

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k090964

B. Purpose for Submission:

To obtain clearance for a Premarket notification

C. Measurand:

Staphylococcus aureus specific proteins

D. Type of Test:

The BinaxNOW® *Staphylococcus aureus* Test is a qualitative, *in vitro* immunochromatographic assay for the presumptive identification of *Staphylococcus aureus*.

E. Applicant:

Binax, Inc

F. Proprietary and Established Names:

BinaxNOW® *Staphylococcus aureus* Test

G. Regulatory Information:

1. Regulation section:

CFR 866.2660

2. Classification:

I

3. Product code:

JWX: Microorganism differentiation and identification device

4. Panel:

83 Microbiology

H. Intended Use:

1. Intended use(s):

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.

2. Indication(s) 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.

3. Special conditions for use statement(s):

Prescription use

4. Special instrument requirements:

Not applicable

I. 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.

J. Substantial Equivalence Information:

1. Predicate device name(s):

S. aureus PNA FISH™ (AdvanDx)

2. Predicate 510(k) number(s):

k060099

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	For detection of <i>Staphylococcus aureus</i>	For detection of <i>Staphylococcus aureus</i>
Reporting	<i>Staphylococcus aureus</i> from positive blood cultures	Same
Reading	Manual	Manual

Differences		
Item	Device	Predicate
Technology	immunochromatographic membrane assay	Fluorescent <i>in situ</i> hybridization
Detection mechanism	Polyclonal antibodies to detect <i>S. aureus</i> specific protein	Protein nuclei acid probes to detect <i>S. aureus</i> -specific 16S ribosomal RNA
Reading method	Test strip contained in a cardboard, hinged book-shaped device	Fluorescent microscopy

K. Standard/Guidance Document Referenced (if applicable):

Non applicable

L. Test Principle:

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. The protein-specific 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.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Reproducibility study was done at three sites, by two operators in duplicates for five days. Reproducibility was greater than 95%.

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The controls for the BinaxNOW® *Staphylococcus aureus* Test are:

1. Built-in procedural controls with each testing strip

- i. The appearance of a pink-purple line at the “control line” position is an internal positive procedural control to ensure capillary flow has occurred.
- ii. The clearing of the background color from the result window is a negative background control and should be white within 10 minutes.
- iii. Results are invalid without the pink-purple “control-line”. There were no invalid results in the clinical studies.

2. External Positive and Negative Controls

The overall expected results were greater than 95%.

d. *Detection limit:*

The LoD for the BinaxNOW® *Staphylococcus aureus* Test was: 5.42×10^8 cells/mL.

An additional study was conducted to demonstrate the cells/mL in CFU/mL.

There is no significant difference:

$$5.42 \times 10^8 \text{ cells/mL} = 4.8 \times 10^8 \text{ CFU/mL}$$

e. *Analytical specificity:*

Reactivity

The detection rate was 98.2% (54/55) with the *S. aureus* tested in the

reactivity study. *S. aureus* ATCC 14993 tested negative with the BinaxNOW® *Staphylococcus aureus* Test.

Cross Reactivity Study

The study included 96 non-staphylococcal bacteria, three yeasts and 25 coagulase-negative *Staphylococcus* (CNS). It demonstrated that *Clostridium perfringens* (four different ATCC strains), *C. bifermentans*, *C. histolyticum*, and *Staphylococcus schleiferi* subspecies *coagulans* tested positive with the BinaxNOW® *Staphylococcus aureus* Test.

Interference Study

No interference observed with the 20 substances such as medications, human blood components, and supplements normally found in blood culture bottle media.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

The reference methods in the clinical studies are:

- Latex agglutination
- Tube coagulase
- Automated identification systems

b. Matrix comparison:

Not applicable

3. Clinical studies:

A total of 325 Standard Aerobic (SA) and Standard Anaerobic (SN) blood culture bottles of the BacT/ALERT® Automated Microbial Detection System were evaluated in the BinaxNOW® *Staphylococcus aureus* Test and compared to standard methods used routinely by the testing laboratories. It was conducted at three geographically diversified hospital laboratories within the U.S.

The study included 272 (83.7%) prospective samples (74 SA and 198 CNS), and 53 retrospective samples (11 SA and 42 CNS). The table below was the overall performance data:

BinaxNOW® *Staphylococcus aureus* Test Compared to Reference Method

BinaxNOW® <i>Staphylococcus aureus</i> Test	Reference Method	
	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%)

a. *Clinical Sensitivity:*

See table above

b. *Clinical specificity:*

See table above

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

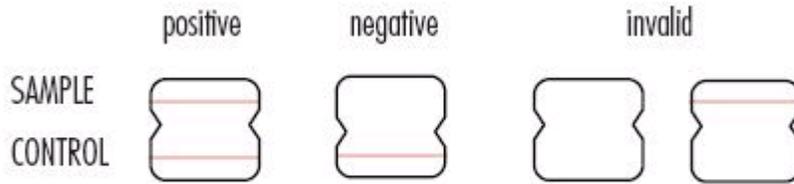
Not applicable

5. Expected values/Reference range:

For a **POSITIVE SAMPLE**, the blue Control line turns a pink to purple color and a second pink to purple Sample Line appears above it in the top half of the window. Any Sample Line, even when very faint, is positive.

For a **NEGATIVE SAMPLE**, the blue Control Line turns a pink to purple color. No other line appears.

A test is **INVALID** if the blue Control Line does not turn a pink to purple color, or does not appear at all, whether a Sample Line is present or not.



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%.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The information submitted in this premarket notification is complete and supports a substantial equivalence decision.