

**K212204 Synovasure Alpha Defensin Lateral Flow Test Kit (1 Kit), Synovasure Alpha Defensin Lateral Flow Test Kit (5 Test), Synovasure Alpha Defensin Lateral Flow Test Kit (10 Test), Synovasure Alpha Defensin Flow Test Kit (30 Test), Synovasure Alpha Defensin Control Kit**Aug 11, 2021  
27 days to decisionK212204 · Product code: **QGN** · Microbiology  
Source: <https://www.510kdatabase.net/k212204/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lateral Flow Immunochromatography Assay For Host Infection Biomarkers (QGN)
Date received	Jul 15, 2021
Decision date	Aug 11, 2021
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cd Diagnostics, Inc.</b>
Location	Claymont, DE, US
Contact	Pragnya Bakka
510(k) history	2 submissions · 1 cleared · 2019-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212204/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026