510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number
k251053

B Applicant

Hangzhou AllTest Biotech Co., Ltd.

C Proprietary and Established Names

Shinetell Plus™ Digital Early Pregnancy Test

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:
Shinetell Plus™ Digital Early Pregnancy Test is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

C Special Conditions for Use Statement(s):
OTC - Over the Counter

D Special Instrument Requirements:
None

IV Device/System Characteristics:

A Device Description:

The Shinetell Plus™ Digital Early Pregnancy Test is a digital test that consists of a single test strip assembled in plastic housing with an absorbent tip. The test detects light intensity using the Light Emitting Diode (LED) to display the result, "Pregnant" or "Not Pregnant" on the display screen. The test is designed to be used in dip or midstream sampling mode and is provided a ready-to-use format and in a sealed pouch with instructions for use.

B Principle of Operation:

Shinetell Plus™ Digital Early Pregnancy Test is a lateral flow immunoassay for the in vitro detection of human chorionic gonadotropin (hCG) in urine. Testing is conducted by immersing the absorbent tip in urine (dip mode) for 15 seconds or urinating on the absorbent tip (midstream mode) for 10 seconds. The hCG in the urine will react with anti-β-hCG antibody-colloidal gold conjugate and form a compound. As the liquid flows to the test line of the test strip, the compound will be captured by the anti-α-HCG antibody immobilized on the test line and a colored line will form if hCG is present, which is detected by the LED light source. The "Pregnant" or "Not Pregnant" result is displayed in the display screen within 3 minutes.
If the sample is added improperly, the test result is invalid and "?" is displayed on the screen.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Wondfo One Step HCG Urine Pregnancy Test Strip, Wondfo One Step HCG Urine Pregnancy Test Cassette, Wondfo One Step HCG Urine Pregnancy Test Midstream

B Predicate 510(k) Number(s):

C Comparison with Predicate(s):

Device & Predicate Device(s):	K251053	K150022
Device Trade Name	Shinetell Plus™ Digital Early Pregnancy Test	Wondfo One Step HCG Urine Pregnancy Test Strip, Wondfo One Step HCG Urine Pregnancy Test Cassette, Wondfo One Step HCG Urine Pregnancy Test Midstream
General Device Characteristic Similarities		
Intended Use	Early detection of pregnancy	Same
Early Detection Claim	Pregnancy can be detected as early as six (6) days before the day of the missed period (five days before the day of the expected period)	Same
Intended Use Environment	Over-the-counter	Same
Specimen	Urine	Same
hCG sensitivity	10 mIU/mL	Same
General Device Characteristic Differences		
Time to Result	3 minutes	5 minutes
Result format	Midstream/Dip	Strip, Cassette and Midstream/Dip
Readout	Digital/LCD screen	Visually read
Traceability	Calibrated against WHO 5th IS	Calibrated against WHO 4th IS

VI Standards/Guidance Documents Referenced:

IEC 60601-1-2:2014 (including amendment 1:2021) Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests (including Amendment 1 (2021).

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility

A precision study was performed using pooled female negative urine samples spiked with hCG to obtain samples with hCG concentrations of 0, 3, 5, 7.5, 8, 10, 25, and 50 mIU/mL. Each sample was tested using three lots of the Shinetell Plus™ Digital Early Pregnancy Test in both midstream and dip sampling methods. The tests were performed by three different operators over five consecutive days, in replicates of ten. The sensitivity of the device was determined to be 10 mIU/mL hCG.

Shinetell Plus™ Digital Early Pregnancy Test (dip sampling mode):

hCG Concentration (mIU/mL)	Operator 1 Lot 1		Operator 2 Lot 2		Operator 3 Lot 3		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	50	0	50	0	50	0	150	0	100%	0%
3	50	0	50	0	50	0	150	0	100%	0%
5	50	0	50	0	50	0	150	0	100%	0%
7.5	35	15	36	14	36	14	107	43	71%	29%
8	24	26	24	26	24	26	72	78	48%	52%
10	0	50	0	50	0	50	0	150	0%	100%
25	0	50	0	50	0	50	0	150	0%	100%
50	0	50	0	50	0	50	0	150	0%	100%

Shinetell Plus™ Digital Early Pregnancy Test (midstream sampling mode)

hCG Concentration (mIU/mL)	Operator 1 Lot 1		Operator 2 Lot 2		Operator 3 Lot 3		Combined result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	50	0	50	0	50	0	150	0	100%	0%
3	50	0	50	0	50	0	150	0	100%	0%
5	50	0	50	0	50	0	150	0	100%	0%
7.5	35	15	35	15	36	14	106	44	71%	29%
8	25	25	24	26	24	26	73	77	49%	51%
10	0	50	0	50	0	50	0	150	0%	100%
25	0	50	0	50	0	50	0	150	0%	100%
50	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:

Interference from endogenous and exogenous compounds
Negative female urine samples were pooled and used to prepare samples with hCG concentrations of 0 mIU/mL, 5 mIU/mL and 10 mIU/mL. These samples were then spiked with the potentially interfering exogenous and endogenous substances listed below. Test samples and control samples containing no test substance were tested with three lots of Shinetell Plus™ Digital Early Pregnancy Test in triplicate by three operators. No interference effect was observed at the tested concentrations shown in the table below.

Substance tested	Highest concentration tested that demonstrated no interference
Acetaminophen	20 mg/dL
Acetylsalicylic	20 mg/dL
Albumin	20 mg/dL
Ampicillin	20 mg/dL
Ascorbic acid	20 mg/dL
Atropine	20 mg/dL
Benzoylecgonine	10 mg/dL
β-hydroxybutyrate	2000 mg/dL
Bilirubin	2 mg/dL
Caffeine	20 mg/dL
Cannabinol	10 mg/dL
Codeine	0.006 mg/dL
EDTA	80 mg/dL
Ephedrine	20 mg/dL
Ethanol	1.0%
Gentisic acid	20 mg/dL
Glucose	2000 mg/dL
Hemoglobin	20 mg/dL
Ketone	20 mg/dL
Phenothiazine	20 mg/dL
Phenylpropanolamine	20 mg/dL
Pregnanediol	1.5 mg/dL
Salicylic Acid	20 mg/dL
Tetracycline	20 mg/dL
Thiophene	20 mg/dL

Cross-reactivity of similar compounds
To evaluate cross-reactivity, negative female urine sample pools containing hCG concentrations of 0 mIU/mL, 5 mIU/mL and 10 mIU/mL hCG were spiked with the following potential cross

reactants: 1000 mIU/mL luteinizing hormone (LH), 1000 mIU/mL follicle-stimulating hormone (FSH), 1 mIU/mL thyroid-stimulating hormone (TSH). Samples were tested in replicates of ten using three lots of Shinetell Plus™ Digital Early Pregnancy Test by three different operators. No cross-reactivity was observed at the tested concentrations.

Effect of urine pH

A study was performed to evaluate the effect of urine specific gravity on device performance. Negative female urine sample pools containing hCG concentrations of 0, 5, and 10 mIU/mL hCG were adjusted to specific gravity values from 1.000 to 1.035 and tested using three lots of the candidate device in triplicate by three operators. The results demonstrated that samples within the specific gravity range of 1.000 to 1.035 do not interfere with either positive or negative results from the device.

Effect specific gravity

A study was performed to evaluate the effect of pH on device performance. Negative female urine sample pools were spiked with hCG to concentrations of 0, 5, and 10 mIU/mL were adjusted to pH values from 4.0 to 9.0 and tested using three lots of the candidate device in triplicate by three operators. 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 device.

High dose hook effect

Negative female sample pools were spiked up to 500,000 mIU/mL hCG were tested in replicates of five using three lots of the candidate device by three operators. No hook effect was observed at concentrations of up to 500,000 mIU/mL hCG.

Effect of hCG β-core fragment

Negative female urine sample pools were used to prepare samples with hCG concentrations of 0 mIU/mL, 5 mIU/mL, 10 mIU/mL and 20,000 mIU/mL hCG and were then 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. Samples were tested in replicates of ten using three lots of the candidate device by three different operators. The results show that the candidate device is not affected by hCG β-core fragment concentrations up to 500,000 pmol/L.

4. Assay Reportable Range:

   Not applicable.

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

   Shinetell Plus™ Digital Early Pregnancy Test is calibrated against the World Health Organization's 5th International Standard for human chorionic gonadotropin (NIBSC code 07/364).

6. Detection Limit:

   A detection limit study was performed using negative female human urine samples spiked with 0, 3, 5, 7.5, 8, 9, 10, 15 and 25 mIU/mL hCG (traceable to the 5th WHO International

Standard). Samples were tested by dip and midstream sampling methods in replicates of twenty for each of three lots of the device by three different operators. The claimed analytical sensitivity or cutoff is 10 mIU/mL hCG.

7. Assay Cut-Off:

The device cutoff is 10 mIU/mL hCG. See Precision/Reproducibility (Section VII.A.1.) and Detection Limit (Section VII.A.6.) above.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Urine samples were collected from a total of 200 women who presented at three clinical sites for pregnancy testing. Participants suspected they were in the early stages of pregnancy of less than 5 weeks. Ages of the women ranged from 18 to 45 years. Samples were masked and randomized by people who labeled the samples but did not participate in the testing. A total of 100 samples were tested for the dip sampling mode and 100 were testing with the midstream sampling mode. Samples were tested by medical professionals using both the candidate and predicate devices. The results are summarized in the tables below.

Summary results of Shinetell Plus™ Digital Early Pregnancy Test (dip sampling mode)

Candidate device	Predicate device		
	Positive	Negative	Total
Positive	49	0	49
Negative	0	51	51
Total	49	51	100

Summary results of Shinetell Plus™ Digital Early Pregnancy Test (midstream sampling mode)

Candidate device	Predicate device		
	Positive	Negative	Total
Positive	48	0	48
Negative	0	52	52
Total	48	52	100

The test performance of Shinetell Plus™ Digital Early Pregnancy Test was 100% concordant when compared to the predicate.

2. Matrix Comparison:

Not applicable. This device is intended for use 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)

   Detection of hCG in Early Pregnancy Clinical Samples
   A total of 650 urine samples were collected from 65 pregnant women from the intended use population. The women ranged from 21 to 45 years old. Testing was conducted starting on 8 days before (-8) the expected menstrual cycle (EMP) to 1 day after (+1). Each sample was tested using both dip and simulated midstream methods using three lots of the device. Pregnant women were later confirmed to be pregnant via ultrasound. Representative results are summarized in the table below:

Days Before Expected Menstrual Period (EMP)	Total (n)	Positive (n)	Overall Pregnancy Detection Rate (%)
-8	65	3	4.6%
-7	65	8	12.3%
-6	65	23	35.3%
-5	65	44	67.7%
-4	65	56	86.2%
-3	65	62	95.4%
-2	65	64	98.5%
-1	65	65	100%
0	65	65	100%
+1	65	65	100%

   Lay User Study
   A total of 200 women with varying educational and occupational backgrounds with an age range of 18 to 45 years old from three clinical sites tested their own urine specimen.
   A total of 100 lay users tested using the dip sampling mode and 100 tested using the midstream sampling mode. Each lay user also provided a sample for professional testing. The data demonstrated 100% agreement between lay user results and professional results.

   Summary results of Shinetell Plus™ Digital Early Pregnancy Test (dip sampling mode)

Dip sampling mode	Professional		
	Positive	Negative	Total
Positive	49	0	49
Negative	0	51	51
Total	49	51	100

   Summary results of Shinetell Plus™ Digital Early Pregnancy Test (midstream sampling mode)

Dip sampling mode	Professional

	Positive	Negative	Total
Positive	49	0	49
Negative	0	51	51
Total	49	51	100

Lay user spiked sample study

Urine samples were prepared at 5, 7.5, 8, or 10 mIU/mL hCG by spiking hCG into negative pooled urine specimens. Each sample was aliquoted and blind-labeled by the person who prepared the samples and didn't take part in the sample testing. A total of 200 lay persons performed the testing and each person tested 2 blinded samples. Spiked samples were also tested by professionals. The results are summarized in the tables below:

hCG Concentration (mIU/mL)	Lay person 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%
7.5	29	71	29%	31	69	31%	98%
8	50	50	50%	48	52	48%	98%
10	100	0	100%	100	0	100%	100%

Specificity study to Determine False Positive Result Rate

A study was performed to determine the incidence of false positive test results from Shinetell Plus™ Digital Early Pregnancy Test at three different sites. Urine samples were collected from 300 non-pregnant women from each of these three cohorts: pre-menopausal women (aged 18-40 years), peri-menopausal women (aged 41-55 years), and post-menopausal women (> 55 years of age). Both midstream and dip testing were evaluated for the device using three lots of the candidate device. For each cohort, 50 participants self-tested in midstream sampling mode and 50 participants self-tested in dip sampling mode. Results of the study are shown in the table below:

Cohort	Dip mode	Midstream mode	Total
Pre-menopausal	0+/50-	0+/50-	0+/100-
Peri-menopausal	0+/50-	0+/50-	0+/100-
Post-menopausal	0+/50-	0+/50-	0+/100-

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.