

**K031296 LIQUI-HEME GLYCO A1C ASSAY**Oct 15, 2004  
541 days to decisionK031296 · Product code: **LCP** · Chemistry  
Source: <https://www.510kdatabase.net/k031296/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Apr 23, 2003
Decision date	Oct 15, 2004
Days to decision	541 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Biodiagnostic Intl</b>
Location	Mchenry, IL, US
Contact	PAUL ANAND
510(k) history	11 submissions · 11 cleared · 1983-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031296/> 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 29, 2026