

K904027 ABBOTT VISION(TM) GLYCATED HBFeb 7, 1991
161 days to decisionK904027 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k904027/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Aug 30, 1990
Decision date	Feb 7, 1991
Days to decision	161 days
Third-party review	No

APPLICANT

Company	Abbott Laboratories
Location	Abbott Park, IL, US
Contact	CAROL COOPER
Website	http://www.abbott.com
510(k) history	883 submissions · 868 cleared · 1976-2026

Abbott Laboratories is an American multinational medical devices and health care company headquartered in Abbott Park, Illinois. The company operates in over 160 countries and produces pharmaceuticals, diagnostics, nutritional products, and medical devices. Abbott maintains a substantial FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 1976. The company's cleared devices span chemistry, microbiology, hematology, immunology, and toxicology categories. The latest clearance in 2025 reflects continued regulatory activity and product de...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k904027/>. 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 26, 2026