

**K113437 ACE HEMOGLOBIN ALC(HBALC) REAGENT, ACE
CEDIA T UPTAKE REAGENT, ACE T4 REAGENT, ACE FERRITIN
REAGENT**Aug 6, 2012
259 days to decisionK113437 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k113437/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Nov 21, 2011
Decision date	Aug 6, 2012
Days to decision	259 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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