

**K982622 EL-ANA PROFILES: EL-ENA/5**Aug 13, 1998  
56 days to decisionK982622 · Product code: LLL · Immunology  
Source: <https://www.510kdatabase.net/k982622/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Jun 18, 1998
Decision date	Aug 13, 1998
Days to decision	56 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Theratest Laboratories, Inc.</b>
Location	Chicago, IL, US
Contact	MARIUS TEODORESCU
510(k) history	22 submissions · 22 cleared · 1991-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k982622/> 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 21, 2026