

K241580 Alinity m SARS-CoV-2 AMP Kit (09N78-096)Dec 6, 2024
186 days to decisionK241580 · Product code: **QQX** · Microbiology
Source: <https://www.510kdatabase.net/k241580/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Specimen Nucleic Acid Sars-cov-2 Test (QQX)
Date received	Jun 3, 2024
Decision date	Dec 6, 2024
Days to decision	186 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Alinity m SARS-CoV-2 CTRL Kit (09N78-086)

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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