January 10, 2019

Weihai Kangzhou Biotechnology Engineering Co., Ltd
% Raymond Luo, Technical Manager
Shanghai SUNGO Management Consulting Company Limited
1500# Century Avenue, Room 1309
Shanghai, 200122
China

Re: k183097
Trade/Device Name: Kangzhou One Step hCG Test Strip
Kangzhou One Step hCG Test Cassette
Kangzhou One Step hCG Test Midstream
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX
Dated: November 5, 2018
Received: November 13, 2018

Dear Raymond Luo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or post marketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
k183097

Device Name
Kangzhou One Step hCG Test Strip
Kangzhou One Step hCG Test Cassette
Kangzhou One Step hCG Test Midstream

Indications for Use *(Describe)*
The Kangzhou One Step hCG Test Strip is an in vitro diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is intended for over-the-counter (OTC) use.
The Kangzhou One Step hCG Test Cassette is an in vitro diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is intended for over-the-counter (OTC) use.
The Kangzhou One Step hCG Test Midstream is an in vitro diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is intended for over-the-counter (OTC) use.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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# Section 5:

# 510(K) Summary

**K183097**

Date of Summary Preparation: January 3rd, 2019

## A. Applicant

Name: Weihai Kangzhou Biotechnology Engineering Co., Ltd
Address: Room401, Building B, Innovation Entrepreneurship Base, High District, Weihai City, Shandong, People's Republic of China

Official Contact Person Information
Name: Raymond Luo
Tel: 0086-21-68828050
Mail: fda.sungo@gmail.com

## B. Device

| | |
|---|---|
| Trade name: | Kangzhou One Step hCG Test Strip<br>Kangzhou One Step hCG Test Cassette<br>Kangzhou One Step hCG Test Midstream |
| Common name: | KIT, TEST, PREGNANCY, HCG, OVER THE COUNTER |
| Classification name: | KIT, TEST, PREGNANCY, HCG, OVER THE COUNTER |
| Regulation Medical Specialty | Clinical Chemistry |
| Regulation Number | 862.1155 |
| Product Code | LCX |
| Classification | Class II |

## C. Predicate device

510 (K) Number: K132085
Co-Innovation One Step hCG Test Strip
Co-Innovation One Step hCG Test Cassette
Co-Innovation One Step hCG Test Midstream
Produced by Co-Innovation Biotech Company Ltd.

## D. Intended use of the device

Intended use(s):
The Kangzhou One Step hCG Test Strip is an in vitro diagnostic visual qualitative

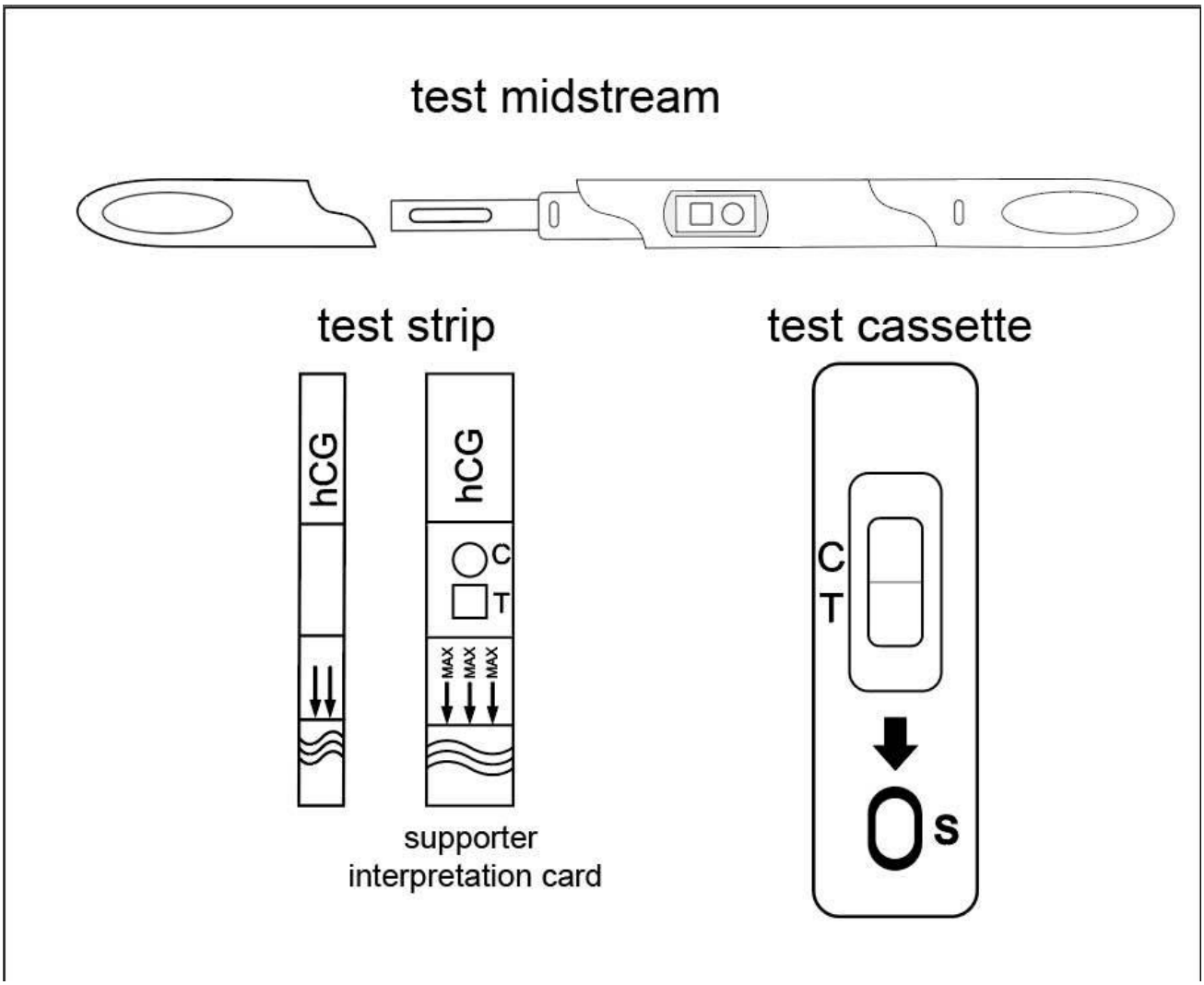
immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is intended for over-the-counter (OTC) use.

The Kangzhou One Step hCG Test Cassette is an in vitro diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is intended for over-the-counter (OTC) use.

The Kangzhou One Step hCG Test Midstream is an in vitro diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is intended for over-the-counter (OTC) use.

## E. Device Description

The Pregnancy One Step Rapid Test is a qualitative, solid phase, two-site sandwich immunoassay for the detection of human chorionic gonadotropin (hCG) in urine, as an aid in the early detection of pregnancy. The membrane is pre-coated with anti-hCG antibodies on the test band region and anti-mouse antibodies on the control band region. During testing, the urine sample reacts with the dye conjugate (mouse anti-hCG antibody-colloidal gold conjugate) which has been pre-coated on the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action to react with anti-hCG antibodies on the membrane and generate a red band. Presence of the red band indicates a positive result, while its absence indicates a negative result. Regardless of the presence of hCG, as the mixture continues to migrate across the membrane to the immobilized goat anti-mouse region, a red band at the control band region will always appear. The presence of this red band serves as verification for sufficient sample volume and proper flow and as a control for the reagents.




**F. Comparison with predicate**

A summary comparison of features of the Kangzhou One Step hCG Test and the predicate devices is provided in the following Table:

| Device | New Device | Predicate Device (K132085) |
|---|---|---|
| Manufacturer | Weihai Kangzhou Biotechnology Engineering Co., Ltd | Co-Innovation Biotech Company Ltd. |
| Intended use | Qualitative detection of human chorionic gonadotropin ("HCG") in urine | Same |
| Specimen | Urine | Same |
| Clinical cut-off | 25mIU/mL | Same |
| Indications | Over the Counter (OTC) | Same |
| Read time | 5 minutes | Same |

| | | |
|---|---|---|
| Test Principle | Colloidal Gold Immunoassay | Same |
| Traceability | WHO 5th IS | WHO 3rd IS |
| Format | Strip, cassette, midstream | Same |
| Result | Qualitative | Same |
| Antibodies | Monoclonal anti-β hCG antibody colloidal gold conjugate on the pre-dried pad. Monoclonal anti-α hCG antibodies (on the test region) Goat anti mouse IgG (on the control region). | Same |
| Sensitivity | 25mIU/mL | Same |
| Specificity | LH at 500 mIU/mL, FSH at 1000 mIU/mL, and TSH at 1000 mIU/mL | Same |
| pH Interference | No interference for urine with pH 3-9 | Same |
| Specific Gravity Interference | No interference for urine with Specific Gravity 1.000-1.040 | Same |
| High Dosage Hook effect | No high dosage hook effect for hCG up to 1,000,000 mIU/mL | Same |

There are no differences identified between new device and the predicate device for intended use, clinical cut-off, read time, test principle, test format, etc. The only difference identified is that the assay of the new device is traceable to the WHO 5th International Standard reference material, while the assay of the predicate device is traceable to the WHO 3rd International Standard reference material. However, this difference does not have any significant impact on the safety or performance of the device. The Kangzhou One Step hCG Test Strip/cassette/midstream, and the predicate device, Co-Innovation One Step hCG Test Strip/cassette/midstream (K132085) use the same chemistry with essentially the same test design, thus they are substantial equivalent.

**G. Standard/Guidance Document Referenced (if applicable)**

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

**H. Test Principle**

The assay of each device uses a double antibody sandwich method. Each test device contains mouse monoclonal anti-β-hCG antibody colloidal gold conjugate pre-dried on a pad. Mouse

monoclonal anti-α-hCG antibody (on the Test Line) and goat anti mouse IgG polyclonal antibody (on the Control Line) are coated and immobilized on a nitrocellulose membrane. During the test procedures, hCG in the urine specimen reacts with the dye conjugate (mouse anti-β-hCG antibody-colloidal gold conjugate specific to the beta subunit of hCG) and forms a complex. Because of capillary and chromatographic effects of the nitrocellulose membrane, the complex migrates along the membrane to the α-hCG antibody line (T), and remains captured in the T line. As a result a red colored band develops in the T line, indicating a positive result. If there is no hCG in the urine, there is no red band in the test zone, indicating a negative result. The Control line should develop in the control zone regardless of the test result.

**I. Antibody Information**

| **Antibody** | **The biological source** | **The location** | **Specific target antigen** |
|---|---|---|---|
| Monoclonal anti-p-HCG antibody | Mouse | Conjugate pad | Specific to the beta subunit of hCG |
| Monoclonal anti-a-H-CG antibody | Mouse | Nitrocellulose membrane | Specific to the alpha subunit of hCG |
| goat anti mouse lgG polyclonal antibody | Goat | Nitrocellulose membrane | |

**J. Components and Function of Internal Control**

The membrane is pre-coated with anti-mouse antibodies on the control band region. During the testing, the mixture continues to migrate across the membrane to the immobilized goat anti-mouse region, a red band at the control band region will always appear. The presence of this red band serves as verification for sufficient sample volume and proper flow and as a control for the reagents. The Control line should develop in the control zone regardless of the test result. A red line appearing in the control region （C）is considered an internal positive procedural control. A clear background in the results window in considered an internal negative procedural control. If the Control (C) line does not give the expected reaction on any sample, the test is invalid, and must be repeated.

**K. Performance characteristic**

1. Analytical performance

*a. Precision/Reproducibility:*

30 clinical samples were took from normal, nonpregnant females spiked with the HCG (traceable to WHO 5$^{th}$ IS）at different concentration 0mIU/ml, 12.5mIU/ml, 18.75mIU/ml, 25mIU/ml, 50mIU/ml, 100mIU/ml（all the concentration was determined by immunoassay of ELISA). The controls were build coded. Separate sets of the blind coded were assigned. Samples were also randomized prior to testing. The study was conducted 3 runs / day and lasted 10 days and was conducted by 3 hospital laboratories. There are 3 batches Kangzhou One Step HCG Test of three formats and each laboratory should conduct one batch separately. The midstream format were performed with both of these midstream test sample application methods (simulated midstream and dip). the result was recorded as the following:

**The results of precision (strip)**

| HCG concentration | LOT 1 | | LOT 2 | | LOT 3 | |
|---|---|---|---|---|---|---|
| | positive | negative | positive | negative | positive | negative |
| 0mIU/ml | 0 | 30 | 0 | 30 | 0 | 30 |
| 12.5mIU/ml | 0 | 30 | 0 | 30 | 0 | 30 |
| 18.75mIU/ml | 0 | 30 | 0 | 30 | 0 | 30 |
| 25mIU/ml | 30 | 0 | 30 | 0 | 30 | 0 |
| 50mIU/ml | 30 | 0 | 30 | 0 | 30 | 0 |
| 100mIU/ml | 30 | 0 | 30 | 0 | 30 | 0 |

**The results of precision (cassette)**

| HCG concentration | LOT 1 | | LOT 2 | | LOT 3 | |
|---|---|---|---|---|---|---|
| | positive | negative | positive | negative | positive | negative |
| 0mIU/ml | 0 | 30 | 0 | 30 | 0 | 30 |
| 12.5mIU/ml | 0 | 30 | 0 | 30 | 0 | 30 |
| 18.75mIU/ml | 0 | 30 | 0 | 30 | 0 | 30 |
| 25mIU/ml | 30 | 0 | 30 | 0 | 30 | 0 |
| 50mIU/ml | 30 | 0 | 30 | 0 | 30 | 0 |
| 100mIU/ml | 30 | 0 | 30 | 0 | 30 | 0 |

**The results of precision (midstream, using the dip method)**

| HCG concentration | LOT 1 | | LOT 2 | | LOT 3 | |
|---|---|---|---|---|---|---|
| | positive | negative | positive | negative | positive | negative |
| 0mIU/ml | 0 | 30 | 0 | 30 | 0 | 30 |
| 12.5mIU/ml | 0 | 30 | 0 | 30 | 0 | 30 |
| 18.75mIU/ml | 0 | 30 | 0 | 30 | 0 | 30 |
| 25mIU/ml | 30 | 0 | 30 | 0 | 30 | 0 |
| 50mIU/ml | 30 | 0 | 30 | 0 | 30 | 0 |
| 100mIU/ml | 30 | 0 | 30 | 0 | 30 | 0 |

**The results of precision (midstream, using the simulated midstream method)**

| HCG concentration | LOT 1 | | LOT 2 | | LOT 3 | |
|---|---|---|---|---|---|---|
| | positive | negative | positive | negative | positive | negative |
| 0mIU/ml | 0 | 30 | 0 | 30 | 0 | 30 |
| 12.5mIU/ml | 0 | 30 | 0 | 30 | 0 | 30 |
| 18.75mIU/ml | 0 | 30 | 0 | 30 | 0 | 30 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 25mIU/ml | 30 | 0 | 30 | 0 | 30 | 0 |
| 50mIU/ml | 30 | 0 | 30 | 0 | 30 | 0 |
| 100mIU/ml | 30 | 0 | 30 | 0 | 30 | 0 |

The results show that the precision of Kangzhou One Step HCG Test in 3 batches of different formats are good. Kangzhou One Step HCG Test exhibited reproducibility of results.

*b. Linearity/assay reportable range:*
Not applicable. This is a qualitative assay.

*c. Traceability, Stability, Expected values (controls, calibrators, or methods):*
Traceability:
The 510(k) describes traceability of the assay to the WHO 5$^{th}$ reference material. Stability testing information (protocols and acceptance criteria) to support the claimed shelf life (2 years) was reviewed and deemed acceptable.
Stability:
The stability data supports that the products have the shelf life of 36 months when stored at

2-30℃.

*d. Detection limit*/Sensitivity study*:*
See Precision section above. According to the results of precision data above, the sensitivity of Kangzhou One Step HCG Test is 25mIU/ml.

*e. Analytical specificity:*
e.1) To evaluate cross-reactivity, 60 fresh urine specimens obtained from healthy non- pregnant females were spiked with different concentrations of Lutenizing Hormone (LH), Follicle stimulating Hormone (FSH), and thyroid stimulating hormone (TSH) into negative (0 mIU/mL) and positive (25mIU/ml) samples. 3 lots of samples were tested. The results demonstrated no cross reaction with LH at 500mIU/ml, FSH at 1000 mIU/mL, and TSH at 1000 mIU/mL. Results are tabulated below.

**Results of the negative sample**

| | Lot 1 | | Lot 2 | | Lot 3 | |
|---|---|---|---|---|---|---|
| | Positive | Negative | Positive | Negative | Positive | Negative |
| 500 mIU/mL hLH | 0 | 60 | 0 | 60 | 0 | 60 |
| 1000 mIU/mL hFSH | 0 | 60 | 0 | 60 | 0 | 60 |
| 1000 mIU/mL hTSH | 0 | 60 | 0 | 60 | 0 | 60 |

**Results of the positive sample**

| | Lot 1 | Lot 2 | Lot 3 |
|---|---|---|---|

| | Positive | Negative | Positive | Negative | Positive | Negative |
|---|---|---|---|---|---|---|
| 500 mIU/mL hLH | 60 | 0 | 60 | 0 | 60 | 0 |
| 1000 mIU/mL hFSH | 60 | 0 | 60 | 0 | 60 | 0 |
| 1000 mIU/mL hTSH | 60 | 0 | 60 | 0 | 60 | 0 |

The standards used in this evaluation were: hLH, WHO 2nd IS (80/552); hFSH, WHO 2nd IRP (78/549); hTSH, WHO 2nd IRP (80/558).

e.2) To evaluate the potential for interference by certain exogenous compounds and potentially interfering clinical conditions. Each substance was prepared by diluting stock interference material to the desired concentration. Normal, nonpregnant female's urine specimens containing 0 and 25mIU/ml HCG were spiked with the interferents to obtain the desired test concentration. Three batches of each format were tested. The results show that no interferences were observed from substance at the following concentrations for both negative and positive HCG urine samples.

| Interfering substances | Substances concentration |
|---|---|
| Acetaminophen | 20mg/dL |
| Aspirin | 20mg/dL |
| Ascorbic acid | 20mg/dL |
| Atropine | 20mg/dL |
| Caffeine | 20mg/dL |
| Glucose | 2000mg/dL |
| Hemoglobin | 500mg/dL |
| Tetracycline | 20mg/dL |
| Ampicillin | 20mg/dL |
| Albumin | 2000mg/dL |
| Bilirubin | 2mg/dL |
| Leukocyte | > 500/ul |
| Erythrocytes | > 250/uL |
| Uric acid | 0.58 mMol/L |
| Ketone | > 80 mg/dL |
| Ethanol | 1% |

e.3) To evaluate the effects of the HCG β-core fragment normal nonpregnant female urine specimens containing 0 and 25mIU/ml HCG were spiked with the HCG β-core fragment (traceable to WHO reference reagent 99/708) at the concentration of 125000, 250000, 500000 and 1000000 pmol/mL. Three batches of each format were tested. The data shows that there's no interference in the test result when the HCG β-core fragment at the highest levels at which it is likely to be found on patient samples.

e.4) PH study
The PH of an aliquot negative urine pool is adjusted to a PH range of 3 to 9 in 1 PH unit increments

and spiked with HCG at 25mIU/ml and 0mIU/ml and 3 batches of Kangzhou One Step HCG Test were tested repeatedly. The result demonstrates that varying ranged of PH do not interfere with the performance of the test.

e.5) Specific gravity
Purified water and specimen with HCG 25mIU/ml were formulated into the solution with specific gravity at 1.01, 1.02, 1.03, 1.04 separately. Three lots of Kangzhou One Step HCG Test were tested. The data show that there's no interference in the test result when the specific gravity is between 1.01-1.04.

e.6) HOOK effect study
The test was evaluated for high dose hook effect. HCG free specimens spiked with the HCG at different concentration containing 62500mIU/ml, 125000mIU/ml, 250000mIU/ml, 500000mIU/ml, 1000000mIU/ml. Three lot of tests were tested. The result show that Kangzhou One Step HCG Test can get the positive result when the HCG concentration is range from 62,500 to 1,000,000mIU/ml, while the T line get to light as the concentration above 125,000mIU/ml.

**2. Comparison studies:**
a. Professional method comparison
Urine samples were collected from 360 women at hospital laboratory to test for pregnancy. Patients included women who suspected pregnancy, and who had late periods, as well as those later in pregnancy. Samples were randomly collected at various times throughout the day. Ages were from 18 to 45 years. Each specimen was blind coded. Separate sets of the blind coded were assigned. Samples were also randomized prior to testing. The tests performed by laboratory professionals were conducted at two laboratories (namely professional A and professional B). Each person tested the candidate device and the predicate device at the same time, but not sequentially. The data show that the agreement of Kangzhou One Step HCG Test with the predicate device was 100%.

**The results of professional method comparison (strip)**

| Candidate device | | Predicate device professional | |
|---|---|---|---|
| | | Positive | Negative |
| Professional A | Positive | 43 | 0 |
| | Negative | 0 | 47 |
| Professional B | Positive | 43 | 0 |
| | Negative | 0 | 47 |

**The results of professional method comparison (cassette)**

| Candidate device | Predicate device professional |
|---|---|

| | | Positive | Negative |
|---|---|---|---|
| Professional A | Positive | 37 | 0 |
| | Negative | 0 | 53 |
| Professional B | Positive | 37 | 0 |
| | Negative | 0 | 53 |

**The results of professional method comparison (midstream, using dip method)**

| Candidate device | | Predicate device professional | |
|---|---|---|---|
| | | Positive | Negative |
| Professional A | Positive | 55 | 0 |
| | Negative | 0 | 35 |
| Professional B | Positive | 55 | 0 |
| | Negative | 0 | 35 |

**The results of professional method comparison (midstream, using the simulated method)**

| Candidate device | | Predicate device professional | |
|---|---|---|---|
| | | Positive | Negative |
| Professional A | Positive | 50 | 0 |
| | Negative | 0 | 40 |
| Professional B | Positive | 50 | 0 |
| | Negative | 0 | 40 |

**b. The lay user method comparison:**

Urine samples were collected from 360 women at hospital laboratory to test for pregnancy. Ages were from 18 to 45 years. The 360 lay users test their own urine using the English package insert as guide to perform the test. This included 90 lay users using test strip, 90 using test cassette, 180 using actual midstream method and the dip method respectively for test midstream. They were asked to fill out and English questionnaire after finishing the test and collected samples for tests by laboratory professionals using the candidate devices. Each specimen was blind coded. Separate sets of the blind coded were assigned. Samples were also randomized prior to testing. The tests performed by laboratory professionals were conducted at a laboratory.

**The results of the lay user method comparison (strip)**

| Candidate device | | Candidate device professional | |
|---|---|---|---|
| | | Positive | Negative |
| Lay users | Positive | 43 | 0 |

| | | | |
|---|---|---|---|
| | Negative | 0 | 47 |

**The results of the lay user method comparison (cassette)**

| Candidate device | | Candidate device professional | |
|---|---|---|---|
| | | Positive | Negative |
| Lay users | Positive | 37 | 0 |
| | Negative | 0 | 53 |

**The results of the lay user method comparison (midstream, using dip method)**

| Candidate device | | Candidate device professional | |
|---|---|---|---|
| | | Positive | Negative |
| Lay users | Positive | 55 | 0 |
| | Negative | 0 | 35 |

**The results of the lay user method comparison (midstream, using the actual midstream method)**

| Candidate device | | Candidate device professional | |
|---|---|---|---|
| | | Positive | Negative |
| Lay users | Positive | 50 | 0 |
| | Negative | 0 | 40 |

**c. The performance tested by OTC user:**

To evaluate its suitability to be used by the home use consumers (lay persons), spiked urine samples were tested by the lay persons and the results were compared with professional laboratory results. The study was performed at 3 different point-of-care sites in Shanghai, Qingdao and Beijing. HCG free specimens spiked with the HCG (material traceable to WHO $5^{th}$ IS) at 18.75mIU/ml and 31.25mIU/ml. Both the concentration was determined by immunoassay of ELISA. Each concentration urine specimens were divided into 120 individual containers for a total of 240 aliquot. All aliquot were blindly labeled by a nonparticipant. Samples were also randomized prior to testing. 240 female subjected with various education backgrounds and the ages from 18 to 45 participated in the lay user study. All of the subjects had no the experience of using the test before and were the untrained operators. Each subject conducted 1 test on one test format or one sample application method for the "midstream" using the English package insert as guide. Masked spiked urine were tested by professional laboratory personnel at the manufacturer site. The results show that Kangzhou One Step HCG Test can be used by the untrained operator and get the correct results.

**Results of performance tested by OTC user**

| Formats | Masked spiked sample | | Masked spiked sample Professional users | |
|---|---|---|---|---|
| | | | +(31.25mIU/ml) | -(18.75mIU/ml) |
| strip | Lay users | +(31.25mIU/ml) | 30 | 0 |
| | | -(18.75mIU/ml) | 0 | 30 |
| Cassette | Lay users | +(31.25mIU/ml) | 30 | 0 |
| | | -(18.75mIU/ml) | 0 | 30 |
| Midstream, using dip method | Lay users | +(31.25mIU/ml) | 30 | 0 |
| | | -(18.75mIU/ml) | 0 | 30 |
| Midstream, using the simulated midstream method | Lay users | +(31.25mIU/ml) | 30 | 0 |
| | | -(18.75mIU/ml) | 0 | 30 |

After recording their results, participants were asked to evaluate the test. All participants thought the test was either "very easy" or "easy" to read and interpret (on a scale ranging from very difficult to very easy).

*d. 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):*
4. Clinical cut-off**:**
2SmIU/mL
5. Expected values/Reference range:
Not applicable

**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.