PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

Sensitivity studies, performed by testing dilutions of cultures of *Streptococcus pyogenes*, ATCC no. 19615, determined the BinaxNOW Strep A Card limit of detection to be 1.8×10^5 CFU per test. In addition, a mucoid *Streptococcus* Group A strain tested positive in the BinaxNOW Strep A Card at 10^5 CFU per test. Strep organisms were quantitated using standard microbiological methods.

Clinical Sensitivity and Specificity

The BinaxNOW Strep A Card was used to evaluate 145 throat swab specimens collected from physician office patients presenting with pharyngitis. Each swab was used to inoculate an SXT selective media plate before being assayed in the BinaxNOW Strep A Card. Plates were incubated for 18-48 hours at 33 to 37°C in an aerobic 5% CO_2 atmosphere. Presumptive positive beta-hemolytic colonies were confirmed to be Group A Streptococci by a latex agglutination test. The results summarized below are consistent with performance characteristics of other commercially available rapid chromatographic Group A *Streptococcus* immunoassays.[13-17]

In this study, test sensitivity was 92% (36/39) with 95% confidence limits of 84 to 100% relative to culture. Test specificity was 100% (106/106) and overall agreement was 98% (142/145) with 95% confidence limits of 96 to 100%.

BinaxNOW™ Strep A Card vs. Culture		
Sensitivity	92%	36/39
Specificity	100%	106/106
Overall Agreement	98%	142/145

Test sensitivity is influenced by the proportion of low culture positive specimens in a given population. The BinaxNOW Strep A Card detected 4 of 5 1+ culture positive specimens, 14 of 16 2+ specimens, 10 of 10 3+ specimens and 8 of 8 4+ specimens.

Reproducibility Study

A blind study of the BinaxNOW Strep A Card was conducted at three physician offices using a panel of coded specimens. Testing was performed by physician office personnel with diverse educational backgrounds. The proficiency panel contained negative, low positive, moderate positive and high positive specimens. Each specimen level was tested fifteen times at each site over a period of 3 days.

The results obtained at each site ranged from 98% to 100% agreement with expected results. No significant differences were observed within-site, between-site or between medical doctor (MD) and non MD users.

Cross Reactivity

Bordetella pertussis, Candida albicans, Corynebacterium pseudodiptheriticum, Enterococcus faecalis, Escherichia coli, Haemophilus influenzae type b, *Klebsiella pneumoniae, Moraxella catarrhalis, Neisseria subflava, Neisseria gonorrhoeae, Neisseria meningitidis, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus aureus and epidermidis, Streptococcus agalactiae, pneumoniae,* Group C, Group F, Group G, *mitis, mutans*, and parasanguis were tested in the BinaxNOW Strep A Card at levels exceeding 10^7 organisms per test and did not cross react.

Interference

The BinaxNOW Strep A Card was found to perform as expected with both positive and negative samples in the presence of 2 commercially available sore throat medications. Overall agreement was 100%.

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ORDERING and CONTACT INFORMATION

Reorder numbers:

#730-025: BinaxNOW Strep A Card CLIA Waived 25 Test Kit

#730-010: BinaxNOW Strep A Control Swab Pack

Phone: 1 877 441 7440

Fax: 1 877 441 7441

Technical Support

Advice Line

Further information can be obtained from your distributor or by contacting Abbott Technical Support at:

1 877 866 9340 TS.SCR@abbott.com

SYMBOLS

Consult instructions for use	Manufacturer
Temperature limitation	*In vitro* diagnostic medical device
Rx Only Prescription Only	Hazard Pictogram. See precautions.

Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, Maine 04074 USA
www.abbott.com/poct

IN400001 Rev. 9 2020/01

Abbott

BinaxNOW™ STREP A CARD
PRODUCT INSTRUCTIONS

Rx Only

COMPLEXITY: WAIVED

Any modifications by the laboratory to the test system or FDA cleared test system instructions will result in the test no longer meeting the requirements for waived categorization.

For *In Vitro* diagnostic use.

INTENDED USE

The BinaxNOW™ Strep A Card is a rapid immunochromatographic assay for the qualitative detection of *Streptococcus pyogenes* Group A antigen from throat swab specimens.

SUMMARY and EXPLANATION of the TEST

Group A *Streptococcus* is the most significant pathogen causing pharyngitis. Accurate diagnosis of the etiological agent is necessary to properly treat the disease. In the case of Group A *Streptococcus*, antibiotic therapy is the treatment of choice. If left untreated, serious sequelae such as rheumatic fever may occur.[1]

Conventional methods for detecting Group A streptococcal infection involve 24-48 hour culture of throat swab specimens followed by confirmation of beta-hemolytic colonies as Group A *Streptococcus*.[2] Presumptive positives can be detected by observing the susceptibility of the organism to a bacitracin disc placed on a sheep blood agar plate.[3,4] Immunological confirmation of Group A *Streptococcus* is based on the antigenic characteristics of the group specific carbohydrate.[5]

The BinaxNOW Strep A Card is an immunochromatographic method which employs antibodies specific to Group A *Streptococcus*. The test design allows for "on-board" antigen extraction. There is no transferring step, and the sample is completely contained within the test card.

PRINCIPLES of the PROCEDURE

The BinaxNOW Strep A Card is an immunochromatographic membrane assay to detect *Streptococcus pyogenes* Group A antigen from throat swabs. A stripe of anti-Strep A antibody, referred to as the Sample Line, is absorbed to a nitrocellulose membrane. An anti-species antibody, the Control Line, is absorbed to the same membrane as a second stripe. Anti-Strep A antibodies and species antibody are each conjugated to visualizing particles that are dried onto an inert fibrous support. The resulting conjugate pad is combined with the striped membrane to construct the test strip. This test strip and a well to hold the throat swab are mounted on opposite sides of a book-shaped hinged test card.

To perform the test, a throat swab is inserted into the test card. Extraction reagents are added from dropper bottles. The swab is rotated three times. After a one minute incubation, the test card is closed to bring the extracted sample in contact with the test strip. Strep A antigen captured by immobilized anti-Strep A reacts to bind conjugated antibody. Immobilized species antibody captures the second visualizing conjugate. A positive test result is read visually in 5 minutes. A negative BinaxNOW Strep A Card result, read in 5 minutes, indicates a presumptive negative for the presence of Group A streptococcal antigen.

The test is interpreted by the presence or absence of visually detectable pink-to-purple colored lines. A positive result will include the detection of both a Sample and a Control Line, while a negative assay will produce only the Control Line. Any other test result indicates an invalid assay.

MATERIALS

Materials Provided:

- **Test Cards** - A membrane coated with anti-Strep A and anti-species antibodies is combined with anti-Strep A/species antibody conjugate cocktail in a hinged test card.
- **Extraction Reagent One** - 2 M sodium nitrite with Tween® 20. ⚠
- **Extraction Reagent Two** - 0.125 M acetic acid with Tween® 20.
- **Sterile Swabs** - Designed for use in the BinaxNOW Strep A Card.
- **Positive Control Swab** - Heat inactivated *Streptococcus pyogenes* Group A dried onto swab.
- Product Instructions.

Additional Materials Available:

BinaxNOW Strep A Control Swab Pack (product number 730-010) contains:

- 5 Positive Control Swabs - Heat inactivated *Streptococcus pyogenes* Group A dried onto swabs.
- 5 Negative Control Swabs - Heat inactivated *Streptococcus* Group C dried onto swabs.

Materials Not Provided:

- Clock, timer, or stopwatch.
- Alternate swabs (see Specimen Collection below).

PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Do not use reagents beyond expiration dates.
3. Do not mix reagent vial caps.
4. Do not mix components from different kit lots.
5. INVALID RESULTS can occur when an insufficient volume of the two liquid reagents is added to the test card. To insure delivery of adequate volumes, hold vials vertically, 1-1½ inches above the swab well, and dispense drops slowly.
6. Control Swabs contain heat inactivated microorganisms. However, handle Control Swabs as though they were capable of transmitting infectious disease.
7. The Control Swabs are designed for use only with the BinaxNOW Strep A Card.
8. Add reagent drops to the hole in the orange triangle, ▲ NOT to the hole above it.
9. Swab must be rotated or twirled CLOCKWISE (to the right).
10. Test cards must remain sealed in the protective foil pouch until just prior to use.
11. Extraction Reagent One contains sodium nitrite. Warning; harmful if swallowed, causes serious eye irritation. ⚠
12. All patient samples, controls and test cards should be handled as though they were capable of transmitting disease and should be disposed of accordingly. Observe established precautions for microbial hazards.
13. Do not use swabs that have been stored in transport or growth media.
14. Safety Data Sheets for this product are available upon request.
15. Follow your national, regional, and local ordinances accordingly for waste disposal regulations.

STORAGE and STABILITY

Store at 2 - 30°C. The BinaxNOW Strep A Card kit and reagents are stable until the expiration dates marked on their outer packaging and containers.

SPECIMEN COLLECTION and HANDLING

Using the swab provided in the kit, collect specimen by sampling material from the back of the throat and any white patches in the tonsillar area.[6,7]

Avoid contact with teeth, gums, tongue or cheek surfaces.[8] Process patient samples immediately following specimen collection.

If a culture result is also desired, inoculate the culture plate with the swab prior to performing the BinaxNOW Strep A Card by rolling it firmly over a small portion of one quadrant of the agar plate. Alternatively, a second throat swab specimen may be taken. Streak the plate with a sterile loop to obtain isolated colonies.[9,10]

Do not perform the BinaxNOW Strep A Card before inoculating the culture plate, as the extraction reagents render the bacteria on the swab nonviable. Process the swab immediately following culture plate inoculation.

When immediate testing is not possible, place the patient swab into a dry test tube for transport or storage. Throat swab specimens may be stored refrigerated at 2 - 8°C for up to 72 hours.[11]

The use of transport media is not recommended with this product.

Use of alternate swab:

It is recommended that you use the swab included in the BinaxNOW Strep A Card kit. However, the use of alternate swabs has been validated for use with this kit. For a list of commercial products containing these alternate swabs, contact Technical Services.

QUALITY CONTROL (QC)

Daily Quality Control:

The BinaxNOW Strep A Card has built-in procedural controls. For daily quality control, Abbott suggests that you record these controls for each test run.

Procedural Controls:

A. The pink-to-purple line at the "Control" position is an internal procedural control. If the test flows and the reagents work, this line will always appear.

B. The clearing of background color from the result window is a negative background control. The background color in the window should be light pink to white within 5 minutes. Background color should not hinder reading of the test.

External Positive and Negative Controls:

Good laboratory practice suggests the use of positive and negative controls to ensure that:

- test reagents are working, and
- the test is correctly performed, including the antigen extraction.

BinaxNOW Strep A Card Kits contain 1 Positive Control Swab. This swab, with an appropriate negative control, will monitor the entire assay. Run these controls:

- with each new test kit opened,
- with each new operator, and
- as deemed necessary by your internal quality control procedures.

Additional Positive and Negative Control Swabs are available separately (product number 730-010). To use controls, simply process like a patient sample.

Other controls may be tested in order to conform with:

- local, state and/or federal regulations,
- accrediting groups, and/or,
- your lab's standard QC procedures.

Refer to 42 CFR 493 1256 for guidance on proper QC practices.

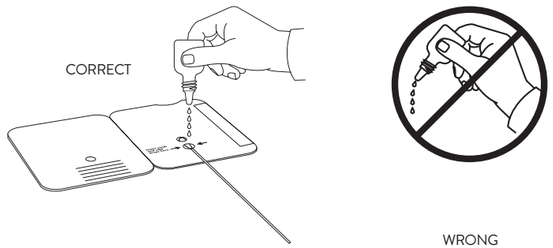
When invalid control results are obtained do not report patient results. Contact Abbott Technical Services.

ASSAY PROCEDURE

Open the test card just prior to use, lay it flat, and perform assay as follows:

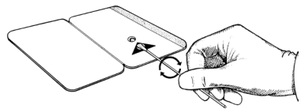
1. Insert sample or control swab into orange triangle (▲) and firmly push upwards so that the swab tip is visible in the hole above the triangle.

2. Hold Reagent One vial vertically, 1 to 1½ inches above the card. Slowly add 4 DROPS to the ▲. Then, add 4 DROPS of Reagent Two to the ▲.



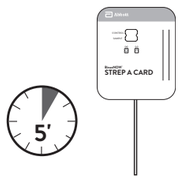
NOTE: *Improper delivery of liquid reagents can cause INVALID test results.*

3. Rotate (twirl) swab shaft 3 times CLOCKWISE (to the right). Do not remove swab.



4. Wait 1 minute.

5. Peel off adhesive liner from right edge of the test card. Close and securely seal the card. Read result in window 5 minutes after closing the card. Results read before or after 5 minutes may be inaccurate.



INTERPRETATION of RESULTS

A **negative sample** will give a single pink to purple Control Line in the top half of the window, indicating a presumptive negative result. This Control Line means that the detection portion of the test was done right, but no Strep A antigen was detected.	**NEGATIVE RESULT**  CONTROL SAMPLE
A **positive sample** will give two pink to purple lines. This means that Strep A antigen was detected. Specimens with low levels of antigen may give a faint Sample Line. Any visible pink to purple line is positive.	**POSITIVE RESULT**  CONTROL SAMPLE
If no lines are seen, or if just the Sample Line is seen, the assay is invalid. Invalid tests should be repeated with a new sample. If the problem persists, call Technical Services.	**INVALID RESULT**  CONTROL SAMPLE **INVALID RESULT**  CONTROL SAMPLE

Notify Abbott Technical Services of any performance, perceived or validated, that does not meet test specifications described in this insert.

LIMITATIONS of the PROCEDURE

The BinaxNOW Strep A Card does not differentiate between viable and nonviable organisms. Patients that have recently been treated for Strep A or similar infections may give positive results for a period of time following effective treatment due to the presence of Group A Strep antigen in nonviable organisms.

Pharyngitis can be caused by organisms other than Group A *Streptococcus*. Further diagnostic testing, including culture, should be performed if laboratory findings are inconsistent with clinical presentation.

The BinaxNOW Strep A Card will not differentiate asymptomatic carriers of Group A *Streptococcus* from those exhibiting streptococcal infection.

A negative result may be obtained if the amount of extracted antigen is below the sensitivity of the test. Culture confirmation is recommended for all BinaxNOW Strep A Card negative test results.[12]

A single swab that is used both to inoculate a culture plate and to perform the rapid test may have reduced sensitivity in the BinaxNOW Strep A Card.

Abbott
BinaxNOW
Strep A Card

PI - US

Size:
17.0 in. x 11.0 in.

Printed Colors

Black

PN: IN400001
Rev: 9

Date of Last Revision:
9.8 2020/01/03