

**K202525 Alinity i STAT High Sensitivity Troponin-I**May 19, 2022  
625 days to decisionK202525 · Product code: **MMI** · Chemistry  
Source: <https://www.510kdatabase.net/k202525/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)         |
| Submission type       | Traditional                                |
| Device classification | Immunoassay Method, Troponin Subunit (MMI) |
| Date received         | Sep 1, 2020                                |
| Decision date         | May 19, 2022                               |
| Days to decision      | 625 days                                   |
| Third-party review    | No   |
| Summary / Statement   | Summary                                    |

**APPLICANT**

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|----------------|---|
| Company        | <b>Abbott Laboratories Diagnostics Division</b> |
| Location       | Abbott Park, IL, US                             |
| Contact        | Judi Wallach                                    |
| 510(k) history | 4 submissions · 4 cleared · 2019-2024           |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202525/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026