Biopanda Reagents

Product Insert: RAPG-STRA-001

CE

Strep A Rapid Test

Catalogue Number: RAPG-STRA-001

TEST KIT DESCRIPTION

The Biopanda Strep A Rapid Test qualitatively detects Strep A antigens in throat swab samples. This is a rapid test to aid in the diagnosis of Group A Streptococcal infections.

PRINCIPLE

The Biopanda Strep A Rapid Test is a qualitative, sandwich lateral flow immunoassay for the detection of Strep A carbohydrate antigen in a throat swab. Strep A carbohydrate antigen present in the extracted throat swab sample reacts with the antibodies to Strep A that are pre-coupled onto particles. The antigen, antibody, and/or antigen-antibody complex migrate up the membrane and react with the antibodies pre-coated on the membrane in the test line and control regions of the cassette. The presence of a coloured line in the test line region indicates a positive result. To serve as a procedural control, a coloured line will always appear in the control region to show the test has been performed properly.

KIT CONTENTS

- 20 x foil wrapped cassettes with desiccant.
- 20 x sterile swabs
- 1 x Extraction Reagent 1 bottle (2M $NaNO_2$)
- 1 x Extraction Reagent 2 bottle (0.027M Citric Acid)
- 20 x Extraction tubes and tips
- 1 x Positive Control solution (non-viable Strep A; 0.01% Proclin300)
- 1 x Negative Control solution (non-viable Strep C; 0.01% Proclin300)
- 1 x workstation
- 1 x product insert

STORAGE AND STABILITY

Store the kit between 2-30°C and ensure the kits are not frozen or stored in direct sunlight. The test is valid until the expiration date printed on the foil wrapping.

PRECAUTIONS

Follow these instructions for the best results:

- This kit is for *in vitro* diagnostic use only and should only be used by trained health professionals.
- All samples should be considered as potentially infectious and handled accordingly. Disposable gloves and a laboratory coat should be worn.
- Dispose of used tests in a safe manner following good laboratory procedures.
- Ensure the test kit is at room temperature before running the test. Humidity and temperature can adversely affect results.
- Keep the cassette inside the foil wrapper until it is needed.
- Ensure each test is used only once.
- Test kits that have reached their expiry date should not be used.
- Only use reagents from this kit when performing the test to ensure quality controlled testing.
- Reagent B contains an acidic solution. If the solution comes into contact with skin or eyes flush with large volumes of water.
- The positive and negative controls contain Proclin300 as a preservative.
- Do not interchange reagent or external control bottle caps.

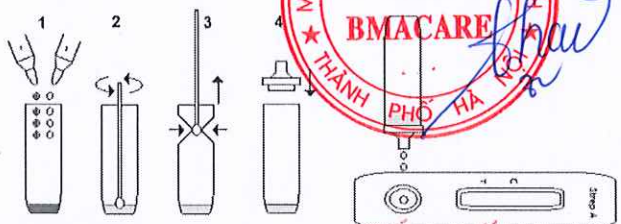
SAMPLE COLLECTION AND PREPARATION

Pharyngeal (throat) swab sample: Insert a sterile swab into the pharyngeal area, collecting a sample by wiping the swab at the back of the throat between the tonsillar pillars and tonsils, including inflamed areas. Be careful not to touch any other mouth areas or saliva. Use of a tongue depressor (not provided) to hold the tongue down is advised.

Testing should ideally be performed immediately after sample collection. However swab samples may be stored in a clean, dry plastic tube for up to 8 hours at room temperature or 72 hours at 2-8°C. If a culture is desired, lightly roll the swab tip in a Group A selective (GAS) blood agar plate before using the swab in the assay.

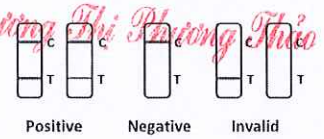
TEST PROCEDURE

1. Ensure specimen and test reagents are brought to room temperature before testing.
2. Add 4 drops of extraction reagent 1 (red in colour) and 4 drops of extraction reagent 2 (colourless) to an extraction tube (See illustration 1).
3. Mix the solution gently by swirling the extraction tube. The colour will change from red to yellow.
4. Immediately place the swab into the Extraction Tube. Rotate the swab vigorously 15 times and leave inside the tube for 1 minute.
5. Remove the swab while squeezing the swab head against the inner wall of the Extraction Tube as you remove it to expel as much liquid as possible (See illustration 3). Discard the swab in accordance with your biohazard waste disposal protocol.
6. Place the extraction tube tip on top of the tube. (See illustration 4).
7. Remove the test cassette from the sealed pouch and place the test cassette on a clean and level surface. (Use as soon as possible).
8. Add three drops of the solution from the extraction tube (approx. 100 µl) to the sample well and then start the timer. Read the result at 5 minutes. Results read after 10 minutes are considered invalid.



TEST RESULTS

POSITIVE:* Two distinct coloured lines appear. One coloured line should be in the control region (C) and another coloured line should be in the test line region (T). A positive result indicates that Strep A was detected in the sample.



***NOTE:** The intensity of the colour in the test line region will vary based on the amount of Strep A present in the sample. So any shade of colour in the test region should be considered positive.

NEGATIVE: One coloured line appears in the control region (C). No apparent coloured line appears in the test line region indicating that Strep A antigen was not present in the sample or is below detectable levels. A patient's specimen should be cultured to confirm the absence of Strep A infection.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

INTERNAL QUALITY CONTROL

Internal procedural controls are included in the test. A red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural techniques.

EXTERNAL QUALITY CONTROL

It is recommended that a positive and negative external control be run as deemed necessary by your internal laboratory procedures. A positive and negative control are supplied with the kit. Some commercial controls may contain interfering preservatives and are not recommended.

EXTERNAL QUALITY CONTROL PROCEDURE

1. Add 4 drops of extraction reagent 1 (red in colour) and 4 drops of extraction reagent 2 (colourless) to an extraction tube (See illustration 1).
2. Add 1 drop of positive or negative control solution to the extraction tube. Place a clean swab into the tube and agitate the swab in the solution by rotating the swab vigorously about 15 times. Remove the swab while squeezing the swab head against the inner wall of the Extraction Tube as you remove it to expel as much liquid as possible.
3. Continue by following Steps 6 to 8 of the **TEST PROCEDURE.** If the controls do not yield the expected results, do not use the test results.

Repeat the test and contact your distributor if there are any further issues.

LIMITATIONS OF THE TEST PROCEDURE

1. The Biopanda Strep A Rapid Test is for professional *in vitro* diagnostic use only. The test should be used for the detection of Strep A antigen in throat swab specimens. 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. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. A negative result obtained from this kit should be confirmed by culture. A negative result may be obtained if the concentration of the Strep A antigen in the throat swab is not adequate or is below the detectable level of the test.
5. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result.
6. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The Biopanda Strep A Rapid Test has been evaluated with specimens obtained from patients exhibiting symptoms of pharyngitis . Cultures were taken and results were confirmed with a leading latex agglutination grouping kit. A comparison between the Biopanda Strep A Rapid Test and cultured samples showed a sensitivity of 95.1%, specificity of 97.8%, and an overall accuracy of 97.1%.

REFERENCES

1. Murray, P.R., et al. Manual of Clinical Microbiology, 6th Edition, ASM Press, Washington D.C., 1995, p. 299-307.
2. Webb, KH. Does Culture Confirmation of High-sensitivity Rapid Streptococcal Tests Make Sense? A Medical Decision Analysis. Pediatrics (Feb 1998), 101:2, 2.
3. Bisno AL, Gerber MA, Gwaltney JM, Kaplan EL, Schwartz RH. Diagnosis and Management of Group A Streptococcal Pharyngitis. Clinical Infectious Diseases (1997), 25: 574-83.
4. Needham CA, McPherson KA, Webb KH. Streptococcal Pharyngitis: Impact of a High-sensitivity Antigen Test on Physician Outcome. Journal of Clinical Microbiology (Dec 1998), 36: 3468-3473.
5. Shea, Y.R., Specimen Collection and Transport, Clinical Microbiology Procedures Handbook, Isenberg, H.D., American Society of Microbiology, Washington D.C., 1.1.1-1.1.30, 1992.
6. 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.
7. 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.

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

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