

K243410 simpli-COLLECT STI TestJan 30, 2025
90 days to decisionK243410 · Product code: **QYA** · Microbiology
Source: <https://www.510kdatabase.net/k243410/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System For Detection Of Nucleic Acid From Non-viral Microorganism(s) Causing Stis Using Specimens Collected At Home (QYA)
Date received	Nov 1, 2024
Decision date	Jan 30, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Molecular
Location	Des Plaines, IL, US
Contact	Stacy Ferguson
510(k) history	2 submissions · 2 cleared · 2024-2025

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