

Wondfo®

One Step Strep A Swab Test

Catalog No.: W039P0001 [for 1 test]
W39-CH [for 2 tests]

Wondfo One Step Strep A Swab Test is a rapid, one step lateral flow immunoassay for the qualitative detection of the group A streptococcal antigen from throat swab specimens to aid in the early diagnosis of group A streptococcal infection.

For *in vitro* use only. For self-testing use.

HOW DOES IT WORK?

Group A streptococcus is one of the most significant human pathogens causing acute pharyngitis, tonsillitis, impetigo, and scarlet fever. It is very important to differentiate streptococcal infection from other etiologic agents (e.g., viral, mycoplasmal, or chlamydial) so that appropriate therapy may be initiated. Early diagnosis and treatment of group A streptococcal pharyngitis infections will reduce the severity of symptoms and further complications such as rheumatic fever and glomerulonephritis. So it is useful having a home test within reach to be able to make a diagnosis at the appearance of the first symptoms.

When the sample is added into the specimen well, capillary action carries the specimen to migrate along the membrane. When the group A streptococcal antigen levels in specimens are at or above the target cutoff, there is a visible colored band in the test region and indicates a positive result. Absence of this colored band in the Test region (T) suggests 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.

CONTENT OF THE TEST KIT

For W039P0001:

- 1 Individual sealed pouch, each containing:
 - Test Device
 - Desiccant PouchThe desiccant is for storage purposes only, and is not used in the test procedures.
 - 1 Extraction Tube
 - 1 Sterile Throat Swab. The swab is for collecting samples.
(Manufacturer: Puritan Medical Products Company LLC
31 School Street
Guilford, ME 04443
USA
- CE₂₇₉₇ MDD 93/42/EEC)
4. Buffer A and B (Warning: Buffer B Toxic if swallowed).
 5. Leaflet with Instructions For Use.

For W39-CH:

- 2 Individual sealed pouches, each containing:
 - Test Device
 - Desiccant PouchThe desiccant is for storage purposes only, and is not used in the test procedures.
 - 2 Extraction Tubes
 - 2 Sterile Throat Swabs. The swab is for collecting samples.
(Manufacturer: Puritan Medical Products Company LLC
31 School Street
Guilford, ME 04443
USA
- CE₂₇₉₇ MDD 93/42/EEC)
4. Buffer A and B (Warning: Buffer B Toxic if swallowed).
 5. Leaflet with instructions for use.

WHAT ELSE DO YOU NEED?

- Timer
- Tongue depressor

PRECAUTIONS

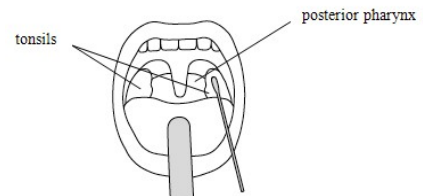
1. This kit is for *in vitro* use only. Do not swallow.
2. Do not interchange caps among reagents.
3. Do not use test kit beyond the expiration date.
4. Keep out of the reach of children.
5. Do not use the kit if the pouch is punctured or not well sealed.
6. Discard after use. The test device cannot be used more than once.
7. Avoid contact buffer A and B 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.
8. Do not eat, drink or smoke in the area where the specimens and kits are handled.
9. Protection glove should be worn when handling the specimen. Wash hands thoroughly afterwards.
10. Please follow local regulations to discard used tests.

STORAGE AND STABILITY

1. Store at 4~30°C in the sealed pouch up to the expiration date.
2. Keep away from sunlight, moisture and heat.
3. DO NOT FREEZE.
4. Preferably open the pouch only shortly before the test. Please use the test kit within 1 hour after opening the pouch.

SPECIMEN COLLECTION AND PREPARATION

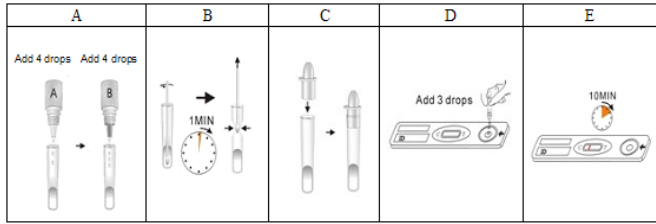
1. Collect the throat swab specimen with the sterile swab that is provided in the kit.
2. Hold the tongue down with a tongue depressor. Swab the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.
3. Testing should be ideally performed immediately after the specimens have been collected.



HOW TO DO THE TEST?

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

1. Add 4 drops of buffer A and 4 drops of buffer B respectively into the extraction tube and fully mix. The color of mixed liquid should become yellow.
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 pouch by tearing at the notch and place it on a clean, dry, level surface. Add 3 drops 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 show.
5. Wait for 10 minutes and read the results. Do not read results after 15 minutes.



HOW TO READ THE RESULTS?

Positive (+)

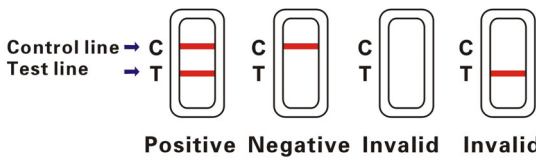
If two color bands are visible both in the test (T) band and the control (C) band, the result is positive. It indicates that you may be in a stage of Strep A infection and should consult with your doctor.

Negative (-)

If only one colored band appears in the control (C) region, no color band appears in the test region, the result is negative. It indicates that the concentration of the group A streptococcal 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. This is an indication of procedure error and/or that test reagent deterioration has occurred. Repeat test with a new test kit. If test still fails, please contact the distributor or the store where you bought the product, with the lot number.



Positive Negative Invalid Invalid

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

LIMITATIONS

- Results of this test are not to be used to determine your infection of Pharyngitis, because the 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. So you should consult with your doctor about the results.
- A negative result may be obtained due to poor sample collection, or not add enough amount of the buffer A and B. If symptoms persist or intensify, you should consult with your doctor.
- Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result. Don't touch the tongue, cheeks, teeth or any bleeding areas of your mouth with the swab when collecting specimens.
- As it is with any diagnostic procedure, a confirmed diagnosis should only be made by a physician after evaluating all clinical and laboratory findings.
- Since there is toxic composition reagent in the test device and the highest morbidity rate of upper respiratory infection was found in children, the test should be operated by their parents or other adult family member for the children who are younger than 16 years old.

PERFORMANCE CHARACTERISTICS

Sensitivity

Wondfo One Step Strep A Swab Test will detect group A streptococcal antigen of 1.5×10^5 CFU/test or greater.

QUESTIONS & ANSWERS

1. What should I do if the test result is invalid?

If it is invalid, you should take a new test kit to do the test again.

2. If the test is positive, what should I do?

A positive test indicates you may be with group A streptococcal infection. Please see a doctor for medical aid.

3. My test is negative. Does that mean I'm not infected?

No. While a negative test result means that you are probably not infected, if you are serious complication, including rheumatic fever and inflammation you should consult with your doctor.

4. Can I read the test result more than 15 minutes?

No, test results must be read in 15 minutes. Though a positive result should not change for several days, but a negative result may change to a false positive within minutes after the end of the testing period, which would not be an accurate reading.

5. When to do this test?

When you have the symptoms such as throat or tonsils inflamed you can do this test at home as an early diagnosis of group A streptococcal infection.

BIBLIOGRAPHY OF SUGGESTED READING

- Bisno AL. Group A streptococcal infections and acute rheumatic fever. N. Engl. J. Med. 325: 783-793 (1991).
- Carey, R. B., and G. L. Ahlers. 1993. Strep A OIA: an optical immunoassay to detect group A streptococcal antigen from throat swabs, abstr. C-343, p. 507. In Abstracts of the 93rd General Meeting of the American Society for Microbiology 1993. American Society for Microbiology, Washington, D.C.
- 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.

MEANING OF SYMBOLS ON PACKAGE

	In Vitro Diagnostic Use		See Instruction for Use		Expiry Date
	Tests per Kit		Manufacturing Date		Keep Dry
	Batch Number		Authorized Representative		Keep away from Sunlight
	Manufacturer		Do not reuse		Catalog #
	Store between 4~30°C				



Guangzhou Wondfo Biotech Co., Ltd.
 No.8 Lizhishan Road, Science City, Luogang District,
 510663, Guangzhou, P.R.China
 Tel: (+86)400-830-8768
 E-mail: sales@wondfo.com.cn
 Website: en.wondfo.com.cn



0123



Qarad BV
 Cipalstraat 3
 2440 Geel, Belgium

Rev. A2
 Rev.: 2022/03/29