

**K053559 PF4 ENHANCED SOLID PHASE ELISA**Jan 20, 2006  
30 days to decisionK053559 · Product code: **LCO** · Hematology  
Source: <https://www.510kdatabase.net/k053559/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Platelet Factor 4 Radioimmunoassay (LCO)
Date received	Dec 21, 2005
Decision date	Jan 20, 2006
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Genetic Testing Institute</b>
Location	Mchenry, IL, US
Contact	LEIGH ANN TIDEY
510(k) history	6 submissions · 6 cleared · 1984-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k053559/> 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 24, 2026