

K253759 cobas liat CT/NG/MG nucleic acid testMay 15, 2026
171 days to decisionK253759 · Product code: **QEP** · Microbiology
Source: <https://www.510kdatabase.net/k253759/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Nucleic Acid Detection System For Non-viral Microorganism(s) Causing Sexually Transmitted Infections (QEP)
Date received	Nov 25, 2025
Decision date	May 15, 2026
Days to decision	171 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	51 submissions · 48 cleared · 1993-2026

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