

**K231221 MDx-Chex for BC-GP**

Jul 27, 2023  
90 days to decision

K231221 · Product code: **PMN** · Microbiology  
Source: <https://www.510kdatabase.net/k231221/>

**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	Apr 28, 2023
Decision date	Jul 27, 2023
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	Megan Hiveley
510(k) history	33 submissions · 33 cleared · 2005-2026

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