

K021398 APL IGA ELISA KITAug 27, 2002
117 days to decisionK021398 · Product code: **MID** · Immunology
Source: <https://www.510kdatabase.net/k021398/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	May 2, 2002
Decision date	Aug 27, 2002
Days to decision	117 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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