SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k112315

B. Purpose for Submission:

New device

C. Measurand:

Human chorionic gonadotropin (hCG) in human urine

D. Type of Test:

Qualitative immunochromatographic assay

E. Applicant:

NewScen Coast Bio-Pharmaceutical Co., Ltd.

F. Proprietary and Established Names:

The y.b.t. Pregnancy Test Strip; The y.b.t. Pregnancy Test Cassette

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:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indication for use below

2. Indication(s) for use

   The y.b.t. Pregnancy Test Strip is an immunochromatographic assay for the qualitative determination of hCG in human urine. The test is intended for use as an aid in the early detection of pregnancy.

   The y.b.t. Pregnancy Test Casette is an immunochromatographic assay for the qualitative determination of hCG in human urine. The test is intended for use as an aid in the early detection of pregnancy.

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   None

I. Device Description:

The y.b.t. Pregnancy Test will be marketed in two formats: cassette and test strip. The test strip kit consists of one test device and a package insert. The cassette kit consists of one test device and a disposable plastic dropper, and a package insert. The device is a qualitative assay based on immunochromatography principle used to detect levels of hCG over the cut-off value (25 IU/L) of the device. The device utilizes mouse monoclonal anti-β-hCG gold conjugated antibody as a signal reagent and a goat anti- mouse anti-α-hCG polyclonal antibody as solid phase capture antibody. The control antibodies are goat anti-mouse IgG.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Acon One Step Pregnancy Test Strip (Urine)

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

   k993203

3. Comparison with predicate:

Items	NewScen y.b.t. Pregnancy Test k112315 (Candidate Device)	Acon One Step Pregnancy Test k993203 (Predicate Device)
Similarities		
Intended Use	Same	Qualitative detection of hCG in human urine to aid in the early detection of pregnancy.
Methodology	Same	Chromatographic immunoassay
Storage	Same	2 ^{0}C to 30 ^{0}C
Assay cut-offs	Same	25 IU/L
Traceability	Same	3rd IRP WHO
Differences		
Specimen	urine	urine or serum
Format	Strip and Cassette	Strip

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

None were referenced.

L. Test Principle:

The test utilizes monoclonal gold conjugated antibody as a signal reagent and a polyclonal antibody as solid phase capture antibody. As the urine sample flows through the absorbent sample pad, the urine reconstitutes the dried beta hCG conjugate. The hCG in the urine sample will bind to this conjugate antibody and migrate further up the membrane to the test line immobilized with capture hCG antibody. A complex is formed at this site indicated by a pink line. When the concentration of hCG is lower than 25 IU/L no complex is formed and no pink line is observed.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

An in-house precision study was performed by 1 laboratory technician using male urine samples spiked with different concentrations of hCG. Ten different concentrations (0, 25,

50, 100, 6,250, 12,500, 25,000, 50,000, 100,000, and 500,000 IU/L) were tested on two lots of strips and one lot of cassettes. The samples were masked and randomized prior to analysis. The test was performed 10 times on each concentration for each lot as per package insert instructions. Results are summarized as follows:

hCG concentrations	Strip		Cassette	
IU/L	Positive	Negative	Positive	Negative
0	0	20	0	10
25	20	0	10	0
50	20	0	10	0
100	20	0	10	0
6,250	20	0	10	0
12,500	20	0	10	0
25,000	20	0	10	0
50,000	20	0	10	0
100,000	20	0	10	0
500,000	20	0	10	0

A point-of-care precision study was performed at three different sites by three intended users using 3 lots of each device format and 30 measurements per each hCG concentration listed in the table below. All the samples were randomized and masked before giving to users to test and interpret the result. Results are summarized as follows:

hCG concentrations	Strip						Cassette					
Unit	Site 1		Site 2		Site 3		Site 1		Site 2		Site 3	
IU/L	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
0	0	10	0	10	0	10	0	10	0	10	0	10
25	10	0	10	0	10	0	10	0	10	0	10	0
50	10	0	10	0	10	0	10	0	10	0	10	0
100	10	0	10	0	10	0	10	0	10	0	10	0
100,000	10	0	10	0	10	0	10	0	10	0	10	0

b. Linearity/assay reportable range:

Linearity is not applicable since this is a qualitative test.

A hook effect study was performed at levels of 0- 500,000 IU/L (0, 25, 50, 100, 6,250, 12,500, 25,000, 50,000, 100,000, and 500,000 IU/L) for each format of test in

combination with the precision study in section 1.a. No hook effect was observed up to 500,000 IU/L of hCG.

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

The devices are traceable to the WHO 3rd International Standard for hCG.

Stability testing protocols and acceptance criteria were reviewed and found to be acceptable. Accelerated stability and real-time stability studies were performed on both test strip and cassette formats. The sponsor states that the shelf-life of the device is 18 months when stored at 25° C.

d. Detection limit:

Not applicable to qualitative test

e. Analytical specificity:

Interference studies were conducted on common interfering substances listed in the table below using two human male urine pools: 1) negative male urine control (0 IU/L of hCG) and 2) male urine samples spiked with 25 IU/L of hCG, with both strips and cassettes. Various concentrations of each interferent listed below were added to the tested urine pools to see if the interferent will affect the reading of the tested specimens. For each interferent tested, the highest concentration without resulting in interference for the device is summarized below:

Interference substance	**Concentration**	**Results 0 IU/L hCG (Negative)**	**Results after Spiked with 25 IU/L hCG (Positive)**
Acetylsalicylic acid	20 mg/dl	Negative	Positive
Acetaminophen	20 mg/dl	Negative	Positive
Ampicillin	20 mg/dl	Negative	Positive
Ascorbic acid	20 mg/dl	Negative	Positive
Atropin	20 mg/dl	Negative	Positive
Bilirubin	1000 mg/dl	Negative	Positive
Caffeine	20 mg/dl	Negative	Positive
Gentisic acid	20 mg/dl	Negative	Positive
Glucose	2 mg/dl	Negative	Positive
Hemoglobin	1 mg/dl	Negative	Positive
Tetracycline	20 mg/dl	Negative	Positive
Cortisol	200 ng/dl	Negative	Positive
Albumin	2000 mg/dl	Negative	Positive
DHEAS	500 ng/dl	Negative	Positive

Estradiol (E-2)	25 ng/dl	Negative	Positive
Estriol (E-3)	25 ng/dl	Negative	Positive
Uric acid	10 mg/dl	Negative	Positive

Cross-reactivity studies were performed to evaluate the interferences from other glycoprotein hormones, hFSH, hLH, and hTSH. Human FSH (1000 IU/L, WHO 2nd HMG), hLH (1000 IU/L, WHO 68/38), and hTSH (1000 IU/L, WHO 2nd HMG) were added to male urine samples at two hCG concentrations (0 and 25 IU/L). Each sample was run on three lots of strips and cassettes and a total of 90 urine samples were tested. The results of these studies showed that there is no cross-reactivity at 1000 IU/L hFSH, 1000 IU/L hLH, or 1000 IU/L hTSH.

Cross-reactivity studies to β-core hCG were also performed; the results indicate there was no cross-reactivity with β-core hCG up to 20,000,000 pmol/L.

The effects of pH and specific gravity were evaluated by testing urine samples spiked with hCG (at 0, 25 and 100 IU/L) at pH 4-8 or specific gravity of 1.010-1.027. No interference was observed for these pH or specific gravities tested.

f. Assay cut-off:

The sponsor performed an in-house cut-off study separately from the precision study for the test strip and cassette formats. The claimed cut-off is 25 IU/L. Negative human urine samples were spiked with purified hCG traceable to the WHO International 3rd Standard to reach 5, 10, 20 (-20% cutoff), 23, 25, 30(+20% cutoff), 50 and 100 IU/L of hCG final concentrations. For each concentration, the performance was evaluated 40 times using three lots of the test strips and cassettes. The results are shown in the table below.

hCG Concentration (IU/L)	**Strip**								
	0	5	10	20	23	25	30	50	100
No. of Positive Specimens	0	0	2	22	39	40	40	40	40
	0%	0%	5%	55%	97.5%	100%	100%	100%	100%
No. of Negative Specimens	40	40	38	18	1	0	0	0	0
	100%	100%	95%	45%	2.5%	0%	0%	0%	0%
Total number	40	40	40	40	40	40	40	40	40

hCG Concentration (IU/L)	**Cassette**								
	0	5	10	20	23	25	30	50	100
No. of Positive Specimens	0	0	2	22	39	40	40	40	40
	0%	0%	5%	55%	97.5%	100%	100%	100%	100%
No. of Negative Specimens	40	40	38	18	1	0	0	0	0
	100%	100%	95%	45%	2.5%	0%	0%	0%	0%
Total number	40	40	40	40	40	40	40	40	40

POC precision near cutoff

The detection limit was evaluated in 3 point-of-care sites by testing 40 hCG-negative urine samples per site by three intended users. Freshly collected urine samples, from healthy men were spiked with 0, 5, 8, 10, 20, 23, 25, and 50 IU/L of hCG. The samples were masked and randomized prior to analysis. The intact hCG used in this study is traceable to WHO 3rd standard. The results are shown below:

hCG IU/L	**strips**											
	Lot# 1				Lot # 2				Lot # 3			
	Pos		Neg		Pos		Neg		Pos		Neg	
0	0	0%	120	100%	0	0%	120	100%	0	0%	120	100%
5	0	0%	120	100%	0	0%	120	100%	0	0%	120	100%
8	0	0%	120	100%	3	2.5%	117	97.5%	1	2.5%	117	97.5%
10	6	5%	114	95%	6	5%	114	95%	6	5%	114	95%
20	65	54.2%	55	45.8%	66	55%	54	45%	65	54.2%	55	45.8%
23	117	97.5%	3	2.5%	115	95.8%	5	4.2%	116	96.7%	4	3.3
25	120	100%	0	0%	120	100%	0	0%	120	100%	0	0%
30	120	100%	0	0%	120	100%	0	0%	120	100%	0	0%

hCG IU/L	**cassettes**											
	Lot# 1				Lot # 2				Lot # 3			
	Pos		Neg		Pos		Neg		Pos		Neg	
0	0	0%	120	100%	0	0%	120	100%	0	0%	120	100%
5	0	0%	120	100%	0	0%	120	100%	0	0%	120	100%
8	0	0%	120	100%	3	2.5%	117	97.5%	1	2.5%	117	97.5%
10	6	5%	114	95%	6	5%	114	95%	6	5%	114	95%
20	64	53.3%	56	46.7%	66	55%	54	45%	65	54.2%	55	45.8%
23	117	97.5%	3	2.5%	116	96.7%	4	3.3%	114	95%	6	5%
25	120	100%	0	0%	120	100%	0	0%	120	100%	0	0%
30	120	100%	0	0%	120	100%	0	0%	120	100%	0	0%

The device reached a 97.5% positive rate at 23 IU/L hCG, 95% negative rate at 10 IU/L hCG and 100% % positive rate at 25 IU/L hCG (the cutoff).

2. Comparison studies:

a. Method comparison with predicate device:

Comparison studies between 1) the test strip and predicate device; 2) the test cassette and predicate device, were conducted by total of 7 healthcare professionals at 3 clinical sites on 3 lots of each device format. Each site collected 60 samples (N=180) for each format. The samples were collected from women who were of childbearing age, peri-menopausal, or suspected of being pregnant, and those in their early or late pregnancy. All samples were masked and randomized prior to analysis. Users performed the testing according to the labeling. Test results are summarized below:

		Predicate Device, strips		
		Positive	Negative	Total Agreement
Test Strips (N= 180)	Positive	90	0	100%
	Negative	0	90	
	Total	90	90	

		Predicate Device, cassette		
		Positive	Negative	Total Agreement
Test Cassette (N= 180)	Positive	90	0	100%
	Negative	0	90	
	Total	90	90	

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

Healthy non-pregnant women should not have any detectable hCG.

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.