

**K053236 DAVID PREGNANCY TEST (MIDSTREAM)**Jul 18, 2006  
242 days to decisionK053236 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k053236/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Nov 18, 2005
Decision date	Jul 18, 2006
Days to decision	242 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Runbio Biotech Co.,Ltd</b>
Location	Tacoma, WA, US
Contact	JESSICA VAGATA
510(k) history	3 submissions · 3 cleared · 2006-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k053236/> 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