510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k152768

B. Purpose for Submission:

New device

C. Measurand:

Human Chorionic Gonadotropin (hCG)

D. Type of Test:

Qualitative chromatographic immunoassay

E. Applicant:

Assure Tech. (Hangzhou) Co., Ltd.

F. Proprietary and Established Names:

Assure Tech hCG Pregnancy Serum/Urine Combo Test Cassette
Assure Tech hCG Pregnancy Serum/Urine Combo Test Strip

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1155 Human chorionic gonadotropin (hCG) test system

2. Classification:

   Class II

3. Product code:

   JHI

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indication for use below.

2. Indication(s) for use:

   The Assure Tech hCG Pregnancy Serum/Urine Combo Test Cassette is a rapid visual immunoassay for the qualitative, presumptive detection of human chorionic gonadotropin in human urine or serum specimens. This kit is intended for use as an aid in early detection of pregnancy.

   This product is intended for prescription use in clinical laboratories and point-of-care use settings.

   The Assure Tech hCG Pregnancy Serum/Urine Combo Test Strip is a rapid visual immunoassay for the qualitative, presumptive detection of human chorionic gonadotropin in human urine or serum specimens. This kit is intended for use as an aid in early detection of pregnancy.

   This product is intended for prescription use in clinical laboratories and point-of-care use settings.

3. Special conditions for use statement(s):

   This product is intended for prescription use in clinical laboratories and point-of-care use settings.

4. Special instrument requirements:

   None, this device is a visually-read, single-use device

I. Device Description:

The Assure Tech hCG Pregnancy Serum/Urine Combo Test Strip consists of a reagent strip, which includes an absorbent pad, coated membrane, gold conjugate pad and sample pad. The Assure Tech hCG Pregnancy Serum/Urine Combo Test cassette contains the same reagent strip except that the strip is assembled in plastic device housing. The Assure Tech hCG Pregnancy Serum/Urine Combo Test (Cassette, Strip) is designed to be tested as a single cassette or dipstick device. The specimen migrates via capillary action along the membrane to react with the colored conjugate. This test measures the presence of the hCG in human urine or serum for the early detection of pregnancy. Users are able to read serum test results in 5 minutes, and read urine test results in 3 minutes.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   QuickVue+ One-Step hCG Combo test from Quidel Corporation

2. Predicate 510(k) number(s):

   K973858

3. Comparison with predicate:

Similarities		
Item	Device: k152768	Predicate: k973858
Intended Use	Rapid qualitative detection of hCG to aid in the early detection of pregnancy.	Same
Sample Matrix	Urine or serum	Same
Test Principle	Lateral flow sandwich immuno chromatographic assay	Same
Detection reagent	Colloidal gold	Same
Read time	Serum: 5 minutes Urine: 3 minutes	Same
Detection Limits	10 mIU/mL for serum and 20 mIU/mL for urine	Same
Specificity	LH at 300 mIU/mL, FSH at 1000 mIU/mL, and TSH at 1000 µIU/mL	Same
Differences		
Item	Device: k152768	Predicate: k973858
Storage	4 – 30°C	15 - 30°C
Usage	Prescription use and point of care testing	Prescription use only
Traceability	WHO 4th International Standard	WHO 3rd International Standard
Configuration	Strip and cassette	Cassette
Hook effect	hCG concentrations up to 2000 IU/mL	N/A
pH effect	ranges of pH 4 to 9 No effect	ranges of pH 5 to 9 No effect
Specific gravity effect	ranges of 1.000 to1.035 No effect	Not provided
Reading Control Window	1 window for result reading and control reading	2 windows: Small Control Window and Large Read Result

Similarities		
Item	Device: k152768	Predicate: k973858
		Window
Read Result Window	No preprinted line on membrane	Pre-printed horizontal blue line on membrane
Positive result	2 colored red/pinkish horizontal lines in control and test regions	Pink and blue plus sign in large Window, along with a blue line in small Window
Negative result	1 colored line in control region only	Blue horizontal line in Large Window, along with a blue line in small Window

K. Standard/Guidance Document Referenced:

None

L. Test Principle:

The Assure Tech hCG Pregnancy Serum/Urine Combo Test (Strip, Cassette) is a qualitative, lateral flow chromatographic immunoassay for the detection of human chorionic gonadotropin (hCG) in serum and urine. When the absorbent end is immersed into a sample (strip format) or a sample is applied to the absorbent end (cassette format), the sample will mix with the antibody-dye conjugate (mouse anti-beta hCG monoclonal antibody), and then flow across the pre-coated (goat anti hCG polyclonal antibody) membrane. If there is sufficient hCG in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The presence of colored line in the "C" region serves as an internal procedural control. No line in the "C" region indicates that the test is invalid.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility/cut-off values:

A precision study was performed using negative human urine and serum samples spiked with hCG traceable to the WHO 4th international standard. Serum samples were tested with hCG concentrations of 0, 4, 6, 8, 10, 12, 14, 16, 20, and 50 mIU/mL. Urine samples were tested with hCG concentrations of 0, 5, 10, 12, 16, 20, 24, 30, 50 and 100 mIU/mL. The samples were measured in 10 replicates per day for 5 days using 3 different lots for each device format at three testing sites (including 2 POC sites) by 3 different operators at each site. The results are summarized in the following tables:

Serum Strip format

hCG Concentration (mIU/ml)	Site 1	Site 2	Site 3	Total result	% Negative	%Positive
0	50-/0+	50-/0+	50-/0+	150-/0+	100	0
4	50-/0+	50-/0+	50-/0+	150-/0+	100	0
6	50-/0+	50-/0+	50-/0+	150-/0+	100	0
8	25-/25+	23-/27+	24-/26+	72-/78+	48	52
10	0-/50+	0-/50+	0-/50+	0-/150+	0	100
12	0-/50+	0-/50+	0-/50+	0-/150+	0	100
14	0-/50+	0-/50+	0-/50+	0-/150+	0	100
16	0-/50+	0-/50+	0-/50+	0-/150+	0	100
20	0-/50+	0-/50+	0-/50+	0-/150+	0	100
50	0-/50+	0-/50+	0-/50+	0-/150+	0	100

Serum Cassette format

hCG Concentration (mIU/ml)	Site 1	Site 1	Site 1	Total result	% Negative	%Positive
0	50-/0+	50-/0+	50-/0+	150-/0+	100	0
4	50-/0+	50-/0+	50-/0+	150-/0+	100	0
6	50-/0+	50-/0+	50-/0+	150-/0+	100	0
8	24-/26+	25-/25+	25-/25+	74-/76+	49.3	50.7
10	0-/50+	0-/50+	0-/50+	0-/150+	0	100
12	0-/50+	0-/50+	0-/50+	0-/150+	0	100
14	0-/50+	0-/50+	0-/50+	0-/150+	0	100
16	0-/50+	0-/50+	0-/50+	0-/150+	0	100
20	0-/50+	0-/50+	0-/50+	0-/150+	0	100
50	0-/50+	0-/50+	0-/50+	0-/150+	0	100

Urine Strip format

hCG Concentration (mIU/ml)	Site 1	Site 2	Site 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
10	50-/0+	50-/0+	50-/0+	150-/0+	100	0
12	50-/0+	50-/0+	50-/0+	150-/0+	100	0
16	24-/26+	24-/26+	25-/25+	73-/77+	48.7	51.3
20	0-/50+	0-/50+	0-/50+	0-/150+	0	100
24	0-/50+	0-/50+	0-/50+	0-/150+	0	100
30	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

Urine Cassette format

hCG Concentration (mIU/ml)	Site 1	Site 2	Site 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
10	50-/0+	50-/0+	50-/0+	150-/0+	100	0
12	50-/0+	50-/0+	50-/0+	150-/0+	100	0
16	25-/25+	24-/26+	22-/28+	71-/79+	47.3	52.7
20	0-/50+	0-/50+	0-/50+	0-/150+	0	100
24	0-/50+	0-/50+	0-/50+	0-/150+	0	100
30	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

b. Linearity/assay reportable range:

Not applicable, this is a qualitative test.

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

Traceability:
The tests are calibrated with reference material traceable to the World Health Organization (W.H.O.) 4th International Standard for hCG.

Stability/Shelf life:
The stability testing protocol and acceptance criteria used to support the shelf life were reviewed and found acceptable. The sponsor claims that devices are stable for 24 months when stored at 39-86°F (4-30°C).

d. Detection limit:

See precision section above (M(1)(a)).

e. Analytical specificity:

An interference study was performed by adding known amounts of potential exogenous and endogenous interfering substances to both negative and positive samples (10 and 20 mIU/mL hCG for urine samples, and 5 and 10 mIU/mL for serum samples). The testing was done with three lots of the cassette format. No interference was observed from the following substances at the concentrations listed below:

Substance	Concentration
Acetaminophen	20mg/dL
Acetoacetic Acid	2000mg/dL
Ascorbic Acid	20mg/dL
β-hydroxybutyrate	2000mg/dL
Caffeine	20mg/dL
Ephedrine	20mg/dL
Gentisic Acid	20mg/dL
Phenylpropanolamine	20mg/dL
Salicylic Acid	20mg/dL
Phenothiazine	20mg/dL
EDTA	80mg/dL
Acetylsalicylic Acid	20mg/dL
Benzoylecgonine	10mg/dL
Cannabinol	10mg/dL
Codeine	6ug/dL
Ethanol	1.0%
Methanol	10%
Albumin	2000mg/dL
Glucose	2000mg/dL
Bilirubin	2000mg/dL
Atropine	20mg/dL
Estriol-17-beta	1400ug/dL
Hemoglobin	2000mg/dL
Pregnanediol	1500ug/dL
Thiophene	20mg/dL
Ampicillin	20mg/dL
Tetracycline	20mg/dL
Ketone	20mg/dL
Cholesterol	250mg/dL
Triglyceride	500mg/dL

Hook effect:

Negative urine and serum samples were spiked with varying hCG concentrations from 62.500 IU/mL to 2000 IU/mL. The spiked samples were tested by 3 different operators using 3 different lots. The results demonstrated no hook effect at hCG concentrations up to 2000 IU/mL.

Effects of hCG β-core fragment:

Serum samples with 5mIU/mL and 10mIU/mL hCG, and urine samples with 10mIU/mL and 20mIU/mL hCG were spiked with varying concentrations of hCG β-core fragment up to $2x10^6$ pmol/L. These samples were tested by 3 different operators using 3 different lots. The results demonstrated no interference when hCG β-core fragment is ≤200 pmol/L. The sponsor has the following warning in their package insert:

High levels of hCG β-core fragment (>200 pmol /L) can lead to false positive results for both serum and urine samples.

Cross reactivity:
Serum samples with 5mIU/mL and 10mIU/mL hCG, and urine samples with 10mIU/mL and 20mIU/mL hCG were spiked with varying concentrations of glycoprotein hormones: Luteinizing hormone (LH), follicle-stimulating hormone (FSH), and thyroid stimulating hormone (TSH). These samples were tested by 3 different operators using 3 different lots. The results demonstrate no cross reactivity from these glycoprotein hormones up to the following concentrations:

Glycoprotein Hormones	Concentrations
LH	300 mIU/mL
FSH	1000 mIU/mL
TSH	1000 μIU/mL

Effects of urine pH:
Negative and positive urine samples containing 10 and 20 mIU/mL hCG were tested at pH values ranging from 4 to 9 using 3 different lots by 3 different operators. The results demonstrate no interference effect to the test performance from pH values of 4 to 9.

Effects of urine Specific Gravity:
Negative and positive urine samples containing 10 and 20 mIU/mL hCG were tested with Specific Gravity values ranging from 1.007 to1.032 using 3 different lots by 3 different operators. The results demonstrate no interference from urine Specific Gravity ranging from 1.007 to1.032.

f. Assay cut-off:

See precision section above (M(1)(a)).

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison studies were conducted at three different OB/GYN Physician's Offices. A total of 120 urine and 120 serum samples were collected from 120 donors (ages ranging from 18 to 49 years old and about half of them were pregnant at less than 5 weeks early stage). Samples were randomly collected at various times throughout the day, and tested at each site by six different healthcare professionals (three operators for strip format and three operators for cassette format) using both the proposed and the predicate devices. All samples were tested using each device format (strip and cassette). Each operator performed tests using one device format with three different lots of the candidate device and one predicate device at the same time, but not sequentially. All 3 lots of candidate devices gave the same result for each sample and the following tables summarize the representative results from one

lot:

Serum Strip format

Candidate device	Predicate device	+	-
	+	60	0
	-	0	60

Serum Cassette format

Candidate device	Predicate device	+	-
	+	60	0
	-	0	60

Urine Strip format

Candidate device	Predicate device	+	-
	+	60	0
	-	0	60

Urine Cassette format

Candidate device	Predicate device	+	-
	+	60	0
	-	0	60

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not Applicable

*b. Clinical specificity**:***

Not Applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not Applicable

4. Clinical cut-off**:**

Not Applicable

5. Expected values/Reference range:

Not applicable because this is a qualitative device.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.