510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY TEMPLATE

A. 510(k) Number:

k072500

B. Purpose for Submission:

New device

C. Measurand:

Human chorionic gonadotropin (hCG)

D. Type of Test:

Qualitative, Immunochromatographic

E. Applicant:

Guangzhou Wondfo Biotech Co., Ltd.

F. Proprietary and Established Names:

One Step HCG Urine/Serum Test

G. Regulatory Information:

1. Regulation section:

   21CFR §862.1155-Human Chorionic Gonadotropin (HCG) test system

2. Classification:

   Class II

3. Product code:

   DHA

4. Panel:

   Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indication for use below.

2. Indication(s) for use:

   The Wondfo One Step hCG Urine/Serum *in vitro* diagnostic test is used for the qualitative determination of human chorionic gonadotropin (hCG) in urine or serum to aid in the early detection of pregnancy. It is intended for professional use only (Clinical Laboratory Use).

3. Special conditions for use statement(s):

   Professional use only

   In the package insert the manufacturer has stated the following limitation:

   When hCG is equal to or greater than 100 IU/mL, it may present a negative result because of hook effect.

4. Special instrument requirements:

   None

I. Device Description:

The Wondfo One Step hCG Urine/Serum Test will be sold in two formats: test strip and cassette. The test strip kit consists of one test device and a package insert. The cassette kit consists of one test device, a disposable plastic dropper, and a package insert. Each test device contains mouse monoclonal anti-ß HCG antibody coated membrane and a pad containing mouse monoclonal anti- α hCG antibody colloidal gold conjugate. The control antibodies are goat anti-mouse IgG.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   ACON hCG One Step Urine/Serum Pregnancy Test

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

   k980736

3. Comparison with predicate:

Similarities and differences		
Item	**ACON HCG One Step (Predicate device) k980736**	**Wondfo One Step HCG Urine/Serum Test (Candidate device)**
Intended Use	For qualitative detection of HCG in urine or serum to aid in the early detection of pregnancy	Same
Standardization	WHO 3rd International Standard	Same
Methodology	Lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Formats	Strip	Strip and cassette
Antibodies	Goat and mouse	Same
Sample Type	Serum and urine	Same
Storage temperature	15-30^{O}C	4-30^{O}C
Read time	3 to 5 minutes	Same. Do not read after 5 minutes
Cut-off	25 mIU/mL	Same

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

FDA Guidance Document, *Review Criteria for Assessment of Professional Use Human Chorionic Gonadotropin (HCG) In Vitro Diagnostic Devices*, November 6, 1996.

L. Test Principle:

The Wondfo One Step HCG test uses a monoclonal antibody against purified β-hCG. The kit is a rapid qualitative assay based on the principle of double antibodies sandwich immunoassay. When the strip is immersed in a urine or serum sample, the urine/serum migrates upward. The hCG is first captured by monoclonal antibodies to β-hCG in the sample pad and then by monoclonal antibodies to α-hCG on the T line and anti-mouse IgG on the C line coated in the membrane. If the hCG is at or above 25 mIU/ml red bands appear both in T line and C line which indicates a positive result. If the hCG is below 25 mIU/ml, only the red band in C line should appear. The band at the C line indicates sufficient volume has been added.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

i.) For Urine Samples:

Reproducibility of the device was evaluated by testing negative urine samples spiked with hCG (to 500 IU/mL, 200 IU/mL, 100 IU/mL, 5 IU/mL, 1000 mIU/mL, 500 mIU/mL, 100 mIU/mL, 25 mIU/mL, 20 mIU/mL, 15 mIU/mL, and 10 mIU/mL hCG), one positive patient urine sample came from pregnant woman (containing 29 mIU/mL hCG by ELISA), and one negative patient urine sample(from male) 10 times with multiple lots of test strips (total N = 30). The results are summarized below:

hCG concentrations tested	N	Positive	Negative
500 IU/mL	30	0	30
200 IU/mL	30	27	3
100 IU/mL	30	30	0
5 IU/mL	30	30	0
1,000 mIU/mL	30	30	0
500 mIU/mL	30	30	0
100 mIU/mL	30	30	0
25 mIU/mL	30	29	1
20 mIU/mL	30	2	28
15 mIU/mL	30	0	30
10 mIU/mL	30	0	30
Positive patient (29 mIU/mL)	30	30	0
Negative patient (0 mIU/mL)	30	0	30

ii.) For Serum Samples:

Reproducibility of the device was evaluating by testing negative serum samples spiked with hCG (to 500 IU/ml, 200 IU/ml, 100 IU/ml, 5 IU/ml, 1000 mIU/ml, 500 mIU/ml, 100 mIU/ml, 25 mIU/ml, 20 mIU/ml, 15 mIU/ml, and 10 mIU/ml hCG), one positive serum sample came from pregnant woman (containing 29.4 mIU/mL hCG by ELISA), and one negative serum sample (male serum) 10 times with multiple lots of test strips (total N = 30). The results are summarized below:

hCG concentrations tested	N	Positive	Negative
500 IU/mL	30	0	30
200 IU/mL	30	27	3
100 IU/mL	30	30	0
5 IU/mL	30	30	0
1,000 mIU/mL	30	30	0
500 mIU/mL	30	30	0
100 mIU/mL	30	30	0
25 mIU/mL	30	30	0
20 mIU/mL	30	2	28
15 mIU/mL	30	0	30
10 mIU/mL	30	0	30
Positive patient (29.4 mIU/mL)	30	30	0
Negative patient (0 mIU/mL)	30	0	30

b. Linearity/assay reportable range:

High dose hook effect was evaluated by spiking high hCG concentrations into negative urine and serum samples and evaluating the test result lines. The concentrations tested ranged from 10 mIU/mL to 500 IU/mL. Each sample was tested in triplicate. Results indicate that for urine/serum samples with HCG > 100 IU/mL (>100,000 mIU/mL) a hook effect may be seen. The sponsor included the following warning in their package insert:

"When hCG is equal to or greater than 100 IU/mL it may present negative result because of hook effect".

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

The Wondfo One Step HCG Urine/Serum Test is traceable to the WHO 3rd International Standard.

d. Detection limit:

The sensitivity of the device was tested by spiking 60 negative urine and 60 negative serum samples (from non-pregnant females or males) with varying concentrations (12.5, 18.75, 25, 50, 100 mIU/mL) of hCG. Results are summarized below (units = mIU/mL).

For Urine Samples:

Concentration	**Positive**	**Negative**	**Total (N)**
0	0	5	5
12.5	0	5	5
18.75	0	5	5
25	29	1	30
50	10	0	10
100	5	0	5
Total	44	16	60

For Serum Samples:

Concentration	**Positive**	**Negative**	**Total (N)**
0	0	5	5
12.5	0	5	5
18.75	0	5	5
25	29	1	30
50	10	0	10
100	5	0	5
Total	44	16	60

The sponsor claims a cutoff for positive of 25 mIU/mL.

e. Analytical specificity:

i.) An interference study was carried out by adding known amounts of potential interfering substances to urine and serum samples that contains 0, 25, and 50 mIU/mL of hCG, and evaluated the test result lines. The results are shown below:

For Urine Samples:

Interfering substances	hCG 0 mIU/mL	hCG 25 mIU/mL	hCG 50 mIU/mL
Acetaminophen 20 mg/dL	-	+	+
Acetylsalicylic acid 20 mg/dL	-	+	+
Ascorbic acid 20 mg/dL	-	+	+
Atropine 20 mg/dL	-	+	+
Caffeine 20 mg/dL	-	+	+
Centesic acid 20 mg/dL	-	+	+
Glucose 2 g/dL	-	+	+
Hemoglobin 20 mg/dL	-	+	+
Tetracycline 20 mg/dL	-	+	+
Ampicillin 20 mg/dL	-	+	+
Albumin 20 mg/dL	-	+	+
Bilirubin 2 mg/dL	-	+	+

For Serum Samples:

Interfering substances	hCG 0 mIU/mL	hCG 25 mIU/mL	hCG 50 mIU/mL
Acetaminophen 20 mg/dL	-	+	+
Acetylsalicylic acid 20 mg/dL	-	+	+
Ascorbic acid 20 mg/dL	-	+	+
Atropine 20 mg/dL	-	+	+
Caffeine 20 mg/dL	-	+	+
Centesic acid 20 mg/dL	-	+	+
Glucose 2 g/dL	-	+	+
Hemoglobin 20 mg/dL	-	+	+
Tetracycline 20 mg/dL	-	+	+
Ampicillin 20 mg/dL	-	+	+
Albumin 20 mg/dL	-	+	+
Bilirubin 40 mg/dL	-	+	+
Triglycerides 1200 mg/dL	-	+	+

ii.) A cross-reactivity study was carried out by adding known amounts of potential cross reactants such as LH, FSH, and TSH to a total of 90 negative urine and serum samples and evaluated the test result lines. The cross-reactivity results are shown below:

For Urine Samples:

(mIU/mL)		Lot I		Lot II		Lot III	
		+	-	+	-	+	-
LH	**100**	0	30	0	30	0	30
	300	0	30	0	30	0	30
	500	1	29	1	29	0	30
FSH	**100**	0	30	0	30	0	30
	300	0	30	0	30	0	30
	500	0	30	1	29	0	30
TSH	**750**	0	30	0	30	0	30
	1000	0	30	0	30	0	30
	1250	0	30	0	30	1	29

For Serum Samples:

(mIU/mL)		Lot I		Lot II		Lot III	
		+	-	+	-	+	-
LH	**100**	0	30	0	30	0	30
	300	0	30	0	30	0	30
	500	1	29	1	29	1	29
FSH	**100**	0	30	0	30	0	30
	300	0	30	0	30	0	30
	500	1	29	1	29	0	30
TSH	**750**	0	30	0	30	0	30
	1000	0	30	0	30	0	30
	1250	0	30	1	29	1	29

No cross-reactivity was observed for either both urine or serum samples up to the following concentrations: LH = 300 mIU/mL, FSH = 300 mIU/mL, and TSH = 1000 mIU/mL.

iii.) A pH study was performed to evaluate the device and the sponsor concluded that urine and serum samples with pH 4-9 were not adversely affected and produced the expected results.

iv.) A specific gravity study was performed to evaluate the device and the sponsor concluded that urine samples with densities between 1.000 – 1.040 and serum samples with densities between 1.000 – 1.050 were not adversely affected and produced the expected results.

f. Assay cut-off:

See 1.d. above

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was performed comparing the Wondfo One Step hCG Urine/Serum test strips and cassettes formats to the Acon hCG test strips (predicate device). Samples included 282 hCG positive serum/urine samples from pregnant women (aged 20-45), and 300 hCG negative serum/urine samples randomly collected from non-pregnant women and male. Results are summarized below:

Table 1: Comparison between Wondfo test strips and Acon test strips for urine samples

		Wondfo hCG test strip		
		+	-	**Total**
Acon HCG test trip(Predicate device)	+	281	1	282
	-	2	298	300
	Total	283	299	582

Table 2: Comparison between Wondfo cassettes and Acon test strips for urine samples

		Wondfo hCG cassette		
		+	-	**Total**
Acon HCG test trip (Predicate device)	+	281	1	282
	-	2	298	300
	Total	283	299	582

Table 3: Comparison between Wondfo test strips and Acon test strips for serum samples

		Wondfo hCG test strip		
		+	-	**Total**
Acon HCG test trip (Predicate device)	+	280	2	282
	-	2	298	300
	Total	282	300	582

Table 4: Comparison between Wondfo cassettes and Acon test strips for serum samples

		Wondfo hCG cassette		
		+	-	**Total**
Acon HCG test trip	+	280	2	282
	-	2	298	300
(Predicate device)	**Total**	282	300	582

Table 5: Agreement rate between Wondfo hCG test results with Acon test strips:

Agreement	Wondfo hCG test strip		Wondfo hCG cassette	
	Urine samples	Serum samples	Urine samples	Serum samples
Positive	99.6%	99.3%	99.6%	99.3%
Negative	99.3%	99.3%	99.3%	99.3%
Total	99.5%	99.3%	99.5%	99.3%

b. Matrix comparison:

This test is only applicable to urine or serum samples. Performance with both of these matrices is described in the performance sections above.

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:

As stated in the package insert, “all non-pregnant females should test negative for hCG.”

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.