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

A. 510(k) Number:

k171136

B. Purpose for Submission:

New Device

C. Measurand:

Human Chorionic Gonadotrophin (hCG)

D. Type of Test:

Lateral flow immunoassay

E. Applicant:

LIA Diagnostics

F. Proprietary and Established Names:

Lia Pregnancy Test

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1155 Human chorionic gonadotrophin

2. Classification:

   Class II

3. Product code:

   LCX

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indications for use below

2. Indication(s) for use:

   Lia Pregnancy Test is intended for non-professional, over-the-counter use for the qualitative identification of the elevated levels of human Chorionic Gonadotropin (hCG) in urine to aid in the determination of pregnancy.

   The Lia Pregnancy Test is intended for Over-the-Counter use.

3. Special conditions for use statement(s):

   For over-the-counter use

4. Special instrument requirements:

   None

I. Device Description:

The Lia Pregnancy Test is designed to detect human Chorionic Gonadotropin (hCG) when used in midstream urine collection mode. Each device contains an airtight pouch that includes the assay, a desiccant, and instructions for use. The test strip is encased in the mid-section of the Urine Collection Pad. Each test reagent strip consists of a Goat anti-alpha hCG polyclonal antibody coated membrane and a dried chemical pad containing mouse monoclonal anti-β-hCG anybody colloidal gold conjugate. The control antibodies coated on the membrane are goat anti-mouse IgG. The device is designed to yield 100% positive results at a concentration of 22 mIU/mL hCG.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   OSOM hCG Urine Test

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

   k974159

3. Comparison with predicate:

Similarities		
Item	Lia Pregnancy Test (k171136)	Predicate (OSOM hCG Urine Test k974159)
Intended Use	For qualitative detection of hCG hormone in urine to aid early detection of pregnancy.	Same
	Over the counter use	Prescription use
Test Principle	dyed latex-based lateral-flow sandwich immunochromatographic assay	Same
Read Time	At 5 min	Same
Shelf-life	18 months	Same
Specimen	Urine	Same
Lowest hCG concentration yielded 100% positive:	22 mIU/mL	25 mIU/mL

Differences		
Item	Lia Pregnancy Test	Predicate (k974159)
Traceability	WHO 5th International Standard	WHO 3rd International Standard
Format	Cassette	Dipstick
Specimen Application	Midstream	Dipstick

K. Standard/Guidance Document Referenced (if applicable):

None referenced.

L. Test Principle:

The method employs a combination of monoclonal-dye conjugate and polyclonal-solid phase antibodies to selectively identify hCG in the test samples. The Lia Pregnancy Test is a lateral flow chromatographic immunoassay. When a mid-stream urine sample is applied to the absorbent end, the sample enters the device by capillary action and mixes with the antibody-dye conjugate, flowing across the pre-coated membrane. During the test, hCG in the urine specimen reacts with the dye conjugate and forms a complex. The complex migrates along the cellulose strip to the α-hCG antibody line (T), and remains captured in the T line. As a result, a red colored band develops in the T line, indicating a positive result. If there is no hCG in the urine, there is no red band in the test zone, indicating a negative result. The control line develops in the Control (C) zone regardless of the result.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision studies were performed using hCG-free urine samples spiked with hCG to achieve the following concentrations: 50, 33, 25, 22, 18, 16, 14, 11, 9. 7, 4 and 2 mIU/ml hCG. The hCG used for spiking was purified intact hCG traceable to the WHO International 5th Standard. Precision testing included 3 lots of devices, and the results are summarized in the below table.

hCG conc. (mIU/mL)	Positive results/Total results			
	Lot#1	Lot #2	Lot#3	Combined
50	10/10	10/10	10/10	30/30
33	10/10	10/10	10/10	30/30
25	10/10	10/10	10/10	30/30
22	10/10	10/10	10/10	30/30
18	9/10	10/10	7/10	26/30
16	7/10	7/10	5/10	19/30
14	5/10	7/10	3/10	15/30
11	1/10	1/10	0/10	2/30
9	1/10	0/10	0/10	1/30
7	0/10	0/10	0/10	0/30
4	0/10	0/10	0/10	0/30
2	0/10	0/10	0/10	0/30

b. Linearity/assay reportable range:

Not applicable.

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

Traceability:
The test is calibrated against the WHO 5th International Standards for hCG.

Stability:
The accelerated stability testing has been completed to support shelf life of 18 months at 36-86 °F. The real-time stability study is on-going. The stability protocols and acceptance criteria were reviewed and found to be acceptable.

d. Detection limit:

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

e. Analytical specificity:

Cross reactivity:
To determine if structurally similar analytes to hCG would interfere with test results, three glycoprotein hormones were analyzed: Luteinizing hormone (LH), follicle-stimulating hormone (FSH), and thyroid stimulating hormone (TSH). Negative and positive hCG urine samples (50 mIU/mL) were spiked with different levels of hormones; LH: 500 mIU/mL, FSH: 1000 mIU/mL, and TSH: 1000 µIU/mL. Results demonstrated no interference from LH, FSH and TSH at the concentrations tested.

Interference:
A study was conducted to evaluate interference of specific exogenous compounds. Negative and positive hCG urine samples (25 mIU/mL) were individually spiked with the substances listed in the table below. One replicate/lot, 3 lots of devices were tested. No interference was observed from the compounds at the concentrations listed below.

Substance	Concentration
Ephedrine	20 mg/dL
Estriol	1.5 mg/dL
Acetylsalicylate Acid	20 mg/dL
Acetaminophen	20 mg/dL
EDTA	80mg/dL
Acetone	1%
Ethanol	1%
Methanol	1%
Ampicillin	5.3 mg/dL
Albumin (Human)	2000 mg/dL
Ascorbic Acid	20 mg/dL
Atropine	20 mg/dL
Bilirubin	2 mg/dL
Caffeine	20 mg/dL
Cannabinol	10 mg/dL
DL-β-Hydroxybutyric Acid	2000 mg/dL
Gentisic Acid	20 mg/dL
Glucose	2000 mg/dL
Hemoglobin	250 mg/dL
Ibuprofen	40 mg/dL
Methadone	10 mg/dL
Morphine	10 mg/dL
Nicotine	20 mg/dL
Phenylpropanolamine	20 mg/dL
Salicylic acid	20 mg/dL
Tetracycline	1.5 mg/dL
Uric acid	20 mg/dL

Effects of urine pH and Specific Gravity:

A study was conducted, using 3 lots of devices, to evaluate the effect of pH and specific gravity of urine specimens. Negative and positive hCG urine samples (0 mIU/mL, 7 mIU/mL, 22mIU/mL, and 38 mIU/mL) were tested across a pH range of 4.58-8.57 and specific gravity range of 1.003-1.036. No interference was observed in samples from the pH ranges of 4.56-8.87 and specific gravity ranges of 1.003-1.036.

High Dose /Hook effect:
The sponsor completed testing, using 3 lots of devices, with urine samples containing high concentrations of hCG to determine if high hCG concentrations would cause false negative results. Negative urine samples were spiked with hCG to achieve concentrations of 2.5, 25, 100, 150, 500 IU/mL. The test results demonstrated no hook effect at hCG concentrations up to 500 IU/mL.

hCG β-core fragment test:
To evaluate hook effects of the hCG β-core fragment, negative (0 mIU/mL) and positive hCG urine samples (250 IU/mL) were spiked with β-core hCG fragment standard (traceable to WHO reference reagent 99/708) at concentrations up to 500,000 pmol/L. Each spiked urine sample was tested using 3 lots of devices. The results demonstrated that no hook effect was observed at an hCG β-core fragment concentration up to 500,000 pmol/L.

hCG β-core fragment testing also demonstrated that hCG β-core fragment concentrations above 1,000 pmol/L produce positive results with the Lia Pregnancy Test.

f. Assay cut-off:

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

2. Comparison studies:

a. Method comparison with predicate device:

A lay-user study was conducted with 159 female participants, ages 18-49 years, who tested their own urine on the Lia Pregnancy Test following instructions in the package insert. The Lia Pregnancy Test result recorded by each lay user was compared to the result obtained by professional interpretation of each lay user's device. In addition, a matching fresh urine specimen from each participant was collected in a cup and tested by health care professionals using the predicate device, and the results from this test were compared to the corresponding lay user's result. Following the instructions for use, 153 lay users successfully recorded positive or negative results from the device, 5 lay users obtained invalid results, and 1 participant did not complete the study.

The following table is a summary of the lay user results obtained with the Lia Pregnancy Test compared to the results obtained by professionals interpreting the

same lay user's devices (N=153):

		Lay User results		
		Positive	Negative	Total
Professional interpretation	Positive	75	1	76
	Negative	1	76	77
	Total	76	77	153

The following table is a summary of the lay user results obtained with the Lia Pregnancy Test compared to the results obtained by professionals using the predicate device (N=153):

		Lia Pregnancy Test		
		Positive	Negative	Total
Predicate device	Positive	76	0	76
	Negative	0	77	77
	Total	76	77	153

The sponsor conducted a post-test questionnaire, where 98% of users said that the printed instructions were clear and usable, 91 % of subjects were confident that they had performed the test correctly, and 98% said it was easy to use the device.

A Flesch-Kincaid reading analysis was also performed on the package insert, demonstrating a reading Grade Level of 6.6.

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):

None

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

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.