January 15, 2025

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

Re: K243573
Trade/Device Name: FaStep Early Pregnancy Rapid Test Strip; FaStep Early Pregnancy Rapid Test Cassette; FaStep Early Pregnancy Rapid Test Midstream
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test System
Regulatory Class: Class II
Product Code: LCX
Dated: November 18, 2024
Received: November 19, 2024

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: 2025.01.15 10:19:37 -05'00'

Joseph Kotarek, Ph.D.
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)*
K243573

Device Name
FaStep Early Pregnancy Rapid Test Strip;
FaStep Early Pregnancy Rapid Test Cassette;
FaStep Early Pregnancy Rapid Test Midstream

Indications for Use *(Describe)*

FaStep Early Pregnancy Rapid Test Strip is used for qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine. This test is intended for use as an aid in early detection of pregnancy, in some cases as early as six (6) days before the day of the missed period, (i.e. as early as five (5) days before the day of the expected period). For over-the-counter use.

FaStep Early 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 early detection of pregnancy, in some cases as early as six (6) days before the day of the missed period, (i.e. as early as five (5) days before the day of the expected period). For over-the-counter use.

FaStep Early Pregnancy Rapid Test Midstream is used for qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine. This test is intended for use as an aid in early detection of pregnancy, in some cases as early as six (6) days before the day of the missed period, (i.e. as early as five (5) days before the day of the expected period). 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."

510(k) SUMMARY

K243573

1. Date: November 18, 2024

2. Submitter:
Assure Tech. LLC
1521 Concord Pike, Suite 201
Wilmington, Delaware, 19803

3. Contact person:
Jenny Xia
LSI International Inc.
504 East Diamond Ave., Suite H
Gaithersburg, MD 20877
Telephone: 301-525-6856
Email: jxa@lsi-consulting.org

4. Device Name:
FaStep Early Pregnancy Rapid Test Strip
FaStep Early Pregnancy Rapid Test Cassette
FaStep Early Pregnancy Rapid Test Midstream

Classification: Class II
Product Code: LCX
CFR: 862.1155

5. Predicate Devices:
Wondfo One Step HCG Urine Pregnancy Test Midstream,
Wondfo One Step HCG Urine Pregnancy Test Strip,
Wondfo One Step HCG Urine Pregnancy Test Cassette
(K150022)

6. Intended Use

FaStep Early Pregnancy Rapid Test Strip is used for qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine. This test is intended for use as an aid in early detection of pregnancy, in some cases as early as six (6) days before the day of the missed period, (i.e. as early as five (5) days before the day of the expected period). For over-the-counter use.

FaStep Early 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 early detection of pregnancy, in some cases as early as six (6) days before the day of the missed period, (i.e. as early as five (5) days before the day of the expected period). For over-the-counter use.

FaStep Early Pregnancy Rapid Test Midstream is used for qualitative detection of

Human Chorionic Gonadotropin (HCG) in human urine. This test is intended for use as an aid in early detection of pregnancy, in some cases as early as six (6) days before the day of the missed period, (i.e. as early as five (5) days before the day of the expected period). For over-the-counter use.

7. Device Description

FaStep Early Pregnancy Rapid Test will be sold in Strip, Cassette and Midstream format. The Strip format is a single test strip. The Cassette format consists of a single test strip assembled in a plastic housing. The Midstream format consists of a single test strip assembled in a plastic housing with an absorbent tip, and is designed to be tested in dip or midstream mode.

FaStep Early Pregnancy Rapid Test Strip, FaStep Early Pregnancy Rapid Test Cassette and FaStep Early Pregnancy Rapid Test Midstream each contains a pouch with the device and instructions, and in addition, cassette format is packaged with pipette dropper.

The devices utilize a combination of antibodies to detect hCG in urine as well as to serve as a run control. 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. 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	Predicate device
Intended use	Early detection of pregnancy	Same
Specimen	Urine	Same
Assay technical	Immunochromatographic assay	Same
Sensitivity	10 mIU/mL	Same
Results	Qualitative	Same
Device format	Strip, Cassette, Midstream	Same
Differences		
Item	Device	Predicate
Target user	For over-the-counter use	Prescription use and OTC use
Read time	3-10 minutes	5 minutes

9. Test Principle

FaStep Early Pregnancy Rapid Test Strip, FaStep Early Pregnancy Rapid Test Cassette and FaStep Early Pregnancy Rapid Test Midstream use lateral flow immunoassay for in vitro qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine. If hCG is present in the sample, it will reach the Test Zone (T) of the membrane and form a colored line. When the test is performed properly, a colored line will always appear in the Control Zone (C). The test result is shown in the result window and read visually in 3-10 minutes of urine addition. Two distinct colored lines, one in the Test Zone (T) and another in the Control Zone (C) indicate a positive test result (pregnant). Absence of a colored line in the Test Zone (T) and only a colored line in the Control Zone (C) indicates a negative test result (not pregnant). 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, 5, 7.5, 8, 10, 15, 20, 25 and 50 mIU/mL. Each sample was tested in 10 replicates per day for 5 days for each device lot. Total of three device lots for each format were tested and each operator tested one lot separately. Tests were performed by three different operators for each sample concentration. The midstream format was performed using both dip and in-stream methods.

The results are summarized in the table below:

Strip format

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%
5	50	0	50	0	50	0	150	0	100%	0%
7.5	31	19	29	21	30	20	90	60	60.0%	40.0%
8	24	26	25	25	24	26	73	77	48.7%	51.3%
10	0	50	0	50	0	50	0	150	0%	100%
15	0	50	0	50	0	50	0	150	0%	100%
20	0	50	0	50	0	50	0	150	0%	100%
25	0	50	0	50	0	50	0	150	0%	100%
50	0	50	0	50	0	50	0	150	0%	100%

Cassette format

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%
5	50	0	50	0	50	0	150	0	100%	0%
7.5	29	21	30	20	30	20	89	61	59.3%	40.7%
8	25	25	23	27	24	26	72	78	48.0%	52.0%
10	0	50	0	50	0	50	0	150	0%	100%

15	0	50	0	50	0	50	0	150	0%	100%
20	0	50	0	50	0	50	0	150	0%	100%
25	0	50	0	50	0	50	0	150	0%	100%
50	0	50	0	50	0	50	0	150	0%	100%

Midstream format (in-stream method)

hCG Concentration (mIU/mL)	Operator 1 Lot I		Operator 2 Lot II		Operator 3 Lot III		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	50	0	50	0	50	0	150	0	100%	0%
5	50	0	50	0	50	0	150	0	100%	0%
7.5	29	21	30	20	29	21	88	62	58.7%	41.3%
8	25	25	25	25	24	26	74	76	49.3%	50.7%
10	0	50	0	50	0	50	0	150	0%	100%
15	0	50	0	50	0	50	0	150	0%	100%
20	0	50	0	50	0	50	0	150	0%	100%
25	0	50	0	50	0	50	0	150	0%	100%
50	0	50	0	50	0	50	0	150	0%	100%

Midstream format (dip method)

hCG Concentration (mIU/mL)	Operator 1 Lot I		Operator 2 Lot II		Operator 3 Lot III		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	50	0	50	0	50	0	150	0	100%	0%
5	50	0	50	0	50	0	150	0	100%	0%
7.5	30	20	28	22	31	19	89	61	59.3%	40.7%
8	26	24	24	26	25	25	75	75	50.0%	50.0%
10	0	50	0	50	0	50	0	150	0%	100%
15	0	50	0	50	0	50	0	150	0%	100%
20	0	50	0	50	0	50	0	150	0%	100%
25	0	50	0	50	0	50	0	150	0%	100%
50	0	50	0	50	0	50	0	150	0%	100%

FaStep Early Pregnancy Rapid Test exhibited reproducibility of results.
Based on the above results, the sensitivity of FaStep Early Pregnancy Rapid Test is demonstrated to be 10 mIU/mL.

b. Linearity/assay reportable range:

Linearity is not applicable since this is a qualitative test.
The test device was evaluated for high dose or hook effect.

Hook effect test:

Negative urine samples were spiked with varying hCG concentrations (6,250 mIU/mL, 12,500 mIU/mL, 25,000 mIU/mL, 50,000 mIU/mL, 100,000 mIU/mL, and 200,000 mIU/mL). The results demonstrated that no hook effect was observed at hCG concentration up to 200,000 mIU/mL.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):
Traceability:
FaStep Early Pregnancy Rapid Test is calibrated against reference material traceable to WHO International Standard 5th edition, NIBSC code 07/364.

Stability:
The shelf-life of the FaStep Early Pregnancy Rapid Test 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 FaStep Early Pregnancy Rapid Test, urine samples containing 0 mIU/mL, 5 mIU/mL and 10 mIU/mL hCG were spiked with interfering substances to the concentrations listed below. No interference effect was observed at the tested concentrations.

Substance	***Concentration***
Acetaminophen	20 mg/dL
Acetylsalicylic Acid	20 mg/dl
Albumin	20 mg/dL
Amoxicillin	20 mg/dL
Ampicillin	20 mg/dL
Ascorbic acid	20 mg/dL
Aspirin	80 mg/dL
Atropine	20 mg/dL
Benzoylecgonine	10 mg/dL
Bilirubin	2 mg/dL
Caffeine	20 mg/dL
Cannabinol	10 mg/dL
Codeine	0.006 mg/dL
EDTA	80 mg/dL
Ephedrine	20 mg/dL
Ethanol	0.1%
Folic acid	0.03 mg/dL
Gentisic acid	20 mg/dL
Glucose	2000 mg/dL
Hemoglobin	20 mg/dL
Ibuprofen	40 mg/dL
Ketone	20 mg/dL
Methanol	1%
Phenothiazine	20 mg/dL
Phenylpropanolamine	20 mg/dL
Pregnanediol	1.5 mg/dL
Salicylic Acid	20 mg/dL

Substance	*Concentration*
Tetracycline	20 mg/dL
Thiophene	20 mg/dL
Uric acid	23.5 mg/dL
Vitamin B1	80 mg/dL
β-hydroxybutyrate	2000 mg/dL

Cross-reactivity：
To evaluate cross-reactivity, negative and positive urine samples (0 mIU/mL, 5 mIU/mL and 10 mIU/mL hCG) were spiked with potential cross reactants (500 mIU/mL hLH, 1000 mIU/mL hFSH, 1000 μIU/mL hTSH). 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 5 mIU/mL hCG) and positive urine samples (10 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 500,000 pmol/L. The performance of FaStep Early Pregnancy Rapid Test was not affected by hCG β-core fragment concentrations up to 500,000 pmol/L.

Effects of urine pH:

To evaluate the effect of urine pH on the results of FaStep Early Pregnancy Rapid Test, urine samples containing 0 mIU/mL, 5 mIU/mL and 10 mIU/mL hCG were tested at pH values of 4, 5, 6, 7, 8 and 9. The results indicated that urine pH ranges between 4 and 9 does not affect the performance of FaStep Early Pregnancy Rapid Test.

Effects of urine density:
To evaluate the effect of urine density on the results of FaStep Early Pregnancy Rapid Test, urine samples containing 0 mIU/mL, 5 mIU/mL and 10 mIU/mL hCG were tested at density values of 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030 and 1.035. The results indicated that urine with a relative density rang of 1.000 to 1.035 does not affect the performance of FaStep Early Pregnancy Rapid Test.

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 321 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.

All samples were tested by at least one professional at each site using the candidate device and by one professional at each site using the predicate device. 110 samples

were tested for strip format, and 105 samples were tested for cassette format; for the midstream format, both dip testing and in-stream testing were evaluated for 106 samples. The samples were blinded and randomized before being tested by professionals. All results are summarized in the table below.

Candidate device		Predicate device		
		Positive	Negative	Total
Strip format	Positive	61	0	61
	Negative	0	49	49
	Total	61	49	110

Candidate device		Predicate device		
		Positive	Negative	Total
Cassette format	Positive	54	0	54
	Negative	0	51	51
	Total	54	51	105

Candidate device		Predicate device		
		Positive	Negative	Total
Midstream format (dip method)	Positive	57	0	57
	Negative	0	49	49
	Total	57	49	106

Candidate device		Predicate device		
		Positive	Negative	Total
Midstream format (in-stream method)	Positive	57	0	57
	Negative	0	49	49
	Total	57	49	106

The conformity between FaStep Early Pregnancy Rapid Test (strip / cassette / midstream) 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

First study:

A lay user study was performed at three sites with a total of 321 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 device according to the instructions for use and provided a sample for professional testing. 110 subjects tested the strip format, 105 subjects tested the cassette format, 53 subjects tested the midstream format using dip method, and 53 subjects tested the midstream format using in-stream method.
The results are summarized in the table below.

Strip format

Strip format		Professional		
		Positive	Negative	Total
Layperson	Positive	61	0	61
	Negative	0	49	49
	Total	61	49	110

Cassette format

Cassette format		Professional		
		Positive	Negative	Total
Layperson	Positive	54	0	54
	Negative	0	51	51
	Total	54	51	105

Midstream format

Midstream format (dip method)		Professional		
		Positive	Negative	Total
Layperson	Positive	32	0	32
	Negative	0	21	21
	Total	32	21	53

Midstream format (in-stream method)		Professional		
		Positive	Negative	Total
Layperson	Positive	25	0	25
	Negative	0	28	28
	Total	25	28	53

From the above tables, the lay person results showed 100% positive and 100% negative conformity with the professional results.

Second study:

Negative urine sample pools were spiked with 5 mIU/mL, 7.5 mIU/mL, 8 mIU/mL and 10 mIU/mL hCG. All aliquots were blind labeled by the person who prepared the samples and didn't take part in the sample testing. A total of 300 laypersons performed the testing, of which 100 using the strip format, 100 using the cassette format and 100 using the midstream format. Each layperson tested 4 blind-labeled

samples (5 mIU/mL, 7.5 mIU/mL, 8 mIU/mL and 10 mIU/mL), and the spiked urine samples were also tested by professionals.
Results of spiked samples are summarized in the table below.

Strip format:

hCG Concentration (mIU/mL)	Layperson result			Professional result			Percent Agreement
	No. of Positive	No. of Negative	% positive	No. of Positive	No. of Negative	% positive	
5	0	100	0%	0	100	0%	100%
7.5	39	61	39%	41	59	41%	98%
8.0	51	49	51%	53	47	53%	98%
10	100	0	100%	100	0	100%	100%

Cassette format:

hCG Concentration (mIU/mL)	Layperson result			Professional result			Percent Agreement
	No. of Positive	No. of Negative	% positive	No. of Positive	No. of Negative	% positive	
5	0	100	0%	0	100	0%	100%
7.5	40	60	40%	42	58	42%	98%
8.0	51	49	51%	52	48	52%	99%
10	100	0	100%	100	0	100%	100%

Midstream format:

hCG Concentration (mIU/mL)	Layperson result			Professional result			Percent Agreement
	No. of Positive	No. of Negative	% positive	No. of Positive	No. of Negative	% positive	
5	0	100	0%	0	100	0%	100%
7.5	39	61	39%	42	58	42%	97%
8.0	49	51	49%	51	49	51%	98%
10	100	0	100%	100	0	100%	100%

The results above show that FaStep Early Pregnancy Rapid Test can be used by the laypersons and get the correct results.

3.2 Early pregnancy detection study

A study was performed to evaluate the early pregnancy detection rate of FaStep Early Pregnancy Rapid Test. A total of 680 early pregnancy urine samples from day -9 to 0 relative to the day of the expected menstrual period were collected from 68 pregnant women. Each sample was tested with each format of the FaStep Early Pregnancy Rapid Test. For the midstream format, both dip and in-stream methods were evaluated.
The specific detection rates per day are summarized in the table below.

Strip format:

Test date	EMP-9	EMP-8	EMP-7	EMP-6	EMP-5	EMP-4	EMP-3	EMP-2	EMP-1	EMP
# of positive results of B-ultrasound	68	68	68	68	68	68	68	68	68	68
# of positive results of HCG	0	5	10	28	47	61	66	67	68	68
Detection rate	0%	7.4%	14.7%	41.2%	69.1%	89.7%	97.1%	98.5%	100%	100%

Cassette format:

Test date	EMP-9	EMP-8	EMP-7	EMP-6	EMP-5	EMP-4	EMP-3	EMP-2	EMP-1	EMP
# of positive results of B-ultrasound	68	68	68	68	68	68	68	68	68	68
# of positive results of HCG	0	5	10	27	47	62	66	67	68	68
Detection rate	0%	7.4%	14.7%	39.7%	69.1%	91.2%	97.1%	98.5%	100%	100%

Midstream format (in-stream method):

Test date	EMP-9	EMP-8	EMP-7	EMP-6	EMP-5	EMP-4	EMP-3	EMP-2	EMP-1	EMP
# of positive results of B-ultrasound	68	68	68	68	68	68	68	68	68	68
# of positive results of HCG	0	5	10	27	47	61	66	67	68	68
Detection rate	0%	7.4%	14.7%	39.7%	69.1%	89.7%	97.1%	98.5%	100%	100%

Midstream format (dip method):

Test date	EMP-9	EMP-8	EMP-7	EMP-6	EMP-5	EMP-4	EMP-3	EMP-2	EMP-1	EMP
# of positive results of B-ultrasound	68	68	68	68	68	68	68	68	68	68
# of positive results of HCG	0	5	10	27	47	61	66	67	68	68
Detection rate	0%	7.4%	14.7%	39.7%	69.1%	89.7%	97.1%	98.5%	100%	100%

The detection rate of FaStep Early Pregnancy Rapid Test (strip/cassette/ midstream) in EMP-5 (i.e. five days before the expected menstrual period, 6 days before the missed menstrual period) was 69.1%, in EMP-4 was 89.7%, and in EMP-1 was 100%.

3.3 Specificity Study to Determine False-Positive Results Rate

900 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. 300 participants for each age group. In each age group, 100 participants tested test strip, 100 participants tested test cassette, 100 participants tested test midstream using dip method, or in-stream method. Three batches of each format were used in the study. No false positive results were

observed for all age groups.

Strip format:

Group	Lot 1	Lot 2	Lot 3	Total result
Pre-menopausal	0+/34-	0+/33-	0+/33-	0+/100-
Peri-menopausal	0+/33-	0+/34-	0+/33-	0+/100-
Post-menopausal	0+/33-	0+/33-	0+/34-	0+/100-

Cassette format:

Group	Lot 1	Lot 2	Lot 3	Total result
Pre-menopausal	0+/34-	0+/33-	0+/33-	0+/100-
Peri-menopausal	0+/33-	0+/34-	0+/33-	0+/100-
Post-menopausal	0+/33-	0+/33-	0+/34-	0+/100-

Midstream format:

Group	Lot 1	Lot 2	Lot 3	Total result
Pre-menopausal	0+/34-	0+/33-	0+/33-	0+/100-
Peri-menopausal	0+/33-	0+/34-	0+/33-	0+/100-
Post-menopausal	0+/33-	0+/33-	0+/34-	0+/100-

11. Conclusion

Based on the test principle and performance characteristics of the device including precision, cut-off, interference, specificity, method comparison, lay-user study and early pregnancy detection study of the devices, it can be concluded that FaStep Early Pregnancy Rapid Test is substantially equivalent to the predicate device.