

K191442 Campylobacter ChekJun 20, 2019
21 days to decisionK191442 · Product code: **LQP** · Microbiology
Source: <https://www.510kdatabase.net/k191442/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Campylobacter Spp. (LQP)
Date received	May 30, 2019
Decision date	Jun 20, 2019
Days to decision	21 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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