

**K121610 COBAS C 501 TINA-QUANT HBA1CDX GEN.3 ASSAY**Aug 8, 2013  
433 days to decisionK121610 · Product code: **PDJ** · Chemistry  
Source: <https://www.510kdatabase.net/k121610/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobin A1c Test System (PDJ)
Date received	Jun 1, 2012
Decision date	Aug 8, 2013
Days to decision	433 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diagnostics Operations</b>
Location	Indianapolis, IN, US
Contact	Susan Hollandbeck
510(k) history	5 submissions · 5 cleared · 2012-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121610/> 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