

K251604 CareSuperb COVID-19/Flu A&B Antigen Combo Home TestAug 22, 2025
87 days to decisionK251604 · Product code: **SCA** · Microbiology
Source: <https://www.510kdatabase.net/k251604/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Respiratory Virus Antigen Detection Test (SCA)
Date received	May 27, 2025
Decision date	Aug 22, 2025
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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