

**K992552 COPALIS TREPONEMAL ANTIGEN TOTAL ANTIBODY ASSAY**Dec 16, 1999  
139 days to decisionK992552 · Product code: **LIP** · Microbiology  
Source: <https://www.510kdatabase.net/k992552/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorption Assay, Treponema Pallidum (LIP)
Date received	Jul 30, 1999
Decision date	Dec 16, 1999
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>DiaSorin, Inc.</b>
Location	Ellicott City, MD, US
Contact	JUDITH J SMITH
510(k) history	71 submissions · 70 cleared · 1998-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k992552/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026