

**K983379 GTI-PF4 ELISA**Mar 9, 1999  
165 days to decisionK983379 · Product code: **LCO** · Hematology  
Source: <https://www.510kdatabase.net/k983379/>**SUBMISSION DETAILS**

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|                       |                                          |
|-----------------------|------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Traditional                              |
| Device classification | Platelet Factor 4 Radioimmunoassay (LCO) |
| Date received         | Sep 25, 1998                             |
| Decision date         | Mar 9, 1999                              |
| Days to decision      | 165 days                                 |
| Third-party review    | No                                       |
| Summary / Statement   | Statement                                |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Genetic Testing Institute</b>      |
| Location       | Mchenry, IL, US                       |
| Contact        | MICHAEL MOGHADDAM                     |
| 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/k983379/> 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