510(k) SUMMARY

NOV - 9 2006

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: K062109

The purpose of this 510(k) submission is to expand the Indications for Use claim to add nasal swab specimens, modify the caution statement related to the determination of sensitivity by testing of archived specimens, expand the Analytical Reactivity claim to include two additional influenza A strains, provide data supporting the use of additional transport media, and to update the labeling in compliance with FDA Guidance: In Vitro Diagnostic Devices to Detect Influenza A Viruses: Labeling and Regulatory Path, as well as minor modifications consistent with competitor claims of the currently 510(k) cleared BinaxNOW® Influenza A & B Test (510(k) #K053126, originally cleared as 510(k) #K041049).

To establish substantial equivalence to the predicate, the BinaxNOW® Influenza A & B Test was compared to the BD Directigen™ Flu A+B Test (510(k) # K001364).

SUBMITTER
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DATE PREPARED
July 17, 2006

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
BD Directigen™ Flu A+B Test; K001364

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 respiratory 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, saline, 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 (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 results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decision.

TECHNOLOGICAL CHARACTERISTICS

The BinaxNOW® Influenza A & B Test uses lateral flow immunochromatographic technology while the BD Directigen™ Flu A+B test is an enzyme immunoassay (EIA) membrane test. 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

The clinical performance of the BinaxNOW® Influenza A & B Test was established in multi-center, prospective, clinical studies conducted at a central testing laboratory outside the US during the 2004 respiratory season and at three US trial sites during the 2005-2006 respiratory season. Additional performance testing was conducted on retrospective frozen clinical samples 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.

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 x 10^2 $TCID_{50}$/ml
Flu A/Vietnam/1194/04 (H5N1)	–	1.0 x 10^4 $TCID_{50}$/ml
Flu A/Chicken/NY/117228-7/01 (H5N2)	–	1.0 x 10^4 EID_{50}/ml
Flu A/Turkey/VA/SEP-66/02 (H7N2)	–	1.0 x 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

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
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), between sites (3 sites), or between operators (6 operators).

Signed_____ Date _____
Pamela Angell
Director, Worldwide Clinical Affairs, IMPD Scarborough
Binax, Inc., d/b/a Inverness Medical Professional Diagnostics

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
2098 Gaither Road
Rockville MD 20850

Ms. Angela Drysdale
Clinical Affairs Specialist
Binax, Inc.
10 Southgate Road
Scarborough, ME 04074

NOV - 9 2006

Re: k062109
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: October 28, 2006
Received: October 30, 2006

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.

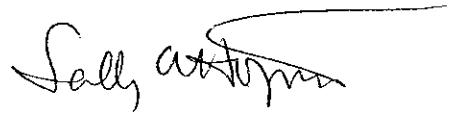
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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); 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K062109

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 results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decision.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K062109