Strep A FIA Rapid Test Device

(Throat Swab)

FI2-STRA-001

A rapid test for measuring Strep A antigens in throat swab specimens with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000). For professional in vitro diagnostic use only.

INTENDED USE

The Strep A FIA Rapid Test Device is based on Fluorescence Immunoassay to detect Strep A antigens from throat swab specimens to aid in the diagnosis of Group A Streptococcal infections.

SUMMARY

Streptococcus pyogenes is non-motile gram-positive cocci, which contains the Lancefield group A antigens that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis. Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess. Traditional identification procedures for Group A Streptococci infection involve the isolation and identification of viable organisms using techniques that require 24 to 48 hours or longer.

The Biopanda Strep A FIA Rapid Test Device qualitatively detects the presence of Strep A antigens in throat swab specimens, providing results within 5 minutes. The test utilizes antibodies specific for whole cell Lancefield Group A Streptococcus to selectively detect Strep A antigens in a throat swab specimen.

PRINCIPLE

The Strep A FIA Rapid Test Device detects Strep A carbohydrate antigen in a throat swab based on Fluorescence Immunoassay. In this test, antibody specific to Strep A carbohydrate antigen is coated on the test line region of the test. During testing, the extracted throat swab specimen reacts with an antibody to Strep A that is coated onto particles. The mixture migrates along the membrane to react with the antibody to Strep A on the membrane. If the specimen contains Strep A antigen, it attaches to the fluorescent microspheres-conjugated Strep A antibodies. Then the complex is captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of Strep A in the sample correlates with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and the standard curve. The concentration of Strep A in the sample can be calculated by Biopanda Fluorescence Immunoassay Device to show Strep A concentration in specimen.

REAGENTS

The test contains Strep A antibody coated particles and Strep A antibodies coated on the membrane.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
3. The used test should be discarded according to local regulations.
4. Humidity and temperature can adversely affect results.
5. Do not use test if pouch is damaged.
6. Reagent 2 contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water.
7. The positive and negative controls contain Proclin300 as a preservative.
8. Do not interchange reagent bottle caps.
9. Do not interchange external control solution bottle caps.
10. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
11. Read the entire procedure carefully prior to any testing.
12. The Biopanda Strep A FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device by approved medical professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

KIT COMPONENTS

- 25 x foil wrapped Strep A Rapid Test Devices
- 25 x sterile swabs
- 1 x Extraction Reagent 1 bottle (2M $NaNO_2$)
- 1 x Extraction Reagent 2 bottle (0.027M Citric Acid)
- 25 x Extraction tubes and tips
- 1 x workstation
- 1 x ID card (Strep A)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Pipette
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

SPECIMEN COLLECTION AND PREPARATION

1. Collect the throat swab specimen with the sterile swab that is provided in the kit. Transport swabs containing modified Stuart's or Amies medium can also be used with this product. Swab the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.
2. 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.
3. If a culture is desired, lightly roll the swab tip onto a Group A selective (GAS) blood agar plate before using the swab in the Strep A Test Device (Throat Swab).

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for the complete instructions on use of the Test. The test should be conducted at room temperature.

Allow the test, reagents, throat swab specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Turn on the Analyser. Then according to the user requirement, select "Standard test" or "Quick test" mode.
2. Take out the ID card and insert it into the Analyser port.
3. Remove the rapid test device from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
4. Hold the Extraction Reagent 1 bottle vertically and add **4 full drops (240 µL) of Extraction Reagent 1** to an extraction tube. Extraction Reagent 1 is red in colour. Hold the Extraction **Reagent 2** bottle vertically and add **4 full drops (240 µL)** to the tube. Extraction Reagent 2 is colourless. Mix the solution by gently swirling the extraction tube. The addition of Extraction Reagent 2 to Extraction Reagent 1 changes the colour of the solution from red to yellow.
5. Immediately add the swab into the extraction tube, agitate the swab vigorously **15 times**, and leave the swab in the extraction test tube for **1 minute**.
6. Press the swab against the side of the tube and squeeze the bottom of the tube while removing the swab so that most of the liquid stays in the tube. Discard the swab.
7. Place the test device on a clean and level surface. **Add 3 drops (approx. 120 µL) diluted specimen** into the sample well of the test device. Start the timer at the same time.
8. There are two test modes for the Biopanda Fluorescence Immunoassay Device; Standard Test mode and Quick Test mode. Please refer to the user manual of the Biopanda Fluorescence Immunoassay Device for details.

"Quick test" mode: Insert the test device into the Analyser at 15 minutes after sample application and click "New Test", the Analyser will automatically give

the test result after a few seconds.
"Standard test" mode: Insert the test device into the Analyser immediately after sample application, click "New test" at the same time, the Analyser will automatically count down the 15 minutes. After the countdown, the Analyser will give the result at once.

INTERPRETATION OF RESULTS

The result of tests for Strep A is calculated by the Biopanda Fluorescence Immunoassay Device and displays the result on the screen. For additional information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Device.

QUALITY CONTROL

INTERNAL QUALITY CONTROL

Internal procedural controls are included in the test. A coloured line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

EXTERNAL QUALITY CONTROL

It is recommended that a positive and negative external control be run every 25 tests, and as deemed necessary by internal laboratory procedures. External positive and negative controls are supplied in the kit. Alternatively, other Group A and non-Group A Streptococcus reference strains may be used as external controls. Some commercial controls may contain interfering preservatives; therefore, other commercial controls are not recommended.

PROCEDURE FOR EXTERNAL QUALITY CONTROL TESTING

1. Add **200uL of Extraction Reagent 1** and **200uL of Extraction Reagent 2** into an extraction tube. Tap the bottom of the tube gently to mix the liquid.
2. Add **40uL of positive or negative control solution** into the tube, holding the bottle upright.
3. Place a clean swab into this extraction tube and agitate the swab in the solution by rotating it at least **15 times**. Leave the swab in the extraction tube for **1 minute.** Then express the liquid from the swab head by rolling the swab against the inside of the extraction tube and squeezing the extraction tube as the swab is withdrawn. Discard the swab.
4. Continue with Step 7 of Directions For Use.

If the controls do not yield the expected results, do not use the test results. Repeat the test or contact your distributor.

LIMITATIONS

1. The Biopanda Strep A FIA Rapid Test Device 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.
2. This test will only indicate the presence of Strep A antigen in the specimen from both viable and non-viable Group A Streptococcus bacteria.
3. A negative result should 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.
4. 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 and any bleeding areas of the mouth with the swab when collecting specimens.
5. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

EXPECTED RESULTS

Approximately 15% of pharyngitis in children ages 3 months to 5 years is caused by Group A beta hemolytic Streptococcus.[1] In school-aged children and adults, the incidence of Strep throat infection is about 40%.[2] This disease usually occurs in the winter and early spring in temperate climates.

PERFORMANCE CHARACTERISTICS

SENSITIVITY AND SPECIFICITY

Using three medical centres for evaluation, a total of 125 throat swabs were collected from patients exhibiting symptoms of pharyngitis. Each swab was rolled onto a sheep blood agar plate, and then tested by the Biopanda Strep A FIA Rapid Test Device. The plates were further streaked for isolation, and then incubated at 37°C with 5-10% CO2 and a Bacitracin disk for 18-24 hours. The negative culture plates were incubated for an additional 18-24 hours. Possible GAS colonies were subculture and confirmed with a commercially available latex agglutination grouping kit. Of the 125 total specimens, 46 were confirmed to be negative and 79 were confirmed to be positive by culture.

Method		Culture		Total Results
Biopanda Strep A FIA Rapid Test	Result	Positive	Negative	
	Positive	76	2	78
	Negative	3	44	47
Total Results		79	46	125

Relative Sensitivity: 96.2% (95%CI:89.3%-99.2%)
Relative Specificity: 95.7% (95%CI:*85.2%-99.5%)
Overall accuracy: 96.0% (95%CI:*90.9%-98.7%) *Confidence Intervals

Positive Culture Classification	Strep A Test/Culture	% Agreement
Rare	8/10	80.0%
1+	11/12	91.7%
2+	17/17	100.0%
3+	19/19	100.0%
4+	21/21	100.0%

CROSS-REACTIVITY

The following organisms were tested at 1.0 x 106 organisms per test and were all found to be negative when tested with the Strep A FIA Rapid Test. No mucoid-producing strains were tested.

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

REFERENCES

1. Nussinovitch, M, Finkelstein Y, Amir J, Varsano, I. Group A beta-hemolytic streptococcal pharyngitis in preschool children aged 3 months to to 5 years. Clinical Pediatrics (June 1999), 38: 357-360.
2. Woods WA, Carter CT, Stack M, Connors Jr AF, Schlager TA. Group A Streptococcal Pharyngitis in Adults 30 to 65 years of age. Southern Medical Journal (May 1999), 491-492.

Index of Symbols

	Manufacturer		Tests per kit		Do not reuse test
IVD	*In vitro* diagnostic medical device		Expiration date	REF	Catalogue number
	Store between 4-30°C	LOT	Lot Number		Consult instructions for use
	Do not use if package is damaged				

Thank you for purchasing Biopanda's Strep A FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.

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