Proflow™ Streptococcus A

(for *In Vitro* Diagnostic use only)

PRODUCT CODE PL.3026 **20 Tests**

INTENDED USE

The Proflow™ Streptococcus A test is a single use rapid membrane immunoassay for the qualitative detection of Group A Streptococcus (GAS) antigen in human throat swab samples to aid in the diagnosis of Group A Streptococcus infection (“strep throat”). For *In Vitro* Diagnostic Use.

SUMMARY AND EXPLANATION

GAS 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 GAS, and it's very common among children and teenagers. The symptoms of “strep throat” include fever, stomach pain and red, swollen tonsils.

PRINCIPLE OF THE TEST

The Proflow™ Streptococcus A test is a single use rapid membrane immunoassay for the qualitative detection of Group A Streptococcus antigen in human throat swab samples or GAS colonies recovered from culture.
Monoclonal antibodies to Streptococcus A antigen are coated onto the test line region of the strip. During testing the sample migrates along the membrane by capillary action and is allowed to react with the conjugate on the test strip.
In the case of a positive result the specific antibodies present on the membrane will capture the coloured conjugate. A blue line should always appear in the control line region to show that sufficient volume was added, proper flow was obtained and the reagents functioned correctly. Failure of the control line to appear, whether or not test lines are present, indicates an invalid assay.
The test is interpreted by the presence or absence of visibly detectable coloured lines in the test region at 10 minutes or less depending on the concentration of antigen present. A positive result will show a pink/red test line and a blue control line, indicating that Streptococcus A antigen is present in the sample. A negative test result, read at 10 minutes, will show only a blue control line, indicating that Streptococcus A antigen was not detectable in the sample.

MATERIALS PROVIDED

- PL.3126 Proflow™ Streptococcus A Test Device: 20 devices
- PL.3226 Proflow™ Streptococcus A Diluent A
- PL.3326 Proflow™ Streptococcus A Diluent B
- Proflow™ test tubes: 20
- Plastic pipette: 20
- Proflow™ swabs: 20
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Sample collection container
- Timer or stopwatch
- Biohazard disposal container
- Disposable gloves

STABILITY AND STORAGE

- Store all components at 2-30ºC.
- Do not freeze or overheat.
- Do not use beyond the expiration date printed on the outer package label.
- The test kits should be kept away from direct sunlight, moisture and heat.

PRECAUTIONS

- For *In Vitro* Diagnostic Use only.
- For professional use only.
- Directions should be read and followed carefully.
- Tests are for single use only. Do not reuse.
- Reagents are provided at the necessary working strength. Do not dilute reagents.
- Do not interchange reagents between kits with different lot numbers.
- Do not use kits or reagents beyond the stated expiration dates.
- Microbial contamination of reagents may decrease the accuracy of the assay.
- Treat all materials as if they were infectious and dispose of all material in accordance with local regulation.

SAMPLE STORAGE AND COLLECTION

THROAT SWAB METHOD

- Remove the swab from its packaging.
- Collect specimen by inserting the swab into the back of the mouth and 'sweeping' across the tonsils and/or back of the throat. Avoid the teeth, tongue, gums, or cheek surfaces.
- Process the specimen as soon as possible after collection.

COLONY METHOD

- Examine the plates after the incubation period. Select Streptococcus typical colonies showing characteristic beta haemolysis.
- Use a sterile swab to pick up 1-3 suspect colonies.
- Process the selected colonies as soon as possible after collection.

Test sample as soon as possible. Allow the tests, samples and diluent to reach room temperature 15-30ºC prior to testing. Cool sample to 2-8ºC (36-46ºF) during storage and transport for 8 hours prior to testing.

TEST PROCEDURE

1. Remove the test from its pack just before use. Place the test on a clean flat surface.
2. Label each test with appropriate patient information.
3. Use a separate pipette and test for each sample or control.
4. Add 5 drops (or 200uL) of diluent A and 5 drops (or 200uL) of diluent B and mix.
5. The colour of the solution changes from pink to light yellow (colourless).
6. Put the swab into the test tube and agitate to remove cells from swab.
7. Dispense 3 drops (or 100µL) of the sample mix into the circular window.
8. Read the result at 10 minutes. Do not read the results after 10 minutes as they may be inaccurate.

QUALITY CONTROL PROCEDURE

It is recommended that a positive and negative control be used to ensure that the test is performing as expected.
The control line (C) is a procedural control and will show that the test has been performed correctly; proper flow occurred and that the test reagents functioned as expected. When a blue line appears at the control line position this indicates the test has been performed correctly. The control line will appear on all valid tests, whether or not the sample is reactive or non-reactive (refer to the Interpretation of Results section).

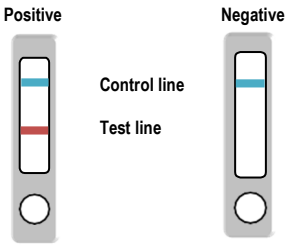
INTERPRETATION OF RESULTS

Positive

A pink/red line of any intensity appears at the test line position; a blue line of any intensity appears at the control line position. This indicates a reactive result that is interpreted as positive for Streptococcus A antigen.

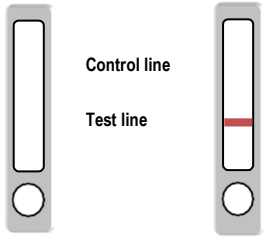
Negative

A single blue line of any intensity appears in the test window at the control line position. There is no line at the test line position. This indicates a non-reactive result that is interpreted as negative for Streptococcus A antigen.



Invalid

No line appears in the test window at the control line position. This is an invalid result and cannot be interpreted. This is irrespective of whether or not a pink/red line appears in the test window at the test line position. If either condition below occurs, the test should be repeated with a new test.



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LIMITATIONS OF THE PROCEDURE

- The Proflow™ Streptococcus A test will only indicate the presence of GAS in the sample (qualitative detection) and should be used for the detection of GAS antigens in throat swab samples only. Neither the quantitative value nor the rate of increase in GAS antigen concentration can be determined by this test.
- The test must be carried out within 2 hours of opening the sealed pack.
- 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.
- 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 clinician.

PERFORMANCE CHARACTERISTICS

EXPECTED VALUES

There are several million cases of 'strep throat' each year. About 9,400 cases of invasive GAS disease occurred in the US in 1999.

SENSITIVITY AND SPECIFICITY

The Proflow™ Streptococcus A test was compared with another commercially available rapid assay. The Proflow™ Streptococcus A test showed:

Specificity >99%
Sensitivity >99%

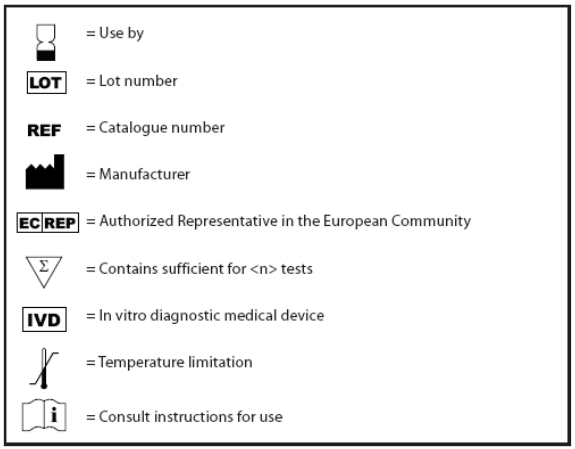
CROSS-REACTIVITY

An evaluation was performed to determine the cross-reactivity of the Proflow™ Streptococcus A test. No cross-reactivity was observed with the following pathogens:

- Influenza type A
- Influenza type B
- Adenovirus
- Group D Streptococcus
- Enterococcus

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.



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