510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K203272

B Applicant

Hangzhou AllTest Biotech Co., Ltd

C Proprietary and Established Names

Alltest Pregnancy Rapid Combo Test Cassette

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JHI	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 Alltest Pregnancy Rapid Combo Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine or serum to aid in the early detection of pregnancy.

The test is for health care professionals use including professionals at point of care (POC).

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

D Special Instrument Requirements:
None

IV Device/System Characteristics:

A Device Description:
The Alltest Pregnancy Rapid Combo Test Cassette measures the presence of the hormone Human Chorionic Gonadotrophin (hCG) in human urine or serum for the early detection of pregnancy. The Alltest Pregnancy Rapid Combo Test is used as a single cassette device. Each device contains a test strip that includes an absorbent pad, coated membrane, gold conjugate pad, and sample pad.

B Principle of Operation:
The Alltest Pregnancy Rapid Combo Test is a lateral flow chromatographic immunoassay. When a sample is added, 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. At analyte concentration above the target cut off, it produces a colored test line that indicates a positive result. When analyte concentration is below the cutoff, no colored band shows in the test region, indicating a negative result. No line in the "C" region indicates that the test is invalid.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Fastep S10 Hcg Serum/urine Combo Test

B Predicate 510(k) Number(s):
K132834

C Comparison with Predicate(s):

Device & Predicate Device(s):	K203272	K132834
Device Trade Name	Alltest Pregnancy Rapid Combo Test Cassette	Fastep S10 Hcg Serum/urine Combo Test
General Device Characteristic Similarities		

Device & Predicate Device(s):	K203272	K132834
Intended Use/Indications For Use	For the qualitative detection of hCG in serum and urine to aid in the early detection of pregnancy.	Same
Principle	Lateral flow Sandwich Immunochromatography	Same
Cut-off values	10 mIU/mL for serum and 20 mIU/mL for urine	Same
General Device Characteristic Differences		
Read time	Serum: 5 minutes Urine: 3 minutes	5 minutes for both serum and urine

VI Standards/Guidance Documents Referenced:

None referenced.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility/Cut-Off Value:

Negative serum or urine specimens were spiked with varying hCG concentrations. The spiked samples were measured in 6 replicates each day for 5 days using 3 different lots at three testing sites representative of the intended use environment. Tests were performed by 6 different operators for each sample concentration. The cut-off values of serum and urine are 10 mIU/mL and 20 mIU/mL hCG, respectively. Results are shown in the following tables.

Serum

hCG Concentration (mIU/mL)	Site 1 Lot 2		Site 2 Lot 3		Site 3 Lot 1		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	30	0	30	0	30	0	90	0	100	0
3	30	0	30	0	30	0	90	0	100	0
5	30	0	30	0	30	0	90	0	100	0
8	7	23	7	23	8	22	22	68	24.4	75.6
10	0	30	0	30	0	30	0	90	0	100
12	0	30	0	30	0	30	0	90	0	100
15	0	30	0	30	0	30	0	90	0	100
20	0	30	0	30	0	30	0	90	0	100
50	0	30	0	30	0	30	0	90	0	100

Urine

hCG Concentration (mIU/mL)	Site 1 Lot 2		Site 2 Lot 3		Site 3 Lot 1		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	30	0	30	0	30	0	90	0	100	0
5	30	0	30	0	30	0	90	0	100	0
10	30	0	30	0	30	0	90	0	100	0
15	15	15	16	14	15	15	46	44	51.1	48.9
17.5	6	24	6	24	6	24	18	72	20	80
20	0	30	0	30	0	30	0	90	0	100
30	0	30	0	30	0	30	0	90	0	100
50	0	30	0	30	0	30	0	90	0	100
100	0	30	0	30	0	30	0	90	0	100

2. Linearity:

Not applicable. This is a qualitative test.

3. Analytical Specificity/Interference:

Cross-reactivity:
The sponsor performed a study to evaluate potential cross-reactivity from LH, FSH and TSH. Negative and positive samples (10 and 20 mIU/mL hCG for urine, and 5 and 10 mIU/mL hCG for serum) were spiked with various concentrations of other glycoprotein hormones such as LH, FSH, and TSH. Samples were tested using three device lots of by three operators. No interference was observed for these samples for the device at LH concentrations up to 500 IU/mL, FSH concentrations up to 1000 mIU/mL, and TSH concentrations up to 1000 μIU/mL.

Interference:
The sponsor performed a study to evaluate potential interference from certain exogenous compounds, each interferent was made at 100X concentrate bulk and spiked in both hCG negative (5 mIU/mL for serum, 10 mIU/mL for urine) and hCG positive (10 mIU/mL for serum, 20 mIU/mL for urine) samples. Each spiked urine sample was mixed for 5 minutes to ensure a homogeneous solution before testing. Each sample was tested using 3 device lots of the testing kit. Results are shown in the following table.

The results showed that no interferences were observed from substances at the following concentrations for both negative and positive hCG urine and serum samples.

Interferents	Concentration
Acetaminophen	20 mg/dL
Acetoacetic Acid	2000 mg/dL

Interferents	Concentration
Ascorbic Acid	20 mg/dL
Atropine	20 mg/dL
Acetosalicylic Acid	20 mg/dL
Albumin	2000 mg/dL
Bilirubin (Urine)	2 mg/dL
Bilirubin (Serum)	40 mg/dL
Caffeine	20 mg/dL
Codeine	10 mg/dL
Ephedrine	20 mg/dL
EDTA	80 mg/dL
Ethanol	1%
Gentisic Acid	20 mg/dL
Glucose	2000 mg/dL
Hemoglobin	2000 mg/dL
Methadone	10 mg/dL
Phenylpropanolamine	20 mg/dL
Phenothiazine	20 mg/dL
Pregnanediol	1.5 mg/dL
Salicylic Acid	20 mg/dL
B-hydroxybutyrate	2000 mg/dL
Benzoylecgonine	10 mg/dL
Cannabinol	10 mg/dL
Methanol	10%
Estriol-17-beta	1.4 mg/dL
Thiophene	20 mg/dL
Ampicillin	20 mg/dL
Tetracycline	20 mg/dL
Ketone	20 mg/dL
Total cholesterol (Serum only)	250 mg/dL
Triglycerides (Serum only)	1200 mg/dL
High-density lipoprotein (Serum only)	70 mg/dL

Effect of hCG beta-core fragment:

To evaluate potential interference by hCG β-core fragment, negative and positive samples (5 and 10 mIU/mL hCG in serum; 10 and 20 mIU/mL hCG in urine) were spiked with various concentrations of hCG β -core fragment (0 to $2x10^6$ pmol/L). These samples were tested by 3 operators using 3 different lots. No false negative results were identified for the sample with 2.0×10^6 pmol/L of hCG β -core fragment. The results indicate that high levels of hCG β -core fragment (≥ 100 pmol /L) can lead to a false positive results for hCG-free samples (in both serum and urine formats).

Effect of urine pH:
To evaluate potential interference from changes in urine pH, negative and positive urine samples containing 10 and 20 mIU/mL hCG were tested with 3 lots of device by 3 operators using samples at pH 4 to 9. Data show that there is no interference from pH ranging from 4 to 9 of tested urine samples.

Effect of urine specific gravity:
To evaluate potential interference from changes in specific gravity, negative and positive urine samples containing 10 and 20 mIU/mL hCG were tested with 3 lots of device by 3 operators using samples at density values ranging from 1.001 to1.035. Data show that there is no interference from density values ranging from 1.001 to1.035 of tested urine samples.

Hook effect study:
To evaluate high dose hook effect, negative urine and serum samples were spiked with hCG concentrations ranging from 500 to 2,000,000 mIU/mL. The spiked samples were tested by 3 different operators using 3 device lots. The results showed no hook effect up to 2,000,000 mIU/mL.

4. Assay Reportable Range:
   Not applicable. This is a qualitative test.

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

   Traceability:
   The Alltest Pregnancy Rapid Combo Test Cassette is traceable to the WHO 5th International Standard (IS) for Chorionic Gonadotropin (hCG) 07/364.

6. Detection Limit:
   Not applicable; see section VII. A.1. for precision near the device cutoff for urine and serum samples.

7. Assay Cut-Off:
   Analytical sensitivity/cutoff study was performed using Alltest Pregnancy Rapid Combo Test Cassette. Negative serum and urine specimens were spiked with varying hCG (commercially available and traceable to the 5th WHO international Standard) concentrations. The spiked samples were randomly labeled and tested using three different lots of the device by 3 different operators. Twenty replicates were tested for each sample concentration and each device lot. The data demonstrate that the cut-off values of serum and urine are 10 mIU/mL and 20 mIU/mL hCG, respectively. Results are shown in the following tables.

Data Summary for Serum Samples

hCG Concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	20	0	20	0	20	0	60	0	100	0

hCG Concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
3	20	0	20	0	20	0	60	0	100	0
5	20	0	20	0	20	0	60	0	100	0
8	5	15	3	17	5	15	13	47	22	78
10	0	20	0	20	0	20	0	60	0	100
12	0	20	0	20	0	20	0	60	0	100
15	0	20	0	20	0	20	0	60	0	100
20	0	20	0	20	0	20	0	60	0	100
50	0	20	0	20	0	20	0	60	0	100

Data Summary for Urine Samples

hCG Concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	20	0	20	0	20	0	60	0	100	0
5	20	0	20	0	20	0	60	0	100	0
10	20	0	20	0	20	0	60	0	100	0
15	10	10	11	9	10	10	31	29	52	48
17.5	5	15	4	16	6	14	15	45	25	75
20	0	20	0	20	0	20	0	60	0	100
30	0	20	0	20	0	20	0	60	0	100
50	0	20	0	20	0	20	0	60	0	100
100	0	20	0	20	0	20	0	60	0	100

8. Accuracy (Instrument):
   Not applicable.

9. Carry-Over:
   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

A method comparison study was performed, comparing the results obtained from the Alltest hCG Pregnancy Rapid Combo Test Cassette to the results from predicate devices (k132834). A total of 105 urine and 107 serum samples were collected from 212 women, between the ages of 20 to 49, from three POC testing sites (about half of them were less than 5 weeks pregnant). Samples were randomly collected at various times throughout the day. All samples were randomly masked prior to analysis. Samples were tested by two different health professionals, at each site, with the candidate device (using three different lots) and the predicate device. The results are shown in the tables below.

Summary Results for Serum

Candidate Device	Predicate device	+	-
	+	58	0
	-	0	49

Summary Results for Urine

Candidate Device	Predicate device	+	-
	+	53	0
	-	0	52

The study result shows that 100% agreement for both serum and urine samples.

2. Matrix Comparison:
   Not applicable.

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):
   Not Applicable.

D Clinical Cut-Off:
Not Applicable.

E Expected Values/Reference Range:
Not applicable.

F Other Supportive Instrument Performance Characteristics Data:
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.