

K052464 TINA-QUANT HEMOGLOBIN A1C GEN.2 TESTSep 30, 2005
22 days to decisionK052464 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k052464/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Sep 8, 2005
Decision date	Sep 30, 2005
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	THERESA M AMBROSE
510(k) history	264 submissions · 263 cleared · 1999-2013

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