Streptococcus pneumoniae Test: Binax NOW®

Introduction

- The Binax NOW® *Streptococcus pneumoniae* Test is a moderately complex *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.

Specimen Requirements

- Collect urine specimens in standard containers.
- Store at room temperature [59-86°F, 15-30°C] if assayed within 24 hours of collection.
- Alternatively, store urine at 2-8°C or frozen for up to 14 days before testing.
- When necessary, ship urine specimens in leak-proof containers at 2-8°C or frozen.
- Boric acid may be used as a preservative.

Safety

- All reagents and controls should be handled as though capable of transmitting infectious diseases. Wear appropriate personal protective equipment when running patient samples or performing scheduled maintenance.
- Refer to Laboratory Policy and Procedure Manual Safety Section (11).

Materials provided in kit

- Test Devices
- Reagent A: Citrate/Phosphate buffer with sodium lauryl sulfate, Tween 20 and sodium azide.
- Swabs: Designed for use in the Binax NOW® *Streptococcus pneumoniae* Test.

  Warning!
  Do not use other swabs.

- Positive Control Swab
- Negative Control Swab

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Materials not provided in kit

- Clock, timer or stopwatch
- Standard urine collection containers or urine transport tubes with boric acid preservative

Kit Storage Requirements

- Store kit at room temperature [59-86°F, 15-30°C].
- The Binax NOW® *Streptococcus pneumoniae* test kit and reagents are stable until the expiration dates marked on their outer packaging and containers.

Assay Procedure – Binax NOW® Swab Controls

Follow these steps to perform the procedure on Binax NOW® Swab Controls.

- Remove device from the pouch **just before use.**
- Lay device flat.

Step	Action
1	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.**
2	• 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. ***Warning!*** ***Improper delivery of liquid reagents can cause invalid results.***

3	• **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.
	  • Record results on the external control log.

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Assay Procedure – Patient Urine Samples and Liquid Controls

Follow these steps to perform the procedure on patient urine samples and liquid controls. [Refer to **Patient Sample Procedure Card**.]

Before you begin:
- Remove test device from the pouch **just before use.**
- Lay device flat and run test as follows:

Warnings
- Observe established precautions against microbiological hazards throughout all procedures.
- All specimens should be handled according to CDC/NIH [Centers for Disease Control and Prevention/National lnstitutes of Health] recommendations for any potentially infectious samples.

Step	Action
1	• Bring patient urine sample[s] and/or liquid control[s] to room temperature [59-86°F, 15-30°C]. • Swirl gently to mix.
2	Dip a Binax swab into the sample to be tested, completely covering the head of the swab. 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. ***Warning!*** • ***Improper delivery of liquid reagents can cause invalid results.***

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.

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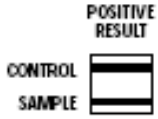
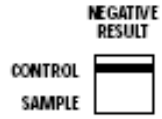
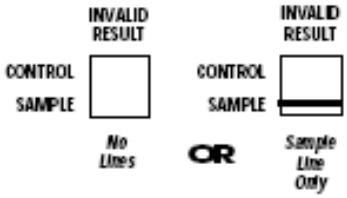
Interpretation of Results

Appearance of Test Device Window	Interpretation	Result
Two pink-to-purple colored lines will appear in the window. 	• *S. pneumoniae* antigen was detected. • Specimens with low levels of antigen may give a faint sample line. • **Any visible line is positive.**	**Positive**
A **single** pink-to-purple colored line will appear in the top half of the window. 	Control line means that the detection part of the test was done correctly, but **no** *S. pneumoniae* antigen was detected.	**Negative**
No lines are seen, or just the sample line is seen. 	• Assay is invalid [refer to the first Procedure Note on Page 6]. • **Repeat the test**.	**Reject result using "ITRE" Technical Error**

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Quality Control

Built-in procedural control:

- The Binax NOW® *Streptococcus pneumoniae* Test contains built-in positive and negative procedural controls.
- The built-in control is a pink-to-purple colored Control Line, which will appear on all valid tests, whether or not the sample is negative or positive.
- The validity of the control line is documented in LMS as "P" = "Present"; or "N" = "Not Present" for every patient testing.

External quality controls:

- Daily perform one positive and one negative control swabs.
- Use patient log sheet to document all Q.C. results performed.

Parallel Testing:

- Reagents should be tested according to the requirements of the laboratory or applicable local, state or accrediting agencies.

Warning!

- ***Do not report patient test results if expected control results are not obtained.***
- ***Consult a Supervisor.***

Reporting Results

Use the codes listed below when reporting results.

Result	Code	Description
Positive	**P**	STREPTOCOCCAL PNEUMONIAE ANTIGEN DETECTED. ADULTS WITH PNEUMOCOCCAL PNEUMONIA SENSITIVITY 50-80%; SPECIFICITY 90% CHILDREN WITH PNEUMOCOCCAL PNEUMONIA SENSITIVITY 80-90%; SPECIFICITY 60-80%
Negative	**N**	STREPTOCOCCAL PNEUMONIAE ANTIGEN NOT DETECTED. ADULTS WITH PNEUMOCOCCAL PNEUMONIA SENSITIVITY 50-80%; SPECIFICITY 90% CHILDREN WITH PNEUMOCOCCAL PNEUMONIA SENSITIVITY 80-90%; SPECIFICITY 60-80%

Invalid	**REJECT** test using code **"ITRE"**	Instrument/Technical Related Error.

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Procedure Notes

- **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 to 1 inch above the swab well, and slowly add free falling drops.
- 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.
- Do not use kit past its expiration date.
- Do not mix components from different kit lots.
- Swabs in the kit are approved for use in the Binax NOW® Test. **Do not use other swabs**.
- 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.
- Clean catch urine is not necessary for the NOW® test. Therefore, urine specimens for this test may not be appropriate for bacteriological culture.

Limitations of the Procedure

- The Binax NOW® *Streptococcus pneumoniae* Test has been validated using urine samples only.
- Other samples (e.g., plasma or other body fluids) that may contain *S. pneumoniae* antigen have not been evaluated.
- A negative Binax NOW® 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 Binax NOW® *Streptococcus pneumoniae* Test has not been evaluated on patients taking antibiotics for greater than 24 hours or on patients who have recently completed an antibiotic regimen.

- The accuracy of the Binax NOW® test in urine has not been proven in young children.
- The literature suggests that this test is not useful for discriminating between children with pneumococcal pneumonia from those who are colonized.
- *Streptococcus pneumoniae* vaccine may cause false positive results in urine in the Binax NOW® *Streptococcus pneumoniae* Test in the 48 hours following vaccination.
- Hence, it is recommended that the Binax NOW® *Streptococcus pneumoniae* Test not be administered within 5 days of receiving the *S. pneumoniae* vaccine.

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Signature responsible person/date	Med. Dir. Reviewed/ Date	Lab Manager reviewed/ date	Date change Imp.
Major	Changed frequency of performing external controls to once per day.	Cindy Schwartz			1/13/16

Non-controlled Documents

The following non-controlled documents support this procedure:

- Attachment 1: Binax NOW® *Streptococcus pneumoniae* Patient Sample Procedure Card
- NOW® *Streptococcus pneumoniae* Test product instructions [package insert]
- CDC Laboratory Biosafety Level Criteria
- Dowell, S.F., R. L. Garman, G. Liu, O.S. Levine & Y. Yang. 2001. Evaluation of Binax NOW, an assay for the detection of pneumococcal antigen in urine samples, performed among pediatric patients. CID. 32:824-5.
- Navarro, D., L. Garcia-Maset, C. Gimeno, A. Esribano, J. Garcia-de-Lomas & The Spanish Pneumococcal infection Study Network. 2004. Performance of the Binax NOW *Streptococcus pnemoniae* Urinary Antigen Assay for Diagnosis of pneumonia in children with underlying pulmonary diseases in the absence of acute pneumococcal infection. JCM. 42:4853-4855.

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