STREPA MonlabTest®

DIM-100001 25 TESTS

One Step Streptococcus Group A Test Device

CE IVD

A rapid, one step test for the qualitative detection of Group A *Streptococcus* (GAS) from throat swab.
For professional *in vitro* diagnostic use only.

INTENDED USE

The Strep A MonlabTest® is a rapid chromatographic immunoassay for the qualitative detection of Group A *Streptococcus* from throat swab to aid in the diagnosis of GAS infection ("strep throat").

SYNTHESIS

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

Strep A MonlabTest® 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 Group A *Streptococcus* antigens on the test line region. During testing, the sample reacts with the particle coated with anti-Group A 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 coloured lines. A blue coloured band always appears in the control line and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

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.
- Reactive 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. EC R-phrases: R8, R25, R50. EC Hazard class: T, O, N.

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.

MATERIALS PROVIDED	MATERIALS REQUIRED BUT NO PROVIDED
- 25 Tests - Instructions for use - 1 Diluent B (Sample diluent) - 1 Diluent A (Sample diluent) - 25 Sterile swabs - 1 Strep A control + - 25 Testing tubes or vials - 25 Plastic pipettes	- Specimen collection container - Disposable gloves - Timer

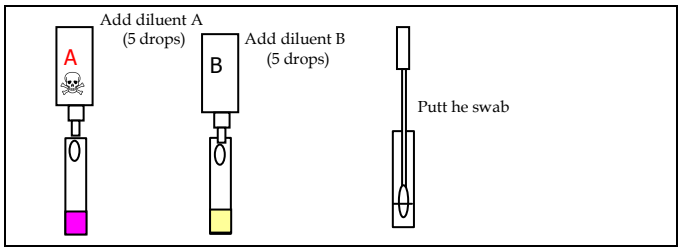
SPECIMEN COLLECTION AND PREPARATION

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 four hours prior to testing, or 24 hours at 2-4ºC/36-40ºF).

PROCEDURES

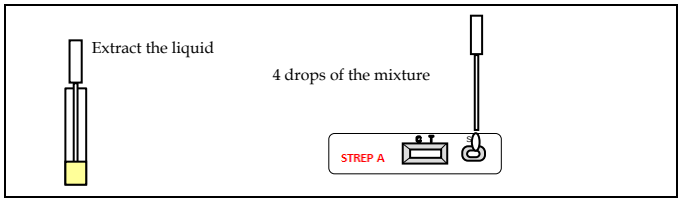
Allow the tests, samples and diluents to reach to room temperature (15-30°C/59-86°F) prior to testing. Do not open the tube until ready to perform the assay.
To process the collected throat swab sample (see illustration 1):
Use a separate testing tube or vial for each sample (swab). Add the diluent A (5 drops) into the testing tube or vial. Add the diluent B (5 drops) and mix, the colour of the solution changes from pink to yellow. Put the throat swab, mix and extract as much liquid possible from the swab.

Illustration 1



Remove the Strep A MonlabTest®from its sealed pouch and use it as soon as possible. Use a separate device 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

Illustration 2



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INTERPRETATION OF RESULTS

Illustration 3

POSITIVE: Two lines appears across the central window, in the result line region (**red** test line marked with the letter T) and in the control line region (**blue** control line marked with the letter C).

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

INVALID: A total absence of the **blue** control coloured band regardless the appearance or not of the **red** test line. 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 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 green line appearing in the control line region (C). It confirms sufficient specimen volume and correct procedural technique.

External Quality Control

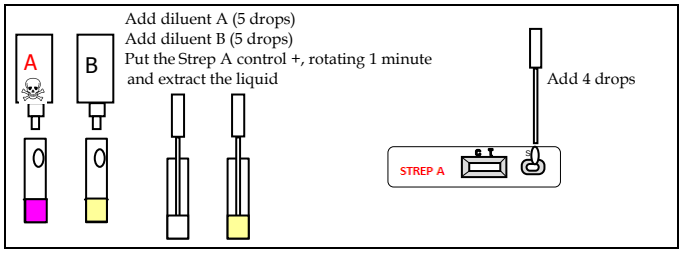
Each kit contains a positive control material. Use the control swab to check that the extraction reagents and the test are working properly. Also use the controls to test that you are able to correctly perform the test procedure.

Quality Control Procedure:

Strep A Positive Control: Remove the Strep A positive control from its sealed pouch. Add the diluent A (5 drops) in a testing tube. Add the diluent B (5 drops) and mix, the colour of the solution changes from pink to yellow. Put the Strep A, positive control swab, mix 60 seconds and extract as much liquid possible from the swab. Discard the swab. Remove the test from its sealed pouch and dispense 4 drops or 100 uL of the positive control liquid into the specimen well (S).

Result: Strep A POSITIVE (see interpretation of results).

Illustration 4



LIMITATIONS

1. Strep A MonlabTest® 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 CHARACTERISTICS

Sensitivity and specificity

Using an independent laboratory for evaluation, different bacterial preparations from cultures of *Streptococcus pyogens* (10^1 CFU/mL-10^8 CFU/mL) were tested directly in the sample diluent or spiked in negative throat specimens in accordance with the kit instructions. Detection limit: 10^5 CFU/mL.

The detection of GAS with Strep A MonlabTest® showed >99% of sensitivity compared with another commercial rapid test and showed >99% of specificity compared with that commercial rapid test.

Cross-Reactivity

It was performed an evaluation to determine the cross reactivity of Strep A MonlabTest®. There is not cross reactivity with common respiratory pathogens:

- Respiratory syncytial virus
- Adenovirus
- *Group D Streptococcus*

REFERENCES

1. Vincent MT, Celestin N, Hussain AN. Pharyngitis. Am Fam Physician 2004;69:1465-70.
2. 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

	Manufacturer	IVD	For *in vitro* diagnostic use only
	Don't re-use		Consult instructions for use
Σ n	Contains sufficient for <n> tests		Keep dry
REF	Catalogue Code		Temperature limitation
LOT	Lot Number		Use by

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