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

A. 510(k) Number:

K150063

B. Purpose for Submission:

New Device

C. Measurand:

Human Chorionic Gonadotrophin (hCG)

D. Type of Test:

Lateral flow immunoassay

E. Applicant:

Coretests, Inc.

F. Proprietary and Established Names:

ACCU NEWS One Step hCG Pregnancy Test Strip

ACCU NEWS One Step hCG Pregnancy Test Midstream

ACCU NEWS One Step hCG Pregnancy Test Cassette

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:

   The ACCU NEWS One Step hCG Pregnancy Test Strip is a lateral flow immunoassay to qualitatively detect the presence of human Chorionic Gonadotropin (hCG) hormone in urine specimen to aid early detection of pregnancy for both prescription use and OTC use.

   The ACCU NEWS One Step hCG Pregnancy Test Midstream is a lateral flow immunoassay to qualitatively detect the presence of human Chorionic Gonadotropin (hCG) hormone in urine specimen to aid early detection of pregnancy for both prescription use and OTC use.

   The ACCU NEWS One Step hCG Pregnancy Test Cassette is a lateral flow immunoassay to qualitatively detect the presence of human Chorionic Gonadotropin (hCG) hormone in urine specimen to aid early detection of pregnancy for both prescription use and OTC use.

3. Special conditions for use statement(s):

   For over-the-counter use and for prescription use

4. Special instrument requirements:

   None

I. Device Description:

The ACCU NEWS One Step hCG Pregnancy Test (Strip, Cassette, Midstream) is a qualitative lateral flow immunoassay for the detection of hCG. The device comes in three formats: strip, cassette, and midstream. Each device contains an airtight pouch that includes the assay, a desiccant, and instructions for use. The OTC strip format also contains a urine collection cup. The OTC cassette format contains a dropper pipette. The nitrocellulose test strip of the midstream device is encased in plastic housing. These tests are conducted by immersing the test strips in urine 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 test results in 5 minutes. The assay cut-off is 25 mIU/mL.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Wondfo One Step hCG Urine Pregnancy Test

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

   K043443

3. Comparison with predicate:

Similarities		
Item	Device (k150063)	Predicate (k043443)
Intended Use	Intended for both prescription and OTC use for qualitative detection of hCG hormone in urine to aid early detection of pregnancy.	Same
Specimen	Urine	Same
Detection limit	25 mIU/mL	Same
Test Principle	Colloidal Gold Immunoassay	Same
Traceability	WHO 3rd International Standard	Same
Format	Strip, cassette, midstream	Same

Differences		
Item	Device	Predicate
Read Time	At 5 min	3-5 minutes
High Dosage Hook Effect	No high dosage hook effect for hCG up to 500,000 mIU/mL	No high dosage hook effect for hCG up to 100,000 mIU/mL
Specificity	LH at 1000 mIU/mL, FSH at 1000 mIU/mL, and TSH at 1000 μIU/mL	LH at 300 mIU/mL, FSH at 300 mIU/mL, and TSH at 1000 mIU/mL
pH Interference	No interference for urine with pH 2-9	No interference for urine with pH 4-9
Specific Gravity Interference	No interference for urine with Specific Gravity 1.003-1.030	No interference for urine with Specific Gravity 1.000-1.050

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

None referenced.

L. Test Principle:

The ACCU NEWS One Step hCG Pregnancy Test (Strip, Cassette, Midstream) uses a double antibody sandwich method. The membrane of the test strip is coated with mouse anti-β hCG monoclonal antibody and anti-α hCG antibody immobilized on the test line region (T-line), and goat anti-mouse immobilized on the control line region (C-line). During testing, the urine specimen is mixed with the mouse anti-β hCG monoclonal antibody-colloidal gold conjugate that allows β hCG to react with the antibody. The mixture then moves upward on the membrane chromatographically and reacts with the anti-α hCG antibody on the T-line. If β hCG is present, a pink line will appear indicating a positive result. If no β hCG is present, no test result line will appear indicating a negative result. The mixture will continue to travel up the test strip and react with the goat anti mouse on the C-line. Regardless of the presence of hCG, as the mixture continues to move across the membrane to the immobilized goat anti-mouse IgG polyclonal antibody, a pink-colored line at the C-line will always appear. This serves as an internal procedural control.

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: 0, 12.5, 18.75, 25, 50, and 100 mIU/mL. The hCG used for spiking contains the purified intact hCG traceable to the WHO International 3rd Standard. The precision study was carried out at three different sites; one internal site and two external point of care sites. Each study site tested a unique lot of test device for each of the three formats (strip, cassette, midstream), for a total of three lots of each test format. Each site performed blinded testing of the samples with a total of 60 urine samples (10 from each urine sample) over 3-5 days. The results are shown below for each test format:

Strip format:

hCG conc. (mIU/mL)	Sites						Total	
	#1		#2		#3			
	+	-	+	-	+	-	+	-
0	0	10	0	10	0	10	0	30
12.5	0	10	0	10	0	10	0	30
18.75	0	10	0	10	0	10	0	30
25	10	0	10	0	10	0	30	0
50	10	0	10	0	10	0	30	0
100	10	0	10	0	10	0	30	0

Cassette format

hCG conc. (mIU/mL)	Sites						Total	
	#1		#2		#3			
	+	-	+	-	+	-	+	-
0	0	10	0	10	0	10	0	30
12.5	0	10	0	10	0	10	0	30
18.75	0	10	0	10	0	10	0	30
25	10	0	10	0	10	0	30	0
50	10	0	10	0	10	0	30	0
100	10	0	10	0	10	0	30	0

Midstream

hCG conc. (mIU/mL)	Sites						Total	
	#1		#2		#3			
	+	-	+	-	+	-	+	-
0	0	10	0	10	0	10	0	30
12.5	0	10	0	10	0	10	0	30
18.75	0	10	0	10	0	10	0	30
25	10	0	10	0	10	0	30	0
50	10	0	10	0	10	0	30	0
100	10	0	10	0	10	0	30	0

b. Linearity/assay reportable range:

Not applicable.

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

Traceability:
The test is calibrated against the WHO 3rd International Standards for hCG.

Stability:
The device is stable for 2 years when stored at 4-30°C. The stability protocols and acceptance criteria were reviewed and found 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 (25 mIU/mL) were spiked with different levels of hormones; LH: 750, 1000, 3750, and 7500 mIU/mL, FSH: 750, 1000, 3750, and 7500

mIU/mL, and TSH: 750, 1000, 3750, and 7500 µIU/mL. Five test devices for each format were tested with each of the spiked urine samples. Results demonstrated no interference from LH, FSH and TSH up to 1000 mIU/mL, 1000 mIU/mL, and 1000 µIU/mL respectively.

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. Five devices of each format were tested. No interference was observed from the compounds at the concentrations listed below.

Substance	Concentration
(1R,2S)-(-)-Ephedrine	20 mg/dL
(1S,2R)-(+)-Ephedrine	20 mg/dL
Acetylsalicylate Acid	20 mg/dL
Acetaminophen	20 mg/dL
Acetone	20 mg/dL
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 to evaluate the effect of pH and specific gravity of urine specimens. Negative and positive hCG urine samples (25 mIU/mL) were tested across a pH range of 2.0-9.0 and specific gravity range of 1.003-1.030. Five devices of each format were tested. No interference was observed in samples from the pH ranges of 2.0-9.0 and specific gravity ranges of 1.003-1.030.

High Dose /Hook effect:

The sponsor completed testing with urine samples containing high concentrations of hCG to determine if they would cause false negative results. Negative urine samples were spiked with hCG standard to achieve concentrations of 50, 100, 200, 300, and 500 IU/mL. Three devices of each format were tested at each hCG concentration (three tests per device format per concentration). 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 and positive hCG urine samples (25 mIU/mL) were spiked with β-core hCG fragment standard (traceable to WHO reference reagent 99/708) at several different concentrations up to 1,000,000 pmol/L. Each spiked urine sample was tested using three devices from each format. However, the results demonstrated that no hook effect was observed at an hCG β-core fragment concentration up to 100,000 pmol/L.

f. Assay cut-off:

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

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was conducted at 1 internal site and to external point of care sites to compare results obtained from each test format of the candidate device to test results obtained from the predicate device in the hands of professional users. A total of 250 urine samples were collected from 250 donors (age ranging between 18-43 years old), and approximately half of the participants were suspected to be pregnant. Data of tested participants are below.

		ACCU NEWS One Step hCG Pregnancy Test					
		Midstream		**Cassette**		**Test Strips**	
		Positive	**Negativ**	**Positive**	**Negativ**	**Positive**	**Negative**
Predicate Device Result	**Positive**	124	0	124	0	124	0
	Negative	0	126	0	126	0	126
	Total%	124	126	124	126	124	126
	Agreement	100%		100%		100%	

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):

Lay-user study:

A lay-user study was conducted with 250 female participants from ages 18-43 who tested their own urine following instructions in the package inserts. A matching fresh urine specimen from each participant was tested by health care professionals using all three formats of the device as well. The results for each test format are shown below:

Strip format

		Lay User Test Result (Strip Format)	
		Positive	**Negative**
Professional Test Result (Strip Format)	**Positive**	124	0
	Negative	0	126
	Total	124	126
	% Agreement	100%	

Cassette format

		Lay User Test Result (Cassette Format)	
		Positive	**Negative**
Professional Test Result (Cassette Format)	**Positive**	124	0
	Negative	0	126
	Total	124	126
	% Agreement	100%	

Midstream format

		Lay User Test Result (Midstream Format)	
		Positi	**Negativ**
Professional Test Result (Midstream Format)	**Positive**	124	0
	Negative	0	126
	Total	124	126
	% Agreement	10	

All participants completed a post-study questionnaire and the evaluation of the questionnaire results demonstrated that the participants found the ACCU NEWS One

Step hCG Pregnancy Test easy to use and understand and did not have trouble with interpreting results. A Flesch-Kincaid reading analysis was also performed on the package insert for each device format for OTC portions and professional portions of the labeling. The scores demonstrated a reading Grade Level of 6 for the OTC labeling portion and a Grade Level of 9 for the professional labeling portion.

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.