

**K080696 ARCHITECT IPHENYTOIN REAGENTS AND
ARCHITECH IPHENYTOIN CALIBRATORS WITH MODELS 1P34,
AND 1P34-01**Sep 11, 2008
183 days to decisionK080696 · Product code: **DIP** · Toxicology
Source: <https://www.510kdatabase.net/k080696/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Diphenylhydantoin (DIP)
Date received	Mar 12, 2008
Decision date	Sep 11, 2008
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Laboratories
Location	Abbott Park, IL, US
Contact	CAROL JOCHUM
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...