

**K141133 VIDAS H. pylori IgG, VIDAS 3, VIDAS Lyme IgG II, VIDAS RUB IgG, VIDAS TOXO M, VIDAS Human Chorionic Gonadotropin, VIDAS T4, VIDAS Testosterone, VIDAS TSH, and VIDAS D-Dimer Exclusion II**Jul 9, 2015  
434 days to decisionK141133 · Product code: LYR · Microbiology  
Source: <https://www.510kdatabase.net/k141133/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	May 1, 2014
Decision date	Jul 9, 2015
Days to decision	434 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>BIOMERIEUX</b>
Location	Craponne, FR
Contact	JOHN ALBRIGHT
510(k) history	3 submissions · 3 cleared · 2010-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k141133/> 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 24, 2026