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

A. 510(k) Number:
k050741

B. Purpose for Submission:
Addition of professional use (device has not been changed and was previously cleared for over the counter use)

C. Measurand:
Human Chorionic Gonadotropin

D. Type of Test:
Qualitative Sandwich Immunoassay

E. Applicant:
IND Diagnostics, Inc.

F. Proprietary and Established Names:
IND Diagnostics One Step hCG Pregnancy Urine Test Cassette

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1155
2. Classification:
   Class II
3. Product code:
   JHI
4. Panel:
   Clinical Chemistry

H. Intended Use:

1. Intended use(s):
   The IND One Step hCG Pregnancy Test - Cassette Format is a qualitative, two site sandwich immunoassay test device designed for the determination of human chorionic gonadotropin (hCG) concentration in urine.
2. Indication(s) for use:
   The IND One Step hCG Pregnancy Test - Cassette Format is a qualitative, two site sandwich immunoassay test device designed for the determination of human chorionic gonadotropin (hCG) concentration in urine, and therefore is an aid in the early detection of pregnancy. These test devices are intended for professional use.
3. Special conditions for use statement(s):
   Professional Use (device was previously cleared for over the counter use)
4. Special instrument requirements:
   Not Applicable

I. Device Description:
This device consists of a strip coated with reagents and enclosed in a plastic cassette. The sample well where urine is applied is at one end, and the test and control regions are near the middle. A dropper is supplied with each test.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   IND Diagnostic One Step HCG Pregnancy Test – Strip Format
2. Predicate 510(k) number(s):
   k951705
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Detection Limit	Same	20 mIU/mL
Specificity	Same	No effect from: LH at 300 mIU/mL FSH at 1000 mIU/mL TSH at 1000 µIU/mL Acetaminophen at 20 mg/mL Acetylsalicylic Acid at 20 mg/mL Ascorbic Acid at 20 mg/mL Atropine at 20 mg/mL Caffeine at 20 mg/mL Gentisic Acid at 20 mg/mL Glucose 2 g/dL Hemoglobin 1 mg/dL
Control Line Antibody	Same	Goat anti-mouse
Test Line Antibody	Same	Mouse anti-HCG
Endpoint	Same	Visible pink line
Storage	2-30 ^{o}C	20-30 ^{o}C

Differences		
Item	Device	Predicate
Format	Cassette	Dipstick
Standardization	WHO 4th IRP (75/589)	WHO 1st IRP (75/537)

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

Guidance for Over-the-Counter (OTC) Human Chorionic Gonadotropin (hCG) 510(k)s, July 22, 2000

L. Test Principle:

The urine sample is added to the sample well and migrates by capillary action along the membrane to the test region. Specimens containing hCG will react with the antibody-hCG-colored conjugate and form a pink line at the test line region of the membrane. Absence of this line at the test region is interpreted as a negative result. As a procedural control, a pink line should always appear in the control region.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

To assess the precision of the assay, the sponsor analyzed urine samples spiked with hCG at concentrations of 0, 10, 15, 20, 40, and 100 mIU/mL. Twenty samples were tested at each concentration. Results were as follows:

Spiked Concentration (mIU/mL)	**0**	**10**	**15**	**20**	**40**	**100**
Negative	20	20	19	1	0	0
Positive	0	0	1	19	20	20

b. Linearity/assay reportable range:

Not applicable.

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

This assay is standardized to the World Health Organization's 4th International Standard (75/589) for Chorionic Gonadotropin.

d. Detection limit:

The sponsor's claimed detection limit is 20 mIU/mL. To assess the detection limit, the sponsor analyzed urine samples spiked with hCG at concentrations of 0, 10, 15, 20, 25, and 30 mIU/mL. Twenty samples were tested at each concentration. Results were as follows:

Spiked Concentration (mIU/mL)	**0**	**10**	**15**	**20**	**25**	**30**
Negative	20	20	19	0	0	0
Positive	0	0	1	20	20	20

e. Analytical specificity:

Cross-reactivity was tested at 0, 20, and 100 mIU/mL hCG with LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000mIU/mL) with no variation from expected results. In addition, the sponsor investigated the effect of the following endogenous and exogenous compounds: hemoglobin, bilirubin, albumin, acetaminophen, acetylsalicylic acid, ascorbic acid, atropine, caffeine, Gentisic acid, and glucose. Again, there was no variation from the expected results.

f. Assay cut-off:

See detection limit above.

2. Comparison studies:

a. Method comparison with predicate device:

To assess the accuracy of IND Diagnostic One-Step hCG test kit, a commercially available qualitative test kit (ICON hCG) was used to compare with IND Diagnostic One-Step hCG test kit in 803 unaltered clinical urine samples. Results were as follows:

		IND result	
		+	-
ICON result	+	484	1
	-	7	311

Agreement among positives was > 99%
Agreement among negatives was 98%
Overall agreement was 99%

The discrepant samples were further tested with a quantitative hCG method with the following results:

Quantitative Result (mIU/mL)	IND Result
25	-
100	+
28	+
25	+
40	+
26	+
50	+
28	+

b. Matrix comparison:

Not applicable. This device is intended for one matrix only.

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):

4. Clinical cut-off**:**
   Not Applicable.
5. Expected values/Reference range:
   Human Chorionic Gonadotropin is not found in healthy males or healthy non-pregnant females in concentrations that can be detected by this device.

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.