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**Intended Use:**

 The ImmoCard STAT Strep A test is intended for the qualitative detection of Group A Streptococcal antigen from throat swabs or confirmation of presumptive Group A Streptococcal colonies recovered from culture.

**Summary and Explanation of Test:**

 Group A Streptococcus is one of the most important causes of acute upper respiratory 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 ImmuCard STAT Strep A Test detects either viable or nonviable organisms directly from a throat swab, providing results in five minutes.

**Biological Principles:**

 The ImmuCard STAT Strep A test uses color immunochromatographic dipstick technology with rabbit antibodies coated on a 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.

**Reagents/Materials Provided:**

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

 Materials required, but not provided: A timer or stopwatch

**Storage:**

 Store test sticks and reagents tightly capped at 15-30 C.

 Do not use test sticks or reagents after expiration date.

**Precautions:**

 For in vitro diagnostic use.

Follow laboratory/hospital guidelines in the identification, collection, handling, storage, and disposal of controls, patient specimens, and all items exposed to patient specimens.

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 0.1% sodium azide which can react with lead or copper plumbing to form potentially explosive metal azide. For sites permitted to dispose of material down the sink, large quantities of water must be used to flush discarded control material down the sink>

Do not interchange or mix components from different kit lots.

**Specimen Collection and Preparation:**

Collect specimens with a sterile swab from the tonsils and/or back of the throat taking care to avoid teeth, gums, tongue and cheek surfaces.

* 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.
* Two swabs must be collected from each patient. The procedure for Immucard STAT Group A and the negative confirmation (if necessary) both require an extraction procedure and the sample in both cases become nonviable afterward.
* Process the swab as soon as possible after collection. If you do not perform the test immediately, store the swab either at room temperature for refrigerated for up to 48 hours. The swabs and the test kit must be at room temperature prior to testing.

Sample transport:

* The test does not require live organism for testing, a rayon transport swab containing Stuart’s or Amies media may be used in place of the swabs that come with the kit.

**Test Procedure:**

* Just before testing add 3 drops of Reagent 1(pink) and 3 drops of Reagent 2 to the rest tube (the solution should turn light yellow).
* Immediately put the swab in the tube
* Vigorously mix the solution my rotating the swab forcefully against the sides of the tube at least ten times. The best results are obtained when the specimen is vigorously extracted in the solution.
* Let stand for 1 minute.
* 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 the test stick from the container; immediately recap the container.
* Place the absorbent end of the test stick into the extracted sample.
* Read the result at 5 minutes. Positive results may be read as soon as the red control line appears, negative results must wait the full 5 minutes.
* **Reults are invalid after the stated read time.**

**Interpretation of Results:**

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

**POSITIVE:**

 A blue test line and red control line is a positive result for the detection of Group A Streptococcus antigen. Note that the blue line can be any shade of blue and can be lighter or darker.

**NEGATIVE:**

 A red control line, but no blue test line is a presumptive negative test result.

**INVALID:**

 If no control line appears or the background color makes reading the red control line impossible, the result is invalid. If this occurs, repeat the test on a new test stick or contact Meridian Bioscience Technical Services.



**Quality Control:**

**Internal Controls**-The ImmuCard STAT Strep A test provides three levels of procedural controls with each test run:

1. The color of the liquid changes from pink to light yellow as you add the 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.
2. The red control line is an internal positive procedural control. The test stick must absorb the proper amount of sample and the test stick must be working properly for the red control line to appear. For the test stick to work properly, the capillary flow must occur.
3. A 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 be clear. A discernible result will be seen.

**External Quality Controls**- Each kit contains Positive and Negative Control material. The controls are for external quality control testing. Use the controls to test that the reagents and the test sticks are working. Also use the controls to test that you are able to correctly perform the test procedure. Some commercial controls may contain interfering additives. Therefore Meridian Bioscience recommends that you do not use other commercial controls with the ImmuCard STAT Strep A test.

External quality control will be performed each new lot, delivery, or every 30 days in accordance with CLIA regulations.

**External Quality Control Procedure:**

1. Dispense 3 drops Reagent 1 and 3 drops Reagent 2 into a test tube.
2. Vigorously mix the control contents. Add 1 free falling drop of Control fron dropper bottle.
3. Place a clean into test tube.
4. Continue as you would for a patient sample, as instructed in the Procedure section.

**Expected Values:**

 Approximately 19% of all upper respiratory infections are caused by Group A Streptococci. 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-aged children.

**Performance Characteristics:**

 In a multicenter evaluation, a total of 639 throat swabs collected from patienting with pharyngitis. Each swab was inoculated to a sheep blood agar plate, then tested by the ImmunoCard STAT Group A Strep test. Plates were incubated for 18-24 hours at 35-37 C at 5-10% CO2 with a Bacitracin disk. Presumptive GAS colonies were confimrd with commercially available Strep A testing kits.

 Of the 639 total specimens, 464 were found to be negative by culture and 454 were also negative by ImmunoCard STAT Strep A test, for a specificity of 97.8%. Of the 175 specimens found to be positive by culture, 168 were also positive by ImmuCard STAT Strep A test, for a sensitivity of 96.0%. The 95% confidence intervals were calculated to be 96.6-99.0% for a specificity and 94.4-97.6% for sensitivity. Overall agreement between culture and the ImmunoCard STAT Strep A test was 97.3% (622/639).

 In addition, the ImmunoCard STAT Strep A test was used to confirm the identification of Group A Strep on blood agar plates. As a culture confirmation test, the ImmunoCard STAT Strep A test was 100% sensitive (62/62) and 100% specific (39/39).

**Crossreactivity:**

 The following organisms tested at levels of approximately 1 x 10^8 organisms per test were found to be negative when used with the ImmunoCard STAT Strep A test.

Streptococcus Group B Staphylococcus aureus Bordetella pertussis

Streptococcus Group C Staphylococcus epidermidis Neisseria meningitides

Streptococcus Group F Corynebacterium diphtheria Neisseria gonorrhoeae

Streptococcus Group G Serratia marcescens Neisseria sicca

Streptococcus pneumoniae Candida albicans Neisseria subflava

Streptococcus sanguis Klebsiella pneumoniae Branhamella catarrhalis

Streptococcus mutans Pseudomonas aeruginosa Hemophilus influenza

Enterococcus faecalis

**POL Studies:**

 An evaluation of the ImmunoCard STAT Strep A test was conducted at three physicians’ offices where testing was performed by personnel with diverse educational backgrounds. Each site tested the randomly coded panel consisting of 6 negative, 3 low positive, and 3 moderate positive specimens for three days. The results obtained had >99% agreement (107/108) with the expected results.

 Reviewed (No Changes):

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