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

A. 510(k) Number:

k050305

B. Purpose for Submission:

New Device

C. Measurand:

Human chorionic gonadotropin

D. Type of Test:

Qualitative

E. Applicant:

Bioscreen Medical Inc.

F. Proprietary and Established Names:

One Step hCG Pregnancy Urine Test, Formats: Strip, Cassette and Midstream

One Step hCG Pregnancy Urine/Serum Test, Formats: Strip and Cassette

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1155

2. Classification:

   Class II

3. Product code:

   LCX, JHI

4. Panel:

   Chemistry (75)

H. Intended Use:

1. Intended use(s):

   The One Step hCG Pregnancy Urine Test (strip, cassette, and midstream format) is a rapid one step test for the qualitative detection of human chorionic gonadotropin (hCG) in urine. For over-the-counter in vitro diagnostic use.

   The One Step hCG Pregnancy Urine Test Strip is a rapid one step test for the qualitative detection of human chorionic gonadotropin (hCG) in urine. For professional in vitro diagnostic use only.

   The One Step hCG Pregnancy Urine/Serum Test Strip is a rapid one step test for the qualitative detection of human chorionic gonadotropin (hCG) in urine and serum. For professional in vitro diagnostic use only.

   The One Step hCG Pregnancy Urine Test Cassette is a rapid one step test for the qualitative detection of human chorionic gonadotropin (hCG) in urine. For professional in vitro diagnostic use only.

   The One Step hCG Pregnancy Urine/Serum Test Cassette is a rapid one step test for the qualitative detection of human chorionic gonadotropin (hCG) in urine and serum. For professional in vitro diagnostic use only.

2. Indication(s) for use:

   One Step hCG Pregnancy Urine Test device is a qualitative, two sites sandwich immunoassay test device designed for the determination of human chorionic gonadotropin (hCG) concentration in urine samples, and therefore is an aid in the early detection of pregnancy. These test devices available in strip, cassette and midstream formats are intended for over-the-counter (OTC) use. The test devices in cassette and strip format are for professional use as well. For in-vitro diagnostic use only.

   One Step hCG Pregnancy Urine/Serum Test device is a qualitative, two sites sandwich immunoassay test device designed for the determination of human chorionic gonadotropin (hCG) concentration in urine and serum samples, and therefore is an aid in the early detection of pregnancy. These test devices available in strip and cassette formats are intended for professional use only. For in-vitro diagnostic use only.

3. Special conditions for use statement(s):

   The One Step hCG Pregnancy Urine Test is for OTC use in addition to prescription use.

4. Special instrument requirements:

   None

I. Device Description:

The One-Step hCG Pregnancy Urine Test (strip and cassette) and the One-Step hCG Pregnancy Urine/Serum Test (strip and cassette) kits each consist of 1 pregnancy test, 1 dropper, and 1 desiccant. The One-Step hCG Pregnancy Test (midstream) kit consists of 1 pregnancy test and 1 desiccant. The hCG test contains the following antibodies: goat anti-mouse (IgG) polyclonal antibody, mouse monoclonal anti-hCG antibody A, and colloidal gold conjugate of monoclonal anti-hCG antibody B.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   IND One Step hCG Pregnancy Test (IND Diagnostic One Step Urine Cassette, Urine Strip, Urine Midstream, Combo Urine/Serum Cassette, and Combo Urine/Serum Strip)

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

   K023638, K951705, K974059, K974009, K974060, respectively

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Qualitative detection of hCG for early detection of pregnancy	Same
	For professional and OTC uses	Same
Specimen	Urine and serum	Same
Test Principle	Chromatographic immunoassay	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 test is a chromatographic immunoassay, utilizing a combination of antibodies to detect elevated levels of hCG. The assay is conducted by holding the test device in the urine stream, dipping the test in the urine/serum sample, or adding urine/serum sample to the test device and observing the formation of pink colored lines. Specimen migrates via capillary action along the membrane to react with the colored conjugate.

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):

WHO 4th I.S. for Chorionic Gonadotropin

d. Detection limit:

To evaluate the sensitivity/detection limit, urine and serum samples from 120 known non-pregnant subjects were spiked with hCG to concentrations of 0, 10, 15, 20, 40, and 100 mIU/mL. A total of twenty samples at each concentration were blindly labeled and tested. The results are summarized below.

One Step hCG Urine Pregnancy Test (strip, cassette, midstream)

hCG level	**0**	**10**	**15**	**20**	**40**	**100**
Negative	20	20	18	1	0	0
Positive	0	0	2	19	20	20

One Step hCG Urine/Serum Pregnancy Test (strip, cassette – urine samples)

hCG level	0	10	15	20	40	100
Negative	20	20	18	1	0	0
Positive	0	0	2	19	20	20

One Step hCG Urine Pregnancy Test (strip, cassette – serum samples)

hCG level	0	10	15	20	40	100
Negative	20	20	17	0	0	0
Positive	0	0	3	20	20	20

e. Analytical specificity:

Specificity was determined from cross reaction studies with known amounts of luteinizing hormone (300 mIU/mL), follicle stimulating hormone (1000 mIU/mL), and thyroid stimulating hormone (1000 μIU/mL). Urine and serum samples at hCG concentrations of 0, 20, and 100 mIU/mL were mixed with the LH, FSH, and TSH samples and tested on the device. All the 0 mIU/mL samples produced negative results and all the samples equal to or greater than 20 mIU/mL hCG were positive, as expected.

Interference was evaluated by testing urine and serum hCG samples containing negative, 20 mIU/mL, and 50 mIU/mL spiked with various prescription and over-the-counter drugs and urine metabolites. None of the substances at the concentrations tested (refer to package insert) interfered in the assay.

To check for possible interference from visibly hemolyzed, lipemic, and icteric samples, human hemoglobin, bilirubin, or albumin was spiked into urine and serum samples and tested. No significant interference was observed in 20 sample testing results that were either positive or negative for hCG.

f. Assay cut-off:

See "Detection limit" above.

2. Comparison studies:

a. Method comparison with predicate device:

An external clinical evaluation was conducted comparing the results obtained using the One Step hCG Pregnancy Test to another commercially available One Step hCG Pregnancy Test. Technicians assessed the performance of Bioscreen strip and cassette formats. The study included 100 positive or negative urine samples, as well as 100 positive or negative serum samples, per

format. All the results demonstrated between 98% to 99% agreement when trained technicians performed comparison testing on the urine and serum tests.

The subject device was also subjected to over-the-counter home use equivalence testing with IND One Step hCG Pregnancy Test. Subjects were randomly selected by telephone invitation to participate and invited to the test site. A number of known pregnant females in different stages of pregnancy were invited to confirm positive sampling. Each of the 100 females was asked to perform the urine stream method and the dip stick method on the subject device. The remaining urine sample from each participant was then collected, coded, and tested separately by trained technicians on the IND One Step Pregnancy Test strip and midstream formats. The comparison between the results obtained on the predicate versus those obtained on the Bioscreen Test shows 94% agreement for the urine stream method and 95% agreement for the dip stick method.

Data was presented to support performance relative to positive results in the original consumer study. Five lay persons were each given the three test formats for One Step hCG Pregnancy Test, the corresponding inserts, and 8 coded samples. Subjects were asked to test each sample on each test format without any supervision. The results are shown below.

Coded Sample	Positive	Negative
1 (25 mIU/mL)	0	15
2 (5 mIU/mL)	0	15
3 (35 mIU/mL)	15	0
4 (50 mIU/mL)	15	0
5 (10 mIU/mL)	0	15
6 (0 mIU/mL)	0	15
7 (20 mIU/mL)	14	1
8 (20 mIU/mL)	12	3

Lay persons were able to correctly read the results 116 out of 120 times (96.7%). At the cutoff of 20 mIU/mL, lay persons were able to get the correct result 26 out of 30 times or 86.7% of the time.

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 Method comparison with predicate device section for information on consumer studies.

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

The expected values were 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.