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

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

k172627

**B. Purpose for Submission:**

New device

**C. Measurand:**

Human chorionic gonadotropin (hCG)

**D. Type of Test:**

Qualitative lateral flow immunoassay

**E. Applicant:**

Runbio Biotech Co., Ltd.

**F. Proprietary and Established Names:**

David Home Pregnancy Test Cassette

David Professional 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:

   LCX

   JHI

4. Panel:

   Clinical Chemistry (75)

## H. Intended Use:

1. Intended use(s):

   See Indication(s) for use below.

2. Indication(s) for use:

   David Home Pregnancy Test Cassette is an in-vitro diagnostic test for the qualitative determination of human chorionic gonadotropin (HCG) in urine to aid in early detection of pregnancy, based on lateral flow immunoassay. It is intended for Over-the-Counter Use only.

   David Professional Pregnancy Test Cassette is an in-vitro diagnostic test for the qualitative determination of human chorionic gonadotropin (HCG) in the urine to aid in early detection of pregnancy, based on lateral flow immunoassay. It is intended for prescription use only.

3. Special conditions for use statement(s):

   David Professional Pregnancy Test Cassette: For prescription use only

4. Special instrument requirements:

   None.

## I. Device Description:

The David Home Pregnancy Test Cassette and the David Professional Pregnancy Test Cassette have the same design, and are composed of α-hCG monoclonal antibody and anti-mouse IgG labeled nitrocellulose membrane, and colloidal gold labeled anti β-hCG monoclonal antibody. Each device includes one test cassette sealed in a foil aluminum bag with a desiccant pack, a disposable plastic dropper, and a package insert.

## J. Substantial Equivalence Information:

1. Predicate device name(s):

   Wondfo One Step HCG Urine Pregnancy Test

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

   k043443

3. Comparison with predicate:

| Similarities and Differences | | |
|---|---|---|
| Item | Candidate Device<br>David Home Pregnancy Test Cassette | Predicate Device<br>One Step HCG Urine Pregnancy Test (k043443) |
| Intended use | Qualitative detection of human chorionic gonadotropin(hCG) in urine to aid in the early detection of pregnancy. | Same |
| Format | Cassette | Cassette, test strip, and midstream |
| Test principle | Sandwich immunochromatographic assay | Same |
| Detection antibody | Mouse monoclonal anti-β antibody | Same |
| Intended user | Over-the-counter use | Over the counter and prescription use |
| Sensitivity | 25 mIU/mL | Same |
| Read time | 5 to 10 minutes | 3 to 5 minutes |
| Traceability | WHO 5$^{th}$ International Standard | WHO 3$^{rd}$ International Standard |

| Similarities and Differences | | |
|---|---|---|
| Item | Candidate Device<br>David Professional Pregnancy Test Cassette | Predicate Device<br>One Step HCG Urine Pregnancy Test (k043443) |
| Intended use | Qualitative detection of human chorionic gonadotropin(hCG) in urine to aid in the early detection of pregnancy. | Same |
| Format | Cassette | Cassette, test strip, and midstream |
| Test principle | Sandwich immunochromatographic assay | Same |
| Detection antibody | Mouse monoclonal anti-β antibody | Same |
| Intended user | Prescription use | Over the counter and |

| Similarities and Differences | | |
|---|---|---|
| Item | Candidate Device<br>David Professional<br>Pregnancy Test Cassette | Predicate Device<br>One Step HCG Urine<br>Pregnancy Test (k043443) |
| | | prescription use |
| Sensitivity | 25 mIU/mL | Same |
| Read time | 5 to 15 minutes | 3 to 5 minutes |
| Traceability | WHO 5th International Standard | WHO 3rd International Standard |

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

None referenced.

**L. Test Principle:**

The test is a qualitative, solid phase, double antibody sandwich immunochromatographic assay. Each test device contains mouse monoclonal anti-β-hCG antibody colloidal gold conjugate pre-dried on a pad. Mouse monoclonal anti-α-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, 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. The complex migrates along the membrane to the mouse anti--α-antibody test region, and remains captured on the test line (resulting in a visible test line if hCG is present at concentrations above the cutoff), and excess mouse anti-β-hCG antibody-colloidal gold conjugate migrates to the control line (resulting in a visible line, indicating the test results are valid).

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

1. Analytical performance:

*a. Precision/Reproducibility:*

A precision study was performed at three hospital sites by 9 operators who tested urine specimens, using the candidate device, that were spiked to hCG urine concentrations of 0, 16, 18.75, 20, 25, 27.5, and 100 mIU/mL, with hCG traceable to the WHO 5th International Standard. Each sample was tested using 10 devices from each of the 3 device lots at each of the 3 sites, over 5 days. A total of 150 test results per lot of device for each concentration were obtained. The positive results observed over the total number of tests are summarized in the following table:

| hCG level (mIU/ml) | Lot 1 | Lot 2 | Lot3 | % Positive |
|---|---|---|---|---|
| 0 | 0/150 | 0/150 | 0/150 | 0 % |
| 16 | 0/150 | 0/150 | 0/150 | 0 % |
| 18.75 | 1/150 | 1/150 | 1/150 | 0.7% |
| 20 | 5/150 | 3/150 | 2/150 | 2.2 % |
| 25 | 150/150 | 150/150 | 150/150 | 100% |
| 27.5 | 150/150 | 150/150 | 150/150 | 100% |
| 100 | 150/150 | 150/150 | 150/150 | 100% |

b. *Linearity/assay reportable range:*

Not applicable.

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

Traceability:
The test is calibrated against the WHO 5$^{th}$ International Standards for chorionic gonadotropin 07/364.

Stability:
The shelf-life stability protocols and acceptance criteria were reviewed and found acceptable. Real time shelf-life stability studies are on-going.

d. *Detection limit:*

Not applicable; see section M.1.a. for precision near the device cutoff.

e. *Analytical specificity:*

Cross reactivity:
To determine if structurally similar analytes to hCG interfere with hCG results from the candidate device, urine samples with 0 mIU/mL and 25 mIU/mL hCG were spiked with 500 mIU/mL LH, 1000 mIU/mL FSH, and 1000 mIU/mL TSH and tested with the device. No cross reactivity or interference was observed with the device at these test concentrations.

Interference:
A study was performed to evaluate interference of common, structurally unrelated substances on the test results obtained by the candidate device. Common endogenous and exogenous substances were added to negative (0 mIU/mL) and positive (25 mIU/mL) urine samples. Testing was performed using 3 lots of the device. No interference or cross-reactivity was observed from the compounds at the concentrations listed below.

| Substance | Highest Concentration tested at which no interference was observed. |
|---|---|
| Glucose | 2 g/dL |
| Albumin | 2 g/dL |
| Protein | 2 g/dL |
| Bilirubin | 2 mg/dL |
| Hemoglobin | 1 mg/dL |
| Acetaminophen | 20 mg/dL |
| Atropine | 20 mg/dL |
| Aspirin | 20 mg/dL |
| Ascorbic acid | 20 mg/dL |
| Ampicillin | 20 mg/dL |
| Vitamin C | 20 mg/dL |
| Caffeine | 20 mg/dL |
| Gentisate | 20 mg/dL |
| Gentisic acid | 20 mg/dL |
| Tetracycline | 20 mg/dL |
| Acetylsalicylic acid | 20 mg/dL |
| Salicylic acid | 20 mg/dL |
| Phenothiazine | 20 mg/dL |
| Thiphene | 20 mg/dL |
| Ephedrine | 20 mg/dL |
| Ethanol | 1% |
| Phenylpropanolamine | 20 mg/dL |

Effects of urine pH and specific gravity

Urine samples containing 0 and 25 mIU/mL hCG were adjusted to the following pH levels: 3, 4, 5, 6, 7, 8, 9, and 10. The samples were tested in duplicate using 3 lots of the candidate device. The study showed that urine pH levels ranging from 3-10 do not affect the expected results of the testing.

Negative (0 and 16 mIU/mL hCG) and positive (27.5 mIU/mL hCG) urine samples were adjusted to have specific gravities of 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.035, 1.040, 1.045, and 1.050. Each sample was tested in replicates of 5 per lot using 3 lots of the candidate device. The positive and negative hCG results were not affected by urine specific gravity concentrations between 1.000 and 1.050.

High dose/hook effect:
High dose hook effect was evaluated by spiking negative urine samples with hCG to obtain 16 evenly spaced increasing hCG concentrations spanning the range of 10-2,000,000 mIU/mL. No high dose hook effect was observed using the candidate device with up to hCG levels of 2,000,000 mIU/mL.

hCG β-core fragment test:

Negative urine hCG samples containing 0 and 16 mIU/mL hCG and positive urine samples containing 27.5 mIU/mL hCG were spiked with hCG beta core fragment standard traceable to WHO reference reagent 99/708 at various concentrations up to 1,000,000 pmol/L. Each sample concentration was tested using three lots of the device for 10 replicates per lot. No interference or cross-reactivity was observed at concentrations of up to 100,000 pmol/L hCG β-core fragment.

*f. Assay cut-off:*

See section M.1.a.

2. Comparison studies:

*a. Method comparison with predicate device and lay user study:*

A method comparison study was performed at 3 hospital sites to compare the results obtained from 360 lay-users, testing their own urine with the David Home Pregnancy Test Cassette, to results obtained by professionals who tested those same urine samples using the predicate device, Wondfo One Step HCG Urine Pregnancy Test. Lay users followed the English language instructions for use. The results are summarized in the table below:

| | | Lay User Test Result with Candidate device | |
|---|---|---|---|
| | | Positive | Negative |
| Professional Test Result with predicate device | Positive | 153 | 0 |
| | Negative | 0 | 207 |
| | Total | 153 | 207 |

Lay user performance on the candidate device was assessed in a lay user study by comparing 360 lay user test results to test results obtained by professionals, each using the candidate device. The results are summarized in the table below:

| | | Lay User Test Result with Candidate device | |
|---|---|---|---|
| | | Positive | Negative |
| Professional Test Result with candidate device | Positive | 153 | 0 |
| | Negative | 0 | 207 |
| | Total | 153 | 207 |

In addition, 120 subjects completed a questionnaire after completing the testing to evaluate the ease of use of the device. The results of the questionnaire were found to be acceptable.

The Flesch-Kincaid analysis was performed on the David Home Pregnancy Test Cassette package insert. The score demonstrated a reading Grade Level of 8.

*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):

Not applicable.

4. Clinical cut-off:

Not applicable.

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.