

**K202977 Alinity m STI Assay**Apr 29, 2022  
576 days to decisionK202977 · Product code: **QEP** · Microbiology  
Source: <https://www.510kdatabase.net/k202977/>**SUBMISSION DETAILS**

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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	Sep 30, 2020
Decision date	Apr 29, 2022
Days to decision	576 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202977/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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