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

## I Background Information:

### A 510(k) Number

K230038

### B Applicant

Guangzhou Decheng Biotechnology Co., Ltd.

### C Proprietary and Established Names

MissLan® Pregnancy Rapid Test (Strip)
MissLan® Pregnancy Rapid Test (Midstream)

### 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 |

## 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:

MissLan® Pregnancy Rapid Test (Strip) is used for qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine, as an aid in early detection of pregnancy. It is intended for use by people who would like to find out whether they are pregnant in a home environment. Only for use outside the body. For over the counter use.

MissLan® Pregnancy Rapid Test (Midstream) is used for qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine, as an aid in early detection of pregnancy. It is intended for use by people who would like to find out whether they pregnant in a home environment. Only for use outside the body. For over the counter use.

### C Special Conditions for Use Statement(s):

OTC - Over The Counter

### D Special Instrument Requirements:

None

## IV Device/System Characteristics:

### A Device Description:

The MissLan® Pregnancy Rapid Test (Strip) and MissLan® Pregnancy Rapid Test (Midstream) are lateral flow immunoassays for the detection of human chorionic gonadotropin (hCG). The test strip format is packaged as a single test strip sealed in a desiccated aluminum pouch, with a urine collection cup and instructions for use. The midstream format is a test strip assembled in a plastic housing with an absorbent tip and is packaged as a single test sealed in a desiccated aluminum pouch with instructions for use. The result is displayed within the "test window" by two distinct colored lines, one control line and one test line.

### B Principle of Operation:

The MissLan® Pregnancy Rapid Test (Strip) and MissLan® Pregnancy Rapid Test (Midstream) use a lateral flow immunoassay to detect hCG, in human urine. The test comes in two formats; 1) Midstream, in which a user can apply a specimen by keeping the absorbent tip in a urine mid-stream for five (5) to ten (10) seconds or by dipping the entire absorbent tip into urine collected in a cup for five (5) to ten (10) seconds; and 2) test strip format, in which a user dips the sample pad into urine collected in a cup for five (5) seconds.

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 on the test area (i.e., test line). A colored line will always develop in the control zone "C" (i.e., control line) if sufficient sample volume has been applied to the test strip. The test result is shown in the result window and read visually between 3 and 5 minutes of urine application. Two distinct colored lines, one in the test zone and another in the control zone indicate a positive test result (pregnant). Absence of a colored line in the test zone and only a colored line in the control zone indicates a negative test result (not pregnant). Absence of a colored line in the control zone, even in the presence of a colored line in the test zone, 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):** | K230038 | K043443 |
|---|---|---|
| Device Trade Name | MissLan® Pregnancy Rapid Test (Strip) and MissLan® Pregnancy Rapid Test (Midstream) | One Step HCG Urine Pregnancy Test |
| **General Device Characteristic Similarities** | | |
| Intended Use/Indications For Use | Qualitative detection of Human Chorionic Gonadotropin (HCG) to aid in the early detection of pregnancy | Same |
| Sample Matrix | Urine | Same |
| Test Principle | Chromatographic immunoassay | Same |
| hCG Sensitivity | 25 mIU/mL | Same |
| Read Time | 3-5 minutes | Same |
| **General Device Characteristic Differences** | | |
| Device Format | Strip, Midstream | Midstream, Strip, Cassette |
| Conditions for Use | Over the Counter | Prescription and Over the Counter |
| Traceability | Traceable to the 5$^{th}$ | Traceable to the 3$^{rd}$ |

| Device & Predicate Device(s): | K230038 | K043443 |
|---|---|---|
| | World Health Organization (WHO) International Standard | World Health Organization (WHO) International Standard |

## VI Standards/Guidance Documents Referenced:

None referenced.

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

### A Analytical Performance:

1. Precision/Reproducibility:
   A pooled urine sample from non-pregnant females (negative) was spiked with hCG to provide nine urine samples with hCG concentrations of 0, 12.5, 15, 18.75, 22.5, 25, 50, 100 and 200 mIU/mL. Each sample was tested using 3 lots of the MissLan® Pregnancy Rapid Test (Strip) and 3 lots of the MissLan® Pregnancy Rapid Test (Midstream). Testing on the midstream format was performed using both the mid-stream sampling method and dip sampling method. The tests were performed in replicates of 10, over the course of 5 non-consecutive days by 3 different operators for each sample concentration. A total of 150 tests per concentration were performed per tested sampling method. The device cut-off is 25 mIU/mL hCG.

**Table #1. Midstream format (mid-stream sampling method) precision results**

| hCG concentration (mIU/mL) | Operator 1 Lot 1 | | Operator 2 Lot 2 | | Operator 3 Lot 3 | | Total number of results | | Overall precision | |
|---|---|---|---|---|---|---|---|---|---|---|
| | - | + | - | + | - | + | - | + | % Negative | % Positive |
| 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100 | 0 |
| 12.5 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100 | 0 |
| 15 | 25 | 25 | 26 | 24 | 23 | 27 | 74 | 76 | 49.3 | 50.7 |
| 18.75 | 12 | 38 | 13 | 37 | 12 | 38 | 37 | 113 | 24.7 | 75.3 |
| 22.5 | 5 | 45 | 4 | 46 | 4 | 46 | 13 | 137 | 8.7 | 91.3 |
| 25 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100 |
| 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100 |
| 100 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100 |
| 200 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100 |

**Table #2. Midstream format (dip sampling method) precision results**

| hCG concentration (mIU/mL) | Operator 1 Lot 1 | | Operator 2 Lot 2 | | Operator 3 Lot 3 | | Total number of results | | Overall precision | |
|---|---|---|---|---|---|---|---|---|---|---|
| | - | + | - | + | - | + | - | + | % Negative | % Positive |
| 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100 | 0 |
| 12.5 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100 | 0 |
| 15 | 25 | 25 | 27 | 23 | 24 | 26 | 76 | 74 | 50.7 | 49.3 |
| 18.75 | 12 | 38 | 13 | 37 | 13 | 37 | 38 | 112 | 25.3 | 74.7 |
| 22.5 | 5 | 45 | 5 | 45 | 4 | 46 | 14 | 136 | 9.3 | 90.7 |
| 25 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100 |
| 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100 |
| 100 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100 |
| 200 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100 |

**Table #3. Strip format precision results**

| hCG concentration (mIU/mL) | Operator 1 Lot 1 | | Operator 2 Lot 2 | | Operator 3 Lot 3 | | Total number of results | | Overall precision | |
|---|---|---|---|---|---|---|---|---|---|---|
| | - | + | - | + | - | + | - | + | % Negative | % Positive |
| 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100 | 0 |
| 12.5 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100 | 0 |
| 15 | 25 | 25 | 24 | 26 | 24 | 26 | 73 | 77 | 48.7 | 51.3 |
| 18.75 | 11 | 39 | 12 | 38 | 13 | 37 | 36 | 114 | 24 | 76 |
| 22.5 | 5 | 45 | 4 | 46 | 5 | 45 | 14 | 136 | 9.3 | 90.7 |
| 25 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100 |
| 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100 |
| 100 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100 |
| 200 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100 |

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). Urine specimens from non-pregnant females were pooled and used to prepare samples with hCG levels of 0 mIU/mL, 5 mIU/mL and 25 mIU/mL that were then spiked with each cross reactant at the following concentrations: 500 mIU/mL LH, 1000 mIU/mL FSH, and 1000 mIU/mL TSH. Samples were tested in replicates of 3 with 3 lots of the candidate devices. The results demonstrated no cross reactivity at the LH, FSH and TSH concentrations tested in either negative or positive urine samples.

Interference Study:
To evaluate potential interference for the MissLan® Pregnancy Rapid Test (Strip) and the MissLan® Pregnancy Rapid Test (Midstream), a urine pool from non-pregnant females was used to prepare samples with hCG levels of 0 mIU/mL, 5 mIU/mL and 25 mIU/mL that were then spiked with potentially interfering exogenous and endogenous substances (test samples). Samples were tested in 3 replicates on 3 lots by 3 operators on the candidate devices. The results demonstrated no interference from substances at the concentrations shown in the table below.

**Table #4. Potentially interfering substances tested**

| Potential Interferent | Highest concentration tested that demonstrated no interference (mg/dL) |
|---|---|
| Endogenous Interferents | |
| Albumin | 2000 |
| Bilirubin | 40 |
| Hemoglobin | 1000 |
| Glucose | 2000 |
| Uric Acid | 23.5 |
| Exogenous Interferents | |
| Acetaminophen | 20 |
| Amoxicillin | 20 |
| Ampicillin | 20 |
| Ascorbic Acid | 20 |
| Aspirin | 80 |
| Atropine | 20 |
| 17 β-estradiol | 8 (mg/mL) |
| β-hydroxybutyrate | 2000 |
| Benzoylecgonine | 10 |
| Caffeine | 20 |
| Cannabinol | 10 |
| EDTA | 80 |
| Ephedrine | 20 |
| Estradiol valerate | 20 (mg/mL) |
| Ethanol | 1% |
| Folic Acid | 0.03 |
| Gentisic Acid | 20 |
| Ibuprofen | 40 |
| Ketone | 20 |
| Phenylpropanolamine | 20 |
| Phenothiazine | 20 |
| Pregnanediol | 1.5 |
| Progesterone | 8 (mg/mL) |
| Salicylic Acid | 20 |
| Tetracycline | 20 |
| Thiophene | 20 |
| Vitamin B1 | 80 |

Effect of hCG β-core fragment:
Urine samples from non-pregnant females (negative) (0 and 5 mIU/mL hCG) were used to prepare samples with hCG levels of 25 mIU/mL and 20,000 mIU/mL. Samples were spiked with hCG β-core fragment at concentrations of 50,000 pmol/L, 125,000 pmol/L, 250,000 pmol/L and 500,000 pmol/L. The results demonstrated that the candidate devices are not affected by concentrations of hCG β-core fragment up to 500,000 pmol/L.

Effect of urine pH:
To evaluate potential interference from changes in urine pH, urine samples containing 0 mIU/mL, 5 mIU/mL and 25 mIU/mL hCG were adjusted to pH values of 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 and tested using the candidate devices. The results demonstrated that changes in pH ranging from 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, 5 mIU/mL, and 25 mIU/mL hCG were adjusted to specific gravities of 1.000, 1.005, 1.010, 1.020, 1.030 and 1.035. The results demonstrated that changes in specific gravity ranging from 1.000 to 1.035 do not interfere with either positive or negative results from the devices.

High dose hook effect study:
Pooled urine samples from non-pregnant females (negative) were spiked with varying hCG concentrations (6,250, 12,500, 25,000, 50,000, 100,000, 200,000, and 500,000 mIU/mL) and tested on 3 lots of the candidate devices. No hook effect was observed at concentrations up to 500,000 mIU/mL hCG.

4. Assay Reportable Range:

   Not applicable.

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

   MissLan® Pregnancy Rapid Test (Strip) and MissLan® Pregnancy Rapid Test (Midstream) are calibrated against reference material traceable to WHO International Standard 5th edition, NIBSC code 07/364.

6. Detection Limit:

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

7. Assay Cut-Off:

   The device's cut-off is 25 mIU/mL. See Precision/Reproducibility (Section VII.A.1.) section above.

## B Comparison Studies:

1. Method Comparison with Predicate Device:

A total of 200 urine samples were collected from women whose ages ranged from 18 to 45 years, who presented to 3 clinics for pregnancy testing. Approximately half of the 200 women were suspected to be pregnant and most of them were in the early stages of pregnancy (less than 5 weeks). The samples were masked and randomized prior to testing by professionals using 3 lots of the candidate devices and a single lot of the predicate device (One Step HCG Urine Pregnancy Test). One hundred (100) samples were tested using the MissLan® Pregnancy Rapid Test (Midstream) in each sampling mode (100 of the samples were tested in the dip sampling mode and the other 100 samples were tested in mid-stream sampling mode), and all 200 urines samples were tested using the MissLan® Pregnancy Rapid Test (Strip). A summary of the results is presented in the tables below:

**Table #5: Test strip format method comparison results**

| Candidate device | | Predicate device | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| Test Strip | Positive | 101 | 0 | 101 |
| | Negative | 0 | 99 | 99 |
| | Total | 101 | 99 | 200 |

**Table #6: Midstream format mid-stream sampling method comparison results**

| Candidate device | | Predicate device | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| Midstream Device mid-stream sampling | Positive | 52 | 0 | 52 |
| | Negative | 0 | 48 | 48 |
| | Total | 52 | 48 | 100 |

**Table #7: Midstream format dip sampling method comparison results**

| Candidate device | | Predicate device | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| Midstream Device Dip sampling | Positive | 49 | 0 | 49 |
| | Negative | 0 | 51 | 51 |
| | Total | 49 | 51 | 100 |

The data shows that the agreement of the MissLan® Pregnancy Rapid Test (Strip) and MissLan® Pregnancy Rapid Test (Midstream) with the predicate device was 100%.

2. Matrix Comparison:

Not applicable. The device is intended to be used with urine samples 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):

a. Lay-User Study:

A lay user study was conducted at 3 sites with 200 volunteers with diverse educational and occupational backgrounds who were between the ages of 18 and 45. This included 100 lay-users using the MissLan® Pregnancy Rapid Test (Strip) and 100 lay-users using the MissLan® Pregnancy Rapid Test (Midstream), split between 50 users performing dip-test sampling and 50 users performing mid-stream sampling. The lay-users tested their own urine sample and also provided a sample for professional testing. 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. The data shows that the agreement between lay-user results and professional results was 100% (below):

**Table #8: Test strip format dip sampling lay user results**

| Test Strip | | Professional user | | |
|---|---|---|---|---|
| | | Positive | Negative | Total |
| Lay-user | Positive | 52 | 0 | 52 |
| | Negative | 0 | 48 | 48 |
| | Total | 52 | 48 | 100 |

**Table #9: Midstream format mid-stream sampling lay user results**

| Midstream device (mid-stream sampling) | | Professional user | | |
|---|---|---|---|---|
| | | Positive | Negative | Total |
| Lay-user | Positive | 26 | 0 | 26 |
| | Negative | 0 | 24 | 24 |
| | Total | 26 | 24 | 50 |

**Table #10: Midstream format dip sampling lay user results**

| Midstream device (dip sampling) | | Professional user | | |
|---|---|---|---|---|
| | | Positive | Negative | Total |
| Lay-user | Positive | 23 | 0 | 23 |
| | Negative | 0 | 27 | 27 |
| | Total | 23 | 27 | 50 |

## D Clinical Cut-Off:

Not applicable.

## E Expected Values/Reference Range:

Not applicable.

## VIII Proposed Labeling:

The labeling supports or 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.