

**K053196 ISCHEMIA ALBUMIN COBALT BINDING TEST (ACB TEST)**Dec 16, 2005  
30 days to decisionK053196 · Product code: **NJV** · Chemistry  
Source: <https://www.510kdatabase.net/k053196/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Test, Albumin Cobalt Binding (NJV)
Date received	Nov 16, 2005
Decision date	Dec 16, 2005
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Inverness Medical Innovations, Inc.</b>
Location	Waltham, MA, US
Contact	JAMES M DELANEY
510(k) history	6 submissions · 6 cleared · 2001-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k053196/> 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 26, 2026