510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K233174

B Applicant

Assure Tech (Hangzhou) Co., Ltd.

C Proprietary and Established Names

FaStep™ Pregnancy Rapid Test Strip; FaStep™ Pregnancy Rapid Test Midstream

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LCX	Class II	21 CFR 862.1155 - Human Chorionic Gonadotropin (HCG) Test System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Human chorionic gonadotropin (hCG)

C Type of Test:

Qualitative chromatographic immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The FaStep™ Pregnancy Rapid Test Strip is a rapid, visual immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine. The test is an in-vitro diagnostic strip intended for use as an aid in the early detection of pregnancy. The FaStep™ Pregnancy Rapid Test Strip is designed for self-testing use.

The FaStep™ Pregnancy Rapid Test Midstream is a rapid, visual immunoassay for the qualitative detection of human chorionic gonadotropin(hCG) in urine. The test is an in-vitro diagnostic device intended for use as an aid in the early detection of pregnancy. The FaStep™ Pregnancy Rapid Test Midstream is designed for self-testing use.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

D Special Instrument Requirements:

None.

IV Device/System Characteristics:

A Device Description:

The FaStep™ Pregnancy Rapid Test Strip and FaStep™ Pregnancy Rapid Test Midstream are qualitative, lateral flow immunoassays for the detection of human chorionic gonadotropin (hCG) in urine. The Strip format consists of a single test strip sealed in a desiccated aluminum pouch, a urine collection cup, and a package insert. The test strip format is used by dipping the strip into a urine sample collected into the provided collection cup. The Midstream format consists of a single test strip assembled in a plastic housing with an absorbent tip, designed to be tested in dip or midstream mode, sealed in a desiccated aluminum pouch, and a package insert. The midstream format is used by placing the strip directly into the urine stream or by dipping the strip into a urine sample collected into a clean, dry container.

B Principle of Operation:

Anti-hCG antibodies are immobilized on the test region of the strip membrane. During testing, the hCG in urine, if present, binds to anti-hCG antibodies conjugated to colored particles. As the urine specimen migrates along the strip by capillary action and interacts with reagents on the membrane, the complex will be captured by the anti-hCG antibodies at the test region. If hCG is present in the urine, a colored line appears at the Test Zone (“T”) line. If hCG is not present or the concentration is below the sensitivity limit, no colored line appears at the Test Zone. A colored line should always appear in the Control Zone region, indicating that the test has been performed correctly. The FaStep™ Pregnancy Rapid Test Strip result is shown in the test region

of the strip and is read visually between 3 and 10 minutes. The FaStep™ Pregnancy Rapid Test Midstream test result is read when the "red" color indicator is visualized in the heart-shaped hole of the device. Two (2) distinct colored lines, 1 at the Test Zone and another at the Control Zone indicate a positive test result (pregnant). Absence of a colored line in the Test Zone and only a colored line in the Control Zone indicates a negative test result (not pregnant). Absence of a colored line in the Control Zone, even in the presence of a colored line in the test zone, indicates an invalid test result.

V Substantial Equivalence Information:

A Predicate Device Name(s):
FaStep™ At-Home Pregnancy Test

B Predicate 510(k) Number(s):
K122907

C Comparison with Predicate(s):

Device & Predicate Device(s):	K233174	K122907
Device Trade Name	FaStep™ Pregnancy Rapid Test Strip; FaStep™ Pregnancy Rapid Test Midstream	FaStep™ At-Home Pregnancy Test
General Device Characteristic Similarities		
Intended Use/Indications For Use	Qualitative detection of hCG as an aid in early detection of pregnancy	Same
Sample Matrix	Urine	Same
Test Principle	Chromatographic immunoassay	Same
Sensitivity (hCG)	20 mIU/mL	Same
Intended use environment	Over-the-counter use	Same
General Device Characteristic Differences		
Traceability	Traceable to the 5th World Health Organization (WHO) International Standard (IS)	Traceable to the 4th World Health Organization (WHO) International Standard (IS)
Time to result	3-10 minutes	3-5 minutes

VI Standards/Guidance Documents Referenced:

None referenced.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Urine samples from non-pregnant females (negative) were spiked with hCG (traceable to the 5th WHO IS) to obtain samples with hCG concentrations of 0, 10, 12.5, 15, 17.5, 20, 50, 100, and 200 mIU/mL. Each sample was tested using 3 lots of the FaStep™ Pregnancy Rapid Test Strip and the FaStep™ Pregnancy Rapid Test Midstream. Testing on the midstream format was performed using both the instream and dip sampling methods whereas testing with the strip format was performed only in dip sampling method. The tests were performed in replicates of 10, over the course of 5 consecutive days by 3 different operators. A total of 150 replicates were performed per sampling method per hCG concentration. The device cut-off is 20 mIU/mL hCG. Summary of results are presented in the following tables.

FaStep™ Pregnancy Rapid Test Strip results:

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	45	5	44	6	134	16	89.3%	10.7%
15	23	27	26	24	24	26	73	77	48.7%	51.3%
17.5	7	43	5	45	6	44	18	132	12.0%	88%
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%

FaStep™ Pregnancy Rapid Test Midstream – dip sampling method:

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	44	6	44	6	46	6	134	16	89.3%	10.7%
15	24	26	26	24	27	23	77	73	51.3%	48.7%
17.5	7	43	5	45	4	46	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%

FaStep™ Pregnancy Rapid Test Midstream – instream sampling method:

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	46	4	45	5	43	7	134	16	89.3%	10.7%
15	22	28	27	23	25	25	74	76	49.3%	50.7%
17.5	6	44	6	44	5	45	17	133	11.3%	88.7%
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%

2. Linearity:

Linearity is not applicable since this is a qualitative test.

3. Analytical Specificity/Interference:

Cross-reactivity

The candidate device was tested using negative and hCG-positive urine samples for potential cross-reactivity from human luteinizing hormone (LH), human follicle-stimulating hormone (FSH), and human thyroid-stimulating hormone (TSH). Urine specimens from non-pregnant females were pooled and used to prepare samples with hCG levels of 0, 10, and 20 mIU/mL which were then spiked with each potential cross-reactant. Samples were tested in replicates of 3 with 3 lots of the candidate device by 3 different test operators. The results demonstrated no cross-reactivity from LH up to 500 mIU/mL, FSH up to1000 mIU/mL, and TSH up to 1 mIU/mL in either negative or positive urine samples.

Effect from interfering substances

To evaluate potential interference, urine specimens from non-pregnant females were pooled and used to prepare samples with hCG levels at 0 mIU/mL 10 mIU/mL and 20 mIU/mL. The potential interfering substance was then added to these prepared samples with concentration of 0 mIU/mL, 10 mIU/m, and 20 mIU/mL hCG, respectively. Samples were tested in replicates of 3 with 3 lots of the candidate device by 3 different operators. The test results demonstrated no interference from substances at the concentrations shown in the table below:

Potential Interfering Substance	Highest concentration tested that demonstrated no interference (mg/dL)
Acetaminophen	20
Acetylsalicylic Acid	20
Albumin	2000
Amoxicillin	20
Ampicillin	20
Ascorbic Acid	20
Aspirin	80
Atropine	20
Benzoylecgonine	10
Bilirubin	40
Caffeine	20
Cannabinol	10
Ethylenediaminetetraacetic Acid (EDTA)	80
Ephedrine	20
Ethanol	1% v/v
Folic Acid	0.03
Gentisic Acid	20
Glucose	2000
Hemoglobin	1000
Ibuprofen	40
Ketone	20
Methanol	1% v/v
Phenothiazine	20
Phenylpropanolamine	20
Pregnanediol	1.5
Salicylic Acid	20
Tetracycline	20
Thiophene	20
Uric Acid	23.5
Vitamin B1	80
β-hydroxybutyrate	2000

Effect of urine specific gravity

To evaluate potential interference from changes in specific gravity, urine samples containing 0 mIU/mL, 10 mIU/mL, and 20 mIU/mL hCG were adjusted to specific gravities of 1.000, 1.005, 1.011, 1.015, 1.019, 1.024, 1.029, and 1.035. Aliquots of each specific gravity urine sample were spiked with hCG to concentrations of 0, 10, and 20 mIU/mL. Samples were tested in replicates of 3 with 3 lots of the candidate device by 3 different operators. The test results demonstrated that the performance of the candidate device is not affected by urine with specific gravities of 1.000 to 1.035.

Effect of hCG β-core fragment:

The candidate device was tested using negative and hCG-positive urine samples with various concentrations of hCG β-core fragment (hCGβcf). Four (4) different hCG concentrations of female urine sample pools (0, 10, 20, and 20,000 mIU/mL) were each spiked with hCGβcf at

concentrations of 50,000, 125,000, 250,000, and 500,000 pmol/L. Samples were tested in replicates of 3 with 3 lots of the candidate device. The test results demonstrated that the performance of the candidate device is not affected by hCGβcf up to 500,000 pmol/L.

Effect of urine pH
To evaluate potential interference from pH, urine samples at a pH of 4.0, 5.0, 6.0, 7.0, 8.0, and 9.0 were prepared. The samples were then spiked with hCG to concentrations of 0, 10, and 20 mIU/mL. Samples were tested in replicates of 3 with 3 lots of the candidate device by 3 different operators. The test results demonstrated that the performance of candidate device is not affected by varying urine pH in the range of 4.0 to 9.0.

High dose hook effect study:
The candidate device was tested using negative female urine samples spiked with varying hCG concentrations (6,250, 12,500, 25,000, 50,000, 100,000, 200,000, and 500,000 mIU/mL) and tested in replicates of 5 with 3 lots of the candidate device by 3 different operators. The test results demonstrated that there is no hook effect at hCG concentrations up to 500,000 mIU/mL.

4. Assay Reportable Range:

   Not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Traceability:
FaStep™ Pregnancy Rapid Test Strip and FaStep™ Pregnancy Rapid Test Midstream are calibrated against reference material traceable to WHO International Standard 5th Edition, NIBC code 07/364.

6. Detection Limit:

The detection limit was determined in the precision study. See Precision/Reproducibility (Section VII.A.1.) section above.

7. Device Cut-Off:

The device cut-off is 20 mIU/mL. See Precision/Reproducibility (Section VII.A.1.) section above.

8. Method Comparison with Predicate Device:

FaStep™ Pregnancy Rapid Test Strip:
Urine samples were collected from a total of 140 women with ages ranging from 18 to 45 years who presented at 3 clinical sites for pregnancy testing. Of the 140 women, 74 women were pregnant, and most of them were in the early stage of less than 5 weeks. Samples were collected randomly at various times throughout the day. Samples were masked and randomized by people who labeled the samples but did not conduct the testing. A single reagent lot was used for the study, and 3 professional operators read the results of the candidate device (FaStep™ Pregnancy Rapid Test Strip), with a different operator at each of the three test sites. Another professional

tested the samples using 1 lot of the predicate device (FaStep™ At-Home Pregnancy Test). A summary of the results is presented in the following table:

FaStep™ Pregnancy Rapid Strip (dip method)	Predicate Device		Total
	Positive (+)	Negative (-)	
Positive (+)	74	0	74
Negative (-)	0	66	66
Total	74	66	140

FaStep™ Pregnancy Rapid Test Midstream:
Urine samples were collected from a total of 127 women with ages ranging from 18 to 49 years who presented to 3 clinical sites for pregnancy testing. Of the 127 women, 65 women were pregnant, and most of them were in the early stage of less than 5 weeks. Samples were collected randomly at various times throughout the day. Samples were masked and randomized by people who labeled the samples but did not conduct the testing. A single reagent lot was used for the study, and 3 professional operators read the results of the candidate device (FaStep™ Pregnancy Rapid Test Midstream), with a different operator at each of the three test sites. Another professional tested the samples using 1 lot of the predicate device (FaStep™ At-Home Pregnancy Test). Both dip testing and simulated instream sampling methods were performed using the candidate device. A summary of the results is presented in the following tables:

FaStep™ Pregnancy Rapid Midstream (dip method)	Predicate Device		Total
	Positive (+)	Negative (-)	
Positive (+)	65	0	65
Negative (-)	0	62	62
Total	65	62	127

FaStep™ Pregnancy Rapid Midstream (instream method)	Predicate Device		Total
	Positive (+)	Negative (-)	
Positive (+)	65	0	65
Negative (-)	0	62	62
Total	65	62	127

9. Matrix Comparison:

Not applicable. The device is intended to be used with urine samples only.

B Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

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

Lay user study:
A lay user study was conducted at 3 sites with a total of 267 women with diverse educational and professional backgrounds whose ages ranged from 18-49 years. Approximately half of the women were less than 5 weeks pregnant. Each lay user tested their own urine samples and provided a sample for professional testing. Lay users performed the testing following the package insert instructions without any assistance. Their results were compared to the results obtained from trained technicians testing the urine sample. Ease of use of the devices was assessed through a questionnaire that was completed at the end of the study. The data demonstrated that the agreement between lay user results and professional user results was 100%. The results are summarized below:

A total of 140 subjects tested their urine samples using the FaStep™ Pregnancy Rapid Test Strip (all in dip sampling method).

FaStep™ Pregnancy Rapid Test Strip		Professional Result		Total
		Positive (+)	Negative (-)	
Lay User Result	Positive (+)	74	0	74
	Negative (-)	0	66	66
Total		74	66	140

A total of 127 lay users tested their urine samples using the FaStep™ Pregnancy Rapid Test Midstream (using dip and instream sampling method).

FaStep™ Pregnancy Rapid Test Midstream (instream and dip method)		Professional Result		Total
		Positive (+)	Negative (-)	
Lay User Result	Positive (+)	65	0	65
	Negative (-)	0	62	27
Total		65	62	127

C Clinical Cut-Off:

Not applicable.

D Expected Values/Reference Range:

Not applicable.

E Other Supportive Instrument Performance Characteristics Data:

Not applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is incomplete and does not support a substantial equivalence decision.