

**K131330 GOLD STANDARD DIAGNOSTICS ANTI-NUCLEAR  
ANTIBODY (ANA) SCREEN ELISA TEST KIT**Jan 28, 2014  
265 days to decisionK131330 · Product code: **LJM** · Immunology  
Source: <https://www.510kdatabase.net/k131330/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	May 8, 2013
Decision date	Jan 28, 2014
Days to decision	265 days
Third-party review	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/k131330/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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