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

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

k052694

**B. Purpose for Submission:**

New Device

**C. Measurand:**

Human Chorionic Gonadotropin (hCG)

**D. Type of Test:**

Qualitative

**E. Applicant:**

IND Diagnostic, Inc.

**F. Proprietary and Established Names:**

One Step HCG Pregnancy Test 2000 mIU/mL

**G. Regulatory Information:**

1. Regulation section:

   21 CFR § 862.1155

2. Classification:

   Class II

3. Product code:

   JHI

4. Panel:

   Clinical Chemistry (75)

## H. Intended Use:

1. Intended use(s):

   Refer to Indications for Use.

2. Indication(s) for use:

   One Step HCG Pregnancy Test 2000 mIU / mL is a qualitative, two sites sandwich immunoassay test device designed for the determination of human chorionic gonadotropin (HCG) concentration in urine samples with a cutoff of 2000 mIU / mL to aid in the detection of pregnancy. This test device is intended for professional central laboratory use only.

3. Special conditions for use statement(s):

   This test device is intended for professional central laboratory use only.

4. Special instrument requirements:

   Not Applicable

## I. Device Description:

The One Step HCG Pregnancy Test 2000 mIU / mL contains 1 hCG pregnancy test, 1 dropper, and 1 desiccant.

One Step hCG Pregnancy Test 2000 mIU/mL is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the diagnosis of pregnancy. The test utilizes a combination of antibodies including a monoclonal hCG antibody to detect elevated levels of hCG.

Coated antibodies in the control region consist of polyclonal goat anti-mouse.

Coated antibodies in the test region consist of monoclonal mouse anti-hCG (antibody A)

Labeled antibodies conjugated to gold are monoclonal mouse anti-hCG (antibody B)

## J. Substantial Equivalence Information:

1. Predicate device name(s):

   AmeriTek, Inc. dBest hCG 2 IU/mL Test Kit

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

   k001215

3. Comparison with predicate:

| Similarities | | |
|---|---|---|
| Item | Device | Predicate |
| Cutoff | Same | 2000 mIU/mL |
| Intended Use | Same | Qualitative detection of hCG for early detection of pregnancy |
| Intended Users | Prescription use in central laboratories only | Prescription use in physician's offices and clinical laboratories |
| Read Time | Same | 5 – 10 minutes |
| Antibodies | Combination of goat polyclonal and mouse monoclonal | Combination of goat/rabbit polyclonal and mouse monoclonal |

| Differences | | |
|---|---|---|
| Item | Device | Predicate |
| Matrix | Urine | Urine and Serum |
| Immunoassay Type | Two site sandwich | Competitive inhibition |

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

FDA Guidance Documents

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

2. Review Criteria for Assessment of Professional Use Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices (IVDs)

Recognized Reference Standards

3. Chorionic Gonadotropin, WHO 4$^{th}$ International Standard 75/589

4. Follicle Stimulating Hormone, WHO 1$^{st}$ International Standard 92/510

5. Luteinizing Hormone, Pituitary, WHO 2$^{nd}$ International Standard 80/552

6. Thyroid Stimulating Hormone, WHO 1$^{st}$ International Standard 90/672

**L. Test Principle:**

Users add a urine specimen to the specimen well of the test device and observe the formation of pink colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate.

Positive specimens react with the specific antibody-hCG-colored conjugate and form a pink colored line at the test line region of the membrane. Absence of this pink colored line is interpreted as a negative result. A pink colored line appearing at the control line region indicates that the immunochromatographic strip is intact and that a sufficient volume of urine has been added to the sample well.

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

1. Analytical performance:

   *a. Precision/Reproducibility:*

   See Detection limit below

   *b. Linearity/assay reportable range:*

   Not applicable

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

   WHO 4$^{th}$ International Standard 75/589

   *d. Detection limit:*

   To assess the reproducibility and detection limit of the assay, the sponsor spiked hCG into urine samples from known non-pregnant participants. The concentrations chosen were 0 mIU/mL, cutoff – 50%, cutoff – 25%, cutoff, cutoff + 25%, and cutoff + 50%. Trained technicians performed the testing with the following results:

| hCG concentration | 0 | 1000 | 1500 | 2000 | 2500 | 3000 |
|---|---|---|---|---|---|---|
| Negative | 20 | 20 | 19 | 0 | 0 | 0 |
| Positive | 0 | 0 | 1 | 20 | 20 | 20 |

*e. Analytical specificity:*

The sponsor evaluated potential interference from LH, FSH, and TSH by spiking these compounds into urine samples with hCG concentrations of 0, 2000, and 4000 mIU/mL. There were no deviations from the expected results:

| hCG concentration (mIU/mL) | no interferents added<br># neg / # pos | FSH @ 1000 mIU/mL<br># neg / # pos | LH @ 300 mIU/mL<br># neg / # pos | TSH @ 1000 µIU/mL<br># neg / # pos |
|---|---|---|---|---|
| 0 | 10/0 | 10/0 | 10/0 | 10/0 |
| 2000 | 0/10 | 0/10 | 0/10 | 0/10 |
| 4000 | 0/10 | 0/10 | 0/10 | 0/10 |

The sponsor also performed a similar study to assess the potential interference from endogenous and exogenous compounds. Urine samples with known concentrations of 0, 2000, and 4000 mIU/mL were tested with the following compounds. No deviation from the expected results was observed at the following concentrations:

| **Potential Interferent** | **Concentration Tested** |
|---|---|
| Acetaminophen | 20 mg/dL |
| Acetylsalicylic Acid | 20 mg/dL |
| Albumin | 100 mg/mL |
| Ascorbic Acid | 20 mg/mL |
| Atropine | 20 mg/mL |
| Bilirubin | 2 mg/dL |
| Caffeine | 20 mg/mL |
| Gentisic Acid | 20 mg/mL |
| Glucose | 2 g/dL |
| Hemoglobin | 1 g/dL |

*f. Assay cut-off:*

See Detection limit above

2. Comparison studies:

*a. Method comparison with predicate device:*

Clinical urine specimens from 100 individuals were evaluated with the One Step HCG Pregnancy Test 2000 mIU/mL and the predicate device. The assays were in agreement on 96 out of the 100 samples. Summary results were as follows:

| | Predicate | |
|---|---|---|
| **IND One Step** | + | - |
| + | 24 | 3 |
| - | 1 | 72 |

*b. Matrix comparison:*

Not applicable. This device is intended to be used with urine samples 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.