

**K222379 Alinity m STI Assay**Mar 3, 2023  
210 days to decisionK222379 · Product code: **QEP** · Microbiology  
Source: <https://www.510kdatabase.net/k222379/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nucleic Acid Detection System For Non-viral Microorganism(s) Causing Sexually Transmitted Infections (QEP)
Date received	Aug 5, 2022
Decision date	Mar 3, 2023
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Abbott Molecular, Inc.</b>
Location	Des Plaines, IL, US
Contact	Paul Matushek
510(k) history	17 submissions · 16 cleared · 2008-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222379/> 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 14, 2026