## TITLE: Alere Streptococcus pneumonia

PRINCIPLE:

The Alere™ BinaxNOW® *Streptococcus pneumoniae* Antigen Card is an *in vitro* rapid immuno­chromatographic (ICT) assay for the detection of *Streptococcus pneumoniae (S. pneumoniae)* antigen in the urine of patients with pneumonia. It is intended, in conjunction with culture and other methods, to aid in the diagnosis of pneumococcal pneumonia.

Rabbit anti-*Streptococcus pneumoniae* antibody, the Sample Line, is adsorbed onto nitrocellulose membrane. Control antibody is ad­sorbed onto the same membrane as a second stripe. Both rabbit anti-*Streptococcus pneumoniae* and anti-species antibodies are conjugated to visualizing par­ticles that are dried onto an inert fibrous support. The resulting conjugate pad and the striped membrane are combined to construct the test strip. This test strip and a well to hold the swab specimen are mounted on opposite sides of a hinged, book-shaped test device.

Pneumococcal antigen present in the sample re­acts to bind anti-*Streptococcus pneumoniae* conjugated antibody. The resulting antigen-conjugate complexes are captured by immobilized anti-*Streptococcus pneumoniae* antibody, forming the Sample Line. Immobilized control antibody captures anti-species conjugate, forming the Control Line.

### PERSONNEL:

 Medical Technologist

## REAGENTS AND EQUIPMENT:

1. **Reagents and Materials Provided**

|  |  |  |
| --- | --- | --- |
|  **Component** | **Content** | **Quantity** |
| Test Device | A membrane coated with rabbit antibody specific for *S.* *pneumoniae* antigen and with control antibody is combined with rabbit anti-*Streptococcus pneumoniae* antigen and anti-species conjugates in a hinged test device.  | 12/22 |
| Reagent A | Citrate / Phosphate buffer with sodium lauryl sulfate, with Tween® 20 and sodium azide.  | 1 |
| Swabs | Designed for use in the Alere™ BinaxNOW® *Streptococcus pneumoniae* Antigen Card. **Do Not Use Other Swabs**.  | 12/22 |
| Positive Control Swab | Inactivated *S. pneumoniae* antigen dried onto swab.  | 1 |
| Negative Control Swab  | *S. pneumoniae* negative swab.  | 1 |

1. **Reagents and Materials not Provided**

Clock, timer or stopwatch

Standard urine collection containers

1. **Storage and Stability**

Store Test Kit at 2-30°C. The Alere™ BinaxNOW® *Streptococcus pneumoniae* kit and reagents are stable until the expiration dates marked on their outer packaging and containers. Do not use kit beyond its labeled expiration date.

### SPECIMEN:

|  |  |
| --- | --- |
| A. Specimen: | Acceptable: Urine Unacceptable: Specimens collected from other sources. |
| B: Urine Collection Container:  | Use standard urine collection container. |
| C. Urine Preservative: | Boric Acid may be used as a preservative.Unacceptable: Use of other preservatives. |
| D. Specimen Transport: | Transport in a leak proof container. |
| E. Urine Specimen Storage: | Samples may be stored at room temperature if assayed within 24 hours. Alternatively, samples may be refrigerated or frozen for up to 14 days before testing. |
| F. Handling Precautions: | Patient samples, controls, and test devices should be handled as though they could transmit disease. Observe established precautions against microbial hazards. |

## QUALITY CONTROL:

* 1. **Internal Procedural Controls**

###### The Alere™ BinaxNOW® *Streptococcus pneumoniae* has built-in procedural controls. Alere suggests that you record these controls, at minimum, for the first sample tested each day.

* Positive Procedural Control – The pink-to-purple line at the “Control” position can be considered an internal positive procedural control. If capillary flow has occurred and the functional integrity of the device was maintained, this line will always appear.
* Negative Procedural Control – The clearing of the background color in the result 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 result.
	1. **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.

Alere™ kits contain Positive and Negative Control Swabs. These swabs will monitor the entire assay. Test these swabs with each new ship­ment received and every thirty days thereafter.

If the correct control results are not obtained, do not report patient results. Contact Technical Support at 1-877-866-9340 during normal business hours.

## STEPWISE PROCEDURE:

1. **Test Procedure**

**Patient Urine Samples and Liquid Controls Procedure**

Use a **URINE** sample when testing for **PNEUMOCOCCOAL PNEUMONIA.**

**NOTE: Use 3 drops of Reagent A when testing liquid samples.**

1. Allow reagents and devices to equili­brate to room temperature (15-30°C) before use. Bring patient sample(s) and/or liquid control(s) to room temperature (59-86°F, 15-30°C), then swirl gently to mix. Remove device from its pouch **just before use** and lay flat.
2. Dip an Alere™ swab into the sample to be tested, completely covering the swab head. If the swab drips, touch swab to side of collection container to remove excess liquid.
3. There are two holes on the inner right panel of the device. Insert swab into the **BOTTOM** hole (swab well). Firmly push upwards so that the swab tip is fully visible in the top hole. **DO NOT REMOVE SWAB.**
4. Hold Reagent A vial vertically, ½ to 1 inch above the device. Slowly add **three (3)** free falling drops of Reagent A to the **BOTTOM** hole.
5. Immediately peel off adhesive liner from the right edge of the test device. Close and securely seal the device. Read result in window 15 minutes after closing the device. Results read beyond 15 minutes may be inaccurate. However, some positive patients may produce a visible sample line in less than 15 minutes.

NOTE: For convenience, the swab shaft has been scored and may be snapped off **after** closing the device. Avoid dislodging the swab from the well when doing so.

**Control Swab Test Procedure:**

**NOTE: Use 6 drops of Reagent A for Control Swabs.**

1. Allow reagents and devices to equili­brate to room temperature (15-30°C) before use. Remove device from the pouch **just before use**. Lay device flat.
2. There are two holes on the inner right panel of the device. 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**.
3. Hold Reagent A vial vertically, ½ to 1 inch above the device. Slowly add **six (6)** free falling drops of Reagent A to the **BOTTOM** hole.
4. Immediately peel off adhesive liner from the right edge of the test device. Close and securely seal the device. Read result in window 15 minutes after closing the device. Results read beyond 15 minutes may be inaccurate. However, the Positive Control swab sample line may be visible in less than 15 minutes.

### REPORTING RESULTS:

Test results are interpreted by the presence or absence of visually detect­able pink-to-purple colored lines. A positive test result, read in 15 minutes, will include the detection of both a Sample and a Control Line. A negative test result, read in 15 minutes, will produce only a Control Line, indicating that *S. pneumoniae* antigen was not detected in the sample. Failure of the Control Line to appear, whether the Sample Line is present or not, indicates an invalid assay.

**Negative Result:** A single pink-to-purple colored Control Line in the top half of the window, indicating a presumptive negative result. This Control Line means that the detection part of the test was done correctly, but no *Streptococcus pneumoniae* antigen was detected.

**Positive Result:** Two pink-to-purple colored lines are visible in the window. This means that antigen was detected. Specimens with low levels of antigen may give a faint Sample Line. **Any visible line is positive**.

**Invalid Result:** If no lines are seen, or if just the Sample Line is seen, the assay is **invalid**. Invalid tests should be repeated.

### NOTES:

**Control swabs require six (6) drops of Reagent A. Patient specimens require three (3) drops of Reagent A.**

1. Invalid Results, indicated by no control line, can occur when an insufficient volume of Reagent A is added to the test device. To ensure delivery of an adequate volume, hold vial vertically, ½ - 1 inch above the swab well, and slowly add free falling drops.
2. For *in vitro* diagnostic use.
3. If the kit is stored in a refrigerator, allow all kit components to equili­brate to room temperature (15-30°C) before use.
4. The test device is sealed in a protective foil pouch. Do not use if pouch is damaged or open. Remove test device from pouch just prior to use. Do not touch the reaction area of the test device.
5. Do not use kit past its expiration date.
6. Do not mix components from different kit lots.
7. Swabs in the kit are approved for use with the Alere™ test. **Do not use other swabs.**
8. Solutions used to make the control swabs are inactivated using standard methods. However, patient samples, controls, and test devices should be handled as though they could transmit disease. Observe established precautions against microbial hazards.
9. Clean catch urine is not necessary for the Alere™ test. Therefore, urine specimens used for this test may not be appropriate for bacteriological culture.

 **LIMITATIONS:**

* The Alere™ BinaxNOW® *Streptococcus pneumoniae* has been validated using urine only. Other samples (e.g. plasma or other body fluids) that may contain *S. pneumoniae* antigen have not been evaluated.
* A negative Alere™ test does not exclude infection with *S*. *pneumoniae.* Therefore, the results of this test as well as culture results, serology, or other antigen detection methods should be used in conjunction with clinical findings to make an accurate diagnosis.
* The Alere™ BinaxNOW® *Streptococcus pneumoniae* has not been evaluated on patients taking antibiotics for greater than 24 hours or on patients who have recently completed an antibiotic regimen.
* *Streptococcus pneumoniae* vaccine may cause false positive results in urine in the Alere™ BinaxNOW® *Streptococcus pneumoniae* in the 48 hours following vaccination. Hence, it is recommended that the Alere™ BinaxNOW® *Streptococcus pneumoniae* not be administered within 5 days of receiving the *S. pneumoniae* vaccine.
* The accuracy of the Alere™ BinaxNOW® *Streptococcus pneumoniae* in urine has not been proven in young children.

##

REFERENCES:

Alere BinaxNOW® *Streptococcus pneumonia* Antigen Card CLSI + More Packet