K090301

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: k090301

SUBMITTER

Binax, Inc.
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APR 16 2010

CONTACT PERSON

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DATE PREPARED

April 12th, 2010

TRADE NAME

BinaxNOW® PBP2a Test

COMMON NAME

BinaxNOW® PBP2a Test, BinaxNOW® PBP2a, Binax NOW® PBP2a Test, Binax NOW® PBP2a, NOW® PBP2a Test, NOW® PBP2a

CLASSIFICATION NAME

System, Test, Genotypic Detection, Resistant Markers, Staphylococcus Colonies (MYI) (per 21 CFR 866.1640)

PREDICATE DEVICES

Mueller Hinton Agar w/4% NaCl w/Antibiotics (Remel) K850291
PBP2' Latex Agglutination Test (Oxoid) K011710

DEVICE DESCRIPTION

The BinaxNOW® PBP2a Test is a rapid immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect the PBP2a protein directly from blood cultures which have been identified as being positive for *S. aureus*. 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 *Staphylococcus aureus*. 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® PBP2a Test is a qualitative, *in vitro* immunochromatographic assay for the rapid detection of penicillin-binding protein 2a (PBP2a) present in methicillin-resistant *Staphylococcus aureus* (MRSA). The test is performed directly on blood culture samples positive for *S. aureus*.

The BinaxNOW® PBP2a Test is not intended to diagnose MRSA nor to guide or monitor treatment for MRSA infections. Subculturing positive blood cultures is necessary to recover organisms for susceptibility testing or epidemiological typing.

Performance Characteristics

Clinical Performance

The clinical performance of the BinaxNOW® PBP2a Test was established in a multi-center clinical study conducted in 2008-09 at four geographically diverse hospital laboratories within the US.

A total of 199 *S. aureus* samples were evaluated in the BinaxNOW® PBP2a Test and compared to standard methods used routinely by the laboratories: Cefoxitin (30 µg) disc diffusion, Oxacillin (1 µg) disc diffusion, and automated Minimum Inhibitory Concentration (MIC) Systems. Individual samples were evaluated by multiple laboratory methods, and in all cases there was 100% agreement between the reference methods. Among the clinical samples tested, only three clinical samples (3/199 or 1.5%) produced discrepant results. Overall, the BinaxNOW® PBP2a assay identified 97.1% of the specimens positive for MRSA and 100.0% of the specimens negative for MRSA.

The table below presents BinaxNOW® PBP2a Test performance by reference method. Because each sample was tested on more than one reference method, there are more observations in this table (n=317) than the total number of samples (n=199).

BinaxNOW® PBP2a Test Performance vs. Reference Methods

Reference Method	Positive Agreement (95% CI)	Negative Agreement (95% CI)
Cefoxitin (30 µg) disc diffusion	96.9% (62/64) (89.3 - 99.1%)	100.0% (67/67) (94.6 - 100.0%)
Oxacillin (1 µg) disc diffusion	96.5% (55/57) (88.1 - 99.0%)	100.0% (58/58) (93.8 - 100.0%)
Automated Antimicrobial Susceptibility Test System	97.6% (41/42) (87.7 - 99.6%)	100.0% (29/29) (88.3- 100.0%)

Expected Values

In the clinical evaluation of the BinaxNOW® PBP2a Test conducted in 2008-09 at four geographically diverse hospital laboratories within the US, the overall expected rate of PBP2a (MRSA) was 51.3% (102/199), and among the four site populations the expected positive rate ranged from 48.3% to 61.5%.

Analytical Reactivity
The human pathogenic Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) and American Type Culture Collection (ATCC) methicillin-resistant *Staphylococcus aureus* (MRSA) strains listed below tested positive in the BinaxNOW® PBP2a Test as expected.

Methicillin-Resistant *Staphylococcus aureus* (MRSA)

Bacterium	Bacterium
Staphylococcus aureus ATCC 33591	*Staphylococcus aureus* NRS643(USA300)
Staphylococcus aureus ATCC 33592	*Staphylococcus aureus* NRS647(USA300)
Staphylococcus aureus ATCC 43300	*Staphylococcus aureus* NRS657(USA300)
Staphylococcus aureus ATCC 49476	*Staphylococcus aureus* NRS658(USA100)
Staphylococcus aureus ATCC 51153	*Staphylococcus aureus* NRS659(USA300)
Staphylococcus aureus ATCC 700698	*Staphylococcus aureus* NRS660(USA100)
Staphylococcus aureus ATCC 700699	*Staphylococcus aureus* NRS661(USA100)
Staphylococcus aureus ATCC 700789	*Staphylococcus aureus* NRS667(USA300)
Staphylococcus aureus ATCC BAA1026	*Staphylococcus aureus* NRS670(USA100)
Staphylococcus aureus ATCC BAA38	*Staphylococcus aureus* NRS671(USA100)
Staphylococcus aureus ATCC BAA39	*Staphylococcus aureus* NRS672(USA100)
Staphylococcus aureus ATCC BAA41	*Staphylococcus aureus* NRS673(USA100)
Staphylococcus aureus ATCC BAA43	*Staphylococcus aureus* NRS674(USA100)
Staphylococcus aureus ATCC BAA44	*Staphylococcus aureus* NRS679(USA100)
Staphylococcus aureus NRS123(USA 400)	*Staphylococcus aureus* NRS687(USA300)
Staphylococcus aureus NRS172	*Staphylococcus aureus* NRS688(USA300)
Staphylococcus aureus NRS192	*Staphylococcus aureus* NRS693(USA300)
Staphylococcus aureus NRS193	*Staphylococcus aureus* NRS694(USA300)
Staphylococcus aureus NRS194	*Staphylococcus aureus* NRS697(USA100)
Staphylococcus aureus NRS22(USA 600)	*Staphylococcus aureus* NRS699(USA100)
Staphylococcus aureus NRS241	*Staphylococcus aureus* NRS710(USA100)
Staphylococcus aureus NRS245	*Staphylococcus aureus* NRS711(USA100)
Staphylococcus aureus NRS248	*Staphylococcus aureus* NRS716(USA300)
Staphylococcus aureus NRS249	*Staphylococcus aureus* NRS717(USA100)
Staphylococcus aureus NRS382(USA 100)	*Staphylococcus aureus* NRS721(USA100)
Staphylococcus aureus NRS383(USA 200)	*Staphylococcus aureus* NRS725(USA300)
Staphylococcus aureus NRS384(USA 300)	*Staphylococcus aureus* NRS732(USA300)
Staphylococcus aureus NRS385(USA 500)	*Staphylococcus aureus* NRS733(USA300)
Staphylococcus aureus NRS386(USA 700)	*Staphylococcus aureus* NRS736(USA300)
Staphylococcus aureus NRS387(USA 800)	*Staphylococcus aureus* NRS739(USA300)

Analytical Specificity (Cross-Reactivity)
To determine the analytical specificity of the BinaxNOW® PBP2a Test, methicillin-susceptible *Staphylococcus aureus* (MSSA), Staphylococcal strains (other than *S. aureus*) and non-Staphylococcal strains were tested. All strains tested negative in the BinaxNOW® test except *Cryptococcus neoformans and Staphylococcus sciuri.*

Methicillin-Sensitive *Staphylococcus aureus* (MSSA)

Bacterium	Bacterium
Staphylococcus aureus ATCC 33862	*Staphylococcus aureus* NRS167
Staphylococcus aureus ATCC 13150	*Staphylococcus aureus* NRS168
Staphylococcus aureus ATCC 11632	*Staphylococcus aureus* NRS169
Staphylococcus aureus ATCC 14776	*Staphylococcus aureus* NRS170
Staphylococcus aureus ATCC 6538P	*Staphylococcus aureus* NRS171
Staphylococcus aureus ATCC 29213	*Staphylococcus aureus* NRS173
Staphylococcus aureus ATCC BAA977	*Staphylococcus aureus* NRS174
Staphylococcus aureus NRS164	*Staphylococcus aureus* NRS175
Staphylococcus aureus NRS165	*Staphylococcus aureus* NRS176
Staphylococcus aureus NRS166	*Staphylococcus aureus* NRS177
Staphylococcus aureus ATCC 9144	*Staphylococcus aureus* Lafferty
Staphylococcus aureus ATCC 51740	*Staphylococcus aureus* ATCC 31153
Staphylococcus aureus ATCC 29737	*Staphylococcus aureus* ATCC 12600
Staphylococcus aureus ATCC 15564	*Staphylococcus aureus* ATCC14993
Staphylococcus aureus ATCC 14775	*Staphylococcus aureus* ATCC 33862
Staphylococcus aureus ATCC 25923	*Staphylococcus aureus subsp. Anaerobius* ATCC 35844

Staphylococcal Strains (other than *S. aureus*)

Bacterium	ATCC#	Bacterium	ATCC#
Staphylococcus simulans	27851	*Staphylococcus equorum*	43958
Staphylococcus warneri	49454	*Staphylococcus lentus*	700403
Staphylococcus lugdunensis	43809	*Staphylococcus hyicus*	11249
Staphylococcus sciuri	29601	*Staphylococcus carnosus*	51365
Staphylococcus saprophyticus	15305	*Staphylococcus capitis*	35661
Staphylococcus schleiferi	43808	*Staphylococcus arlettae*	43957
Staphylococcus haemolyticus	29970	*Staphylococcus piscifermentans*	51136
Staphylococcus kloosii	43959	*Staphylococcus hominis*	27844
Staphylococcus cohnii	29972	*Staphylococcus caprae*	51548
Staphylococcus xylosus	49148	*Staphylococcus pasteuri*	51128
Staphylococcus succinus	700337	*Staphylococcus chromogenes*	43764
Staphylococcus vitulinus	51162	*Staphylococcus lutrae*	700373
Staphylococcus pulvereri	51698	*Staphylococcus muscae*	49910
Staphylococcus intermedius	29663	*Staphylococcus felis*	49168
Staphylococcus gallinarum	700401	*Staphylococcus auricularis*	33753
Staphylococcus epidermidis	14990	*Staphylococcus delphini*	49171
Staphylococcus epidermidis	12228	*Staphylococcus saccharolyticus*	14953
Staphylococcus epidermidis	35984	*Staphylococcus schleiferi subsp coagulans*	49545
Staphylococcus fleurettii	BAA-274	*Staphylococcus pseudintermedius*	49444

Non- Staphylococcal Strains

Bacterium	ATCC#	Bacterium	ATCC#
Acinetobacter calcoaceticus	51432	*Macrococcus caseolyticus*	35662
Aerococcus viridans	10400	*Macrococcus equipercicus*	51831
Aeromonas hydrophila	35654	*Micrococcus luteus*	27141
Bacillus cereus	11778	*Moraxella catarrhalis*	25238
Bacillus subtilis	6633	*Morganella morganii*	25830-T
Bacteroides fragilis	23745	*Neisseria gonorrhoeae*	49226
Beta Strep Group F	12392	*Neisseria meningitidis*, serogroup A	13077
Burkholderia cepacia	25416-T	*Neisseria sicca*	9913
Candida parapsilosis	90018	*Parvimonas micra* (formerly *Peptostreptococcus micros)*	33270
Candida krusei	14243	*Pasturella multocida*	51687
Cellulomonas turbata (formerly *Oerskovia)*	25835	*Pediococcus acidilactici*	12697
Citrobacter freundii	8090	*Peptostreptococcus anaerobius*	27337
Citrobacter koseri	25408	*Planococcus citreus*	14404
Clostridium perfringens	3624	*Proteus mirabilis*	7002
Corynebacterium xerosus	7711	*Proteus vulgaris*	33420
Corynebacterium amycolatum	49368	*Providencia stuartii*	49809
Corynebacterium diphtheriae	13812	*Pseudomonas aeruginosa*	15442
Corynebacterium glutamicum	13869	*Pseudomonas fluorescens*	49271
Corynebacterium jeikeium	43734	*Pseudomonas putida*	49128
Corynebacterium pseudodiphtheriticum	10700-T	*Rhodococcus equi*	10146
Corynebacterium urealyticum	43042	*Rothis mucilaginosa (Stomatococcus)*	25296
Cryptococcus neoformans	14116	*Salmonella adelaide*	10718
Escherichia coli (ESBL producer)	Clinical isolate	*Serratia marcescens*	13880
Enterobacter aerogenes	35029	*Stenotrophomonas maltophilia*	12637-T
Enterobacter cloacae	49141	*Streptococcus agalactiae*, group B	13813
Enterococcus avium	49465	*Streptococcus anginosis (milleri)*	33397
Enterococcus casseliflavus	12817	*Streptococcus dysgalactiae*, group C (strain C74)	12388
Enterococcus durans	49135	*Streptococcus dysgalactiae*, group G (strain Lf D166B)	12394
Enterococcus faecalis	49474	*Streptococcus intermedius (milleri)*	27335
Enterococcus faecium	12952	*Streptococcus mitis*	49456
Enterococcus gallinarum	49608	*Streptococcus mutans*	25175
Enterococcus hirae	10541	*Streptococcus pasteurianus(bovis)*	49133
Enterococcus mundtii	43187	*Streptococcus pneumoniae*	33400
Enterococcus raffinosus	49464	*Streptococcus pneumoniae*	49136
Escherichia coli	10798	*Streptococcus pneumoniae*	SSI-1
Finegoldia magna (formerly *Peptostreptococcus magnus)*	15794	*Streptococcus pneumoniae*	SSI-10A
Gemella bergeri	700627	*Streptococcus pneumoniae*	6301

Haemophilus influenzae	49247	*Streptococcus pneumoniae*	33938
Haemophilus parainfluenzae	33392-T	*Streptococcus pneumoniae*	49619
Klebsiella oxytoca	49131	*Streptococcus pneumoniae*	51937
Klebsiella pneumoniae	49472	*Streptococcus pneumoniae*	SSI-14
Klebsiella pneumoniae (ESBL prod and KPC pos)	Clinical isolate	*Streptococcus pneumoniae*	SSI-7F
Kocuria kristinae	BAA752	*Streptococcus pneumoniae*	51938
Kytococcus chroeter	13884	*Streptococcus pyogenes*, group A	12384
Lactobacillus casei	393	*Streptococcus salivarius*	13419
Lactococcus garvieae	49157	Yeast	ATCC#
Leuconostoc mesenteroides	10877	*Candida albicans*	60193
Listeria monocytogenes, serotype 4b	19115	*Candida glabrata*	66032
		Candida tropicalis	750

Interfering Substances:
The 20 potentially interfering substances listed below produced appropriate results in the BinaxNOW® PBP2a 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® PBP2a Test in ATCC strain BAA44 at a turbidity level of 0.03 is 2.5 x 10^7 cells/mL, and the equivalent concentration in CFU/mL is 2.36 x 10^7.

Bacterial Concentration/mL	Number Detected	% Detection

$3.33x10^7$	20/20	100
$2.5x10^7$	19/20	95
$4.94x10^6$	13/20	65
$2.19x10^6$	3/20	15
Whole Blood	0/20	0

Reproducibility Study:
A study of the BinaxNOW® PBP2a 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 100% (599/599) 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 4/12/10
Suzanne M. Vogel, MPH
Clinical Affairs
Binax, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center-WO66-G609
Silver Spring, MD 20993-0002

Binax, Inc
c/o Ms. Suzanne Vogel
Department of Clinical Affairs
Inverness Medical
10 Southgate Rd.
Scarborough, Maine 04074

APR 14 2010

Re: K090301
Trade/Device Name: BinaxNOW® PBP2a Test
Regulation Number: 21 CFR§ 866.1640
Regulation Name: Methicillin Resistant *Staphylococcus aureus* (MRSA)
Regulatory Class: Class II
Product Code: MYI
Dated: March 29, 2010
Received: March 31, 2010

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 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, 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): k090301

Device Name: BinaxNOW® PBP2a Test

Indications for Use:

The BinaxNOW® PBP2a Test is a qualitative, *in vitro* immunochromatographic assay for the rapid detection of penicillin-binding protein 2a (PBP2a) present in methicillin-resistant *Staphylococcus aureus* (MRSA). The test is performed directly on blood culture samples positive for *S. aureus*.

The BinaxNOW® PBP2a Test is not intended to diagnose MRSA nor to guide or monitor treatment for MRSA infections. Subculturing positive blood cultures is necessary to recover organisms for susceptibility testing or epidemiological typing.

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) K090301