

**K121842 ARCHITECT HBA1C, ARCHITECT HBA1C, AND
ARCHITECT HBA1C**Dec 12, 2012
170 days to decisionK121842 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k121842/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Jun 25, 2012
Decision date	Dec 12, 2012
Days to decision	170 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Axis-Shield Diagnostics, Ltd.
Location	Dundee, GB
Contact	CLAIRE I DORA
Website	http://www.axis-shield.com/
510(k) history	24 submissions · 24 cleared · 2002-2026

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