

**K031506 ACCESS IMMUNOASSAY SYSTEM TOXO IGM II ASSAY**Jun 2, 2003  
19 days to decisionK031506 · Product code: **LGD** · Microbiology  
Source: <https://www.510kdatabase.net/k031506/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	May 14, 2003
Decision date	Jun 2, 2003
Days to decision	19 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Beckman Coulter, Inc.</b>
Location	Chaska, MN, US
Contact	LYNN WEIST
Website	<a href="https://www.beckmancoulter.com">https://www.beckmancoulter.com</a>
510(k) history	270 submissions · 270 cleared · 1993-2026

Beckman Coulter, Inc. is a diagnostic device manufacturer headquartered in Chaska, US. The company specializes in clinical laboratory and immunodiagnostic systems. Beckman Coulter has received FDA 510(k) clearances from total submissions since its first clearance in 1993. The company maintains active regulatory status, with the latest clearance in 2026. Its portfolio spans chemistry devices, microbiology testing systems, hematology analyzers, and immunoassay platforms. Recent cleared devices include chemistry assays for cardiac markers, microbiology susceptibility panels,...