

K243346 cobas liat SARS-CoV-2 v2 nucleic acid testApr 11, 2025
165 days to decisionK243346 · Product code: **QWR** · Microbiology
Source: <https://www.510kdatabase.net/k243346/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Simple Point-of-care Device To Detect Sar-cov-2 Nucleic Acid Targets From Clinical Specimens In Near-patient Settings (QWR)
Date received	Oct 28, 2024
Decision date	Apr 11, 2025
Days to decision	165 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	Deborah Leu
510(k) history	49 submissions · 46 cleared · 1993-2025

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