

K212576 MDx-Chex for BCID2Jan 19, 2022
156 days to decisionK212576 · Product code: **PMN** · Microbiology
Source: <https://www.510kdatabase.net/k212576/>**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	Aug 16, 2021
Decision date	Jan 19, 2022
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Streck, Inc.
Location	La Vista, NE, US
Contact	Deborah S. Kipp
510(k) history	3 submissions · 2 cleared · 2020-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212576/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026