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Area: *Laboratory-Microbiology*
Key Words:
Applicability: *All Beaumont Hospitals*

Strep Screen, Group A

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document describes the performance and reporting of the test for detection of *Streptococcus pyogenes* in throat swabs. The procedure is to be performed by trained qualified Laboratory staff.

II. CLINICAL SIGNIFICANCE:

Detection of *Streptococcus pyogenes* (Lancefield Group A) antigen in throat specimens aids in the rapid diagnosis of pharyngitis due to Group A Streptococcus.

III. PRINCIPLE:

The rapid antigen detection test (RADT) for Group A Streptococcus (GAS) is a qualitative, lateral flow immunoassay for the detection of GAS antigen in throat swabs.

IV. SPECIMEN COLLECTION AND HANDLING:

A. Refer to the Laboratory Test Directory (LTD) for detailed collection information.

B. **Specimen**

1. Throat and pharynx swabs in E-swab transport system.

C. **Shipping and Handling**

1. Room Temperature (20-26°C or 68-78.8°F): 8 hours
2. Refrigerated (2-8°C or 36-46°F): 72 hours
3. Frozen (-20°C/-4°F or below): Unacceptable

D. **Rejection Criteria**

1. Specimens collected with calcium alginate swabs.
2. Specimens submitted in amies charcoal, amies gel, and liquid Stewarts media.

E. **Storage**

1. Room Temperature (20-26°C or 68-78.8°F) or Refrigerated (2-8°C or 36-46°F) : 7 days

V. REAGENTS AND MEDIA:

A. Timer

B. Block tube holder

C. Group A Strep rapid antigen detection test kit

VI. QUALITY CONTROL:

A. Each test kit, new shipment, and lot number are tested upon receipt with external positive and negative controls against the lot in use.

   1. Internal Controls

      a. A red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

      b. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

      c. If internal controls were acceptable document in the work card by selecting "Device validation control OK." If the internal controls did not pass repeat the test, if still after repeating internal controls did not pass then notify management.

   2. External Positive and Negative Controls (provided in kit)

      a. External positive and negative controls are tested with each test kit,new shipment, and lot number to assure functionality of reagents and proper performance of the assay procedure.

      b. Run external positive and negative controls every 30 days thereafter.

B. Test external controls following these instructions:

   1. Add 4 drops of Reagent 1 and 4 drops of Reagent 2 into an extraction tube, gently mix tube mixture should appear clear.

   2. Add 1 drop of positive or negative control to the tube.

   3. Place swab from kit into tube and spin swab 10 times to mix, leave swab in tube for 1 minute.

   4. Press the swab against the side of the tube and squeeze the bottom of the tube when removing the swab leaving most of the liquid in the tube.

   5. With arrows facing down, insert test strip into tube. Set a timer and read at 5 minutes. Results are invalid after 10 minutes.

C. See the Quality Control procedure and forms to record the results.

   1. All Quality Control (QC) test results must be recorded.

   2. All unexpected QC results must be recorded, addressed, and documented.

D. The laboratory participates in the appropriate required proficiency testing (PT)/external quality assessment (EQA) program accepted by CAP.

VII. SPECIAL SAFETY PRECAUTIONS:

A. Personnel are required to follow Standard Precautions. During the COVID-19 pandemic, it is

recommended that a second barrier of protection be used during testing such as a well-fitting cloth mask, face shield, or splash guard.

VIII. PROCEDURE:

A. Testing is performed immediately following specimen receipt in lab.

B. E-Swab Transport Media

1. **NOTE: For E-Swabs, the liquid media must be used for the test. The swab in the E-Swab tube can NOT be used for the test.**
2. Vortex the sample briefly to release the sample into the liquid medium.
3. Add 4 drops of Reagent 1 and 4 drops of Reagent 2 into an extraction tube, gently mix tube mixture should appear clear.
4. Use a transfer pipette to dispense 3 drops of the liquid medium into tube, use pipette to mix contents.
5. Let extraction take place for 1 minute.
6. With arrows facing down, insert test strip into tube. Set a timer and read at 5 minutes. Results are invalid after 10 minutes.

C. Traditional Stuart's/Amies Transport Swab

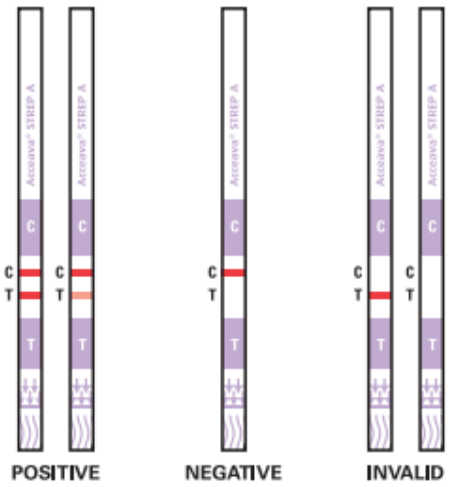
1. Add 4 drops of Reagent 1 and 4 drops of Reagent 2 into an extraction tube, gently mix tube mixture should appear clear.
2. Place swab into tube and spin swab 10 times to mix, leave swab in tube for 1 minute.
3. Press the swab against the side of the tube and squeeze the bottom of the tube when removing the swab leaving most of the liquid in the tube.
4. With arrows facing down, insert test strip into tube. Set a timer and read at 5 minutes. Results are invalid after 10 minutes.

D. Specimens from patients <16 years of age that test negative automatically reflex to confirmation by nucleic acid amplification testing

IX. INTERPRETATION:

A. Internal controls must be acceptable to report patient results.

B. Result interpretations are as follows:



C. NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of Group A Streptococcus present in the sample. Therefore, any shade of red in the test region (T) should be considered positive.

X. REPOR TING:

A. Enter the result by typing the interpretation in the appropriate field.
    1. POSITIVE:
        a. Report will be flagged as 'significant' (ABNORMAL) on chart report.
        b. Report will read: Positive: ABNORMAL RESULT
    2. NEGATIVE:
        a. Patient >/= 16 years of age (one or duo-swab submitted for testing), report will read: Negative
        b. Patient <16 years of age
            i. When one swab is submitted
                a. Report will read: Negative
                b. "The presence of Group A Strep. Group A Strep. cannot be entirely ruled out by antigen testing. Please submit a throat swab specimen for Group A Strep nucleic acid amplification testing."
            ii. When duo-swab or flocked E-Swab submitted
                a. Report will read: Negative
                b. "Reflex confirmation testing will be performed automatically for patients <16 years old with a negative result. See separate report for Group A Strep by nucleic acid amplificaiton."
    3. INVALID:
        a. Report will be flagged as 'significant' (ABNORMAL) on chart report.
        b. When one swab submitted
            i. Report will read: Unable to interpret results
            ii. "Please submit a throat swab specimen for Group A Strep nucleic acid amplification."

c. When duo-swab or flocked E-swab submitted

i. Report will read: Unable to interpret results

ii. “Reflex testing will be performed. See separate report for Group A Strep nucleic acid amplification test results.”

XI. LIMITATIONS:

A. The test should be used for the detection of Strep antigen in throat swab specimens only.

B. Neither the quantitative value nor the rate of increase in Strep A antigen concentration can be determined by this qualitative test.

C. Excess blood or mucus on the swab specimen may interfere with the test performance and may yield a false positive result.

D. Avoid touching the tongue, cheeks, and teeth, and any bleeding areas with the swab when collecting specimens.

E. A negative result may be obtained if the concentration of the Strep A antigen present in the throat swab is not adequate or is below the detectable level of the test.

F. Pharyngitis may be caused by viral or bacterial pathogens other than Group A Streptococcus.

XII. REFERENCES:

A. Campos, J., 2010. Group A Streptococcus: Culture and Non-culture Tests, In Garcia, L.S. (ed.) Clinical Microbiology Procedure Handbook, 3rd Ed., Chapter 3.11.8, American Society for Microbiology, pp. 397-404.

B. Shulman, S.T., A.L. Bisno, H.W. Clegg, M.A. Gerber, E.L. Kaplan, G. Lee, J.M. Martin, C.V. Beneden., 2012. Clinical Practice Guideline for Group A Streptococcal Pharyngitis: 2012 Update by the Infectious Diseases Society of America. Clin. Infect. Dis. doi: 10.1093/cid/cis629. Published online 9/9/2012.

C. College of American Pathologists (CAP), 7/31/2012, Microbiology Checklist MIC.2140.

D. Acceava Strep A Instructions for Use, 2018, Alere San Diego, Inc., San Diego, CA.

Attachments

IFU Acceava.pdf
One Swab Workflow.docx

Approval Signatures

Step Description	Approver	Date
	Hassan Kanaan: OUWB Clinical Faculty	10/29/2024
	Muhammad Arshad: Chief, Pathology	10/29/2024
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Step Description	Approver	Date
	Ann Marie Blenc: System Med Dir, Hematopath	10/28/2024
	Masood Siddiqui: Staff Pathologist	10/28/2024
	Ryan Johnson: OUWB Clinical Faculty	10/28/2024
	John Pui: Chief, Pathology	10/28/2024
Policy and Forms Steering Committee Approval (if needed)	Corey Webber: Mgr, Division Laboratory	10/28/2024
	Ben Von Bredow: Technical Director Microbiology	10/28/2024
	Corey Webber: Mgr, Division Laboratory	9/24/2024
	Corey Webber: Mgr, Division Laboratory	9/24/2024

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne