

K030404 C. DIFFICILE TOX A/B IIApr 24, 2003
77 days to decisionK030404 · Product code: LLH · Microbiology
Source: <https://www.510kdatabase.net/k030404/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagents, Clostridium Difficile Toxin (LLH)
Date received	Feb 6, 2003
Decision date	Apr 24, 2003
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Techlab, Inc.
Location	Blacksburg, VA, US
Contact	DAVID A WALL
Website	http://www.techlab.com/
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...
