

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

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

k110889

**B. Purpose for Submission:**

Addition of OTC claim for previously cleared device (k951705)

**C. Measurand:**

Human chorionic gonadotropin (hCG)

**D. Type of Test:**

Qualitative, Immunochromatographic

**E. Applicant:**

IND Diagnostic Inc.

**F. Proprietary and Established Names:**

IND One Step hCG Urine Pregnancy Test (Strip)

**G. Regulatory Information:**

Product Code	Classification	Regulation Section	Panel
LCX	Class II	21 CFR§ 862.1155	Chemistry (75)

**H. Intended Use:**

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

IND One Step hCG Urine Pregnancy Tests Device is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine to help in the early

determination of pregnancy. The device is designed for over-the-counter use.

3. Special conditions for use statement(s):

For in vitro diagnostic use

For over-the-counter 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 A, and colloidal gold conjugate of mouse monoclonal anti-hCG antibody B. The test is available as a strip format.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

One Step HCG Urine Pregnancy Test (Strip)

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

K062703

3. Comparison with predicate:

<b>Item</b>	<b>Candidate Device</b>	<b>Predicate Device</b>
Intended Use	IND One Step hCG Urine Pregnancy Tests Device is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine to help in the early determination of pregnancy.	Same
Specimen type	Urine	Same
Principle	Lateral flow immunochromatographic sandwich assay	Same
Test Format	Test Strip/Dip-Cup	Same

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

None were referenced

**L. Test Principle:**

The test is a two-site sandwich immunoassay. The analyte pad end of the test strip is briefly immersed into the urine sample and removed, allowing the colloidal gold-mono-clonal anti-hCG conjugate to bind with hCG present in urine. The gold labeled antibody-antigen complex is brought through the test and control lines of the test through lateral flow. Urine absent of hCG will lack the necessary antigen component to form the gold-labeled antibody-antigen complex. As a procedural control, free colloidal gold labeled antibody accumulates in the control region of the test strip. A positive result is indicated by presence of both a colored test and control line. A negative result is indicated by presence of a colored control line, with the absence of a test line.

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

1. Analytical performance:

a. *Precision/Reproducibility:*

A reproducibility study was conducted with 100 lay-users and 2 trained lab technicians using contrived urine samples with hCG concentrations near the cut-off of the candidate device (20 mIU/mL hCG). Each lay-user tested one urine sample. Reproducibility data are presented in the tables below.

	Lay Users					
Percent of Cutoff	Negative	-20%	-10%	Cutoff	10%	20%
hcG added (mIU/ml)	0	16	18	20	22	24
# of samples	50	10	10	10	10	10
Negative	50	8	5	1	0	0
Positive	0	2	5	9	10	10

	Lab Technicians					
Percent of Cutoff	Negative	-20%	-10%	Cutoff	10%	20%
hcG added (mIU/ml)	0	16	18	20	22	24
# of samples	50	10	10	10	10	10
Negative	50	6	3	0	0	0
Positive	0	4	7	10	10	10

b. *Linearity/assay reportable range:*

See previously cleared linearity data in k951705.

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

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

*d. Detection limit:*

One Step hCG Urine Pregnancy Test detects urine hCG concentrations greater than 20 mIU/mL. However, samples less than 20 mIU/mL hCG may produce a positive result. See previously cleared detection limit data in k951705.

*e. Analytical specificity:*

See previously cleared specificity data in k951705.

*f. Assay cut-off:*

See previously cleared detection limit data in k951705.

2. Comparison studies:

*a. Method comparison with predicate device:*

One hundred female urine samples were analyzed by two trained laboratory technicians using the candidate device (IND Test) and the commercially available predicate device. The results are summarized as follows:

	One Step Predicate			Subtotal
		+	-	
IND Test	+	38	2	40
	-	1	59	60
Subtotal		39	61	100

The 3 discrepant samples contained hCG concentrations near the cut-off of the candidate device (16 mIU/mL (2 samples) and 18 mIU/mL (1 sample)).

*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 lay-user study was conducted using 100 female subjects up to 56 years of age. Upon arrival, subjects were provided a test kit package containing the following: a test insert, pre- and post- study questionnaires, a random urine test sample, and the candidate device. The subjects were told to perform the tests using the coded urine samples provided. Two trained laboratory technicians also tested the urine samples on the candidate device. The results of the comparison between lay users and trained technicians with the candidate device are as follows:

	Lab Technicians			Subtotal
		+	-	
Lay Users	+	36	0	36
	-	4	60	64
Subtotal		40	60	100

The 4 discrepant samples contained hCG concentrations near and at the cut-off of the candidate device (16 mIU/mL (2 samples), 18 mIU/mL (1 sample), and 20 mIU/mL (1 sample)). Comparison of test results between the lay-users and laboratory technician showed an overall 96% agreement. The survey results collected showed that most of the women had at least some college education and 95% had never used a pregnancy test before. The majority of women felt the package insert was easy to understand (97%) and that the results were easy to understand (100%). Ninety-nine percent felt the test was easy to perform.

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 Part 809.10.

**O. Conclusion:**

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