

K102510 DIMENSIONS HB1C KIT, MODEL DF105AMay 13, 2011
259 days to decisionK102510 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k102510/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Aug 27, 2010
Decision date	May 13, 2011
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics
Location	Newark, DE, US
Contact	ANNA MARIE ENNIS
510(k) history	92 submissions · 92 cleared · 2008-2025

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