510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K232864

B Applicant

Nantong Egens Biotechnology Co., Ltd.

C Proprietary and Established Names

EGENS Pregnancy Test Midstream I, EGENS Pregnancy Test Midstream II

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:

The EGENS Pregnancy Test Midstream I 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.

EGENS Pregnancy Test Midstream II 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.

Special Conditions for Use Statement(s):

OTC - Over The Counter

C Special Instrument Requirements:

None

IV Device/System Characteristics:

A Device Description:

EGENS Pregnancy Test Midstream I and EGENS Pregnancy Test Midstream II are qualitative immunochromatographic assays consisting of a single nitrocellulose test strip assembled in a plastic housing with an absorbent tip. The tests can be used in dip or instream mode.

B Principle of Operation:

EGENS Pregnancy Test Midstream I and EGENS Pregnancy Test Midstream II are lateral flow chromatographic immunoassays. When the absorbent end is immersed into a sample, the sample is absorbed into the device by capillary action and mixes with the antibody-dye conjugate (mouse anti-beta hCG monoclonal antibody), flowing across the pre-coated (goat anti-hCG polyclonal antibody) membrane. If present in the sample, hCG reacts with the dye conjugate and forms a complex. The complex migrates along the membrane to the hCG antibody line (T) and remains captured in the T line.

In the EGENS Pregnancy Test Midstream I test, a single red colored band develops in the test zone (T line), indicating a positive result. If there is no hCG in the urine, there is no red band in the test zone, indicating a negative result. In the EGENS Pregnancy Test Midstream II test, a plus sign (+) appears at the T line, indicating a positive result. A single vertical line at the T line (|) indicates a negative result. The control line (C line) should develop in the control zone regardless of the test result on both tests. If the control line does not appear (no color appears at the control line after application of the sample), the test is invalid, and the specimen should be retested with a new device.

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):
K150022

C Comparison with Predicate(s):

Device & Predicate Device(s):	K232864	K150022
Device Trade Name	EGENS Pregnancy Test Midstream I, EGENS Pregnancy Test Midstream II	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/Indications for Use	Qualitative detection of human chorionic gonadotropin (hCG) as an aid in early detection of pregnancy	Same
Early Detection Claim	Pregnancy can be detected as early as five (5) days before the expected period (as early as six (6) days before the day of the missed period)	Same
Methodology	Chromatographic immunoassay	Same
Specimen type	Urine	Same
Sensitivity	10 mIU/mL	Same
General Device Characteristic Differences		
Time to results	3 minutes	5 minutes
Target User	Over-the-counter use	Over-the-counter and Prescription use

VI Standards/Guidance Documents Referenced:

None**.**

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:
   A precision study was performed using negative female urine samples spiked with hCG traceable to the 5th WHO IS to obtain samples with hCG concentrations of 0, 2.5, 5, 6.5, 8, 9, 10, 15, 25 and 50 mIU/mL. Each sample was tested using three lots of EGENS Pregnancy Test Midstream I and three lots of EGENS Pregnancy Test Midstream II. Samples were tested in replicates of 5 per concentration, over 5 consecutive days, by 3 different operators (1 per lot) per device, in both dip and instream sampling methods (150 total results per concentration). The tables below summarize the precision data when both dip and instream sampling methods are combined. The data is representative of each sampling method.

   EGENS Pregnancy Test Midstream I (instream and dip sampling methods combined)

hCG Conc. (mIU/mL)	Lot 1		Lot 2		Lot 3		Total results		% 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%
6.5	47	3	46	4	47	3	140	10	93%	7%
8	25	25	22	28	27	23	74	76	49%	51%
9	7	43	5	45	4	46	16	134	11%	89%
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%
50	0	50	0	50	0	50	0	150	0%	100%

EGENS Pregnancy Test Midstream II (instream and dip sampling methods combined)

hCG Conc. (mIU/mL)	Lot 1		Lot 2		Lot 3		Total results		% 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%
6.5	48	2	47	3	46	4	141	9	94%	6%
8	27	23	24	26	24	26	75	75	50%	50%
9	5	45	3	47	7	43	15	135	10%	90%
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%
50	0	50	0	50	0	50	0	150	0%	100%

The device cutoff is 10 mIU/mL hCG.

2. Linearity:

Linearity is not applicable since this is a qualitative test.

3. Analytical Specificity

Interference from exogenous and endogenous substances:

To evaluate potential interference from certain exogenous and endogenous substances, negative urine samples from normal healthy females containing were spiked to contain 0, 5 and 10 mIU/mL hCG and then spiked with potentially interfering substances at the concentrations listed in the table below. Samples were tested by 3 operators, in triplicate, using 3 lots of the test. No interference was observed at the concentrations shown in the table below:

Substance	Concentration
Acetaminophen	20 mg/dL
Acetylsalicylic	20 mg/dL
Ascorbic acid	20 mg/dL
Atropine	20 mg/dL
Caffeine	20 mg/dL
Gentisic acid	20 mg/dL
Glucose	2 g/dL
Hemoglobin	20 mg/dL
Tetracycline	20 mg/dL
Ampicillin	20 mg/dL
Albumin	20 mg/dL
β-hydroxybutyrate	2000 mg/dL
Ephedrine	20 mg/dL
Phenylpropanolamine	20 mg/dL
Phenothiazine	20 mg/dL
EDTA	80 mg/dL
Salicyclic Acid	20 mg/dL
Benzoylecgonine	10 mg/dL
Cannabinol	10 mg/dL
Codeine	6ug/dL
Ethanol	1.0%
Bilirubin	2mg/dL
Pregnanediol	1500µg/dL
Thiophene	20 mg/dL
Ketone	20 mg/dL

Cross-reactivity of similar compounds:
To evaluate cross-reactivity, urine pools from healthy, non-pregnant females were spiked to contain 0, 5 and 10 mIU/mL hCG and then spiked with potential cross reactants. Samples were spiked with 500 mIU/mL luteinizing hormone (LH), 1000 mIU/mL follicle-stimulating hormone (FSH), and 1 mIU/mL thyroid-stimulating hormone (TSH). The samples were tested in triplicate using 3 lots of the test by three different operators. No cross-reactivity was observed at tested concentrations.

Effects of urine pH
To evaluate the effect of urine pH on test results, urine samples containing 0, 5 and 10 mIU/mL hCG were tested at pH values of 4, 5, 6, 7, 8 and 9. The samples were tested in triplicate using three lots of the test device by 3 operators. The results demonstrated that urine pH ranges between 4 and 9 do not affect test performance.

Effects of urine specific gravity
To evaluate the effect of urine specific gravity on test results, urine samples containing 0, 5 and 10 mIU/mL hCG were tested at specific gravities of 1.000, 1.005, 1.010, 1.015, 1.020,

1.025, 1.030 and 1.035. The results demonstrated that urine with a specific gravity ranging from 1.000 to 1.035 does not affect test performance.

Hook Effect
Negative urine samples were spiked with varying hCG concentrations up to 500,000 mIU/mL. The samples were tested in five replicates, using three lots, by three operators. All tested concentrations gave a positive result. The results demonstrated that no hook effect was observed at hCG concentration up to 500,000 mIU/mL.

Effects of hCG β-core fragment
Urine samples (0, 5, 10, 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, 250,000pmol/L and 500,000pmol/L. Test performance 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):

   EGENS Pregnancy Test Midstream I and EGENS Pregnancy Test Midstream II are calibrated against reference material traceable to WHO International Standard (IS) 5th edition (NIBSC code 07/364).

6. Detection Limit:

   A detection limit study was performed using negative urine samples spiked with 0, 5, 6.5, 8, 9, 10, 15, and 25mIU/mL hCG (hCG traceable to the 5th WHO IS). The samples were tested using both devices (EGENS Pregnancy Test Midstream I and EGENS Pregnancy Test Midstream II) using both instream and dip testing sampling methods in replicates of 20 for each of three lots of devices by 24 different operators (2 operators per lot per format and per testing method). The device cut-off is 10 mIU/mL hCG.

7. Assay Cut-Off:

   The device cut-off is 10 mIU/mL. See Detection Limit (Section VII.A.6) and Precision/Reproducibility (Section VII.A.1) sections above.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Urine samples from women aged 21 to 48 years who were suspected of being pregnant were collected. Approximately half of the women were suspected to be pregnant in the early stage of less than 5 weeks. These samples were masked and randomized prior to testing by professionals using the EGENS Pregnancy Test Midstream I, and EGENS Pregnancy Test Midstream II, and the predicate device, in dip and simulated instream sampling methods).

A total of 300 samples were tested using the EGENS Pregnancy Test Midstream I, 151 in dip sampling mode and 149 in instream sampling mode. Results are summarized below:

Summary of EGENS Pregnancy Test Midstream I (instream)

Midstream I (Instream)		Predicate device		
		Positive	Negative	Total
Candidate device	Positive	77	0	77
	Negative	0	74	74
	Total	77	74	151

Summary of EGENS Pregnancy Test Midstream I (dip)

Midstream I (Dip)		Predicate device		
		Positive	Negative	Total
Candidate device	Positive	74	0	74
	Negative	0	75	75
	Total	74	75	149

A total of 306 samples were tested using the EGENS Pregnancy Test Midstream II, 153 in dip sampling mode and 153 in instream sampling mode. Results are summarized below:

Summary of EGENS Pregnancy Test Midstream II (instream)

Midstream II (Instream)		Predicate device		
		Positive	Negative	Total
Candidate device	Positive	76	0	76
	Negative	0	77	77
	Total	76	77	153

Summary of EGENS Pregnancy Test Midstream II (Dip)

Midstream II (Dip)		Predicate device		
		Positive	Negative	Total
Candidate device	Positive	78	0	78
	Negative	0	75	75
	Total	78	75	153

The test performance of the EGENS Pregnancy Test Midstream I and EGENS Pregnancy Test Midstream II is 100% concordant when compared to the predicate.

2. Matrix Comparison:

Not Applicable. The device is intended for urine samples only.

C Clinical Studies:

1. Clinical Sensitivity:
   Not applicable.

2. Clinical Specificity:

   Specificity study to determine the false-positive result rate

   The clinical specificity of the EGENS Pregnancy Test Midstream I and EGENS Pregnancy Test Midstream II was evaluated to determine the incidence of false positive tests results from the candidate device. Urine samples from 100 healthy, non-pregnant female from each of three cohorts: pre-menopausal (ages 18-40 years old), peri-menopausal (41-55 years old) and post-menopausal (>55 years old) women (300 subjects total) were tested. The clinical specificity was calculated as 300/300, or 100%. There was no difference between the two sampling methods (dip and instream). The results are summarized in the tables below:

   EGENS Pregnancy Test Midstream I

Group	Test result	
	Dip method	Instream method
Pre-menopausal (18-40 yrs)	0+/50-	0+/50-
Peri-menopausal (41-55 yrs)	0+/50-	0+/50-
Post-menopausal (>55 yrs)	0+/50-	0+/50-

   EGENS Pregnancy Test Midstream II

Group	Test result	
	Dip method	Instream method
Pre-menopausal (18-40 yrs)	0+/50-	0+/50-
Peri-menopausal (41-55 yrs)	0+/50-	0+/50-
Post-menopausal (>55 yrs)	0+/50-	0+/50-

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

   Detection of hCG in Early Pregnancy Clinical Samples
   A total of 585 urine samples were collected from 65 pregnant women confirmed to be pregnant by ultrasound. The women ranged from 21 to 40 years old and testing was conducted starting from 8 days before the expected menstrual period to the day of the expected menstrual period. Each sample was tested using both formats of the device. The same results were observed for both devices and both sampling methods. The following is a summary for the result for all conditions tested.

Days before your expected period	Percentage of pregnancy
0	100%
1	100%
2	98%
3	97%
4	91%
5	69%
6	38%
7	14%
8	5%

Lay User Study

Three hundred and six (306) women with varying educational and occupational backgrounds with an age range of 21 to 50 years old tested their own urine specimen. Two hundred (200) lay users tested with the EGENS Pregnancy Test Midstream I devices and 106 lay users tested with EGENS Pregnancy Test midstream II devices. Each subject also provided a sample for professional testing. The data demonstrated 100% agreement between lay user results and professional results.

EGENS Pregnancy Test Midstream I

EGENS Midstream I (instream and dip method)		Professional Result		Total
		Positive	Negative	
Lay user Result	Positive	101	0	101
	Negative	0	99	99
Total		101	99	200

EGENS Pregnancy Test Midstream II

EGENS Midstream II (instream and dip method)		Professional Result		Total
		Positive	Negative	
Lay user Result	Positive	54	0	54
	Negative	0	52	52
Total		54	52	106

Lay user spiked sample study

Urine samples were prepared at 5mIU/mL, 6.5mIU/mL, 8.0mIU/mL and 10mIU/mL hCG concentrations by spiking hCG into negative pooled urine specimens. Each sample was aliquoted into individual containers and blind-labeled. These samples were tested by 200 lay persons of varying educational and occupational backgrounds aged 21 to 50 years old using either the EGENS Pregnancy Test Midstream I or the EGENS Pregnancy Test Midstream II devices in both dip and instream sampling methods. The testing was performed at 3 sites. The results are summarized in the tables below (both dip and instream data combined). The data is representative of each sampling method:

EGENS Pregnancy Test Midstream I

Number of samples	hCG concentration (mIU/mL)	Lay user Result		Professional Result		Percent Agreement
		Number of positive	Number of negative	Number of positive	Number of negative	
100	5	0	100	0	100	100%
100	6.5	5	95	7	93	98%
100	8	49	51	51	49	98%
100	10	100	0	100	0	100%

EGENS Pregnancy Test Midstream II

Number of samples	hCG concentration (mIU/mL)	Lay user Result		Professional Result		Percent Agreement
		Number of positive	Number of negative	Number of positive	Number of negative	
100	5	0	100	0	100	100%
100	6.5	6	94	7	93	99%
100	8	50	50	52	48	98%
100	10	100	0	100	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.