

**K260041 MDx-Chex for BCP**Mar 27, 2026  
80 days to decisionK260041 · Product code: **PMN** · Microbiology  
Source: <https://www.510kdatabase.net/k260041/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assayed External Control Material For Microbiology Nucleic Acid Amplification (nat) Assays (PMN)
Date received	Jan 6, 2026
Decision date	Mar 27, 2026
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Streck, LLC</b>
Location	La Vista, NE, US
Contact	Iris Servellon
Website	<a href="https://www.streck.com">https://www.streck.com</a>
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...