

**K894659 ANA ANTISERA CONTROL KIT**Sep 21, 1989  
59 days to decisionK894659 · Product code: **DHN** · Immunology  
Source: <https://www.510kdatabase.net/k894659/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Jul 24, 1989
Decision date	Sep 21, 1989
Days to decision	59 days
Third-party review	No

**APPLICANT**

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Company	<b>Lipogen, Inc.</b>
Location	Knoxville, TN, US
Contact	CRAIG DEES
510(k) history	15 submissions · 15 cleared · 1987-1990

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