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Owner:	*Kelly Cwikla: Mgr-Lab*
Area:	*Laboratory - Collection*
References:	

OSOM Strep A

Binghamton, New York

REGULATORY REFERENCES:	CROSS REFERENCES:
NYS, CAP, JCAHO	

POLICY

The OSOM Strep A test is intended as a qualitative screening for Group A Streptococcal antigen from a throat swab.

The OSOM Strep A test uses color immunochromatographic dipstick technology with rabbit antibodies coated on the nitrocellulose membrane. 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 line will appear to indicate a positive result.

PROCEDURE:

REAGENTS, MATERIALS, AND STORAGE REQUIREMENTS

1. Kit Contents:
   50 Test Sticks
   50 Test Tubes
   50 Sterile swabs
   1 Reagent 1 (2M Sodium Nitrite)
   1 Reagent 2 (0.3M Acetic Acid)
   1 Positive control (Non viable Group A Streptococci, 0.1% Sodium Azide)
   1 Negative control (Nonviable Group C Streptococci, 0.1% Sodium Azide)
   1 Directional Insert
2. Timer or watch
   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.

SPECIMEN TYPE- A freshly collected throat swab from the posterior pharynx and both tonsils collected using

a swab from the OSOM kit or a Culturette swab. Swabs with wooden shafts are not acceptable. Swabs with a gel transport (Amies swabs) are not acceptable for testing as the gel can interfere with the test system.

COLLECTION-
Pharyngeal specimens are collected by having the patient open his or her mouth widely, depressing the tongue to improve visibility, and inserting a swab supplied in the kit. (See limitations of Procedure) The tip of the swab must make contact with the exudative, inflamed regions of the posterior pharynx and tonsils. Process the swab as soon as possible after collecting the specimen. If a confirmation culture is needed, a second swab collected using a Culturette must be submitted to the laboratory. A culture confirmation is needed for any negative rapid results.

IDENTIFICATION and **LABELING**: the patient will be identified using 2 identifiers, patient full name and date of birth. The swab will be labeled with these identifiers.

TEST PERFORMANCE

1. Obtain patient specimens as described in specimen requirements.
2. Label a test tube for each patient and/or control.
3. To test tube add 3 drops of Reagent 1
4. To test the tube add 3 drops of Reagent 2.
5. Place the patient swab into the test tube and mix vigorously by rotating the swab 10 times.
6. Let stand for 1 minute.
7. Express liquid from the swab by pressing the swab firmly against the side of the test tube.
8. Discard the swab into a biohazard receptacle.
9. Remove Test Stick from the container, re-cap container immediately.
10. Place the Absorbent end of Test Stick into liquid in the test tube.
11. Let stand 5 minutes.
12. Read and Record result.

RESULT INTERPRETATION

Results are invalid after the 5 minute read time. Positive results may be read as soon as the red control line appears.
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 Result: a Red control line and a Blue Test line of any intensity
Negative Result: a Red Control line only.
Invalid Result: no Red Control line. (Repeat test using a fresh throat swab)

Expected Values- Normal range: Negative

RESULT REPORTING

Patient results are not reported unless the quality control is acceptable.
The patient's results must be recorded in the patient's chart as well as the accession log with the patient's

name, date of birth, the date and time of test and signature of the person performing the test. The accession record must also have the OSOM kit lot number and expiration date.

QUALITY CONTROL

External Quality Control Testing:
Each kit contains Positive and Negative Control material.
Controls must be tested and within range each day of testing before any patient testing can be performed.

1. Dispense 3 drops of Reagent 1 and 3 drops of Reagent 2 into a Test Tube.
2. Vigorously mix the control contents. Add 1 free falling drop of Control from the bottle
3. Place a clean swab into the Test Tube.
4. Continue as you would for a patient sample as instructed in the PROCEDURE
5. Record on the appropriate form with lot numbers and expiration dates.

Internal Procedural Controls:
The OSOM Strep a Test provides three levels of procedural controls with each test run.

1. 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.
2. 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.
3. 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
4. The internal control acceptability must be recorded with the controls.

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.

FOLLOW UP RECOMMENDATIONS A positive screening result may be used by the practitioner as a diagnostic tool for determining a treatment regimen.
If a Rapid Group A Streptococcus direct antigen test is performed on pediatric patients, confirmatory testing is performed on negative samples.

LIMITATIONS

1. 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.
2. The results obtained with this kit yield data that must be used only as an adjunct to other information available to the physician. This test does not differentiate between viable and nonviable Group A Streptococci.
3. The OSOM Strep a Test should be used only with throat swabs. 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.

4. This test does not differentiate between carriers and acute infections. Pharyngitis may be caused by organisms other than Group A Streptococcus.
5. A negative result may be obtained if the specimen is inadequate or antigen concentration is below the sensitivity of the test.

Electronic Authorizations:

Michael Zur, MD, Medical Director of Laboratory

Kelly Cwikla, MT(ASCP)SM, Clinical Manager of Microbiology

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
	Michael Zur	11/2021
	Kelly Cwikla: Mgr-Lab	11/2021