

K041635 G5 I HBA1C TEST, G5 II HBA1C TESTAug 16, 2004
61 days to decisionK041635 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k041635/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Jun 16, 2004
Decision date	Aug 16, 2004
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Provalis Diagnostics , Ltd.
Location	Rockville, MD, US
Contact	THOMAS M TSAKERIS
510(k) history	3 submissions · 3 cleared · 2000-2004

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