

**K090699 VARIANT II TURBO HBA1C KIT KIT-20 AND  
WASH/DILUENT SOLUTION SET, MODELS 270-2455, 270-2730**Jul 27, 2009  
132 days to decisionK090699 · Product code: LCP · Chemistry  
Source: <https://www.510kdatabase.net/k090699/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Mar 17, 2009
Decision date	Jul 27, 2009
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bio-Rad Laboratories, Inc.</b>
Location	Chaska, MN, US
Contact	JACKIE H BUCKLEY
Website	<a href="http://www.bio-rad.com">http://www.bio-rad.com</a>
510(k) history	82 submissions · 82 cleared · 1991-2019

Bio-Rad Laboratories, Inc. is an American developer and manufacturer of specialized technological products for life science research and clinical diagnostics. Founded in 1952 in Berkeley, California, the company is based in Hercules, California, with operations worldwide. Bio-Rad has received FDA 510(k) clearances from total submissions between 1991 and 2019. The company's regulatory record reflects a strong focus on chemistry devices, including hemoglobin testing systems, quality control materials, and diagnostic assays. Additional cleared devices span immunology, hemato...

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