

**K152245 ONLINE TDM Vancomycin Gen.3**Jan 8, 2016  
151 days to decisionK152245 · Product code: **LEH** · Chemistry  
Source: <https://www.510kdatabase.net/k152245/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Vancomycin (LEH)
Date received	Aug 10, 2015
Decision date	Jan 8, 2016
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diagnostics Operations (Rdo)</b>
Location	Indianapolis, IN, US
Contact	BARBARA MCWHORTER
510(k) history	14 submissions · 14 cleared · 2014-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152245/> 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 May 31, 2026