



28 Pierre Koenig St., Talpiot Industrial Area
P.O.B 53231 Jerusalem 91531 ISRAEL
Phone: 972-2-6781861; Fax : 972-2-6781852
e-mail: info@novamed.co.il
www.novamed.co.il



StrepA One Step Cassette Swab Device

One-Step Test for Direct Determination of Group A Streptococcus

Catalog Number R-6057 (20 Determinations)

Directions for Use

SUMMARY AND EXPLANATION

Among the beta-hemolytic streptococci causing infections in humans, the A, B, C and G groups figure most prominently⁵. Group A streptococci continue to be a focus of interest not only because of their causal role in acute streptococcal pharyngitis and other pyogenic infections but also because of their association with post streptococcal sequelae, specifically acute rheumatic fever and acute glomerulonephritis^{1,2}. In order to properly treat the disease using antibiotic therapy, it is important to use an accurate diagnostic method to identify the pathologic agent. For the screening of group A streptococcal infection several methods are currently used including susceptibility of the organism to a bacitracin disc placed on a sheep blood agar plate, latex agglutination and enzyme immunoassay^{3,4}. The Strep A One Step Cassette Swab Device is a rapid test to qualitatively detect the presence of Strep A antigen in specimens, providing results within 5-10 minutes. The test utilizes antibodies specific for whole cell Lancefield Group A Streptococcus to selectively detect Strep A antigen in a specimen.

PRINCIPLE

The Novamed Strep A One Step Cassette Swab Device is a rapid qualitative, lateral flow immunoassay for the detection of Streptococcus Group A carbohydrate antigen. The method employs polyclonal antibody-dye conjugate and polyclonal solid phase antibodies to selectively identify streptococcus A with a high degree of sensitivity. As the test sample flows through the absorbent device, the labeled antibody-dye conjugate binds to the Strep A carbohydrate antigen forming an antibody-antigen complex. This complex binds to the anti-Strep A antibody in the test zone producing a purple color band. In the absence of Strep A there is no line in the test zone. The reaction mixture continues flowing through the absorbent device. Unbound conjugate binds to the reagents in the control zone producing a purple color band, indicating that proper volume of specimen has been added and membrane and the reagents are functioning correctly.

COMPONENTS:

- 20 test cassettes placed in individual pouches with desiccant;
- 20 empty test tubes placed in a plastic stand;
- 1 dropper with Extraction Reagent (0.4M Acetic Acid);
- Instructions for Use

STORAGE AND STABILITY

Strep A One Step Cassette Swab Device is to be stored at 2 to 25°C in the tightly closed tube. **Do not freeze the test kit.**

PRECAUTIONS

1. This test is designed for "*IN VITRO*" use only.
2. Extraction reagent may cause irritation to skin, eyes and mucus membranes. Wash off immediately if extraction reagent came in contact with skin.
3. Read carefully instruction notice before using this test.
4. Do not use beyond expiry date that appears in the package label.

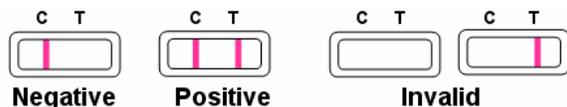
SPECIMEN COLLECTION

- Only use reagents and sterile swabs provided in the kit.
- Collect the throat swab specimen with the sterile swab that is provided in the kit. Swab the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab⁶.
- Testing should be performed immediately after the specimens have been collected. Swab specimens may be stored in a clean, dry plastic tube for up to 8 hours at room temperature or 72 hours at 2-8°C.
- If a culture is desired, lightly roll the swab tip onto a Group A selective (GAS) blood agar plate before using the swab with the Strep A One Step Cassette Swab Device.

ASSAY PROCEDURE

1. Hold the Extraction Reagent bottle vertically and **add 5-6 full drops** (approximately 200-240 µL) into the test tube.
2. **Immediately insert** the specimen loop into the test tube containing the extraction solution and twirl the loop to mix the bacteria thoroughly. Discard the loop into hazardous waste container.
3. **Take 100-150 µl** of the resulting solution and load it into the sample well of the Strep A One Step Cassette Swab Device and start the timer.
4. Wait for the colored line(s) to appear. **Read results within 5 minutes.** Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS



Negative: only one purple band appears in the Control window. No band is visible in the Test window.

Positive: in addition to the Control band a clearly distinguishable purple band also appears in the Test window.

Invalid: If no control band is visible the test is inconclusive. The test should be repeated using a new device.

QUALITY CONTROL

Internal Quality Control

Internal procedural controls are included in the test. A colored line appearing in the control line region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Cross-Reactivity

The following organisms were tested at 1.0×10^6 - 1.0×10^8 organisms per test and were all found to be negative when tested with the Strep A One Step Cassette Swab Device (Throat Swab).

Group B Streptococcus

Streptococcus pneumoniae

Streptococcus mutans

Staphylococcus aureus

Group C Streptococcus

Enterococcus faecalis

Aerococcus viridans

Staphylococcus saprofiticus

Staphylococcus epidermidis

Neisseria meningitidis

Neisseria sicca

Klebsiella pneumoniae

Pseudomonas aeruginosa

Haemophilus influenzae

Candida albicans

Intra-batch variability

Method		<i>S. pyogenes</i>		<i>S. agalactiae</i>	<i>S. equi</i>
Strep A One Step Cassette Swab Device	Results	Positive	Negative	Positive	Positive
	Positive	6	0	0	0
	Negative	0	6	6	6

Inter-batch variability

Method		<i>S. pyogenes</i>		<i>S. agalactiae</i>	<i>S. equi</i>
Strep A One Step Cassette Swab Device	Results	Positive	Negative	Positive	Positive
	Positive	3	0	0	0
	Negative	0	3	3	3

LIMITATIONS OF THE TEST

- Strep A One Step Cassette Swab Device is for *in vitro* diagnostic use only.
- This test will only indicate the presence of Strep A antigen in the specimen from both viable and non-viable Group A Streptococcus bacteria.

BIBLIOGRAPHY

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