

**K090847 PLATELIA TOXO IGM KIT MODEL 26211**Jul 1, 2009  
93 days to decisionK090847 · Product code: **LGD** · Microbiology  
Source: <https://www.510kdatabase.net/k090847/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	Mar 30, 2009
Decision date	Jul 1, 2009
Days to decision	93 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Bio-Rad Laboratories</b>
Location	Hauts-De-Seine, FR
Contact	PRIYA BONDRE
Website	<a href="http://www.bio-rad.com">http://www.bio-rad.com</a>
510(k) history	46 submissions · 45 cleared · 2007-2019

Bio-Rad Laboratories is an American biotechnology firm founded in 1952 in Berkeley, California. The company develops and manufactures specialized products for life science research and clinical diagnostics, with operations worldwide. Bio-Rad has received FDA 510(k) clearances from total submissions between 2007 and 2019. The company's cleared devices span chemistry devices, microbiology, and immunology categories, with notable focus on diagnostic control materials and multiplex immunoassay systems. This regulatory record reflects the company's historical activity in the c...

---