

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

A. 510(k) Number:

k062703

B. Purpose for Submission:

New device

C. Measurand:

Human chorionic gonadotropin (hCG)

D. Type of Test:

Qualitative

E. Applicant:

AI DE Diagnostic Co., Ltd.

F. Proprietary and Established Names:

One Step HCG Urine Pregnancy Test – Strip Format
One Step HCG Urine Pregnancy Test – Cassette Format
One Step HCG Urine Pregnancy Test – Midstream Format
One Step HCG Serum/Urine Combo Pregnancy Test – Strip Format
One Step HCG Serum/Urine Combo Pregnancy Test – Cassette Format

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
<u>JHI, LCX</u>	<u>II</u>	<u>21 CFR 862.1155</u>	<u>Chemistry (75)</u>

H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

One Step HCG Urine Pregnancy Test is a rapid device, two sites sandwich immunoassay test device designed for the qualitative determination of human chorionic gonadotropin (hCG) concentration in human urine samples, and therefore is an aid in the early detection of pregnancy. These test devices are available in the formats of strip, cassette and midstream. The midstream format is intended for OTC use. The cassette and strip format are intended for both over-the counter (OTC) use and use in clinical laboratories.

One Step HCG Serum/Urine Combo Pregnancy Test is a rapid device, two sites sandwich immunoassay test device designed for the qualitative determination of human chorionic gonadotropin (hCG) concentration in human urine or serum samples, and therefore is an aid in the early detection of pregnancy. These test devices are available in strip format and cassette format, and are intended for professional use in clinical laboratories.

3. Special conditions for use statement(s):

The urine strip, urine cassette, and midstream formats are for both over-the-counter and professional use.

4. Special instrument requirements:

None required

I. Device Description:

Each test device contains goat anti-mouse (IgG) polyclonal antibody, mouse monoclonal anti-hCG antibody, and colloidal gold conjugate of monoclonal anti-hCG antibody. The tests, which are to be sold 1 per kit, are available in strip, cassette, and midstream formats for OTC use and strip and cassette formats for professional use.

J. Substantial Equivalence Information:

One Step HCG Pregnancy Test – Urine Strip (k951705)
One Step HCG Pregnancy Test – Urine Cassette (k023638)
One Step HCG Pregnancy Test – Urine Midstream (k974059)
One Step HCG Pregnancy Test – Combo Strip (k974060)
One Step HCG Pregnancy Test – Combo Cassette (k974009)

Similarities		
Item	Device	Predicate
Indications for Use	Qualitative detection of hCG for the early detection of pregnancy	Same
Specimen Types	Urine and urine/serum	Same
Principle	Sandwich immunoassay	Same

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

Guidance for Over-the-Counter (OTC) Human Chorionic Gonadotropin (hCG) 510(k)s

L. Test Principle:

The tests are two-site sandwich immunoassays.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Not applicable

b. *Linearity/assay reportable range:*

Normal urine and serum that were spiked with hCG concentrations of 62,500, 125,000, 250,000, 500,000, 1,000,000, and 2,000,000 mIU/mL were used to study the high dose hook effect on the One Step hCG Pregnancy Test. It was observed that both the test and control bands were visible. However, when hCG levels were over 500,000 mIU/mL, the higher the hCG concentration became, the lighter the band at the test region became on all formats.

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

The device is standardized to the World Health Organization's 4th International Standard for Chorionic Gonadotropin.

d. *Detection limit:*

One Step hCG Pregnancy Test detects urine or serum hCG concentrations greater than 20 mIU/mL for all formats. However, samples containing less than 20 mIU/mL hCG may produce a positive result.

To evaluate sensitivity, urine and serum samples from 120 non-pregnant subjects were spiked with hCG to the concentrations of 0, 10, 15, 20, 40, and 100 mIU/mL. Twenty masked samples at each concentration were tested by trained technicians. The results were as follows:

Strip Format (urine)

hCG (mIU/mL)	0	10	15	20	40	100
# of Samples	20	20	20	20	20	20
Negative	20	20	17	0	0	0
Positive	0	0	3	20	20	20

Cassette Format (urine)

hCG (mIU/mL)	0	10	15	20	40	100
# of Samples	20	20	20	20	20	20
Negative	20	19	18	0	0	0
Positive	0	1	2	20	20	20

Midstream Format (urine)

hCG (mIU/mL)	0	10	15	20	40	100
# of Samples	20	20	20	20	20	20
Negative	20	19	18	0	0	0
Positive	0	1	2	20	20	20

Strip Format (urine & serum)

hCG (mIU/mL)	0	10	15	20	40	100
# of Samples	20	20	20	20	20	20
Negative	20	20	16	0	0	0
Positive	0	0	4	20	20	20

Cassette Format (urine & serum)

hCG (mIU/mL)	0	10	15	20	40	100
# of Samples	20	20	20	20	20	20
Negative	20	20	17	0	0	0
Positive	0	0	3	20	20	20

e. *Analytical specificity:*

Specificity of the One Step hCG Pregnancy Test was determined from cross reaction studies with known amounts of luteinizing hormone (LH), follicle stimulating hormone (FSH), and thyroid stimulating hormone (TSH).

Samples of both urine and serum with different hCG concentrations (0, 20, and 100 mIU/mL) were mixed individually with 1000 mIU LH/mL, 1000 mIU FSH/mL, and 1000 μ IU TSH/mL and gave expected results.

The One Step hCG Pregnancy Test was checked for possible interference from visibly hemolyzed, lipemic and icteric samples. Human hemoglobin, bilirubin and albumin were spiked into samples (urine or serum) with different concentrations of hCG (0 and 20 mIU/mL) and tested on all format types. Unspiked samples were used as controls. No significant interference was observed with the concentrations tested. The 0 mIU/mL samples gave all negative results, and the 20 mIU/mL samples gave all positive results.

Other substances (drugs and common urine and serum analytes) were also added in negative hCG, 20 mIU/mL, and 50 mIU/mL urine and serum samples. None of the substances (Table 1 of the package insert) at the concentrations tested interfered in this assay.

f. Assay cut-off:

See Detection limit above.

2. Comparison studies:

a. Method comparison with predicate device:

Two hundred (200) female urine samples collected from a hospital were analyzed by trained technicians on each format and on the commercially available pregnancy test. The urine results were as follows:

Strip Format		IND Test		Subtotal
AI DE Test		+	-	
	+	122	0	122
	-	2	76	78
Subtotal		124	76	200
Cassette Format		IND Test		Subtotal
AI DE Test		+	-	
	+	123	0	123
	-	1	76	77
Subtotal		124	76	200

Two hundred (200) female serum samples collected from a hospital were analyzed by trained technicians on each format and on the commercially available pregnancy test. The serum results were as follows:

Strip Format		IND Test		Subtotal
AI DE Test		+	-	
	+	122	1	123
	-	2	75	77
Subtotal		124	76	200
Cassette Format		IND Test		Subtotal
AI DE Test		+	-	
	+	122	0	122
	-	2	76	78
Subtotal		124	76	200

See Other clinical supportive data for additional information.

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):

A consumer study was conducted using one hundred (100) female subjects between 23-38 years of age. Upon arrival, subjects were provided an instructional insert, a field survey form, and three lots of the subject devices (strip, cassette, and midstream formats). The subjects were told to perform the tests and provide urine samples for coding and testing by trained technicians. The technicians ran urine on the subject devices as well as commercially available pregnancy tests.

The results of the comparison between lay persons and trained technicians using the predicate device were as follows:

Strip Format		IND Test		Subtotal
AI DE Test		+	-	
	+	33	1	36
	-	3	63	64
Subtotal		36	64	100

Cassette Format		IND Test		Subtotal
AI DE Test		+	-	
	+	35	0	35
	-	2	63	65
Subtotal		37	63	100
Midstream Format		IND Test		Subtotal
AI DE Test		+	-	
	+	35	1	36
	-	2	62	64
Subtotal		36	63	100

A comparison of the consumers' and professionals' agreement to the predicate device is tabulated below:

	Strip	Cassette	Midstream
Professionals	98%	99%	99%
Consumers	96%	98%	97%

The survey results collected showed that most of the women had a secondary school education or higher and 82% had used a pregnancy test before. Ninety-five percent (95%) felt the package insert was easy to read and understand and that the results were easy to read. Ninety-three percent (93%) felt the test was easy to perform.

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The expected values are based on literature.

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.