

**K944791 ENTAMOEBA TEST**Mar 9, 1995  
162 days to decisionK944791 · Product code: **KHW** · Microbiology  
Source: <https://www.510kdatabase.net/k944791/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Id, Ha, Cep, Entamoeba Histolytica & Rel. Spp. (KHW)
Date received	Sep 28, 1994
Decision date	Mar 9, 1995
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Techlab, Inc.</b>
Location	Blacksburg, VA, US
Contact	PATRICIA SHRADER
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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