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THE STANDARDS INSTITUTION OF ISRAEL

StrepA*ID* ONE STEP DEVICE (single test)

One-Step Test for detection of group A Streptococcal antigen directly from a patient throat swab with no reagent manipulation.

Catalog Number R-5001

Directions for Use

INTENDED USE

StrepA*ID* is a real one step LFIA test. Novamed's novel approach allows for fast and reliable detection of group A Streptococcal antigen directly from a patient throat swab with no reagent manipulation.

SUMMARY

Among the beta-hemolytic streptococci causing infections in humans, the A, B, C and G groups figure most prominently [5]. 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 *StrepAID* is a rapid 1-step 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 throat swab specimen.

PRINCIPLE

The Novamed *StrepAID* test is a rapid qualitative, lateral flow immunoassay for the detection of Streptococcus Group A carbohydrate antigen. The method employs polyclonal-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.

MATERIALS

1 *StrepAID* device;
1 sterile throat swab;
Instructions for Use

STORAGE AND STABILITY

StrepAID is to be stored at 2 to 25°C in the tightly closed tube.
Do not freeze the test kit.

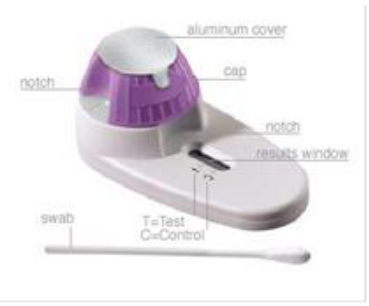
SPECIMEN COLLECTION

- Only use 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 swab.[6]
- 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 *StrepAID*.

ASSAY PROCEDURE

1. Remove the device from the sealed pouch and place it on a flat horizontal surface (Fig. A below).
2. Hold the device stable with one hand. Carefully remove the aluminum cover of the purple cap with the other hand. Note! The purple cap contains liquid.
3. Remove swab from the wrapper.
4. Collect the throat swab specimen with the sterile swab that is provided in the kit.
5. Rotate the swab in the liquid placed in the purple cap, for 20sec (Fig. B below).
6. Pull out the swab carefully while squeezing it against the inner wall of the purple cap. **Discard the swab**.
7. Hold the device stable with one hand. Turn the purple cap counterclockwise until it stops (b), and then turn it back to starting point (a) (Fig. C below).
8. Repeat step no.7 two more times. In the final position the notches on the purple cap and the white base must be aligned (b).
9. Read results after 5 minutes. A purple line should appear at the control (C) mark. In case of positive results, an additional purple line should appear at the test (T) mark. In case of negative or unclear result read again after 5 more minutes. Do not interpret thereafter.

A



B

C

INTERPRETATION OF RESULTS

T C	***Negative:*** only one purple band appears in the Control spot. No band is visible in the Test spot.
T C	***Negative:*** only one purple band appears in the Control spot. No band is visible in the Test spot.
T C	***Negative:*** only one purple band appears in the Control spot. No band is visible in the Test spot.

PRECAUTIONS

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

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 10^6- 10^8 organisms per test and were all found to produce a negative result when tested with the *StrepAID*.

Group B Streptococcus
Streptococcus pneumoniae
Streptococcus mutans
Staphylococcus aureus
Group C Streptococcus
Enterococcus faecalis
Aerococcus viridans
Staphylococcus saprofiticus
Staphylococcus epidermidis
Neisseria meningitides
Neisseria sicca
Klebsiella pneumoniae
Pseudomonas aeruginosa
Haemophilus influenzae
Candida albicans
* Samples very heavily inoculated with certain *S. Aureus* strains may produce a fade false positive result.

Intra-batch variability

Method		*S. pyogenes*		*S. agalactiae*	*S. equi*
StrepAID	**Results**	**Positive**	**Negative**	**Positive**	**Positive**
	Positive	6	0	0	0
	Negative	0	6	6	6

Inter-batch variability

Method		*S. pyogenes*		*S. agalactiae*	*S. equi*
StrepAID	**Results**	**Positive**	**Negative**	**Positive**	**Positive**
	Positive	3	0	0	0
	Negative	0	3	3	3

LIMITATIONS OF THE TEST

- The *StrepAID* is for *in vitro* diagnostic use only. The test should be used for the detection of Strep A antigen in throat swab specimens only. Neither the quantitative value nor the rate of increase in Strep A antigen concentration can be determined by this qualitative test.
- This test will only indicate the presence of Strep A antigen in the specimen from both viable and non-viable Group A Streptococcus bacteria.
- A negative result must be confirmed by culture. 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.
- The sterile swabs provided with this test must be used for specimen collection. Other swabs have not been validated with this test.
- Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result. Avoid touching the tongue, cheeks, and teeth[6] and any bleeding areas of the mouth with the swab when collecting specimens.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

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