

**K254166 MDx-Chex for BCN**Mar 23, 2026  
90 days to decisionK254166 · Product code: **PMN** · Microbiology  
Source: <https://www.510kdatabase.net/k254166/>**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	Dec 23, 2025
Decision date	Mar 23, 2026
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Streck</b>
Location	La Vista, NE, US
Contact	Iris Servellon
510(k) history	33 submissions · 33 cleared · 2005-2026

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