K090964

510(k) SUMMARY

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 090964.

SUBMITTER

Binax, Inc.
10 Southgate Road
Scarborough, Maine 04074
(207) 730-5733 (Office)
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Establishment Registration Number: 1221359

DEC 16 2009

CONTACT PERSON

Suzanne Vogel
suzanne.vogel@invmed.com (email)

DATE PREPARED

December 12, 2009

TRADE NAME

BinaxNOW® Staphylococcus aureus Test

COMMON NAME

BinaxNOW® Staphylococcus aureus Test, BinaxNOW® Staphylococcus aureus, BinaxNOW® S. aureus, Binax NOW® Staphylococcus aureus Test, Binax NOW® Staphylococcus aureus, Binax NOW® S. aureus, NOW® Staphylococcus aureus Test, NOW® Staphylococcus aureus, NOW® S. aureus

CLASSIFICATION NAME

Microorganism differentiation and identification device (JWX) (per 21 CFR 866.2660)

PREDICATE DEVICE

S. aureus PNA FISH™ (AdvanDx) K#060099

DEVICE DESCRIPTION

The BinaxNOW® *Staphylococcus aureus* Test is a rapid immunochromatographic membrane assay that uses highly sensitive polyclonal antibodies to detect a *Staphylococcus aureus* specific protein directly from blood cultures which have been identified as being positive for Gram-positive cocci in clusters. These antibodies and a control antibody are immobilized onto a test strip as two distinct lines and combined with other reagents/pads. This test strip is mounted inside a cardboard, book-shaped hinged test device.

Specimens are aliquots from blood cultures which have been identified as positive for Gram-positive cocci in clusters. After the sample is prepared, it is added to the sample pad at the top of the test strip and the device is closed. Results are read at 10 minutes.

INTENDED USE

The BinaxNOW® *Staphylococcus aureus* Test is a qualitative, *in vitro* immunochromatographic assay for the presumptive identification of *Staphylococcus aureus*. The test is performed directly on blood culture samples positive for Gram-positive cocci in clusters. The BinaxNOW® *Staphylococcus aureus* Test is not intended to diagnose *Staphylococcus aureus* nor to guide or monitor treatment for *Staphylococcus aureus* infections. Subculturing positive blood cultures is necessary to recover organisms for susceptibility testing and/or differentiation of mixed growth.

TECHNOLOGICAL CHARACTERISTICS

The BinaxNOW® *Staphylococcus aureus* Test is a rapid immunochromatographic membrane assay that uses highly sensitive polyclonal antibodies to detect a *Staphylococcus aureus* specific protein directly from blood cultures bottles positive for Gram-positive cocci in clusters.

PERFORMANCE SUMMARY

Clinical Performance

The clinical performance of the BinaxNOW® *Staphylococcus aureus* Test was established in a multi-center clinical study conducted in 2008-09 at three geographically-diverse hospital laboratories within the US.

A total of 325 blood culture samples with Gram-positive cocci in clusters were evaluated at the three sites in the BinaxNOW® *Staphylococcus aureus* Test and compared to standard methods used routinely by the testing laboratories. The BinaxNOW® *Staphylococcus aureus* Test identified 98.8% of the specimens positive for *Staphylococcus aureus* and 100.0% of the specimens negative for *Staphylococcus aureus* relative to the reference method.

BinaxNOW® *Staphylococcus aureus* Test Compared to Reference Method

	Reference Method	
BinaxNOW® *Staphylococcus aureus* Test	**Positive**	**Negative**
Positive	84	0
Negative	1	240

		95% C.I.
Positive Agreement:	98.8%	(93.6 – 99.8%)
Negative Agreement:	100.0%	(98.4% - 100.0%)

Expected Values

In the external clinical evaluation of BinaxNOW® *Staphylococcus aureus* Test, the overall expected rate of *S. aureus* in blood culture was 26.2% (85/325), and among the three site populations the expected positive rate ranged from 16.9% to 41.5%.

Analytical Reactivity

The 54 human pathogenic Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) and American Type Culture Collection (ATCC) *Staphylococcus aureus* strains listed below tested positive in the BinaxNOW® test.

***Staphylococcus aureus* strains**

Bacterium	Bacterium
Staphylococcus aureus ATCC 13150	*Staphylococcus aureus* NRS172
Staphylococcus aureus ATCC 11632	*Staphylococcus aureus* NRS241
Staphylococcus aureus ATCC 14776	*Staphylococcus aureus* NRS245
Staphylococcus aureus ATCC 14458	*Staphylococcus aureus* NRS248
Staphylococcus aureus ATCC 6517	*Staphylococcus aureus* NRS249
Staphylococcus aureus ATCC 29737	*Staphylococcus aureus* NRS164
Staphylococcus aureus ATCC 29213	*Staphylococcus aureus* NRS165
Staphylococcus aureus ATCC 49476	*Staphylococcus aureus* NRS166
Staphylococcus aureus ATCC 33592	*Staphylococcus aureus* NRS167
Staphylococcus aureus ATCC BAA38	*Staphylococcus aureus* NRS168
Staphylococcus aureus ATCC 14775	*Staphylococcus aureus* NRS169
Staphylococcus aureus ATCC BAA43	*Staphylococcus aureus* NRS170
Staphylococcus aureus Lafferty	*Staphylococcus aureus* NRS171
Staphylococcus aureus ATCC 6538P	*Staphylococcus aureus* NRS173
Staphylococcus aureus ATCC BAA1026	*Staphylococcus aureus* NRS174
Staphylococcus aureus ATCC BAA977	*Staphylococcus aureus* NRS175
Staphylococcus aureus ATCC BAA39	*Staphylococcus aureus* NRS176
Staphylococcus aureus ATCC51153	*Staphylococcus aureus* NRS177
Staphylococcus aureus ATCC 700789	*Staphylococcus aureus* NRS382 (USA100)
Staphylococcus aureus ATCC BAA41	*Staphylococcus aureus* NRS383 (USA200)
Staphylococcus aureus ATCC 33591	*Staphylococcus aureus* NRS384 (USA300)
Staphylococcus aureus ATCC BAA44	*Staphylococcus aureus* NRS123 (USA400)
Staphylococcus aureus ATCC 700698	*Staphylococcus aureus* NRS385 (USA500)
Staphylococcus aureus ATCC 43300	*Staphylococcus aureus* NRS22 (USA600)
Staphylococcus aureus ATCC 700699	*Staphylococcus aureus* NRS386 (USA700)
Staphylococcus aureus NRS193	*Staphylococcus aureus* NRS387 (USA800)
Staphylococcus aureus NRS194	*Staphylococcus aureus* NRS192

Analytical Specificity (Cross-Reactivity)

To determine the analytical specificity of the BinaxNOW® *Staphylococcus aureus* Test, coagulase-negative *Staphylococcus* strains, yeasts and non-staphylococcal strains were tested in the BinaxNOW® Test. All strains in the tables below tested negative.

Coagulase-negative *Staphylococcus* strains

Bacterium
Staphylococcus auricularis ATCC 33753

Staphylococcus capitis ATCC 35661
Staphylococcus caprae ATCC 51548
Staphylococcus cohnii ATCC 29972
Staphylococcus delphini ATCC 49171
Staphylococcus epidermidis ATCC 700579
Staphylococcus haemolyticus ATCC 29970
Staphylococcus hominis ATCC 27844
Staphylococcus hyicus ATCC 11249
Staphylococcus intermedius ATCC 29663
Staphylococcus kloosii ATCC 43959
Staphylococcus lentus ATCC 700403
Staphylococcus *lugdunensis* ATCC 43809
Staphylococcus lutrae ATCC 700373
Staphylococcus pasteuri ATCC 51128
Staphylococcus pseudintermedius ATCC 49444
Staphylococcus pulvereri ATCC 51698
Staphylococcus saprophyticus ATCC 35552
Staphylococcus schleiferi ATCC 43808
Staphylococcus sciuri ATCC 49575
Staphylococcus stimulans ATCC 27851
Staphylococcus vitulinus ATCC 51162
Staphylococcus warneri ATCC 49454
Staphylococcus xylosus ATCC 49148

Non- Staphylococcal Strains

Bacterium	Bacterium
Acinetobacter calcoaceticus ATCC 51432	*Pasteurella multocida* ATCC 51687
Aerococcus urinae ATCC 700306	*Pediococcus acidilactici* ATCC 12697
Aerococcus viridans ATCC 10400	*Peptostreptococcus anaerobius* ATCC 27337
Aeromonas hydrophilia ATCC 35654	*Planococcus citreus* ATCC 14404
Bacillus cereus ATCC 11778	*Proteus mirabilis* ATCC 7002
Bacillus subtilis ATCC 6633	*Proteus vulgaris* ATCC 33420
Bacteroides fragilis ATCC 23745	*Providencia stuartii* ATCC 49809
Beta strep group F ATCC 12392	*Pseudomonas aeruginosa* ATCC 15442
Burkholdaria cepacia ATCC 25416-T	*Pseudomonas fluorescens* ATCC 49271
Citrobacter freundii ATCC 8090	*Pseudomonas putida* ATCC 49128
Clostridium septicum ATCC 12646	*Rhodococcus equi* ATCC 10146
Clostridium sordelli ATCC 9714	*Salmonella adelaide* ATCC 10718
Corynebacterium amycolatum ATCC 49368	*Serratia marcescens* ATCC 13880
Corynebacterium diphtheriae ATCC 13812	*Stenotrophomonas maltophilia* ATCC 13637-T
Corynebacterium glutamicum ATCC 13869	*Stomatococcus (Rothia mucilaginosa)* ATCC 25296
Corynebacterium jeikeium ATCC 43734	*Stomatococcus (Rothia mucilaginosa)* ATCC 49040
Corynebacterium pseudodiptheriticum ATCC 10700-T	*Stomatococcus (Rothia mucilaginosa)* ATCC 49041
Corynebacterium urealyticum ATCC 43042	*Stomatococcus (Rothia mucilaginosa)* ATCC 49042
Corynebacterium xerosus ATCC 7711	*Streptococcus agalactiae* (Beta Strep Group B) ATCC 13813

Enterobacter aerogenes ATCC 35029	*Streptococcus anginosis (milleri)* ATCC 33397
Enterobacter cloacae ATCC 49141	*Streptococcus dysgalactiae* (Group C) ATCC 12388
Enterococcus avium ATCC 49462	*Streptococcus dysgalactiae* (Group G) ATCC 12394
Enterococcus casseliflavus ATCC 12817	*Streptococcus intermedius (milleri)* ATCC 27355
Enterococcus durans ATCC 49135	*Streptococcus mitis* ATCC 49456
Enterococcus faecalis ATCC 49474	*Streptococcus mutans* ATCC 25175
Enterococcus faecium ATCC 12952	*Streptococcus pasteurans (bovis)* ATCC 49133
Enterococcus gallinarum ATCC 49608	*Streptococcus pneumoniae* ATCC 33400
Enterococcus hirae ATCC 10541	*Streptococcus pneumoniae* ATCC 39938
Enterococcus mundtii ATCC 43187	*Streptococcus pneumoniae* ATCC 49136
Enterococcus raffinosus ATCC 49464	*Streptococcus pneumoniae* ATCC 49619
Escherichia coli ATCC 10798	*Streptococcus pneumoniae* ATCC 51937
Gemella spp. bergeri ATCC 700627	*Streptococcus pneumoniae* ATCC 51938
Haemophilus influenzae ATCC 49247	*Streptococcus pneumoniae* ATCC 6301
Klebsiella oxytoca ATCC 49131	*Streptococcus pneumoniae* ATCC SSI-1
Klebsiella pneumoniae ATCC 49472	*Streptococcus pneumoniae* ATCC SSI-10A
Lactobacillus casei ATCC 393	*Streptococcus pneumoniae* ATCC SSI-14
Lactococcus spp.garvieae ATCC 49157	*Streptococcus pneumoniae* ATCC SSI-7F
Leuconostoc mesenteriodes ATCC 10877	*Streptococcus pyogenes*, group A ATCC 12384
Listeria monocytogenes ATCC 19115	*Streptococcus salivarius* ATCC 13419
Macrococcus caseolyticus (formerly *Staph cohnii* subsp. *cohnii*) ATCC 35662	*Streptococcus salivarius* ATCC 13419
Micrococcus luteus ATCC 27141	Yeasts
Moraxella catarrhalis ATCC 25238	*Candida albicans* ATCC 60193
Morganella morganii ATCC 25830-T	*Candida glabrata* ATCC 66032
Neisseria meningitides (serogroup A) ATCC 13077	*Candida tropicalis* ATCC 750
Neisseria sicca ATCC 9913	

Interfering Substances:
None of the 20 potentially interfering substances listed below produced false results in the BinaxNOW® *Staphylococcus aureus* test.

Anti-Inflammatory Drugs	**Test Concentration**	**Endogenous Blood Components**	**Test Concentration**
Acetaminophen	1324 µmol/L	Hemoglobin	2 g/L
Acetylsalicyclic acid	3.62 mmol/L	Triglyceride sera	37 mmol/L
Ibuprofen	2425 µmol/L	Conjugated bilirubin	342 µmol/L
Antibiotics	**Test Concentration**	Unconjugated bilirubin	342 µmol/L
Amoxicillin	206 µmol/L	γ- globulin	120g/L
Cephalexin	337 µmol/L	**Anti-coagulant**	**Test Concentration**
Chloramphenicol	155 µmol/L	Sodium Polyanetholesulfonate (SPS)	1%
Ciprofloxacin	30.2 µmol/L		
Erythromycin	81.6 µmol/L		
Gentamicin	21 µmol/L		

Tetracycline	34 μmol/L
Sulfisoxazole	1.12 mmol/L
Sulfamethoxazole	1.58 mmol/L
Trimethoprim	138 μmol/L
Vancomycin	69 μmol/L

Analytical Sensitivity:
The analytical limit of detection of the BinaxNOW® *Staphylococcus aureus* Test is 5.42 x 10^8 cells/mL.

Bacterial Concentration cells/mL	Number Detected	% Detection
2.71 x 10^9	26/26	100
5.42 x 10^8	25/26	96
1.14 x 10^8	15/26	75
7.07 x 10^7	10/26	50

Reproducibility Study:
A study of the BinaxNOW® *Staphylococcus aureus* Test was conducted at 3 separate sites using panels of blind coded specimens containing negative and positive samples. Participants tested each sample twice on 5 different days. There was 98% (588/600) agreement with expected test results, with no significant differences within run (replicates tested by one operator), between run (5 different days), between sites (3 sites), or between operators (6 operators).

Signed_____ Date _____
Angela Drysdale
Clinical Affairs
Binax, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

DEC 16 2009

Binax, Inc.
c/o Ms. Suzanne Vogel
Clinical Affairs Inverness Medical
10 Southgate Road
Scarborough, ME 04074

Re: k090964

Trade Name: BinaxNow® Staphylococcus Aureus Test
Regulation Number: 21 CFR §866.2660
Regulation Name: Microorganism differentiation and identification device
Regulatory Class: Class I
Product Codes: JWX
Dated: October 23, 2009
Received: October 30, 2009

Dear Ms. Vogel:

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.

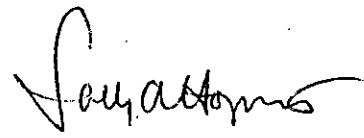
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

ATTACHMENT 14: INDICATIONS FOR USE FORM

510(k) Number: 090964

Device Name: BinaxNOW® *Staphylococcus aureus* Test

Indications for Use:

The BinaxNOW® *Staphylococcus aureus* Test is a qualitative, *in vitro* immunochromatographic assay for the presumptive identification of *Staphylococcus aureus*. The test is performed directly on blood culture samples positive for Gram-positive cocci in clusters. The BinaxNOW® *Staphylococcus aureus* Test is not intended to diagnose *Staphylococcus aureus* nor to guide or monitor treatment for *Staphylococcus aureus* infections. Subculturing positive blood cultures is necessary to recover organisms for susceptibility testing and/or differentiation of mixed growth.

Prescription Use √ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (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) k090964