

K153730 ARCHITECT Syphilis TP Reagent, ARCHITECT Syphilis TP Calibrator, ARCHITECT Syphilis TP ControlJun 15, 2016
170 days to decisionK153730 · Product code: **LIP** · Microbiology
Source: <https://www.510kdatabase.net/k153730/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorption Assay, Treponema Pallidum (LIP)
Date received	Dec 28, 2015
Decision date	Jun 15, 2016
Days to decision	170 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Laboratories
Location	Abbott Park, IL, US
Contact	Laura Yelviggi Joglekar
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...

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Device record: <https://www.510kdatabase.net/k153730/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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