

**K013249 TINA-QUANT APOLIPOPROTEIN VER.2**Nov 16, 2001  
49 days to decisionK013249 · Product code: **DER** · Chemistry  
Source: <https://www.510kdatabase.net/k013249/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alpha-1-lipoprotein, Antigen, Antiserum, Control (DER)
Date received	Sep 28, 2001
Decision date	Nov 16, 2001
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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