

K221925 ID NOW COVID-19 2.0Aug 10, 2023
405 days to decisionK221925 · Product code: **QWR** · Microbiology
Source: <https://www.510kdatabase.net/k221925/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Simple Point-of-care Device To Detect Sar-cov-2 Nucleic Acid Targets From Clinical Specimens In Near-patient Settings (QWR)
Date received	Jul 1, 2022
Decision date	Aug 10, 2023
Days to decision	405 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Diagnostics Scarborough, Inc.
Location	Scarborough, ME, US
Contact	Jessica E. Stahle
510(k) history	6 submissions · 6 cleared · 2019-2025

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