KETTERING Health Network

Binax NOW *Streptococcus pneumoniae* Antigen

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I. PRINCIPLE

The Alere Binax NOW *Streptococcus pneumoniae* Antigen card is an in vitro rapid immunochromatographic (ICT) assay for the detection of Streptococcus pneumonia antigen in the urine of patients with pneumoni. It is intended, in conjunction with culture and other methods, to aid in the diagnosis of both pneumococcal pneumonia and pneumococcal meningitis.

II. SPECIMEN COLLECTION, TRANSPORT, AND HANDLING

A. Urine specimens should be collected in a standard container. Store at room temperature (15-30°C) and assay within 24 hours of collection. Specimens may be stored at 2-8°C or frozen for up to 14 days. Boric acid may be used as a preservative. Allow all specimens to equilibrate to room temperature before testing.

III. MATERIALS

A. **B**inax NOW Streptococcus pneumoniae Antigen Card
B. Reagent A: Citrate/Phosphate buffer with sodium lauryl sulfate, Tween 20, and sodium azide.
C. Positive Control Swab: inactivated *S. pneumoniae* antigen dried onto swab.
D. Negative Control Swab: *S. pneumoniae* antigen negative swab.
E. Swabs provided into the kit. DO NOT USE OTHER SWABS.
F. Timer

IV. STORAGE AND STABILITY

A. The kit is stored at room temperature (2-30°C). It is stable until the expiration date marked on the outer packaging and containers. Do not use the kit after the expiration date.

V. QUALITY CONTROL

A. The Alere BinaxNow *S. pneumoniae* antigen card kit contains internal quality controls and external quality controls.
    1. **Internal Controls**: The internal quality controls are built-in to each test card and are performed with each test.
        a. **Positive Control:** The pink-to-purple line at the Control position is an internal positive procedural control. If capillary flow has occurred, this line will always appear. The internal control does not assure functionality of the specific detection reagents. It only assures that the device is working properly.
        b. **Negative Control**: The clearing of the background color in the window provides a negative background control. The background color in the window should be light pink to white within 15 minutes and should not interfere with the reading of the test.
        c. Documentation of the internal control functionality is provided under Results Entry in Epic Beaker. Following the entry of the test result in Beaker, document the internal control as "pass" or "fail". If the internal control failed, the test is invalid and must be repeated.
    1. **External Controls:** The external quality controls are provided in the test kit and must be run with each new lot or each new shipment.
        a. Procedure for BinaxNow Swab Controls:
            1) Allow reagents and cards to equilibrate to room temperature (15-30°C) before testing. Remove card from the pouch just before use and lay the test card flat. There are two holes on the inner right panel of the card. Insert swab into the **BOTTOM** hole.

Firmly push upwards so that the swab tip is fully visible in the top hole. **DO NOT REMOVE SWAB**.

2) Hold Reagent A vial vertically, ½ to 1 inch above the card. Slowly add **six (6)** free falling drops of **Reagent A** to the **BOTTOM** hole. Immediately peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Read result in window 15 minutes after closing the card. Results read beyond 15 minutes may be inaccurate. However, the positive control swab specimen line may be visible in less than 15 minutes.

Control	Expected Results	Interpretation
Kit Positive Control Swab	Positive	Pink-Purple lines at the control and sample positions
Kit negative Control Swab	Negative	Pink to purple line at the control position and no line at the sample position.

3) Do not use the kit or report patient results if positive and negative controls do not perform as expected. Contact the Microbiology Supervisor.

VI. PROCEDURE

A. Open the test device just prior to use, lay flat, and perform assay. Equilibrate patient urine to room temperature before testing.
B. Dip a swab (provided in the kit) into the urine specimen to be tested, completely immersing the swab head. If necessary, touch the swab to the side of the urine container to remove excess liquid.
C. There are two holes in the inner right panel of the device. Insert the swab into the **BOTTOM** hole, and gently push upwards so that the swab tip is visible in the top hole.
D. DO NOT REMOVE THE SWAB.
E. Hold the Reagent A vial vertically, 1 to 1½ inches above the device and slowly add **3 drops of Reagent A** to the **BOTTOM** hole.
F. Immediately peel off the adhesive liner from the right edge of the test device. Close and securely seal the device.
G. Read the result in the window 15 minutes after closing the device. Results read beyond 15 minutes may be inaccurate. However, some positive patients may produce a visible specimen line in less than 15 minutes.

VII. INTERPRETATION

A. **Positive:** Two pink-purple colored lines appear; one line is at the control position and one line is at the sample position. A positive test means that the antigen was detected. Specimens with low levels of the antigen may give a faint sample Line**. Any visible line is positive.**
B. **Negative:** One pink-purple line is at the control position (top half of the window) and there is no line at the sample position. The control line means that the detection part of the test was done correctly, but no *S. pneumoniae* antigen was detected.
C. **Invalid:** If no lines are seen, or if only the sample line is seen (no control line), then the test is invalid. Invalid tests must be repeated. If the problem persists, call Binax Technical Services at 1-800-323-3199 for further instruction. Additionally, contact the Clinical Microbiologist or Microbiology Supervisor

VIII. REPORTING RESULTS

A. **Resulting in Epic Beaker**
   1. Select result entry and enter the specimen number.
      a. Verify patient information matches patient information on the test card.
   2. Click on "Edit"
   3. Enter the result of positive or negative in the value box for the Urine Streptococcal Antigen Test.
   4. Enter the internal qc result as "pass" or "fail".
      a. Note: Patient results should not be reported if the QC fails. The test should be repeated.
   5. Final verify the results.

IX. CRITICAL DETERMINANTS

A. The Reagent A vial must be held VERTICALLY for correct dispense volume.
B. The Reagent A vial must be held 1 - 1½ inches from the bottom hole to correctly dispense drops.
C. The test device must remain sealed in its protective pouch until just prior to use.
D. The card must be closed and sealed immediately after the addition of the reagent.
E. Do not mix components from different kit lots.
F. Do not use swabs other than those provided in the kit.
G. Alere Binax Streptococcus pneumonia has been validated for urine.
H. A negative test does not exclude infection with Streptococcus pneumonia.

X. REFERENCES

A. BinaxNOW Streptococcus pneumoniae Antigen Product Technical Insert, Alere Scarborough, Inc., Rev. 2018/07