

**K964296 N-ASSAY TIA APO B TEST KIT**Aug 1, 1997  
276 days to decisionK964296 · Product code: **DER** · Immunology  
Source: <https://www.510kdatabase.net/k964296/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alpha-1-lipoprotein, Antigen, Antiserum, Control (DER)
Date received	Oct 29, 1996
Decision date	Aug 1, 1997
Days to decision	276 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Crestat Diagnostics, Inc.</b>
Location	Portland, OR, US
510(k) history	29 submissions · 29 cleared · 1990-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964296/>; 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 28, 2026