

K191534 ID NOW Influenza A & B 2Jul 11, 2019
31 days to decisionK191534 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k191534/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Jun 10, 2019
Decision date	Jul 11, 2019
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Diagnostics Scarborough, Inc.
Location	Scarborough, ME, US
Contact	Angela Drysdale
510(k) history	6 submissions · 6 cleared · 2019-2025

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