Rapid Group A Streptococcus Test – OSOM

Adopted: 5/1/23
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I. PRINCIPLE

The OSOM Strep A Test is intended for the qualitative detection of Group A Streptococcal antigen from throat swab.

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 24 to 48 hours or longer. The OSOMStrep A Test detects either viable or nonviable organisms directly from a throat swab, providing results within 10 minutes.

The OSOM Strep A Test uses color immunochromatographic 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.

II. AVAILABILITY

The rapid strep test is offered as a STAT test.

III. TEST CODE

The test code is STREP.

IV. SPECIMEN

A. Throat specimen

1. Specimens should be collected with a single or double swab Dacron sterile collection kit (BBL). The swab should be from the tonsils and/or the back of the throat taking care to avoid the teeth, gums, tongue, or cheek surfaces.

2. Do not use swabs that have cotton tips or wooden shafts. Do not use calcium alginate swabs. Do not use a collection system that contains charcoal or semisolid transport media.

3. Process the specimen as soon as possible after collection. 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 extraction reagents will cause the specimen to become nonviable so only use one swab from the double swab collection kit.

4. The swabs and the test kit must be at room temperature before you perform the test.

V. MATERIALS AND EQUIPMENT

A. The materials provided in the test kit are sufficient for testing specimens.

1. Kit Contents

a. 50 Test Stick
b. 50 Test Tubes
c. 50 Sterile Swabs
d. 1 Reagent 1 (2 M Sodium Nitrite)
e. 1 Reagent 2 (0.3 M Acetic Acid)
f. 1 Positive Control (Nonviable Group A Streptococci, 0.1% Sodium Azide)
g. 1 Negative Control (Nonviable Group C Streptococci, 0.1% Sodium Azide)
h. 1 Package Insert

2. Equipment Required - NOT provided in the kit
    a. Timer, gloves, clean area for test performance, handwashing sink, biohazard trash

HANDLE SPECIMENS AS IF CAPABLE OF TRANSMITTING AN INFECTIOUS AGENT

VI. 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.

VII. QUALITY CONTROL

A. Daily Quality Control

1. The OSOM Strep A Test provides three levels of procedural controls with each test run. The manufacturer's recommendation is to document these controls for each sample run.

a. 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.

b. The [redacted] is an internal positive procedural control. The Test Strip must absorb the proper amount of sample and the Test Strip must be working properly for the red Control Line to appear. For the Test Stick to be working properly, the capillary flow must occur.

c. 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.

d. If the Red Control Line does not appear, the test is **invalid.**

e. If the background does not clear and interferes with the test result, the test is **invalid.**

2. External Quality Control

a. External Quality Control with known positive and negative material is done by the Microbiology Laboratory for each new lot number as it is received. The date received and date opened is marked on the side of the box. Concurrent testing is performed with each lot #. The test kit MUST pass the External Quality Control and concurrent testing controls before use and shipment to other sites.

b. When kits are received at Bristol Lab, QC will be run on one kit from the shipment and documented on qc sheet.

3. Each kit contains Positive and Negative Control material.

   a. Controls are for external quality control testing. Use the Controls to test that the extraction reagents and the Test Stick are working.

   b. Controls may also be used to assess correct performance of the test procedure for training purposes. Use only controls provided with the OSOM Strep A Test to perform QC or assessment of test performance.

   c. Concurrent testing will be done with reagents of previous kit and performed by microbiology when the kit is received.

4. Personnel
   Intended for use by clinical personnel who have received training and demonstrated competency in this procedure. Personnel who have difficulties with color discrimination must demonstrate ability to read the test.

a. TEST PROCEDURE

A. Just before testing, add 3 drops Reagent 1 (pink) and 3 drops Reagent 2 to the Test Tube (the solution should turn light yellow).

B. Immediately put the swab into the Tube.

C. 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.

D. Let stand for **1 minute**.

E. Express as much liquid as possible from the swab by squeezing the sides of the tube as the swab is withdrawn.

F. Discard the swab.

G. Remove Test Stick(s) from the container; re-cap container immediately.

H. Place the Absorbent End of the Test Stick into the extracted sample.

I. Read results at **5 minutes**. Positive results may be read as soon as the red Control Line appears.

J. Results are invalid after the stated read time.

VIII. INTERPRETATION

A. **Positive**

A blue Test Line and a [redacted] is a positive result for the detection of Group A Streptococcus antigen. Note that the blue line can be any shade of blue.

B. **Negative**

A red Control Line but no blue Test Line is a negative result.

C. **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.

IX. NOTES

A. A blue or red line which appears uneven in color density is considered a valid result.

B. 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.

IX. REPORTING RESULTS

A. If the internal control QC has failed; do not report patient results. Result is invalid. See VIII Interpretation above.

B. For reporting of results, refer to Appendix A: *Rapid Strep A Antigen Resulting.*

C. For all NEGATIVE rapid tests, consider sending a E-swab for GAS Probe (GASPR) Testing if clinical suspicion is high.

X. PRECAUTIONS

A. For in vitro diagnostic use only.

B. Dispose of materials as described in the Safety Manual.

C. Reagent 2 contains Acetic Acid and causes severe eye irritation. Avoid contact with eyes. Wash thoroughly after handling. In case of contact, immediately flush eyes with plenty of water. Get medical attention.

D. 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.

E. Do not interchange or mix components from different lots.

XI. LIMITATIONS

A. 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 Steptococcal cononies recovered from culture is not waived.

B. 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. The test does not differentiate between viable and nonviable Group A Streptococci. Patients with previous positive results for GAS within 3-6 weeks should be assessed by culture or prove rather than antigen tests because of the high false positive rate secondary to persistence of nonviable antigen.

C. 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.

D. The test does not differentiate between carriers and acute infection Pharyngitis may be caused by organisms other than Group A Streptococcus.

E. A negative result may be obtained if the specimen is inadequate, or antigen concentration is below the sensitivity of the test.

F. A negative OSOM Strep A Test result should be followed up with testing using the GAS Probe if clinically indicated.

XII. TECHNICAL SUPPORT

Call Sekisui Diagnostics Technical Service at 800-332-1042

XIII. REFERENCES

A. Youmans, G.P., Paterson, P.Y. and Sommers, H.M. Upper Respiratory Tract Infection: General Considerations, in The Biologic and Clinical Basis of Infectious Diseased, W.B. Saunders Co., Philadelphia, 1770183, 1980.

B. Faklam, R.R. and Washington, J.A. Streptococcus and Related Catalase-Negative Gram- Positive Cocci, in Manual of Clinical Microbiology, 5th Edition, Balows, A. Hausler, W.J.m Hermann, K.L., Isenberg, H.D., and Shadomy, H.J., Eds., Am. Society of Microbiology, Washington, D.C., 238-257, 1991.

C. CDC, Biosafety in Microbiological and Biomedical Laboratories, 2nd Ed., HHS Publication NO. 8808395, 4-6, 1988.

D. American Academy of Pediatrics. Summaries of Infectious Disease. In: Pickering LK, ed. 2000 Red Book: Report of the Committee on Infectious Diseases. 25th ed. Elk Grove Village IL: American Academy of Pediatrics; 2000 528.

E. Lauer, B.A., Reller, L/B., and Mirrett, S., Effect of Atmosphere and Duration of Incubation on Primary Isolation of Group A Streptococci from Throat Cultures, J. Clin. Microb., 17: 338-340, 1983.

F. Wannamaker, L.W., Differences Between Streptococcal Infection sof the Throat and of the Skin, N. Eng. J. Med., 282:23-31, 78-85, 1970.

Rapid Strep A Antigen Resulting

When the test is ordered in soft, a QC test will be automatically reflexed when the order is saved. This is where you will **result your internal control** QC.

A. For a **Negative** result:
   1. Click on @NEGS: 'Negative for group A strep antigen'.

B. For a **Positive** result:
   1. Click on @POSS: 'Positive for group A strep antigen'
   2. Notify floor or health care provider

C. For an **Invalid** result:
   1. Click on @INVM: 'Test invalid. Control Line not present. Please resubmit another specimen'.
   2. Notify floor or health care provider. Offer them the GASPR test as an alternative.

D. For the **QC** result:
   1. Next to the test INTQC, choose @INTQ off the keypad.
   2. 'Internal Controls OK'

E. When a **Phone Report** is made for **Positives** or **Invalids**:
   1. Put curser in STREP result box.
   2. Click on Comment.
   3. Choose canned message @CALM and type in the name of the person you spoke to and their location,
   4. Click [DATE], [TIME] and then [OK].
   5. Choose Verify All.
   6. Check your instant report to make sure results and phone report are there.

F. Verify result

G. Save your results.

On all pediatric patients (<18yrs) with NEGATIVE rapid test, submit second throat swab to Microbiology department for GAS Probe (GASPR) Testing.

H. To **Add a Strep DNA Probe**:
   1. Click on the 'Run Order Entry' icon. Enter the order number.
   2. Click on the empty box under the 'STREP' order.
   3. Order test code GASPR
   4. Click on it and a window opens asking you to confirm adequate specimen for additional testing. Click [YES].
   5. Click the save icon.
   6. Click [YES].

I. You **must** cancel the GASPR if not needed and it shares same order number as STREP.
J. Cancel the GASPR through Order Entry→ Cancel Test as Not performed.

K. **Resulting Notes-**
   1. If Rapid is Positive, cancel GASPR..
   2. If Rapid is Negative and pt is <18 years old, add GASPR.
   3. If Rapid is Negative (no GASPR ordered) and pt is >18yrs old, save swab and send daily batch to Microbiology for further testing if requested.