January 31, 2022

Hangzhou AllTest Biotech Co., Ltd
% Joe Shia
Director
LSI International Inc
504E Diamond Ave, Suite J
Gaithersburg, Maryland 20877

Re: K203272
Trade/Device Name: Alltest Pregnancy Rapid Combo Test Cassette
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test System
Regulatory Class: Class II
Product Code: JHI
Dated: November 1, 2021
Received: November 2, 2021

Dear Joe Shia:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k203272

Device Name
Alltest Pregnancy Rapid Combo Test Cassette

Indications for Use *(Describe)*
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).

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.

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510(k) SUMMARY
K203272

1. Date: December 23, 2021
2. Submitter: Hangzhou AllTest Biotech Co., Ltd.
   No. 550, Yinhai Street
   Hangzhou, China, 310018

3. Contact person: Joe Shia
   LSI International Inc.
   504 East Diamond Ave., Suite I
   Gaithersburg, MD 20877
   Telephone: 240-505-7880
   Fax: 301-916-6213
   Email:shiajl@yahoo.com

4. Device Name: Alltest Pregnancy Rapid Combo Test Cassette

Classification: ClassII

Product Code	**CFR #**	**Panel**
JHI	862.1155, Human chorionic gonadotropin (HCG) test system	Clinical Chemistry

5. Predicate Devices:
   k132834, Clarity Diagnostics Clarity hCG Pregnancy Combo Test Cassette

6. Intended 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).

7. 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. During pregnancy, HCG is produced by the placenta shortly after the embryo attaches to the uterine lining. The test device is used as a single cassette device.

8. Substantial Equivalence Information

A summary comparison of features of the Alltest Pregnancy Rapid Combo Test Cassette and the predicate device is provided in the following table.

Item	Device	Predicate
Intended Use	Rapid qualitative detection of hCG to aid in the early detection of pregnancy.	Same
Specimen	Urine or serum	Same
Principle	Lateral flow Sandwich Immunochromatographic Assay	Same
Detection reagent	Colloidal gold	Same
Read time	Serum: 5 minutes Urine: 3 minutes	5 minutes for both serum and urine
Usage	For prescription use	Same
Cut-Off Values	10 mIU/mL for serum and 20 mIU/mL for urine	Same
Configurations	Cassette	Same
Storage	2 – 30°C	Same

9. Test Principle

It 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.

10. Performance Characteristics

Analytical Performance

a. Precision/Reproducibility/Cut-Off Value

Negative serum or urine specimens were spiked with varying hCG (commercially available and traceable to the 5th WHO international Standard) concentrations. The spiked samples were measured in 6 replicates each day for 5 days using 3 different lots at three testing sites. Tests were performed by six different operators for each sample concentration. Results are shown in the following tables.

Serum

hCG Concentration	Site 1 Lot 2	Site 2 Lot 3	Site 3 Lot 1	Total result	% Negative	% Positive

(mIU/mL)	-	+	-	+	-	+	-	+		
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

Cut-off values of 10 mIU/mL for serum and 20 mIU/mL for urine are verified.

b. Stability

Stable at 2-30℃ for 24 months based on the accelerated stability study at 55^{o}C.

c. Specificity / Cross Reactivity

High Dose Effect

Negative urine (serum) samples were spiked with varying high hCG concentrations ranging from 500 to 2,000,000 mIU/mL. The spiked samples were tested by 3 different lots and 3 different operators. No hook effect was observed at these concentrations.

Effects of 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 β -core fragment hCG (0 to $2x10^{6}$pmol/L). These samples were tested by 3 different lots and 3 different operators. No difference was observed for different lots and different operators. No interference was observed for these samples for the devices except that false positive was observed above the 100 pmol/L β -core fragment hCG.

Effects of glycoprotein 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 different lots 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.

d. Interference

To evaluate potential interference from certain exogenous compounds, each interferent was made at 100X concentrate bulk and spiked in both hCG negative (5mIU/mL for serum, 10mIU/mL for urine) and hCG positive (10mIU/mL for serum, 20mIU/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 different lots of the testing kit. Results are shown in the following table.

Interferents	**Concentration**	**Negative hCG**			**Positive hCG**		
		Lot1	Lot2	Lot3	Lot1	Lot2	Lot3
Acetaminophen	20 mg/dl	-	-	-	+	+	+
Acetoacetic Acid	2000 mg/dl	-	-	-	+	+	+
Ascorbic Acid	20 mg/dl	-	-	-	+	+	+
Atropine	20 mg/dl	-	-	-	+	+	+
Acetosalicylic Acid	20 mg/dl	-	-	-	+	+	+
Albumin	2000mg/dl	-	-	-	+	+	+
Bilirubin	2mg/dl	-	-	-	+	+	+
Caffeine	20 mg/dl	-	-	-	+	+	+
Codeine	10mg/dl	-	-	-	+	+	+
Ephedrine	20 mg/dl	-	-	-	+	+	+
EDTA	80 mg/dl	-	-	-	+	+	+
Ethanol	1%	-	-	-	+	+	+
Gentisic Acid	20 mg/dl	-	-	-	+	+	+
Glucose	2000mg/dl	-	-	-	+	+	+
Hemoglobin	2000mg/dl	-	-	-	+	+	+
Methadone	10mg/dl	-	-	-	+	+	+
Phenylpropanolamine	20 mg/dl	-	-	-	+	+	+
Phenothiazine	20 mg/dl	-	-	-	+	+	+
Pregnanediol	1.5 mg/dl	-	-	-	+	+	+
Salicylic Acid	20 mg/dl	-	-	-	+	+	+
B-hydroxybutyrate	2000mg/dL	-	-	-	+	+	+
Benzoylecgonine	10mg/dL	-	-	-	+	+	+
Cannabinol	10mg/dL	-	-	-	+	+	+
Methanol	10%	-	-	-	+	+	+

Estriol-17-beta	1.4mg/dL	-	-	-	+	+	+
Thiophene	20mg/dl	-	-	-	+	+	+
Ampicillin	20mg/dl	-	-	-	+	+	+
Tetracycline	20mg/dl	-	-	-	+	+	+
Ketone	20mg/dl	-	-	-	+	+	+
Total cholesterol（serum only）	250mg/dl	-	-	-	+	+	+
Triglycerides（serum only）	1200mg/dl	-	-	-	+	+	+
High-density lipoprotein（serum only）	70mg/dl	-	-	-	+	+	+

All data show that there is no interference for the listed compounds at the stated concentrations.

e.Effect of Urine Specified Gravity and Urine pH

Negative and positive urine samples containing 10 and 20 mIU/mL hCG were tested at pH values from 4 to 9 or at density values ranging from 1.001 to1.035 using 3 different lots by 3 different operators. Data show that there is no interference from pH ranging from 4 to 9 and specific gravity ranging from 1.001 to 1.035 of tested urine samples.

2. Comparison Studies

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). 105 urine and 107 serum samples were collected from 212 women (about half of them were pregnant, early stage at less than 5 weeks) from three testing sites. Samples were randomly collected at various times throughout the day. Ages ranged from 20 to 49 years. Samples were tested by different health professionals with the proposed and the predicate devices at each site. The obtained results are shown in the following tables.

Summary Results for Urine Cassette

	Cleared device	+	-
New Device	+	**53**	**0**
	-	**0**	**52**

Summary Results for Serum Cassette

	Cleared device	+	-
New Device	+	**58**	**0**
	-	**0**	**49**

The study result shows that 100% agreement for all samples.

3. Clinical Studies

Not applicable

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity and method comparison of the devices, it's concluded that Alltest hCG Pregnancy Serum/Urine Combo Test Cassette is substantially equivalent to the predicate.