

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

**A. 510(k) Number:**

k173229

**B. Purpose for Submission:**

New Device

**C. Measurand:**

Human chorionic gonadotropin

**D. Type of Test:**

Qualitative

**E. Applicant:**

Guangzhou Wondfo Biotech Co., Ltd.

**F. Proprietary and Established Names:**

Preview Digital Pregnancy Test

**G. Regulatory Information:**

1. Regulation section:

21 CFR 862.1155

2. Classification:

Class II

3. Product code:

LCX

4. Panel:

Chemistry (75)

**H. Intended Use:**

1. Intended use(s):

See Indication for use, below.

2. Indication(s) for use:

Preview Digital Pregnancy Test is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy.

3. Special conditions for use statement(s):

The device is intended for over-the counter use.

4. Special instrument requirements:

Not applicable.

**I. Device Description:**

The Preview Digital Pregnancy Test is a qualitative lateral-flow immunochromatographic assay that consists of a single test strip encased in a plastic device housing, with an absorbent tip. The device incorporates a digital readout of the test result which is displayed on an LCD screen. The device is distributed in one pouch with a desiccant and the instructions for use leaflet. The device can be used in both dip and midstream modes. The device contains mouse monoclonal anti  $\beta$ -hCG antibody colloidal gold conjugate pre-dried on a pad. Mouse monoclonal anti- $\alpha$ -hCG antibody (on the Test Line) and goat anti-mouse IgG polyclonal antibody (on the Control Line) are coated and immobilized on the nitrocellulose membrane.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

One Step HCG Urine Pregnancy Test

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

k043443

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Early detection of pregnancy	same
Specimen	Urine	same

Similarities		
Item	Device	Predicate
Assay technical	Immunochromatographic assay	same
Sensitivity	25 mIU/mL	same
Results	Qualitative	same
Target use	Over the counter use	same
Device format	Midstream and dip	Cassette, test strip, and midstream

Differences		
Item	Device	Predicate
Readout	Digital/LCD	Visual interpretation of color line(s)

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

Not applicable.

**L. Test Principle:**

The Preview Digital Pregnancy Test is lateral flow sandwich immunochromatographic assay. During the test procedures, hCG in the urine specimen reacts with the mouse anti $\beta$ -hCG antibody-colloidal gold conjugate to form a complex. By capillary action, the complex migrates along the membrane to the  $\alpha$ -hCG antibody line (T), and remains captured in the T line. As a result a colored band develops in the T line, indicating a positive result. If there is no hCG in the urine, no colored band develops in the test zone, indicating a negative result. A colored line will develop in the control zone if sufficient sample volume has been applied to the test strip.

The Preview Digital Pregnancy Test device utilizes LED as a light source and light reflection to determine the presence or absence of the colored test and control lines. The intended user dips the absorbent tip into the urine for 10 seconds and the final reading is observed between 3 and 5 minutes by digital display of the results (“Yes+”, “No-” or “Invalid”) on the display screen.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

A precision study was performed using negative human urine samples spiked with hCG (commercially available and traceable to the 4th WHO international standard) to create samples with hCG concentrations of 0 mIU/mL, 5 mIU/mL, 12.5 mIU/mL, 15 mIU/mL, 18.75 mIU/mL, 25 mIU/mL, 50 mIU/mL, 100 mIU/mL and 1000 mIU/mL. These samples were tested in replicates of 10, by three laboratory technicians, using three lots of Preview Digital Pregnancy Test for five consecutive days. Testing was

performed by both dip method and mid-stream methods, and the results are summarized in the table below:

Dip-mode results summary:

	hCG concentration (mIU/mL)								
	0	5	12.5	15	18.75	25	50	100	1000
Lot I	0+/50-	0+/50-	0+/50-	0+/50-	4+/46-	50+/0-	50+/0-	50+/0-	50+/0-
Lot II	0+/50-	0+/50-	0+/50-	0+/50-	5+/45-	50+/0-	50+/0-	50+/0-	50+/0-
Lot III	0+/50-	0+/50-	0+/50-	0+/50-	6+/44-	50+/0-	50+/0-	50+/0-	50+/0-

Mid-stream results summary:

	hCG concentration (mIU/mL)								
	0	5	12.5	15	18.75	25	50	100	1000
Lot I	0+/50-	0+/50-	0+/50-	0+/50-	5+/45-	50+/0-	50+/0-	50+/0-	50+/0-
Lot II	0+/50-	0+/50-	0+/50-	0+/50-	5+/45-	50+/0-	50+/0-	50+/0-	50+/0-
Lot III	0+/50-	0+/50-	0+/50-	0+/50-	6+/44-	50+/0-	50+/0-	50+/0-	50+/0-

A second precision study was conducted using hCG spiked urine samples containing hCG at concentrations of 0 mIU/mL, 5 mIU/mL, 12.5 mIU/mL, 15 mIU/mL, 18.75 mIU/mL, 25 mIU/mL, 50 mIU/mL, and 100 mIU/mL. These samples were tested by nine operators with three lots of Preview Digital Pregnancy Test. The results obtained were similar to those in the first precision study conducted (shown above).

*b. Linearity/assay reportable range:*

Linearity is not applicable since this is a qualitative test.

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

The test is calibrated against reference material traceable to WHO International Standard 4th edition for hCG.

The stability testing protocol and acceptance criteria used to support the shelf life were reviewed and found to be acceptable. The sponsor claims a 30 months shelf-life when stored at 4-30°C in the sealed foil pouch. Real time stability studies are ongoing.

*d. Detection limit:*

See Section M.1.a., above.

*e. Analytical specificity:*

To evaluate the potential for interference by certain exogenous compounds, each

potentially interfering substance was prepared by spiking the substance to the desired concentration into urine samples containing 0, 5 mIU/mL, 25 mIU/mL and 100 mIU/mL hCG. No interference was observed from the exogenous compounds tested at the concentrations noted in the table below, for either negative or positive hCG urine samples.

Interfering substance	Concentration
Acetaminophen	20 mg/dL
Acetylsalicylic acid	20 mg/dL
Albumin	20 mg/dL
Amoxicillin	20 mg/dL
Ampicillin	20 mg/dL
Ascorbic acid	20 mg/dL
Aspirin	80 mg/dL
Atropine	20 mg/dL
Benzoylcegonine	10 mg/dL
B-hydroxybutyrate	2000 mg/dL
Bilirubin	2 mg/dL
Caffeine	20 mg/dL
Cannabinol	10 mg/dL
EDTA	80 mg/dL
Ephedrine	20 mg/dL
Ethanol	1% mg/dL
Folic Acid	0.03 mg/dL
Gentisic acid	20 mg/dL
Glucose	2000 mg/dL
Hemoglobin	50 mg/dL
Ibuprofen	40 mg/dL
Ketone	20 mg/dL
Phenothiazine	20 mg/dL
Phenylpropanolamine	20 mg/dL
Pregnanediol	1.5 mg/dL
Salicylic acid	20 mg/dL
Tetracycline	20 mg/dL
Thiophene	20 mg/dL
Uric Acid	20 mg/dL
Vitamin B1	80 mg/dL

*Hook effect study:*

To determine if the Preview Digital Pregnancy Test has a hook effect due to high levels of hCG, negative urine samples were spiked with varying hCG concentrations (6,250, 12,500, 25,000, 50,000, 100,000, 200,000 and 500,000 mIU/mL). These samples were evaluated with Preview Digital Pregnancy Test device according to

package insert instructions in triplicates using 3 reagent lots and three operators. No hCG hook effect was observed at hCG levels up to 500,000 mIU/mL.

*Cross-Reactivity:*

To evaluate cross-reactivity, negative and positive urine samples (0 mIU/mL, 5 mIU/mL and 25 mIU/mL) were spiked with various concentrations of glycoprotein hormones LH, FSH, TSH and hCG  $\beta$ -core fragment. The results support that there is no interference due to 500 mIU/mL LH, 1000 mIU/mL FSH, 1000 mIU/mL TSH or 250,000 pmol/L hCG  $\beta$ -core fragment in either negative or positive urine samples.

*pH interference study:*

To evaluate potential interference from changes in urine pH, urine samples containing 0 mIU/mL, 5 mIU/mL, 25 mIU/mL and 100 mIU/mL hCG were tested at pH values of 4, 5, 6, 7, 8 and 9. The results indicated that changes in pH range of 4~9 do not interfere with either positive or negative results from the device.

*Specific Gravity interference study:*

To evaluate potential interference from changes in specific gravity, urine samples containing 0 mIU/mL, 5 mIU/mL, 25 mIU/mL and 100 mIU/mL hCG were tested at specific gravity values ranging from 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030 and 1.035. The results indicated that changes in specific gravity do not interfere with either positive or negative results from the device.

*f. Assay cut-off:*

See Section M.1.a., above.

2. Comparison studies:

*a. Method comparison with predicate device:*

Urine samples were collected from 300 women presenting to 3 clinics for suspected pregnancy. Ages of subjects ranged from 20 to 45 years. Samples were randomly collected at various times throughout the day, and all samples were tested with both the subject and predicate devices. Approximately half the samples were tested by dip method and half by mid-stream method. A summary of results is presented in the table below:

Summary dip testing results:

(Dip Testing)		Predicate device	
		Positive	Negative
Preview Digital Pregnancy Test	Positive	83	0
	Negative	0	72

Summary of mid-stream testing results:

(Mid-stream Testing)		Predicate device	
		Positive	Negative
Preview Digital Pregnancy Test	Positive	76	0
	Negative	0	69

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 performed with 200 female subjects recruited from three study sites, each with varying educational and occupational backgrounds. Each subject tested her own urine sample using either mid-stream (100) or dip testing (100 samples) methods on the candidate device according to the package insert, and provided a sample for professional testing using the subject device.

Summary of results is presented in the table below:

		Professional	
		+	-
Lay person	+	86	0
	-	0	114

A second lay user study was performed by the same 200 female subjects, using negative urine samples spiked with hCG near the device cutoff. The results from this study were found to be acceptable.

Each lay person was given a questionnaire to assess the readability of the labeling. The results of the questionnaire were found to be acceptable.

The readability of the labeling was found to be at the 7th grade level using a Flesch-

Kincaid analysis.

Pre-, Peri- and Post-Menopausal study

To evaluate the false positive rate of the Preview Digital Pregnancy Test in non-pregnant females, 100 urine samples were collected from normal, non-pregnant females in each of the following age ranges: 18-40 years of age (pre-menopausal), 41-55 years of age (peri-menopausal), and >55 years of age (post-menopausal). All samples were tested with three lots of Preview Digital Pregnancy Test. Half of the samples from each group were tested by dip method, and half by mid-stream method. No positive results were obtained from any of the samples tested, in either of the test modes.

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 Parts 801 and 809, as applicable.

**O. Conclusion:**

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