

**K121905 ALERE PBP2A TEST**Jul 26, 2012  
27 days to decisionK121905 · Product code: **MYI** · Microbiology  
Source: <https://www.510kdatabase.net/k121905/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Genotypic Detection, Resistant Markers, Staphylococcus Colonies (MYI)
Date received	Jun 29, 2012
Decision date	Jul 26, 2012
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Alere Scarborough, Inc.</b>
Location	Scarborough, ME, US
Contact	Angela Drysdale
510(k) history	17 submissions · 16 cleared · 2012-2019

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121905/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026