

K254167 MDx-Chex for BCYMar 17, 2026
84 days to decisionK254167 · Product code: **PMN** · Microbiology
Source: <https://www.510kdatabase.net/k254167/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assayed External Control Material For Microbiology Nucleic Acid Amplification (nat) Assays (PMN)
Date received	Dec 23, 2025
Decision date	Mar 17, 2026
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Streck, LLC
Location	La Vista, NE, US
Contact	Megan Hiveley
Website	https://www.streck.com
510(k) history	2 submissions · 2 cleared · 2026-2026

Streck, LLC develops quality control products, sample stabilization solutions, and laboratory diagnostic tools. Founded in 1971, the company is headquartered in La Vista, Nebraska, and operates with a mission to ensure every laboratory test result is trusted and reliable. Streck has received FDA 510(k) clearances from total submissions, with all submissions focused on Microbiology devices. The company's first clearance was in 2026, with the latest clearance also in 2026, demonstrating active regulatory engagement in this category. The company specializes in Microbiology q...