

K252481 cobas CMVNov 3, 2025
88 days to decisionK252481 · Product code: **PAB** · Microbiology
Source: <https://www.510kdatabase.net/k252481/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cytomegalovirus (cmv) Dna Quantitative Assay (PAB)
Date received	Aug 7, 2025
Decision date	Nov 3, 2025
Days to decision	88 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	Sun Austin
510(k) history	49 submissions · 46 cleared · 1993-2025

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