

K250117 FaStep Pregnancy Rapid Test CassetteFeb 13, 2025
28 days to decisionK250117 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k250117/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Jan 16, 2025
Decision date	Feb 13, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Fastep HCG Rapid Test Cassette

APPLICANT

Company	Assure Tech., LLC
Location	Wilmington, DE, US
Contact	Shisheng Ling
510(k) history	5 submissions · 5 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	LSI International, Inc.
Contact	Jenny Xia

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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