

**K122722 COBAS C TINA-QUANT LIPOPROTEIN (A) GEN 2  
ASSAY MODEL 05852625190**Nov 29, 2012  
85 days to decisionK122722 · Product code: **DFC** · Chemistry  
Source: <https://www.510kdatabase.net/k122722/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipoprotein, Low-density, Antigen, Antiserum, Control (DFC)
Date received	Sep 5, 2012
Decision date	Nov 29, 2012
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary
Other names	PRECISSET LP (A) GEN 2 CALIFRATOR SET MODEL 05852641160

**APPLICANT**

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Company	<b>Roche Diagnostics</b>
Location	Indianapolis, IN, US
Contact	LISA K KLINEDINST
Website	<a href="https://diagnostics.roche.com">https://diagnostics.roche.com</a>
510(k) history	182 submissions · 180 cleared · 2005-2026

Roche Diagnostics is a Swiss multinational healthcare company specializing in diagnostic devices and solutions. The company operates its U.S. diagnostics division from Indianapolis. Roche Diagnostics maintains a strong FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 2005. The company's portfolio spans chemistry devices, immunology assays, microbiology testing, and hematology systems. The latest clearance in 2026 reflects continued innovation and regulatory engagement. Recent cleared devices include glucose monitoring systems, elec...