

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

A. 510(k) Number:

k070921

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 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 Cassette and Dipstick Tests are rapid chromatographic immunoassays for the visual, qualitative detection of human chorionic gonadotropin (hCG) in urine 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):

This device is intended for prescription use (clinical laboratory and physician's office laboratory (POL) use).

4. Special instrument requirements:

Not applicable, as the device is a visually-read single-use device.

I. Device Description:

The Bionexia™ hCG Pregnancy Tests are rapid chromatographic immunoassays for the visual, qualitative detection of human chorionic gonadotropin (hCG) in urine.

Each reagent strip contains mouse monoclonal anti- α -hCG antibody coated membrane and a dried chemical pad containing mouse monoclonal anti- β -hCG antibody colloidal gold conjugate. The control antibodies are goat anti-mouse IgG.

Both devices are single-use and visually read. One is a dipstick device and the other is a cassette device.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Acon One Step Pregnancy Urine Test

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

k993203

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Rapid qualitative detection of hCG to aid in the early detection of pregnancy. For POLs setting.	Same
Specimen	Urine	Same
Read Time	3 minutes	Same

Differences		
Item	Device	Predicate
Cutoff	20 mIU/mL	25 mIU/mL

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

None referenced

L. Test Principle:

The Bionexia™ hCG Pregnancy Cassette and Dipstick Tests are a competitive binding immunoassay in which human chorionic gonadotropin (hCG) in a urine sample competes with immobilized conjugate for limited labeled antibody binding sites. When sufficient amount of sample is applied to the sample pad of the test device, the sample migrates through the test device by capillary action. If the hCG concentration in the sample is above the cutoff level, the antibody-hCG-antibody-colloidal gold particles complex will form a colored line in the test band region, a positive result. If the concentration of hCG in the sample is below the cutoff level it will bind with antibodies conjugates with colloidal gold particles so that no line will develop in the test region, a negative result. The colloidal gold antibody conjugate should bind to the control region and form a colored band regardless of the presence of hCG in the urine specimen.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Male urine samples were spiked with different concentrations of hCG (0, 10, 12.5, 15, 17.5, 20, 25, 30, 35, 40 and 100 mIU/mL). 25 devices were tested on each level using three different lots of the Bionexis hCG Pregnancy Cassette and on one lot of Dipstick Tests. All the 0 and 10 mIU/mL test samples were negative while all of the 20, 25, 30, 35, 40 and 100 mIU/mL were all positive. The results of the weak negative testing are in the table below:

Concentration	12.5 mIU/mL		15 mIU/mL		17.5 mIU/mL	
	Neg	Pos	Neg	Pos	Neg	Pos
Cassette Lot 1	23	2	11	14	2	23
Cassette Lot 2	19	6	10	15	1	24
Cassette Lot 3	21	4	14	11	3	22
Dipstick Lot 1	24	1	9	16	2	23
Total	87	13	44	56	8	92
% Correct	87%	13%	44%	56%	8%	92%

b. Linearity/assay reportable range:

Not applicable this is a qualitative test.

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

The assay was standardized to the WHO Fourth International Standard.

d. Detection limit:

A 20mIU/mL cutoff is claimed for urine.
See Precision/Reproducibility section M.1.a above.

e. Analytical specificity:

Luteinizing hormone (300 mIU/mL), follicle stimulating hormone (1000 mIU/ml) and thyroid stimulating hormone (1000 µIU/mL) were added to hCG negative and hCG positive (20 mIU/mL hCG added) pooled negative urine split into six aliquots. None of the substances at the concentrations tested interfered with the assay.

Commonly found substances (Prescription, OTC, chemical and biological analytes – listed in the package insert) were added to hCG negative and hCG positive (20 mIU/mL). No interference was observed at the concentrations tested.

The “hook” effect was tested by spiking hCG control specimens at the following hCG concentrations 0, 10, 20, 100, 62,500, 125,000, 250,000, 500,000, 1,000,000 and 2,000,000 mIU/mL. All samples tested up to 2,000,000 mIU/mL showed 100% expected results, indicating the absence of a hook affect up to 2,000,000 mIU/mL.

Negative and positive (20 mIU/mL) urine samples were tested with specific gravity ranging from 1.00 to 1.03 and pH ranging from 3.0 to 8.5 and shown not to affect the results at these levels.

f. *Assay cut-off:*

This device has a 20mIU/mL cutoff.

2. Comparison studies:

a. *Method comparison with predicate device:*

95 clinical urine samples were collected from women during a routine pre-screening at two POLs (Physicians Office Laboratories). Site 1 tested 19 positive and 27 negative samples and Site 2 tested 29 positive and 20 negative samples. The samples were run on the Bionexia hCG Pregnancy test and compared to the predicate, ACON One Step Pregnancy Urine Test. The results are present in the table below:

		ACON One Step hCG Urine test Card		Total # Tested
Bionexia hCG Pregnancy Test		Positive	Negative	
	Positive	48	0	48
	Negative	0	47	47
	Total # Tested	48	47	95
% Agreement to predicate		100%	100%	

Samples from Site 2 were tested at a third physician's office lab site. The testing showed the same performance.

b. *Matrix comparison:*

Not applicable. This device is for use 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):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Expected values were established in the 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.