

K913106 ABBOTT IMX TOXO IGM POSITIVE CONTROLNov 29, 1991
140 days to decisionK913106 · Product code: **LGD** · Microbiology
Source: <https://www.510kdatabase.net/k913106/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	Jul 12, 1991
Decision date	Nov 29, 1991
Days to decision	140 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Abbott Laboratories
Location	Abbott Park, IL, US
Contact	JEAN FRYDMAN
Website	http://www.abbott.com
510(k) history	883 submissions · 868 cleared · 1976-2026

Abbott Laboratories is an American multinational medical devices and health care company headquartered in Abbott Park, Illinois. The company operates in over 160 countries and produces pharmaceuticals, diagnostics, nutritional products, and medical devices. Abbott maintains a substantial FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 1976. The company's cleared devices span chemistry, microbiology, hematology, immunology, and toxicology categories. The latest clearance in 2025 reflects continued regulatory activity and product de...
