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

A. 510(k) Number:

k131236

B. Purpose for Submission:

New Device

C. Measurand:

Human chorionic gonadotropin (hCG)

D. Type of Test:

Qualitative chromatographic immunoassay

E. Applicant:

UCP Biosciences, Inc.

F. Proprietary and Established Names:

UCP Home Pregnancy Midstream Test

UCP Home Pregnancy Dip Card/Strip

UCP Home Pregnancy Cassette Test

UCP Pregnancy Dip Card/Strip

UCP Pregnancy Cassette Test

G. Regulatory Information:

1. Regulation section:

   21 CFR § 862.1155, Human chorionic gonadotropin (hCG) Test System

2. Classification:

   Class II

3. Product code:

   LCX, JHI

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   UCP Home Pregnancy Cassette Test is rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The device is intended for Over the Counter Use Only.

   UCP Home Pregnancy Dip Card/Strip is rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The device is intended for Over the Counter Use Only.

   UCP Home Pregnancy Midstream Test is rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The device is intended for Over the Counter Use Only.

   UCP Pregnancy Cassette Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The device is intended for Prescription Use Only including at point of care sites.

   UCP Pregnancy Dip Card/Strip is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The device is intended for Prescription Use Only including at point of care sites.

3. Special conditions for use statement(s):
   UCP Home Pregnancy Cassette Test, UCP Home Pregnancy Dip Card/Strip, and UCP Home Pregnancy Midstream Test are for Over-the Counter use.

   UCP Pregnancy Cassette Test and UCP Pregnancy Dip Card/Strip are for Prescription Use Only including at point of care sites.

4. Special instrument requirements:
   None

I. Device Description:

UCP Home Pregnancy Tests and UCP Pregnancy Tests use nitrocellulose strips in Midstream, Dip Card/Strip, and Cassette test formats. The tests are lateral flow immunoassays that are conducted by immersing the test strips in urine specimen and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate. Users are able to read tests results in 3 minutes.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Quik-Check Home Pregnancy Test

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

   k012215

3. Comparison with predicate:

Parameter	**UCP Home Pregnancy Test, UCP Pregnancy Test**	**Quik-Check Home Pregnancy Test** (Predicate Device)
Indications for Use	For the qualitative detection of hCG in urine to aid in the early detection of pregnancy.	Same
Intended Population	Over-the Counter and Prescription Use	Over-the-Counter Use
Format	Midstream, Dip Card/Strip, and Cassette	Strip, Cassette
Test Principle	Chromatographic immunoassay, lateral flow	Same
Test Time	3 minutes	Same
Sensitivity	25 mIU/mL	Same

Standardization	WHO Fourth International Standard	WHO Third International Standard

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

Guidance for Industry and FDA Reviewers/Staff – Guidance for Over the Counter (OTC) Human Chorionic Gonadotropin (hCG) 510(k)s.

L. Test Principle:

UCP Home Pregnancy Test and UCP Pregnancy Test use nitrocellulose strips. The test utilizes a mixture of monoclonal (mouse) and polyclonal (goat) antibodies to selectively identify the elevated level of hCG in human urine. A colloidal gold conjugate is used to visualize the immunological reaction. The assay is conducted by immersing the test strips in a urine specimen and observing the formation of colored lines. The urine specimen migrates via capillary action along the membrane to react with the colored conjugate. A negative specimen produces no line in the test zone (T), and one colored line in the control zone (C). A positive specimen produces distinct colored lines in both the test zone (T) and the control zone (C). An invalid specimen produces either no lines or one line in the test zone (T) and no line in the control zone (C).

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The precision/reproducibility study was conducted at three sites (one internal site and 2 POC sites) using three lots by three operators over multiple days, with 20 replicates for each standard tested (0, 12.5, 18.75, 25, 31.25, 50, 100 mIU/mL hCG). Standards used for spiking contain the purified intact hCG traceable to the WHO International 4th Standard. The testing results are summarized in the following:

Pregnancy DipCard/Strip

HCG Concentration (mIU/mL)	Total Numbers of Determinations	Lot#: A	Lot#:B	Lot#:C
		Results #Neg/# Pos	Results #Neg/#Pos	Results #Neg/#Pos
0	20	20/0	20/0	20/0
12.5	20	20/0	20/0	20/0
18.75	20	18/2	20/0	19/1
25	20	0/20	0/20	0/20
31.25	20	0/20	0/20	0/20
50	20	0/20	0/20	0/20
100	20	0/20	0/20	0/20

Pregnancy Cassette

HCG Concentration (mIU/mL)	Total Numbers of Determinations	Lot#: A	Lot#:B	Lot#:C
		Results #Neg/# Pos	Results #Neg/#Pos	Results #Neg/#Pos
0	20	20/0	20/0	20/0
12.5	20	20/0	20/0	20/0
18.75	20	20/0	20/0	19/1
25	20	0/20	0/20	0/20
31.25	20	0/20	0/20	0/20
50	20	0/20	0/20	0/20
100	20	0/20	0/20	0/20

Pregnancy Midstream

HCG Concentration (mIU/mL)	Total Numbers of Determinations	Lot#: A	Lot#:B	Lot#:C
		Results #Neg/# Pos	Results #Neg/#Pos	Results #Neg/#Pos
0	20	20/0	20/0	20/0
12.5	20	20/0	20/0	20/0
18.75	20	20/0	20/0	19/1
25	20	0/20	0/20	0/20
31.25	20	0/20	0/20	0/20
50	20	0/20	0/20	0/20
100	20	0/20	0/20	0/20

b. Linearity/assay reportable range:

Not applicable. The assay is intended for qualitative use.

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

The tests are calibrated with reference material traceable to the World Health Organization (W.H.O.) 4th International Standard for Chorionic Gonadotropin (75/589).

The stability testing protocol and acceptance criteria used to support the shelf life were reviewed and found to be acceptable. The sponsor claims a 24 month shelf life from manufacturing date when stored at room temperature, 15-28°C (59-82°F).

d. Detection limit:

The detection limit is 25 mIU/mL. See "Precision/Reproducibility" M.1.a for test results summary.

e. Analytical specificity:

The analytical specificity was conducted by spiking Luteinizing Hormone (500

mIU/mL), Follicle Stimulating Hormone (1000 mIU/mL) and Thyroid Stimulating Hormone (1000 mIU/mL) separately into urine samples that contain 0 and 25 mIU/mL hCG. The samples were tested by all device formats. The results demonstrate that the tested levels of LH, FSH, or TSH do not cross react with UCP Pregnancy tests.

The hCG ß core fragment at the concentrations 250,000 pmol/L, 500,000 pmol/L, 1,000,000 pmol/L, respectively, was spiked into negative urine, urine samples that contain 0 and 25 mIU/mL hCG, then tested using 3 lots of each UCP Pregnancy test device formats. The results demonstrate that the hCG ß core fragment does not interfere with UCP Pregnancy tests.

Various prescription, over the counter drugs, and chemicals (at a concentration of 100 ug/mL or above) and potential endogenous interferents were tested by each UCP Pregnancy Test format and showed no cross-reactivity with urine samples containing 0 and 25 mIU/mL hCG. The testing results are summarized in the following:

Interfering substance	**Concentration**
Acetaminophen	100ug/ml
Acetone	100ug/ml
Albumin	100ug/ml
Ampicillin	100ug/ml
Ascorbic Acid	100ug/ml
Aspartame	100ug/ml
Aspirin	100ug/ml
Atropine	100ug/ml
Benzocaine	100ug/ml
Bilirubin	100ug/ml
Caffeine	100ug/ml
Chloroquine	100ug/ml
(+)-Chlorpheniramine	100ug/ml
(+/-)-Chlorpheniramine	100ug/ml
Creatine	100ug/ml
Dexbrompheniramine	100ug/ml
Dextromethorphan	100ug/ml
Diphenhydramine	100ug/ml
Dopamine	100ug/ml
(+/-)-Epinephrine	100ug/ml
Erythromycin	100ug/ml
Ethanol	100ug/ml
Furosemide	100ug/ml
Glucose	100ug/ml
Guaiacol Glyceryl Ether	100ug/ml
Hemoglobin	100ug/ml
Ibuprofen	100ug/ml
(+/-)-Isoproterenol	100ug/ml
Ketamine	100ug/ml
Levorphanol	100ug/ml

Lidocaine	100ug/ml
(+)-Naproxen	100ug/ml
Niacinamide	100ug/ml
Nicotine	100ug/ml
(+/-)-Norephedrine	100ug/ml
Oxalic Acid	100ug/ml
Penicillin-G	100ug/ml
Pheniramine	100ug/ml
Phenothiazine	100ug/ml
1-Phenylephrine	100ug/ml
β-Phenylethylamine	100ug/ml
Procaine	100ug/ml
Quinidine	100ug/ml
Ranitidine	100ug/ml
Riboflavin	100ug/ml
Sodium Chloride	100ug/ml
Sulindac	100ug/ml
Theophylline	100ug/ml
Tyramine	100ug/ml
4-Dimethylaminoantipyrine	100ug/ml
(1R,2S)-(-)-N-Methyl-Ephedrine	100ug/ml
Albumin	5 mg/ml
Bilirubin	50mg/L
Creatine	200mg/dl
Hemoglobin	50 mg/L
Glucose	500mg/ml
Vitamin(L-Ascorbic Acid)	50mg/ml
Uric Acid	8mg/dl

To evaluate potential interference of urine pH on the test results, negative and positive urine samples (with hCG at 0 and 25 mIU/mL, respectively) were adjusted to pH ranges from 4.5 to 9, then tested by each UCP Pregnancy Test format. The results demonstrate urine pH ranging from 4.5 to 9 does not interfere with UCP Pregnancy Tests.

To evaluate potential interference of urine specific gravity on the test results, negative and positive urine samples (with hCG at 0 and 25 mIU/mL, respectively) were adjusted to the specific gravity values from 1.002 to 1.035, using unaltered urine as a control, and then tested by each UCP Pregnancy Test format. The results demonstrate urine specific gravity values from 1.002 to 1.035 do not interfere with UCP Pregnancy Tests.

f. Assay cut-off:

See detection limit section M.1.d.

2. Comparison studies:

a. Method comparison with predicate device:

Comparison studies between each UCP Pregnancy Test format and the predicate device were conducted at a physician's office by lab professionals using 100 masked randomized urine specimens. The urine specimens were collected from 100 women who fit the following categories: childbearing age, suspected pregnant women, and women in early pregnancy (first trimester of pregnancy). The women collected urine samples in cups to be used for this study. The results of all formats of UCP Pregnancy Tests and the predicate device were 100% in agreement when tested by the lab professionals. The UCP Pregnancy Dip Card/Strip and Cassette contains the same test strip for home use and prescription use versions and identical testing results were obtained for each version. The testing results from lab professionals are summarized in the following:

UCP Home Pregnancy Midstream (Dip Method) vs. Predicate Device

	Positive by Predicate	Negative by Predicate
Positive by UCP Home Pregnancy Midstream	49	0
Negative by UCP Home Pregnancy Midstream	0	51

UCP Pregnancy Dip Card/Strip (Home and Prescription use versions) vs. Predicate Device

	Positive by Predicate	Negative by Predicate
Positive by UCP Pregnancy Dip Card/Strip	49	0
Negative by UCP Pregnancy Dip Card/Strip	0	51

UCP Pregnancy Cassette (Home and Prescription use versions) vs. Predicate Device

	Positive by Predicate	Negative by Predicate
Positive by UCP Pregnancy Cassette	49	0
Negative by UCP Pregnancy Cassette	0	51

Lay-user studies were also conducted. Each UCP Home Pregnancy Test format was tested by lab professionals and each UCP Home Pregnancy Test format was tested by lay users. For the Midstream Test format study, each of 100 lay users tested their own midstream urine using the UCP Home Pregnancy Midstream test in addition to collecting the urine specimen in a cup for professional testing. Before testing, the lay users were given the Test Instructions (English) to read. The results of all formats of

the UCP Home Pregnancy Tests performed by lay users and the results from all formats of the UCP Home Pregnancy Tests performed by lab professionals were 100% in agreement. The testing results are summarized in the following:

UCP Home Pregnancy Midstream Test

	Positive by Lay Users	Negative by Lay Users
Positive by Professionals	49	0
Negative by Professionals	0	51

UCP Home Pregnancy Dip Card/Strip

	Positive by Lay Users	Negative by Lay Users
Positive by Professionals	49	0
Negative by Professionals	0	51

UCP Home Pregnancy Cassette Test

	Positive by Lay Users	Negative by Lay Users
Positive by Professionals	49	0
Negative by Professionals	0	51

Lay users participating in the study represented a diversity of age and various educational backgrounds. When the testing was complete, the users were asked to complete a questionnaire. The post-study survey indicated the lay users understood the test instructions, the meaning of the test results and can perform the test satisfactorily by following the test instruction. A Flesh-Kincaid reading analysis was performed on the test instructions and the score revealed a read grade level of 7.

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

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.