

**K972257 N-ASSAY TIA ANTITHROMBIN III TEST KIT**Oct 20, 1997  
125 days to decisionK972257 · Product code: **DDQ** · Hematology  
Source: <https://www.510kdatabase.net/k972257/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Antiserum, Control, Antithrombin Iii (DDQ)
Date received	Jun 17, 1997
Decision date	Oct 20, 1997
Days to decision	125 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k972257/> 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