

**K243455 cobas Respiratory 4-flex for use on the cobas  
5800/6800/8800 Systems**Jul 31, 2025  
266 days to decisionK243455 · Product code: **QOF** · Microbiology  
Source: <https://www.510kdatabase.net/k243455/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-target Respiratory Specimen Nucleic Acid Test Including Sars-cov-2 And Other Microbial Agents (QOF)
Date received	Nov 7, 2024
Decision date	Jul 31, 2025
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Molecular Systems, Inc.</b>
Location	Somerville, NJ, US
Contact	Claudia Machay
510(k) history	49 submissions · 46 cleared · 1993-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243455/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026