Wondfo® One Step Strep A Swab Test

Catalog No. W39-C

INTENDED USE

Wondfo One Step Strep A Swab Test is a rapid chromatographic immunoassay intended for use by healthcare professionals and as qualitative screening *in vitro* diagnostic test for detection of group A streptococcal antigen from throat swab specimens. The test is intended for use as an aid in the diagnosis of group A streptococcal infection.

For in vitro diagnostic use only.

SUMMARY

Beta-hemolytic group A streptococcus is the most common cause of upper respiratory infection in human. The most commonly occurring disease is pharyngitis. The highest morbidity rate is found in children. The infection can lead to serious complication, including rheumatic fever and acute glomerulonephritis. Rapid diagnosis and appropriate antibiotic therapy appear to be the best means of preventing these complications. The traditional method of detecting group A streptococcal infection involves 24~48 hours' culture of throat swab specimens or other exudates, confirming beta-hemolysis, and showing susceptibility to bacitracin. This long process of diagnosis often causes physicians to administer therapy without first knowing the etiologic agent involved. Wondfo One Step Strep A Swab Test requires only 12 minutes after collection of the specimen.

PRINCIPLE

Wondfo One Step Strep A Swab Test uses double antibodies sandwich immunoassay for the detection of Group A Streptococcal antigen. The test device consists of plastic housing containing a test strip which has been pre-coated with rabbit anti-Strep A polyclonal antibody on the test band region and goat anti-rabbit antibody on the control band region. When the specimen is added into the test device, the specimen is absorbed into the device by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane.

When the group A streptococcal antigen level in the specimen is at or above the target cutoff (the detection limit of the test), the antigen bound to the antibody-dye conjugate are captured by rabbit anti-Strep A antibody immobilized in the Test Region (T) of the device, and this produces a colored test band that indicates a positive result.

When the group A streptococcal antigen level in the specimen is zero or below the target cut off, there is not a visible colored band in the Test Region (T) of the device. This indicates a negative result.

To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly.

PRECAUTIONS

1. This kit is for in vitro use only. Do not swallow.
2. Do not interchange materials from different product lots.
3. Do not interchange caps among reagents.
4. Do not interchange control solution bottle caps.
5. Do not use test kit beyond the expiration date.
6. Do not use the kit if the pouch is punctured or not well sealed.
7. Discard the test after use. Each test cannot be used more than once.
8. The extraction tube and swab are single use items – do not use with multiple specimens.
9. Reagent A and B are slightly caustic. Avoid contact with eyes, sensitive mucous membranes, cuts, abrasions, etc. If these reagents come in contact with the skin or eyes, flush with a large volume of water.
10. The control solutions contain sodium azide, which, on contact with lead or copper plumbing, may react to form explosive metal azides. Use a large volume of water to flush reagents on disposal.
11. Do not eat, drink or smoke in the area where the specimens and kits are handled.
12. All specimens should be treated as biohazards. Protection glove should be worn when handling the specimen. Wash hands thoroughly afterwards.
13. All specimens and used-devices have infectious risks. The disposal process must follow the local infectious disposal law or laboratory rule.

MATERIAL

Material Provided

1. 40 Individual sealed pouches, each containing:
   ■ Test cassette
   ■ Desiccant pouch
   (The desiccant is for storage purposes only, and is not used in the test procedures.)
2. 40 Extraction tubes
3. 40 Sterile throat swabs
4. 2 Extraction Reagent A (8 mL/bottle): 2.0 M sodium nitrite solution (Warning: R25 Toxic if swallowed)
5. 2 Extraction Reagent B (8 mL/bottle): 0.4 M acetic acid solution
6. Standard controls
   ■ 1 Positive control (1 mL/vial): Extracted (non-infective) group A streptococcus antigen in phosphate buffer containing 0.1% NaN3. (Warning: R22 Harmful if swallowed)
   ■ 1 Negative control (1 mL/vial): Phosphate buffer containing 0.1% NaN3. (Warning: R22 Harmful if swallowed)
7. Leaflet with instructions for use

Material Required But Not Provided

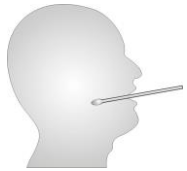
1. Timer

STORAGE AND STABILITY

1. Store at 4ºC~30ºC in the sealed pouch up to the expiration date printed on the package.
2. Keep away from sunlight, moisture and heat.
3. DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

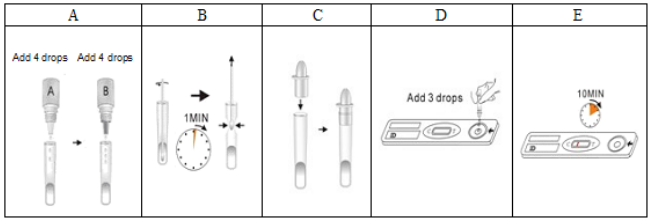
1. Collect the throat swab specimen with the sterile swab that is provided in the kit. Transport swabs containing modified Stuart's or Amies medium can also be used with this product. Swab the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.
2. Testing should be ideally performed immediately after the specimens have been collected. Swab specimens may be stored in a clean, dry plastic tube for up to 8 hours at room temperature or 72 hours at 2°C~8°C.
3. If a culture is desired, lightly roll the swab tip onto a Group A selective (GAS) blood agar plate before using the swab in the Wondfo One Step Strep A Swab Test.



TEST PROCEDURE

Allow the device and extraction reagents to equilibrate to room temperature (10°C~30°C) prior to testing.

1. Add 4 drops (about 200 µL) of extraction reagent A and 4 drops (about 200 µL) of extraction reagent B respectively into the extraction tube and fully mix.
2. Place the specimen extraction swab into the tube. Swirl the swab for ten times. Leave the swab in the tube for one minute. Then remove the swab while squeezing the swab head against the inside of the extraction tube as you remove it to expunge as much liquid as possible from the swab. Discard the swab.
3. Cap the tube and mix contents by gently swirling. **The extraction specimen must be tested immediately.**
4. Remove the test cassette from its sealed foil pouch by tearing at the notch and place it on a clean, dry, level surface. Add 3 drops (about 100 µL) of mixed liquid specimen from the extraction tube to the sample well (with an arrow mark) of the test cassette by inverting and squeezing the tube as shown.
5. Test results must be read at 10 minutes. **Do not read results after 20 minutes.**

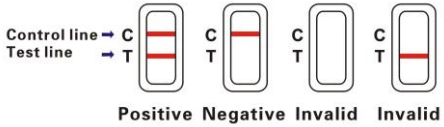


INTERPRETATION OF RESULTS

Positive (+)
Colored bands are visible in both the control region and the test region. It indicates a positive result for Strep A antigen.

Negative (-)
A colored band is visible only in the control region. No color band appears in the test region. It indicates that the concentration of the Strep A antigen is zero or below the detection limit of the test.

Invalid
No visible band at all, or there is a visible band only in the test region but not in the control region. Repeat with a new test kit. If test still fails, please contact Wondfo or the distributor for technical assistance.



Note: There is no meaning with line color intensity or width.

QUALITY CONTROL

Internal Procedural Control

There is an internal procedural control line built in this device. The appearance of this control line verifies that the test device is intact and that a sufficient volume of sample has migrated to the test reaction area. The internal control does not ensure that the device is working correctly with patient samples.

External Positive and Negative Controls

Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and the test is correctly performed, including the antigen extraction.
Wondfo One Step Strep A Swab Test kit contains 1 Positive control and 1 Negative control. The Controls will monitor the entire assay. Run these controls:

- with each new test kit opened;
- with each new operator

The positive control will produce a moderate positive result (two lines—one at the Test Region (T) and the other at the Control Region (C)) when the test has been performed correctly and the test device is functioning properly. The negative control will yield a negative result (Control line only) when the test has been performed correctly and the test device is functioning properly.

Procedure for External Quality Control Testing

Allow the device, extraction reagents and controls to equilibrate to room temperature (10°C~30°C) prior to testing.

1. Add 4 drops of extraction reagent A and 4 drops of extraction reagent B respectively into the extraction tube and fully mix.
2. After thoroughly mixing the control, add 3 drops of positive or negative control into this tube.
3. Continue with step 3 to step 5 of test procedure.

The use of positive and negative controls from other commercial kits has not been established with Wondfo One Step Strep A Swab Test.

LIMITATIONS OF PROCEDURE

1. This test procedure, precautions and interpretation of results for this test must be followed when testing.
2. This test has been developed for testing throat swab specimen only. The performance of this test using other specimens has not been substantiated.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of group A streptococcal antigen.
4. Pharyngitis can be caused by organisms other than group A streptococcus. This test does not provide any further information about pharyngitis other than the possibility of Strep A infection. If clinical signs and symptoms are not consistent with laboratory results, a follow-up throat culture and grouping procedure should be performed.
5. A negative result may be obtained due to poor sample collection, or at the onset of the disease due to a low antigen level below the sensitivity limit of the test. If symptoms persist or intensify, retesting with a fresh sample is recommended.
6. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result. Avoid touching the tongue, cheeks, teeth or any bleeding areas of the mouth with the swab when collecting specimens.
7. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
8. Do not mix reagent of different lots.

EXPECTED RESULTS

Group A streptococcus infection exhibits a seasonal variation and is most prevalent in the winter and early spring. Approximately 19% of all upper respiratory tract infections are caused by group A streptococcus. The highest incidence of this disease is found in high density populations, such as school aged children and military bases. Males and females are equally affected by the disease.

PERFORMANCE CHARACTERISTICS

Sensitivity

For Streptococcus Group A, the lowest detection limit of the test is $1.5x10^5$ CFU/test.

Accuracy

Of the 379 total samples collected from the patients exhibiting symptoms of pharyngitis, 265 were found to be negative by culture and 114 were found to be positive by culture. All these samples were tested by Wondfo One Step Strep A Swab Test. Compare the results between the culture method and Wondfo One Step Strep A Swab Test, the results of the comparative study are as follows:

		Wondfo One Step Strep A Swab Test		
		+	-	Total
Conventional culture method	+	111	3	114
	-	4	261	265
	Total	115	265	379

(1) Sensitivity of Wondfo One Step Strep A Swab Test: 111/114×100%=97.4%
(2) Specificity of Wondfo One Step Strep A Swab Test: 261/265×100%=98.5%
(3) Accuracy of Wondfo One Step Strep A Swab Test: (111+261)/379×100%=98.2%

Cross-reactivity

To confirm the analytical specificity (cross-reactivity) of Wondfo One Step Strep A Swab Test, organisms is likely to be found in the respiratory tract, as listed below, were tested at 1×10^7 organisms per test and were all found to be negative when tested with the Wondfo One Step Strep A Swab Test.

Bordetella pertussis	Group G Streptococcus	Staphylococcus aureus
Bordetella pertussis	Hemophilus influenzae	Staphylococcus epidermidis
Candida albicans	Klebsiella pneumoniae	Streptococcus anginosus
Corynebacterium diphtheriae	Neisseria gonorrhea	Streptococcus intermedius
Enterococcus faecalis	Neisseria meningitidis	Streptococcus mitis
Escherichia coli	Neisseria sicca	Streptococcus mutans
Group B streptococcus	Neisseria subflava	Streptococcus oralis
Group C streptococcus	Pseudomonas aeruginosa	Streptococcus pneumoniae
Group F streptococcus	Serratia marcescens	Streptococcus sanguinis

Precision

1. Within-run precision was determined by using four specimens with different concentrations of antigen to do the test, and each specimen was tested repeatedly for 10 times.

2. Between-run precision was determined by using four specimens with different concentrations of antigen to do the test, and each specimen was tested with 3 different lots of test cassette.

BIBLIOGRAPHY OF SUGGESTED READING

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3. **Harbeck, R. J., J. Teague, G. R. Crossen, D. M. Maul, and P. L. Childers.**1993. Novel, rapid optical immunoassay technique for detection of group A streptococci from pharyngeal specimens: comparison with standard culture techniques. J. Clin. Microbiol. 31:839–844.
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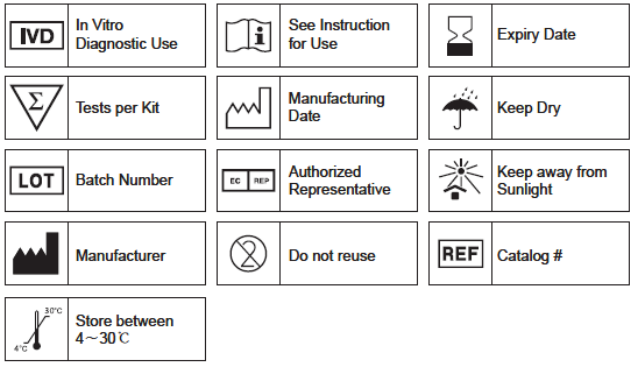
5. American Academy of Pediatrics. Peter, G, ed. 1994 Red Book: Report of the Committee on Infectious Diseases. 23rd ed. Elk Grove Village, IL; American Academy of Pediatrics; 1994: p. 433.
6. **Lauer BA, Reller LB** and **Mirrell S.** Effect of atmosphere and duration of incubation on primary isolation of group A streptococci from throat cultures. *J. Clin. Microb.* 17:338-340 (1983).

INDEX OF SYMBOLS



Guangzhou Wondfo Biotech Co., Ltd.
No. 8 Lizhishan Road, Science City,
Luogang District
Guangzhou 510663
China

EC REP

Qarad b.v.b.a.
Cipalstraat 3
B-2440 Geel
Belgium