

K243489 Alinity m EBV (09N43-095)Jul 28, 2025
258 days to decisionK243489 · Product code: **QLX** · Microbiology
Source: <https://www.510kdatabase.net/k243489/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nucleic Acid Amplification Test For The Quantitation Of Epstein-barr Virus (ebv) Dna (QLX)
Date received	Nov 12, 2024
Decision date	Jul 28, 2025
Days to decision	258 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	Jennifer Peterson
510(k) history	17 submissions · 16 cleared · 2008-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243489/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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