February 13, 2025

Assure Tech LLC
% Jenny Xia
Director
LSI International Inc
504E Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K250117
Trade/Device Name: FaStep Pregnancy Rapid Test Cassette; Fastep HCG Rapid Test Cassette
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX, JHI
Dated: January 9, 2025
Received: January 16, 2025

Dear Jenny Xia:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joseph A. Kotarek -S
Digitally signed by Joseph A. Kotarek -S
Date: 2025.02.13 16:11:02 -05'00'

Joseph Kotarek, PhD
Toxicology Branch Chief
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K250117

Device Name
FaStep Pregnancy Rapid Test Cassette

Indications for Use *(Describe)*
FaStep Pregnancy Rapid Test Cassette is used for qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine. This test is intended for use as an aid in the early detection of pregnancy. For over-the-counter use.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K250117

Device Name
Fastep HCG Rapid Test Cassette

Indications for Use *(Describe)*
The Fastep HCG Rapid Test Cassette is a rapid visual immunoassay for the qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine. This test is intended for use as an aid in the early detection of pregnancy. The test kits are for health care professionals use including professionals at physician's office labs (POLs).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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# 510(k) SUMMARY

# K250117

| | | |
|---|---|---|
| **1.** | **Date:** | January 15, 2025 |
| **2.** | **Submitter:** | Assure Tech LLC<br>1521 Concord Pike, Suite 201<br>Wilmington, Delaware, 19803 |
| **3.** | **Contact person:** | Jenny Xia<br>LSI International Inc.<br>504 East Diamond Ave., Suite H<br>Gaithersburg, MD 20877<br>Telephone: 301-525-6856<br>Email: jxa@lsi-consulting.org |
| **4.** | **Device Name:** | FaStep Pregnancy Rapid Test Cassette<br>Fastep HCG Rapid Test Cassette |
| | **Classification:** | Class II |
| | **Product Code:** | LCX; JHI |
| | **CFR:** | 862.1155 |
| **5.** | **Predicate Devices:** | Assure Tech hCG Pregnancy Serum/Urine Combo Test Cassette, (K152768) |

## 6. Intended Use

FaStep Pregnancy Rapid Test Cassette is used for qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine. This test is intended for use as an aid in the early detection of pregnancy. For over-the-counter use.

The Fastep HCG Rapid Test Cassette is a rapid visual immunoassay for the qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine. This test is intended for use as an aid in the early detection of pregnancy. The test kits are for health care professionals use including professionals at physician's office labs (POLs).

## 7. Device Description

The FaStep Pregnancy Rapid Test Cassette and the Fastep HCG Rapid Test Cassette are the same device with the first intended for over-the counter use and the second for prescription use. The devices contain individually wrapped pouches containing the device, instructions for use, and pipette droppers.

The devices utilize a combination of antibodies to detect hCG in urine as well as to serve as a run control. The result is displayed to the user in the test window as two lines for a 'Pregnant' positive result and one line for a 'Not Pregnant' negative result.

## 8. Substantial Equivalence Information

| Similarities | | |
|---|---|---|
| Item | Candidate device:<br>FaStep Pregnancy Rapid Test Cassette and Fastep HCG Rapid Test Cassette (K250117) | Predicate device:<br>Assure Tech hCG Pregnancy Serum/Urine Combo Test (K152768) |
| Intended use | Rapid qualitative detection of hCG to aid in the early detection of pregnancy. | Same |
| Specimen | Urine | Urine or serum |
| Assay technical | Immunochromatographic assay | Same |
| Sensitivity | 20 mIU/mL | Same |
| Results | Qualitative | Same |
| Device format | Cassette | Same |
| Differences | | |
| Item | Device | Predicate |
| Target user | For over-the-counter use;<br>For prescription use | Prescription use |
| Read time | 3-10 minutes | 5 minutes |

## 9. Test Principle

FaStep Pregnancy Rapid Test Cassette and Fastep HCG Rapid Test Cassette use lateral flow immunoassay for in vitro qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine. Each device contains mouse monoclonal anti-β-hCG antibody colloidal gold conjugate pre-dried on the sample pad. Mouse monoclonal anti-α-hCG antibody (on the Test Line) and goat anti mouse IgG polyclonal antibody (on the Control Line) are coated and immobilized on a nitrocellulose membrane. When the specimen is applied, the gold-antibody conjugate is rehydrated and if there is sufficient HCG in the specimen, the HCG interacts with the gold-conjugated antibodies. The antigen-antibody-gold complex then migrates towards the test window until the Test Zone (T) where it gets captured by immobilized antibodies, forming a visible line (Test line), indicating a positive result. If there is not sufficient HCG in the specimen, no line will be visible in the Test Zone (T), indicating a negative result.

As an internal process control, a colored line will always appear in the Control

Zone (C). Absence of a colored line in the Control Zone(C) even in the presence of a colored line in the Test Zone (T) indicates an invalid test result.

## 10. Performance Characteristics

### A. Analytical performance

**a. Precision/Reproducibility/Sensitivity**

Negative female urine was spiked with hCG standard (Traceable to the 5th WHO) to hCG concentrations of 0, 10, 12.5, 15, 17.5, 20, 50, 100 and 200 mIU/mL. Each sample was tested in 10 replicates per day for 5 days for each device lot. Total of three device lots were tested and each operator tested one lot separately. Tests were performed by three different operators for each sample concentration.
The results are summarized in the table below:

| hCG Concentration (mIU/mL) | Operator 1 Lot 1 | | Operator 2 Lot 2 | | Operator 3 Lot 3 | | Total result | | % Negative | % Positive |
|---|---|---|---|---|---|---|---|---|---|---|
| | - | + | - | + | - | + | - | + | | |
| 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% | 0% |
| 10 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% | 0% |
| 12.5 | 45 | 5 | 44 | 6 | 44 | 6 | 133 | 17 | 88.7% | 11.3% |
| 15 | 26 | 24 | 23 | 27 | 25 | 25 | 74 | 76 | 49.3% | 50.7% |
| 17.5 | 6 | 44 | 4 | 46 | 6 | 44 | 16 | 134 | 10.7% | 89.3% |
| 20 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0% | 100% |
| 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0% | 100% |
| 100 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0% | 100% |
| 200 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0% | 100% |

The test devices exhibited reproducibility of results.
Based on the above results, the sensitivity of the test devices is demonstrated to be 20 mIU/mL.

**b. Linearity/assay reportable range:**

Linearity is not applicable since this is a qualitative test. The test devices were evaluated for high dose or hook effect and none were observed.

**Hook effect test:**

Negative urine samples were spiked with varying hCG concentrations (25000 mIU/mL, 50000 mIU/mL, 100000 mIU/mL, 200000 mIU/mL, 500000 mIU/mL, 1000000 mIU/mL and 2000000 mIU/mL). Samples were tested in replicates of 5 with 3 lots of the test devices by 3 different operators. The results demonstrated that no hook effect was observed at hCG concentrations up to 2,000,000 mIU/mL.

**c. Traceability, Stability, Expected values (controls, calibrators, or methods):**

**Traceability:**

The test devices are calibrated against reference material traceable to WHO International Standard 5th edition, NIBSC code 07/364.

**Stability:**
The shelf-life of the test devices at 2~30°C is 24 months based on real time stability data.

**d. Analytical specificity**

**Interfering substance:**
To evaluate potential interfering substances of the test devices, urine samples containing 0 mIU/mL, 10 mIU/mL and 20 mIU/mL hCG were spiked with interfering substances to the concentrations listed below. Samples were tested in replicates of 3 with 3 lots of the test devices by 3 different operators. No interference effect was observed at the tested concentrations.

| Substance | Tested Concentration |
|---|---|
| Acetaminophen | 20 mg/dL |
| Acetoacetic Acid | 2000mg/dL |
| Acetylsalicylic Acid | 20 mg/dL |
| Albumin | 2000 mg/dL |
| Amoxicillin | 20 mg/dL |
| Ascorbic acid | 20 mg/dL |
| Atropine | 20 mg/dL |
| Ampicillin | 20 mg/dL |
| Aspirin | 80 mg/dL |
| Benzoylecgonine | 10 mg/dL |
| Bilirubin | 40 mg/dL |
| Caffeine | 20 mg/dL |
| Cannabinol | 10 mg/dL |
| Cholesterol | 250 mg/dL |
| Codeine | 6 µg/dL |
| EDTA | 80 mg/dL |
| Ephedrine | 20 mg/dL |
| Estriol-17-beta | 1.4 mg/dL |
| Ethanol | 1% |
| Folic acid | 0.03 mg/dL |
| Gentensic Acid | 20 mg/dL |
| Glucose | 2000 mg/dL |
| Gentisic acid | 20 mg/dL |
| Hemoglobin | 2000 mg/dL |
| Ibuprofen | 40 mg/dL |
| Ketone | 20 mg/dL |
| Methanol | 10% |
| Phenothiazine | 20 mg/dL |
| Phenylpropanolamine | 20 mg/dL |
| Pregnanediol | 1.5 mg/dL |

| | |
|---|---|
| Salicylic Acid | 20 mg/dL |
| Tetracycline | 20 mg/dL |
| Thiophene | 20 mg/dL |
| Triglyceride | 500 mg/dL |
| β-hydroxybutyrate | 2000 mg/dL |
| Uric acid | 23.5 mg/dL |
| Vitamin B1 | 80 mg/dL |
| Lipoprotein | 70 mg/dL |

**Cross-reactivity：**
To evaluate cross-reactivity, negative and positive urine samples (0 mIU/mL, 10 mIU/mL and 20 mIU/mL hCG) were spiked with potential cross reactants (500 mIU/mL hLH, 1000 mIU/mL hFSH, 1000 μIU/mL hTSH). Samples were tested in replicates of 3 with 3 lots of the test devices by 3 different operators. No cross-reactivity was observed at tested concentration.

**Effects of hCG β-core fragment:**
To evaluate the effect of the hCG β-core fragment, negative urine samples (0 mIU/mL and 10 mIU/mL hCG) and positive urine samples (20 mIU/mL and 20,000 mIU/mL hCG) were spiked with hCG β-core fragment (hCGβcf) at concentrations of 50,000 pmol/L, 125,000 pmol/L, 250,000 pmol/L and 2,000,000 pmol/L. Samples were tested in replicates of 3 with 3 lots of the test devices by 3 different operators. The performance of the test devices were not affected by hCG β-core fragment concentrations up to 2,000,000 pmol/L.

**Effects of urine pH:**
To evaluate the effect of urine pH on the results of the test devices, urine samples containing 0 mIU/mL, 10 mIU/mL and 20 mIU/mL hCG were tested at pH values of 4, 5, 6, 7, 8 and 9. Samples were tested in replicates of 3 with 3 lots of the test devices by 3 different operators. The results indicated that urine pH ranges between 4 and 9 do not affect the performance of the test devices.

**Effects of urine density:**
To evaluate the effect of urine density on the results of the test devices, urine samples containing 0 mIU/mL, 10 mIU/mL and 20 mIU/mL hCG were tested at density values of 1.000, 1.005, 1.011, 1.015, 1.019, 1.024, 1.029 and 1.035. Samples were tested in replicates of 3 with 3 lots of the test devices by 3 different operators. The results indicated that urine with a relative density range of 1.000 to 1.035 do not affect the performance of the test devices.

**B. Method comparison study**
Method comparison with predicate device:
The performance of the candidate device was compared to the predicate device.

Urine samples were collected from 112 women aged 18 to 50 at three clinical sites. Approximately half of the subjects were pregnant in the early stage of less than 5 weeks. Samples were randomly collected at various time throughout the day.

A single lot was used for the study, and 3 professional operators read the results of the candidate device, with a different operator at each of the three test sites. A separate professional tested the samples using 1 lot of the predicate device, with a different operator at each of the three test sites. The samples were blinded and randomized before being tested by professionals. All results are summarized in the table below.

| FaStep Pregnancy Rapid Test Cassette/ Fastep HCG Rapid Test Cassette | Predicate Test (Assure Tech hCG Pregnancy Serum/Urine Combo Test Cassette) | | Total |
|---|---|---|---|
| | Positive (+) | Negative (-) | |
| Positive (+) | 59 | 0 | 59 |
| Negative (-) | 0 | 53 | 53 |
| Total | 59 | 53 | 112 |

The conformity between the test devices and the predicate device is 100%.

## C. Clinical studies

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

3.1 Lay person study

A lay user study was performed at three sites with a total of 112 females with diverse educational and occupational backgrounds and ages ranging from 18 to 50 years old. Each subject tested her own urine sample using the FaStep Pregnancy Rapid Test Cassette according to the instructions for use and provided a sample for professional testing. Their results were compared to the results obtained from professionals. Ease of use of the FaStep Pregnancy Rapid Test Cassette was assessed through a questionnaire that was completed at the end of the study and the device was determined to be easy to use. The data demonstrated that the agreement between lay user results and professional user results was 100%. The results are summarized in the table below.

| **FaStep Pregnancy Rapid Test Cassette** | | **Professional Result** | | **Total** |
|---|---|---|---|---|
| | | **Positive** | **Negative** | |
| | **Positive** | 59 | 0 | 59 |

| | | | | |
|---|---|---|---|---|
| **Lay user Result** | **Negative** | 0 | 53 | 53 |
| **Total** | | 59 | 53 | 112 |

The results above show that the FaStep Pregnancy Rapid Test Cassette can be used by laypersons to obtain correct results.

3.2 Specificity Study to Determine False-Positive Results Rate

300 urine samples were collected from non-pregnant females in pre-menopausal (18-40 years old), peri-menopausal (41-55 years old) and post-menopausal (>55 years old) age groups at three sites. 100 participants for each age group. One device lot was used in the study. No false positive results were observed for all age groups.

| Group | Total result |
|---|---|
| Pre-menopausal | 0+/100- |
| Peri-menopausal | 0+/100- |
| Post-menopausal | 0+/100- |

## 11. Conclusion

Based on the test principle and performance characteristics of the device including precision, interference, specificity, method comparison and lay-user study, it can be concluded that FaStep Pregnancy Rapid Test Cassette/ Fastep HCG Rapid Test Cassette is substantially equivalent to the predicate device.