

**K013278 TINA-QUANT APOLIPOPROTEIN A-1 VER.2**Nov 15, 2001  
45 days to decisionK013278 · Product code: **DEL** · Chemistry  
Source: <https://www.510kdatabase.net/k013278/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipoprotein X, Antigen, Antiserum, Control (DEL)
Date received	Oct 1, 2001
Decision date	Nov 15, 2001
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Roche Diagnostics Corp.</b>
Location	Indianapolis, IN, US
Contact	HELEN TORNEY
510(k) history	264 submissions · 263 cleared · 1999-2013

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013278/> 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 June 9, 2026