

**K934146 N-ASSAY TIA MICROALBUMIN**Jan 11, 1994  
140 days to decisionK934146 · Product code: **JIR** · Chemistry  
Source: <https://www.510kdatabase.net/k934146/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator Method, Protein Or Albumin (urinary, Non-quant.) (JIR)
Date received	Aug 24, 1993
Decision date	Jan 11, 1994
Days to decision	140 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Crestat Diagnostics, Inc.</b>
Location	Portland, OR, US
Contact	MARY REES
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/k934146/> 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