

Strep A Test

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EN
OSOM® Strep A Test
Catalog number 141E or 141E-20
CLIA Complexity:Waived

INTENDED USE

The OSOM® Strep A Test is intended for the qualitative detection of Group A Streptococcal antigen from throat swabs or confirmation of presumptive Group A Streptococcal colonies recovered from culture.

SUMMARY AND EXPLANATION OF TEST

Group A Streptococcus is one of the most important causes of acute upper respiratory tract infection. Early diagnosis and treatment of Group A Streptococcal pharyngitis has been shown to reduce the severity of symptoms and further complications such as rheumatic fever and glomerulonephritis¹. Conventional identification procedures for Group A Streptococcus from throat swabs involve the isolation and subsequent identification of viable pathogens by techniques that require 24 to 48 hours or longer². The OSOM Strep A Test detects either viable or nonviable organisms directly from a throat swab, providing results within 5 minutes.

PRINCIPLES OF TEST

The OSOM Strep A Test uses color immunochromatographic dipstick technology with rabbit antibodies coated on the nitrocellulose membrane. In the test procedure, a throat swab is subjected to a chemical extraction of a carbohydrate antigen unique to Group A Streptococcus. The Test Stick is then placed in the extraction mixture and the mixture migrates along the membrane. If Group A Streptococcus is present in the sample, it will form a complex with

the anti-Group A Streptococcus antibody conjugated color particles. The complex will then be bound by the anti-Group A Streptococcus capture antibody and a visible blue Test Line will appear to indicate a positive result.

KIT CONTENTS AND STORAGE

50/20 Test Sticks

50/20 Test Tubes

50/20 Sterile Swabs

1 Reagent 1 (2 M Sodium Nitrite)

1 Reagent 2 (0.3 M Acetic Acid)

1 Positive Control (Nonviable Group A Streptococci, 0.1% Sodium Azide)

1 Negative Control (Nonviable Group C Streptococci, 0.1% Sodium Azide)

1 Directional Insert

Note: Two extra test sticks have been included in the kit for external QC testing. In addition, extra components (swabs, tubes) have been provided for your convenience.

Store Test Sticks and reagents tightly capped at 15°-30°C (59°-86°F).

Do not use Test Sticks or reagents after expiration date.

MATERIALS REQUIRED BUT NOT PROVIDED

A timer or watch

PRECAUTIONS

For *in vitro* diagnostic use

Follow your laboratory safety guidelines in the collection, handling, storage and disposal of controls, patient specimens and all items exposed to patient specimens³.

Reagent 2 contains an acid. If the solution comes in contact with the skin or eyes, flush with large volumes of water.

The Positive and Negative Controls contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azide. Large quantities of water must be used to flush discarded control material down a sink.

Do not interchange or mix components from different lots.

Reagent 1 contains 12-14% sodium nitrite. In the EU this is classified as Toxic with the following Risk and Safety phrases:

R25 Toxic if swallowed

S24/25 Avoid contact with skin and eyes

S26 In case of contact with eyes, rinse immediately with plenty of warm water and seek medical advice

S36/39 Wear suitable protective clothing and eye/face protection

S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

SPECIMEN COLLECTION AND PREPARATION

Collect specimens with a sterile swab from the tonsils and/or the back of the throat. Take care to avoid the teeth, gums, tongue or cheek surfaces².

Use of sterile rayon swabs supplied with the kit is recommended. Swabs from other suppliers have not been validated. Do not use swabs that have cotton tips or wooden shafts. Do not use calcium alginate swabs. Do not use a collection system that contains charcoal or semisolid transport media.

Process the swab as soon as possible after collecting the specimen. If your lab requires a culture result as well as the OSOM Strep A Test result, streak the culture plate with the swab before starting the OSOM Strep A Test procedure. The extraction reagents will cause the specimen to become nonviable.

Because the OSOM Strep A Test does not require live organisms for processing, you may store and transport swabs dry or in Liquid Stuart's transport media. If you do not perform the OSOM Strep A Test immediately, store the swabs at room temperature or refrigerate the swabs for up to 24 hours. The swabs and the test kit must be at room temperature before you perform the test.

CULTURE CONFIRMATION

The OSOM Strep A Test can also be used to confirm the identification of Group A Streptococcus

on blood agar plates. The plates must be less than 72 hours old. Lightly touch 1-3 suspect colonies (showing characteristic beta hemolysis) using a sterile swab. Do not sweep the plate. Follow the instructions in the TEST PROCEDURE section to test the swab.

QUALITY CONTROL

Internal Procedural Controls

The OSOM Strep A Test provides three levels of procedural controls with each test run.

- The color of the liquid changes from pink to light yellow as you add Extraction Reagent 2 to Extraction Reagent 1. This is an internal extraction reagent control. The color change means that you mixed the extraction reagents properly. The color change also means that the reagents are functioning properly.
 - The red Control Line is an internal positive procedural control. The Test Stick must absorb the proper amount of sample and the Test Stick must be working properly for the red Control Line to appear. For the Test Stick to be working properly, the capillary flow must occur.
 - A clear background is an internal background negative procedural control. If no interfering substances are in the specimen and the Test Stick is working properly, the background in the Control Line area will clear. A discernible result will be seen.
- If the red Control Line does not appear, the test may be invalid. If the background does not clear and interferes with the test result, the test may be invalid.

External Quality Control Testing

Each kit contains Positive and Negative Control material. The Controls are for external quality control testing. Use the Controls to test that the extraction reagents and the Test Sticks are working. Also use the Controls to test that you are able to correctly perform the test procedure. If you choose, you may use Group A and non Group A Streptococcus ATCC reference strains as controls. Some commercial controls may contain interfering additives. Therefore it is recommended that you do not use other commercial controls with the OSOM Strep A Test.

Quality Control requirements should be established in accordance with local regulations or accreditation requirements. Minimally, Genzyme Diagnostics recommends that positive and negative external controls be run with each new lot and with each new untrained operator.

QC Testing Procedure:

- Dispense 3 drops Reagent 1 and 3 drops Reagent 2 into Test Tube.
- Vigorously mix the control contents. Add 1 free falling drop of Control from dropper bottle.
- Place a clean swab into the Tube.
- Continue as you would for a patient sample, as instructed in the PROCEDURE section.

LIMITATIONS

- The OSOM Strep A Test has been categorized as CLIA waived only for the application of qualitative detection of Group A Streptococcal Antigen from throat swabs. The application for the confirmation of presumptive Group A Streptococcal colonies recovered from culture is not waived.
- The results obtained with this kit yield data that must be used only as an adjunct to other information available to the physician. The OSOM Strep A Test is a qualitative test for the detection of Group A Streptococcal antigen. This test does not differentiate between viable and nonviable Group A Streptococci.
- The OSOM Strep A Test should be used only with throat swabs or colonies taken directly from a plate. The use of swab specimens taken from other sites or the use of other samples such as saliva, sputum or urine has not been established. The quality of the test depends on the quality of the sample; proper throat swab specimens must be obtained.
- This test does not differentiate between carriers and acute infection. Pharyngitis may be caused by organisms other than Group A Streptococcus^{1,2}.
- A negative result may be obtained if the specimen is inadequate or antigen concentration is below the sensitivity of the test.
- The American Academy of Pediatrics states⁴ "Several rapid diagnostic tests for GAS pharyngitis are available.....The specificities of these tests generally are very high, but the reported sensitivities vary considerably. As with throat cultures, the accuracy of these tests is most dependent on the quality of the throat swab specimen, which must contain pharyngeal and tonsillar secretions, and on the experience of the person who is performing the test. Therefore, when a patient suspected of having GAS pharyngitis has a negative rapid streptococcal test a throat culture should be obtained to ensure that the patient does not have GAS infection." It also states; "Cultures that are negative for GAS infection after 24 hours should be incubated for a second day to optimize isolation of GAS."

EXPECTED RESULTS

Approximately 19% of all upper respiratory tract infections are caused by Group A Streptococci⁵. Streptococcal pharyngitis displays a seasonal variation and is most prevalent during winter and early spring. The highest incidence of this disease is found in crowded populations such as in school-age children⁶.

PERFORMANCE CHARACTERISTICS

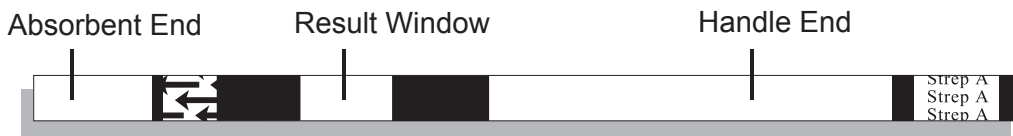
In a multi-center evaluation, a total of 639 throat swabs were collected from patients presenting with pharyngitis. Each swab was inoculated to a sheep blood agar plate, then tested by the OSOM Strep A Test. Plates were incubated for 18-24 hours at 35°-37°C at 5-10% CO₂ with a Bacitracin disk. Presumptive GAS colonies were confirmed with commercially available Strep A testing kits.

Of the 639 total specimens, 464 were found to be negative by culture and 454 were also negative by the OSOM Strep A Test, for a specificity of 97.8%. Of the 175 specimens found to be positive by culture, 168 were also positive by the OSOM Strep A Test, for a sensitivity of 96.0%. The 95% confidence intervals were calculated to be 96.6-99.0% for specificity and 94.4-97.6% for sensitivity. Overall agreement between culture and the OSOM Strep A Test was 97.3% (622/639). The results are summarized below:

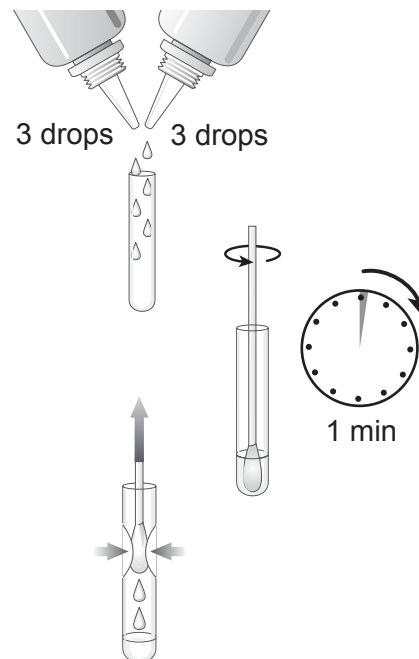
Culture Classification	OSOM/Culture	% Correct
Negative (Specificity)	454/464	97.8%
1+ (≤10 colonies)	3/6	50.0%
2+ (11-50 colonies)	9/13	69.2%
3+ (> 50 colonies)	44/44	100%
4+ (predominant growth)	112/112	100%
Total Positive (Sensitivity)	168/175	96.0%
Total (Overall Agreement)	622/639	97.3%

In addition, the OSOM Strep A Test was used to confirm the identification of Group A Streptococcus on blood agar plates. As a culture confirmation test, the Strep A Test was 100% sensitive (62/62) and 100% specific (39/39).

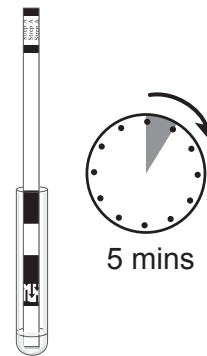
TEST PROCEDURE



- Just before testing, add 3 drops Reagent 1 (pink) and 3 drops Reagent 2 to the Test Tube (the solution should turn light yellow).
- Immediately put the swab into the Tube.
- Vigorously mix the solution by rotating the swab forcefully against the side of the Tube at least ten (10) times. Best results are obtained when the specimen is vigorously extracted in the solution.
- Let stand for 1 minute.
- **Express as much liquid as possible from the swab by squeezing the sides of the tube as the swab is withdrawn.**
- Discard the swab.
- Remove Test Stick(s) from the container; re-cap container immediately.



- Place the Absorbent End of the Test Stick into the extracted sample.
- Read results at 5 minutes. Positive results may be read as soon as the red Control Line appears.
- **Results are invalid after the stated read time. The use of a timer is recommended.**

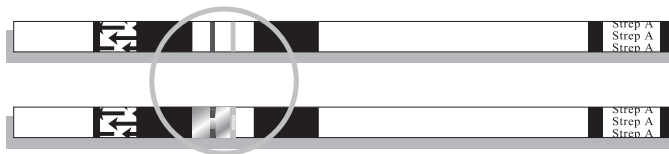


INTERPRETATION OF TEST RESULTS

Notes

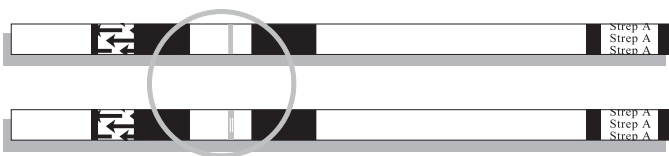
A blue or red line which appears uneven in color density is considered a valid result. In cases of moderate or high positive specimens, some blue color behind the Test Line may be seen; as long as the Test Line and Control Line are visible, the results are valid.

Positive



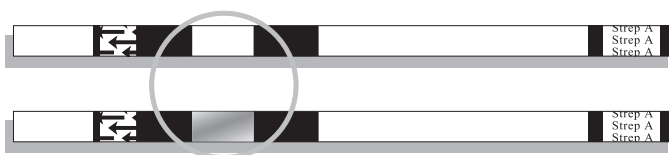
A blue Test Line and a red Control Line is a positive result for the detection of Group A Streptococcus antigen. Note that the blue line can be any shade of blue and can be lighter or darker than the line in the picture.

Negative



A red Control Line but no blue Test Line is a presumptive negative result.

Invalid



If no red Control Line appears or background color makes reading the red Control Line impossible, the result is invalid. If this occurs, repeat the test on a new Test Stick.

Cross-reactivity

The following organisms tested at levels of approximately 1×10^8 organism/test were all found to be negative when tested with the OSOM Strep A Test.

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

POL Studies

An evaluation of the OSOM Strep A Test was conducted at three physicians offices where testing was performed by personnel with diverse educational backgrounds. Each site tested the randomly coded panel consisting of negative (6), low positive (3) and moderate positive (3) specimens for three days. The results obtained had >99% agreement (107/108) with the expected results.