

**K191595 ARCHITECT STAT High Sensitivity Troponin-I**Sep 13, 2019  
88 days to decisionK191595 · Product code: **MMI** · Chemistry  
Source: <https://www.510kdatabase.net/k191595/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Jun 17, 2019
Decision date	Sep 13, 2019
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191595/> 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