

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

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

k071030

**B. Purpose for Submission:**

New device

**C. Measurand:**

Human Chorionic Gonadotropin (hCG)

**D. Type of Test:**

Qualitative

**E. Applicant:**

Applied DNA Technologies, Inc.

**F. Proprietary and Established Names:**

Bionexia hCG Pregnancy Serum/Urine Cassette and Dipstick Tests

**G. Regulatory Information:**

1. Regulation section:

21 CFR 862.1155, Human chorionic gonadotropin (HCG) test system

2. Classification:

Class II

3. Product code:

JHI

4. Panel:

75-Chemistry

## **H. Intended Use:**

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Applied DNA Technologies Bionexia™ hCG Pregnancy Serum/Urine Cassette and Dipstick Tests are rapid chromatographic immunoassays for the visual, qualitative detection of human chorionic gonadotropin (hCG) in serum or urine specimen at 20 mIU/mL and above to help in the early determination of pregnancy.

The test kits are for health care professionals use including professionals at physician's office labs (POLs).

For a final Diagnosis of pregnancy, a more specific alternative clinical method must be used to obtain a confirmed analytical result.

3. Special conditions for use statement(s):

For prescription use only.

For a final diagnosis of pregnancy, a more specific alternative clinical method must be used to obtain a confirmed analytical result.

4. Special instrument requirements:

Not applicable

## **I. Device Description:**

The Bionexia™ hCG Pregnancy Serum/Urine Cassette and Dipstick Test kit contains the test device, disposable specimen pipette and a package insert. Both test devices contain a reagent strip that contains anti-alpha hCG capture antibody coated membrane and colloidal gold particles coated with mouse anti-beta hCG monoclonal antibody.

## **J. Substantial Equivalence Information:**

1. Predicate device name(s):

ACON One Step hCG Urine/Serum Test

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

k041946

3. Comparison with predicate:

<b>Similarities</b>		
Item	Device	Predicate
Intended Use	Rapid qualitative detection of hCG to aid in the early detection of pregnancy. For POLs setting.	Same
Specimen	Urine or serum	Urine or serum
Principle	Lateral flow Sandwich Immunochromatographic Assay	Lateral flow Sandwich Immunochromatographic Assay
Positive result	2 colored lines	2 colored lines
Negative result	1 colored line	1 colored line
Detection reagent	Colloidal gold	Colloidal gold
Read time	Serum: 5 minutes Urine: 3 minutes	Serum: 5 minutes Urine: 3 minutes
Specificity	No effect from: hLH: 300mIU/ml, hFSH: 1000mIU/mL hTSH: 1000 uIU/mL	Same
Storage	2 – 30 °C	2 – 30 °C
<b>Differences</b>		
Item	Device	Predicate
Cutoff	20 mIU/ml	25 mIU/ml

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

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

**L. Test Principle:**

The Bionexia hCG Pregnancy Serum/Urine Cassette and dipstick test is a chromatographic immunoassay for the rapid qualitative determination of human chorionic gonadotropin in urine and serum specimens. The anti-Alpha hCG pre-coated membrane captures antibodies on the test band region and goat anti-mouse on the control band region. The specimen is allowed to react with anti-beta hCG monoclonal antibody. The mixture moves upward via capillary action. For a positive result, a colored band with a specific antibody- hCG-antibody-colloidal gold particle complex will form on the membrane in the test band region. The absence of a colored band in the test band region indicates a negative result.

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

1. Analytical performance:

a. *Precision/Reproducibility:*

The sponsor used five levels of male pooled urine and serum specimens spiked with hCG (WHO Fourth International Standard). Twenty-five devices from three cassette lots and one dipstick lot were tested for each hCG level tested (0, 10, 12.5, 15, 17.5, 20, 25, 30, 35, 40, and 100 mIU/mL) of serum and urine controls.

Level (mIU/mL)	Dipstick		Cassette	
	Urine (-/+) n=75	Serum (-/+) n=75	Urine (-/+) n=25	Serum (-/+) n=25
0	75/0	75/0	25/0	25/0
10	75/0	75/0	25/0	25/0
12.5	63/12	63/12	24/1	23/2
15	37/38	37/38	9/16	11/14
17.5	5/70	8/67	2/23	1/24
20	0/75	0/75	0/25	0/25
25	0/75	0/75	0/25	0/25
30	0/75	0/75	0/25	0/25
35	0/75	0/75	0/25	0/25
40	0/75	0/75	0/25	0/25
100	0/75	0/75	0/25	0/25

The sponsor has chosen a cutoff of 20 mIU/mL based on the above study.

b. *Linearity/assay reportable range:*

Not applicable

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

The test is traceable to a test that has been standardized to the WHO Fourth International Standard.

The sponsor established the shelf life and expiration date (closed unopened product) when stored refrigerated (2-8° C) or at room temperature (up to 30° C) in the sealed pouch for the duration of the shelf life. The sponsors claimed shelf life is 30 months.

d. *Detection limit:*

The detection limit for the ADT's Bionexia hCG Pregnancy Serum/Urine Cassette and Dipstick Test was evaluated in both the reproducibility study and a hook effect study. The sponsor determined that the cutoff is 20 mIU/mL.

e. *Analytical specificity:*

Pooled negative serum and urine specimens were collected, divided into six aliquots each and were supplemented with either 300 mIU/mL luteinizing hormone (hLH), 1000 mIU/mL follicle stimulating (hFSH) or 1000 mIU/mL thyroid stimulating hormone (hTSH) at 0 and 20 mIU/mL hCG levels. Duplicates of each sample were tested using the ADT's Bionexia hCG Pregnancy Serum/Urine Cassette and the results were read. The results demonstrated no unexpected results with the above-listed hormones in the urine or serum samples.

Prescription, OTC drugs, chemical and biological analytes were added to negative (0 mIU/mL) and positive (20 mIU/mL) spiked urine and serum pools. None of the substances tested at the concentrations listed in the package insert interfered in the assay.

Six urine specimens with varying hCG levels were altered to the following pH: normal, 3, 5, 6.5, 7.5, and 8.5 for two hCG levels (0 and 20 mIU/mL) and were tested with six devices. The samples were read and gave all negative results at 0 mIU/mL and all positive results at 20 mIU/mL of hCG.

A urine specific gravity study was conducted on negative urine samples with specific gravity ranging from 1.00 to 1.03 spiked to the following levels: 0 and 20 mIU/mL. Each sample level was tested 6 times with the ADT's Bionexia hCG Pregnancy Serum/Urine Cassette and Dipstick Test. The sponsor's results support the sponsor's claim that the negative and cutoff levels are not affected by differences in specific gravity.

A hook effect study was conducted with spiked hCG serum control specimens that were tested with two cassettes for each of the following concentrations: 0, 10, 12.5, 15, 17.5, 20, 25, 30, 35, 200, 62500, 125000, 250000, 500000, 1 million and 2 million mIU/mL. The results showed that each level indicated 100% agreement in both negative and positive results and that there was no observed hook effect up to 2 million mIU/mL hCG.

f. *Assay cut-off:*

The cutoff for this device is 20 mIU/mL.

2. Comparison studies:

a. *Method comparison with predicate device:*

The ADT's Bionexia hCG Pregnancy Serum/Urine Cassette and Dipstick Test device was evaluated at 3 clinical/professional sites by users with training typical for physician's office labs to ascertain the products accuracy and reproducibility as compared to the predicate. Site one tested 19 positive and 27 negative serum samples. Site two tested 29 positive and 20 negative serum samples. Site one tested 18 positive and 27 negative urine samples and site two tested 29 positive and 20 negative urine samples.

Samples were random, collected at various times throughout the day.

The combined urine and serum results from sites one and two sites are shown in the charts below.

Serum	<i>ACON One Step hCG Urine/Serum Test Card</i>			
		+	-	Total
<b><i>Bionexia™ Panel</i></b>	+	48	0	48
	-	0	47	47
	Total	48	47	95

% Agreement: 100%

Urine	<i>ACON One Step hCG Urine/Serum Test Card</i>			
		+	-	Total
<b><i>Bionexia™ Panel</i></b>	+	47	0	47
	-	0	47	47
	Total	47	47	94

% Agreement: 100%

Addition, 29 positive and 20 negative samples collected from sites 1 and 2 were also tested at a third physician’s office site. The testing showed the same performance.

*b. Matrix comparison:*

Not applicable

3. Clinical studies:

*a. Clinical Sensitivity:*

See method comparison study above.

*b. Clinical specificity:*

See method comparison study above.

*c. Other clinical supportive data (when a. and b. are not applicable):*

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine and serum specimens. The amount of hCG will vary greatly with gestational age and between individuals.

**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.