DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 24, 2016

ASSURE TECH., INC.
C/O JOE SHIA
REGULATORY CONSULTANT
504 EAST DIAMOND AVE. SUITE I
GAITHERSBURG MD 20877

Re: K152768
Trade/Device Name: Assure Tech hCG Pregnancy Serum/Urine Combo Test Cassette
Assure Tech hCG Pregnancy Serum/Urine Combo Test Strip
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI
Dated: February 12, 2016
Received: February 22, 2016

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. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
k152768

Device Name
Assure Tech hCG Pregnancy Serum/Urine Combo Test Cassette
Assure Tech hCG Pregnancy Serum/Urine Combo Test Strip

Indications for Use *(Describe)*
The Assure Tech hCG Pregnancy Serum/Urine Combo Test Cassette is a rapid visual immunoassay for the qualitative, presumptive detection of human chorionic gonadotropin in human urine or serum specimens. This kit is intended for use as an aid in early detection of pregnancy.
This product is intended for prescription use in clinical laboratories and point-of-care use settings.

The Assure Tech hCG Pregnancy Serum/Urine Combo Test Strip is a rapid visual immunoassay for the qualitative, presumptive detection of human chorionic gonadotropin in human urine or serum specimens. This kit is intended for use as an aid in early detection of pregnancy.
This product is intended for prescription use in clinical laboratories and point-of-care use settings.

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

1. Date: February 23, 2016
2. Submitter: Assure Tech. (Hangzhou) Co., Ltd.
   2nd. Floor, Building 1, No.10, Xiyuansan Road
   Hangzhou, China, 310030

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: Assure Tech hCG Pregnancy Serum/Urine Combo Test Cassette
   Assure Tech hCG Pregnancy Serum/Urine Combo Test Strip

   Classification: Class II

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

5. Predicate Devices:
   K973858, QuickVue+ One-Step hCG Combo test, Quidel Corporation

6. Intended Use
   The Assure Tech hCG Pregnancy Serum/Urine Combo Test (Cassette, Strip) is a rapid chromatographic immunoassay for the visual, qualitative detection of human chorionic gonadotropin in human urine or serum specimens to aid in early detection of pregnancy. This device is intended for prescription use in clinical laboratories and point-of-care use settings.
7. Device Description
   Assure Tech hCG Pregnancy Serum/Urine Combo Test (Cassette, Strip) 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 devices are in two different formats: Strip, Cassette.
8. Substantial Equivalence Information
   A summary comparison of features of the Assure Tech hCG Pregnancy Serum/Urine Combo Test (Cassette, Strip) 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<br>Urine: 3 minutes | Same |
| Usage | For prescription use | Same |
| Cut-Off Values | 10 mIU/mL for serum and<br>20 mIU/mL for urine | Same |
| Configurations | Strip and cassette | cassette |
| Storage | 4 – 30°C | 15 - 30°C |
| Reading Control Window | 1 window for result reading and control reading | 2 windows: Small Control Window and Large Read Result Window |
| Read Result Window | No preprinted line on membrane | Pre-printed horizontal blue line on membrane |
| Positive result | 2 colored red/pinkish horizontal lines in control and test regions | Pink and blue plus sign in large Window, along with a blue line in small Window |
| Negative result | 1 colored line in control region only | Blue horizontal line in Large Window, along with a blue line in small Window |

9. Test Principle

   It is a lateral flow chromatographic immunoassay. 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. 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 4th WHO international Standard) concentrations. The spiked samples were measured in 10 replicates using 3 different lots for each format at three testing sites. Tests were performed by three different operators for each sample concentration at each site for 5 days. Results are shown in the following tables.

**Serum Strip format**

| hCG Concentration (mIU/mL) | Site 1 | | Site 2 | | Site 3 | | Total result | | % Negative | % Positive |
|---|---|---|---|---|---|---|---|---|---|---|
| | - | + | - | + | - | + | - | + | | |
| 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% | 0 |
| 4 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% | 0 |
| 6 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% | 0 |
| 8 | 25 | 25 | 23 | 27 | 24 | 26 | 72 | 78 | 48% | 52% |
| 10 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% |
| 12 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% |
| 14 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% |
| 16 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% |
| 20 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% |
| 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% |

**Serum Cassette format**

| hCG Concentration (mIU/mL) | Site 1 | | Site 2 | | Site 3 | | Total result | | % Negative | % Positive |
|---|---|---|---|---|---|---|---|---|---|---|
| | - | + | - | + | - | + | - | + | | |
| 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% | 0 |
| 4 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% | 0 |
| 6 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% | 0 |
| 8 | 24 | 26 | 25 | 25 | 25 | 25 | 74 | 76 | 49.3% | 50.7% |
| 10 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% |
| 12 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% |
| 14 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% |
| 16 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% |
| 20 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% |
| 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% |

**Urine Strip format**

| hCG Concentration (mIU/mL) | Site 1 | | Site 2 | | Site 3 | | Total result | | % Negative | % Positive |
|---|---|---|---|---|---|---|---|---|---|---|
| | - | + | - | + | - | + | - | + | | |
| 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% | 0 |
| 5 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% | 0 |
| 10 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% | 0 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 12 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% | 0 |
| 16 | 24 | 26 | 24 | 26 | 25 | 25 | 73 | 77 | 48.7% | 51.3% |
| 20 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% |
| 24 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% |
| 30 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% |
| 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% |
| 100 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% |

**Urine Cassette format**

| hCG Concentration (mIU/mL) | Site 1 | | Site 2 | | Site 3 | | Total result | | % Negative | % Positive |
|---|---|---|---|---|---|---|---|---|---|---|
| | - | + | - | + | - | + | - | + | | |
| 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% | 0 |
| 5 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% | 0 |
| 10 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% | 0 |
| 12 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% | 0 |
| 16 | 25 | 25 | 24 | 26 | 22 | 28 | 71 | 79 | 47.3% | 52.7% |
| 20 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% |
| 24 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% |
| 30 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% |
| 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% |
| 100 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 150 | 0 | 100% |

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

b. Stability

Stable at 4-30℃ for 24 months based on the accelerated stability study at 50$^{o}$C and real time stability determination at both 4$^{o}$C and 30$^{o}$C.

c. Specificity / Cross Reactivity

**High Dose Effect**

Negative urine (serum) male samples were spiked with varying high hCG concentrations ranging from 62,500 to 2000,000 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 to2x10$^{6}$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 200 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 devices at LH concentrations up to 300 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 free 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** | **3 minutes for urine (5 minutes for serum)** | | | | | | **10 minutes** | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Negative hCG** | | | **Positive hCG** | | | **Negative hCG** | | | **Positive hCG** | | |
| | Lot 1 | Lot 2 | Lot 3 | Lot 1 | Lot 2 | Lot 3 | Lot 1 | Lot 2 | Lot 3 | Lot 1 | Lot 2 | Lot 3 |
| Acetaminophen (20mg/dL) | - | - | - | + | + | + | - | - | - | + | + | + |
| Acetoacetic Acid (2000mg/dL) | - | - | - | + | + | + | - | - | - | + | + | + |
| Asorbic Acid (20mg/dL) | - | - | - | + | + | + | - | - | - | + | + | + |
| B-hydroxybutyrate (2000mg/dL) | - | - | - | + | + | + | - | - | - | + | + | + |
| Caffeine (20mg/dL) | - | - | - | + | + | + | - | - | - | + | + | + |
| Ephedrine (20mg/dL) | - | - | - | + | + | + | - | - | - | + | + | + |
| Gentisic Acid (20mg/dL) | - | - | - | + | + | + | - | - | - | + | + | + |
| Phenylpropanolamine(20mg/dL) | - | - | - | + | + | + | - | - | - | + | + | + |
| Salicylic Acid (20mg/dL) | - | - | - | + | + | + | - | - | - | + | + | + |
| Phenothiazine (20mg/dL) | - | - | - | + | + | + | - | - | - | + | + | + |
| EDTA (80mg/dL) | - | - | - | + | + | + | - | - | - | + | + | + |
| Acetylsalicylic Acid (20mg/dL) | - | - | - | + | + | + | - | - | - | + | + | + |
| Benzoylecgonine (10mg/dL) | - | - | - | + | + | + | - | - | - | + | + | + |
| Cannabinol (10mg/dL) | - | - | - | + | + | + | - | - | - | + | + | + |
| Codeine (6ug/dL) | - | - | - | + | + | + | - | - | - | + | + | + |
| Ethanol (1.0%) | - | - | - | + | + | + | - | - | - | + | + | + |
| Methanol (10%) | - | - | - | + | + | + | - | - | - | + | + | + |
| Albumin (2000mg/dL) | - | - | - | + | + | + | - | - | - | + | + | + |
| Glucose (2000mg/dL) | - | - | - | + | + | + | - | - | - | + | + | + |
| Bilirubin (2mg/dL) | - | - | - | + | + | + | - | - | - | + | + | + |
| Atropine (20mg/dL) | - | - | - | + | + | + | - | - | - | + | + | + |
| Estriol-17-beta (1400ug/dL) | - | - | - | + | + | + | - | - | - | + | + | + |
| Hemoglobin (2000mg/dL) | - | - | - | + | + | + | - | - | - | + | + | + |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Pregnanediol (1500ug/dL) | - | - | - | + | + | + | - | - | - | + | + | + |
| Thiophene (20mg/dl) | - | - | - | + | + | + | - | - | - | + | + | + |
| Ampicillin (20mg/dl) | - | - | - | + | + | + | - | - | - | + | + | + |
| Tetracycline(20mg/dl) | - | - | - | + | + | + | - | - | - | + | + | + |
| Cholesterol (250mg/dl) | - | - | - | + | + | + | - | - | - | + | + | + |
| Triglyceride (500mg/dl) | - | - | - | + | + | + | - | - | - | + | + | + |
| Lipoprotein (70mg/dl) | - | - | - | + | + | + | - | - | - | + | + | + |
| Ketone(20mg/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 1.000 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 1.000 to 1.035 of tested urine samples.

2. Comparison Studies

A method comparison study was performed, comparing the results obtained from the Assure Tech hCG Pregnancy Serum/Urine Combo Test Cassette (Strip) to the results from predicate devices (QuickVue$^{+}$). 120 each urine or serum samples were collected from 120 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 18 to 49 years. Samples were tested by six different health professionals with the proposed and the predicate devices at each site. Each person could only perform tests for one device format. For example, a person who tested the strips could not test the cassettes. Each person tested three different lots of the device and one predicate device at the same time, but not sequentially. Typical results are shown in the following tables.

**Summary Results for Urine Strip**

| | **Cleared device** | **+** | **-** |
|---|---|---|---|
| **New Device** | **+** | **60** | **0** |
| | **-** | **0** | **60** |

**Summary Results for Urine Cassette**

| | **Cleared device** | **+** | **-** |
|---|---|---|---|
| **New Device** | **+** | **60** | **0** |
| | **-** | **0** | **60** |

**Summary Results for Serum Strip**

| | **Cleared device** | **+** | **-** |
|---|---|---|---|
| **New Device** | **+** | **60** | **0** |
| | **-** | **0** | **60** |

**Summary Results for Serum Cassette**

| | | | |
|---|---|---|---|
| **New Device** | **Cleared device** | **+** | **-** |
| | **+** | **60** | **0** |
| | **-** | **0** | **60** |

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 Assure Tech hCG Pregnancy Serum/Urine Combo Test (Cassette, Strip) is substantially equivalent to the predicate.