

**K935296 CLOSTRIDIUM DIFFICILE TOX-B TEST**Apr 26, 1994  
174 days to decisionK935296 · Product code: LLH · Microbiology  
Source: <https://www.510kdatabase.net/k935296/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagents, Clostridium Difficile Toxin (LLH)
Date received	Nov 3, 1993
Decision date	Apr 26, 1994
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Techlab, Inc.</b>
Location	Blacksburg, VA, US
Contact	TRACY B WILKINS
Website	<a href="http://www.techlab.com/">http://www.techlab.com/</a>
510(k) history	36 submissions · 36 cleared · 1992-2019

Techlab, Inc. designs, develops, and manufactures infectious disease diagnostics in the USA. The company specializes in enteric and microbiology diagnostic products distributed worldwide. Techlab holds ISO 13485 certification and MDSAP approval with FDA registration. Techlab received FDA 510(k) clearances from total submissions between 1992 and 2019. The company's portfolio is dominated by microbiology devices, representing 83% of submissions. Notable cleared products include tests for Clostridioides difficile, Helicobacter pylori, parasites, and fecal biomarkers. Techlab...

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