

K133851 ALERE PBP2A SA/CONS CULTURE COLONY TESTSep 3, 2014
258 days to decisionK133851 · Product code: **MYI** · Microbiology
Source: <https://www.510kdatabase.net/k133851/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Genotypic Detection, Resistant Markers, Staphylococcus Colonies (MYI)
Date received	Dec 19, 2013
Decision date	Sep 3, 2014
Days to decision	258 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alere Scarborough, Inc.
Location	Scarborough, ME, US
Contact	DANIELLE A BRIGGEMAN
510(k) history	17 submissions · 16 cleared · 2012-2019

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