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CE IVD

Rapid-VIDITEST

Strep A

A rapid one step test for the qualitative detection of Group A Streptococcus (GAS) antigens in human throat swab specimens

Instruction manual

INTENDED USE:

The Rapid-VIDITEST Strep A is a rapid chromatographic immunoassay for the qualitative detection of Group A *Streptococcus* antigens in human throat swab specimens to aid in the diagnosis of GAS infection (“strep throat”). Only for laboratory use.

INTRODUCTION:

Group A *Streptococcus* is a bacterium often found in the throat and on the skin. People may carry group A streptococci in the throat or on the skin and have no symptoms of illness. Most GAS infections are relatively mild illnesses such as "strep throat," or impetigo. On rare occasions, these bacteria can cause other severe and even life-threatening diseases.
Strep throat is an infection caused by group A *Streptococcus* bacteria, and it's very common among kids and teens. The symptoms of “strep throat” include fever, stomach pain, and red, swollen tonsils. Strep throat may produce mild or severe symptoms.

PRINCIPLE OF THE TEST:

The Rapid-VIDITEST Strep A is a qualitative lateral flow immunoassay for the detection of Group A *Streptococcus* antigen in human throat swab samples. The membrane is pre-coated with monoclonal antibodies against GAS antigens on the test line region. During testing, the sample reacts with the particle coated with anti-GAS antibodies which was pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will react with the mixture conjugate and generate two coloured lines. A BLUE coloured line always appears in the control line and serves as 1) verification that sufficient volume is added, 2) that proper flow is obtained and 3) as an internal control for the reagents.

MATERIALS PROVIDED:

- Card tests (Plastic pipettes included)
- Diluent A (2M Sodium Nitrite) Toxic
- Diluent B (0.15M Acetic Acid)
- Swabs

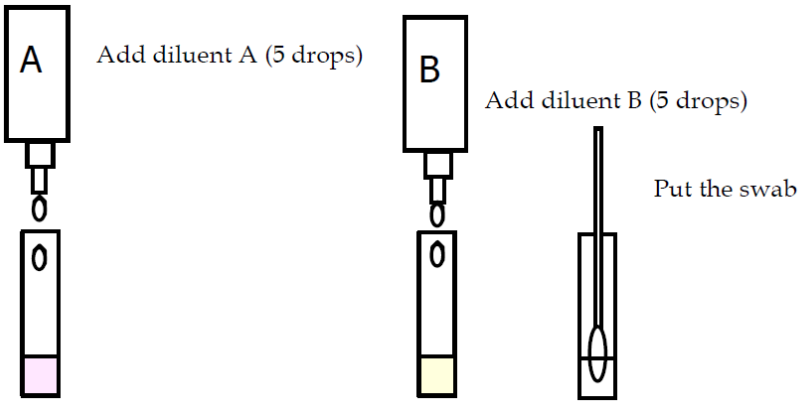
- Testing tubes or vials
- Strep A Control swab
- Instructions for use
  The safety data sheet (MSDS) is available upon request.

MATERIALS REQUIRED BUT NO PROVIDED:
- Specimen collection container
- Disposable gloves
- Timer

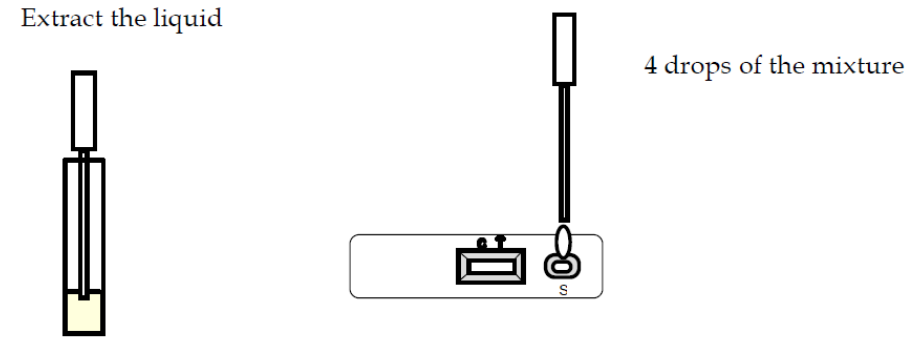
SPECIMEN COLLECTION AND PREPARATION:

Collect the throat swab sample with a sterile swab, from the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.
Send specimen to lab immediately (testing sensitivity decrease over time).
Swab sample may be stored and transport in a clean and dry container at room temperature for up to 8 hours prior to testing, or 24 hours at 2-8ºC/36-46.4ºF).

TEST PROCEDURE:
Allow the tests, samples and diluents to reach room temperature (15-30ºC/59-86ºF) prior to testing. Do not open the pouches until ready to perform the assay.
To process the collected throat swab sample:
Use a separate testing tube or vial for each sample (swab). Add the diluent A (5 drops) into the testing tube or vial. Add the diluent B (5 drops) and mix, the colour of the solution changes from light pink to light yellow (colourless). Put the throat swab, mix and extract as much liquid possible from the swab.



Remove the Rapid-VIDITEST Strep A from its sealed pouch and use it as soon as possible. Use a separate card for each sample. Dispense exactly 4 drops into the specimen well (S). Start the timer. Read the result at **10 minutes** after dispensing the sample.



INTERPRETATION OF RESULTS:

POSITIVE **NEGATIVE** **INVALID** **INVALID**

POSITIVE: Two lines appear across the central window, a **red** test line marked with the letter T and a **blue** control line marked with the letter C.

NEGATIVE: Only one **blue** line appears across the control line region marked with the letter C (control line).

INVALID: Total absence of the blue control coloured line regardless the appearance or not of the red test line. Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact your local distributor.

NOTES ON THE INTERPREATION OF RESULTS:
The intensity of the red coloured band in the result line region (T) will vary depending on the concentration of antigens present in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

QUALITY CONTROL:
Internal procedural controls are included in the test.
- A blue line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS:
1. Rapid-VIDITEST Strep A will only indicate the presence of GAS in the specimen (qualitative detection) and should be used for the detection of GAS antigens in throat swab specimens only. Neither the quantitative value nor the rate of increase in GAS antigens concentration can be determined by this test.

2. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of GAS infection.

3. This test provides a presumptive diagnosis of GAS infections. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

EXPECTED VALUES:

There are several million cases of “Strep throat “each year. About 9,400 cases of invasive GAS disease occurred in the United States in 1999.

PERFORMANCE:

Sensitivity and specificity

The detection of GAS with Rapid-VIDITEST Strep A showed >99% of sensitivity compared with another commercial rapid test and showed >99% of specificity compared with that commercial rapid test (OSOM® Strep A Test, Genzyme Diagnostics).

Cross-Reactivity

It was performed an evaluation to determine the cross reactivity of Rapid-VIDITEST Strep A. There is not cross reactivity with common respiratory pathogens: *Adenovirus*, Group D *Streptococcus Enterococcus, Influenza* type A, *Influenza* type B.

STORAGE AND STABILITY:

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC/36-86ºF). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze.

PRECAUTIONS:

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not use the test if pouch is damaged.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test should be discarded in a proper biohazard container after testing.
- The test must be carried out within 2 hours of opening the sealed bag.

HAZARDOUS INGREDIENTS:

Diluent A (hazardous ingredient: Sodium Nitrite):

- Avoid contact with eyes and skin. Do not ingest or inhale. Toxic by ingestion. Harmful by inhalation and in contact with skin. May cause severe eye irritation. For more information see MSDS.

REFERENCES:

- Vincent MT, Celestin N, Hussain AN. Pharyngitis. Am Fam Physician 2004;69:1465-70.
- McIsaac WJ, Goel V, To T, Low DE. The validity of a sore throat score in family practice. CMAJ 2000;163:811-5.

SYMBOLS FOR IVD COMPONENTS AND REAGENTS:

IVD	*In vitro* diagnostic device	LOT	Batch code
	Use by		Manufacturer
	Temperature limitation	DIL	Diluent (sample diluent)
Σ	Number of tests		

Last Revision: June 2015/A

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