

**K923153 HEMOCARD, HEMOGLOBIN C ASSAY**Jan 27, 1994  
577 days to decisionK923153 · Product code: **MLL** · Hematology  
Source: <https://www.510kdatabase.net/k923153/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobin C (abnormal Hemoglobin Variant) (MLL)
Date received	Jun 29, 1992
Decision date	Jan 27, 1994
Days to decision	577 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Isolab, Inc.</b>
Location	Mchenry, IL, US
Contact	JANET D PERKINS
510(k) history	44 submissions · 44 cleared · 1977-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k923153/> 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 28, 2026