

ImmunoCard STAT! Strep A Test [Manual Tests Manual]		
Doc#:	Section: Microbiology	Effective Date 3/09/2021

SCOPE: This policy applies to UPMC Hanover.

KEYWORDS: Strep A, Rapid Strep Strep screen

PURPOSE: The ImmunoCard 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. It detects either viable or non-viable organisms directly from a throat swab, providing results within five minutes.

EQUIPMENT: (Store kits at 15-30 °C)

- 50 test sticks, 50 test tubes, 50 sterile swabs
- 1 Reagent 1 (2M Sodium nitrite)
- 1 Reagent 2 (0.3 M Acetic acid)
- 1 Positive control (Nonviable Group A Streptococci, 0.1% Sodium Azide)
- 1 Negative control (Nonviable Group C Streptococci, 0.1% Sodium Azide)
- Package Insert
- Timer (not provided)

QUALITY CONTROL:

Performed with each new lot/shipment and every 30 days.

Positive, non-viable Group A Streptococcus-used as patient sample with one drop of positive control in reagents. Add clean swab and mix as patient.

Negative, non-viable Group C streptococcus-used as one drop of negative control in reagents. Add clean swab and mix as patient.

Internal procedural controls include: the color change of solution from pink to light yellow, the red line for the control means capillary flow is acceptable, and the background of the test stick should be clear behind the control line.

SPECIMEN:

Collect specimens with a sterile swab from the tonsils and/or back of the throat, taking care to avoid teeth, gums, tongue or cheek surfaces. Preferably, use a double swab to allow for culture of negative specimens with an A disc.

Do not use cotton swab, wooden shaft, or calcium alginate swabs.

Do not use a collection system that contains charcoal or semisolid transport media.

Use of rayon swabs with Liquid Amies or Stuart's media may also be used.

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Swabs should be processed as soon as possible after collection but may be stored at room temp or refrigerated for up to 48 hours.

The ImmunoCard STAT! Strep A test can also be used to confirm the identification of Group A Streptococcus on blood agar plates. The plates must be less than 72 hour old. Lightly touch 1-3 colonies (showing characteristic beta hemolysis) using a sterile swab. Do not sweep the plate. Follow the instructions under the procedure to test the swab.

PROCEDURE:

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, (Best results are obtained when the specimen is vigorously extracted in the solution.)
3	Set the timer for one minute.
4	At the end of the minute, express as much liquid as possible by squeezing the sides of the tube as the swab is withdrawn.
5	Discard the swab.
6	Remove test stick from the container and immediately recap the container.
7	Place the absorbent end of the test stick into the extracted sample.
8	Read results at 5 minutes. (Positive results may be read as soon as the red control line appears.)
9	Results are invalid after the 5 minute read time.

INTERPRETATION/RESULTS:

A blue test line and a red control like indicate an acceptable positive result for detection of Group A Streptococcus.

A red control line but no blue line indicates an acceptable negative result.

If the control line and test line are not visible, the test is invalid and needs to be rerun.

LIMITATIONS:

This test has been CLIA waived only for the application of qualitative detection of Group A Streptococcal Antigen from throat swabs. The application for the confirmation of presumptive Group A Streptococcal colonies recovered from culture is not waived.

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The results obtained must be used in conjunction with other information available to the physician. The Immunocard STAT! Strep A Test is a qualitative test for the detection of Group A Streptococcal Antigen. It does not differentiate between viable and non-viable organism.

This test should only be used with throat swabs or colonies taken directly from a plate. The use of swab specimens taken from other test sties or use with saliva sputum, or urine has not been established. The quality of the test depends on the quality of the sample; proper throat swab specimens must be obtained.

This test does not differentiate between carriers and acute infection. Pharyngitis may be caused by organisms other than Group A Streptococcus.

A negative result may be obtained if the specimen is inadequate or antigen concentration is below the sensitivity of the test.

REFERENCES:

Package insert for ImmunoCard STAT! Strep A test, Meridian Bioscience, Inc., USA corporate Offices, 3471 River Hills Drive, Cincinnati, Ohio 45244

Document History

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