

K984102 ACL/APS FACS KITMar 18, 1999
121 days to decisionK984102 · Product code: **MID** · Immunology
Source: <https://www.510kdatabase.net/k984102/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Nov 17, 1998
Decision date	Mar 18, 1999
Days to decision	121 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Louisville Apl Diagnostics, Inc.
Location	Louisville, KY, US
Contact	SILVIA S PIERANGELI
510(k) history	3 submissions · 3 cleared · 1994-2002

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