

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

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

k130456

**B. Purpose for Submission:**

New device

**C. Measurand:**

Human chorionic gonadotropin (hCG)

**D. Type of Test:**

Qualitative chromatographic immunoassay

**E. Applicant:**

James Nguyen, M.D.

**F. Proprietary and Established Names:**

Wunder Pregnancy Test

**G. Regulatory Information:**

1. Regulation section:

21CFR 862.1155, Human Chorionic Gonadotropin (hCG) test system

2. Classification:

Class II

3. Product code:

JHI

4. Panel:

75 Clinical Chemistry (CH)

**H. Intended Use:**

1. Intended use(s):

See indication for use below

2. Indication(s) for use:

Wunder Pregnancy Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in human urine. The device is visually read as an aid for the early detection of pregnancy and intended for in vitro single use. This test is for prescription use including at point of care sites.

3. Special conditions for use statement(s):

For prescription use only including at prescription point of care sites

4. Special instrument requirements:

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

**I. Device Description:**

The device includes a test strip housed in a cassette. The device contains a combination of goat monoclonal anti-beta hCG colored conjugate on the membrane; goat polyclonal anti-alpha hCG on the test line; and goat anti-mouse polyclonal antibody on the control line. Antibodies are derived from a protein buffer solution containing sodium azide. A dropper is also provided.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

dBest Pregnancy Test

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

k061257

3. Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>Candidate Device Wunder Pregnancy Test</b>	<b>Predicate dBest Pregnancy Test k061257</b>
Intended Use	Detection of hCG in human urine for early detection of pregnancy.	Same

<b>Similarities</b>		
Item	Candidate Device Wunder Pregnancy Test	Predicate dBest Pregnancy Test k061257
Test Principle	Immunochromatographic lateral flow assay with visual, qualitative screening result	Same
Detection reagent	Colloidal gold	Same
Read time	5 minutes	Same
<b>Differences</b>		
Item	Candidate Device Wunder Pregnancy Test	Predicate dBest Pregnancy Test k061257
Product design	Cassette	Dipstick
Intended Population	For prescription use only.	For prescription and OTC use.

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

Not applicable

**L. Test Principle:**

The Wunder Pregnancy test is a rapid chromatographic immunoassay which utilizes a combination of antibodies (described in the Device Description Section above) to selectively detect elevated levels of hCG. The assay is conducted by adding the urine specimen to the cassette test strip. The 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 sponsor performed a precision study using negative urine samples spiked to 0, 5, 12.5, 20, 25, 37.5, 50 and 100 mIU/mL of hCG with commercially available recombinant hCG traceable to the WHO 3<sup>rd</sup> international standard. The samples were tested at three point-of-care (POC) sites using 420 devices from 3 different lots. Samples were masked and randomized. Testing at each POC site took place over 5 days. Testing was performed by 3 healthcare professionals at each POC site. Results were similar across the 3 sites. Results are tabulated below.

hCG levels mIU/mL	Total No. Tested	% Agreement	Total Results (+/-)
0	60	100	0/60
12.5	60	100	0/60
20	60	99	2/58
25	60	100	60/0
37.5	60	100	60/0
50	60	100	60/0
100	60	100	60/0

*b. Linearity/assay reportable range:*

Linearity is not applicable since this is a qualitative test.

A high dose hook effect study was performed by spiking high levels of hCG into negative urine samples. Concentrations ranged from 125,000-2,500,000 mIU/m and evaluating the test result lines. Results were correct at hCG concentrations up to 1,000,000 mIU/ml. Higher values produced a false negative result. This is noted in the labeling.

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

Traceability

The Wunder Pregnancy Test is calibrated against reference materials traceable to the WHO 3<sup>rd</sup> International Standard.

Stability

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 for the test when stored at room temperature 64 -82°F (18-28°C).

*d. Detection limit:*

Refer to the precision data in 1.a, above for performance near the detection limit.

*e. Analytical specificity:*

Interference studies were performed by adding known amounts of potentially interfering substances to hCG-negative urine samples, as well as hCG positive samples with concentrations near the cutoff of 25mIU/mL. The following substances at the stated concentrations did not interfere with the assay.

Interfering substance	Concentration
Acetaminophen	20 mg/dL
Acetylsalicylic Acid	20 mg/dL
Albumin	100 mg/dL
Ampicillin	20 mg/dL

Ascorbic Acid	20 mg/dL
Atropine	20 mg/dL
Benzoyllecgonine	10 mg/dL
Bilirubin	2 mg/dL
Caffeine	20 mg/dL
Ethanol	1%
Glucose	2 g/dL
Hemoglobin	1 mg/dL
Salicylic Acid	20 mg/dL

To evaluate cross-reactivity, hormones including lutenizing hormone (LH), follicle stimulating hormone (FSH) and thyroid stimulating hormone (TSH) were spiked into negative and positive hCG urine samples. The results of these studies showed that there is no interference at concentrations up to 500 mIU/mL LH, 1000 mIU/mL FSH and 1000 mIU/mL TSH.

A study was performed to evaluate the effects of pH on the device. The device was challenged with negative, and positive near cutoff hCG samples at pH values of 3.0, 4.0, 5.0, 6.0, 7.0, 8.0, and 9.0. No effect of pH was observed on results of the test.

A study was performed to evaluate the effects of urine specific gravity on the device. The device was challenged with negative, and positive near-cutoff hCG samples with specific gravities of 1.000, 1.010, 1.020 and 1.030. Results were correct for all urine samples with specific gravity concentrations between 1.000 and 1.030.

Interference testing was performed to evaluate whether high levels of beta core fragment interfere with the device. Urine samples positive for hCG (12500 and 25,000 mIU/mL) were spiked with hCG beta core fragment at concentrations ranging between 62,500 and 1,500,000 pmol/L. Concentrations of hCG beta core fragment up to 250,000 pmol/L yielded correct results. Higher concentrations caused false negative results. The sponsor included the following limitation in the labeling:

*In pregnancy, the hCG found in urine is comprised of intact hCG as well as a number of other variants including free beta subunits and beta core fragment. A false negative result can occur when hCG beta core fragment is present at concentrations in excess of 250,000 pmol/L, which may occur later in pregnancy*

f. Assay cut-off:

See Section M.1.a above for performance around the cutoff.

2. Comparison studies:

a. Method comparison with predicate device:

Urine samples were collected from 100 women presenting at three different POC sites to test for pregnancy. Approximately half of the women were less than 5 weeks pregnant (based on last menstrual period). The women's ages ranged from 18 to 45 years. The unaltered urine samples were masked, and randomized prior to testing. Testing included three lots of the candidate device. Testing was performed by 3 healthcare professionals at each of the 3 POC sites. The results of the method comparison study are summarized below:

		Predicate device		
		+	-	Total
Wunder Pregnancy Test	+	69	0	69
	-	0	31	31
	Total	69	31	100

*b. Matrix comparison:*

Not applicable (This device is only for use with urine samples)

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:

Negative results are expected in non-pregnant women. The amount of hCG in pregnant women will vary greatly with gestational age and between individuals.

**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.