

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

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

k112449

**B. Purpose for Submission:**

New device

**C. Measurand:**

Human Chorionic Gonadotropin (hCG)

**D. Type of Test:**

Qualitative chromatographic immunoassay

**E. Applicant:**

Tianjin New Bay Bioresearch Co., Ltd.

**F. Proprietary and Established Names:**

QuikResponse™ One Step Midstream Early Pregnancy Test

**G. Regulatory Information:**

Product Code	Classification	Regulation Section	Panel
LCX	Class II	21 CFR § 862.1155 Human Chorionic Gonadotropin (HCG) test system	Clinical Chemistry (75)

**H. Intended Use:**

1. Intended use(s):

Please see indication for use below.

2. Indication(s) for use:

QuikResponse One Step Midstream Early Pregnancy Test is an over-the-counter urine hCG test which is intended for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine. The test detects pregnancy hormone, in some cases as early as 3 days before the expected period.”

3. Special conditions for use statement(s):

QuikResponse One Step Midstream Early Pregnancy Test is for over-the-counter use.

4. Special instrument requirements:

None

**I. Device Description:**

The test consists of a single test strip encased in plastic device housing and test stick containing an immunochromatographic test strip and absorbent wick.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

First Response Early Result Pregnancy Test

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

k030258

3. Comparison with predicate:

Attribute	QuikResponse One Step Midstream Early Pregnancy Test (Candidate Device)	First Response Early Result Pregnancy Test (Predicate - k030258)
Indication for use / Intended for Use	QuikResponse One Step Midstream Early Pregnancy Test is an over-the-counter urine hCG test which is intended for the detection of pregnancy. The test detects pregnancy hormone, in some cases as early as 3 days before the expected period.	Same
User	Over-the-Counter Use	Same
Format	Midstream or Dip	Same
Test principle	Immunochromatographic, Lateral Flow	Same

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

None were referenced.

**L. Test Principle:**

QuikResponse One Step Midstream Early Pregnancy Test is a sandwich immunoassay employing monoclonal (mouse) antibodies specific for hCG and uses chromatographic principles to separate bound from free color label. The appearance of two lines in the test window indicates detection of hCG while the appearance of one line in the test window indicates no detection of hCG. If no line is in the test window the test is invalid. The test is standardized against the World Health Organization (W.H.O.) 4<sup>th</sup> International Standard for Chronic gonadotropin 75/589.

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

1. Analytical performance:

The identity and concentrations of samples used in all studies were masked to the operator.

*a. Precision/Reproducibility:*

An inter lot precision evaluation for midstream and dip cup was performed on three lots by three operators over multiple days, with 15 replicates for each standard tested (0, 6.25, 25, 50 and 100 mIU/ml hCG). Standards used for spiking contain purified hCG traceable to the WHO International 4<sup>th</sup> Standard. Samples with concentrations of 6.25 mIU/mL and below were negative for 100% of measurements. Samples with concentrations of 25 mIU/mL and above were positive for 100% of measurements. See also the detection limit study in Section d below, which included testing additional near-cutoff concentration samples using multiple test lots.

Another study was conducted to evaluate lay user reproducibility using spiked samples. In this study samples were assayed by both lay users and professionals. Negative urine samples were spiked with commercially available purified hCG, traceable to the WHO International 4<sup>th</sup> Standard. Three assay lots were tested in this study and no difference in results was observed between lots. Concentrations of 12 mIU/mL hCG and greater were consistently read as positive (100% agreement), and negative samples were consistently read as negative. A total of 50 lay users participated in the study, each testing one spiked sample (as well as their own urine sample).

*b. Linearity/assay reportable range:*

Not applicable. This is a qualitative device.

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

Traceability

QuikResponse One Step Midstream Early Pregnancy Test is traceable to the manufacturer's quantitative method, which is calibrated with the World Health Organization (W.H.O.) 4<sup>th</sup> International Standard for Chronic Gonadotropin 75/589.

Stability

Real-time and accelerated stability testing showed that the QuikResponse One Step Midstream Early Pregnancy Test device is stable and detection limit was unchanged for 24 months when stored at 36-86°F. Protocol and acceptance criteria were reviewed and found acceptable.

d. *Detection limit:*

To determine the detection limit, studies were performed by multiple operators using both the midstream and dip-cup methods. Negative human urine samples were spiked with commercially available purified hCG. Concentrations (shown in the table below) are traceable to the WHO International 4th Standard. Results are expressed as the number of positive samples to the total number of samples analyzed. See below:

hCG Range (mIU/ml)	Dip-Cup method Dip the wick of the device into samples for 10 seconds		Simulated Midstream method Sample specimens onto the wick of device for 5 seconds	
	No. of positive /Total sample	% Positive urine QuikResponse One Step Midstream Early Pregnancy Test	No. of positive /Total sample	% Positive urine QuikResponse One Step Midstream Early Pregnancy Test
5.0	0/15	0.0 %	0/15	0.0 %
6.0	0/15	0.0 %	0/15	0.0 %
7.0	0/15	0.0 %	0/15	0.0 %
8.0	3/15	20.0%	2/15	13.3%
9.0	5/15	33.3%	6/15	40.0%
10.0	14/15	93.3 %	13/15	87 %
11.0	15/15	100 %	15/15	100 %
12.0	15/15	100 %	15/15	100 %
13.0	15/15	100 %	15/15	100 %
14.0	15/15	100 %	15/15	100 %
15.0	15/15	100 %	15/15	100 %
16.0	15/15	100 %	15/15	100 %
17.0	15/15	100 %	15/15	100 %
18.0	15/15	100 %	15/15	100 %
19.0	15/15	100 %	15/15	100 %
20.0	15/15	100 %	15/15	100 %

21.0	15/15	100 %	15/15	100 %
22.0	15/15	100 %	15/15	100 %

In addition, to demonstrate reproducibility across lots, samples above and below the cutoff were evaluated for multiple lots.

hCG Standards (mIU/ml)	Total# of the Test	Number of Positive Results / Total# of results (%)		
		Lot 1	Lot 2	Lot 3
0	15	0/15	0/15	0/15
6.25	15	0/15	0/15	0/15
8.0	15	6/15	4/15	3/15
10.0	15	10/15	7/15	8/15
12.5	15	15/15	15/15	15/15
15.0	15	15/15	15/15	15/15
25.0	15	15/15	15/15	15/15

See also Section M.1.a – Reproducibility, above.

e. *Analytical specificity:*

An interference study was performed with the QuikResponse One Step Midstream Early Pregnancy Test device using two urine sample pools - one negative for hCG, and one containing 12.5 mIU/mL of hCG standard. Each potential interfering substance was added to both samples and replicates of each sample were tested using multiple lots. The highest interferent concentrations tested, are tabulated below. No interference was observed from these compounds:

Substance tested	No interference above the following concentrations
Acetaminophen	20 mg/dL
Acetylsalicylic acid	20 mg/dL
Ampicillin	20 mg/dL
Ascorbic acid	20 mg/dL
Atropine	20 mg/dL
Caffeine	20 mg/dL
Cortisol	200 ng/dL
DHEAS	500 ng/dL
Estradiol (E-2)	25 ng/dL
Estriol (E-3)	25 ng/dL
Gentisic Acid	20 mg/dL
Glucose	2000 mg/dL
Tetracycline	20 mg/dL
Human Serum Albumin	2000 mg/dL
Uric Acid	10 mg/dL

LH	300 mIU/mL
FSH	1000 mIU/mL
TSH	1000 $\mu$ IU/mL

Cross-reactivity with hyperglycosylated hCG was also evaluated. Samples containing 8-10 mIU/mL hyperglycosylated hCG yielded positive results.

*f. Assay cut-off:*

The detection limit for a positive test using the QuikResponse One Step Midstream Early Pregnancy Test (Midstream and Dip cup Format) is shown above in the detection limit section, 1.b.

2. Comparison studies:

*a. Method comparison with predicate device:*

Comparison studies between the QuikResponse One Step Midstream Early Pregnancy Test and a predicate device were conducted by healthcare professionals, using samples collected at 3 hospital sites, on 3 lots of each device format. Results are tabulated below:

	Predicate negative results	Predicate Positive results
New device positive results	65	0
New device negative results	0	176

In addition to the testing by professionals, 109 lay users tested their own urine samples using the midstream method, following only the proposed package insert instructions. There was 100% agreement between the QuikResponse One Step Midstream Early Pregnancy Test results by lay users and professional results. The results were also in agreement with predicate device results. Questionnaire results were included in the 510(k) to demonstrate that lay users (of various educational backgrounds) felt the test was easy to perform.

*b. Matrix comparison:*

Not applicable.

3. Clinical studies:

a. *Clinical Sensitivity:*

Detection of hCG in early Pregnancy Clinical Samples:

A total of 1020 urine samples were collected from 102 individual women. Selection criteria for subjects in this study were women between the ages of 18-39 attempting to become pregnant. Women were to keep a documented record of three menstrual cycles prior to the collection of samples. Samples were collected from women whose menstrual cycle lengths were within 25-31 days and whose start days were within +/- 3 days from the median day over three months. Samples were collected from each study subject starting 10 days before and ending 2 days after the expected menstrual period. The day of the expected period was estimated based on the average number of menstrual cycle days reported for the previous 3 cycles. Women with negative results were followed up to confirm that they were not pregnant in that cycle. Samples were masked and randomized prior to testing. Testing was performed on 3 device lots. No differences were observed between lots. Results are summarized in the table below.

Days Before Expected Period (days)	% of Pregnant Woman With Positive Results
0	>99%
-1	>99%
-2	98%
-3	90%

The table below tabulates the hCG concentration measured for the patient samples (by a quantitative method calibrated using WHO standards) and demonstrates the concentrations (up to 22 mIU/mL) at which the QuikResponse reports positive results in patient samples.

hCG mIU/mL - Quantitative method	QuikResponse No. of Positive / No. Total
5.0 to 5.9	0/19
6.0 to 6.9	0/16
7.0 to 7.9	0/6
8.0 to 8.9	2/10
9.0 to 9.9	3/8
10.0 to 10.9	2/6
11.0 to 11.9	4/4
12.0 to 12.9	6/6

13.0 to 13.9	5/5
14.0 to 14.9	7/7
15.0 to 15.9	6/6
16.0 to 16.9	3/3
17.0 to 17.9	2/2
18.0 to 18.9	3/3
19.0 to 19.9	8/8
20.0 to 20.9	3/3
21.0 to 21.9	6/6
22.0 to 22.9	8/8

*b. Clinical specificity:*

To demonstrate the incidence of false positive results in older women who may have higher levels of pituitary hCG, samples were collected from 104 pre-menopausal women (estimated as age 17-39), 103 peri-menopausal women (estimated as age 41-55) and 107 menopausal women (age >55) in whom pregnancy was not suspected. No pre-selection or pre-screening of hCG levels was performed prior to testing with this device. No positive results were observed in this study. The product labeling includes a statement that “If you are not sure of the result, you may want to re-test your urine in the week after your missed period. If you are still unsure, you should consult your doctor”.

Cycle Stage	Result (positive/Negative)	ELISA Quantitative hCG Concentration range
pre menopausal urines (age 17-39)	0/104	0-2.8 mIU/ml
peri-menopausal urines (age 41-55)	0/103	0-4.1 mIU/ml
menopausal urines (age >55)	0/107	0-2.3 mIU/ml

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

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Expected and reference values are not applicable since this is a qualitative test.

**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.