

K243485 Alinity m CMVJul 1, 2025
235 days to decisionK243485 · Product code: **PAB** · Microbiology
Source: <https://www.510kdatabase.net/k243485/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cytomegalovirus (cmv) Dna Quantitative Assay (PAB)
Date received	Nov 8, 2024
Decision date	Jul 1, 2025
Days to decision	235 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Molecular, Inc.
Location	Des Plaines, IL, US
Contact	Stacy Ferguson
510(k) history	17 submissions · 16 cleared · 2008-2025

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