

K250273 BinaxNOW COVID-19 Ag Card

Jun 13, 2025
134 days to decision

K250273 · Product code: **QVF** · Microbiology
Source: <https://www.510kdatabase.net/k250273/>

SUBMISSION DETAILS

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Dual Track |
| Device classification | Simple Point-of-care Device To Directly Detect Sars-cov-2 Viral Targets From Clinical Specimens In Near-patient Settings (QVF) |
| Date received | Jan 30, 2025 |
| Decision date | Jun 13, 2025 |
| Days to decision | 134 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 |
