

K091711 S- TEST HEMOGLOBIN ALC (HBA1C), MODEL RC0023Dec 11, 2009
184 days to decisionK091711 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k091711/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Jun 10, 2009
Decision date	Dec 11, 2009
Days to decision	184 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alfa Wassermann Diagnostic Technologies, Inc.
Location	West Caldwell, NJ, US
Contact	HYMAN KATZ
510(k) history	21 submissions · 21 cleared · 2008-2013

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