

**K102914 TQ HBA1C GEN3**Jan 20, 2011  
111 days to decisionK102914 · Product code: **LCP** · Chemistry  
Source: <https://www.510kdatabase.net/k102914/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Oct 1, 2010
Decision date	Jan 20, 2011
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche</b>
Location	Indianapolis, IN, US
Contact	KATHIE J GOODWIN
510(k) history	2 submissions · 2 cleared · 2011-2012

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