

**K241915 CareSuperb™ COVID-19 Antigen Home Test**Jan 29, 2025  
212 days to decisionK241915 · Product code: QYT · Microbiology  
Source: <https://www.510kdatabase.net/k241915/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Covid-19 Antigen Test (QYT)
Date received	Jul 1, 2024
Decision date	Jan 29, 2025
Days to decision	212 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Access Bio, Inc.</b>
Location	Somerset, NJ, US
Contact	Sung Jang
510(k) history	3 submissions · 3 cleared · 2020-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241915/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026