## UPMC HANOVER LABORATORY

| Subject: OSOM Ultra Strep A Test | |
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**PRINCIPLE:**

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. For laboratory and professional *in vitro* diagnostic use only.

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.

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.

**SCOPE:**

This policy applies to UPMC Hanover Hospital laboratory.

**SPECIMEN:**

- 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 surfaces.
- Acceptable swabs for collection are sterile swabs supplied with the kit and culturette swabs with modified Stuart's transport media.
- Unacceptable specimens:
  - Swabs with cotton tips or wooden shafts
  - Calcium alginate swabs
  - Collection systems that contain charcoal or semisolid transport media
  - E swabs

- Process the swab as soon as possible after collection. If immediate testing is not possible, the swab may be stored at RT or refrigerated for up to 48 hours.

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**Refrigerated swabs must be brought to room temperature prior to testing.SUPPLIES AND REAGENTS:**

**Contents: 25 Test Kit**

- 50 Test sticks Coated with Rabbit Anti-Group A Streptococcus
- 50 Test tubes
- 50 Sterile swabs
- 1 Reagent A (2 M Sodium Nitrite). Caution: Harmful if swallowed
- 1 Reagent B (0.3 M Acetic Acid). Warning: Severe eye irritant
- 1 Positive control (Nonviable Group A Streptococci, 0.1% Sodium Azide)
- 1 Negative control (Nonviable Group A Streptococci, 0.1% Sodium Azide)
- 1 Workstation
- 1 Package insert

**Material Storage**

- 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.

**Not Included in Kit**

- Timer or a watch
- Culturette swabs with Modified Stuart's media

**QUALITY CONTROL**

- Internal and external controls are run with each new lot/shipment and by each new user.
- The components of this kit are only to be used within the kit lot and are not mixed with different lots.
- Just before testing, Label 1 test tube as Positive control and 1 test tube as negative control.
- Add 3 drops Reagent A (pink) and 3 drops Reagent B to the Test Tubes (the solution should turn light yellow).
- Vigorously mix control materials prior to adding to the tubes.
- Add one free falling drop of the Positive external control to the Positive control tube and one free falling drop of the Negative external control to the Negative control tube.
- Place a clean swab into each control tube.
- Vigorously mix the solution by rotating the swab forcefully against the side of the tube.
- 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 from the container, recap the container immediately.
- Place the absorbent end of the stick into the extracted sample.
- Read results at 5 minutes.
- Document results including internal QC (indicated by red line), as acceptable.

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**PATIENT PROCEDURE:**

- Just before testing, add 3 drops Reagent A (pink) and 3 drops Reagent B to the Test Tube (the solution should turn light yellow).
- Immediately put the swab in the test tube
- Vigorously mix the solution by rotation the swab forcefully against the side of the test tube at least ten 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 pressing the swab firmly against the sides of the test tube as the swab is withdrawn.
- Discard the swab.
- Remove the test stick from the container, re-cap the container immediately.
- Place the absorbent end of the test stick into the extracted sample.
    - Read the 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.**

**REPORTING RESULTS:**

- Positive result: A blue test line and a red internal control line indicate positive results. Group A Streptococcal antigen has been detected in the specimen. Positive results may read as soon as the red control line appears.
- Negative results: A red internal control line but no blue test line is a negative result. A negative result means that no Group A Streptococcal antigen was detected, or the levels of antigen in the specimen were below the detection level of the assay. Wait a full 5 minutes before reporting negative results.
    - Negative test on patients under the age of 18 are followed up with culture.
    - Plate the second culture swab to BAP and incubate in CO2. Refer to Group A Streptococcus culture for procedure.

**LIMITATIONS:**

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.

**REFERENCES:**

OSOM Ultra Strep A Test package Insert. Sekisui Diagnostics, LLC. 2015.

OSOM Ultra Strep A Test procedure. UPMC Microbiology LSC. 2024.