

K150358 Gold Standard Diagnostics AIX1000 Rapid Plasma Reagin (RPR) Automated Test SystemNov 12, 2015
273 days to decisionK150358 · Product code: **GMQ** · Microbiology
Source: <https://www.510kdatabase.net/k150358/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, Nontreponemal, All (GMQ)
Date received	Feb 12, 2015
Decision date	Nov 12, 2015
Days to decision	273 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gold Standard Diagnostics
Location	Davis, CA, US
Contact	NAPOLEON MONCE
510(k) history	14 submissions · 14 cleared · 2012-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150358/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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