

**K073501 ROCHE ELECSYS TOXO IGG TEST SYSTEM, ROCHE  
ELECSYS PRECICONTROL TOXO IGG**Jun 9, 2008  
179 days to decisionK073501 · Product code: **LGD** · Microbiology  
Source: <https://www.510kdatabase.net/k073501/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	Dec 13, 2007
Decision date	Jun 9, 2008
Days to decision	179 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Roche Diagnostics Corp.</b>
Location	Indianapolis, IN, US
Contact	THERESA A BUSH
510(k) history	264 submissions · 263 cleared · 1999-2013

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k073501/> Data sourced from FDA 510(k) public records (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. - Generated June 9, 2026