

K253051 i-STAT hs-Tnl cartridge with the i-STAT Alinity SystemJun 11, 2026
262 days to decisionK253051 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k253051/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Sep 22, 2025
Decision date	Jun 11, 2026
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Point of Care, Inc.
Location	Princeton, NJ, US
Contact	Jacquelyn Gesumaria
510(k) history	21 submissions · 21 cleared · 2011-2026

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