

**K913505 ENZYGNOST TOXOPLASMOSIS/IGM**Mar 4, 1992  
210 days to decisionK913505 · Product code: **LGD** · Microbiology  
Source: <https://www.510kdatabase.net/k913505/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	Aug 7, 1991
Decision date	Mar 4, 1992
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Behring Diagnostics, Inc.</b>
Location	Mchenry, IL, US
Contact	JOHN E HUGHES
510(k) history	145 submissions · 145 cleared · 1976-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k913505/> 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 28, 2026