

K253539 Alere NT-proBNP for Alinity iFeb 18, 2026
97 days to decisionK253539 · Product code: **NBC** · Chemistry
Source: <https://www.510kdatabase.net/k253539/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Natriuretic Peptide (NBC)
Date received	Nov 13, 2025
Decision date	Feb 18, 2026
Days to decision	97 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Axis-Shield Diagnostics, Ltd.
Location	Dundee, GB
Contact	Claire Dora
Website	http://www.axis-shield.com/
510(k) history	24 submissions · 24 cleared · 2002-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253539/> 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 14, 2026