

**K921523 OPUS(R) TOXO-G TEST SYSTEM**Sep 14, 1992  
167 days to decisionK921523 · Product code: **LGD** · Microbiology  
Source: <https://www.510kdatabase.net/k921523/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	Mar 31, 1992
Decision date	Sep 14, 1992
Days to decision	167 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Pb Diagnostics, Inc.</b>
Location	Westwood, MA, US
Contact	KATHLEEN DRAY-LYONS
510(k) history	4 submissions · 4 cleared · 1991-1993

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k921523/> 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 May 14, 2026