

**K013194 UNIMARK HCG COMBO PREGNANCY TEST**Oct 10, 2001  
15 days to decisionK013194 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k013194/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Sep 25, 2001
Decision date	Oct 10, 2001
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biotech Atlantic, Inc.</b>
Location	Eatontown, NJ, US
Contact	FRANCIS LEE
510(k) history	4 submissions · 4 cleared · 1994-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013194/> 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 29, 2026