

K233349 Alinity m HSV 1 & 2 / VZVMay 3, 2024
217 days to decisionK233349 · Product code: **PGI** · Microbiology
Source: <https://www.510kdatabase.net/k233349/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Herpes Virus (vzv, Hsv1, Hsv2), Dna Detection Assay For Cutaneous And Mucocutaneous Lesion Samples (PGI)
Date received	Sep 29, 2023
Decision date	May 3, 2024
Days to decision	217 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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