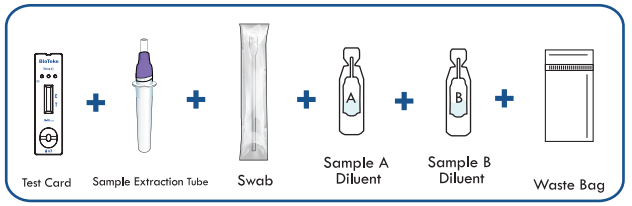
Strep A Antigen Rapid Test Kit

BioTeke
USER INSTRUCTION

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

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

CE IVD

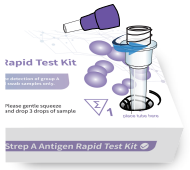


Note: Test cards kept at low temperature should be restored to room temperature before opening to avoid moisture absorption.

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.

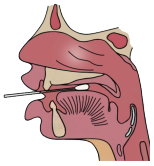
3

Either of the anterior nasal swab collection and the oropharyngeal swab collection can be chosen. Once the collection is complete, the later test steps are the same.
Remove the swab from its wrapper and take out the swab by holding the handle. Do not touch the fabric tip of the swab with your hands.

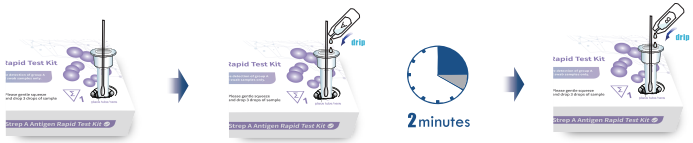
4

Oropharyngeal swabs collection:

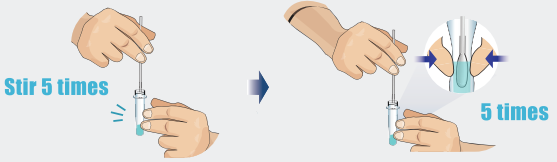
Oropharyngeal swab collection: Insert the swab in the mouth completely into the pharynx, centering on the red swelling of the pharynx wall and upper anterior tonsils. Wipe both sides of pharyngeal tonsils and pharynx posterior wall with moderate force, avoid touching the tongue, and remove the swab.



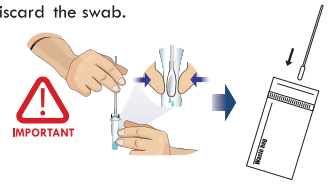
5 Please put the sampling swab into the bottom of the purple dropper, break off the Sample A diluent and add it to the purple dropper first and mix, wait two minutes, then add the Sample B diluent.



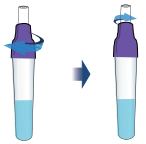
6 Insert the swab into the sample tube. Touch the bottom of the sample tube with the swab tip, and stir at least 5 times. Squeeze the swab in the tube through the outer wall of the tube by fingers 5 times.



7 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.

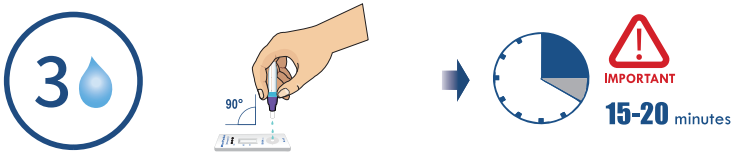


8 Screw the purple tube cap onto the sample tube and then unscrew the top white cap.



9

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 vertically at 90 degrees, gently squeeze to slowly and evenly drip 3 drops of liquid from the dropper into the sample hole of the detection card.
(Note : Improper operation may cause too much or too little liquid to drip into the sample hole, which can affect the detection results.)



10 Results Interpretation

IMPORTANT

NOTE:
The test results should not be read after 30 minutes.

[Positive]

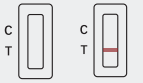
A positive test result indicates that antigens from Group A streptococcus were detected, and the patient is very likely to be infected with the virus and presumed to be contagious.
Note: A positive result means that you are likely to be infected with Group A streptococcus.
Note: Test results should always be interpreted in the context of clinical observations and epidemiological data when making final diagnoses and patient management decisions.

[Negative]

A negative test result indicates that antigens from Group A streptococcus were not detected from the specimen. However, a negative result does not rule out Group A streptococcus 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 Group A streptococcus and confirmed with a molecular assay, if necessary, for patient management.

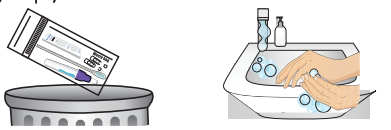
[Invalid]

If any of the control (C) lines do not appear, the test must be interpreted as invalid. An invalid test result means that your test has encountered an error and the results cannot be interpreted You will need to retest using a new test card.



11

All used test components should be disposed of in your household waste. After completing all sampling and testing steps, wash hands or use hand sanitizer.



BioTeke

USER INSTRUCTION

For oropharyngeal swabs.

Strep A Antigen Rapid Test Kit

PRODUCT NAME

Strep A Antigen Rapid Test Kit

PACKAGE SPECIFICATION

1 Test/Kit; 20 Tests/Kit

INTENDED USE

This kit is intended for the in vitro qualitative detection of group A streptococcal antigens in human pharyngeal swab samples only.

TEST PRINCIPLE

The kit is immunochromatographic and uses double-antibody sandwich method to detect Group A streptococcus antigen. During detection, the treated samples are loaded into the sample wells of the test card. When the concentration of Group A streptococcus 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 Group A streptococcus in detection zone on nitrocellulose film (T) to form a pink 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 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 reaction line will appear in the quality control zone (C) ,the pink 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 Extraction Tube , Sample A Diluent , Sample B Diluent , Swab, Waste Bag.

Components	Main Ingredients	Loading quantity (Specification)	
		1 Test/Kit	20 Tests/Kit
Test card	Test strip containing specific Group A Streptococcus monoclonal antibody, Sheep Anti-Rabbit IgG Monoclonal Antibody	1pc	20pcs
Sample Extraction Tube		1pc	20pcs
Sample A Diluent		1pc	20pcs
Sample B Diluent		1pc	20pcs
Swab		1pc	20pcs
Waste Bag		1pc	20pcs

Note:
1. Test cards are sealed together with desiccant in an aluminum foil pouch.
2. Do not use different batches of test cards and sample extraction tubes.

STORAGE CONDITIONS AND SHELF LIFE

The test card and sample extraction tube should be stored at 2°C~30°C, to be valid for 24 months. Test cards should be used as soon as possible (maximum time: within 1 hour) after opening the foil pouch. The bottle of the sample extraction tube should be capped immediately after use and stored at 2°C~30°C. Only use it within the validity period. Date of manufacture and expiration: See package label for details.

SPECIMEN REQUIREMENTS

The swab specimen should be tested immediately after collection.

LIMITATIONS OF THE TEST

1. The test results of this kit can only serves reference for clinicians and should not be used as the sole basis for a clinical diagnosis and treatment. Clinical management of patients should be included the context of their signs and symptoms, their medical historyother laboratory tests, and response to treatment.
2. The quality of the sampling technique and the specimen processing have a greater impact on the detection of pathogens included in this test kit. Thus, 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 tests is generally lower than that of nucleic acid-based test. Therefore, any test interpretation should pay high attention to negative results and make a comprehensive judgment based on other test results. If cinically necessary, negative results in should be checked by nucleic acid test or virus culture identification.
4. When the test result is positive, it is recommended to apply other methods such as PCR or viral culture for further confirmation if clinically relevant. if necessary or mandated by authorities, please also consult with your local public health office appropriate action.
5. Secifically, false-negative results may occur, if:
(i) Improper sample collection, transport and processing, or low viral titers in the sample.
(ii) samples were taken too early or too late after infection, so that peak viral titers were missed. Multiple samplings at multiple sites in the same patient may help avoid false negative results.efore, 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. Analytical specificity
1) Clinical study

Streptococus Pneumoniae		QIAstat-Dx Respiratory SARS-CoV-2 Panel		Total
		Positive	Negative	
Strep A Antigen Rapid Test Kit	Positive	96	0	96
	Negative	7	99	106
Total		103	99	202

Statistic	Value	95%CI
Sensitivity	93.20%	(86.50%~97.22%)
Specificity	100.00%	(96.34%~100.00%)
Total coincidence rate	96.53%	(92.99%~98.60%)

2) Cross-reactivity
There is no cross-reactivity with the following pathogens:

No.	Virus/ Bacteria name	Strain	Concentration / CT value
1	Coronavirus HKU I	GZ/1804-138	CT: 23
2	Coronavirus OC43	VR-1558, OC43	4.2×10^5 $TCID_{50}$/mL
3	Coronavirus NL63	NL63	1.6×10^3 $TCID_{50}$/mL
4	Coronavirus 229E	229E/GZ/1801-3	5.6×10^6 $TCID_{50}$/mL
5	Rhinovirus (group A)	A30/GZ/1710-89	4.2×10^6 $TCID_{50}$/mL
6	Rhinovirus (group B)	70/F02-2547	1.0×10^6 $TCID_{50}$/mL
7	Enterovirus (CA16)	CA16 /Guangzhou/0302/2011	1.8×10^7 $TCID_{50}$/mL
8	Enterovirus (Echo)	ATCC VR-39, HILL	1.0×10^6 $TCID_{50}$/mL
9	Enterovirus (EV71)	EV71/Guangzhou/0402/2012	5.6×10^6 $TCID_{50}$/mL
10	Epstein-barr virus capsid antigen	B95-8	CT: 17
11	Measles virus	Edmonston	1.0×10^7 $TCID_{50}$/mL
12	Human cytomegalovirus	RC256	3.2×10^3 $TCID_{50}$/mL
13	Rotavirus	VR-2018	CT: 20
14	Norovirus	ATCC VR-3234SD	3.6×10^5 Copies/mL
15	Mumps virus	Jones	1.0×10^7 $TCID_{50}$/mL
16	Varicella zoster virus	VR-1367	CT: 13
17	MERS-coronavirus	EMC/2012	1.6×10^5 $TCID_{50}$/mL
18	Human metapneumovirus	GZ/1803-107	1.0×10^5 $TCID_{50}$/mL
19	Haemophilus influenzae	GIM 1.961.	4.8×10^7 CFU/mL
20	Chlamydia pneumoniae	ATTC VRJ-2282, TW183	4.2×10^2 $TCID_{50}$/mL
21	Streptococcus pyogenes	ATCC 19615	1.6×10^8 CFU/mL
22	Pooled human pharyngeal washes	N/A	100%
23	Bordetella pertussis	GDM 1.952	2.6×10^9 CFU/mL
24	Legionella pnuemophila	Philadelphial, Brenner	1.9×10^6 CFU/mL
25	Staphylococcusaureus aureus	CMCC(B) 26003	2.6×10^9 CFU/mL
26	Staphylococcus epidermidis	191 (Winslow and Winslow) Evans	$7.7x10^5$ CFU/mL
27	Candida albicans	CMCC(F) 129002	$1.3x10^8$ CFU/mL
28	Streptococcus pneumoniae	(Klein) Chester	1.0×10^6 CFU/mL
29	Influenza A virus 2009HIN1	L19-A1/Si chuan/ SWL1/2009	4.2×10^6 $TCID_{50}$/mL
30	Influenza A virus seasonal HINI	L6-A1/ Liaoning huanggu /1183/2007	5.6×10^5 $TCID_{50}$/mL
31	Influenza A virus H3N2	L8-A3/ Brisbane/10/2007	1.0×10^6 $TCID_{50}$/mL
32	Influenza A virus H5N1	A/Chicken/Liaoning/ SD007/2017(H5N1)	CT: 20
33	Influenza A virus H7N9	A/Guangd/17SF003 /2016(H7N9)	CT: 20
34	Influenza B virus Yamagata	GZ/174/201803	5.6×10^6 $TCID_{50}$/mL
35	Influenza B virus Victoria	GZ/133/201712	1.0×10^6 $TCID_{50}$/mL
36	Respiratory syncytial virus A	RSVA/GZ/Hecin1705-74	1.3×10^5 $TCID_{50}$/mL
37	Respiratory adenovirus type I	ADVIIGZ/Hecin1608-21	2.4×10^8 $TCID_{50}$/mL
38	Respiratory adenovirus type 2	GZ/1705-34/2017	5.6×10^6 $TCID_{50}$/mL
39	Respiratory adenovirus type 3	ADV3/GZ/0101/2011	1.0×10^6 $TCID_{50}$/mL
40	Respiratory adenovirus type 4	ADV4/GZ/Hecin 1611-72/2016	5.6×10^5 $TCID_{50}$/mL
41	Respiratory adenovirus type 5	ADV/GZ/1801-54	1.0×10^7 $TCID_{50}$/mL
42	Respiratory adenovirus type 7	ADV7/GZ/1706-198	3.2×10^7 $TCID_{50}$/mL
43	Respiratory adenovirus type 55	ADV55/GZ/1612-129	3.2×10^8 $TCID_{50}$/mL
44	SARS-CoV-2	Wild Type	2.8×10^6 $TCID_{50}$/mL
45	Mycoplasma pneumoniae	ATCC 15531	1.0×10^9 Copies/mL
46	Human Parainfluenza virus 1	PIV1/Guangzhou /07011	1.3×10^7 $TCID_{50}$/mL
47	Human Parainfluenza virus 2	PIV2/GZ/Hecin 171134/2017	5.6×10^7 $TCID_{50}$/mL
48	Human Parainfluenza virus3	PIV3/Guangzhou /0903/2012	3.2×10^5 $TCID_{50}$/mL
49	Human Parainfluenza virus 4a	ATCC VR-1378, M-25	4.5×10^5 $TCID_{50}$/mL
50	Human Parainfluenza virus 4b	ATCC VR-1377, CHI 9503	1.3×10^7 $TCID_{50}$/mL
51	Strep A protein	Culture	8×10^3

3) 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 appropriate protective measures should be applied. For example, gloves and masks should be used as appropriate and waste (like used swabs, test cards, extraction tubes) should be handled as potentially biohazardous items.
3. Use the swab and sample extraction tube provided with this reagent for sampling, and do not use different batches of test cards and sample extraction tubes.
4. Use only fresh specimens for testing, do not use repeated freeze-thawn samples.
5. Operate at room temperature. Test cards kept at lower temperatures should be brought to room temperature before opening to avoid moisture absorption.
6. Do not use reagent kits with obvious damage or after their expiration date.
7. The aluminum foil pouch contains desiccant and must not be ingested .
8. Improper sample collection or processing may result in fals e-negative results.
9. Ensure proper sample loading volume, results may not be valid if too much or too little sample loading volume was applied to the test card.
10. In case of a positive result, please adhere to local rules, regulations and practices for reporting to your local public health agency.
11. For any test result, a final diagnosis should only be made by a physician by combining individual information from the medical history, physical examination, signs and symptoms with other test results, as appropriate.
12. If you have any questions or suggestions on the use of this kit, please contact the manufacturer.
13. For unknown reasons, long-term use of some drugs may lead to false positive results of the test, which are not covered by the interfering substances.
14. If the test result is negative but the patient is still symptomatic or suspected of having an infection, serial testing is recommended over the next few days.

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	LOT Batch code
Consult instructions for use	Do not use if package is damaged
CE CE mark of conformity	

EC REP MedUnion S.L.
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