



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.

I. TEST NAME

OSOM[®] Ultra Strep A 25T
CLIA: Waived

II. INTENDED USE

The OSOM Ultra Strep A Test is a color immunochromatographic assay intended for the qualitative detection of Group A Streptococcal antigen directly from throat swab specimens.

III. 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. Conventional identification procedures for Group A Streptococcus from throat swabs involve the isolation and subsequent identification of viable pathogens by techniques that require 18 to 24 hours or longer. The OSOM Ultra Strep A Test detects either viable or nonviable organisms directly from a throat swab, providing results within 7 minutes.

IV. PRINCIPLES OF TEST

The OSOM Ultra Strep A Test is a color immunochromatographic assay using Dual Label Technology (DLT). DLT uses antibody labeled color particles coated at two separate locations in the test device. DLT allows greater sensitivity than the conventional single label technology without sacrificing specificity. 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 complexes with the anti-Group A Streptococcus antibody conjugated color particles located at two separate locations on the Test Stick. 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. A red Control Line will also appear to indicate the test is valid.

V. KIT CONTENTS AND STORAGE

Contents:

25 Test Sticks Coated with Rabbit Anti-Group A Streptococcus

25 Test Tubes

25 Sterile Swabs

25 Extraction Reagent Bottles (2 M Sodium Nitrite and One Ampule with 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 Workstation

1 Directional Insert

Note: 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.
- Store Extraction Reagent Bottles inside the box. Avoid exposure to light.
- Avoid dropping Extraction Reagent Bottles as this may cause ampule breakage.

At this facility, kits are stored: _____.

VI. MATERIALS REQUIRED BUT NOT PROVIDED

A timer or a watch.

VII. 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 specimens.
- Caution: The Extraction Reagent Bottle contains Sodium Nitrite and may be harmful if swallowed. Do not taste or swallow. Wash thoroughly after handling.
- The Extraction Reagent Bottle contains a glass ampule. Crush the glass ampule with care.
- Warning: The Extraction Reagent Bottle contains an acidic solution that will cause skin and eye irritation. If the solution comes in contact with the skin or eyes, flush with large volumes of water.
- If no glass ampule is inside the Extraction Reagent Bottle or the glass ampule appears to be broken before use (reagent is colorless or yellow), discard and use another Extraction Reagent Bottle.
- 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 48 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 (Genzyme 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 specimen's is: _____
_____.

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

IX. QUALITY CONTROL & ASSURANCE

Internal Procedural Controls

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

- The color of the liquid changes from pink to light yellow after the glass ampule is crushed and the extraction reagents are mixed. This is an internal extraction reagent control. The color change means you have 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. For the Test Stick to be working properly, capillary flow must occur. 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.
- 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 will clear. A discernible result will be seen.

If the red Control Line does not appear the test is invalid. If the background does not clear and interferes with the test result, the test is invalid. Call Genzyme 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 properly. Also use the Controls to test that you are able to correctly perform the test procedure, including the antigen extraction portion of the test procedure. If you choose, you may use Group A and non Group A Streptococcus ATCC reference strains as external controls. Some commercial controls may contain interfering additives. Therefore Genzyme Diagnostics recommends that you do not use commercial controls with the OSOM Ultra Strep A Test.

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

QC Testing Procedure:

- Follow the instructions in the TEST PROCEDURE section to dispense the Extraction Reagent into the Test Tube.
- Vigorously mix the Control material. Add 1 free falling drop of the Control from the dropper bottle into the Test Tube.
- Place a clean swab into the Test Tube.
- Follow the instructions in the TEST PROCEDURE section to test the swab.

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: _____
_____.

X. TEST PROCEDURE

- Just before testing, squeeze the Extraction Reagent Bottle to crush the ampule inside. Note: The ampule must be crushed before proceeding to the next step.
- Vigorously shake the Extraction Reagent Bottle 3 to 5 times to mix the contents. The liquid in the Extraction Reagent Bottle should turn from pink to light yellow.
- Add 6 drops of the Extraction Reagent to the Test Tube.
- Immediately put the swab into the Test Tube. Vigorously mix the solution by rotating the swab forcefully against the side of the Test Tube at least ten (10) times. Best results are obtained when the specimen is vigorously extracted in the solution.
- Let stand for 2 minutes.
- 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 the Test Stick(s) from the container; re-cap the 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. Negative results must be confirmed at 5 minutes.

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:
_____.

XI. INTERPRETATION OF RESULTS

Positive

A blue Test Line and a red Control Line is a positive result. A positive result means that the assay detected Group A Streptococcus antigen in the specimen. 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 negative result. A negative result means that no Group A Streptococcus antigen was detected, or the levels of antigen in the specimen were below the detection level of the assay.

Invalid

If after 5 minutes, 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 using a new sample or contact Genzyme Diagnostics Technical Assistance.

Notes

A blue or red line that appears uneven in color density is still considered a valid line. In some cases, a trail of color may remain in the background; 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: _____
_____.

XII. RESULTS REPORTING

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

_____.

XIII. LIMITATIONS

As with all diagnostic assays, the results obtained by this test yield data that must be used only as an adjunct to other information available to the physician. The following factors must be considered to obtain reliable results:

- The OSOM Ultra Strep A Test is a qualitative test for the detection of Group A Streptococcal antigen. This test detects both viable and non-viable Group A Streptococci, and may yield a positive result in the absence of living organisms.
- The quality of the test depends on the quality of the sample; proper throat swab specimens must be obtained. Negative results can occur from inadequate specimen collection or antigen level, which is below the detection limit of the test.
- The OSOM Ultra Strep A Test should be used only with throat swab specimens. 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.
- This test does not differentiate between carriers and acute infection.
- Pharyngitis may be caused by viral or bacterial pathogens other than Group A Streptococcus.
- If the test result is inconsistent with the clinical symptoms, a second throat swab should be collected for repeat testing.

The American Academy of Pediatrics states: "Several rapid diagnostic tests for GAS pharyngitis are available. The specificities of these tests generally are 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."

XIV. 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.

XV. CROSS REACTIVITY

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 Ultra Strep A Test.

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

XVI. PERFORMANCE CHARACTERISTICS & POL STUDIES

Refer to directional insert – OSOM[®] Ultra Strep A Test

XVII. REFERENCES

Refer to directional insert – OSOM[®] Ultra Strep A Test

XVIII. ASSISTANCE

For technical assistance contact Genzyme Diagnostics Technical Assistance at 800-332-1042.