

K170623 ACE Hemoglobin A1c (HbA1c) ReagentFeb 27, 2018
363 days to decisionK170623 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k170623/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Mar 1, 2017
Decision date	Feb 27, 2018
Days to decision	363 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alfa Wassermann Diagnostic Technologies, LLC
Location	West Caldwell, NJ, US
Contact	Barbara Phillips
510(k) history	2 submissions · 2 cleared · 2013-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170623/> 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 May 31, 2026