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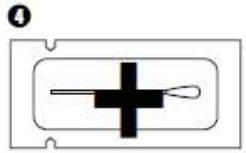
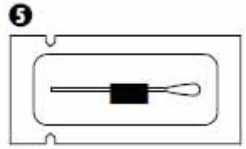
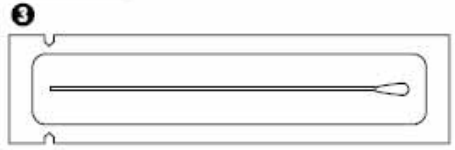
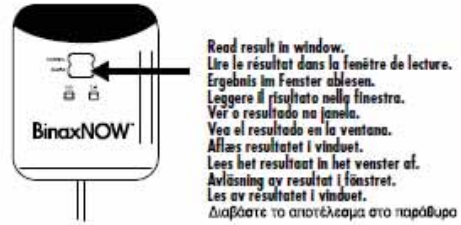






TEST PROCEDURE / ÉPREUVE PROCÉDURE / TESTEN VERFAHREN / ESAME PROCEDURA / TESTE PROCEDIMENTO / PRUEBA PROCESO / OVERHØRE FREMGANGSMÅDE / TOETS WIJZE VAN HANDELEN / PROV PROCEDUR / TEST FREMGANGSMÅTE / δοκιμάζω οδηγίες



EN

INTENDED USE

The Binax NOW® *Streptococcus pneumoniae* Test is an *in vitro* rapid immunochromatographic (ICT) assay for the detection of *Streptococcus pneumoniae (S. pneumoniae)* antigen in the urine of patients with pneumonia and in the cerebral spinal fluid (CSF) of patients with meningitis. It is intended, in conjunction with culture and other methods, to aid in the diagnosis of both pneumococcal pneumonia and pneumococcal meningitis.

SUMMARY AND EXPLANATION OF THE TEST

S. pneumoniae is the leading cause of community-acquired pneumonia and may be the most important agent in community-acquired pneumonia of unknown etiology.[1,2] Pneumococcal pneumonia has a mortality rate as high as 30%, depending on bacteremia, age, and underlying diseases.[1,3] When not properly diagnosed and treated, *S. pneumoniae* infection can lead to bacteremia, meningitis, pericarditis, empyema, purpura fulminans, endocarditis and/or arthritis. [4,5]

Pneumococcal meningitis, a condition that frequently leads to permanent brain damage or death, can occur as a complication of other pneumococcal infection or may arise spontaneously without any preceding illness.[6] It affects persons of all ages, but is most common in children under 5 years, teenagers and young adults, and in the elderly.[7] Progression from mild illness to coma can occur within hours, making immediate diagnosis and antimicrobial treatment critical. Twenty to thirty percent of all pneumococcal meningitis patients will die, often despite several days of appropriate antibiotic treatment.[6] Mortality is even higher among very young and very old patients.[6]

The BinaxNOW® *Streptococcus pneumoniae* Test provides a simple, rapid method for the diagnosis of pneumococcal pneumonia using a urine sample that is conveniently collected, stored and transported. It also provides an immediate and highly accurate diagnosis of pneumococcal meningitis when CSF is tested.

PRINCIPLES OF THE PROCEDURE

The BinaxNOW® *Streptococcus pneumoniae* Test is an immunochromatographic membrane assay used to detect pneumococcal soluble antigen in human urine and CSF. Rabbit anti-*S. 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-*S. 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.

To perform the test (U.S. Patent Nos: 6,017,767; 6,548,309; 6,824,997), a swab is dipped into the specimen (either urine or CSF), removed, and then inserted into the test device. Reagent A, a buffer solution, is added from a dropper bottle. The device is then closed, bringing the sample into contact with the test strip. Pneumococcal antigen present in the sample reacts to bind anti-*S. pneumoniae* conjugated antibody. The resulting antigen-conjugate complexes are captured by immobilized anti-*S. pneumoniae* antibody, forming the Sample Line. Immobilized control antibody captures anti-species conjugate, forming the Control Line.

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 depending on the concentration of antigen present in the specimen, 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.

REAGENTS AND MATERIALS

Materials Provided
Refer to illustration on pull-out flap.

❶ **Test Devices:** A membrane coated with rabbit antibody specific for *S. pneumoniae* antigen and with control antibody is combined with rabbit anti-*S. pneumoniae* antigen and anti-species conjugates in a hinged test device.

❷ **Reagent A:** Citrate / Phosphate buffer with sodium lauryl sulfate, Tween® 20, and sodium azide.

❸ **Sample Swabs:** Designed for use in the BinaxNOW® *Streptococcus pneumoniae* Test. **Do not use other swabs**.

❹ **Positive Control Swab:** Inactivated *S. pneumoniae* antigen dried onto swab.

❺ **Negative Control Swab:** *S. pneumoniae* negative swab.

Materials Not Provided

Clock, timer, or stopwatch; standard urine collection containers, or CSF transport tubes

Accessory Item

BinaxNOW® *Streptococcus pneumoniae* Test Control Swab Pack (catalog number 710-010) containing 5 positive and 5 negative control swabs.

PRECAUTIONS

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. 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.
4. Do not use kit past its expiration date.
5. Do not mix components from different kit lots.
6. Swabs in the kit are approved for use in the BinaxNOW® Test. **Do not use other swabs.**
7. 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.
8. Clean catch urine is not necessary for the BinaxNOW® Test. Therefore, urine specimens used for this test may not be appropriate for bacteriological culture.
9. Once the Binax swab is dipped into CSF specimen, the sample is no longer sterile and may not be appropriate for culture. If CSF specimen will be cultured, either perform culture first or split CSF sample.

STORAGE AND STABILITY

Store kit at room temperature (59-86°F, 15-30°C). The BinaxNOW® *Streptococcus pneumoniae* Test kit and reagents are stable until the expiration dates marked on their outer packaging and containers. Do not use the kit beyond its labeled expiration date.

SPECIMEN COLLECTION

Allow all specimens to equilibrate to room temperature (59-86°F, 15-30°C) before testing in the BinaxNOW® *Streptococcus pneumoniae* Test. Just before testing, mix specimen by swirling gently.

URINE (for diagnosis of pneumonia)
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. Boric acid may be used as a preservative.

When necessary, ship urine specimens in leakproof containers at 2-8°C or frozen.

CSF (for diagnosis of meningitis)
Collect CSF according to standard procedures and store at room temperature (59-86°F, 15-30°C) for up to 24 hours before testing. Alternatively, properly collected CSF may be refrigerated (2-8°C) or frozen (-20°C) for up to 1 week before testing.

QUALITY CONTROL

Daily Quality Control:
The BinaxNOW® *Streptococcus pneumoniae* Test contains built-in positive and negative procedural controls. The manufacturer's minimum recommendation for daily quality control is to document these procedural controls 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 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.

External Positive and Negative Controls:
Good laboratory practice recommends the use of positive and negative controls to assure functionality of reagents and proper performance of assay procedure. Positive Control Swabs and Negative Control Swabs that will monitor the entire assay are provided in the test kits and should be tested using the Control Swab procedure. Controls should be tested once with each test kit opened, and as otherwise required by your laboratory's standard Quality Control procedures. Additional controls may be tested according to the requirements of local, state and/or federal regulations or of accrediting organizations.

If expected control results are not obtained, do not report patient results. Review the procedure and repeat control testing or contact Inverness Medical.

CONTROL SWAB PROCEDURE
Binax NOW® Swab Controls

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

1. 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, 1/2 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.

TEST PROCEDURE
Urine Samples, CSF Samples and Liquid Controls

Use a **URINE** sample when testing for **PNEUMOCOCCAL PNEUMONIA** and a **CSF** sample when testing for **PNEUMOCOCCAL MENINGITIS**.

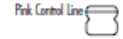
NOTE: Use 3 drops of Reagent A when testing liquid samples. Refer to illustration on pull-out flap.

1. 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 a Binax 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.

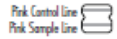
NOTE: For convenience, the swab shaft has been scored and may be snapped off **after** closing the device. Avoid dislodging the swab from the well when doing so.

INTERPRETATION OF RESULTS

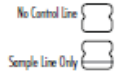
A **negative sample** will give a single pink-to-purple colored Control Line in the top half of the window, indicating a presumptive negative result. This Control Line means that the detection part of the test was done correctly, but no *S. pneumoniae* antigen was detected.



A **positive sample** will give two pink-to-purple colored lines. This means that antigen was detected. Specimens with low levels of antigen may give a faint patient line. **Any visible line is positive**.



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



REPORTING OF RESULT

Result	Recommended Report
Positive Urine	Positive for pneumococcal pneumonia.
Negative Urine	Presumptive negative for pneumococcal pneumonia, suggesting no current or recent pneumococcal infection. Infection due to *S. pneumoniae* cannot be ruled out since the antigen present in the sample may be below the detection limit of the test.
Positive CSF	Positive for pneumococcal meningitis.
Negative CSF	Presumptive negative for pneumococcal meningitis. Infection due to *S. pneumoniae* cannot be ruled out since the antigen present in the sample may be below the detection limit of the test.

LIMITATIONS

The BinaxNOW® *Streptococcus pneumoniae* Test has been validated using urine and CSF samples only. Other samples (e.g. plasma or other body fluids) that may contain *S. pneumoniae* antigen have not been evaluated.

A negative BinaxNOW® 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 BinaxNOW® *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 effects of over-the-counter drugs have not been determined on persons with pneumococcal meningitis.

Streptococcus pneumoniae vaccine may cause false positive results in urine in the BinaxNOW® *Streptococcus pneumoniae* Test in the 48 hours following vaccination. The effect of vaccination has not been determined on persons with pneumococcal meningitis. Hence, it is recommended that the BinaxNOW® *Streptococcus pneumoniae* Test not be administered within 5 days of receiving the *S. pneumoniae* vaccine.

The accuracy of the BinaxNOW® Test in urine has not been proven in young children. Performance on CSF in young children, on the other hand, is established (see Performance Data - CSF).

PERFORMANCE DATA - URINE

ANALYTICAL SENSITIVITY

Serotype Evaluation

Forty-four (44) isolates, representing the 23 *S. pneumoniae* serotypes responsible for at least 90% of serious pneumococcal infection in the United States and worldwide, were grown in culture and found to be positive in the BinaxNOW® Test at concentrations of 10^5 cells/ml.

Limit of Detection

The BinaxNOW® Test limit of detection (LOD), defined as the dilution of positive urine that produces positive BinaxNOW® Test results approximately 95% of the time, was identified by preparing multiple dilutions of a known positive patient urine and running these dilutions in the BinaxNOW® Test.

Five (5) different operators each interpreted 20-40 devices run at each dilution for a total of 100-200 determinations per dilution. The following results identify a 1:250 dilution of this particular patient urine as the BinaxNOW® Test LOD.

Urine Dilution	Positive Results per Devices Run	Overall Detection
1:200	100/100	100%
1:250	**95/100**	**95%**
1:300	160/200	80%
1:400	44/100	44%
1:600	8/100	8%

CLINICAL SENSITIVITY AND SPECIFICITY (Retrospective Study)

As part of the retrospective study, urine specimens from 35 blood culture positive pneumococcal pneumonia patients and 338 presumed *S. pneumoniae* negative patients (373 total patients) were collected at 3 different facilities and evaluated in the BinaxNOW® Test. BinaxNOW® Test performance was calculated using standard methods. Sensitivity was 86%, specificity was 94%, and overall accuracy was 93%. Ninety-five percent (95%) confidence intervals are listed below.

		Blood Culture +	Blood Culture −
BinaxNOW® Result	+	30	21
	−	5	317

Sensitivity	=	**86%**	(71% - 94%)
Specificity	=	**94%**	(91% - 96%)
Accuracy	=	**93%**	(90% - 95%)

CLINICAL SENSITIVITY AND SPECIFICITY (Prospective Study)

In a separate seven-center prospective study, the BinaxNOW® Test was used to evaluate urine specimens collected from 215 hospitalized and outpatients presenting with lower respiratory symptoms or sepsis and from patients otherwise suspected of pneumococcal pneumonia. Patients were considered positive for pneumococcal pneumonia if diagnosed by positive blood culture.

The BinaxNOW® Test performed equivalently on both outpatients and hospitalized patients. Ninety-five percent (95%) confidence intervals are listed below.

Outpatient Performance
Blood Culture

		+	−
BinaxNOW®	+	19	25
Result	−	2	90

Sensitivity	=	**90%**	(70% - 97%)
Specificity	=	**78%**	(70% - 85%)
Accuracy	=	**80%**	(72% - 86%)

Hospitalized Patient Performance
Blood Culture

		+	−
BinaxNOW®	+	9	20
Result	−	1	49

Sensitivity	=	**90%**	(60% - 98%)
Specificity	=	**71%**	(59% - 80%)
Accuracy	=	**73%**	(62% - 82%)

CROSS-REACTIVITY

Urine Testing
Two hundred seventy (270) different organisms were isolated from the 338 negative patients tested as part of the above retrospective study. Of the 165 organisms isolated from patients with urinary tract infections, 15 (9%) produced positive results. These were 2/2 *Enterobacter cloacae*, 1/2 *Staphylococcus aureus*, 1/1 *Streptococcus* (non A,B), 1/1 *Streptococcus* (non D), 1/17 *Streptococcus* (Group D), 1/3 *Providencia stuartii*, 5/78 *Escherichia coli* and 3 with no identified pathogen. Of the 59 organisms isolated from patients with pneumonia, 3 (5%) were positive, including 1/3 *Mycobacterium kansasii* and 2/15 *Mycobacterium tuberculosis*. One of the 41 (2%) organisms isolated from bacteremic patients, *Proteus mirabilis*, was positive. There was no cross-reactivity with the 5 empyema isolates. Lastly, 4/100 urine specimens collected from people with no known infection were positive.

Due to the retrospective nature of this study, only a limited number of patients with each infection were available for testing and the complete clinical history of each is not known. Therefore, the presence of *S. pneumoniae* co-infection cannot be ruled out. When tested in pure culture (data below), these organisms do not cross-react in the BinaxNOW® Test.

Whole Organism Testing
To determine the analytical specificity of the BinaxNOW® Test, a panel of 144 potential cross-reactants was compiled, including organisms associated with pneumonia and those likely to be found in the urogenital tract as normal flora or as a result of urinary tract infection. All were evaluated in the BinaxNOW® Test at concentrations of 10^6 to 10^8 CFU/mL. The BinaxNOW® Test does not cross-react with 143 of the 144 organisms. The single positive organism, *Streptococcus mitis*, is an expected cross-reactant as it shares the antigen against which the BinaxNOW® Test is directed. *Streptococcus mitis* is associated with endocarditis, not pneumonia, and is not likely to appear with any frequency in the population intended to be tested with the BinaxNOW® Test.[8] The following organisms were tested and produced negative results. When more than one strain was tested, the number is listed in parenthesis.

Acinetobacter sp. (4)
Adenovirus* (2&3 pooled)
Alcaligenes faecalis
Bacillus subtilis
*Blastomyces dermatitidis**
Bordetella pertussis
Branhamella catarrhalis
Candida albicans (3)
Candida stellataides
*Coccidiodes immitis**
Corynebacterium sp. (3)
Enterobacter cloacae (4)
Enterococcus avium ◆
Enterococcus durans ◆
Enterococcus faecalis ◆ (6)
Escherichia coli (8)
Escherichia hermannii (2)
Flavobacterium sp. (2)
Gardnerella vaginalis
Haemophilus influenzae (10)
(types a-f & nontypeable)
Haemophilus parainfluenzae
*Histoplasma capsulatum** (2)
Klebsiella oxytoca (2)
Klebsiella pneumoniae (3)
Lactobacillus sp. (5)
Legionella pneumophila
Listeria monocytogenes
Micrococcus luteus (2)
Moraxella osloensis
Morganella morganii
Mycobacterium kansasii
Mycobacterium tuberculosis
*Mycoplasma sp.** (3)
Neisseria cinerea
Neisseria gonorrheae (3)
Neisseria lactamica
Neisseria meningitidis
Neisseria polysaccharea
Neisseria subflava
*Nocardia farcinia**
*Paracoccidiodes brasiliensis**
Parainfluenzae* (2)
Proteus mirabilis (2)
Proteus vulgaris (2)
Providencia stuartii
Pseudomonas sp. (7)
Respiratory Syncitial Virus*
Rhinovirus*
Salmonella sp. (4)
Serratia marcescens
Sphingobacterium multivorum
Staphylococcus aureus (6)
Staphylococcus sp. (8)
Stenotrophomonas maltophilia
Streptococcus anginosus ◆•
Streptococcus bovis ◆
Streptococcus Group A •(2)
Streptococcus Group B • (8)
Streptococcus Group C ◆•
Streptococcus Group F ◆•
Streptococcus Group G ◆•
Streptococcus mutans ◆•
Streptococcus parasanguis ◆•
Streptococcus sanguis ◆•
Trichomonas vaginalis (2)

* Pure cultures from CDC believed to be in high concentration.
◆ *Streptococcus* Non A, B (Total number of strains is 16)
• *Streptococcus* Non D (Total number of strains is 17)

INTERFERING SUBSTANCES

Urine specimens with elevated white blood cells (including loaded per low power field), red blood cells* (including loaded per low power field), protein (including 500 mg/dl), glucose (including >2000 mg/dl), and turbidity (including turbid) were evaluated in the BinaxNOW® *Streptococcus pneumoniae* Test and found not to affect test performance.

*Note that one urine with elevated red blood cells produced an invalid result due to extreme coloration of the test membrane which masked line development.

REPRODUCIBILITY STUDY

A blind study of the BinaxNOW® *Streptococcus pneumoniae* Test was conducted at 3 separate point of care settings using a panel of blind coded specimens containing negative, low positive, moderate positive, and high positive samples. Specimens both with and without boric acid were tested. Participants tested each sample multiple times on 3 different days. Three hundred fifty-seven (357) of the 359 total samples tested (99.4%) produced the expected result.

PERFORMANCE DATA - CSF

ANALYTICAL SENSITIVITY

Limit of Detection

The BinaxNOW® Test limit of detection (LOD) was identified by testing multiple *S. pneumoniae* dilutions in the BinaxNOW® Test.

Ten (10) different operators each interpreted 10 devices run at each dilution for a total of 100 determinations per dilution. The following results identify 5 x 10^4 cells per milliliter as the BinaxNOW® Test LOD.

Concentration of *S. pneumoniae*	Positive Results per Devices Run	Overall Detection
7.5 x 10^4 cells/ml	100/100	100%
5 x 10^4 cells/ml	**100/100**	**100%**
3 x 10^4 cells/ml	91/100	91%
1.5 x 10^4 cells/ml	44/100	44%
0 cells/ml	0/100	0%

Serotype Evaluation

The four (4) serotypes (6, 14, 19, 23) most commonly associated with pneumococcal invasive disease were grown in culture, diluted to 5 x 10^4 cells/ml in CSF and run in the BinaxNOW® Test. Fourteen (14) operators each interpreted 10 devices per serotype for a total of 140 determinations per serotype. All four (4) serotypes were detected 100% of the time at the test LOD (5 x 10^4 cells/ml).

Clinical Sensitivity and Specificity

In a multi-center (4) prospective study, the BinaxNOW® Test was used to evaluate CSF specimens collected from 590 hospitalized and outpatients presenting with symptoms of meningitis or from patients on whom a lumbar puncture was otherwise indicated. Patients were considered positive for pneumococcal meningitis if diagnosed by positive CSF culture.

BinaxNOW® Test performance was calculated using standard methods. Specificity was 99% (557/560), with a 95% confidence interval of 98% to 100%. Sensitivity was 97% (29/30), with a 95% confidence interval of 84% to 100%. The single culture positive specimen not detected in the BinaxNOW® Test was reported as producing only 2 colonies.

		CSF +	CSF –
BinaxNOW® Result	+	29	3
	–	1	557

Sensitivity	=	**97%**	(84% - 100%)
Specificity	=	**99%**	(98% - 100%)
Accuracy	=	**99%**	(98% - 100%)

CROSS-REACTIVITY

CSF Testing

Either enterovirus or bacteria was isolated from 61 of the *S. pneumoniae* negative CSF specimens tested as part of the above prospective study. Sixty (60) of these samples tested negative in the BinaxNOW® Test for a specificity of 98%. The single positive specimen contained *Enterococci*. However, a second clinical CSF containing *Enterococci* tested negative in the BinaxNOW® Test as did the cultured whole organism (see *Whole Organism Testing* on the next page).

Bacteria/Virus Isolated From CSF	Samples Tested	Specificity
Enterovirus	24	100%
Acinetobacter	3	100%
Cryptococcus neoformans	1	100%
C. diphtheriae	1	100%
Enterobacter	2	100%
Enterococci	2	50%
Escherichia coli	2	100%
Haemophilus influenzae type B	1	100%
Klebsiella pneumoniae	2	100%
Morganella morganii	1	100%
Neisseria meningitidis	3	100%
Staphylococcus coagulase negative	9	100%
Staphylococcus coagulase positive	2	100%
Staphylococcus epidermidis	2	100%
Streptococcus Group A	1	100%
Streptococcus Group B	1	100%
Streptococcus viridans	4	100%
Overall Specificity	**61**	**98%**

Whole Organism Testing

In addition to the bacterial and viral infections encountered as part of the prospective study, Binax compiled a panel of potential cross-reactants, including the most common bacterial and viral agents of meningitis. All bacteria were evaluated in the Binax test at concentrations ranging from 10^7 to 10^8 CFU/mL. Viruses were tested at 10^5 I.U./mL or greater. The BinaxNOW® Test demonstrated 100% specificity, producing negative results for all viruses and bacteria tested.

Burkitt's Lymphoma (Epstein Barr)
Coxsackie A7 Virus
Coxsackie B3 Virus
Echovirus
Enterococcus faecium
Haemophilus influenzae A
Haemophilus influenzae B
Haemophilus influenzae C
Haemophilus influenzae D
Haemophilus influenzae E
Haemophilus influenzae F
Haemophilus influenzae, non-typeable (51997)
Haemophilus influenzae, non-typeable (35891)
Herpes Simplex Virus Type 1
Herpes Simplex Virus Type 2
Listeria monocytogenes (19115)
Listeria monocytogenes (19424)
Neisseria meningitidis serogroup A
Neisseria meningitidis serogroup B
Neisseria meningitidis serogroup C
Neisseria meningitidis serogroup D
Neisseria meningitidis serogroup L
Streptococcus oralis (35037)

INTERFERING SUBSTANCES

CSF specimens with elevated white blood cells (1 x 10^4 cells/ml), red blood cells (30 cells/µl), protein (3 g/dl) and bilirubin (100 µg/ml) were evaluated in the BinaxNOW® *Streptococcus pneumoniae* Test and found not to affect test performance.

REPRODUCIBILITY STUDY

A blind study of the BinaxNOW® *Streptococcus pneumoniae* Test was conducted in 3 separate laboratories using a panel of blind coded specimens containing negative, low positive and moderate positive samples. Participants tested each sample multiple times on 3 different days. One hundred percent (100%) of the 270 samples produced the expected result.

ORDERING INFORMATION

Reorder numbers:
710-012: BinaxNOW® *Streptococcus pneumoniae* Test (12 test kit)
710-000: BinaxNOW® *Streptococcus pneumoniae* Test (22 test kit)
710-010: BinaxNOW® *Streptococcus pneumoniae* Control Swab Pack

Contact Information:
Tel: US: 877-441-7440, OUS: 321-441-7200
Fax: 321-441-7400