

**K102400 SYPHILIS HEALTH CHECK**Aug 1, 2011  
342 days to decisionK102400 · Product code: **LIP** · Microbiology  
Source: <https://www.510kdatabase.net/k102400/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorption Assay, Treponema Pallidum (LIP)
Date received	Aug 24, 2010
Decision date	Aug 1, 2011
Days to decision	342 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Diagnostics Direct, LLC</b>
Location	East Stroudsburg, PA, US
Contact	Gary Lehnus
510(k) history	1 submissions · 1 cleared · 2011-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k102400/> 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 18, 2026