

**K033059 HERPES GROUP IGG**Nov 26, 2003  
58 days to decisionK033059 · Product code: **LGC** · Microbiology  
Source: <https://www.510kdatabase.net/k033059/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Herpes Simplex Virus, Non-specific (LGC)
Date received	Sep 29, 2003
Decision date	Nov 26, 2003
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Trinity Biotech, Inc.</b>
Location	Jamestown, NY, US
Contact	BONNIE DEJOY
510(k) history	2 submissions · 2 cleared · 1997-2003

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