

**K241176 Alere NT-proBNP for Alinity i Reagent Kit**Jan 16, 2025  
262 days to decisionK241176 · Product code: **NBC** · Chemistry  
Source: <https://www.510kdatabase.net/k241176/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Natriuretic Peptide (NBC)
Date received	Apr 29, 2024
Decision date	Jan 16, 2025
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Abbott Laboratories</b>
Contact	Claire Dora

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241176/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026