

OnSite® Strep A Rapid Test

REF R0184C CE

Instructions for Use

INTENDED USE

The OnSite Strep A Rapid Test is a lateral flow immunoassay for the qualitative detection of *Streptococcus pyogenes* group A (Strep A) in throat swab specimens. It is intended to be used by professionals as a preliminary test result to aid in the diagnosis of infection with Strep A.

Any use or interpretation of this preliminary test result must also rely on other clinical findings and the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

SUMMARY AND EXPLANATION OF THE TEST

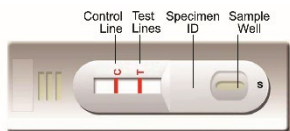
Streptococci are gram-positive bacteria that can be serologically classified as Lancefield groups A, B, C, D, F and G¹. Strep A is a β-hemolytic Streptococcus which is spread through direct contact with mucus from the nose or throat of an infected person². Symptoms can take up to 24 hours to present, and include fever, sore throat, swollen neck lymph nodes, and white or yellow spots on the tonsils with a bright red throat. In some cases, scarlet fever can occur which may be dangerous if not treated promptly.

Throat culture is the most reliable method to detect a *Streptococcus* infection. However, cultures require 24-48 hours of incubation to provide a reliable diagnosis. Therefore, immunochromatographic rapid tests have been developed for the direct detection of Group A streptococcal antigen from throat swabs^{3,4,5}.

The OnSite Strep A Rapid Test is an immunological antigen test that provides an instant test result in 5-10 minutes by minimally skilled personnel without the use of laboratory equipment.

TEST PRINCIPLE

The OnSite Strep A Rapid Test is a lateral flow immunoassay. The key test component consists of: 1) a conjugate pad containing anti-Strep A antibody conjugated with colored particles (antibody conjugates), and a control antibody conjugated with colored particles and, 2) a nitrocellulose membrane containing a test line (T line) and a control line (C line). The T line is pre-coated with Strep A antibody, and the C line is pre-coated with a control line antibody.



The Strep A antigen is first extracted from the swab specimen with the extraction reagent mixture. The extracted sample is added to the sample well. The extracted sample migrates by capillary action across the test strip. Strep A antigen, if present in the extracted sample, binds to the antibody conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-Strep A antibody forming a colored T line, indicating a Strep A positive test result. Absence of the T line suggests a negative result.

The test contains an internal control (C line) which should exhibit a colored line of the immunocomplex of the control line antibodies, regardless of any color development on the T line. Otherwise, the test result is invalid, and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
 - One cassette device
 - One desiccant
- Sample extraction tubes
- Sterile swabs, each sealed in a plastic-paper pouch
- Extraction Reagent A (REF SB-R0184A, 10 mL/bottle)
- Extraction Reagent B (REF SB-R0184B, 10 mL/bottle)
- Strep A Positive Control (200 µL/vial)
- Strep A Negative Control (200 µL/vial)
- Instructions for Use

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer

WARNINGS AND PRECAUTIONS

For in vitro Diagnostic Use

- Read these Instructions for Use completely before performing the test. Failure to follow the insert may lead to inaccurate test results.
- Do not open the sealed pouch unless ready to conduct the assay.
- Do not use expired devices or components.
- Bring all reagents to room temperature (15-30°C) before use.
- Do not use the components in any other type of test kit as a substitute for the components in this kit.
- Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
- Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
- Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
- Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
- Handle the negative and positive controls in the same manner as the patient specimens.
- The test result should be read 5-10 minutes after a specimen is applied to the sample well. Any results interpreted outside 5-10 minutes should be considered invalid and must be repeated.

- Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

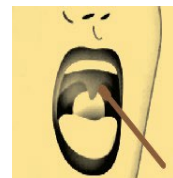
REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to 15-30°C before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

- Specimen collection:**
To collect a throat swab specimen, open an unused, sterile swab packet. Remove the sterile swab and rub on both tonsil surfaces and the posterior pharynx.
- Specimen transport and storage:**
Testing should be performed immediately after the specimens have been collected. Specimens extracted from the swab may be stored at 2-8°C for up to one day. For long term storage, specimens should be kept frozen at -20°C.

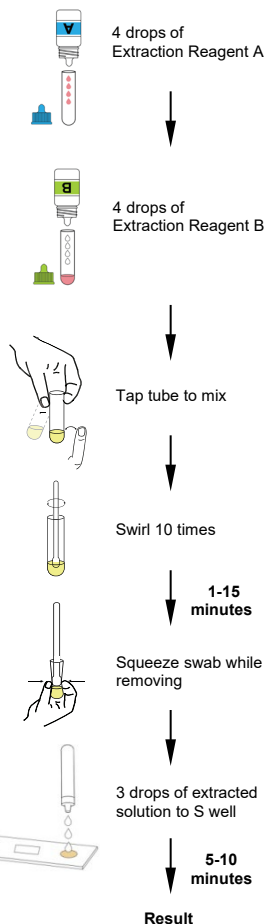


ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature (15-30°C) if refrigerated or frozen. Once thawed, mix the specimen well prior to performing the assay.

Step 2: Strep A antigen extraction process

- Holding Extraction Reagent A (blue cap bottle) vertically, add 4 drops (approximately 240 µL) to the sample extraction tube. Extraction Reagent A has a red color liquid.
- Add 4 drops (approximately 200 µL) of Extraction Reagent B (green cap bottle) to the same tube. Extraction Reagent B has a colorless liquid.
- Mix by tapping the bottom of the tube.
- Insert patient swab sample into the sample extraction tube solution. Swirl the swab at least 10 times while pressing the head against the bottom and side of the tube.
- Let stand for 1-15 minutes at room temperature (15-30°C), then squeeze the swab firmly against the tube to expel as much liquid as possible from the swab. Cap the extraction tube with the attached dropper tip. Discard the swab following the guidelines for handling infectious agents.



Step 3: Open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 4: Be sure to label the device with the specimen's ID number.

Step 5: Holding the extraction tube vertically, add 3 drops (150 µL) of extracted solution from the extraction tube into the center of the sample well (S well), making sure there are no air bubbles.

Step 6: Set up timer.

Step 7: Results can be read at 5-10 minutes. Positive results can be visible in as soon as 1 minute. Negative results must be confirmed at the end of 10 minutes only.

Any results interpreted outside the 5-10 minute window should be considered invalid and must be repeated. Discard used devices after interpreting the result following local laws governing the disposal of devices.

CONTROL PROCEDURE

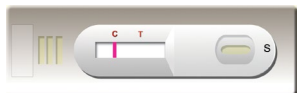
- Add 4 drops of Extraction Reagent A and 4 drops of Extraction Reagent B to an extraction tube.
- Mix by tapping the bottom of the tube.
- Add 1 drop of positive control or negative control to the tube.
- Continue as described from Step 3 of the Assay Procedure section above.
- If controls do not yield expected results, consider the test invalid and repeat the test or contact your distributor.

QUALITY CONTROL

- Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding the extracted solution. If the C line does not develop, review the entire procedure and repeat the test with a new device.
- External Control:** Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
 - A new operator uses the kit, prior to performing the testing of specimens.
 - A new lot of test kits is used.
 - A new shipment of test kits is used.
 - The temperature during storage of the kits falls outside of 2-30°C.
 - The temperature of the test area falls outside of 15-30°C.
 - To verify a higher than expected frequency of positive or negative results.
 - To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

- NEGATIVE RESULT:** If only the C line develops, the test indicates that no detectable Strep A antigen is present in the specimen. The result is negative or non-reactive.



- POSITIVE RESULT:** If both the C and the T lines develop, the test indicates the presence of detectable Strep A antigen in the specimen. The result is positive or reactive.



Specimens with positive or reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made.

- INVALID:** If no C line develops, the assay is invalid regardless of any color development on the T line as indicated below. Repeat the assay with a new device.



PERFORMANCE CHARACTERISTICS

1. Correlation on Clinical Specimens

A total of 525 patient samples were collected from susceptible subjects and tested by the OnSite Strep A Rapid Test and by culture method. Comparison for all subjects is shown in the following table:

Culture Method	OnSite Strep A Rapid Test		Total
	Positive	Negative	
Positive	117	7	124
Negative	11	390	401
Total	128	397	525

Relative Sensitivity: 94.4% (95% CI: 88.7-97.7%),

Relative Specificity: 97.3% (95% CI: 95.1-98.6%),

Overall Agreement: 96.6% (95% CI: 94.6-98.0%)

2. Cross-Reactivity

The organisms listed below were tested for cross-reactivity with the OnSite Strep A Rapid Test at 1.0x10⁷ organisms per test. No cross-reactivity was observed for the organisms listed.

<i>Bordetella pertussis</i>	<i>Neisseria gonorrhoea</i>
<i>Branhamella catarrhalis</i>	<i>Neisseria meningitides</i>
<i>Candida albicans</i>	<i>Neisseria sicca</i>
<i>Corynebacterium diphtheria</i>	<i>Neisseria subflava</i>
<i>Enterococcus faecalis</i>	<i>Pseudomonas aeruginosa</i>
Group B <i>Streptococcus</i>	<i>Serratia marcescens</i>
Group C <i>Streptococcus</i>	<i>Staphylococcus aureus</i>
Group F <i>Streptococcus</i>	<i>Staphylococcus epidermis</i>
Group G <i>Streptococcus</i>	<i>Streptococcus mutans</i>
<i>Hemophilus influenza</i>	<i>Streptococcus pneumonia</i>
<i>Klebsiella pneumonia</i>	<i>Streptococcus sanguis</i>

3. Interfering Substances

No interference was observed on the OnSite Strep A Rapid Test from commercially available cough drops, cough syrups, throat sprays, or mouthwashes.

LIMITATIONS OF TEST

- The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of Strep A in swab specimens from individual subjects. For optimal test performance, proper sample collection and extraction is critical. Failure to follow the procedure may lead to inaccurate results.
- The OnSite Strep A Rapid Test is limited to the qualitative detection of group A *Streptococcus* (Strep A). The intensity of the test line does not have a linear correlation with the bacterial titer in the specimen.
- A negative or non-reactive test result does not preclude the possibility of exposure to or infection with Strep A.

- A negative or non-reactive result can occur if the bacteria titer in the specimen is below the level detectable by the assay or if the bacterial antigens detected are not present in the swab specimen sampled. Strain variations of Strep A can also lead to modified antigens that are not recognized by the antibodies used in the test.
- Infection may progress rapidly. If the symptom persists, while the result from the OnSite Strep A Rapid Test remains negative or non-reactive, it is recommended to test with an alternative test method.
- Excess blood or mucus on the swab may interfere with the test and may lead to a false positive result. Avoid touching tongue, cheeks, teeth and any bleeding area of the mouth with swab.
- Results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

- Lancefield, R. C. A serological differentiation of human and other groups of beta-hemolytic streptococci. J. Exp. Med. 57:571-595 (1993).
- Ruoff, K. L., et al. Streptococcus p. 283-296 in Manual of Clinical Microbiology, 7th ed. American Society for Microbiology, Washington DC.
- Anhalt, J.P., et al. Comparison of three methods for detection of group A streptococci in throat swabs. J. Clin. Microbiol. 30:2135-2138 (1993).
- Harbeck, R.J., et al. Novel rapid optical immunoassay technique for detection of group A streptococci from pharyngeal specimens: comparison with standard culture methods. J. Clin. Microbiol. 31:839-844 (1993).
- Yu, P.K., et al. Evaluation of TestPack Strep A for the detection of group A streptococci in throat swabs. Mayo Clin. Proc. 63:33-36 (1988).

Index of CE Symbols

	Consult instructions for use		For <i>in vitro</i> diagnostic use only		Use by
	Catalog #		Lot Number		Tests per kit
	Store between 2-30°C		Authorized Representative		Do not reuse
	Manufacturer		Date of manufacture		

CTK Biotech, Inc.
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 Poway, CA 92064, USA
 Tel: 858-457-8698
 Fax: 858-535-1739
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 Schiffgraben 41
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 PI-R0184C Rev. A2.1
 Date released: 2022-07-06
 English Version

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