Title: Rapid Strep OSOM Procedure

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Purpose

This document outlines policies and procedures that pertain to Rapid Strep A testing with the OSOM kit. In an effort to be concise some information from the manufacturer’s recommended procedure may be excluded. It is recommended that operators familiarize themselves with the manufacturer’s product information that accompanies each package.

Scope

Level of Personnel: All RNs, NPs, PCAs, and MAs who have successfully completed initial training and maintained annual competency.

Testing Site: All sites approved and on file with the Pathology Service’s POCT Program.

Policy and Procedure Statement

The OSOM™ Strep A Test has been categorized as a CLIA waived test only for the application of qualitative detection of Group A Streptococcal Antigen from throat swabs. The results obtained with this kit yield data that must be used only as an adjunct to other information available to the physician.

Test Principle

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.

Regulatory Requirements

1. Each testing site must have a documented quality control program, which is developed in collaboration with or has been approved by the MGH Pathology Service.

2. All test results must be maintained in patient records with all required information for four years.

   Required information:
   1. Patient’s name
   2. Medical Record Number
   3. Patient’s gender
   4. Patient’s age or date of birth
   5. Date & time test collected, performed and reported
   6. Ordering Physician
   7. Responsible physician (if not 6)
   8. Reference or Target Range
   9. Test Performed
   10. Test units
   11. Lab name
3. Additional information that must be retained for four years:
   1. Testing personnel records
   2. Quality control results
   3. Product information (i.e. serial number, lot numbers, expiration dates, etc.), information on quality control and any remedial action
   4. QC charts, maintenance sheets, reference and critical ranges

4. Other
   1. Universal precautions must be observed when handling any patient specimen.
   2. A physician’s order or standing order is required prior to performing test.
   3. The Hospital Hand Hygiene policy must be adhered to at all times.

**Critical Elements**

1. Do not use kit beyond expiration date imprinted on the container or box.
2. Dispose of all test sticks in a proper biohazard container.
3. Internal Procedural Controls must be performed and documented with each test.
4. External Quality Control must be performed and documented with each new box, with each untrained operator, or whenever the test performance is questioned.
5. Adhere to hospital policy for proper patient identification.

**Test Kits/Supplies**

<table>
<thead>
<tr>
<th>Product</th>
<th>Vendor</th>
<th>Manufacturer #</th>
<th>Peoplesoft #</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sekisui® OSOM™ Strep A</td>
<td>Fisher HealthCare</td>
<td>Fisher# 22-071-059</td>
<td>N/A</td>
<td>Room Temp Storage</td>
</tr>
<tr>
<td>Non-sterile gloves (Nitrile or Vinyl)</td>
<td>Medline</td>
<td>Medline</td>
<td>119308-Large 119307-Medium 119306-Small</td>
<td>Order glove of choice</td>
</tr>
<tr>
<td>B.D. Culturette</td>
<td>Owens and Minor</td>
<td>B.D. Microbiology Systems 4155220099</td>
<td>41874</td>
<td>Room Temp Storage</td>
</tr>
<tr>
<td>Traceable Timer</td>
<td>Fisher HealthCare</td>
<td>Fisher# 02-401-7</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

**Contents: OSOM™ Strep A Kit**

<table>
<thead>
<tr>
<th>Components</th>
<th>Quantity Provided</th>
<th>Storage/Stability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Sticks</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>Test Tubes</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>Sterile Swabs</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>Reagent 1 (2M Sodium Nitrite)</td>
<td>1 Bottle</td>
<td>All test kit components are stored at room temperature (15° to 30° C)</td>
</tr>
<tr>
<td>Reagent 2 (0.3 M Acetic Acid)</td>
<td>1 Bottle</td>
<td></td>
</tr>
<tr>
<td>Positive Control</td>
<td>1 Bottle</td>
<td></td>
</tr>
<tr>
<td>(Nonviable Group A Streptococci,</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
0.1% Sodium Azide) | 1 Bottle
---|---
Negative Control (Nonviable Group C Streptococci, 0.1% Sodium Azide) | 1 Bottle
Package Insert | 1ea.

Materials required but not provided.

- Calibrated Timer

Safety Precautions

- 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. Do not discard control material down a sink.

Specimen Collection

Follow hand hygiene protocol and put on gloves. Collect the specimen using two sterile swabs from the tonsils and/or back of the throat, taking care to avoid the teeth, gums, tongue or cheek. One swab will be used for the Rapid Strep Screen, (i.e. OSOM™ Swab), and the second swab (i.e. B.D. Culturette), will be sent to the lab for a culture if the screen is negative. Label each swab with two patient identifiers. If there is a delay before testing, remove gloves and perform hand hygiene.

Test Procedure

Perform hand hygiene and put on gloves. Label a test tube with 2 patient identifiers (or the EPIC label) per hospital policy.
1. Add 3 drops Reagent 1 (pink) and 3 drops Reagent 2 to the test tube. (the solution should turn light yellow)
2. Immediately put the swab into the tube. Vigorously mix the solution by rotating the swab forcefully against the side of the tube at least 10 times. Let stand for 1 minute.
3. 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 from the container; re-cap container immediately.
4. Place the Absorbent End for the Test Stick into the extracted sample.
5. Read results at 5 minutes. Positive results may be read as soon as the red Control Line appears. Results are invalid after the stated read time. The use of a timer is recommended. Remove gloves and perform hand hygiene.

**Interpretation of Results**

**Negative Results**
A red Control Line but no blue Test Line is a presumptive negative result. It is recommended that all negative Rapid Strep results be followed by culture. Refer to the MGH Laboratory Handbook for ordering throat cultures.

**Positive Results**
A blue Test Line and a red Control Line is a positive result for the detection of Group A Streptococcus antigen. The blue line can be any shade of blue.
Invalid Results
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. If problem persists, contact the POCT program coordinators via email at mghpoctcoordinators or pager 35058.

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

Documentation
The patient’s results and the Performance Monitor results must be recorded concurrently in one of the following manners:

1. in the patient’s record, or
2. on a patient log, or
3. on another approved permanent record.

All records must be retained and retrievable for 4 years.

Quality Control
1. Internal Procedural Controls:
   The Genzyme® OSOM™ Strep A Test provides three levels of procedural controls with each test run. These must be documented for each test performed.

<table>
<thead>
<tr>
<th>Action</th>
<th>Expected Response</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Addition of Reagent 2 to Reagent 1</td>
<td>Color Change from Pink to Light Yellow</td>
<td>Reagents mixed properly. Reagents functioning properly.</td>
</tr>
<tr>
<td>2. Insertion of Strip into reagent</td>
<td>Red Control Line appears on Strip within 5 minutes</td>
<td>Sufficient sample. Proper capillary flow. Test Stick absorbed the proper amount of sample.</td>
</tr>
<tr>
<td>3. Read the test stick at 5 minutes</td>
<td>Clear Background in Control Line area</td>
<td>No interfering substances. Test Stick working properly.</td>
</tr>
</tbody>
</table>

Note: 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. Email or page the POCT program coordinators at mghpoctcoordinators or 35058.

2. External Quality Control
Each kit contains external Positive and Negative Control material. These Controls ensure that the extraction reagents and the test sticks are working properly and that the operator is competent.
A negative and a positive external control must be analyzed whenever a new test kit box is opened, with each untrained operator, or whenever the test performance is questioned.

QC Testing Procedure:
- Perform hand hygiene and put on gloves.
- Dispense 3 drops Reagent 1 and 3 drops Reagent 2 into each of two test tubes.
- Vigorously mix the control bottles. Add 1 free falling drop of control solution into the corresponding tube.
- Place a clean swab into each tube.
- Continue as you would for a patient sample, as indicated in the Test Procedure section.
- If either the positive control or the negative control fails to give expected results, repeat.
- If QC again fails, repeat using a new test kit box. Contact the POCT Coordinators for assistance if the controls fail using the new test kit box. Pager 35058 or email mghpoctcoordinators.

Limitations of the Procedure

- 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 swabs specimens must be obtained.
- This test does not differentiate between carrier and acute infection. Pharyngitis may be caused by organisms other than Group A Streptococcus.
- Please refer to the manufacturer’s package insert for the complete list of procedural limitations.

Expected Results

Approximately 19% of all upper respiratory tract infections are caused by Group A Streptococci.5 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 children6.

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 Genzyme® OSOM™ Strep A Test.

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

Training/Competency Assessment

Competency is assessed after initial training and annually (within 365 days) using at least two of the following methods:
1. Performing a test on a blind specimen.
2. Supervisor observes performance of routine work.
3. Each user’s quality control performance is monitored.
4. Written testing specific to the method.
Operators that have not completed annual competency should not perform patient testing.

References


7. Sekisui Diagnostics OSOM™ STREP A Test Package Insert, Rev. 3096-0, 06/11

Cross - References

Rapid Strep OSOM Procedure
Rapid Strep OSOM Patient Test Result-QC Log