DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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January 13, 2016

ALERE SCARBOROUGH, INC.
DANIELLE BRIGGEMAN
CLINICAL AFFAIRS SPECIALIST
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SCARBOROUGH ME 04074

Re: K133851
Trade/Device Name: Alere PBP2a SA Culture Colony Test
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial susceptibility test powder
Regulatory Class: Class II
Product Code: MYI
Dated: August 13, 2014
Received: August 20, 2014

Dear Ms. Briggeman:

This letter corrects our substantially equivalent letter of September 03, 2014.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ribhi Shawar -S

For Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133851

Device Name
Alere™ PBP2a SA Culture Colony Test

Indications for Use *(Describe)*
The Alere™ PBP2a SA Culture Colony Test is a qualitative, in vitro immunochromatographic assay for the rapid detection of penicillin-binding protein 2a (PBP2a) in isolates identified as Staphylococcus aureus as an aid in identifying methicillin-resistant Staphylococcus aureus (MRSA).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K133851: 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: K133851

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DATE PREPARED
August 14, 2014

TRADE NAME
Alere™ PBP2a SA Culture Colony Test

COMMON NAME
Alere™ SA PBP2a Test, Alere™ PBP2a *Staphylococcus aureus* Test, Alere™ Culture Colony Test

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

CLASSIFICATION
Class II

PRODUCT CODE
MYI

PANEL
Microbiology (83)

PREDICATE DEVICE
Oxoid PBP2' Latex Agglutination Test (#K011710)

DEVICE DESCRIPTION

The Alere™ PBP2a SA Culture Colony Test is a rapid immunochromatographic membrane assay intended for the detection of penicillin-binding protein 2a (PBP2a) in isolates identifies as *Staphylococcus aureus* as an aid in identification of MRSA. The test uses highly sensitive recombinant monoclonal antibody fragments (rFabs) to detect the PBP2a protein directly from bacterial isolates. The rFab and a control antibody are immobilized onto a nitrocellulose membrane as two distinct lines and combined with a sample pad, a pink/purple 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 test strip is placed in the assay tube. Results are read visually at 5 minutes.

INTENDED USE

The Alere™ PBP2a SA Culture Colony Test is a qualitative, *in vitro* immunochromatographic assay for the rapid detection of penicillin-binding protein 2a (PBP2a) in isolates identified as *Staphylococcus aureus* as an aid in identifying methicillin-resistant *Staphylococcus aureus* (MRSA).

TECHNOLOGICAL CHARACTERISTICS

The Alere™ PBP2a SA Culture Colony Test and the predicate device, Oxoid PBP2' Latex Agglutination Test, have a similar intended use, indications for use, and utilize similar basic principles of operation. They are both assays for the qualitative detection of PBP2a in isolates sampled directly from culture plates.

DEVICE COMPARISON

The Alere™ PBP2a SA Culture Colony Test was compared to the legally marketed predicate device, Oxoid Penicillin-Binding Protein (PBP2') Latex Agglutination Test.

Parameter	**Alere™ PBP2a SA Culture Colony Test**	**Oxoid Penicillin-Binding Protein (PBP2') Latex Agglutination Test K011710**
INTENDED USE	The Alere™ PBP2a SA Culture Colony Test is a qualitative, *in vitro* immunochromatographic assay for the rapid detection of penicillin-binding protein 2a (PBP2a) in isolates identified as *Staphylococcus aureus* as an aid in identifying methicillin-resistant *Staphylococcus aureus* (MRSA).	Same. The test is a rapid latex agglutination assay, detecting PBP2' (also called PBP2a) in isolates of *Staphylococcus*, as an aid in identifying methicillin-resistant *Staphylococcus aureus* (MRSA) and methicillin-resistant coagulase-negative staphylococci.
ANALYTE	PBP2a	Same.
TECHNOLOGY	A qualitative, *in vitro* immunochromatographic assay	A rapid latex agglutination assay
SPECIMEN TYPE	Isolates identified as *S. aureus.*	Same.
TIME TO RESULT	5 minutes after sample preparation	Within 3 minutes after sample/test preparation
PERFORMANCE	Compared to Cefoxitin (30µg) Disk Diffusion (95% confidence intervals included in parenthesis)	Compared to NCCLS methods (95% confidence intervals included in parenthesis and estimated per performance values and known sample size in product insert)

Parameter	Alere™ PBP2a SA Culture Colony Test	Oxoid Penicillin-Binding Protein (PBP2') Latex Agglutination Test K011710
	Tryptic Soy Agar with 5% Sheep Blood Plate:	
	S. aureus Isolates: Sensitivity: 99.1% (96.7%, 99.8%) Specificity: 99.2% (97.0%, 99.8%)	*S. aureus* Isolates: Sensitivity: 100.0% (94.7%, 100.0%) Specificity: 99.0% (95.8%, 99.9%) CoNS Isolates: Sensitivity: 96.5% (91.4%, 98.6%) Specificity: 100.0% (92.1%, 100.0%)
	Columbia Agar with 5% Sheep Blood Plate:	
	S. aureus Isolates: Sensitivity: 98.6% (96.0%, 99.5%) Specificity: 99.2% (97.0%, 99.8%)	*S. aureus* Isolates: Sensitivity: 100.0% (94.7%, 100.0%) Specificity: 100.0% (97.1%, 100.0%) CoNS Isolates: Sensitivity: 99.5% (97.4%, 99.9%) Specificity: 99.5% (97.3%, 99.9%)
	Mueller Hinton Plate:	
	S. aureus Isolates: Sensitivity: 99.1% (96.7%, 99.8%) Specificity: 99.6% (97.7%, 99.9%)	*S. aureus* Isolates: Sensitivity: 100.0% (94.7%, 100.0%) Specificity: 100.0% (97.1%, 100.0%) CoNS Isolates: Sensitivity: 95.6% (90.2%, 98.1%) Specificity: 98.0% (88.4%, 99.6%)

PERFORMANCE SUMMARY

CLINICAL STUDIES
The clinical performance of the Alere™ PBP2a SA Culture Colony Test was established in a multi-center clinical study conducted in 2013 at three (3) geographically-diverse laboratories.

A total of 454 *S. aureus* isolates were evaluated in the Alere™ PBP2a SA Culture Colony Test, compared to results of 30 µg cefoxitin disk diffusion and interpreted according to CLSI standards. Alere™ PBP2a SA Culture Colony Test performance, including 95% confidence intervals, versus cefoxitin disk diffusion, stratified by plate type is provided below.

All positive and negative daily controls generated the expected results.

ALERE™ PBP2A SA CULTURE COLONY TEST PERFORMANCE VS. CEFOXITIN (30µg) DISK DIFFUSION: RESULTS BY PLATE TYPE

***S. aureus* Isolates**

Plate Type	Sensitivity	95% C.I.	Specificity	95% C.I.
Primary Plate[1]	100.0% (129/129)	(97.1%, 100.0%)	98.5% (134/136)	(94.8%, 99.6%)
Tryptic Soy Agar with 5% sheep blood	99.1% (213/215)	(96.7%, 99.8%)	99.2% (237/239)	(97.0%, 99.8%)
Columbia Agar with 5% sheep	98.6%	(96.0%,	99.2%	(97.0%,

blood	(212/215)	99.5%)	(237/239)	99.8%)
Mueller Hinton with 30µg Cefoxitin Induction	99.1% (213/215)	(96.7%, 99.8%)	99.6% (238/239)	(97.7%, 99.9%)

[1:] Alere™ PBP2a SA Culture Colony Test was performed from primary plates at 2 out of 3 clinical sites. Primary plates were either Tryptic Soy Agar or Columbia Agar, with the exception of two samples of unknown plate type.

ANALYTICAL STUDIES

Please note: isolates tested in the following studies were not cultured using Columbia agar plates. All positive and negative daily controls generated the expected results.

ANALYTICAL SENSITIVITY

Alere™ PBP2a SA Culture Colony Test limit of detection (LOD or C_{95}), defined as the concentration of PBP2a producing *Staphylococci* that produces positive Alere™ PBP2a SA Culture Colony Test results approximately 95% of the time, was identified by evaluating different concentrations of one (1) PBP2a producing *S. aureus* isolate . The concentration identified as the LOD (or C_{95}) level is listed below.

Staphylococcus species	Concentration (CFU/ml)	# Detected per Total Tests	% Detected
S. aureus (ATCC BAA44)	7.30×10^8	19/20	95%

REACTIVITY TESTING

162 strains of methicillin resistant *Staphylococcus aureus* were tested with the Alere™ PBP2a SA Culture Colony Test with positive results. The strains were obtained from the Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA), American Type Culture Collection (ATCC) and Department of Infectious Disease Epidemiology of the Imperial College in London, England.

ANALYTICAL SPECIFICITY (CROSS-REACTIVITY)

To determine the analytical specificity of the Alere™ PBP2a SA Culture Colony Test, the following list of methicillin-sensitive *Staphylococcus aureus* (MSSA) and non-Staphylococcal strains were tested. All of the organisms tested were negative. When more than one strain was tested, the number is listed in parenthesis.

Species
Staphylococcus aureus (MSSA) (112)
Non-Staphylococcal Strains:
Aerococcus urinae
Planococcus citreus
Kytococcus schroeteri
Stomatococcus (Rothia mucilanginosa)
Kocuria kristinae
Micrococcus luteus

REPRODUCIBILITY

The Alere™ PBP2a SA Culture Colony Test reproducibility study was conducted at 3 separate sites using panels of blind coded specimens containing negative and positive samples in duplicate for each panel. Participants (2 per site) each tested one panel on 5 different days. There was 100.0% (600/600) agreement with expected test results for *Staphylococcus aureus*. There were 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
VP, Regulatory & Clinical Affairs – Infectious Disease
Alere Scarborough, Inc.