

**K032897 C. DIFFICILE TOXIN A + B FECAL ANTIGEN  
DETECTION MICROWELL ELISA KIT MODEL**May 27, 2004  
253 days to decisionK032897 · Product code: LLH · Microbiology  
Source: <https://www.510kdatabase.net/k032897/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagents, Clostridium Difficile Toxin (LLH)
Date received	Sep 17, 2003
Decision date	May 27, 2004
Days to decision	253 days
Third-party review	No
Summary / Statement	Statement
Other names	CDIFF-96

**APPLICANT**

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Company	<b>Ivd Research, Inc.</b>
Location	Carlsbad, CA, US
Contact	DAVE LAMBILLOTTE
510(k) history	5 submissions · 5 cleared · 2002-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k032897/> 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 23, 2026