

K243406 cobas liat SARS-CoV-2, Influenza A/B & RSV nucleic acid testApr 25, 2025
175 days to decisionK243406 · Product code: **QOF** · Microbiology
Source: <https://www.510kdatabase.net/k243406/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Multi-target Respiratory Specimen Nucleic Acid Test Including Sars-cov-2 And Other Microbial Agents (QOF)
Date received	Nov 1, 2024
Decision date	Apr 25, 2025
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Roche Molecular Systems, Inc.
Location	Somerville, NJ, US
Contact	Sumedha Sinha
510(k) history	49 submissions · 46 cleared · 1993-2025

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