# k190705

# 510(k) SUMMARY

**1. Date:** April 12, 2019

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**4. Device Name:** WHOLEPOWER® Pregnancy Rapid Test Cassette
WHOLEPOWER® Pregnancy Rapid Test Midstream
WHOLEPOWER® Pregnancy Rapid Test Strip

**Classification:** Class II
**Product Code** LCX
**CFR** 862.1155

**5. Predicate Devices:** WHPM One Step Pregnancy Test (K041273)

**6. Intended Use**

WHOLEPOWER Pregnancy Rapid Test Cassette is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy.

WHOLEPOWER Pregnancy Rapid Test Midstream is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy.

WHOLEPOWER Pregnancy Rapid Test Strip is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy.

**7. Device Description**

WHOLEPOWER Pregnancy Rapid Test measures the presence of the hormone Human Chorionic Gonadotrophin (HCG) in human urine for the early detection of pregnancy. The test devices are in three different formats: Strip, Cassette and

Midstream. Each test kit contains a test device sealed in a desiccated aluminum pouch and a package insert. The cassette format also contains a dropper.

## 8. Substantial Equivalence Information

| Similarities | | |
|---|---|---|
| Item | Candidate device | Predicate device K041273, WHPM One Step Pregnancy Test |
| Intended use | Early detection of pregnancy | Early detection of pregnancy |
| Specimen | Urine | Urine |
| Assay technical | Immunochromatographic assay | Immunochromatographic assay |
| Sensitivity | 25 mIU/mL | 25 mIU/mL |
| Results | Qualitative | Qualitative |
| Target user | Over the counter use | Over the counter use |
| Device format | Strip, Cassette, Midstream | Strip, Cassette, Midstream |
| Differences | | |
| Item | Device | Predicate |
| Reading Time | 3 minute | 5 minute |

## 9. Test Principle

The test uses colloidal gold immunochromatography assay to detect human chorionic gonadotropin (hCG) in urine at cut-off 25 mIU/ml. When hCG concentration is higher than the cut-off, it will bind to rat anti β-hCG Mab which is labelled by colloidal gold. As the sample migrates on the nitrocellulose matrix of test strip by tomographic action, the complexes of detector antibody with β-hCG are separately captured to α-hCG antibody that has been immobilized on test strip, a red line appears in test zone (T) and the test result is positive. When hCG concentration is lower than the cut-off, there is no red line shows in test zone (T) and test result is negative. There is goat anti-mouse IgG polyclonal antibody immobilized in nitrocellulose filter membrane control zone (C) that bind to rat anti β-hCG Mab labelled by colloidal gold. When proper amount sample is applied a red line will appear in control zone (C).

## 10. Performance Characteristics

### A. Analytical performance

#### a. Precision/Reproducibility/Sensitivity

Negative urine was spiked with hCG standard (Traceable to the 4th WHO) to hCG concentrations of 0, 12.5, 18.75, 22.5, 25, 50, 100 and 200mIU/mL. The spiked samples were measured in replicates using 3 different lots for each format. Tests were performed by three different operators for each sample concentration in 2 runs per day for 15 days. The results are summarized in the table below:

**Strip format**

| hCG Concentration (mIU/mL) | Lot 1 | | Lot 2 | | Lot 3 | | Total result | | % Negative | % Positive |
|---|---|---|---|---|---|---|---|---|---|---|
| | - | + | - | + | - | + | - | + | | |
| 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100 | 0 |
| 12.5 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100 | 0 |
| 18.75 | 21 | 9 | 24 | 6 | 23 | 7 | 68 | 22 | 76 | 24 |
| 22.5 | 1 | 29 | 1 | 29 | 0 | 30 | 2 | 88 | 2 | 98 |
| 25 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100 |
| 50 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100 |
| 100 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100 |
| 200 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100 |

**Cassette format**

| hCG Concentration (mIU/mL) | Lot 1 | | Lot 2 | | Lot 3 | | Total result | | % Negative | % Positive |
|---|---|---|---|---|---|---|---|---|---|---|
| | - | + | - | + | - | + | - | + | | |
| 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100 | 0 |
| 12.5 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100 | 0 |
| 18.75 | 23 | 7 | 22 | 8 | 25 | 5 | 70 | 20 | 78 | 22 |
| 22.5 | 0 | 30 | 1 | 29 | 3 | 27 | 4 | 86 | 4 | 96 |
| 25 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100 |
| 50 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100 |
| 100 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100 |
| 200 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100 |

**Midstream format**

| hCG Concentration (mIU/mL) | Lot 1 | | Lot 2 | | Lot 3 | | Total result | | % Negative | % Positive |
|---|---|---|---|---|---|---|---|---|---|---|
| | - | + | - | + | - | + | - | + | | |
| 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100 | 0 |
| 12.5 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100 | 0 |
| 18.75 | 22 | 8 | 23 | 7 | 26 | 4 | 71 | 19 | 79 | 21 |
| 22.5 | 2 | 28 | 1 | 29 | 2 | 28 | 5 | 85 | 6 | 94 |
| 25 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100 |
| 50 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100 |
| 100 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 200 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 | 100 |

Based on the above results, the sensitivity of WHOLEPOWER® Pregnancy Rapid Test is demonstrated to be 25 mIU/mL.

**b. Linearity/assay reportable range:**
Linearity is not applicable since this is a qualitative test.

**c. Hook effect test:**
Negative urine samples were spiked with varying hCG concentrations (62500, 125000, 250000, 500000, 1000000 and 2000000 mIU/mL). All tested concentrations gave a positive result. The results demonstrated that no hook effect was observed at hCG concentrations ranging from 62500 to 2000000 mIU/mL.

**d. Traceability, Stability, Expected values (controls, calibrators, or methods):**
WHOLEPOWER® Pregnancy Rapid Test is calibrated against reference material traceable to WHO International Standard 4th edition.
A shelf-life stability test of the devices was performed by accelerated testing. The results showed that the devices were stable for 24 months when stored at 4~30°C in the sealed foil pouch. Real time stability studies are on going.

**e. Specificity and cross reactivity**
To evaluate specificity and cross-reactivity, negative and positive urine samples (12.5 mIU/mL and 25 mIU/mL) were spiked with various concentrations of glycoprotein hormones LH, FSH, TSH and hCG β-core fragment. The results showed that there is no interference at 500 mIU/mL LH, 1000 mIU/mL FSH, 1000 mIU/L TSH and 2000,000 pmol/L hCG β-core fragment for both negative and positive urine samples.

**f. Interfering substance**
To evaluate the potential for interference by certain exogenous compounds, each interfering substance was prepared by diluting stock interfering material to the desired concentration. Urine samples containing 12.5 mIU/mL and 25 mIU/mL hCG were spiked with the interfering substance to obtain the desired test concentration. No interferences were observed from exogenous compounds at the following concentrations for both negative and positive hCG urine samples.

| **Substances** | **Concentration** |
|---|---|
| Acetaminophen | 20mg/dL |
| Acetoacetic Acid | 2000mg/dL |
| Asorbic Acid | 20mg/dL |
| B-hydroxybutyrate | 2000mg/dL |
| Caffeine | 20mg/dL |
| Ephedrine | 20mg/dL |
| Gentisic Acid | 20mg/dL |
| Phenylpropanolamine | 20mg/dL |

| | |
|---|---|
| Salicylic Acid | 20mg/dL |
| Phenothiazine | 20mg/dL |
| EDTA | 80mg/dL |
| Acetylsalicylic Acid | 20mg/dL |
| Benzoylecgonine | 10mg/dL |
| Cannabinol | 10mg/dL |
| Codeine | 6ug/dL |
| Ethanol | 1.0% |
| Methanol | 10% |
| Albumin | 2000mg/dL |
| Glucose | 2000mg/dL |
| Bilirubin | 2mg/dL |
| Atropine | 20mg/dL |
| Estriol-17-beta | 1400ug/dL |
| Hemoglobin | 500mg/dL |
| Pregnanediol | 1500ug/dL |
| Thiophene | 20mg/dl |
| Ampicillin | 20mg/dl |
| Tetracycline | 20mg/dl |
| Ketone | 20mg/dl |

To evaluate potential interference from changes in pH, urine samples containing 12.5 mIU/mL and 25 mIU/mL hCG were tested at pH values of 4, 5, 6, 7, 8 and 9. The results indicated that changes in pH range of 4~9 do not interfere in the results that were either positive or negative for hCG.

To evaluate potential interference from changes in specific gravity, urine samples containing 12.5 mIU/mL and 25 mIU/mL hCG were tested at density values ranging from 1.002, 1.007, 1.012, 1.018, 1.025 and 1.032. The results indicated that changes in specific gravity do not interfere in the results that were either positive or negative for hCG.

**B. Method comparison study**

Method comparison with predicate device

The performance of the new device was compared to the predicate test. Urine samples were collected from 120 women presenting to test for pregnancy at OB/GYN Physician's offices. Approximately half of the 120 women were suspected to be pregnant and most of them are in the early stage of less than 5 weeks. All samples were tested by two different health professionals for each format at each of the 3 OB/GYN Physician's offices for a total of 18 operators with the proposed and the predicate devices.

| Strip Format | | Predicate device | |
|---|---|---|---|
| | | Positive | Negative |
| WHOLEPOWER® Rapid Pregnancy Test | Positive | 63 | 1 |
| | Negative | 0 | 56 |

| Cassette | | Predicate device | |
|---|---|---|---|
| | | Positive | Negative |
| WHOLEPOWER® Rapid Pregnancy Test | Positive | 64 | 0 |
| | Negative | 0 | 56 |

| Midstream | | Predicate device | |
|---|---|---|---|
| | | Positive | Negative |
| WHOLEPOWER® Rapid Pregnancy Test | Positive | 64 | 0 |
| | Negative | 0 | 56 |

The above results indicate an over 98% agreement between the proposed and the predicate.

**C. Lay person study**:

300 women's individual pregnancy status was self-tested, varying educational and occupational backgrounds from three sites were chosen for the study. Each subject tested her own urine sample using the candidate device according to the package insert. Each subject also provided a sample for professional testing with the candidate device as well.

Summary

| WHOLEPOWER Pregnancy Rapid Test Strip | | Professional | |
|---|---|---|---|
| | | + | - |
| Lay person | + | 53 | 0 |
| | - | 1 | 46 |

| WHOLEPOWER Pregnancy Rapid Test Cassette | | Professional | |
|---|---|---|---|
| | | + | - |
| Lay person | + | 48 | 0 |
| | - | 0 | 52 |

| WHOLEPOWER Pregnancy Rapid Test Midstream | | Professional | |
|---|---|---|---|
| | | + | - |
| Lay person | + | 40 | 0 |
| | - | 1 | 59 |

From the above tables, the lay person results showed 100% positive and >97% negative conformity with the professional results.

Each lay person was given a questionnaire to assess the readability of the labeling. The results of the questionnaire reflected that the consumers found the test easy to

use and that they did not have trouble understanding the labeling and interpreting the results.

## 11. Conclusion

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