

**K911145 BORRELIA BURGENDORFERI POLYVAL IGG/IGM  
ANTIBODY TEST**May 10, 1991  
70 days to decisionK911145 · Product code: **LSR** · Microbiology  
Source: <https://www.510kdatabase.net/k911145/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Mar 1, 1991
Decision date	May 10, 1991
Days to decision	70 days
Third-party review	No

**APPLICANT**

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Company	<b>Medical Diagnostic Technologies, Inc.</b>
Location	Augusta, GA, US
Contact	DAVID A WALL
510(k) history	57 submissions · 57 cleared · 1985-2006

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k911145/>; 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 18, 2026