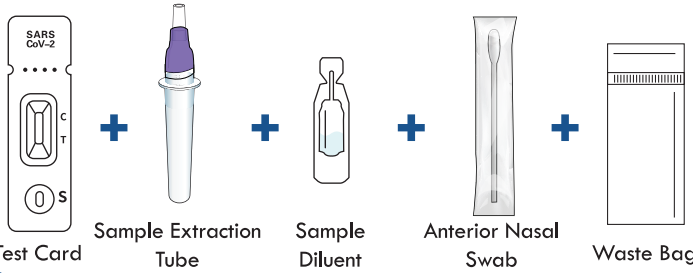
SARS-COV-2 ANTIGEN TEST KIT

BioTeke
USER INSTRUCTION

·1. Read this instruction guide carefully.
·2. Prepare a watch(or a clock/timer), tissues and either hand sanitizer or soap and warm water.
·3. Check the test kit contents. Make sure that nothing is damaged or broken.

-For anterior nasal swabs.
-Please read the instructions carefully before you begin testing.



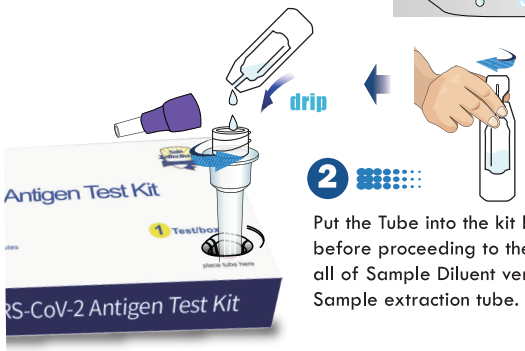
Test Card + Sample Extraction Tube + Sample Diluent + Anterior Nasal Swab + Waste Bag

- Note: Test cards kept at low temperature should be restored to room temperature before opening to avoid moisture absorption.
- Note: Materials required but not provided
  (1) Watch (or a clock/timer),
  (2) Tissues,
  (3) Hand sanitizer / soap.

1

Wash your hands thoroughly for at least 20 seconds before the test.

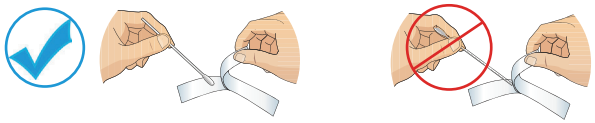
2



Put the Tube into the kit box holder before proceeding to the tube. Add all of Sample Diluent vertically to the Sample extraction tube.

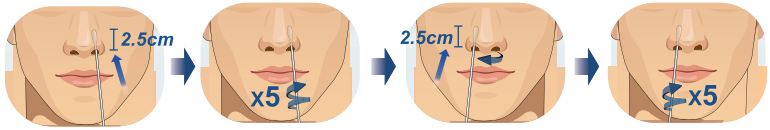
3

NOTE:Please blow your nose before collection.
Remove the swab from its wrapper and take out the swab by holding the handle. Being careful not to touch the fabric tip of the swab with your hands.



4

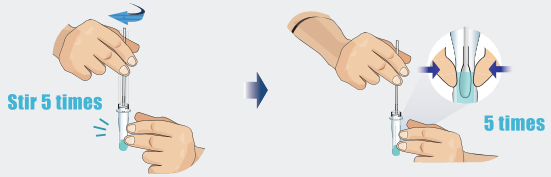
Gently insert the swab into your nostril less than one inch (about 2.5cm). Slowly rub the swab against all of the inside walls of your nostril. Make at least 5 big circles. Do not just spin the swab. Repeat this step in your other nostril using the same swab.



NOTE : With children, the maximum depth of insertion into the nostril may be less than 3/4 inch.

5

Insert the swab into the sample tube. Touch the bottom of the sample tube with the swab tip, and stir at least 5 times. Squeeze the swab in the tube through the outer wall of the tube by finger 5 times.

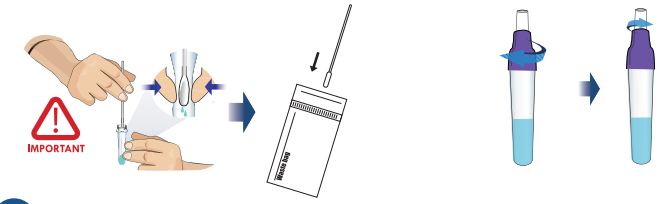


6

Remove the swab by rotating against the sample tube while squeezing the sides of the tube to release the liquid from the swab. Remove and discard the swab into waste bag provided.

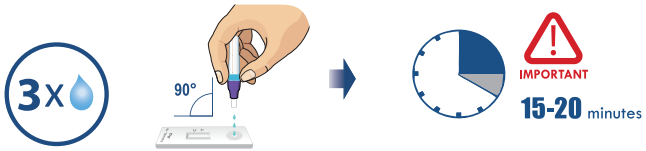
7

Screw the purple tube cap onto the sample tube and then unscrew the top white cap.



8

Open the pouch and take out the Test Card. Place it on a flat, dry and clean surface. Turn the tube integrated dropper cap upside down and slowly squeeze 3 drops onto the sample well of the Test Card.



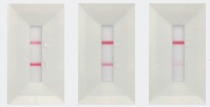
9 Results Interpretation

IMPORTANT

NOTE:
The test results should not be read after 20 minutes.

COVID-19 Detected (Positive)

A positive test result indicates that antigens from COVID-19 were detected, and the patient is very likely to be infected with the virus and presumed to be contagious. Test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. You should contact your doctor/general practitioner or the local health department immediately. Comply with the local guidelines for self-isolation. Carry out a PCR confirmation test.

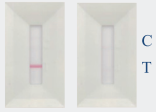


COVID-19 Not Detected (Negative)

A negative test result indicates that antigens from COVID-19 were not detected from the specimen. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19 and confirmed with a molecular assay, if necessary, for patient management.

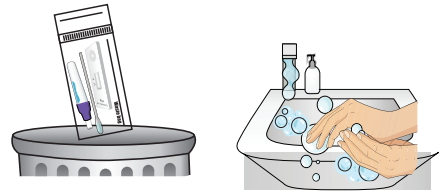
Invalid

Invalid barcode or absence of a purple-colored line next to "C". Re-test with a COVID-19 test may be needed. An invalid test result indicates that your test has experienced an error and is unable to interpret the result of the test. You will need to re-test with a new test. If the test results remain invalid, contact doctor or COVID-19 test center.



10

All used test components should be disposed of in waste bag provided. After completing all steps, wash hands or use hand sanitizer.



BioTeke

USER INSTRUCTION

For anterior nasal swabs, for self-testing

SARS-COV-2 ANTIGEN TEST KIT

PRODUCT NAME

SARS-CoV-2 Antigen Test Kit

PACKAGE SPECIFICATION

1 Test/Kit (REF#,TC1002ST1);
3 Tests/Kit (REF#,TC1002ST3);
5 Tests/Kit (REF#,TC1002ST5)

INTENDED USE

This kit is a lateral flow immunoassay intended for the in vitro qualitative detection of SARS-CoV-2 nucleocapsid protein antigen from human anterior nasal swabs specimens of individuals who are suspected of COVID-19 within the first 7 days of symptom onset. This kit is intended to be used manually by untrained lay users (self testing) in a private setting to aid in the diagnosis of an active SARS-CoV-2 infection. This product is suitable for users over 1 years old. Children between 1-14 years should be supervised by an adult.

TEST PRINCIPLE

The kit is immunochromatographic and uses double-antibody sandwich method to detect SARS-CoV-2 antigen. During detection, the treated samples 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.

MAIN COMPONENTS

Components	Main Ingredients	Loading quantity (Specification)		
		1 Test/Kit	3 Tests/Kit	5 Tests/Kit
Test card	Test strip containing SARS-CoV-2 monoclonal antibody, Anti-mouse IgG polyclonal antibody	1 pc	3pcs	5 pcs
Sample diluent		0.5mL	0.5mL*3	0.5mL*5
Sample extraction tube		1 pc	3pcs	5 pcs
Anterior nasal swab		1 pc	3pcs	5 pcs
Waste bag		1 pc	3pcs	5 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.
3.Information about anterior nasal swab:
Name: Disposable Sterile Sampling Swab
Model: SS001-4 CE mark: CE 2797

STORAGE CONDITIONS AND SHELF LIFE

The test card and sample diluent should be stored at 2°C~30°C, valid for 24 months. Test cards should be used as soon as possible within 1 hour after opening the foil pouch.
Date of manufacture and expiration: See package label for details.

SPECIMEN REQUIREMENTS

Direct swab specimen should be tested immediately after collection.

LIMITATIONS OF THE TEST

1. The accuracy of the test is dependent on the quality of the sample.
2. Improper sampling or contamination, storage, transport and processing, and low viral titers in the sample may lead to false negative results.
3. Remove the swab by rotating against the sample tube while squeezing the sides of the tube is important, and improper progressing may lead to false negative results.
4. Test results can also be affected by temperature and humidity. Test should be performed under environmental temperatures at 10-30°C, with the humidity at 30%~75%.
5. Negative results may be caused by low concentration of SARS-CoV-2 antigens in the sample and therefore cannot completely rule out the possibility of infection.
6. Some medication (e.g. high concentration of over-the-counter (OTC) or prescription medication such as nasal spray) in the collected samples may interfere with the test result. Please perform the test again if the result is in doubt.
7. This product is only for qualitative testing and the specific concentration of each indicator must be measured using other quantitative methodologies.
8. The results of this test are for clinical reference only and should not be the only basis for diagnosis. Results should be used in combination with clinical observations and other testing methods.

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 is $1.25x10^3$ $TCID_{50}$ /mL.
5. Clinical performance
1) Sensitivity and Specificity
The SARS-CoV-2 Antigen Test Kit was compared with the PCR Comparator Method on anterior nasal swab specimens.

Bioteke reagent	PCR reagent		Total
	Positive	Negative	
Positive	216	0	216
Negative	14	906	920
Total	230	906	1136

Clinical sensitivity = 93.91%
(95% CI: 90.00%~96.63%)
Clinical specificity = 100.00%
(95% CI: 99.59%~100.00%)
Accuracy = 98.77%
(95% CI: 97.94%~99.32%)
Kappa value = 0.9610

2) Cross reactivity & Microbial Interference Study
There is no cross-reactivity and microbial interference with the following pathogens:

No.	Virus/ Bacteria/Parasite name	No.	Virus/ Bacteria/Parasite name
1	Coronavirus HKU1	26	Measles virus
2	Coronavirus OC43	27	Human cytomegalovirus
3	Coronavirus NL63	28	Rotavirus
4	Coronavirus 229E	29	Norovirus
5	Influenza A virus 2009H1N1	30	Mumps virus
6	Influenza A virus seasonal H1N1	31	Varicella zoster virus
7	Influenza A virus H3N2	32	Human Parainfluenza virus 1
8	Influenza A virus H5N1	33	Human Parainfluenza virus 2
9	Influenza A virus H7N9	34	Human Parainfluenza virus 3
10	Influenza B virus Yamagata	35	Human Parainfluenza virus 4a
11	Influenza B virus Victoria	36	Human Parainfluenza virus 4b
12	Respiratory syncytial virus A	37	MERS-coronavirus
13	Rhinovirus (group A)	38	Human metapneumovirus (hMPV)
14	Rhinovirus (group B)	39	Mycoplasma pneumoniae
15	Respiratory adenovirus type 1	40	Chlamydia pneumoniae
16	Respiratory adenovirus type 2	41	Haemophilus influenzae
17	Respiratory adenovirus type 3	42	Streptococcus pneumoniae
18	Respiratory adenovirus type 4	43	Streptococcus pyogenes
19	Respiratory adenovirus type 5	44	Pooled human nasal washes
20	Respiratory adenovirus type 7	45	Bordetella pertussis
21	Respiratory adenovirus type 55	46	Legionella pnuemophila
22	Enterovirus (CA16)	47	Staphylococcus aureus
23	Enterovirus (Echo)	48	Staphylococcus epidermidis
24	Enterovirus (EV71)	49	Candida albicans
25	Epstein-barr virus capsid antigen		

3) Interfering substance: The following interfering substances will also not interfere with the results of the kit:

No.	Potential Interfering Substances	Active Ingredient
1	Antiviral drug	α-interferon
2		Zanamivir
3		Ribavirin
4		Oseltamivir
5		Peramivir
6		Lopinavir
7		Ritonavir
8		Arbidol
9	Antibiotic	Levofloxacin
10		Azithromycin
11		Ceftriaxone
12		Meropenem
13	Systemic antibacterial drugs	Tobramycin
14	Mucin	Mucin protein, Type I-S
15	Human blood	
16	Nasal spray	Epinephrine (phenylephrine)
17		Oxymetazoline
18		Sodium chloride (with preservatives)
19		Cromolyn sodium
20	Nasal corticosteroids	Beclomethasone
21		Dexamethasone
22		Flunisolide
23	Nasal corticosteroids	Triamcinolone acetonide
24		Budesonide
25		Mometasone
26		Fluticasone
27	Allergic symptom relief drug	Histamine Hydrochloride
28	Throat tablets, oral anesthetics and analgesics	Menthol
29		Ethyl 4-aminobenzoate
30	Zicam Cold Remedy Nasal Gel	Sulphur
31	Antibiotics, nasal ointment	Mupirocin
32	Naso Gel (NeilMed)	Saline
33	Alkalol	Galphimia glauca, Luffa operculata, Sabadilla
34	Sore Throat Phenol Spray	Phenol

4) Hook effect: No high dose hook effect was observed when testing up to a concentration of 2.5×10^6 $TCID_{50}$ / mL.
5) Usability study

		PCR results		Total
		Positive	Negative	
Self-test results	Positive	50	0	50
	Negative	10	40	50
Total		60	40	100

Statistic	Value	95% CI
Sensitivity	83.33%	83.33% (71.48%~91.71%)
Specificity	100.00%	100.00% (91.19%~100.00%)
Total accuracy	90.00%	90.00% (82.38%~95.10%)

PRECAUTIONS

1. This is a single-use in vitro diagnostic reagent, do not reuse, and do not use expired products.
2. Dispose of all specimens, reaction kits and potentially contaminated materials (i.e. Swab, Tube, Test card) in bag provided.
3. Do not use the aluminium foil bag if it is damaged.
4. Do not open the sealed foil pouch before use and use it as soon as possible after opening the aluminium foil bag.
5. Use fresh specimens for testing, do not use repeated freeze-thaw samples.
6. Operate at room temperature. Test cards kept at low temperature should be restored to room temperature before opening to avoid moisture absorption.
7. Do not use reagent kits with obvious damage or test cards with damaged or expired packaging.
8. The aluminum foil bag contains desiccant and must not be taken orally.
9. Remove the swab by rotating against the sample tube while squeezing the sides of the tube is important, and improper progressing may lead to false negative results.
10. Improper sample collection or processing may result in false-negative results.
11. If the initial screen is a positive sample, contact your local public health agency.
12. As with the diagnostic reagents used, the final diagnosis should be made by a physician after combining the various test parameters and clinical symptoms.
13. If you have any questions or suggestions on the use of this kit, please contact the manufacturer.
14. Detergent, perfume and other substances may contain similar disinfectant ingredients. If exposed to samples collected, it may cause false negative results. Hands should be thoroughly cleaned before sampling.
15. Samples stored for a long time may lead to the decrease of virus content. It may cause false negative results. Please test immediately after sampling.

REFERENCES

1.LY Wang, PR Chen, G W Zheng, et al. Research progress on novel coronavirus test methods. Modern Medicine and Clinic, 2020, 35(3):411-416.
2. K Tugba, W Ralph,L Hakho. Molecular and Immunological Diagnostic Tests of COVID-19: Current Status and Challenges.
Science,2020,23(8): Doi:10.1016/j.isci.2020.101406

SYMBOLS

Date of manufacture
Keep away from sunlight
Manufacturer
Keep dry
Do not re-use
2°C 30°C Temperature limit
IVD *in vitro* diagnostic device
Contains sufficient for <n> test
Use-by date
Consult instructions for use
LOT Batch code
Do not use if package is damaged
CE 1434 CE mark

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