510(k) SUMMARY

AUG 12 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K092223

The purpose of this 510(k) submission is to expand the Analytical Reactivity claims of the currently 510(k) cleared BinaxNOW® Influenza A & B Test (510(k) K062109).

SUBMITTER
Binax, Inc.
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CONTACT PERSON
Angela Drysdale
Angela.drysdale@invmed.com (email)

DATE PREPARED
August 10, 2009

TRADE NAME
BinaxNOW® Influenza A & B Test

COMMON NAME
NOW® Flu A/B Test, NOW® Influenza A/B, NOW® Influenza A & B, Binax NOW® Influenza A & B, Binax NOW® Influenza A/B

CLASSIFICATION NAME
Antigen, CF (including CF Controls), Influenza Virus A, B, C (per 21 CFR 866.3330)

PREDICATE DEVICE
Binax NOW® Influenza A & B Test; K062109

DEVICE DESCRIPTION:
The BinaxNOW® Influenza A & B Test is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect influenza type A & B nucleoprotein antigens in nasopharyngeal (NP) swab, nasal swab, and nasal wash/aspirate 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 off the swab into elution solution or transport media. 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.

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 swab, nasal 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 culture.

TECHNOLOGICAL CHARACTERISTICS

The Expanded Claim BinaxNOW® Influenza A & B Test is exactly the same as the currently 510(k) cleared BinaxNOW® Influenza A & B Test. Both tests use identical lateral flow immunochromatographic technology. Both tests are rapid immunoassays that employ specific antibodies immobilized onto a solid phase to capture and visualize influenza nucleoprotein antigens.

PERFORMANCE SUMMARY

CLINICAL STUDIES

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

A total of 846 prospective specimens collected from children (less than 18 years of age) and adults (18 years or older) were evaluated in the BinaxNOW® Influenza A & B Test and compared to culture/DFA. Evaluated specimens include nasopharyngeal swabs and nasal swabs collected from patients presenting with influenza-like symptoms. Forty-four percent (44%) of the population tested was male, 56% female, 54% pediatric (< 18 years), and 46% adult (≥ 18 years). No differences in test performance were observed based on patient age or gender. A/H3 and A/H1 were the predominant influenza subtypes observed during this time.

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

BinaxNOW® Influenza A & B Test Performance vs. Cell Culture/DFA for Detection of Flu A

	Test Sensitivity				Test Specificity			
Sample	+/+	-/+	% Sens	95% CI	-/-	+/-	% Spec	95% CI
NP Swab	53	16	77%	65-86%	278	3	99%	97-100%
Nasal Swab	85	17	83%	74-90%	378	16	96%	93-98%
Overall	138	33	81%	74-86%	656	19	97%	96-98%

BinaxNOW® Influenza A & B Test Performance vs. Cell Culture/DFA for Detection of Flu B

	Test Sensitivity				Test Specificity			
Sample	+/+	-/+	% Sens	95% CI	-/-	+/-	% Spec	95% CI
NP Swab	2	2	50%	9-91%	346	0	100%	99-100%
Nasal Swab	9	4	69%	39-90%	481	2	100%	98-100%
Overall	11	6	65%	39-85%	827	2	100%	99-100%

BinaxNOW® Influenza A & B Test Performance vs. Cell Culture / DFA - Retrospective Study

A total of 293 retrospective frozen clinical samples were evaluated in the BinaxNOW® Influenza A & B Test and compared to culture/DFA. 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, 62% pediatric (<18 years) and 38% adult (≥ 18 years). Nasal wash/aspirate specimens comprised approximately 61% of the samples tested, while NP swabs represented 39%. No differences in test performance were observed based on patient age and gender or based on sample type tested.

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

BinaxNOW® Influenza A & B Test Performance vs. Cell Culture/DFA for Detection of Flu A

	Test Sensitivity				Test Specificity			
Sample	+/+	-/+	% Sens	95% CI	-/-	+/-	% Spec	95% CI
NP Swab	19	8	70%	50-86%	77	9	90%	81-95%
Wash/Aspirate	51	6	89%	78-96%	117	6	95%	89-98%
Overall	70	14	83%	73-90%	194	15	93%	88-96%

BinaxNOW® Influenza A & B Test Performance vs. Cell Culture/DFA for Detection of Flu B

	Test Sensitivity				Test Specificity			
Sample	+/+	-/+	% Sens	95% CI	-/-	+/-	% Spec	95% CI
NP Swab	0	0	N/A	N/A	111	2	98%	93-100%
Wash/Aspirate	8	7	53%	27-78%	155	10	94%	89-97%
Overall	8	7	53%	27-78%	266	12	96%	92-98%

ANALYTICAL STUDIES

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 devices 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.

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

Influenza B/Harbin		
Concentration (ng/ml)	# Detected	% Detected
6.05×10^1 (LOD)	23/24	96
2.42×10^1 (Cutoff)	11/24	46
1.51×10^1 (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.

REACTIVITY TESTING

The influenza A and B strains listed tested positive in the BinaxNOW® Influenza A & B Test at concentrations specified. Although the specific influenza strains causing infection in humans can vary year to year, all contain the conserved nucleoproteins targeted by the BinaxNOW® test.[1] Performance characteristics of the BinaxNOW® Influenza A & B Test for detecting influenza A virus from human specimens was established when H1 and H3 subtypes were prevalent. Performance characteristics of the test when other influenza A virus subtypes are emerging as human pathogens have not been established.

Influenza Strain	ATCC #	Concentration
Flu A/WS/33 (H1N1)	VR-825	10^2-10^6 $CEID_{50}$/ml
Flu A/NWS/33 (H1N1)	VR-219	10^2-10^6 $CEID_{50}$/ml
Flu A/Hong Kong/8/68 (H3N2)	VR-544	10^2-10^6 $CEID_{50}$/ml
Flu A/Aichi/2/68 (H3N2)	VR-547	10^2-10^6 $CEID_{50}$/ml
Flu A/New Jersey/8/76 (Hsw1N1)	VR-897	10^2-10^6 $CEID_{50}$/ml
Flu A/Mal/302/54 (H1N1)	VR-98	10^2-10^6 $CEID_{50}$/ml
Flu A/Port Chalmers/1/73 (H3N2)	VR-810	10^2-10^6 $CEID_{50}$/ml
Flu A/Hong Kong/156/97 (H5N1)	-	1.3×10^2 $TCID_{50}$/ml
Flu A/Vietnam/1194/04 (H5N1)	-	1.0×10^4 $TCID_{50}$/ml
Flu A/California/04/2009 (H1N1) swl (swine lineage)		5.63×10^4 $TCID_{50}$/ml
Flu A/ Auckland / 1 / 2009 A (H1N1) swl		1.0×10^5 $TCID_{50}$/ml
Flu A/ Auckland / 3 / 2009 A (H1N1) swl	-	1.0×10^5 $TCID_{50}$/ml
Flu A/Chicken/NY/117228-7/01 (H5N2)	-	1.0×10^4 EID_{50}/ml
Flu A/Turkey/VA/SEP-66/02 (H7N2)	-	1.0×10^5 EID_{50}/ml
Flu B/Lee/40	VR-101	10^2-10^6 $CEID_{50}$/ml
Flu B/Brigit	VR-786	10^2-10^6 $CEID_{50}$/ml
Flu B/Russia/69	VR-790	10^2-10^6 $CEID_{50}$/ml
Flu B/Hong Kong/5/72	VR-791	10^2-10^6 $CEID_{50}$/ml
Flu B/R75	VR-789	10^2-10^6 $CEID_{50}$/ml

Although this test has been shown to detect the Flu A/California/04/2009 (H1N1) virus cultured from a positive human specimen, the performance characteristics of this device with human specimens infected with the 2009 H1N1 influenza virus have not been established. The BinaxNOW® test can distinguish between influenza A and B viruses, but it does not differentiate seasonal influenza A virus from the novel influenza A (i.e. 2009 H1N1) and it's ability to detect human infection with the 2009 H1N1 influenza virus in clinical specimens is unknown.

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 10^6 $TCID_{50}$/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
Brain Heart Infusion Broth
Dulbecco Medium
Hank's Balanced Salt Solution

M4 Media
M4-RT Media
M5 Media
Phosphate Buffer Solution
Saline
Stuart's Media
Tryptose Phosphate Broth
UTM-RT Media
Veal Infusion Broth

It has been determined that Sucrose-Phosphate Buffer may not be suitable for use with this test.

REPRODUCIBILITY

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) or between sites (3 sites).

Signed Angela Drysdale Date 8/10/09
Angela Drysdale
Sr. Manager, Clinical Affairs

1) Dowdle, W.R, Kendal, A.P., and Noble, G.R. 1980. Influenza Virus, p 836-884. Manual of Clinical Microbiology, 3rd edition, In Lennette, et. Al (ed.). American Society for Microbiology, Washington, D.C.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

AUG 12 2009

BINAX, INC.
Angela Drysdale
10 Southgate Road
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Re: k092223
Trade/Device Name: BinaxNOW Influenza A & B Test
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza Virus Serological Reagents
Regulatory Class: Class I
Product Code: GNX
Dated: July 20, 2009
Received: July 23, 2009

Dear Ms. Drysdale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, Ph.D.
Director, Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K092223

Device Name: BinaxNOW® Influenza A & B Test

Indications For 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, nasal 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.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

MAH WL for UXS
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K092223