

**K140654 Hemoglobin A1c Assay, Hemoglobin A1c Calibrators,
Hemoglobin A1c Controls**May 22, 2015
434 days to decisionK140654 · Product code: PDJ · Chemistry
Source: <https://www.510kdatabase.net/k140654/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobin A1c Test System (PDJ)
Date received	Mar 14, 2014
Decision date	May 22, 2015
Days to decision	434 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Laboratories
Location	Abbott Park, IL, US
Contact	JUDITH R WALLACH
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...

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Device record: <https://www.510kdatabase.net/k140654/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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