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**510(K) SUMMARY**

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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: K 121905.

JUL 26 2012

**SUBMITTER**

Alere Scarborough, Inc.  
10 Southgate Road  
Scarborough, ME 04074  
Establishment Registration Number: 1221359

**CONTACT PERSON**

Angela Drysdale  
(207) 730-5737 (Office)  
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[Angela.drysdale@alere.com](mailto:Angela.drysdale@alere.com) (email)

**DATE PREPARED**

6/27/2012

**TRADE NAME**

Alere™ PBP2a Test

**COMMON NAME**

Alere™ PBP2a Test, Alere™ PBP2a

**CLASSIFICATION NAME**

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

**CLASSIFICATION**

Class II

**PRODUCT CODE**

MYI

**PANEL**

Microbiology

**PREDICATE DEVICES**

Alere™ PBP2a Test, K091766

**DEVICE DESCRIPTION**

The Alere™ PBP2a Test is a rapid immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect the PBP2a protein directly from bacterial isolates. These antibodies and a control antibody are immobilized onto a nitrocellulose membrane as two distinct lines and combined with a sample pad, a blue conjugate pad, and an absorption pad to form a test strip.

Isolates are sampled directly from the culture plate and eluted into an assay tube containing Reagent 1. Reagent 2 is then added and the dipstick is placed in the assay tube. Results are read visually at 5 minutes.

**INTENDED USE**

The Alere™ PBP2a Test is a qualitative, *in vitro* immunochromatographic assay for the detection of penicillin-binding protein 2a (PBP2a) in isolates identified as *Staphylococcus aureus*, as an aid in detecting methicillin-resistant *Staphylococcus aureus* (MRSA). The Alere™ PBP2a Test is not intended to diagnose MRSA nor to guide or monitor treatment for MRSA infections.

**TECHNOLOGICAL CHARACTERISTICS**

The Alere™ PBP2a Test uses lateral flow immunochromatographic technology. The test is a rapid immunoassay that employs specific antibodies immobilized onto a solid phase to detect PBP2a from bacterial isolates.

**PERFORMANCE SUMMARY****Clinical Performance**

The clinical performance of the Alere™ PBP2a Test was established in a multi-center clinical study conducted in 2009 at three geographically-diverse laboratories.

A total of 457 *S. aureus* samples were evaluated in the Alere™ PBP2a Test, compared to results of 30 µg cefoxitin disk diffusion and interpreted according to CLSI standards. Performance results by plate type are listed in Table 1 below.

**Table 1: Alere™ PBP2a Test Performance Compared to Cefoxitin (30 µg) Disk Diffusion in *S. aureus* Isolates: Results by Plate Type**

Plate Type	Sensitivity	95% C.I.	Specificity	95% C.I.
<b>Tryptic Soy Agar with 5% sheep blood</b>	98.1% (206/210)	( 95.2-99.3%)	98.8% (244/247)	( 96.5-99.6%)
<b>Columbia Agar with 5% sheep blood</b>	99.0% (208/210)	( 96.6-99.7%)	98.8% (244/247)	( 96.5-99.6%)
<b>Mueller Hinton with 1 µg oxacillin induction</b>	99.5% (209/210)	( 97.4-99.9%)	98.8% (244/247)	( 96.5-99.6%)

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**Analytical Performance****Analytical Reactivity and Specificity**

162 strains of methicillin-resistant *Staphylococcus aureus* (MRSA) and 112 strains of methicillin-sensitive *Staphylococcus aureus* (MSSA) were tested in the Alere™ PBP2a Test with expected results. These bacterial strains were obtained from the Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA), American Type Culture Collection (ATCC) and a collection of strains from Department of Infectious Disease Epidemiology of the Imperial College in London, England.

**Reproducibility Study**

A study of the Alere™ 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 97.3% (580/596) agreement with expected test results.

Signed \_\_\_\_\_

Date \_\_\_\_\_

Angela Drysdale  
Director of Clinical Affairs  
Alere Scarborough, Inc.



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

Alere Scarborough, Inc.  
c/o Angela Drysdale  
Director of Clinical Affairs  
10 Southgate Road  
Scarborough, ME 04074

JUL 26 2012

Re: K121905  
Trade Name: Alere™ PBP2a Test  
Regulation Number: 21 CFR §866.1640  
Regulation Name: Antimicrobial susceptibility test powder.  
Regulatory Class: Class II  
Product Code: MYI  
Dated: June 27, 2012  
Received: June 29, 2012

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

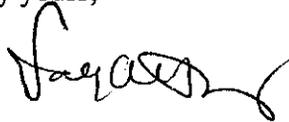
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. 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 Part 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):

K121905

Device Name: Alere™ PBP2a Test

## Indications For Use:

The Alere™ PBP2a Test is a qualitative, *in vitro* immunochromatographic assay for the detection of penicillin-binding protein 2a (PBP2a) in isolates identified as *Staphylococcus aureus*, as an aid in detecting methicillin-resistant *Staphylococcus aureus* (MRSA). The Alere™ PBP2a Test is not intended to diagnose MRSA nor to guide or monitor treatment for MRSA infections.

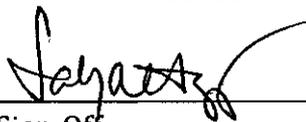
Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 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)



Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k)

K121905

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