

K101946 VIDAS TOXO IGG AVIDITYMay 18, 2011
310 days to decisionK101946 · Product code: **LGD** · Microbiology
Source: <https://www.510kdatabase.net/k101946/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	Jul 12, 2010
Decision date	May 18, 2011
Days to decision	310 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	bioMerieux, Inc.
Location	Mchenry, IL, US
Contact	MARLENE CHAVAROCHE
510(k) history	251 submissions · 250 cleared · 1983-2026

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