

K173217 CAMPYLOBACTER QUIK CHEKJan 22, 2018
111 days to decisionK173217 · Product code: **LQP** · Microbiology
Source: <https://www.510kdatabase.net/k173217/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Campylobacter Spp. (LQP)
Date received	Oct 3, 2017
Decision date	Jan 22, 2018
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Techlab, Inc.
Location	Blacksburg, VA, US
Contact	Donna T. Link
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...

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Device record: <https://www.510kdatabase.net/k173217/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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