

**K203295 Gold Standard Diagnostics Borrelia burgdorferi IGM  
ELISA Test Kit**Mar 22, 2021  
133 days to decisionK203295 · Product code: **LSR** · Microbiology  
Source: <https://www.510kdatabase.net/k203295/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Nov 9, 2020
Decision date	Mar 22, 2021
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gold Standard Diagnostics</b>
Location	Davis, CA, US
Contact	Napoleon Monce
510(k) history	14 submissions · 14 cleared · 2012-2021

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203295/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026