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SUBJECT: Group A Strep, Immunocard Stat Strep A Test

1. PRINCIPLE:

The ImmunoCard STAT Strep A Test uses color immunochormatographic 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.

2. CLINICAL SIGNIFICANCE:

Group A Streptococcus is one of the most important causes of acute upper respiratory tract infection. Early diagnosis and treatment of Group A Streptococcus pharyngitis has been shown to reduce the severity of symptoms and further complications such as rheumatic fever and glomerulonephrits.

3. SPECIMEN:

A. COLLECTION AND PROCESSING:

Collect specimens with a sterile swab from the tonsils and /or back of the throat taking care to avoid the teeth, gums, tongue or cheek surfaces. Sterile swabs are provided with the kit or rayon transport swabs containing Stuart's or Amies media may be used.

If culture is indicated, an additional swab must be collected. Testing should begin ASAP after collection, however if there is a delay the swabs may be stored for up to 48 hours at either room temperature or refrigerated.

B. REJECTION:

Do not use swabs with cotton tips, wooden shafts or calcium alginate swabs. Do not use a collection system that contains charcoal or semisolid transport media.
Mislabeled or improperly labeled specimens will not be accepted.

C. STORAGE AND PRESERVATION:

Swabs can be stored at room temperature or refrigerated for up to 48 hours. Allow refrigerated swabs to reach room temperature prior to testing.

4. REAGENTS, STANDARDS, AND CONTROLS:

The following are included in the kit:

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 (Nonviable Group A Streptococci, 0.1% Sodium Azide)
1 Negative Control (Nonviable Group C Streptococci, 0.1% Sodium Azide)
1 Directional Insert

Store Test Sticks and reagents tightly capped at 15-30° C.
Do not use test sticks or reagents after expiration date.

Do not mix components from one kit with another.

B. CONTROL PROCEDURE:

Internal Procedural Controls:
The ImmunoCard STAT Strep A Test provides 3 levels of procedural controls with each 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 control. The color change means that you mixed the reagent properly. The color change also means that the reagents are functioning properly.
2. The red Control Line is an internal positive procedural control. The Test Stick must absorb the proper amount of sample and Test Stick must be working properly for the red Control line to appear.
3. The clear background is an internal background negative procedural 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.

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.

External Procedural Control Testing:
Each kit contains Positive and Negative Control material. These controls are for external quality control testing. Use these controls to test that the extraction reagent and test sticks are working properly. Also, use controls to see if test procedure is being performed correctly.

Testing procedure:

- Dispense 3 drops reagent 1 and 3 drops reagent 2 into Test tube.
- Vigorously mix the control contents. Add 1 free falling drop of Control from dropper bottle.
- Place a clean swab into the Tube.
- Continue as you would for a patient sample, as instructed in the Procedure section.

A positive and negative control must be tested with each new box opened. An equivalent QC study was performed and is on file with the kit validation.

Some commercial controls contain interfering additives and should not be used.

5. EQUIPMENT: N/A

6. PROCEDURE:

A. PERFORMANCE:

1. Add 3 drops Reagent 1 and 3 drops Reagent 2 to the Test Tube. The solution should turn yellow.
2. Immediately put the swab into the Tube.
3. Vigorously mix the solution by rotating the swab forcefully against the side of the Tube at least 10 times. Best results are obtained when the specimen is vigorously extracted in the solution.
4. Let stand for 1 minute.
5. Express as much liquid as possible from the swab by squeezing the sides of the tube as the swab is withdrawn.
6. Discard the swab.
7. Remove Test Stick from the container and recap immediately.
8. Place the absorbance end of the Test Stick into the extracted sample.
9. Read results at 5 minutes. Positive results may be read as soon as the red control line appears.
10. Results are invalid after the stated 5 minute read time. The use of a timer is recommended.

B. INTERPRETATION OF RESULTS:

POSITIVE:
A blue Test Line and a red Control line of any intensity is a positive result for the detection of Group A Streptococcus.

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

INVALID:
If no red Control line appears or background color makes reading he red Control Line impossible, the result is invalid. If this occurs, repeat the test on a new Test Stick. If problem persist, contact POCT office or Meridian Bioscience Technical Services at 1-800-343-3858.

7. QC PERFORMANCE POLICY:

Positive and negative external controls treated under the same conditions as the patient sample must be tested when opening a new test kit. Do not use kit if the external positive or the internal negative controls do not yield appropriate results. Refer to the label on the box for the lot numbers and expiration dates and record result on the kit log and in the LIS. Mark box with date QC performed & initials. If the controls do not meet acceptable limits, contact POCT or NVML.

B. FAILURE/REMEDIAL ACTION:

Do not report patients if controls fail. Open a new box. If QC still fails, borrow a new kit with a different lot number from New Vision Medical Lab, SRMC.

8. EXPECTED RESULTS:

A. REPORTABLE RANGE:

Report as Positive or Negative. All negatives will reflex to a culture.

C. REFERENCE RANGE:

Negative

D. CRITICALVALUES:

N/A

10. PROCEDURAL NOTES:

A. BACKUP FOR INOPERABLE SYSTEM

In instances of need for immediate testing, the properly labeled specimen will be sent to New Vision Medical Laboratory, SRMC for testing.

C. SUBMISSION/HANDLING OF REFERRAL SPECIMENS:

Any specimen transported must be packaged in compliance with NVML regulations covering the transportation of etiologic agents.

11. LIMITATIONS AND INTERFERRING SUBSTANCES:

The accuracy of the test depends on the quality of the swab. False negatives may result from improper sample collection or storage. A negative result may be obtained from patients at the onset of the disease due to a low concentration of the antigen. Therefore ALL negatives must have a culture set up. This should automatically reflex. The ImmunoCard STAT Strep A Test can 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.
This test does not differentiate between carriers and acute infection. Pharyngitis may be caused by organisms other than Group A Streptococcus.

12. METHOD VALIDATION:
November 23 – December 20 2012.

13. REFERENCES:

Package insert, ImmunoCard STAT Strep A Test, catalogue number 755250.

Policy Approval:

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