RapidFor™ Strep A Rapid Test Kit
Reference Number: VMD36
For professional use IVD IFU CE

FOR IN VITRO DIAGNOSTIC USE

This instructions for use (IFU) must be read carefully prior to use. Instructions for use must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions for use.

SUMMARY

Streptococcus pyogenes are non-motile gram-positive cocci, which can colonize different parts of the human body and cause serious infections. Beta-hemolytic group A Streptococci (Streptococcus pyogenes) are the main cause for infections of the upper respiratory tracts like tonsillitis, pharyngitis, and other respiratory infections, moreover impetigo, endocarditis, puerperal sepsis, meningitis, and arthritis. Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscesses. An early diagnosis and treatment of Group A Streptococcal pharyngitis has been shown to reduce the severity of symptoms and further complications, such as rheumatic fever and glomerulonephritis. Conventional methods for detecting Strep A infections are dependent on isolation and subsequent identification of the organism, and often require 24-48 hours.
The RapidFor™ Strep A Rapid Test Kit is a rapid test for the detection of Strep A antigens in throat providing results within 15 minutes. It allows the medical practitioner for a rapid diagnosis and an immediate and selective therapy. The RapidFor™ Strep A Rapid Test Kit utilize antibodies specific for whole cell Lancefield Group A Streptococcus for the sensitive detection of Strep A antigens in throat swab specimens.

INTENDED USE

The RapidFor™ Strep A Rapid Test Kit is an immunochromatographic rapid test for the qualitative, presumptive detection of Group A Streptococcus antigens in throat swab specimens. This kit is intended for use as an aid in the diagnosis of Strep A infections.

PRINCIPLE OF THE PROCEDURE

The RapidFor™ Strep A Rapid Test Kit is a qualitative, lateral flow immunoassay for the detection of Strep A carbohydrate antigen in throat swab specimens.
In this test, antibodies specific to Strep A antigens are immobilized in the test line area. During the test, the antigens extracted from the swab specimen are captured by Strep A specific antibodies, which are adhered to pointer particles. The mixture migrates along the membrane and the antigen-antibody-particle complex binds to the specific antibody in the test line area. The agglomeration of complexes creates a color line in the test line area.
The appearance of the color line in the test (T) line area indicates a positive result, while its absence indicates a negative result. A red line should always appear in the control (C) line area. It serves as a procedural control, confirming that sufficient specimen volume was used and indicates an adequate membrane wicking and proper procedural technique.

REAGENTS AND MATERIALS SUPPLIED

COMPONENT	25 Test/box
Test Device	25 Test cassettes (1 Test/pouch x 25 pouches)
Buffer A	1 bulk bottle with extraction solution A
Buffer B	1 bulk bottle with extraction solution B
Tube	25 single use unsealed empty sample tube
Specimen Collection Swab	25 single-use oropharyngeal swab
Dropper	25 single use droppers
Packing Insert	1 instruction for use

Materials Required But Not Provided

- Timer or stopwatch
- Specimen collection container

STORAGE AND STABILITY

1. Store as packaged in the sealed pouch at temperature 2~30°C and relative humidity between 40%-60%.. The kit is stable within the expiration date printed on the labeling.
2. Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
3. The LOT and the expiration date were printed on the labeling.

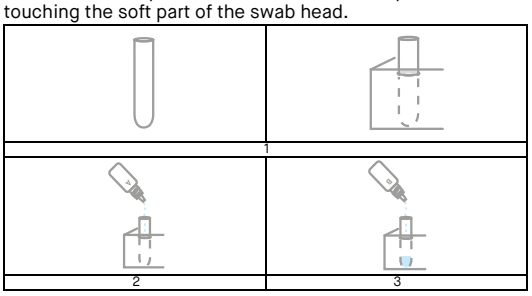
WARNINGS AND PRECAUTIONS

1. For professional in vitro diagnostic use only. Do not use after expiration date.
2. Do not eat, drink, or smoke in the area where the specimens and kits are handled.
3. Handle all specimens as if they contain infectious agents.
4. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are assayed.
6. Follow standard biosafety guidelines for handling and disposal of potential infective material.
7. Humidity and temperature can adversely affect results.

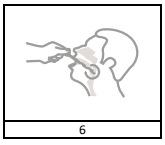
TEST PROCEDURE

Allow the test cassette and buffer to reach room temperature (18-30°C) before the test.
Detailed visual step explanations given in the end of the procedure.

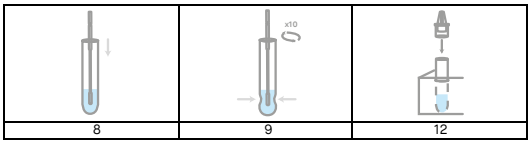
Test Preparation:
1. Place the given empty sample tube to the holder.
2. Add 5 drops (200µL) of Buffer A to the empty sample tube.
3. Add 5 drops (200µL) of Buffer B to the sample tube that Buffer A added.
4. Gently mix the two buffers.
5. Take the sample collection swab and open it without touching the soft part of the swab head.



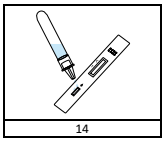
Sample Collection:
6. Pass the sterile swab past the palatal cusp, to the posterior pharyngeal wall.
7. Rotate the swab 10 times along the posterior pharyngeal wall and both tonsils. Then remove the swab.
NOTE: Avoid contact of the swab head with the tongue during specimen collection.



Specimen Processing:
8. Put the sample collection swab into the mixed buffer solution where the soft part of the swab inside first.
9. Rotate the swab tip with the swab sample 10 times along the inner wall of the bottle.
10. Squeeze the tip of the swab along the inner wall of the bottle to keep as much liquid in the bottle as possible.
11. Take off the sample swab from the buffer mixture.
12. Put the dropper to the bottle which include buffer-sample mixture.

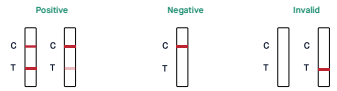


Test Operation:
NOTE: Do not open the pouch until you are ready to perform a test, and the single-use test is suggested to be used under low environment humidity (RH≤70%) within 15 minutes.
NOTE: Best results will be obtained if the test is performed immediately after opening the foil pouch.
13. Open the aluminum foil pouch and place the test cassette on a clean and flat surface.
14. Add 3 drops of buffers-sample mixture to the sample well of the test cassette.
15. Wait 15 minutes to read the result.
NOTE: Do not interpret the test result after 20 minutes. The interpretation of the test result after 20 minutes can yield wrong result from test.
16. Dispose all materials that used during the test operation as a biological waste and clean the area that you performed the test.



INTERPRETATION OF TEST RESULTS

Positive: Both purplish test band and purplish control band appear on the membrane.
Negative: Only the purplish control band appears on the membrane. The absence of a test band indicates a negative result.
Invalid: There should always be a purplish control band in the control region regardless of test result. If control band is not seen, the test is considered invalid. Repeat the test using a new test cassette/strip.



PERFORMANCE CHARACTERIST

1. Sensitivity and Specificity
The RapidFor™ Strep A Rapid Test Kit has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals.

Strep A	Commercial Strep A rapid tests		
	Positive (+)	Negative (-)	Total
Positive	117	0	117
Negative	1	204	205
Total	118	204	322
Sensitivity: 99.15%			
Specificity: 100.0%			
Accuracy: 99.68%			

Analytical Sensitivity
The analytical sensitivity of the assay is 1x 10^5 bacteria/swab. 8 different strains of Strep A were tested, and all showed weak positive results at this concentration.

High Dose Hook
No High Dose Hook Effect was observed up to a concentration of 1.0x10^{10} bacteria /swab. This indicates that the measurement range is at least 1.0 x 10^5 to 1.0 x 10^{10} bacteria /swab.

Cross Reactivity
The following organisms were tested at 3.0×10^6 CFU/mL and were all found to be negative when tested with the test kit.

Group B Streptococcus	Neisseria meningitides
Group C Streptococcus	Neisseria sicca
Group F Streptococcus	Neisseria gonorrhea
Group G Streptococcus	Candida albicans
Staphylococcus aureus	Corynebacterium diphtheria
Streptococcus pneumoniae	Branhamella catarrhalis
Streptococcus sanguis	Neisseria subflava
Streptococcus mutans	Serratia marcescens
Pseudomonas aeruginosa	Bordetella pertussis
Klebsiella pneumoniae	Staphylococcus epidermidis
Enterococcus faecalis	Hemophilus influenza

LIMITATIONS

1. The Strep A Rapid Test is for in vitro diagnostic use only. The test should be used for the detection of Group A Streptococcus antigen in human oropharyngeal swab samples only. Neither the quantitative value nor the rate of increase in Group A Streptococcus antigen can be determined by this qualitative test.
2. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended.

KEY TO SYMBOLS USED

COMPONENT	Material Included	TUBE	Tube
TEST CARD	Test Card	IFU	Instruction for Use
	Consult Instruction for Use		Expiration Date
2°C 30°C	Store at 2°C ~ 30°C		Manufacturer
	Keep Dry		Date of Manufacture
LOT	Lot Number		Do Not Reuse
DILUENT	Sample Buffer	REF	Reference Number
	Keep Away from Sunlight	Σ	Tests per Kit
IVD	In Vitro Diagnostic Medical Device		Do not use if the package is damaged
%40 %60	Store between %40-%60 humidity		
CE	This product fulfils the requirements of the Directive 98/79/EC on in vitro diagnostic medical device		

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