

**K111128 LABONACHECK A1C**Sep 13, 2012  
511 days to decisionK111128 · Product code: **LCP** · Chemistry  
Source: <https://www.510kdatabase.net/k111128/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Apr 21, 2011
Decision date	Sep 13, 2012
Days to decision	511 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ceragem International, Inc.</b>
Location	Washington, DC, US
Contact	RAYMOND CHUNG
510(k) history	3 submissions · 3 cleared · 2006-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111128/> 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 June 5, 2026