BinaxNOW®
Influenza A & B
Test Kit

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.

binax®

INTENDED USE

The BinaxNOW® Influenza A & B Test is an *in vitro* immunochromatographic assay for the qualitative detection of influenza A and B nucleoprotein antigens in nasopharyngeal (NP) swab and nasal wash/aspirate specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections. Negative test results should be confirmed by cell culture.

Caution: Assay sensitivity was determined primarily using archived specimens. Users may want to establish the sensitivity of this test on freshly collected, unfrozen samples.

SUMMARY AND EXPLANATION OF THE TEST

Influenza is a highly contagious, acute, viral infection of the respiratory tract. It is a communicable disease easily transmitted through the coughing and sneezing of aerosolized droplets containing live virus. Influenza outbreaks occur each year during the fall and winter months.[1] Type A viruses are typically more prevalent than type B viruses and are associated with most serious influenza epidemics, while type B infections are usually more mild.

Rapid diagnosis of influenza A and B has become more important due to the availability of effective antiviral therapy. Rapid diagnosis of influenza can lead to reduced hospital stays, antimicrobial use and cost of hospital care.[1]

The BinaxNOW® Influenza A & B Test provides a simple, rapid method for the diagnosis of influenza A and B using NP swab and nasal wash/aspirate specimens. The easy-to-use format and rapid results allow for its use in "STAT" testing where it can provide information to assist with treatment and hospitalization decisions.

There are many different subtypes of type A influenza viruses, some of which can be found in birds.[3] Direct human infection by Avian influenza A (H5N1), an influenza virus subtype that occurs mainly in birds, was first reported in 1997. Since then there have been other cases of H5N1 infections among humans leading to a concern that H5N1 could mutate enabling it to spread more easily from one person to another.[4] Due to the small percentage of documented cases of patients infected with avian influenza, the utility of rapid tests in managing those patients is currently unknown.

PRINCIPLES OF THE PROCEDURE

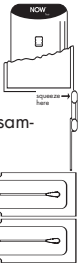
The BinaxNOW® Influenza A & B Test is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect influenza type A and B nucleoprotein antigens in NP specimens. These antibodies and a control antibody are immobilized onto a membrane support as three distinct lines and combined with other reagents/pads to construct a test strip. This test strip is mounted inside a cardboard, book-shaped, hinged, test device.

Swab specimens require a sample preparation step, in which the sample is eluted or washed off the swab into an elution solution. Nasal wash/aspirate samples require no preparation. Sample is added to the top of the test strip and the test device is closed. Test results are interpreted at 15 minutes based on the presence or absence of pink-to-purple colored Sample Lines. The blue Control Line turns pink in a valid assay.

REAGENTS AND MATERIALS

MATERIALS PROVIDED

BinaxNOW® INFLUENZA A & B TEST KIT



Test Devices: A cardboard, book-like, hinged, test device containing the test strip.

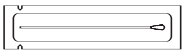
Transfer Pipettes: Fixed volume (100 µl), transfer pipettes used to transfer sample to the test device. Use only pipettes provided by Binax.

Positive Control Swab: Inactivated influenza A and B dried onto swab.

Negative Control Swab: Inactivated *Streptococcus* Group A dried onto swab.

Elution Solution Vials for Control Swabs/Swab Specimens: Vials containing a fixed volume (0.5 ml) of elution solution used to prepare the Control Swabs/Swab Specimens for testing.

NP Swabs: Sterile, foam swabs for use in the BinaxNOW® Influenza A & B Test.



MATERIALS RECOMMENDED BUT NOT PROVIDED

Clock, timer or stopwatch; nasal wash/aspirate collection containers

PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Leave test sealed in its foil pouch until just before use.
3. Do not use kit past its expiration date.
4. Do not mix components from different kit lots.
5. The white sample pad at the top of the test strip contains reagents that extract the target antigen from the virus. To ensure best performance, add the sample **SLOWLY** (drop-by-drop) to the **MIDDLE** of this pad, without touching with the pipet, such that all of the sample absorbs into the pad.
6. Solutions used to make the control swabs are inactivated using standard methods. However, patient samples, controls, and tests should be handled as though they could transmit disease. Observe established precautions against microbial hazards. The use of lab coats, gloves, and safety eye glasses is recommended.
7. All transfer pipettes and test vials are single use items – do not use with more than one specimen.
8. The ability of this test to detect avian influenza was determined using cultured avian influenza viruses, the performance characteristics of this test with specimens collected from humans infected with H5N1 or other avian influenzas is unknown.

STORAGE AND STABILITY

Store kit at room temperature (59-86°F, 15-30°C). The BinaxNOW® Influenza A & B Test Kit and reagents are stable until the expiration dates marked on their outer packaging and containers.

SPECIMEN COLLECTION AND HANDLING

Use fresh NP swabs and nasal wash/aspirates for best test performance.

Collect nasal washes in standard containers. Test as soon as possible. Washes can be held at 36-46°F (2-8°C) for up to 24 hours prior to testing in the BinaxNOW® Test.

Use sterile cotton, rayon, foam or polyester flexible swabs to collect NP sample. Do not use calcium alginate swabs. Elute swab within one hour of collection. Test as soon as possible. Eluted swab samples can be held at 36-46°F (2-8°C) for up to 24 hours before testing in the BinaxNOW® Test. If needed, transport sample at 36-46°F (2-8°C) in a leak-proof container.

Allow samples to warm to room temperature before testing in the BinaxNOW® Test. Swirl gently to mix (without creating bubbles) before testing.

Transport Media:
The following transport media were tested and are acceptable for use in te BinaxNOW® Test.

Amies Media
Hank's Balanced Salt Solution
M4 Media
M4-RT Media
M5 Media
Stuart's Media
Saline

QUALITY CONTROL (QC)

Daily Quality Control:
The BinaxNOW® Test has built-in (internal) procedural controls. For daily quality control, Binax suggests that you record results of these controls for each test run.

Procedural Controls:

A. An untested strip has a blue line at the "Control" position. If the test flows correctly and the reagents work, this blue line will always turn pink on the strip.

B. The clearing of background color from the result window is a negative background control. The background color in the window should change from light pink to white within 15 minutes. Background color should not interfere with the reading of the test.

External Positive and Negative Controls:

Good laboratory practice suggests the use of positive and negative controls to guarantee that:
- test reagents are working; and
- the test is correctly performed.

BinaxNOW® Test Kits contain Positive and Negative Control Swabs. These swabs will verify the entire assay. Test these swabs once with each new kit. 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 NCCLS EP12-A and 42 CFR 493.1202(c) for help on proper QC techniques (U.S. customers only).

If the correct control results are not obtained, do not report patient results. Contact Binax during normal business hours (EST).
- Phone: **1-800-257-9525**
- Fax: 1-207-730-5710

SAMPLE PREPARATION PROCEDURE

Nasal Wash/Aspirate:
Nasal wash/aspirates do not need preparation. Go to Test Procedure.

Precaution: When testing nasal wash/aspirate samples, avoid thick areas of the sample when drawing it into the transfer pipette. If the pipette becomes clogged, and the lower part of the pipette is not full, put the sample back into container by squeezing the top bulb. Redraw the sample into the pipette. Use a new pipette if needed.

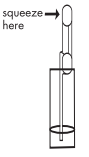
Nasopharyngeal Swabs:
Remove sample from swab in 0.5 to 3.0 ml of saline or transport media/fluid by vigorously rotating the swab in the liquid. Go to Test Procedure. To use Binax Elution Solution to elute swab, follow the Swab Elution procedure below.

Swab (Control & Patient) Elution using Binax Elution Solution:

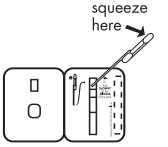
1. Twist off the test vial cap.
2. Put the swab to be tested into test vial. Rotate the swab vigorously (without making a lot of bubbles) three (3) times **in the liquid**.
3. Press the swab against the side of the vial and turn as you remove it from the vial. This removes sample from the swab.
4. Discard the swab into a container intended for contagious material.
5. Test the liquid sample (from the test vial) in the BinaxNOW® Test as soon as possible. Go to Test Procedure.

TEST PROCEDURE

WARNING: INVALID RESULTS can occur when too little sample is added to the test. Be sure that the lower part of the transfer pipette is full and does not have any air spaces before you add the sample to the Sample Pad. If there are air spaces, put the sample back into the container by squeezing the top bulb. Redraw the sample from the bottom of the container into the pipette. Use a new pipette if needed.



1. Remove device from the pouch just prior to testing and lay flat on work bench.
2. Fill pipette by firmly squeezing the top bulb and **then** placing pipette tip into sample. Slowly release bulb while tip is still in sample. This will pull liquid into the pipette. Make sure there are no air spaces in the lower part of the pipette.
3. See arrow on test to find White Sample Pad. **SLOWLY** (drop-by-drop) add entire contents of pipette (100 µl) to the **MIDDLE** of this pad by squeezing the top bulb.
4. Immediately peel off adhesive liner from the test device. Close and securely seal the device. Read result in window 15 minutes after closing the device.



Note: When reading test results, tilt the device to reduce glare on the result window if necessary.

RESULT INTERPRETATION

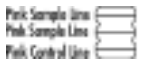
Note: Do not read test results before or after 15 minutes as they may not be correct.

For a **NEGATIVE SAMPLE**, the BLUE Control Line in the **BOTTOM THIRD** of the window turns a pink to purple color. No other line appears.

For a **FLU A POSITIVE SAMPLE**, the BLUE Control Line turns a pink to purple color. A SECOND pink to purple Sample Line appears above it in the **MIDDLE THIRD** of the window. Any shade of a pink to purple Sample Line indicates a positive result.

For a **FLU B POSITIVE SAMPLE**, the BLUE Control Line turns a pink to purple color. A SECOND pink to purple Sample Line appears above it in the **TOP THIRD** of the window. Any shade of a pink to purple Sample Line indicates a positive result.

For a **FLU A and FLU B POSITIVE SAMPLE**, the BLUE Control Line turns a pink to purple color, AND two pink to purple Sample Lines appear above it in the **MIDDLE and TOP** thirds of the window. Any shade of pink to purple Sample Lines indicates positive results.



A test is **INVALID** if the Control Line remains BLUE or is not present at all, whether a Sample Line(s) is present or not. Repeat invalid tests. Call Binax if the problem continues.

1-800-257-9525

REPORTING OF RESULTS

Result	Suggested Report
Positive for Flu A	Positive for Flu A protein antigen.
Positive for Flu B	Positive for Flu B protein antigen.
Positive for Flu A & B	Positive for both Flu A and B protein antigens.
Negative	Negative for Flu A and Flu B protein antigens. Infection due to Flu A and Flu B cannot be ruled out. Flu A and/or Flu B antigen in the sample may be below the detection limit of the test. Binax suggests culture of negative samples.

Notify Binax of any performance (perceived or validated) that does not meet test specifications described in this insert.

LIMITATIONS

A negative test result does not exclude infection with influenza A and/or B. Therefore, the results obtained with the BinaxNOW® Influenza A & B Test should be used in conjunction with clinical findings to make an accurate diagnosis.

The BinaxNOW® Influenza A & B Test detects both viable (live) and non-viable influenza A and B. Test performance depends on the amount of virus (antigen) in the specimen and may or may not compare with cell culture results performed on the same specimen.

Inadequate specimen collection or improper sample handling/transport may yield a false-negative result.

Performance of the BinaxNOW® Influenza A & B Test has not been established for monitoring antiviral treatment of influenza.

Use of visibly bloody samples is not recommended with the BinaxNOW® Influenza A & B Test.

EXPECTED VALUES

The prevalence of influenza varies from year to year, with outbreaks typically occurring during the fall and winter months.[1] The rate of positivity found in influenza testing is dependent on many factors including the method of specimen collection, the test method used, geographic location, and the disease prevalence in specific localities. Type A viruses are typically associated with most serious influenza epidemics, while Type B are typically milder. In a multi-center clinical study conducted by Binax in the U.S. during the 2002 influenza season, the average prevalence of influenza A (as determined by viral cell culture) was 26% in nasal wash samples and 20% in NP swab samples. The average prevalence of influenza B was 21% in nasal wash samples and 20% in NP swab samples. The incidence of infection with both influenza A and B is very rare.

PERFORMANCE CHARACTERISTICS

The sensitivity and specificity of the BinaxNOW® Influenza A & B Test are equivalent to that of the individual Binax NOW® Flu A and Binax NOW® Flu B Tests as demonstrated by comparison studies using retrospective, frozen clinical specimens and inactivated viral standards. The clinical performance of the individual Binax NOW® Flu A and Flu B Tests versus traditional culture methods was originally established in a multi-center prospective study conducted during the 2002 flu season. The specificity of the BinaxNOW® Influenza A & B Test, as compared to cell culture/DFA, is equivalent to that of the individual Binax NOW® Flu A and Binax NOW® Flu B Tests as demonstrated by a prospective study using fresh clinical specimens.

Clinical Studies:

BinaxNOW® Influenza A & B Test Performance vs. Cell Culture / DFA – Prospective Study

The performance of the BinaxNOW® Influenza A & B Test was compared to cell culture and/or DFA, and to the Binax NOW® Flu A Test and the Binax NOW® Flu B Test, in a prospective study conducted in 2004 outside the US. Nasopharyngeal (NP) swab and nasal wash / aspirate specimens, collected at multiple sites from children (less than 18 years of age) and adults (18 years or older) presenting with influenza-like symptoms, were evaluated in the Binax test at a central testing laboratory.

Forty-seven percent (47%) of the population tested was male, 53% female, 40% pediatric (< 18 years), and 60% adult (> 18 years). No differences in test performance were observed based on patient age or gender. There were no invalid tests reported.

One hundred and thirteen (113) NP swab specimens and 1 wash/aspirate specimen were tested. One hundred and eight (108) of the 114 samples tested were influenza negative by culture/DFA, and 6 samples were influenza positive. When compared to culture/DFA, the BinaxNOW® Test was 75% (3/4) sensitive and 100% (110/110) specific for detection of influenza A and 50% (1/2) sensitive and 100% (112/112) specific for

detection of influenza B. There was 100% agreement between the BinaxNOW® Influenza A & B Test and the individual Binax NOW® Flu A and Flu B Tests.

BinaxNOW® Influenza A & B Test specificity by sample type versus cell culture / DFA, including 95% confidence intervals, is listed below.

BinaxNOW® Influenza A & B Test Specificity vs. Cell Culture/DFA

	FLU A SPECIFICITY			
Sample	-/-	+/-	% Spec	95% CI
NP Swab	109	0	100%	97-100%
Wash/aspirate	1	0	100%	16-99%
Overall	110	0	100%	97-100%

	FLU B SPECIFICITY			
-/-	+/-	% Spec	95% CI
111	0	100%	97-100%
1	0	100%	16-99%
112	0	100%	97-100%

BinaxNOW® Influenza A & B Test Performance vs. Binax NOW® Flu A and Flu B Tests:

Performance of the BinaxNOW® Influenza A & B Test was compared to the current NOW® Flu A Test on 306 retrospective frozen clinical samples and to the NOW® Flu B Test on 303 retrospective frozen clinical samples. All clinical samples were collected from symptomatic patients at multiple physician offices, clinics and hospitals located in the southern, northeastern and midwestern regions of the United States and from one hospital in Sweden. Fifty-three percent (53%) of the population tested was male, 47% female, 64% pediatric (< 18 years) and 36% adult (≥ 18 years). Nasal wash/aspirate specimens comprised approximately 57% of the samples tested, while NP swabs represented 42%. No differences in test performance were observed based on patient age and gender or based on sample type tested.

The BinaxNOW® Influenza A & B Test was 100% sensitive and 96% specific for detection of influenza A vs. the NOW® Flu A Test and 93% sensitive and 97% specific for detection of influenza B vs. the NOW® Flu B Test. Test performance by virus type (A vs. B), by sample type (swab vs. wash/aspirate), and overall, including 95% confidence intervals, is detailed in the following tables.

BinaxNOW® Influenza A & B Test vs. NOW® Flu A Test for Detection of Influenza A

	FLU A SENSITIVITY			
Sample	+/+	-/+	% Sens	95% CI
NP Swab	30	0	100%	89-100%
Wash/aspirate	47	0	100%	93-100%
Overall	77	0	100%	95-100%

	FLU A SPECIFICITY			
-/-	+/-	% Spec	95% CI
96	1	99%	94-100%
123	9	93%	88-96%
219	10	96%	92-98%

BinaxNOW® Influenza A & B Test vs. NOW® Flu B Test for Detection of Influenza B

	FLU B SENSITIVITY			
Sample	+/+	-/+	% Sens	95% CI
NP Swab	2	0	100%	16-100%
Wash/aspirate	12	1	92%	65-100%
Overall	14	1	93%	68-100%

	FLU B SPECIFICITY			
-/-	+/-	% Spec	95% CI
126	1	99%	96-100%
152	9	94%	90-97%
278	10	97%	94-98%

The above 95% Confidence Intervals for Sensitivity and Specificity are calculated by the exact method.

Binax NOW® Flu A and Flu B Test Performance vs. Cell Culture

Performance of the Binax NOW® Flu A and Flu B Tests was compared to cell culture on 373 prospective clinical samples collected as part of a multi-center study conducted during the 2002 Flu season at physician offices and clinics located in the Western and mid-Atlantic United States. Fifty-four percent (54%) of the population tested was male, 46% female, 90% pediatric (< 18 years) and 10% adult (≥ 18 years). Nasal wash/aspirates comprised 51% of the samples tested, while NP swabs represented 49%. No differences in performance were observed based on patient age and gender or based on sample type tested.

The Binax NOW® Flu A Test was 80% sensitive and 93% specific while the Binax NOW® Flu B Test was 65% sensitive and 97% specific when compared to cell culture. The performance of the two tests by sample type (swab vs. wash/aspirate) and overall, including 95% confidence intervals, is detailed in the following tables.

Binax NOW® Flu A Test vs. Cell Culture

	FLU A SENSITIVITY			
Sample	+/+	-/+	% Sens	95% CI
NP Swab	29	8	78%	62-88%
Wash/Aspirate	40	9	82%	69-90%
Overall	69	17	80%	71-87%

	FLU A SPECIFICITY			
-/-	+/-	% Spec	95% CI
133	12	92%	86-95%
133	9	94%	89-97%
266	21	93%	89-95%

Binax NOW® Flu B Test vs. Cell Culture

	FLU B SENSITIVITY			
Sample	+/+	-/+	% Sens	95% CI
NP Swab	21	15	58%	42-73%
Wash/Aspirate	29	12	71%	56-83%
Overall	50	27	65%	54-75%

	FLU B SPECIFICITY			
-/-	+/-	% Spec	95% CI
142	4	97%	93-99%
146	4	97%	93-99%
288	8	97%	95-99%

Analytical Sensitivity:

The BinaxNOW® Test limit of detection (LOD), defined as the concentration of influenza virus that produces positive BinaxNOW® Test results approximately 95% of the time, was identified by evaluating different concentrations of inactivated flu A/Beijing and inactivated flu B/Harbin in the BinaxNOW® Test.

Twelve (12) different operators each interpreted 2 tests run at each concentration for a total of 24 determinations per level. The following results identify a concentration of 1.03×10^{2} ng/ml as the LOD for Flu A/Beijing and 6.05×10^{1} ng/ml for Flu B/Harbin.

Flu A/Beijing		
Concentration (ng/ml)	# Detected	% Detected
1.03 x 10^2 (LOD)	23/24	96
5.60 x 10^1 (Cutoff)	*	50
3.27 x 10^1 (High Neg)	4/24	17
True Negative	0/24	0

Flu B/Harbin		
Concentration (ng/ml)	# Detected	% Detected
6.05 x 10^1 (LOD)	23/24	96
2.42 x 10^1 (Cutoff)	11/24	46
1.51 x 10^1 (High Neg)	6/24	25
True Negative	0/24	0

*Linear regression was used to calculate a line equation, which was then used to project the cutoff concentration of Flu A/Beijing.

To demonstrate comparable analytical sensitivity of the BinaxNOW® Influenza A & B Test and the individual NOW® Flu A and Flu B Tests, the flu A and B cutoff levels identified above were evaluated in the NOW® Flu A and Flu B Tests.

The Flu A/Beijing cutoff sample detected 50% of the time in the BinaxNOW® Influenza A & B Test was also detected 50% (12/24) of the time in the NOW® Flu A Test when tested by six (6) operators interpreting a total of 24 tests. Likewise, the Flu B/Harbin cutoff sample detected 46% of the time in the BinaxNOW® Influenza A & B Test was detected 10% (4/40) of the time in the NOW® Flu B Test when tested by ten (10) operators interpreting 40 tests.

These data demonstrate that the analytical sensitivity of the BinaxNOW® Influenza A & B Test is equivalent to or better than that of the individual NOW® Flu A and B Tests.

Analytical Reactivity:
The first seven (7) live influenza A strains and the five (5) live influenza B strains listed tested positive in the BinaxNOW® Influenza A & B Test at concentrations ranging from 10^2 - 10^6 $CEID_{50}$/ml. The last two (2) influenza A strains listed below, A/Hong Kong/156/97 and A/Vietnam/1194/04, tested positive in the Binax test at concentrations of 1.3 x 10^2 and 1.0 x 10^4 $TCID_{50}$/mL respectively. Although the specific influenza strains causing infection in humans can vary year to year, all contain the conserved nucleoproteins targeted by the BinaxNOW® test.[2]

Influenza Strain	ATCC #
Flu A/WS/33 (H1N1)	VR-825
Flu A/NWS/33 (H1N1)	VR-219
Flu A/Hong Kong/8/68 (H3N2)	VR-544
Flu A/Aichi/2/68 (H3N2)	VR-547
Flu A/New Jersey/8/76 (Hsw1N1)	VR-897
Flu A/Mal/302/54 (H1N1)	VR-98
Flu A/Port Chalmers/1/73 (H3N2)	VR-810
Flu A/Hong Kong/156/97 (H5N1)	–
Flu A/Vietnam/1194/04 (H5N1)	–
Flu B/Lee/40	VR-101
Flu B/Brigit	VR-786
Flu B/Russia/69	VR-790
Flu B/Hong Kong/5/72	VR-791
Flu B/R75	VR-789

Analytical Specificity (Cross-Reactivity):
To determine the analytical specificity of the BinaxNOW® Influenza A & B Test, 36 commensal and pathogenic microorganisms (27 bacteria, 8 viruses and 1 yeast) that may be present in the nasal cavity or nasopharynx were tested. All of the following microorganisms were negative when tested at concentrations ranging from 10^4 to 10^8 $TCID_{50}$/ml (viruses), 10^7 to 10^8 organisms/ml (bacteria) and 10^6 organisms/ml (yeast).

Bacteria	Viruses	Yeast
Acinetobacter	Adenovirus	*Candida albicans*
Bordetella pertussis	Coronavirus	
Enterococcus faecalis	Coxsackie B4	
Escherichia coli	Cytomegalovirus (CMV)	
Gardnerella vaginalis	Parainfluenza 1	
Haemophilus influenzae	Parainfluenza 2	
Klebsiella pneumoniae	Parainfluenza 3	
Lactobacillus casei	Respiratory Syncytial Virus (RSV)	
Legionella pneumophila		
Listeria monocytogenes		
Moraxella catarrhalis		
Neisseria gonorrhoeae		
Neisseria meningitidis		
Neisseria sicca		
Neisseria subflava		
Proteus vulgaris		
Pseudomonas aeruginosa		
Serratia marcescens		
Staphylococcus aureus		
Staphylococcus aureus (Cowan protein A producing strain)		
Staphylococcus epidermidis		
Streptococcus, Group A		
Streptococcus, Group B		
Streptococcus, Group C		
Streptococcus, Group F		
Streptococcus mutans		
Streptococcus pneumoniae		

INTERFERING SUBSTANCES

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated in the BinaxNOW® Influenza A & B Test at the concentrations listed and were found not to affect test performance. Whole blood (1%) did not interfere with the interpretation of negative BinaxNOW® Test results, but did interfere with the interpretation of flu A LOD positive samples. Therefore, visibly bloody samples may not be appropriate for use in this test.

Substance	Concentration
1 OTC mouthwash	20%
3 OTC nasal sprays	15%
3 OTC throat drops	15%
2 OTC throat sprays	20%
4-acetamidophenol	10 mg/ml
Acetylsalicylic acid	15 mg/ml
Albuterol	20 mg/ml
Chlorpheniramine	5 mg/ml
Dextromethorphan	10 mg/ml
Diphenhydramine	5 mg/ml
Guaiacol glycerol ether	20 mg/ml
Oxymetazoline	0.05%
Phenylephrine	50 mg/ml
Phenylpropanolamine	20 mg/ml
Rebetol®	500 ng/ml
Relenza®	20 mg/ml
Rimantadine	500 ng/ml
Synagis®	0.1 mg/ml
Tamiflu®	50 mg/ml

Transport Media:
The following transport media were tested in the BinaxNOW® Influenza A & B Test as negative samples (no virus present) and after inoculation with the LOD levels of Influenza A & B. Media did not impact BinaxNOW® Test performance, with the media alone testing negative in the NOW® Test and media inoculated with LOD Influenza A & B testing positive on the appropriate test line in BinaxNOW® Test.

Amies Media
Hank's Balanced Salt Solution
M4 Media
M4-RT Media
M5 Media
Stuart's Media
Saline

Reproducibility Study:
A blind study of the BinaxNOW® Influenza A & B Test was conducted at 3 separate sites using panels of blind coded specimens containing negative, low positive, and moderate positive samples. Participants tested each sample multiple times on 3 different days. There was 97% (242/250) agreement with expected test results, with no significant differences within run (replicates tested by one operator), between run (3 different days), between sites (3 sites), or between operators (6 operators).

Consumer Precision Study:
According to the 1995 CLIA Rule, Binax conducted their Consumer Precision testing of the BinaxNOW® Influenza A & B Test with a total of 120 lay users at 6 sites. Participants tested proficiency panels consisting of high negative, assay cutoff, and limit of detection (LOD) samples for both influenza A and influenza B, as well as true negative samples. Expected results for each sample type were generated by trained laboratorians. Six percent (6%) of the total tests run by the lay users and 0.4% of the tests run by the trained laboratorians resulted in invalid tests. The tables below detail the number of invalid tests generated by each site.

As indicated by the overlapping 95% confidence intervals in the tables below, no significant differences were observed between the lay users and the expected results established by the trained laboratorians. These results demonstrate that users with no formal laboratory training can read the package insert and perform the Binax test with a relatively high level of precision.

Influenza A and Influenza B Sample Testing – Lay Users vs. Trained Laboratorians - Overall Results

	Participant Type	Negative- % Negative (95% CI)	High Negative*- % Detection (95% CI)	Assay Cutoff*- % Detection (95% CI)	LOD- % Detection (95% CI)	% Invalid Tests
Flu A Samples	Lay user	96% (54/56) (88-99)	32% (18/57) (21-44)	78% (46/59) (66-87)	95% (57/60) (86-98)	3.3% (8/240)
	Trained Laboratorian	100% (8/8) (66-100)	22% (8/36) (12-38)	64% (23/36) (47-77)	94% (34/36) (82-98)	0.9% (1/117)
Flu B Samples	Lay user	96% (53/55) (88-99)	4% (2/52) (1-13)	27% (15/56) (17-40)	82% (45/55) (70-90)	9.2% (22/240)
	Trained Laboratorian	100% (9/9) (69-100)	11% (4/36) (4-25)	49% (17/35) (33-64)	92% (33/36) (78-97)	0.0% (0/116)

* These levels are below the detection limit of the test.

WARNING: Invalid test results can occur when an insufficient volume of sample is added to the test device due to misuse of the transfer pipette. Please see the Test Procedure section for detailed instructions on the proper use of the transfer pipette.

Influenza A Sample Testing by Site - Lay Users (LU) and Trained Laboratorians (TL)

	Site #	Negative- % Negative (95% CI)	High Negative- % Detection (95% CI)	Assay Cutoff- % Detection (95% CI)	LOD- % Detection (95% CI)	% Invalid Tests
Lay User (LU) Results	2 LU	100% (18/18) (82-100)	33% (6/18) (16-57)	70% (14/20) (48-85)	90% (18/20) (70-97)	5.0% (4/80)
	4 LU	90% (18/20) (70-97)	45% (9/20) (26-66)	85% (17/20) (64-94)	100% (20/20) (84-100)	0% (0/80)
	6 LU	100% (18/18) (82-100)	16% (3/19) (6-38)	79% (15/19) (56-91)	95% (19/20) (76-99)	5.0% (4/80)
Trained Laboratorian (TL) Results	1 TL	100% (3/3) (40-99)	0% (0/12) (0-25)	25% (3/12) (9-54)	100% (12/12) (75-100)	0% (0/39)
	2 TL	100% (2/2) (29-99)	33% (4/12) (14-61)	92% (11/12) (64-98)	83% (10/12) (54-95)	3% (1/39)
	3 TL	100% (3/3) (40-99)	33% (4/12) (14-61)	75% (9/12) (46-90)	100% (12/12) (75-100)	0% (0/39)

Influenza B Sample Testing by Site - Lay Users (LU) and Trained Laboratorians (TL)

	Site #	Negative- % Negative (95% CI)	High Negative- % Detection (95% CI)	Assay Cutoff- % Detection (95% CI)	LOD- % Detection (95% CI)	% Invalid Tests
Lay User (LU) Results	1 LU	100% (20/20) (84-100)	5% (1/19) (1-25)	25% (5/20) (11-47)	85% (17/20) (64-94)	1% (1/80)
	3 LU	100% (19/19) (83-100)	0% (0/18) (0-18)	25% (5/20) (11-47)	79% (15/19) (56-91)	5% (4/80)
	5 LU	87% (14/16) (63-96)	7% (1/15) (2-30)	31% (5/16) (14-56)	81% (13/16) (57-93)	21% (17/80)
Trained Laboratorian (TL) Results	1 TL	100% (3/3) (40-99)	0% (0/12) (0-25)	9% (1/11) (21-38)	75% (9/12) (46-91)	0% (0/38)
	2 TL	100% (3/3) (40-99)	33% (4/12) (14-61)	67% (8/12) (39-86)	100% (12/12) (75-100)	0% (0/39)
	3 TL	100% (3/3) (40-99)	0% (0/12) (0-25)	67% (8/12) (39-86)	100% (12/12) (75-100)	0% (0/39)

REFERENCES

1) Williams, KM, Jackson MA, Hamilton M. (2002) Rapid Diagnostic Testing for URIs in Children: Impact on Physician Decision Making and Cost. *Infect. Med.* **19(3):** 109-111.
2) Dowdle, W.R, Kendal, A.P., and Noble, G.R. (1980). Influenza Virus, p 836-844. Manual of Clinical Microbiology, 3rd edition, in Lennette, *et. al* (ed.). American Society for Microbiology, Washington, D.C.
3) "Key Facts about Avian Influenza (Bird Flu) and Avian Influenza A (H5N1) Virus" CDC Publication, May 24, 2005. http://www.cdc.gov/flu/avian/gen-info/facts.htm
4) "Avian Influenza Infection in Humans" CDC Publication, May 24, 2005. http://www.cdc.gov/flu/avian/gen-info/avian-flu-humans.htm

ORDERING INFORMATION

Reorder numbers:		
	#416-022:	BinaxNOW® Influenza A & B Test Kit (22 Test Kit)
	#416-110:	BinaxNOW® Influenza A & B Test Kit (10 Test Kit)
	#400-065:	BinaxNOW® Nasopharyngeal Swab Accessory Pack
	#416-080:	Influenza A & B Control Swab Kit

Contact Information:
Binax, Inc.
10 Southgate Road
Scarborough, Maine 04074 USA
Tel: US: 1-800-257-9525
Outside US: +1-609-627-8000
Fax: 207-730-5710

Manufactured by:
Binax, Inc.
10 Southgate Road
Scarborough, Maine 04074 USA
Tel: US: 1-800-257-9525
Outside US: +1-609-627-8000
Fax: (207) 730-5710
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