

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

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

K051963

**B. Purpose for Submission:**

New device

**C. Measurand:**

Human chorionic gonadotropin

**D. Type of Test:**

Qualitative

**E. Applicant:**

Natureplex, LLC

**F. Proprietary and Established Names:**

BE CERTAIN™ Home Pregnancy Test

**G. Regulatory Information:**

1. Regulation section:

21 CFR 862.1155

2. Classification:

Class II

3. Product code:

LCX

4. Panel:

Chemistry (75)

**H. Intended Use:**

1. Intended use(s):

See “Indications for use” below.

2. Indication(s) for use:

The BE CERTAIN Pregnancy Test is intended for the qualitative identification of the elevated level of human Chorionic Gonadotropin (hCG) in urine to aid in the determination of pregnancy. It is for over-the-counter consumer use.

3. Special conditions for use statement(s):

The device is for over-the-counter use.

4. Special instrument requirements:

Not applicable

**I. Device Description:**

The BE CERTAIN test is comprised of a reagent strip in plastic housing. The strip contains colloidal gold particles, polyclonal anti-mouse IgG, anti-β-hCG antibody, and anti-α HCG monoclonal antibody.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

E.P.T.® Pregnancy Test

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

K033658

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use/ Indications for Use	Qualitative detection of hCG to aid in the determination of pregnancy; for OTC use	Same

Similarities		
Item	Device	Predicate
Specimen	Urine	Urine
Test Principle	Immunochromatographic technology	Same
Sensitivity	25 mIU/mL	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 BE CERTAIN™ Home Pregnancy Test is a one-step test based on immunochromatographic technology.

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

1. Analytical performance:

*a. Precision/Reproducibility:*

Not applicable

*b. Linearity/assay reportable range:*

Not applicable

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

The BE CERTAIN™ Home Pregnancy Test is calibrated against the WHO 3<sup>rd</sup> International Standard for hCG.

*d. Detection limit:*

The sensitivity of the BE CERTAIN™ Home Pregnancy Test is 25 mIU/mL. Urine from 30 normal, non-pregnant females or males were spiked with different concentrations of hCG (five replicates at each level) and analyzed on the BE CERTAIN™ Home Pregnancy Test. At 18.75 mIU/mL, three out of five samples were positive; and all were positive at 25 mIU/mL and above.

*e. Analytical specificity:*

To determine the specificity (i.e. cross-reactivity with high physiological concentrations of LH, FSH, and TSH), urine samples from a total of 45 normal, non-pregnant females or males were spiked with various concentrations of LH, FSH, and TSH and analyzed on the BE CERTAIN™ Home Pregnancy Test. The samples contained 0, 10, or 50 mIU/mL hCG.

All 0 and 10 mIU/mL hCG samples spiked with LH up to 500 mIU/mL, FSH up to 500 mIU/mL, and TSH up to 1,250 µIU/mL read negative. All 50 mIU/mL hCG samples spiked with LH up to 500 mIU/mL, FSH up to 500 mIU/mL, and TSH up to 1,250 µIU/mL read positive.

To determine interference by prescription/OTC drugs, chemical analytes, and biological analytes, urine samples from 36 normal, non-pregnant females or males were spiked with the potentially interfering substances and analyzed on the BE CERTAIN™ Home Pregnancy Test. The samples contained 0 or 50 mIU/mL hCG. Additionally, to assess potential interference from pH, a 0 and a 50 mIU/mL hCG sample were titrated with an acid or base to yield pH values of 3 to 10 and analyzed on the subject device.

No interference was observed in the 0 or 50 mIU/mL hCG samples spiked with interfering substances. All tests were negative with the 0 mIU/mL hCG sample and positive with the 50 mIU/mL hCG sample. Similarly, 0 mIU/mL hCG samples and 50 mIU/mL hCG samples in the pH range of 3-10 yielded negative and positive results, respectively.

*f. Assay cut-off:*

See “Detection limit” above.

2. Comparison studies:

*a. Method comparison with predicate device:*

Two comparison studies were performed to determine the correlation of the BE CERTAIN™ Home Pregnancy Test (new test), when used by lay persons, with that of a commercially available test.

The first study assessed performance when using the dip method. In this study, coded, spiked samples were analyzed by 100 non-pregnant females (ages 16 to 48 years) using the new test and a professional using the new test and the predicate test. The results demonstrated a high degree of correlation (100% agreement) between the lay persons and professional user, using the new test. When the lay persons’ results were compared to the professional’s, when using the predicate device, 99% agreement was observed.

The second study assessed performance when using a urine drop method. In

this study, 50 non-pregnant females from the first study analyzed coded, spiked samples using the new test, and their results were compared to the professional's when using the dip method with the predicate test. The results showed 100% agreement between the subject and predicate devices.

At the completion of the study, the subjects completed a questionnaire. All subjects considered the test easy to perform and the labeling instructions clear and easy to follow. The results demonstrate that women of various ages, racial backgrounds, and educational backgrounds should be able to properly use this test.

*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):*

See the consumer study data under "Method comparison with predicate device" above.

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.