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

## I Background Information:

### A 510(k) Number

K233624

### B Applicant

Hangzhou Aichek Medical Technology Co., Ltd.

### C Proprietary and Established Names

HCG One Step Pregnancy Test Strip OTC, HCG One Step Pregnancy Test Strip Rx, HCG One Step Pregnancy Test Midstream OTC, HCG One Step Pregnancy Test Midstream Rx

### D Regulatory Information

| Product Code(s) | Classification | Regulation Section | Panel |
|---|---|---|---|
| LCX | Class II | 21 CFR 862.1155 - Human Chorionic Gonadotropin (HCG) Test System | CH - Clinical Chemistry |
| JHI | Class II | 21 CFR 862.1155 - Human chorionic gonadotropin (HCG) test system | CH - Clinical Chemistry |

## II Submission/Device Overview:

### A Purpose for Submission:

New device

### B Measurand:

Human chorionic gonadotropin (hCG)

### C Type of Test:

Qualitative chromatographic immunoassay

## III Intended Use/Indications for Use:

### A Intended Use(s):
See Indications for Use below.

### B Indication(s) for Use:

The HCG One Step Pregnancy Test Strip OTC is intended for qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in early detection of pregnancy. For in Vitro Diagnostic Use Only. For over-the-counter use.

The HCG One Step Pregnancy Test Strip Rx is intended for qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in early detection of pregnancy. For in Vitro Diagnostic Use Only. For prescription use.

The HCG One Step Pregnancy Test Midstream OTC is intended for qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in early detection of pregnancy. For in Vitro Diagnostic Use Only. For over-the-counter use.

The HCG One Step Pregnancy Test Midstream Rx is intended for qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in early detection of pregnancy. For in Vitro Diagnostic Use Only. For prescription use.

### C Special Conditions for Use Statement(s):
Rx and OTC

### D Special Instrument Requirements:
None

## IV Device/System Characteristics:

### A Device Description:

The HCG One Step Pregnancy Test Strip OTC, HCG One Step Pregnancy Test Strip Rx, HCG One Step Pregnancy Test Midstream OTC and HCG One Step Pregnancy Test Midstream Rx are lateral flow immunoassays for the qualitative detection of human chorionic gonadotropin (hCG). The tests are available in two formats: 1) The midstream format, which consists of a single test strip assembled in a plastic card, with an absorbent tip, and 2) the strip format, which is a single test strip. The strip format tests (HCG One Step Pregnancy Test Strip OTC and HCG One Step Pregnancy Test Strip Rx) are exactly the same and the midstream format tests (HCG One Step Pregnancy Test Midstream OTC and HCG One Step Pregnancy Test Midstream Rx) are exactly the same.

### B Principle of Operation:
The tests are rapid, one-step lateral flow immunoassays that utilize a combination of antibodies including a monoclonal hCG antibody to qualitatively detect hCG in human urine samples. The tests come in two formats, the midstream format and the strip format. Testing is conducted by immersing the absorbent tip in urine (midstream format and strip format) or urinating on the absorbent tip (midstream format) and obtaining the result from the colored lines.

After application of the urine specimen, the hCG within the urine reacts with the anti-βhCG antibody-colloidal gold conjugate to form a compound. The compound is captured by the anti-αhCG antibody immobilized on the test area, then a colored line will form in the test line region. A colored line will always develop in the control line region if sufficient sample volume has been applied to the test strip. The test result is shown in the result window and read visually 3-10 minutes after urine application. Two distinct colored lines, one line in the control line region and another in the test line region, indicate a positive test result (pregnant). Absence of a colored line in the test line region and only a colored line in the control line region indicates a negative test result (not pregnant). Absence of a colored line in the control line region, even in the presence of a colored line in the test line region, indicates an invalid test result.

## V Substantial Equivalence Information:

### A Predicate Device Name(s):
One Step HCG Urine Pregnancy Test

### B Predicate 510(k) Number(s):
K043443

### C Comparison with Predicate(s):

| **Device & Predicate Device(s):** | K233624 | K043443 |
|---|---|---|
| Device Trade Name | HCG One Step Pregnancy Test Strip Rx<br>HCG One Step Pregnancy Test Strip OTC<br>HCG One Step Pregnancy Test Midstream Rx<br>HCG One Step Pregnancy Test Midstream OTC | One Step HCG Urine Pregnancy Test |
| **General Device Characteristic Similarities** | | |
| Intended Use/Indications For Use | For qualitative detection of hCG in urine to aid in the determination of pregnancy. | Same |
| Product Usage | For over-the-counter use and Prescription use. | Same |
| Specimen Type | Urine | Same |
| Test Principle | Chromatographic immunoassay | Same |
| Analytical Sensitivity | 25 mIU/mL | Same |
| **General Device Characteristic Differences** | | |
| Read Time | 3-10 minutes | 3-5 minutes |
| Traceability | WHO 6th International Standard | WHO 3rd International Standard |

## VI Standards/Guidance Documents Referenced:

None

## VII Performance Characteristics (if/when applicable):

### A Analytical Performance:

1. Precision/Reproducibility:

Urine samples from non-pregnant females (negative) were spiked with the hCG WHO 6th IS reference material to provide seven urine samples with hCG concentrations of 0, 12.5, 18.75, 25, 37.5, 50 and 100 mIU/mL. Each sample was tested using 3 lots of each device (i.e., the strip format and the midstream format of the test). Testing on the midstream format was performed using both the dip sampling method and midstream sampling method. Tests were performed in replicates of 2 per day, at 3 sites, by 3 operators, over 15 days for each sample concentration. A total of 90 replicates were tested at each hCG concentration for each format of the device. The sensitivity was determined to be 25mIU/mL hCG. The results are summarized in the tables below:

*Summary Precision Results Using the Strip Format (dip sampling method)*

| hCG Concentration (mIU/mL) | Lot 1 Site 1 Operator 1 | | Lot 2 Site 2 Operator 2 | | Lot 3 Site 3 Operator 3 | | Total Result | | % Positive | % Negative |
|---|---|---|---|---|---|---|---|---|---|---|
| | + | - | + | - | + | - | + | - | | |
| 0 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0.0% | 100.0% |
| 12.5 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0.0% | 100.0% |
| 18.75 | 11 | 19 | 12 | 18 | 11 | 19 | 34 | 56 | 37.8% | 62.2% |
| 25 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100.0% | 0.0% |
| 37.5 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100.0% | 0.0% |
| 50 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100.0% | 0.0% |
| 100 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100.0% | 0.0% |

*Summary Precision Results Using the Midstream Format (dip sampling method)*

| hCG Concentration (mIU/mL) | Lot 1 Site 1 Operator 1 | | Lot 2 Site 2 Operator 2 | | Lot 3 Site 3 Operator 3 | | Total Result | | % Positive | % Negative |
|---|---|---|---|---|---|---|---|---|---|---|
| | + | - | + | - | + | - | + | - | | |
| 0 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0.0% | 100.0% |
| 12.5 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0.0% | 100.0% |
| 18.75 | 13 | 17 | 12 | 18 | 10 | 20 | 35 | 55 | 38.9% | 61.1% |
| 25 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100.0% | 0.0% |
| 37.5 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100.0% | 0.0% |
| 50 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100.0% | 0.0% |
| 100 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100.0% | 0.0% |

*Summary Precision Results Using the Midstream Format (midstream sampling method)*

| hCG Concentration (mIU/mL) | Lot 1 Site 1 Operator 1 | | Lot 2 Site 2 Operator 2 | | Lot 3 Site 3 Operator 3 | | Total Result | | % Positive | % Negative |
|---|---|---|---|---|---|---|---|---|---|---|
| | + | - | + | - | + | - | + | - | | |
| 0 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0.0% | 100.0% |
| 12.5 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0.0% | 100.0% |
| 18.75 | 13 | 17 | 12 | 18 | 10 | 20 | 35 | 55 | 38.9% | 61.1% |
| 25 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100.0% | 0.0% |
| 37.5 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100.0% | 0.0% |
| 50 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100.0% | 0.0% |
| 100 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100.0% | 0.0% |

2. Linearity:

Linearity is not applicable since this is a qualitative test.

3. Analytical Specificity/Interference:

*Cross-Reactivity*
The candidate devices were tested for potential cross-reactivity from luteinizing hormone (LH), follicle-stimulating hormone (FSH), and thyroid-stimulating hormone (TSH). A pooled human urine sample was used to prepare samples with hCG levels of 0 mIU/mL, 25 mIU/mL and 100 mIU/mL that were then spiked with each cross reactant up to the following concentrations: 750 mIU/mL LH, 1000 mIU/mL FSH or 1 mIU/mL TSH. Spiked samples were tested in replicates of 15 using 3 lots of the candidate device for each format (5 replicates per lot). The results demonstrated no cross reactivity with FSH at 1000mIU/mL, and TSH at 1 mIU/mL. The highest concentration of LH at which no cross-reactivity was observed was 500 mIU/mL.

*Interference Study*
To evaluate potential interference, urine samples from non-pregnant females were used to prepare hCG negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) samples that were then spiked with final concentrations of the potential interferents listed in table below. For each substance, 15 replicates were tested on 3 device lots (5 replicates tested by each lot). The results demonstrated no interference from substances at the concentrations shown in the table below.

*Interfering substances and concentrations*

| Interfering Substance | Concentration | Interfering Substance | Concentration |
|---|---|---|---|
| Acetaminophen | 20mg/dL | Hydroxybutyric acid | 2000mg/dL |
| Acetone | 20mg/dL | Ibuprofen | 40mg/dL |
| Acetylsalicylic acid | 20mg/dL | L-ephedrine hydrochloride | 20mg/dL |
| Albumin | 2000mg/dL | Methadone | 20mg/dL |
| Ampicillin | 20mg/dL | Morphin | 10mg/dL |
| Ascorbic acid | 20mg/dL | Nicotine | 10mg/dL |
| Atropine | 20mg/dL | Phenylpropanolamine | 20mg/dL |
| Bilirubin | 2mg/dL | Proephedrine hydrochloride | 20mg/dL |
| Caffeine | 20mg/dL | Salicylic acid | 20mg/dL |
| Cannabinol | 10mg/dL | Tetracycline | 20mg/dL |
| Gentisic acid | 20mg/dL | Uric acid | 20mg/dL |
| Glucose | 2000mg/dL | Ethanol | 1% |
| Hemoglobin | 250mg/dL | Vitamin B | 800µg/mL |
| Blood | 15% | | |

*Effect of hCG β-core fragment*
Urine samples from non-pregnant females were used to prepare samples with hCG levels of 0 mIU/mL (negative samples) and 25 mIU/mL (positive samples). The positive and negative samples then were spiked with hCG β-core fragment at concentrations of 62,500, 125,000, 250,000, 500,000, 1,000,000 pmol/L. All samples were tested in 15 replicates on 3 device lots (5 replicates per lot). The results demonstrated that the candidate devices are not affected by concentrations of hCG β-core fragment up to 1,000,000 pmol/L.

*Effect of urine pH*
To evaluate potential interference from changes in urine pH, urine samples containing 0 mIU/mL and 25 mIU/mL hCG were tested in 15 replicates on 3 lots of device (5 replicates per lot) using samples at pH values of 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0. The results demonstrated that samples within the pH range of 4.0 to 9.0 do not interfere with either positive or negative results from the devices.

*Effect of urine specific gravity*
To evaluate potential interference from changes in specific gravity, urine samples containing 0 mIU/mL and 25 mIU/mL hCG were adjusted to specific gravities of 1.000, 1.015, 1.018, 1.020, 1.022, 1.026, 1.031, 1.035 and tested in 15 replicates on 3 lots of the device (5 replicates per lot). The results demonstrated that changes in specific gravity, ranging from 1.000-1.035, do not interfere with either positive or negative results from the devices.

*High dose hook effect study*
To evaluate high dose hook effect, negative urine sample spiked with hCG at 25 mIU/mL, 100 mIU/mL, 500 mIU/mL, 1,000 mIU/mL, 100,000 mIU/mL, 500,000 mIU/mL, 1,000,000 mIU/mL, and 2,000,000 mIU/mL. The samples were tested on 3 lots of devices (5 replicates

tested by each lot). The results showed no hook effect for hCG concentrations up to 2,000,000 mIU/mL.

4. Assay Reportable Range:

Not applicable. This is a qualitative test.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

The tests are calibrated against reference material traceable to WHO International Standard 6th edition, NIBSC code 18/244.

6. Detection Limit:

The detection limit was determined in the precision study (see Section VII.A.1 above).

7. Assay Cut-Off:

The cutoff for a positive test is 25 mIU/mL. See Precision/Reproducibility section above (Section VII.A.1).

**B Comparison Studies:**

1. Method Comparison with Predicate Device:

The performance of the two device formats (strip, midstream) of the test was compared to the predicate device. Testing was performed by laboratory professionals at three sites with urine samples from 330 women between the age of 18-45 who suspect they are in the early stages of pregnancy. All pregnant women were in the early stages of pregnancy (less than 5 weeks). All samples were tested with candidate and predicate devices at three sites by 3 different professionals (a total of 9 different professionals conducted the study). The results are summarized below.

*Summary of Method Comparison Results Using the Strip Format (dip sampling method)*

| | | Predicate device | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| Candidate device | Positive | 58 | 0 | 58 |
| | Negative | 0 | 52 | 52 |
| Total | | 58 | 52 | 110 |

*Summary of Method Comparison Results Using Midstream Format (dip sampling method)*

| | | Predicate device | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| Candidate device | Positive | 59 | 0 | 59 |
| | Negative | 0 | 52 | 52 |
| Total | | 59 | 52 | 111 |

*Summary of Method Comparison Results Using Midstream Format (midstream sampling method)*

| | | Predicate device | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| Candidate device | Positive | 58 | 0 | 58 |
| | Negative | 0 | 51 | 51 |
| Total | | 58 | 51 | 109 |

The data shows that the agreement with the predicate device was 100%.

2. Matrix Comparison:

Not applicable. This device is for testing with human urine only.

**C Clinical Studies:**

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

*Lay-User Study*
A lay user study was conducted at 3 sites with 330 women who suspect they are in the early stages of pregnancy with diverse educational and occupational backgrounds who were between the ages of 18 and 45. This included 110 lay-users using the strip format of the test and 220 lay-users using the midstream format (111 users in dip sampling method and 109 in midstream sampling method). The lay users tested their own urine sample and provided a sample for professional testing. The data shows that the agreement between lay-user results and professional results was 100%. The results are summarized below.

*Summary of Lay User Testing of Strip Format*

| Candidate device | | Professional test results | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| Lay user test results | Positive | 58 | 0 | 58 |
| | Negative | 0 | 52 | 52 |
| Total | | 58 | 52 | 110 |

*Summary of Lay User Testing of Midstream Format (dip sampling method)*

| Candidate device | | Professional test results | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| Lay user test results | Positive | 59 | 0 | 59 |
| | Negative | 0 | 52 | 52 |
| Total | | 59 | 52 | 111 |

*Summary of Lay User Testing of Midstream (midstream sampling method)*

| Candidate device | | Professional test results | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| Lay user test results | Positive | 58 | 0 | 58 |
| | Negative | 0 | 58 | 58 |
| Total | | 58 | 59 | 109 |

Ease of use of the candidate devices was assessed through a questionnaire that was completed at the end of the study. The questionnaire results indicated that lay-users found the tests easy to use, the results clear and easy to read and the instructions for use easy to understand. A Flesch-Kincaid reading analysis was performed on each OTC package insert and the score demonstrated a reading Grade Level of 7.

**D Clinical Cut-Off:**

Not applicable.

**E Expected Values/Reference Range:**

Not applicable.

## VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

## IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.