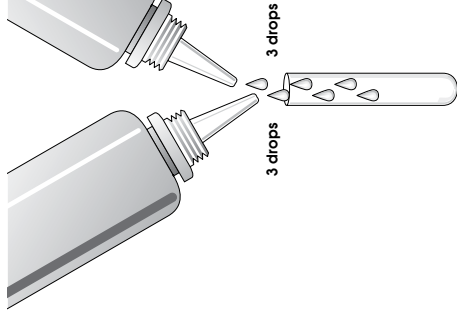
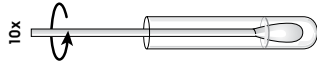


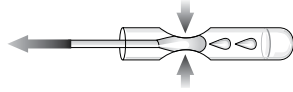
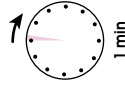
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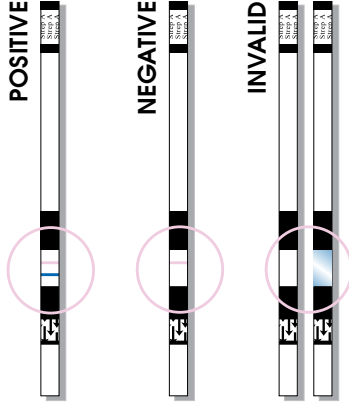
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


ASSISTANCE

For assistance, call Sekisui Diagnostics Technical Service at 800-332-1042.

RE-ORDER

No. 141 (50 Tests)

KEY TO COMPONENT LABELING

	Use by YYYY-MM		Manufacturer/Manufactured by
	Batch code		Consult instructions for use
	Catalog number		Authorized representative in the European Community
	Contents sufficient for <n> tests		Warning, consult SDS for further information
	<i>In vitro</i> diagnostic medical device		Oxidizer, consult SDS for further information
	Temperature limitation		

R_x only Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.

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 Sekisui Diagnostics, LLC 6659 Top Gun Street, San Diego, CA 92121 USA

SEKISUI
DIAGNOSTICS

Tel: 800-332-1042
www.sekisuidiagnostics.com

OSOM[®]

Strep A Test

CLIA Complexity, testing from throat swabs: Waived
 CLIA Complexity, testing from colonies recovered from culture: Moderate

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. For laboratory and professional in vitro diagnostic use only.

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 glomerulonephritis⁽¹⁾. 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 longer⁽²⁾. 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 Test Sticks
- 50 Test Tubes
- 50 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.

WARNINGS AND PRECAUTIONS

Component (s)	Pictogram	Signal Word	Hazard Statement
Reagent 1 Sodium Nitrate		Warning/Oxidizer	H272: May intensify fire; oxidizer H302: Harmful if swallowed
Precautionary Statement (s)	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P220: Keep/Store away from combustible materials. P221: Take any precaution to avoid mixing with combustibles. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P280: Wear protective gloves/protective clothing/eye protection/face protection P301+P330+ P312: IF SWALLOWED: Rinse mouth. Immediately call a POISON CENTER or doctor/ physician. P501: Dispose of contents/container in accordance with local/regional/national/international regulations.		
Reagent 2 Acetic Acid		Warning	H315: Causes skin irritation H319: Causes serious eye irritation
Precautionary Statement (s)	P264: Wash hands thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection/face protection P302+P352: If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice / attention. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P321: Specific treatment (see First Aid Measures on Safety Data Sheet). P337+P313: If eye irritation persists get medical advice/attention. P362+P364: Take off contaminated clothing and wash it before reuse P501: Dispose of contents/container in accordance with local/regional/national/international regulations.		

- For *in vitro* diagnostic use.
- Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- Follow your laboratory safety guidelines in the collection, handling, storage and disposal of controls, patient specimens and all items exposed to patient specimens⁽³⁾.
- The Positive and Negative Controls contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azide. For sites permitted to dispose of material down a sink: large quantities of water must be used to flush discarded control material down a sink.
- Do not interchange or mix components from different kit lots.

SPECIMEN COLLECTION AND PREPARATION

- Collect specimens with a sterile swab from the tonsils and/or the back of the throat⁽²⁾ taking care to avoid the teeth, gums, tongue or cheek surfaces.
 - Do not use swabs with cotton tips, wooden shafts or calcium alginate swabs.
 - Do not use a collection system that contains charcoal or semisolid transport media.
- 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 as the extraction reagents will cause the specimen to become nonviable.
- Process the swab as soon as possible after collecting the specimen. If you do not perform the OSOM Strep A test immediately, store the swabs either at room temperature or refrigerated for up to 72 hours. The swabs and the test kit must be at room temperature prior to running the test.
- Sample Transport:
 - Because the performance characteristics of this product were established with the sterile rayon swabs supplied with the kit, we recommend using these swabs to assure optimal performance. You may purchase the kit swabs in a double swab/dry tube format as an accessory (Sekisui Diagnostics Part #7784).
 - Because the test does not require live organisms for processing, a rayon transport swab containing Stuart's or Amies media may also be used; however, swabs from other suppliers have not been validated.

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. Call Sekisui Diagnostics Technical Service if you experience either of these problems.

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 Sekisui Diagnostics recommends that you do not use other commercial controls with the OSOM Strep A Test.

Quality Control requirements should be established in accordance with local, state and federal regulations or accreditation requirements. Minimally, Sekisui 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 states⁽⁴⁾: "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 Streptococci⁽⁵⁾. 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 military bases and in school-age children⁽⁶⁾.

PERFORMANCE CHARACTERISTICS

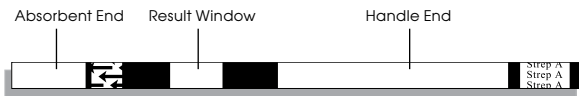
In a multi-center evaluation, a total of 639 throat swabs were collected from patients presenting with pharyngitis. Each swab was inoculated to a sheep blood agar plate, then tested by the OSOM Strep A Test. Plates were incubated for 18–24 hours at 35°–37°C at 5–10% CO₂ with a Bacitracin disk. Presumptive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

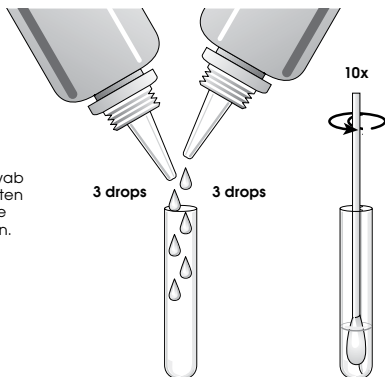
Culture Classifications	OSOM/Culture	% Correct
Negative (Specificity)	454/464	97.8%
1+ (<10 colonies)	3/6	50.0%
2+ (11–50 colonies)	9/13	69.2%
3+ (> 50 colonies)	44/44	100%
4+ (predominant growth)	112/112	100%
Total Positive (Sensitivity)	168/175	96.0%
Total (Overall Agreement)	622/639	97.3%

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 OSOM Strep A Test was 100% sensitive (62/62) and 100% specific (39/39).

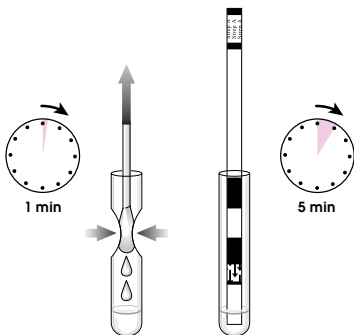
TEST PROCEDURE



- 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.



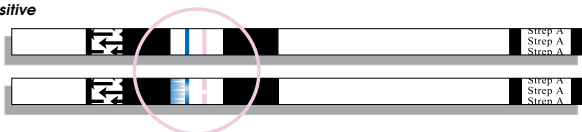
- Let stand for 1 minute.
- Express as much liquid as possible from the swab by squeezing the sides of the tube as the swab is withdrawn. Discard the swab.
- Remove Test Stick(s) from the container; re-cap container immediately.
- Place the Absorbent End of the Test Stick into the extracted sample.
- 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

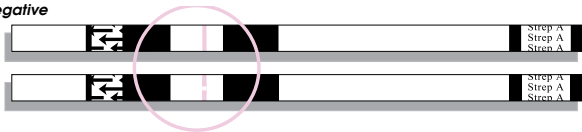
Note: A blue or red line which appears uneven in color density is considered a valid result. In cases of moderate or high positive specimens, some blue color behind the Test Line may be seen; as long as the Test Line and Control Line are visible, the results are valid.

Positive



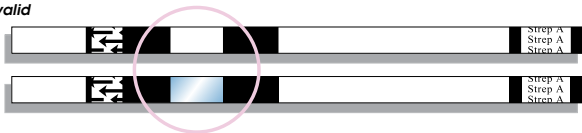
A blue Test Line and a red Control Line is a positive result for the detection of Group A Streptococcus antigen. Note that the blue line can be any shade of blue and can be lighter or darker than the line in the picture.

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 or contact Sekisui Diagnostics Technical Service.

CROSS-REACTIVITY

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

Streptococcus Group B
Streptococcus Group C
Streptococcus Group F
Streptococcus Group G
Streptococcus pneumoniae
Streptococcus sanguis
Streptococcus mutans
Enterococcus faecalis

Staphylococcus aureus
Staphylococcus epidermidis
Corynebacterium diphtheria
Serratia marcescens
Candida albicans
Klebsiella pneumoniae
Pseudomonas aeruginosa

Bordetella pertussis
Neisseria meningitidis
Neisseria gonorrhoeae
Neisseria sicca
Neisseria subflava
Branhamella catarrhalis
Hemophilus influenza

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.