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

A. 510(k) Number:

k123050

B. Purpose for Submission:

New device

C. Measurand:

Human Chorionic Gonadotropin (hCG)

D. Type of Test:

Qualitative chromatographic immunoassay

E. Applicant:

Nantong EGENS Biotechnology Co., Ltd.

F. Proprietary and Established Names:

EGENS One Step HCG Urine Pregnancy Test Kit (Strip)
EGENS One Step HCG Urine Pregnancy Test Kit (Cassette)
EGENS One Step HCG Urine Pregnancy Test Kit (Midstream I)
EGENS One Step HCG Urine Pregnancy Test Kit (Midstream II)

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LCX (OTC) JHI (prescription)	Class II	21 CFR 862.1155, Human Chorionic Gonadotropin (HCG) test system	75 Clinical Chemistry (CH)

H. Intended Use:

1. Intended use(s):

See indication for use below

2. Indication(s) for use:

EGENS One Step HCG Urine Pregnancy Test Kit (Strip)
EGENS One Step HCG Urine Pregnancy Test Kit (Strip) is a rapid chromatographic immunoassay for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine samples to aid in the early detection of pregnancy by both professional and home users.

EGENS One Step HCG Urine Pregnancy Test Kit (Cassette)
EGENS One Step HCG Urine Pregnancy Test Kit (Cassette) is a rapid chromatographic immunoassay for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine samples to aid in the early detection of pregnancy by both professional and home users.

EGENS One Step HCG Urine Pregnancy Test Kit (Midstream I)
EGENS One Step HCG Urine Pregnancy Test Kit (Midstream I) is a rapid chromatographic immunoassay for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine samples to aid in the early detection of pregnancy by home users.

EGENS One Step HCG Urine Pregnancy Test Kit (Midstream II)
EGENS One Step HCG Urine Pregnancy Test Kit (Midstream II) is a rapid chromatographic immunoassay for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine samples to aid in the early detection of pregnancy by home users.

3. Special conditions for use statement(s):

EGENS One Step HCG Urine Pregnancy Test Kit (Strip)and (Cassette) is for over-the-counter and prescription use.

EGENS One Step HCG Urine Pregnancy Test Kit (Midstream I) and (Midstream II) is for over-the-counter use only.

4. Special instrument requirements:

None

I. Device Description:

EGENS One Step HCG Urine Pregnancy Test Kit is manufactured in four formats: Test Strip, Cassette, Midstream I, and Midstream II.

The Test Strip kit consists of one test device in a foil pouch and a package insert. It is a lateral flow chromatographic immunoassay. When the absorbent end is immersed into the urine specimen, the urine sample is introduced into a chromatographic membrane. As it contacts the membrane, the sample dissolves the lyophilized conjugate. In a reactive sample, the HCG antigen will attach to the antibodies in the colloidal solution. As the conjugate moves forward on the membrane, anti-HCG will attach to the antibody affixed on the test zone ("T") will bind the HCG-gold conjugate complex, forming a pink line ("T"). Any sample will cause a pink line to appear in the control zone ("C"). This line is formed by the binding of the polyclonal antibodies (Anti-mouse IgG) affixed onto the control zone to the sample- colloidal gold conjugate. Presence of this line indicates that the test has been performed correctly. In less than 5 minutes, levels of HCG as low as 25 mIU/mL can be detected.

The Cassette kit consists of one test device in a foil pouch, a dropper, and a package insert. The Cassette format has the same performance specifications as the Test Strip format. The difference is that the urine sample is dispensed by dropper onto the sample well on the cassette.

The Midstream I kit consists of one test device in a foil pouch and a package insert. The Midstream I format has the same performance specifications as the Test Strip format. The difference is that the device is placed into the urine stream or dipped into the urine collection cup for 5 to 10 seconds.

The Midstream II kit consists of one test device in a foil pouch and a package insert. The Midstream II format has the same performance specifications as the Midstream I kit. The difference is how a positive result appears on the device. A vertical line is printed on the test area of the device. If the test is positive, a horizontal line forms a pink-colored cross with the vertical line in the test area of the device.

Human source materials was tested by FDA approved methods and found to be negative for the presence of antibodies to HIV-1, HIV-2, HbsAg, and HCV.

J. Substantial Equivalence Information:

1. Predicate device names(s):

   Acon Laboratories, Inc. ACON One Step Pregnancy Test Device

2. Predicate 510(k) number(s):

   k993317

3. Comparison with predicate:

Similarities and Differences		
Item	EGENS One Step HCG Urine Pregnancy Test Kit (candidate device)	ACON One Step Pregnancy Test Device (predicate device) k993317
Indications for Use	For the qualitative determination of hCG in urine.	Same
User	Prescription (cassette and strip) and over the counter (midstream I and II)	Prescription
Format	Strip, cassette, midstream	cassette
Test Principle	Colloidal Gold Immunoassay	Same
Cut-off Value	25 mIU/mL	Same
Traceability	WHO International Standard 3rd Edition	Same

K. Standard/Guidance Document Referenced (if applicable):

ISO 14971:2007, Medical Devices-Application of Risk Management to Medical Devices

L. Test Principle:

One Step HCG Urine Pregnancy Test measures the presence of the hormone Human Chorionic Gonadotropin (HCG) in human urine for the early detection of pregnancy. When the absorbent end is immersed into the urine specimen, the urine sample is introduced into a chromatographic membrane. As it contacts the membrane, the sample dissolves the lyophilized conjugate. In a reactive sample, the HCG antigen will attach to the antibodies in the colloidal solution. As the conjugate moves forward on the membrane, anti-HCG will attach to the antibody affixed on the test zone ("T") will bind the HCG-gold conjugate complex, forming a pink line ("T"). Any sample will cause a pink line to appear in the control zone ("C"). This line is formed by the binding of the polyclonal antibodies (Anti-mouse IgG) affixed onto the control zone to the sample- colloidal gold conjugate. Presence of this line indicates that the test has been performed correctly.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

A precision study was performed using negative human urine samples spiked with varying hCG (commercially available and traceable to the 3rd WHO international standard) concentrations. The spiked urine samples were measured in 10 replicates using 3 different lots for each format. Tests were performed by three different lab technicians in 2 runs per day for 5 days. Results are shown in the following tables.

Strip Format

	Lot 1		Lot 2		Lot 3	
hCG Concentration (mIU/mL)	# of neg	# of pos	# of neg	# of pos	#of neg	#of pos
0	10	0	10	0	10	0
5	10	0	10	0	10	0
10	10	0	10	0	10	0
15	10	0	10	0	10	0
20	10	0	10	0	10	0
21	9	1	9	1	9	1
24	1	9	1	9	0	10
25	0	10	0	10	0	10
30	0	10	0	10	0	10
50	0	10	0	10	0	10
75	0	10	0	10	0	10
100	0	10	0	10	0	10
250	0	10	0	10	0	10

Cassette Format

	Lot 1		Lot 2		Lot 3	
hCG Concentration (mIU/mL)	# of neg	# of pos	# of neg	# of pos	#of neg	#of pos
0	10	0	10	0	10	0
5	10	0	10	0	10	0
10	10	0	10	0	10	0
15	10	0	10	0	10	0
20	10	0	10	0	10	0
21	9	1	10	0	9	1
24	1	9	0	10	1	0
25	0	10	0	10	0	10
30	0	10	0	10	0	10

50	0	10	0	10	0	10
75	0	10	0	10	0	10
100	0	10	0	10	0	10
250	0	10	0	10	0	10

Midstream I Format

	Lot 1		Lot 2		Lot 3	
hCG Concentration (mIU/mL)	# of neg	# of pos	# of neg	# of pos	#of neg	#of pos
0	10	0	10	0	10	0
5	10	0	10	0	10	0
10	10	0	10	0	10	0
15	10	0	10	0	10	0
20	10	0	10	0	10	0
21	9	1	9	1	9	1
24	1	9	0	10	1	9
25	0	10	0	10	0	10
30	0	10	0	10	0	10
50	0	10	0	10	0	10
75	0	10	0	10	0	10
100	0	10	0	10	0	10
250	0	10	0	10	0	10

Midstream II Format

	Lot 1		Lot 2		Lot 3	
hCG Concentration (mIU/mL)	# of neg	# of pos	# of neg	# of pos	#of neg	#of pos
0	10	0	10	0	10	0
5	10	0	10	0	10	0
10	10	0	10	0	10	0
15	10	0	10	0	10	0
20	10	0	10	0	10	0
21	9	1	10	0	9	1
24	1	9	1	9	0	10
25	0	10	0	10	0	10
30	0	10	0	10	0	10
50	0	10	0	10	0	10
75	0	10	0	10	0	10
100	0	10	0	10	0	10
250	0	10	0	10	0	10

b. Linearity/assay reportable range:

Linearity is not applicable since this is a qualitative test.

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

One Step HCG Urine Pregnancy Test is calibrated against reference material traceable to WHO International Standard 3rd edition.

A shelf-life stability test of the devices was performed in real-time and accelerated testing. The results showed that the devices were stable for 24 months when stored at 39-86^{o}F (4-30^{o}C) in the sealed foil pouch. Protocol and acceptance criteria were reviewed and are acceptable.

d. Detection limit:

The detection limit was evaluated in conjunction with the precision testing. Refer to the precision data in 1.a. The detection limit was demonstrated to be 25 mIU/mL.

e. Analytical specificity:

To evaluate cross-reactivity, negative and positive urine samples (0 and 25 mIU/mL) were spiked with various concentrations of glycoprotein hormones such as LH (500mIU/mL), FSH (1000 mIU/mL) and TSH (1000µIU/mL). Tests were performed using 3 different lots of the cassette format by 3 different health care professionals at EGENS laboratories. The results of these studies showed that there is no interference at 1000 IU/L FSH, 500IU/L LH, or 1000 IU/L TSH for both negative and positive urine samples.

To evaluate the potential for interference by certain exogenous compounds, each interferent was prepared by diluting stock interferent material to the desired concentration. Male urine samples containing 0 and 25 mIU/mL hCG were spiked with the interferents to obtain the desired test concentration. The samples were tested using 3 different lots of the cassette format and the results were read after at 5 and 10 minutes. No interferences were observed from exogenous compounds at the following concentrations for both negative and positive hCG urine samples:

Interferent	Test concentration
Acetaminophen	20 mg/dL
Acetoacetic Acid	2000 mg/dL
Ascorbic Acid	20 mg/dL
B-hydroxybutyrate	2000 mg/dL
Caffeine	20 mg/dL

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

To evaluate potential interference from changes in pH, negative and positive urine samples containing 0 and 25 mIU/mL hCG were tested at pH values of 4, 5,6,7,8 and 9 using 3 different lots by 3 different operators. The results indicated that changes in pH range of 4-9 do not interfere in the results that were either positive (25 mIU/L) or negative (0 mIU/L) for HCG.

To evaluate potential interference from changes in specific gravity, negative and positive urine samples containing 5 and 25 mIU/mL hCG were tested at density values ranging from 1.000, 1.010, 1.015, 1.025 and 1.035 using 3 different lots and by 3 different operators. The results indicated that changes in specific gravity do not interfere in the results that were either positive or negative for hCG.

Each test format was evaluated for high dose or hook effect. Negative urine samples were spiked with varying hCG concentrations (62,500, 125,000, 250,000, 500,000, 1,000,000 and 2,000,000 mIU/mL). All tested concentrations gave a positive result. The spiked samples were tested by 3 different lots and 3 different operators. The results demonstrated that no hook effect was observed at hCG concentrations ranging from 62,500 to 2,000,000 mIU/mL.

The sponsor evaluated the effects of the hCG β-core fragment on the performance of the device. A urine sample with 25 mIU/mL was spiked with varying concentrations of β-

core fragment hCG (63,000, 125,000, 250,000, 500,000, and 1,000,000 pmol/L). The samples were tested using 3 different lots by 3 different operators. The results demonstrated that high levels of β-core fragment, up to 1,000,000 pmol/L, do not interfere with a positive test result.

f. Assay cut-off:

The cut-off for a positive test for One Step HCG Urine Pregnancy Test is 25 mIU/mL.

2. Comparison studies:

a. Method comparison with predicate device:

Urine samples were collected from 400 women presenting at a clinic to test for pregnancy. Approximately half of the women were pregnant in the early stage of less than 5 weeks. Samples were randomly collected at various times throughout the day. Ages were from 20 to 49 years. All subjects performed self-test and collected samples for tests by laboratory professionals using the proposed and the predicate devices. A total of 100 samples were tested for each format (strip, cassette, midstream I and midstream II). The tests performed by laboratory professionals were conducted at different sites. Each person tested three different lots of the candidate device and one lot of the predicate device at the same time, but not sequentially. The summary for each format is presented below:

Method comparison results summary for strip format

Candidate device Professional A Lot 1	Predicate device	+	-
	+	48	0
	-	0	52
Candidate device Professional A Lot 2	Predicate device	+	-
	+	48	0
	-	0	52
Candidate device Professional A Lot 3	Predicate device	+	-
	+	48	0
	-	0	52

Candidate device Professional B Lot 1	Predicate device	+	-
	+	48	0
	-	0	52
Candidate device Professional B Lot 2	Predicate device	+	-
	+	48	0
	-	0	52
Candidate device Professional B Lot 3	Predicate device	+	-
	+	48	0
	-	0	52

Candidate device Professional C Lot 1	Predicate device	+	-
	+	48	0
	-	0	52
Candidate device Professional C Lot 2	Predicate device	+	-
	+	48	0
	-	0	52
Candidate device Professional C Lot 3	Predicate device	+	-
	+	48	0
	-	0	52

Candidate device Lay User Lot 1	Predicate device	+	-
	+	47	0
	-	1	52
Candidate device Lay User Lot 2	Predicate device	+	-
	+	47	0
	-	1	52
Candidate device Lay User Lot 3	Predicate device	+	-
	+	47	0
	-	1	52

The discrepant results in this table is from a single sample with a hCG concentration around the cut-off of the device (25 mIU/mL).

Method comparison results summary for cassette format

Candidate device Professional A Lot 1	Predicate device	+	-
	+	53	0
	-	0	47
Candidate device Professional A Lot 2	Predicate device	+	-
	+	53	0
	-	0	47
Candidate device Professional A Lot 3	Predicate device	+	-
	+	53	0
	-	0	47

Candidate device Professional B Lot 1	Predicate device	+	-
	+	53	0
	-	0	47
Candidate device Professional B Lot 2	Predicate device	+	-
	+	53	0
	-	0	47

Candidate device	Predicate device	+	-
Professional B	+	53	0
Lot 3	-	0	47

Candidate device	Predicate device	+	-
Professional C	+	53	0
Lot 1	-	0	47
Candidate device	Predicate device	+	-
Professional C	+	53	0
Lot 2	-	0	47
Candidate device	Predicate device	+	-
Professional C	+	53	0
Lot 3	-	0	47

Candidate device	Predicate device	+	-
Lay User	+	53	0
Lot 1	-	0	47
Candidate device	Predicate device	+	-
Lay User	+	53	0
Lot 2	-	0	47
Candidate device	Predicate device	+	-
Lay User	+	53	0
Lot 3	-	0	47

Method comparison results summary for midstream I format

Candidate device	Predicate device	+	-
Professional A	+	45	0
Lot 1	-	0	55
Candidate device	Predicate device	+	-
Professional A	+	45	0
Lot 2	-	0	55
Candidate device	Predicate device	+	-
Professional A	+	45	0
Lot 3	-	0	55

Candidate device	Predicate device	+	-
Professional B	+	45	0
Lot 1	-	0	55
Candidate device	Predicate device	+	-
Professional B	+	45	0

Lot 2	-	0	55
Candidate device	Predicate device	+	-
Professional B	+	45	0
Lot 3	-	0	55

Candidate device	Predicate device	+	-
Professional C	+	45	0
Lot 1	-	0	55
Candidate device	Predicate device	+	-
Professional C	+	45	0
Lot 2	-	0	55
Candidate device	Predicate device	+	-
Professional C	+	45	0
Lot 3	-	0	55

Candidate device	Predicate device	+	-
Lay User	+	45	0
Lot 1	-	0	55
Candidate device	Predicate device	+	-
Lay User	+	45	0
Lot 2	-	0	55
Candidate device	Predicate device	+	-
Lay User	+	45	0
Lot 3	-	0	55

Method comparison results summary for midstream II format

Candidate device	Predicate device	+	-
Professional A	+	46	0
Lot 1	-	0	54
Candidate device	Predicate device	+	-
Professional A	+	46	0
Lot 2	-	0	54
Candidate device	Predicate device	+	-
Professional A	+	46	0
Lot 3	-	0	54

Candidate device	Predicate device	+	-
Professional B	+	46	0
Lot 1	-	0	54
Candidate device	Predicate device	+	-

Professional B	+	46	0
Lot 2	-	0	54
Candidate device	Predicate device	+	-
Professional B	+	46	0
Lot 3	-	0	54

Candidate device	Predicate device	+	-
Professional C	+	46	0
Lot 1	-	0	54
Candidate device	Predicate device	+	-
Professional C	+	46	0
Lot 2	-	0	54
Candidate device	Predicate device	+	-
Professional C	+	46	0
Lot 3	-	0	54

Candidate device	Predicate device	+	-
Lay User	+	46	0
Lot 1	-	0	54
Candidate device	Predicate device	+	-
Lay User	+	46	0
Lot 2	-	0	54
Candidate device	Predicate device	+	-
Lay User	+	46	0
Lot 3	-	0	54

Conclusion from the above tables:

The average positive conformity rate of Egens Strip Test is 98%
The average negative conformity rate of Egens Strip Test is 100%
The average positive conformity rate of Egens Cassette Test is 100%
The average negative conformity rate of Egens Cassette Test is 100%
The average positive conformity rate of Egens Midstream I Test is 100%
The average negative conformity rate of Egens Midstream I Test is 100%
The average positive conformity rate of Egens Midstream II Test is 100%
The average negative conformity rate of Egens Midstream II Test is 100%

b. Matrix comparison:

None (This device is only for urine samples).

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Lay User Study:
To evaluate its suitability to be used by the home use consumers (lay persons), natural and spiked urine samples were tested by the lay persons and the results were compared with professional laboratory results.

Negative urine sample pools were spiked with 20 and 30 mIU/mL hCG to create samples with concentrations near the cut-off concentration (25 mIU/mL). Each concentration sample pool was further aliquoted into 200 individual containers for a total of 400 aliquots (50 aliquots per concentration for each test format). All aliquots were blindly labeled by a non-participant.

Four hundred women with various education backgrounds and ages ranging from 20-45 years participated in the lay user study. The study was performed at 3 different point –of- care sites. For each of the four formats, 100 female participants suspecting pregnancy tested their own urine and one masked sample using the English package insert as guide to perform the test. Aliquots of the participants' urine and spiked urine were tested by professional laboratory personnel and the results were compared.

All 400 consumer cases were analyzed. Data analysis demonstrated that all of the participants performed the test correctly and the results showed acceptable accuracy. Accuracy for the Strip format was 98%; Cassette format 99%; Midstream I 100%; and Midstream II 98%. Results of the lay user study are summarized in the tables below:

Lay User Study Results

Strip Format	Masked spiked sample Professional users	+ (30 mIU/L)	- (20 mIU/L)
Masked spiked sample Lay users	+ (30 mIU/L)	48	0
	- (20 mIU/L)	2	50

Cassette Format	Masked spiked sample Professional users	+ (30 mIU/L)	- (20 mIU/L)
Masked spiked sample Lay users	+ (30 mIU/L)	50	1
	- (20 mIU/L)	0	49

Midstream I Format	Masked spiked sample Professional users	+ (30 mIU/L)	- (20 mIU/L)
Masked spiked sample Lay users	+ (30 mIU/L)	50	0
	- (20 mIU/L)	0	50

Midstream II Format	Masked spiked sample Professional users	+ (30 mIU/L)	- (20 mIU/L)
Masked spiked sample Lay users	+ (30 mIU/L)	49	1
	- (20 mIU/L)	1	49

Each patient was given an English questionnaire to assess the readability of the labeling. A Flesch-Kincaid reading analysis was performed on all package inserts and the score revealed a reading Flesch-Kincaid Grade Level 7. 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.

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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