SAMPLE PROCEDURE

This “Sample Procedure” is not intended as a substitute for your facility’s Procedure Manual or reagent labeling, but rather as a model for your use in customizing for your laboratory’s needs.

Space has been provided within the document to allow you to update this template with information specific to your facility. It is suggested that a current version of the manufacturer’s directional insert be maintained as a supplement.

PROCEDURE

Title: Sekisui Diagnostics OSOM® Strep A Test

Procedure #:

Institution: _____

Prepared by: _____ Date: _____

Title: _____

Accepted by: _____ Date adopted: _____

Title: _____

Reviewed by:_____ Date:_____

_____ _____

_____ _____

_____ _____

_____ _____

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_____ _____

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_____ _____

_____ _____

_____ _____

_____ _____

Discontinued by:_____ Date:_____

I. TEST NAME

OSOM® Strep A Test
CLIA: Waived

II. INTENDED USE

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

III. SUMMARY AND EXPLANATION OF TEST

Group A Streptococcus is one of the most important causes of acute 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.

IV. 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.

V. 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: Extra components (swabs, tubes) have been provided for your convenience.

Store Test Sticks and reagents tightly capped at 15^{o} – 30^{o} C (59^{o} – 86^{o} F).
Do not use Test Sticks or reagents after expiration date.

At this facility, kits are stored: _____

VI. MATERIALS REQUIRED BUT NOT PROVIDED

A timer or watch.

VII. PRECAUTIONS

For *in vitro* diagnostic use.

Follow your laboratories safety guidelines in the collection, handling, storage and disposal of controls, patient specimens and all items exposed to patient specimens [3].

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 kit lots.

VIII. PATIENT PREPARATION & SPECIMEN COLLECTION

This facility's procedure for patient preparation is: _____.

This facility's procedure for sample labeling is: _____.

Specimen Collection and Handling:

- Collect specimens with a sterile swab from the tonsils and/or 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 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.

This facility's procedure for transporting specimens is: _____.
_____.

This facility's procedure for rejected specimens is: _____.
_____.

IX. 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.

X. QUALITY CONTROL & ASSURANCE

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 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 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 Assistance 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.

QC Testing Frequency and Documentation

For this facility, external QC is run: _____.
_____.

Results of External QC and action(s) taken when control results are unacceptable are documented: _____.
_____.

XI. TEST PROCEDURE

- Just before testing, add three 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 read time. The use of a timer is recommended.**

Discard used test tubes and Test Sticks in suitable biohazardous waste container.

For this facility, sample swabs, used test tubes and Test Sticks are disposed: _____.
_____.

XII. INTERPRETATION OF TEST RESULTS

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 in the directional insert.

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 Assistance.

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.

In the event this test becomes inoperable, this facility's course of action for patient samples is: _____.

XIII. RESULT REPORTING

This facility's procedure for patient result reporting is: _____.

_____.

_____.

_____.

XIV. 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 diagnostics 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."

XV. EXPECTED RESULTS

Approximately 19% of all upper respiratory tract infections are caused by Group A Streptococci. 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].

XVI. CROSS REACTIVITY

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

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

XVII. PERFORMANCE CHARACTERSITICS & POL STUDIES

Refer to Directional Insert –OSOM® Strep A Test

XVIII. REFERENCES

Refer to Directional Insert –OSOM® Strep A Test

XIX. ASSISTANCE

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