

**K983280 VANCOMYCIN EIA ASSAY**Nov 6, 1998  
49 days to decisionK983280 · Product code: **LEH** · Toxicology  
Source: <https://www.510kdatabase.net/k983280/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Vancomycin (LEH)
Date received	Sep 18, 1998
Decision date	Nov 6, 1998
Days to decision	49 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Diagnostic Reagents, Inc.</b>
Location	Walker, MI, US
Contact	YUH-GENG TSAY
510(k) history	66 submissions · 66 cleared · 1982-1998

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k983280/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026