September 09, 2025

Guangzhou Decheng Biotechnology Co., Ltd.
Mango Huang
Regulatory Affairs Manager
Floor 3/4/5/7, Building A1, No.12, Nanyun 1st Road
Science City, Huangpu District
Guangzhou, Guangdong 510663, China

Re: K251040
Trade/Device Name: MissLan® Early Detection Digital Pregnancy Test; MissLan® Early Result Digital Pregnany Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test System
Regulatory Class: Class II
Product Code: LCX
Dated: July 15, 2025
Received: July 15, 2025

Dear Mango Huang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOSEPH A. KOTAREK -S
Digitally signed by JOSEPH A. KOTAREK -S
Date: 2025.09.08 15:18:46 -04'00'

Joseph Kotarek, Ph.D.
Branch Chief, Toxicology Branch
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251040

Device Name
MissLan® Early Detection Digital Pregnancy Test
MissLan® Early Result Digital Pregnancy Test

Indications for Use *(Describe)*
MissLan® Early Detection Digital Pregnancy Test is used for qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine. This test is intended for use as an aid in early detection of pregnancy, in some cases as early as six (6) days before the day of the missed period, i.e. as early as five (5) days before the day of the expected period. 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® Early Result Digital Pregnancy Test is used for qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine. This test is intended for use as an aid in early detection of pregnancy, in some cases as early as six (6) days before the day of the missed period, i.e. as early as five (5) days before the day of the expected period. 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.

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.

510(k) SUMMARY

510(k) number: K251040

1. **Date:** August 22, 2025

2. **Submitter:** Guangzhou Decheng Biotechnology Co., Ltd.
Address: Floor 3/4/5/7, Building A1, No.12, Nanyun 1st Road, Science City, Huangpu District, Guangzhou, Guangdong, 510663, P.R. China
Contact Person: Mango Huang
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3. **Correspondent:** Guangzhou Decheng Biotechnology Co., Ltd.
Address: Floor 3/4/5/7, Building A1, No.12, Nanyun 1st Road, Science City, Huangpu District, Guangzhou, Guangdong, 510663, P.R. China
Contact Person: Mango Huang
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Telephone: (888) 695-5248

4. **Device Name:** MissLan® Early Detection Digital Pregnancy Test
MissLan® Early Result Digital Pregnancy Test

5. **Classification:** Class II

Product Code	Regulation Section	Panel
LCX	21 CFR Part 862.1155 Human chorionic gonadotropin (HCG) test system	Clinical Chemistry

6. **Purpose for Submission**
New device

7. **Predicate Devices**

K150022	Wondfo One Step HCG Urine Pregnancy Test Strip
	Wondfo One Step HCG Urine Pregnancy Test Cassette
	Wondfo One Step HCG Urine Pregnancy Test Midstream

8. **Intended Use**

MissLan® Early Detection Digital Pregnancy Test is used for qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine. This test is intended for use as an aid in early detection of pregnancy, in some cases as early as six (6) days before the day of the missed period, i.e. as early as five (5) days before the day of the expected period. 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® Early Result Digital Pregnancy Test is used for qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine. This test is intended for use as an aid in early detection of pregnancy, in some cases as early as six (6) days before the day of the missed period, i.e. as early as five (5) days before the day of the expected period. 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.

9. Device Description

The MissLan® Early Detection Digital Pregnancy Test and the MissLan® Early Result Digital Pregnancy Test are both over-the-counter (OTC) digital pregnancy tests with a sensitivity of 10 mIU/mL hCG. They are powered by battery and display test results on an LCD screen. The MissLan® Early Detection Digital Pregnancy Test displays test results with graphic symbols, including "+" (pregnant), "-" (not pregnant) and "📖" (invalid); the MissLan® Early Result Digital Pregnancy Test displays test results with text, including "Pregnant", "Not Pregnant" and "Error".

10. Substantial Equivalence Information

Similarities		
Item	**Candidate device**	**Predicate device (K150022)**
Intended use	Early detection of pregnancy	Same
Analyte	hCG	Same
Specimen	Urine	Same
Methodology	Immunochromatographic assay	Same
Sensitivity	10 mIU/mL	Same
Results	Qualitative	Same
Usage type	Single use	Same
Differences		
Item	**Candidate device**	**Predicate device (K150022)**
Target user	Over-the-counter use	Prescription use and over-the-counter use
Device format	Battery-powered: midstream	Non-powered: Strip, Cassette, Midstream
Results display	Results are displayed digitally on LCD screen: ① by graphic symbols: "+" or "-" or "📖" ② by text: "Pregnant" or "Not Pregnant" or "Error"	Visual parallel line: 2 lines = Pregnant 1 line = Not pregnant No line = Invalid

11. Standard/Guidance Document Reference (if applicable)

None referenced.

12. Test Principle

The MissLan® Early Detection Digital Pregnancy Test (herein referred to as the graphic symbol display mode) and the MissLan® Early Result Digital Pregnancy Test (herein referred to as the text display mode) both use lateral flow immunoassay and light reflection for the in vitro qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine. After the urine specimen is applied to the device, the HCG present in the specimen will react with the anti-β-HCG antibody-colloidal gold conjugate and form a compound. As the liquid flows to the Test area of the test strip, the compound will be captured by the anti-α-HCG antibody immobilized on the Test area, then a colored line will be formed on the Test area. The device will detect its light intensity by using the LED as the light source. After that, the result is shown on the display screen within 5 minutes, accompanied by two beep reminders.

13. Performance Characteristics

13.1 Analytical Performance

A. Precision/Reproducibility/Sensitivity

A precision study was performed using pooled negative female urine spiked with hCG (traceable to the 5th World Health Organization International Standard (WHO IS)) to obtain samples with hCG contractions of 0, 2.5, 5, 6, 7, 8, 10, 15 and 25 mIU/mL. Each sample was tested in 10 replicates per day for a total of 5 days for each batch of MissLan® Early Detection Digital Pregnancy Test and MissLan® Early Result Digital Pregnancy Test. Both in-stream and dip sampling methods were tested in this study. A total of six batches for both display modes were tested, with one operator testing one batch separately.

The obtained results are summarized in the following tables.

Graphic symbol display mode (in-stream method)

HCG Concentration (mIU/mL)	Operator 1 Lot I		Operator 2 Lot II		Operator 3 Lot III		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	50	0	50	0	50	0	150	0	100%	0%
2.5	50	0	50	0	50	0	150	0	100%	0%
5	50	0	50	0	50	0	150	0	100%	0%
6	39	11	39	11	38	12	116	34	77.3%	22.7%
7	23	27	24	26	22	28	69	81	46%	54%
8	14	36	15	35	14	36	43	107	28.7%	71.3%
10	0	50	0	50	0	50	0	150	0%	100%
15	0	50	0	50	0	50	0	150	0%	100%
25	0	50	0	50	0	50	0	150	0%	100%

Graphic symbol display mode (dip method)

HCG Concentration (mIU/mL)	Operator 1 Lot I		Operator 2 Lot II		Operator 3 Lot III		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	50	0	50	0	50	0	150	0	100%	0%

2.5	50	0	50	0	50	0	150	0	100%	0%
5	50	0	50	0	50	0	150	0	100%	0%
6	39	11	39	11	39	11	117	33	78%	22%
7	22	28	22	28	22	28	66	84	44%	56%
8	13	37	14	36	14	36	41	109	27.3%	72.7%
10	0	50	0	50	0	50	0	150	0%	100%
15	0	50	0	50	0	50	0	150	0%	100%
25	0	50	0	50	0	50	0	150	0%	100%

Text display mode (in-stream method)

HCG Concentration (mIU/mL)	Operator 1		Operator 2		Operator 3		Total result		% Negative	% Positive
	Lot I		Lot II		Lot III					
	-	+	-	+	-	+	-	+		
0	50	0	50	0	50	0	150	0	100%	0%
2.5	50	0	50	0	50	0	150	0	100%	0%
5	50	0	50	0	50	0	150	0	100%	0%
6	37	13	38	12	38	12	113	37	75.3%	24.7%
7	23	27	25	25	23	27	71	79	47.3%	52.7%
8	13	37	14	36	13	37	40	110	26.7%	73.3%
10	0	50	0	50	0	50	0	150	0%	100%
15	0	50	0	50	0	50	0	150	0%	100%
25	0	50	0	50	0	50	0	150	0%	100%

Text display mode (dip method)

HCG Concentration (mIU/mL)	Operator 1		Operator 2		Operator 3		Total result		% Negative	% Positive
	Lot I		Lot II		Lot III					
	-	+	-	+	-	+	-	+		
0	50	0	50	0	50	0	150	0	100%	0%
2.5	50	0	50	0	50	0	150	0	100%	0%
5	50	0	50	0	50	0	150	0	100%	0%
6	38	12	38	12	38	12	114	36	76%	24%
7	23	27	24	26	23	27	70	80	46.7%	53.3%
8	13	37	13	37	13	37	39	111	26%	74%
10	0	50	0	50	0	50	0	150	0%	100%
15	0	50	0	50	0	50	0	150	0%	100%
25	0	50	0	50	0	50	0	150	0%	100%

Both the graphic symbol display mode and the text display mode exhibited reproducibility of results. Based on the above results, the sensitivity of MissLan® Early Detection Digital Pregnancy Test and MissLan® Early Result Digital Pregnancy Test is demonstrated to be 10 mIU/mL.

B. Linearity/Assay Reportable Range

Linearity is not applicable since this is a qualitative test.

The test device was evaluated for high dose or hook effect.

Hook effect test:
Negative urine samples were spiked with varying high hCG concentrations (6,250 mIU/mL, 12,500 mIU/mL, 25,000 mIU/mL, 50,000 mIU/mL, 100,000 mIU/mL, 200,000 mIU/mL and 500,000 mIU/mL). The results demonstrated that no hook effect was observed at hCG concentration up to 500,000 mIU/mL.

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

Traceability:
The MissLan® Early Detection Digital Pregnancy Test and the MissLan® Early Result Digital Pregnancy Test are calibrated against reference material traceable to WHO International Standard 5th edition, NIBSC code 07/364.

Stability:
The device is stable at 2-30℃ for 30 months based on real time stability study.

D. Analytical Specificity

a. Interfering substances

To evaluate the effect of the potential interfering substances on the device, urine samples containing 0 mIU/mL, 5 mIU/mL and 10 mIU/mL hCG were spiked with interfering substances to the concentrations listed below. No interference effect was observed at the tested concentrations.

Substance	Concentration
Albumin	2000 mg/dL
Bilirubin	40 mg/dL
Glucose	2000 mg/dL
Hemoglobin	1000 mg/dL
Uric acid	23.5 mg/dL
Ketone	20 mg/dL
β-hydroxybutyrate	2000 mg/dL
Pregnanediol	1.5 mg/dL
Acetaminophen	20 mg/dL
Acetylsalicylic acid	80 mg/dL
Amoxicillin	20 mg/dL
Ampicillin	20 mg/dL
Ascorbic acid	20 mg/dL
Atropine	20 mg/dL
Benzoylecgonine	10 mg/dL
Caffeine	20 mg/dL
Cannabinol	10 mg/dL
Codeine	6 μg/dL
EDTA	80 mg/dL
Ephedrine	20 mg/dL

Substance	Concentration
Ethanol	1%
Folic acid	0.03 mg/dL
Salicylic acid	20 mg/dL
Gentisic acid	20 mg/dL
Ibuprofen	40 mg/dL
Phenothiazine	20 mg/dL
Phenylpropanolamine	20 mg/dL
Tetracycline	20 mg/dL
Thiophene	20 mg/dL
Vitamin B1	80 mg/dL

b. Cross-reactivity

To evaluate cross-reactivity, negative and positive urine samples (0 mIU/mL, 5 mIU/mL and 10 mIU/mL hCG) were spiked with potential cross reactants (500 mIU/mL hLH, 1000 mIU/mL hFSH, 1000 μIU/mL hTSH). No cross-reactivity was observed at the tested concentrations.

c. Effect of hCG β-core fragment

To evaluate the effect of the hCG β-core fragment, negative urine samples (0 mIU/mL and 5 mIU/mL hCG) and positive urine samples (10 mIU/mL and 20,000 mIU/mL hCG) were spiked with hCG β-core fragment (hCGβcf) at concentrations of 50,000 pmol/L, 125,000 pmol/L, 250,000 pmol/L and 500,000 pmol/L. The performance of MissLan® Early Detection Digital Pregnancy Test and MissLan® Early Result Digital Pregnancy Test was not affected by hCG β-core fragment concentrations up to 500,000 pmol/L.

d. Effects of urine pH

To evaluate the effect of urine pH on the device, urine samples containing 0 mIU/mL, 5 mIU/mL and 10 mIU/mL hCG were tested at pH values of 4, 5, 6, 7, 8 and 9. The results indicated that urine with a pH ranging from 4 and 9 does not affect the performance of MissLan® Early Detection Digital Pregnancy Test and MissLan® Early Result Digital Pregnancy Test.

e. Effects of urine density

To evaluate the effect of urine density on the device, urine samples containing 0 mIU/mL, 5 mIU/mL and 10 mIU/mL hCG were tested at density values of 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030 and 1.035. The results indicated that urine with a relative density ranging from 1.000 to 1.035 does not affect the performance of MissLan® Early Detection Digital Pregnancy Test and MissLan® Early Result Digital Pregnancy Test.

E. Detection Limit

A detection limit study was performed using negative female urine samples spiked with 0, 2.5, 5, 6, 7, 8, 10, 15 and 25 mIU/mL hCG (hCG traceable to the 5th WHO IS). The samples were tested using both display modes of the device. Each sample was tested in 20 replicates by three different operators, using three batches for each display mode. Both in-stream and dip sampling methods were tested in the study. The sensitivity of the device was determined to be 10 mIU/mL for both display modes.

F. Assay Cut-Off

The claimed cut-off is 10 mIU/mL. See Detection Limit (Section 13.1 E) and Precision/Reproducibility/Sensitivity (Section 13.1 A) sections above.

13.2 Method Comparison Study

Method comparison with predicate device:

The performance of the candidate device was compared to the predicate device. Urine samples were collected from 400 women aged 18 to 51 at three clinical sites. Approximately half of the subjects were suspected to be pregnant and most of them were pregnant in the early stage of less than 5 weeks. Samples were randomly collected at various time throughout the day.

All samples were tested by three professionals at each site using the candidate device and by one professional at each site using the predicate device. 200 samples were tested for graphic symbol display mode device, and 200 samples were tested for text display mode device. For each display mode device, both dip testing (100 samples) and in-stream testing (100 samples) were evaluated. The samples were randomly blinded before being tested by the professionals. All results are summarized in the table below.

Candidate device		Predicate device		
		Positive	Negative	Total
Graphic symbol display mode device (dip method)	Positive	48	0	48
	Negative	0	52	52
	Total	48	52	100

Candidate device		Predicate device		
		Positive	Negative	Total
Graphic symbol display mode device (in-stream method)	Positive	51	0	51
	Negative	0	49	49
	Total	51	49	100

Candidate device		Predicate device		
		Positive	Negative	Total
Text display mode device (dip method)	Positive	49	0	49
	Negative	0	51	51
	Total	49	51	100

Candidate device		Predicate device		
		Positive	Negative	Total
Text display mode device (in-stream method)	Positive	48	0	48
	Negative	0	52	52
	Total	48	52	100

The conformity rate between the candidate device (including graphic symbol display mode and text display mode) and the predicate device is 100%.

13.3 Clinical Studies

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

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

3.1 Lay user study

First study:

A lay user study was performed at three sites with a total of 400 females with diverse educational and occupational backgrounds and ages ranging from 18 to 51 years old. Each subject tested her own urine sample using the device according to the instructions for use and provided a sample for professional testing. 100 subjects tested the graphic symbol display mode device using dip method, 100 subjects tested the graphic symbol display mode device using in-stream method, 100 subjects tested the text display mode device using dip method, and 100 subjects tested the text display mode device using in-stream method.

The results are summarized in the tables below.

Graphic symbol display mode device (dip method):

Graphic symbol display mode device (dip method)		Professional		
		Positive	Negative	Total
Layperson	Positive	48	0	48
	Negative	0	52	52
	Total	48	52	100

Graphic symbol display mode device (in-stream method):

Graphic symbol display mode device (in-stream method)		Professional		
		Positive	Negative	Total
Layperson	Positive	51	0	51
	Negative	0	49	49
	Total	51	49	100

Text display mode device (dip method):

Text display mode device (dip method)		Professional		
		Positive	Negative	Total
Layperson	Positive	49	0	49
	Negative	0	51	51
	Total	49	51	100

Text display mode device (in-stream method):

Text display mode device (in-stream method)		Professional		
		Positive	Negative	Total
Layperson	Positive	48	0	48
	Negative	0	52	52
	Total	48	52	100

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

Second study:

Urine samples were prepared at 5 mIU/mL, 6 mIU/mL, 7 mIU/mL and 10 mIU/mL hCG concentrations by spiking hCG into negative female pooled urine specimens. Each sample was aliquoted into individual containers and blind-labeled by the person who prepared the samples but didn't take part in the sample testing. A total of 200 female laypersons performed the testing by dip method, of which 100 using the graphic symbol display mode device, and 100 using the text display mode device. Each layperson tested 4 blind-labeled samples (5 mIU/mL, 6 mIU/mL, 7 mIU/mL and 10 mIU/mL), and an aliquot of each of the spiked urine samples was also tested by the professional.

The results are summarized in the tables below.

Graphic symbol display mode device:

hCG Concentration (mIU/mL)	Layperson result			Professional result			Percent Agreement
	No. of Positive	No. of Negative	% positive	No. of Positive	No. of Negative	% positive	
5	0	100	0%	0	100	0%	100%
6	24	76	24%	22	78	22%	98%
7	49	51	49%	51	49	51%	98%
10	100	0	100%	100	0	100%	100%

Text display mode device:

hCG Concentration (mIU/mL)	Layperson result			Professional result			Percent Agreement
	No. of Positive	No. of Negative	% positive	No. of Positive	No. of Negative	% positive	
5	0	100	0%	0	100	0%	100%
6	22	78	22%	23	77	23%	99%
7	48	52	48%	51	49	52%	97%
10	100	0	100%	100	0	100%	100%

The above results showed that both the graphic symbol display mode device and the text display mode device can be used by the laypersons and get the correct results.

3.2 Early pregnancy detection study

A study was performed to evaluate the early pregnancy detection rate of the device. A total of 650 early pregnancy urine samples from the 8th day before expected menstrual period (EMP-8) to the first day after the expected menstrual period (EMP+1) were collected from 65 pregnant women. Each sample was tested using both display modes of the device. Both in-stream and dip sampling methods were tested in this study.
The specific detection rates per day are summarized in the table below.

Graphic symbol display mode device (in-stream method):

Test date	EMP-8	EMP-7	EMP-6	EMP-5	EMP-4	EMP-3	EMP-2	EMP-1	EMP	EMP+1
# of positive results of B-ultrasound	65	65	65	65	65	65	65	65	65	65
# of positive results of HCG	2	7	26	51	63	65	65	65	65	65
Detection rate	3.08%	10.77%	40%	78.46%	96.92%	100%	100%	100%	100%	100%

Graphic symbol display mode device (dip method):

Test date	EMP-8	EMP-7	EMP-6	EMP-5	EMP-4	EMP-3	EMP-2	EMP-1	EMP	EMP+1
# of positive results of B-ultrasound	65	65	65	65	65	65	65	65	65	65
# of positive results of HCG	2	7	26	51	63	65	65	65	65	65
Detection rate	3.08%	10.77%	40%	78.46%	96.92%	100%	100%	100%	100%	100%

Text display mode device (in-stream method):

Test date	EMP-8	EMP-7	EMP-6	EMP-5	EMP-4	EMP-3	EMP-2	EMP-1	EMP	EMP+1
# of positive results of B-ultrasound	65	65	65	65	65	65	65	65	65	65
# of positive results of HCG	2	7	26	51	63	65	65	65	65	65
Detection rate	3.08%	10.77%	40%	78.46%	96.92%	100%	100%	100%	100%	100%

Text display mode device (dip method):

Test date	EMP-8	EMP-7	EMP-6	EMP-5	EMP-4	EMP-3	EMP-2	EMP-1	EMP	EMP+1
# of positive results of B-ultrasound	65	65	65	65	65	65	65	65	65	65
# of positive results of HCG	2	7	26	51	63	65	65	65	65	65
Detection rate	3.08%	10.77%	40%	78.46%	96.92%	100%	100%	100%	100%	100%

The detection rate of the device in EMP-5 (i.e. five days before the expected menstrual period, 6 days before the missed menstrual period) was 78.46%, in EMP-4 was 96.92%, and in EMP-1 was 100%.

3.3 Specificity Study to Determine False-Positive Result Rate

600 urine samples were collected from healthy, non-pregnant females in pre-menopausal (18-40 years old), peri-menopausal (41-55 years old) and post-menopausal (>55 years old) age groups at three sites. There were 200 subjects in each age group, 100 of whom were tested using the graphic symbol display mode device (50 using dip method, 50 using in-stream method) and the other 100 were tested using the text display mode device (50 using dip method, 50 using in-stream method). Three batches of each mode device were used in the study. No false positive results were observed for all age groups.

Graphic symbol display mode device:

Age group	Lot I	Lot II	Lot III	Total result	Total % positive
Pre-menopausal	0+/34-	0+/33-	0+/33-	0+/100-	0
Peri-menopausal	0+/33-	0+/34-	0+/33-	0+/100-	0
Post-menopausal	0+/33-	0+/33-	0+/34-	0+/100-	0

Text display mode device:

Age group	Lot I	Lot II	Lot III	Total result	Total % positive
Pre-menopausal	0+/34-	0+/33-	0+/33-	0+/100-	0
Peri-menopausal	0+/33-	0+/34-	0+/33-	0+/100-	0
Post-menopausal	0+/33-	0+/33-	0+/34-	0+/100-	0

14. Conclusion

Based on the test principle and performance characteristics of the device including precision, cut-off, interference, specificity, method comparison, lay-user study and early pregnancy detection study of the devices, it can be concluded that both the MissLan® Early Detection Digital Pregnancy Test and the MissLan® Early Result Digital Pregnancy Test are substantially equivalent to the predicate device.