

**K834328 DAT TEST FOR CHAGAS'S DISEASE**Mar 2, 1984  
84 days to decisionK834328 · Product code: **GNE** · Immunology  
Source: <https://www.510kdatabase.net/k834328/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Latex Agglutination, T. Cruzi (GNE)
Date received	Dec 9, 1983
Decision date	Mar 2, 1984
Days to decision	84 days
Third-party review	No

**APPLICANT**

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Company	<b>Sero-Immuno Diagnostics, Inc.</b>
Location	Walker, MI, US
510(k) history	3 submissions · 3 cleared · 1984-1985

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