

K212778 Alinity m EBV AMP Kit (List No. 09N43-095), Alinity m EBV CTRL Kit (List No. 09N43-085), Alinity m EBV CAL Kit (List No. 09N43-075)Jul 15, 2022
317 days to decisionK212778 · Product code: **QLX** · Microbiology
Source: <https://www.510kdatabase.net/k212778/>**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	Sep 1, 2021
Decision date	Jul 15, 2022
Days to decision	317 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	Gina Sammarco
510(k) history	17 submissions · 16 cleared · 2008-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212778/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026