

**K122472 VARIANT II TURBO HBA1C KIT-2.0 VARIANT II TURBO  
HEMOGLOBIN TESTING SYSTEM**Oct 26, 2012  
73 days to decisionK122472 · Product code: **LCP** · Chemistry  
Source: <https://www.510kdatabase.net/k122472/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Aug 14, 2012
Decision date	Oct 26, 2012
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bio-Rad Laboratories, Inc., Clinical Systems Divis</b>
Location	Hercules, CA, US
Contact	JACKIE BUCKLEY
510(k) history	3 submissions · 3 cleared · 2012-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122472/> 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 9, 2026