

**K002350 REFACTO LABORATORY STANDARD**Oct 5, 2000  
64 days to decisionK002350 · Product code: **GGP** · Hematology  
Source: <https://www.510kdatabase.net/k002350/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Aug 2, 2000
Decision date	Oct 5, 2000
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>The Genetics Institute</b>
Location	Cambridge, MA, US
Contact	MARYANN KRANE
510(k) history	1 submissions · 1 cleared · 2000-2000

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