

K112343 TREPONEMA PALLIDUM TREPONEMAL TEST REAGENTSJan 20, 2012
158 days to decisionK112343 · Product code: **LIP** · Microbiology
Source: <https://www.510kdatabase.net/k112343/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorption Assay, Treponema Pallidum (LIP)
Date received	Aug 15, 2011
Decision date	Jan 20, 2012
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary
Other names	QUALITY CONTROL MATERIALS

APPLICANT

Company	Siemens Healthcare Diagnostics, Inc.
Location	New York, NY, US
Contact	KIRA GORDON
Website	https://www.siemens-healthineers.com
510(k) history	152 submissions · 151 cleared · 2008-2026

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