

**K131334 HERPES SIMPLEX VIRUS TYPE 1 IGG ELISA TEST**Feb 28, 2014  
295 days to decisionK131334 · Product code: **MXJ** · Microbiology  
Source: <https://www.510kdatabase.net/k131334/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunosorbent Assay, Herpes Simplex Virus, Hsv-1 (MXJ)
Date received	May 9, 2013
Decision date	Feb 28, 2014
Days to decision	295 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gold Standard Diagnostics</b>
Location	Davis, CA, US
Contact	NAPLEON 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/k131334/> 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