

K813218 TDX VANCOMYCINDec 8, 1981
29 days to decisionK813218 · Product code: **LEH** · Toxicology
Source: <https://www.510kdatabase.net/k813218/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Vancomycin (LEH)
Date received	Nov 9, 1981
Decision date	Dec 8, 1981
Days to decision	29 days
Third-party review	No

APPLICANT

Company	Abbott Laboratories
Location	Abbott Park, IL, US
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.netDevice record: <https://www.510kdatabase.net/k813218/> 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