

**K992759 COLON ALERT TEST**Dec 6, 1999  
111 days to decisionK992759 · Product code: **KHE** · Hematology  
Source: <https://www.510kdatabase.net/k992759/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Aug 17, 1999
Decision date	Dec 6, 1999
Days to decision	111 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Immunostics Inc.,</b>
Location	Ocean, NJ, US
Contact	VINCENT P LASTELLA
510(k) history	14 submissions · 14 cleared · 1997-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k992759/> 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 May 26, 2026