

K243518 BinaxNOW™ COVID-19 Antigen Self TestFeb 11, 2025
90 days to decisionK243518 · Product code: QYT · Microbiology
Source: <https://www.510kdatabase.net/k243518/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Covid-19 Antigen Test (QYT)
Date received	Nov 13, 2024
Decision date	Feb 11, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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