

**K043386 VITROS CHEMISTRY PRODUCTS VANC REAGENT,
CALBRATOR KIT 11 AND TDM PERFORMANCE VERIFIERS I, II
AND III**Feb 7, 2005
60 days to decisionK043386 · Product code: **LEH** · Toxicology
Source: <https://www.510kdatabase.net/k043386/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Vancomycin (LEH)
Date received	Dec 9, 2004
Decision date	Feb 7, 2005
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho-Clinical Diagnostics, Inc.
Location	Rochester, NY, US
Contact	CAREY A MAYO
510(k) history	106 submissions · 104 cleared · 1997-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k043386/> 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 28, 2026