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Document History:

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Approved by: **Signature:**	Joelle Carlson *Signature on file*	**Date:**	15-OCT-2020
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#	Details of Revisions:	Approval:	Date:
1	New document	S Hoban	01-Jul-2008
2	• Added information re: handling of (+) and (-) kit controls to External Quality Control section • Added clarification re: interpretation of (+) reactions to step #11 • Added reporting information on STRA (-) results for patients ≤ 18 years of age to Procedure Notes	S. Hoban	27-Jan-2012
3	• Added reporting information for (+) STRA antigen tests specific to penicillin allergic patients and antimicrobial susceptibility testing	S. Hoban	18-JUN-2014
4	• Equipment – 'Lab Timer' changed to 'Timer'; Biohazard container added • Supplies – section removed, biohazard container added to Equipment • Specimen – "tonsil and/or" added; specified how to submit • Special safety precautions – section revised as applicable • Quality control – info re: kit contents added to beginning of section; Reagent Control and Procedural Control sections combined, title changed to Internal Procedural Controls; External Quality Control should be run with each new batch, lot number and shipment – changed from just lot number • Interpretation/results – Invalid Result: revised re: repeat test • Procedure notes – bullets 7 and 8: comment that 'should be added' changed to 'automatically added' • Method limitations – section moved to after Procedure notes	J. Carlson	15-OCT-2020

Group A Streptococcal Antigen Detection Test

Purpose The direct Group A Streptococcal antigen detection test is intended for the rapid detection of Group A Streptococcal antigen directly from throat swabs. This test is intended for use as an aid in the diagnosis of pharyngitis caused by *S. pyogenes* (Group A Streptococcus).

Reagents OSOM Ultra Strep A Test Kit™

Equipment Timer
Biohazard container

Specimen Patient tonsil and/or throat swab submitted using dry swab in transport container.

Special safety precautions

Utilize Routine Practices as apply to the handling of bacteria. The extraction reagent bottle contains an acidic solution that will cause skin and eye irritation and sodium nitrite which may be harmful if swallowed. If solution comes in contact with skin or eyes, flush with lots of water.

The positive and negative controls contain sodium azide. If solution comes in contact with the skin or eyes, flush with lots of water. When discarding solution from kit into sink, flush with large volumes of water if one has lead or copper plumbing pipes.

Quality control

Do not use or mix components from different kit lots.
The kit provides two methods of control for the assay: internal procedural controls to aid in determining test validity and external controls to demonstrate proper test function.

Internal Procedural Controls

1. When the glass ampule in the reagent bottle is crushed and mixed with the second reagent in the bottle the resultant liquid changes from pink to light yellow. The colour change indicates that the reagents have been mixed properly and that the resultant reagent is functional.
2. For the test to work properly the Test Stick must absorb the proper amount of sample and capillary flow must occur. The red control line indicates that both of these functions have taken place.
3. A clear background serves as an internal negative procedural control. If there are no interfering substances in the patient sample and the Test Stick is working properly, the background will be clear.

External Quality Control

Each kit contains a positive and a negative control. The external controls should be used to determine that the test kit reagents and test strips are working properly. The external control should be used to evaluate the technologists' competency in test usage. External controls should be run with each new batch, lot number and shipment received and with each new operator or if there are questions regarding appropriate kit storage.
To test the Positive Control, follow steps 1-3 in the Procedure. Vigorously mix the Positive control material. Add 1 free falling drop of the Positive control from the dropper bottle into the prepared test tube. Place a clean swab into the prepared tube and follow steps 5–11 in the Procedure. Repeat same procedure using Negative Control.

Procedure

1. Just prior to testing squeeze the Extraction Reagent Bottle to crush to glass ampule inside.
2. Vigorously shake the Extraction Reagent Bottle 3-5 times to mix the contents. Resultant mixture should turn from pink to light yellow.
3. Add 6 drops of the Extraction Reagent to the Test Tube (labeled with patient identifier).
4. Immediately transfer patient swab into labeled Test Tube.

5. Vigorously mix the solution by rotating the swab forcefully against the side of the Test Tube at least 10 times.
6. Let stand 2 minutes.
7. Express as much liquid as possible from the swab by squeezing the sides of the tube as the swab is withdrawn.
8. Discard the swab into appropriate biohazard receptacle.
9. Remove the Test Stick(s) from the container – recap the container immediately.
10. Place the absorbent end of the Test Stick into the extracted sample.
11. Read results after 5 minutes. Positive results may be read as soon as the red control line appears. Negative results must be confirmed at 5 minutes.

Interpretation/results

Positive Result

A blue Test Line and a red Control Line is a positive result. Positive results (visible blue line) can be read as soon as the red Control Line appears. A positive result indicates the presence of Group A Streptococcal antigen in the sample. The blue colour is caused by the interaction of anti-Group A Streptococcal antibody conjugated colour particles and the extracted Group A Streptococcal antigen. The blue line can be any shade of blue. ***Report as positive for Group A Streptococcal antigen.***

Negative Result

A red control line but no blue test line is visible after 5 minutes. A negative result indicates that no Group A Streptococcal antigen was detected in the sample. ***Report as negative for Group A Streptococcal antigen.*** **Refer to Procedure Notes re: reporting of negative Group A Streptococcal antigen results on patients ≤18 years of age.**

Invalid Result

If after 5 minutes no red control line appears or the background colour makes reading the red control line impossible, the test is invalid. If this occurs, repeat the test using a new test stick. If the test is invalid a second time, ***report as indeterminate results – please re-submit sample.***

Procedure notes

- A blue or red line that appears uneven in colour density is still considered a valid line. In some cases, a trail of colour may remain in the background – as long as the Test Line and Control Line are visible, the results are considered valid.
- Do not use kit beyond expiry date.
- Do not use swabs that have cotton tips or wooden shafts.
- Do not use collection systems that contain charcoal or semi-solid media.
- If both culture and antigen detection is to be done on the same swab, inoculate the culture medium prior to performing the extraction procedure.
- If the test is not performed immediately, samples can be stored at room temperature or refrigerated temperature for up to 48 hours.
- If the sample submitted is from pediatric or adolescent patients (≤18 years of age), the current guidelines indicate that a negative Streptococcal antigen test should be followed up using culture. **On all negative Streptococcal antigen tests (single swab only submitted – no swab submitted for culture) from patients ≤18 years of age, the following comment is automatically added to the test result**: "If clinical symptoms are suggestive of Streptococcal pharyngitis a follow up throat swab should be submitted to the lab for culture".
- **On all Streptococcal antigen positive tests, the following comment is automatically added to the test result**: "Streptococcal A antigen test positive. If patient has a penicillin allergy (and a swab for culture was submitted), please notify lab immediately so antimicrobial susceptibility testing for alternate agents can be performed. If swab for culture not submitted, please collect and submit to lab for susceptibility testing, indicate patient is penicillin allergic."

Method limitations

Respiratory infections including pharyngitis can be caused by Streptococcal groups other than Group A as well as other pathogens. The test will not differentiate asymptomatic carriers of Group A Streptococcus from those exhibiting Group A Streptococcal infection.

As with all other diagnostic assays, results obtained by this test yield data that must be used only as an adjunct to other information available to the physician. If the antigen level is below the detection of the kit, additional follow up testing using the culture method is recommended. Recommend (if culture is available) that a swab for C & S (in transport medium) be submitted along with the sample submitted for rapid antigen testing (dry swab).

References

OSOM Ultra Strep A Test™ Package Insert, Genzyme Diagnostics, Farmingham, MA