

K253882 CorDx Tyfast COVID-19 Ag Rapid Test RxJun 1, 2026
179 days to decisionK253882 · Product code: **QVF** · Microbiology
Source: <https://www.510kdatabase.net/k253882/>**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 | Dec 4, 2025 |
| Decision date | Jun 1, 2026 |
| Days to decision | 179 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | CorDx, Inc. |
| Location | San Diego, CA, US |
| Contact | Aiiso Ally yang |
| 510(k) history | 2 submissions · 2 cleared · 2024-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253882/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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