

K250249 Gold Standard Diagnostics (GSD) AIX1000 Rapid Plasma Reagin (RPR) Automated Test SystemOct 10, 2025
256 days to decisionK250249 · Product code: **GMQ** · Microbiology
Source: <https://www.510kdatabase.net/k250249/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, Nontreponemal, All (GMQ)
Date received	Jan 27, 2025
Decision date	Oct 10, 2025
Days to decision	256 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gold Standard Diagnostics, LLC
Location	Davis, CA, US
Contact	Douglas McGarvey
510(k) history	1 submissions · 1 cleared · 2025-2025

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