

K251753 GenaCheck COVID-19 Rapid Self-TestSep 5, 2025
88 days to decisionK251753 · Product code: **QYT** · Microbiology
Source: <https://www.510kdatabase.net/k251753/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Covid-19 Antigen Test (QYT)
Date received	Jun 9, 2025
Decision date	Sep 5, 2025
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Genabio Diagnostics, Inc.
Location	Bedford, MA, US
Contact	Han Si
Website	https://genabiodiagnostics.com
510(k) history	2 submissions · 2 cleared · 2024-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251753/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026