

**K023889 WIENER LAB. CHAGATEST ELISA RECOMNINANTE  
V.3.0, MODEL 96 TESTS CAT. NR. 1203254**Feb 11, 2004  
447 days to decisionK023889 · Product code: **MIU** · Microbiology  
Source: <https://www.510kdatabase.net/k023889/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunosorbent Assay, T. Cruzi (MIU)
Date received	Nov 21, 2002
Decision date	Feb 11, 2004
Days to decision	447 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wiener Laboratories Saic</b>
Location	Rosario, Santa Fe, AR
Contact	VIVIANA CETOLA
510(k) history	24 submissions · 24 cleared · 2001-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k023889/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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