

**K063306 ACE HEMOGLOBIN A1C REAGENT, MODEL ACI-21,
HEMOGLOBIN A1C CALIBRATORS, MODEL S2-72,
HEMOGLOBIN A1C CONTROLS, MODEL C2-72**Apr 17, 2007
167 days to decisionK063306 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k063306/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Nov 1, 2006
Decision date	Apr 17, 2007
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alfa Wassermann, Inc.
Location	West Caldwell, NJ, US
Contact	MURRAY ROSENTHAL, PHD
510(k) history	5 submissions · 5 cleared · 2007-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k063306/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 22, 2026