

**K924218 BAC-T-SCREEN**Feb 3, 1993  
167 days to decisionK924218 · Product code: **JXA** · Microbiology  
Source: <https://www.510kdatabase.net/k924218/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Screening, Urine (JXA)
Date received	Aug 20, 1992
Decision date	Feb 3, 1993
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biomerieux Vitek, Inc.</b>
Location	Hazelwood, MO, US
Contact	DAVID K BROADWAY
510(k) history	49 submissions · 49 cleared · 1992-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k924218/> 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 28, 2026