

**K955716 VANCOMYCIN FPIA REAGENT SET**Feb 16, 1996  
63 days to decisionK955716 · Product code: **LEH** · Toxicology  
Source: <https://www.510kdatabase.net/k955716/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Vancomycin (LEH)
Date received	Dec 15, 1995
Decision date	Feb 16, 1996
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sigma Diagnostics, Inc.</b>
Location	Mchenry, IL, US
Contact	WILLIAM R GILBERT
510(k) history	164 submissions · 164 cleared · 1984-2002

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