

BIOCARD™ STREP A

Biocard™ Strep A is a rapid, simple and reliable immunochromatographic test for the qualitative detection of group A Streptococci from a throat swab sample. Cat. No. 3-017-400

Carefully read the instructions for use before testing. To perform a Biocard Strep A test you will also need a timer. Perform the test in a well illuminated place.

PRINCIPLE OF THE TEST

Group A Streptococci (*S. pyogenes*) are causing e.g. different respiratory diseases. (pharyngitis, rhinitis, tonsillitis and pneumonia), scarlet fever, pyoderma lesions and wound infections. Group A Streptococci are found also in the blood of patients with erysipilas, puerperal fever, cellulitis and septicemia. Non-suppurative disease such as rheumatic fever and acute glomerulonephritis may follow streptococcal pharyngitis.

Biocard™ Strep A test principle is based on a gold-labeled, group specific polyclonal antibody which together with the antibody immobilized in the test membrane forms the test line (if antigen is present in the sample). The test device also contains an internal control. The antibody dehydrated in the control line detects the unbound gold-labeled antibody dye forming a control line. Control line should always be visible regardless of the test result (positive / negative).

CONTENTS

20 pcs Test Strips
20 pcs Cotton Swabs
20 pcs Extraction Vials
0.5 ml Positive Control
10 ml Extraction Reagent A
10 ml Extraction Reagent B
1 pc Instructions for Use

Material needed but not provided: Timer

SAMPLING

Collect a specimen with the sterile cotton swab provided from the back of the throat. Avoid contact with tongue or the inner parts of the mouth. If the test can not be performed immediately the sample may be stored in a clean, dry vial

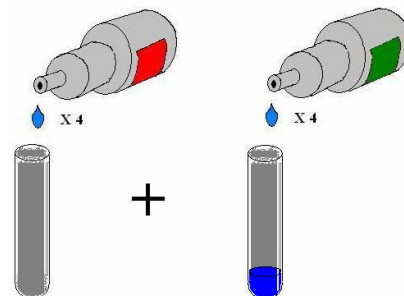
for up to 72 hours. The sample may also be taken from a transport media or from cultured plates.

TEST PROCEDURE

If the samples, controls, test strips or reagents have been stored refrigerated allow them to reach room temperature (18-25 °C) before testing. Open the foil pouch containing the test strip just before use.

A. Extraction

Mark the vial with patient's information and place it on a support. Add 4 drops of reagent A and 4 drops of reagent B into the vial.



Place the sampling swab containing the sample into the vial and stir. Let the swab stand in the vial for at least 2 minutes and no more than 30 minutes.



Remove as much extract from the swab as possible by pressing and rotating the cotton tip against the wall of the extraction vial.

Make sure no liquid is left on the walls of the vial as it might come in touch with the test membrane thus blocking the migration of the test reagents.

Remove the swab from the vial. The extract may be tested immediately or within 60 minutes time.

B. Testing

1. Remove one Biocard Strep A stick from the foil pouch and carefully place it into the extraction vial. Make sure the vial stands properly on the support.
2. Read the result after 5 minutes.



INTERPRETATION OF RESULTS

If only one red line (control line) is visible the test result is negative and the sample contains no group A Streptococci antigen.



If there are two visible red lines the result is positive and the sample contains group A Streptococci antigen. Even a faint test line means that the result is positive.



The test result is invalid if the control line does not become visible within 10 minutes time. Invalid test result may result from not following the instructions for use or if the test reagents or the test strip is not functioning properly. A new test should be performed using a new Biocard™ Strep A stick and a new sample.

CONTROLS

According to good laboratory practice control samples should be performed daily to ensure the proper performance of the tests. Each test kit includes a positive control which is a dilute *Streptococcus pyogenes* solution that has been inactivated in autoclave.

A. Positive Control

Mark the vial as positive control. Add 4 drops of reagent A, 4 drops of reagent B and one drop of positive control. Perform testing in the same manner as with patient samples. A positive result should be indicated by two red lines.

B. Negative Control

A negative control sample may be performed with the extraction reagents. Mark the vial as a negative control. Add 4 drops of reagent A and 4 drops of reagent B. Perform testing in the same manner as with patient samples. A negative result should be indicated by only one visible line (control line).

C. External Controls

Also external controls may be tested. These can be either commercial control preparations or known strains of bacteria cultured and tested from a sample taken with a cotton swab provided.

SPECIFICITY AND SENSITIVITY

A commercial 1.2×10^5 Ps-StrAAg-control (Bioclin Oy) gives a distinct positive result when tested with Biocard™ Strep A test.

Following strains have been tested and found negative:

Candida albicans ATCC 28367

Cryptococcus neoformans

Escherichia coli ATCC 21432

Escherichia coli ATCC 8739

Escherichia coli ATCC 25922

Pseudomonas aeruginosa

Staphylococcus aureus ATCC 6538

Staphylococcus epidermicus

Staphylococcus saprophyticus

ATCC 2866

Streptococcus agalactiae ATCC 27956

Streptococcus faecalis ATCC 19433

Streptococcus Group C

Ascorbic acid, hemoglobin or caffeine were found not to interfere with the test result.

STORAGE

Store the test sticks and reagents in room temperature (+2 - +27 °C). Avoid the exposure of reagent A to light.

Shelf life of the test kit is 18 months, provided that the storage instructions are followed. Expiry date has been printed on the test kit box, the foil pouch of the sticks and on the labels of the reagents.

WARNINGS AND LIMITATIONS

Follow the instructions for use carefully; a failure to do so may result in false test results. Biocard™ Strep A test may only be used for in-vitro qualitative detection of group A Streptococci antigen from a throat swab specimen according to the instructions for use.

A diagnosis should not be made solely according to the Biocard™ Strep A –test result. The result should be used in conjunction with additional diagnostic information available for the physician.

Do not use the test if the foil pouch is damaged. Do not use expired tests or reagents. Only use the reagents that came with the kit. Use each test strip only once.

Reagent A contains sodium nitrite and may be harmful if swallowed. Reagent B is an acidic solution. Avoid contact with skin, eyes or mucous membranes.

The test should be performed in accordance with generally accepted bacteriological principles of handling and containment of potentially hazardous samples. All Streptococci, as well as many other bacterial strains investigated in clinical work, are potential pathogens. Used materials and samples should be disposed of with appropriate caution.

REFERENCES

1. Elmer W. Koneman, Stephen D. Allen, William M. Janda, Paul C Schreckenberger, Washington C Winn Jr.; Color Atlas of Diagnostic Microbiology, fifth edition, 1997, J.B. Lippincott Publishers, pp. 122-131, 577-649
2. James A. Kellogg; Suitability of Throat Culture Procedures for Detection of Group A Streptococci and as Reference Standards for evaluation of Streptococcal Antigen Detection Kits, Journal of Clinical Microbiology, Feb. 1990, pp. 165-169, American Society for Microbiology
3. Bradley Kurtz, Michael Kurtz, Martha Roe and James Todd; Importance of Inoculum Size and Sampling Effect in Rapid Antigen Detection of Streptococcus pyogenes Pharyngitis, Journal of Clinical Microbiology, Jan. 2000, pp. 279-281, American Society for Microbiology
4. Ronald J. Harbeck, Jeri Teague, Gretchen R. Grossen, Diana M. Maul and Patty L. Childers; Novel, Rapid Optical Immunoassay Technique for Detection of Group A Streptococci from Pharyngeal Specimens: Comparison with Standard Culture Methods, Journal of Clinical Microbiology, Apr. 1993, pp. 839-844, American Society for Microbiology
5. Robert D. Sheeler, Margaret S. Houston, Sharon Radke, Jane C. Dale, Steven C. Adamson; Accuracy of Rapid Strep Testing in Patients Who Have Had Recent Streptococcal Pharyngitis, The Journal of American Board of Family Practice, July-August 2002, Vol. 15 No. 4, The Journal of American Board of Family Practice, pp. 261-265

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