

**K161364 BinaxNOW G6PD Test**Jun 17, 2016  
31 days to decisionK161364 · Product code: **JBF** · Hematology  
Source: <https://www.510kdatabase.net/k161364/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Glucose-6-phosphate Dehydrogenase (erythrocytic), Screening (JBF)
Date received	May 17, 2016
Decision date	Jun 17, 2016
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161364/> 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