

**K001525 CAPTIA SYPHILIS-G ELISA TEST SYSTEM**Nov 29, 2000  
197 days to decisionK001525 · Product code: **LIP** · Microbiology  
Source: <https://www.510kdatabase.net/k001525/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorption Assay, Treponema Pallidum (LIP)
Date received	May 16, 2000
Decision date	Nov 29, 2000
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Trinity Biotech, Plc</b>
Location	Jamestown, NY, US
Contact	WAYNE KVETKOSKY
510(k) history	5 submissions · 5 cleared · 1999-2002

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