

**K900617 SERATEST ENA [SSA] KIT**Feb 23, 1990  
15 days to decisionK900617 · Product code: LLL · Immunology  
Source: <https://www.510kdatabase.net/k900617/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Feb 8, 1990
Decision date	Feb 23, 1990
Days to decision	15 days
Third-party review	No

**APPLICANT**

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Company	<b>Hemagen Diagnostics, Inc.</b>
Location	Waltham, MA, US
Contact	CHARLES A WILLAND
Website	<a href="http://www.hemagen.com/">http://www.hemagen.com/</a>
510(k) history	52 submissions · 52 cleared · 1986-2004

Hemagen Diagnostics, Inc. was founded in 1985 by scientists from Boston University School of Medicine. The company provides clinical diagnostic solutions specializing in immunology devices for autoimmune and infectious disease testing. Hemagen offers gold standard IFA products, ELISA, HA, and point-of-care testing formats for human and veterinary diagnostics. Hemagen has received FDA 510(k) clearances from total submissions since its first clearance in 1986. The company's regulatory portfolio focuses on immunology devices, including antibody detection kits, autoimmune scr...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k900617/>; 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