

K251085 iHealth Flu A&B/COVID-19/RSV Rapid TestDec 12, 2025
247 days to decisionK251085 · Product code: **SCA** · Microbiology
Source: <https://www.510kdatabase.net/k251085/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Respiratory Virus Antigen Detection Test (SCA)
Date received	Apr 9, 2025
Decision date	Dec 12, 2025
Days to decision	247 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	iHealth Flu A&B/COVID-19/RSV Rapid Test Pro

APPLICANT

Company	Ihealth Labs, Inc.
Location	Sunnyvale, CA, US
Contact	Yange Wang
510(k) history	4 submissions · 4 cleared · 2024-2025

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