

**K994071 RHIGENE ANA ELISA TEST SYSTEM**Jan 18, 2000  
47 days to decisionK994071 · Product code: **LJM** · Immunology  
Source: <https://www.510kdatabase.net/k994071/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Dec 2, 1999
Decision date	Jan 18, 2000
Days to decision	47 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Rhigene, Inc.</b>
Location	Des Plaines, IL, US
Contact	DAVE KOLESAR
510(k) history	15 submissions · 15 cleared · 2000-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k994071/> 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 June 29, 2026