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

June 4, 2015

ASSURE TECH. CO., LTD
C/O JOE SHIA
REGULATORY CONSULTANT
504 E DIAMOND AVE., SUITE F
GAITHERSBURG MD 20877

Re: K151211
Trade/Device Name: AssureTech Secobarbital Strip
AssureTech Oxycodone Strip
AssureTech Secobarbital/Oxycodone Panel Dip
AssureTech Secobarbital/Oxycodone Quick Cup
AssureTech Secobarbital/Oxycodone Turn Key-Split Cup
Regulation Number: 21 CFR 862.3150
Regulation Name: Barbiturate test system
Regulatory Class: II
Product Code: DIS, DJG
Dated: April 3, 2015
Received: May 6, 2015

Dear Mr. 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 regulations (21 CFR Parts 801 and 809), 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" (21 CFR 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,

Katherine Serrano -S

For: 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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k151211

Device Name
AssureTech Secobarbital Strip, AssureTech Oxycodone Strip, AssureTech Secobarbital/Oxycodone Panel Dip
AssureTech Secobarbital/Oxycodone Quick Cup
AssureTech Secobarbial/Oxycodone Turn Key-Split Cup

Indications for Use *(Describe)*
The AssureTech Secobarbital Strip test is an immunochromatographic assay for the qualitative determination of Secobarbital in human urine at a Cut-Off concentration of 300ng/mL.

The test may yield preliminary positive results when prescription drug Secobarbital is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Secobarbital in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The test is intended for over-the-counter and for prescription use.

The AssureTech Oxycodone Strip test is an immunochromatographic assay for the qualitative determination of Oxycodone in human urine at a Cut-Off concentration of 100ng/mL.

The test may yield preliminary positive results when prescription drug Oxycodone is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Oxycodone in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The test is intended for over-the-counter and for prescription use.

The AssureTech Secobarbital/Oxycodone Panel Dip test is an immunochromatographic assay for the qualitative determination of Secobarbital and Oxycodone in human urine at a Cut-Off concentration of 300ng/mL and 100 ng/mL, respectively.

The test may yield preliminary positive results when prescription drug Secobarbital or Oxycodone is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Secobarbital or Oxycodone in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The test is intended for over-the-counter and for prescription use.

The AssureTech Secobarbital/Oxycodone Quick Cup test is an immunochromatographic assay for the qualitative determination of Secobarbital and Oxycodone in human urine at a Cut-Off concentration of 300ng/mL and 100 ng/mL, respectively.

The test may yield preliminary positive results when prescription drug Secobarbital or Oxycodone is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Secobarbital or Oxycodone in urine. The test

provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The test is intended for over-the-counter and for prescription use.

The AssureTech Secobarbital/Oxycodone Turn Key-Split Cup test is an immunochromatographic assay for the qualitative determination of Secobarbital and Oxycodone in human urine at a Cut-Off concentration of 300ng/mL and 100 ng/mL, respectively.

The test may yield preliminary positive results when prescription drug Secobarbital or Oxycodone is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Secobarbital or Oxycodone in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The test is intended for over-the-counter and for prescription use.

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)

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510(k) SUMMARY

1. Date: June 3, 2015

2. Submitter: Assure Tech. Co., Ltd.
Building 1, No.10, Xiyuansan Road, Westlake Economic Zone
Hangzhou, China, 310030

3. Contact person: Eric Lin
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4. Device Name: AssureTech Secobarbital Strip
AssureTech Oxycodone Strip
AssureTech Secobarbital/Oxycodone Panel Dip
AssureTech Secobarbital/Oxycodone Quick Cup
AssureTech Secobarbital/Oxycodone Turn Key-Split Cup

Classification:

Product Code	CFR	Panel
DIS	21 CFR, 862.3150 Barbiturate Test System	Toxicology
DJG	21 CFR, 862.3650 Opiate Test System	Toxicology

5. Predicate Devices: K052115

FIRST CHECK DIAGNOSTICS LLC FIRST CHECK MULTI DRUG CUP 12

6. Intended Use

The AssureTech Secobarbital Strip test is an immunochromatographic assay for the qualitative determination of Secobarbital in human urine at a Cut-Off concentration of 300ng/mL.

The test may yield preliminary positive results when prescription drug Secobarbital is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Secobarbital in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The test is intended for over-the-counter and for prescription use.

The AssureTech Oxycodone Strip test is an immunochromatographic assay for the qualitative determination of Oxycodone in human urine at a Cut-Off concentration of 100ng/mL.

The test may yield preliminary positive results when prescription drug Oxycodone is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Oxycodone in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The test is intended for over-the-counter and for prescription use.

The AssureTech Secobarbital/Oxycodone Panel Dip test is an immunochromatographic assay for the qualitative determination of Secobarbital and Oxycodone in human urine at a Cut-Off concentration of 300ng/mL and 100 ng/mL, respectively.

The test may yield preliminary positive results when prescription drug Secobarbital or Oxycodone is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Secobarbital or Oxycodone in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The test is intended for over-the-counter and for prescription use.

The AssureTech Secobarbital/Oxycodone Quick Cup test is an immunochromatographic assay for the qualitative determination of Secobarbital and Oxycodone in human urine at a Cut-Off concentration of 300ng/mL and 100 ng/mL, respectively.

The test may yield preliminary positive results when prescription drug Secobarbital or Oxycodone is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Secobarbital or Oxycodone in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The test is intended for over-the-counter and for prescription use.

The AssureTech Secobarbital/Oxycodone Turn Key-Split Cup test is an immunochromatographic assay for the qualitative determination of Secobarbital and Oxycodone in human urine at a Cut-Off concentration of 300ng/mL and 100 ng/mL, respectively.

The test may yield preliminary positive results when prescription drug Secobarbital or Oxycodone is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Secobarbital or Oxycodone in urine. The test provides only preliminary test

results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The test is intended for over-the-counter and for prescription use.

7. Device Description

The AssureTech Secobarbital Strip, AssureTech Oxycodone Strip, AssureTech Secobarbital/Oxycodone Panel Dip, AssureTech Secobarbital/Oxycodone Quick Cup and AssureTech Secobarbial/Oxycodone Turn Key-Split Cup are immunochromatographic assays that use a lateral flow system for the qualitative detection of Secobarbital and/or Oxycodone (target analytes) in human urine. The Quick Cup does not contain a turn-key for device activation. The tests are the first step in a two-step process. The second step is to send the sample for laboratory testing if preliminary positive results are obtained.

8. Substantial Equivalence Information

A summary comparison of features of the candidate devices and the predicate devices is provided in Tables 1 to 4 below.

Table 1: Features Comparison of AssureTech Secobarbital Strip and the Predicate Devices

Item	Device	Predicate - K052115
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same (but the number of drugs detected is different)
Calibrator	Secobarbital (member of Barbiturates drug class)	Barbiturates
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Cut-Off Values	300 ng/mL	Same
Intended Use	For over-the-counter and prescription uses.	For over-the-counter use.
Configurations	Strip	Cup

Table 2: Features Comparison of AssureTech Oxycodone Strip and the Predicate Devices

Item	Device	Predicate - K052115
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same (but the number of drugs detected is different)
Calibrator	Oxycodone	Same

Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Cut-Off Values	100 ng/mL	Same
Intended Use	For over-the-counter and prescription uses.	For over-the-counter use.
Configurations	Strip	Cup

Table 3: Features Comparison of AssureTech Secobarbital/Oxycodone Panel Dip and the Predicate Devices

Item	Device	Predicate - K052115
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same (but the number of drugs detected is different)
Calibrator	Secobarbital and Oxycodone	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Cut-Off Values	300ng/mL for Secobarbital and 100 ng/mL for Oxycodone	Same
Intended Use	For over-the-counter and prescription uses.	For over-the-counter use.
Configurations	Panel Dip	Cup

Table 4: Features Comparison of AssureTech Secobarbital/Oxycodone Cup and the Predicate Devices

Item	Device	Predicate - K052115
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same (but the number of drugs detected is different)
Calibrator	Secobarbital and Oxycodone	Same

Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Cut-Off Values	300ng/mL for Secobarbital and 100 ng/mL for Oxycodone	Same
Intended Use	For over-the-counter and prescription uses.	For over-the-counter use.
Configurations	Cup with or without turn-key	Cup

9. Test Principle

AssureTech Secobarbital Strip, AssureTech Oxycodone Strip, AssureTech Secobarbital/Oxycodone Panel Dip, AssureTech Secobarbital/Oxycodone Quick Cup and AssureTech Secobarbial/Oxycodone Turn Key-Split Cup are rapid tests for the qualitative detection of Secobarbital and/or Oxycodone in urine samples. The tests are lateral flow chromatographic immunoassays. During testing, a urine specimen migrates upward by capillary action. If target drugs present in the urine specimen are below the cut-off concentration, it will not saturate the binding sites of its specific monoclonal mouse antibody coated on the particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the target drug level exceeds its cutoff-concentration because it will saturate all the binding sites of the antibody coated on the particles. A band should form in the control region of the devices regardless of the presence of drug or metabolite in the sample to indicate that the tests have been performed properly.

10. Performance Characteristics

1. Analytical Performance

a. Precision

Precision studies were carried out for samples with concentrations of -100% cut off, -75% cut off, -50% cut off, -25% cut off, +25% cut off, +50% cut off , +75% cut off and +100% cut off. These samples were prepared by spiking drug in negative samples. Each drug concentration was confirmed by GC/MS. All sample aliquots were blindly labeled by the person who prepared the samples and didn't take part in the sample testing. For each concentration, tests were performed two runs per day for 25 days per device in a randomized order. The results obtained are summarized in the following tables.

Secobarbital

AssureTech Secobarbital Strip

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

AssureTech Secobarbital /Oxycodone Panel Dip

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-

AssureTech Secobarbital/Oxycodone Turn-Key Split Cup

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

AssureTech Secobarbital/Oxycodone Quick Cup

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	1-/49+	50+/0-	50+/0-	50+/0-	50+/0-

Oxycodone

AssureTech Oxycodone Strip

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	1-/49+	50+/0-	50+/0-	50+/0-	50+/0-

AssureTech Secobarbital/Oxycodone Panel Dip

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	1-/49+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

AssureTech Secobarbital/Oxycodone Turn-Key Split Cup

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	1-/49+	50+/0-	50+/0-	50+/0-	50+/0-

AssureTech Secobarbital/Oxycodone Quick Cup

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

b. Linearity

Not applicable.

c. Stability

The devices are stable at 4-30 °C for 24 months based on the accelerated stability study at 45 °C and real time stability determination at both 4 °C and 30 °C.

d. Cut-off

A total of 150 samples equally distributed at concentrations of -50% Cut-Off; -25% Cut-Off; Cut-Off; +25% Cut-Off; +50% Cut-Off were tested using three different lots of each device by three different operators. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for both Secobarbital and Oxycodone.

The following cut-off values for the candidate devices have been verified.

Calibrator	**Cut-off (ng/mL)**
Secobarbital	300
Oxycodone	100

e. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentrations at 25% below and 25% above Cut-Off levels. These urine samples were tested using three batches of each device. Compounds that showed no interference at a concentration of 100μg/mL are summarized in the following tables. There were no differences observed for different devices.

Secobarbital:

Acetaminophen	Erythromycin	O-Hydroxyhippuric acid
Acetophenetidin	β-Estradiol	D,L-Octopamine
Acetylsalicylic acid	Estrone-3-sulfate	Oxalic acid
Aminopyrine	Ethyl-p-aminobenzoate	Oxazepam
Amitryptyline	Fenoprofen	Oxolinic acid
Amoxicillin	Furosemide	Oxycodone
DL-Amphetamine sulfate	Gentisic acid	Oxymetazoline
Ampicillin	Hemoglobin	Papaverine
Apomorphine	Hydralazine	Penicillin-G
Ascorbic acid	Hydrochlorothiazide	Pentazocaine
Aspartame	Hydrocodone	Perphenazine
Atropine	Hydrocortisone	Phencyclidine
Benzilic acid	p-Hydroxyamphetamine	Phenelzine

Benzoic acid	p-Hydroxymethamphetamine	β-Phenylethlamine
Benzoylecgonine	3-Hydroxytyramine	Phenylpropanolamine
Bilirubin	Ibuprofen	Prednisolone
Brompheniramine	Imipramine	Prednisone
Caffeine	(-) Isoproterenol	Procaine
Cannabidiol	Isoxsuprine	Promazine
Cannabinol	Ketamine	Promethazine
Chloralhydrate	Ketoprofen	D,L-Propanolol
Chloramphenicol	Labetalol	D-Propoxyphene
Chlorothiazide	Levorphanol	Quinidine
(±) Chlorpheniramine	Loperamide	Quinine
Chlorpromazine	L-Phenylephrine	Ranitidine
Chlorquine	Maprotiline	Salicylic acid
Cholesterol	Meperidine	Serotonin
Clomipramine	Meprobamate	Sulfamethazine
Clonidine	Morphine-3-β-D glucuronide	Sulindac
Cocaine hydrochloride	Methadone	Temazepam
Codeine	Methamphetamine	Tetracycline
Cortisone	(±) - 3,4-Methylenedioxy-amphetamine	Tetrahydrozoline
(-) Cotinine	(±)-3,4-Methylenedioxy-methamphetamine hydrochloride	Thebaine
Creatinine	Morphine Sulfate	Thiamine
Deoxycorticosterone	N-Acetylprocainamide	Thioridazine
Dextromethorphan	Nalidixic acid	Triamterene
Diazepam	Naloxone	Trifluoperazine
Diclofenac	Naltrexone	Trimethoprim
Diflunisal	Naproxen	Trimipramine
Digoxin	Niacinamide	Tryptamine
Diphenhydramine	Nifedipine	D, L-Tyrosine
Doxylamine	Norcodein	Uric acid
Ecgonine hydrochloride	Norethindrone	Verapamil
Ecgonine methylester	D-Norpropoxyphene	Zomepirac
(IR,2S)(-)Ephedrine	Noscapine	

Oxycodone

Acetophenetidin	L-Ephedrine	Oxymetazoline
Nalidixic acid	Ecgonine methylester	Papaverine
Acetylsalicylic acid	Ethyl-p-aminobenzoate	Penicillin-G
Aminopyrine	β-Estradiol	Perphenazine
Amoxicillin	Estrone-3-sulfate	Phenelzine
Ampicillin	Erythromycin	L-Phenylephrine
L-Phenylephrine	Fenoprofen	β-Phenylethylamine
Apomorphine	Furosemide	Phenylpropanolamine
Aspartame	Gentisic acid	Prednisone
Atropine	Hemoglobin	Loperamide

Benzilic acid	Hydralazine	Quinine
Benzoic acid	Hydrochlorothiazide	Quinidine
Benzphetamine	Hydrocortisone	Ranitidine
Bilirubin	O-Hydroxyhippuric acid	Salicylic acid
Deoxycorticosterone	3-Hydroxytyramine	Serotonin
Caffeine	Labetalol	Sulfamethazine
Chloralhydrate	D, L-Isoproterenol	Sulindac
Chloramphenicol	Meprobamate	Tetracycline
Chlorothiazide	Methoxyphenamine	Tetrahydrocortisone
D,L-Chlolrpheniramine	Nalidixic acid	Morphine-3-β-D-gluc uronide
Chlorpromazine	Naloxone	Tetrahydrozoline
Chlorquine	Naltrexone	Thiamine
Cholesterol	Naproxen	Thioridazine
Clonidine	Niacinamide	D,L-Tyrosine
L-Cotinine	Nifedipine	Tolbutamide
Cortisone	Isoxsuprine	Triamterene
Creatinine	D,L-Propanolol	Trifluoperazine
D-Pseudoephedrine	Ketoprofen	Trimethoprim
Dextromethorphan	Norethindrone	Tyramine
β-Dglucuronide	D-Norpropoxyphene	D,L-Tryptophan
Diclofenac	Noscapine	Urine acid
Diflunisal	D,L-Octopamine	Verapamil
Digoxin	Oxalic acid	Zomepirac
Diphenhydramine	Oxolinic acid	

f. Specificity

To test specificity, drug metabolites and other components that are likely to interfere in urine samples were tested using three batches of each device. The lowest concentration that caused a positive result for each compound are listed below. There were no differences observed for different devices.

Secobarbital (Cut-off=300 ng/mL)	**Result**	**% Cross-Reactivity**
Secobarbital	Positive at 300 ng/mL	100%
Amobarbital	Positive at 1000 ng/mL	30%
Alphenol	Positive at 62.5 ng/mL	480%
Aprobarbital	Positive at 250 ng/mL	120%
Butabarbital	Positive at 100 ng/mL	300%
Butathal	Positive at 500 ng/mL	60%
Butalbital	Positive at 5000ng/mL	6%
Cyclopentobarbital	Positive at 500 ng/mL	60%
Pentobarbital	Positive at 200 ng/mL	150%
Phenobarbital	Positive at 300 ng/mL	100%

Oxycodone (Cut-off=100 ng/mL)	**Result**	**% Cross-Reactivity**
Oxycodone	Positive at 100 ng/mL	100%
Codeine	Positive at 100000 ng/mL	0.1%
Acetylmorphine	Positive at 100000 ng/mL	0.1%
Oxymorphone	Positive at 250 ng/mL	40%

Dihydrocodeine	Positive at 100000 ng/mL	0.1%
Hydromorphone	Positive at 100000 ng/mL	0.1%
Hydrocodone	Positive at 3125 ng/mL	3.2%
Morphine	Positive at 100000 ng/mL	0.1%
Buprenorphine	Positive at 100000 ng/mL	0.1%
Ethylmorphine	Positive at 100000 ng/mL	0.1%

g. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, urine samples, with 1.000 to 1.035 specific gravity or urine samples with pH 4 to 9 were spiked with target drugs at 25% below and 25% above Cut-Off levels. These samples were tested using three batches of each device . Results were all positive for samples at and above +25% Cut-Off and all negative for samples at and below -25% Cut-Off. There were no differences observed for different devices.

2. Comparison Studies

Method comparison studies for the candidate devices were performed in-house with three laboratory assistants for each device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were blind labeled and compared to GC/MS results. The results are presented in the tables below:

Secobarbital

Strip		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Viewer B	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Viewer C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

Discordant Results of Secobarbital Strip

Viewer	Sample Number	GC/MS Result	Strip Viewer Results
Viewer A	817130	286	Positive
Viewer B	817130	286	Positive
Viewer C	817130	286	Positive

Panel Dip		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Viewer B	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Viewer C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

Discordant Results of Secobarbital Panel Dip

Viewer	Sample Number	GC/MS Result	Panel Dip Viewer Results
Viewer A	817130	286	Positive
Viewer B	817130	286	Positive
Viewer C	817130	286	Positive
Viewer A	933321	306	Negative

Turn-Key Split Cup		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	14	25
	Negative	1	20	9	1	0
Viewer B	Positive	0	0	0	14	25
	Negative	1	20	10	1	0
Viewer C	Positive	0	0	1	14	25
	Negative	1	20	9	1	0

Discordant Results of Secobarbital Turn-Key Split Cup

Viewer	Sample Number	GC/MS Result	Turn-Key Split Cup
Viewer A	817130	286	Positive
Viewer A	862382	310	Negative
Viewer C	817130	286	Positive
Viewer B	933321	306	Negative
Viewer C	722825	336	Negative

Quick Cup		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Viewer B	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Viewer C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

Discordant Results of Secobarbital Quick Cup

Viewer	Sample Number	GC/MS Result	Quick Cup Viewer Results
Viewer A	216041	241	Positive
Viewer B	126635	252	Positive
Viewer C	126635	252	Positive
Viewer A	358232	315	Negative

Oxycodone (OXY)

Strip		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Viewer B	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Viewer C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

Discordant Results of OXY Strip

Viewer	Sample Number	GC/MS Result	Strip Viewer Results
Viewer A	638805	96	Positive
Viewer A	757887	102	Negative
Viewer B	638805	96	Positive
Viewer C	638805	96	Positive

Panel Dip		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Viewer B	Positive	0	0	0	14	25
	Negative	10	20	10	1	0
Viewer C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

Discordant Results of OXY Panel Dip

Viewer	Sample Number	GC/MS Result	Panel Dip Viewer Results
Viewer A	603216	90	Positive
Viewer C	638805	96	Positive
Viewer B	757887	102	Negative

Turn-Key Split Cup		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	14	25
	Negative	1	20	9	1	0
Viewer B	Positive	0	0	1	15	25
	Negative	1	20	9	0	0
Viewer C	Positive	0	0	0	15	25
	Negative	1	20	10	0	0

Discordant Results of OXY Turn-Key Split Cup

Viewer	Sample Number	GC/MS Result	Split Cup Viewer Results
Viewer A	638805	96	Positive
Viewer A	285248	110	Negative
Viewer B	638805	96	Positive

Quick Cup		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Viewer B	Positive	0	0	0	14	25
	Negative	10	20	10	1	0
Viewer C	Positive	0	0	1	14	25
	Negative	10	20	9	1	0

Discordant Results of OXY Quick Cup

Viewer	Sample Number	GC/MS Result	Quick Cup Viewer Results
Viewer A	638805	96	Positive
Viewer C	603216	90	Positive
Viewer A	757887	102	Negative
Viewer B	508044	116	Negative
Viewer C	285248	110	Negative

Lay-user study

A lay user study was performed at three intended user sites with 1060 lay persons. The lay users had diverse educational and professional backgrounds and ranged in age from 18 to > 50 years. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample and a device. Each device was tested.

Comparison between GC/MS and Lay Person Results for Secobarbital Strip

% of Cutoff	Number of samples	Secobarbital Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100
-75%Cutoff	20	73	0	20	100
-50% Cutoff	20	149	0	20	100
-25% Cutoff	20	228	2	18	90
+25% Cutoff	20	369	20	0	100
+50% Cutoff	20	455	20	0	100
+75% Cutoff	20	530	20	0	100

Comparison between GC/MS and Lay Person Results for OXY Strip

% of Cutoff	Number of samples	Oxycodone Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100
-75%Cutoff	20	22	0	20	100
-50% Cutoff	20	48	0	20	100
-25% Cutoff	20	80	1	19	95
+25% Cutoff	20	127	19	1	95
+50% Cutoff	20	158	20	0	100
+75% Cutoff	20	176	20	0	100

Comparison between GC/MS and Lay Person Results for BAR/OXY Panel DipCard

% Cutoff	No of samples	Concentration by GC/MS(ng/mL)		Lay person results		Correct Results (%)	
		Secobarbital	Oxycodone	BAR	OXY	BAR	OXY
-100%	20	0	0	0+/20-	0+/20-	100	100
-75%	20	73	22	0+/20-	0+/20-	100	100
-50%	20	149	48	0+/20-	0+/20-	100	100
-25%	20	228	80	1+/19-	1+/19-	95	95
+25%	20	369	127	19+/1-	18+/2-	95	90
+50%	20	455	158	20+/0-	20+/0-	100	100
+75%	20	530	176	20+/0-	20+/0-	100	100

Comparison between GC/MS and Lay Person Results for BAR/OXY Turn-Key Split Cup

% Cutoff	No of samples	Concentration by GC/MS(ng/mL)		Lay person results		Correct Results (%)	
		Secobarbital	Oxycodone	BAR	OXY	BAR	OXY
-100%	20	0	0	0+/20-	0+/20-	100	100
-75%	20	73	22	0+/20-	0+/20-	100	100
-50%	20	149	48	0+/20-	0+/20-	100	100
-25%	20	228	80	2+/18-	1+/19-	90	95
+25%	20	369	127	20+/0-	19+/1-	100	95
+50%	20	455	158	20+/0-	20+/0-	100	100
+75%	20	530	176	20+/0-	20+/0-	100	100

Comparison between GC/MS and Lay Person Results for BAR/OXY Quick Cup

% Cutoff	No of samples	Concentration by GC/MS(ng/mL)		Lay person results		Correct Results (%)	
		Secobarbital	Oxycodone	BAR	OXY	BAR	OXY
-100%	20	0	0	0+/20-	0+/20-	100	100
-75%	20	73	22	0+/20-	0+/20-	100	100
-50%	20	149	48	0+/20-	0+/20-	100	100
-25%	20	228	80	1+/19-	1+/19-	95	95

+25%	20	369	127	20+/0-	20+/0-	100	100
+50%	20	455	158	20+/0-	20+/0-	100	100
+75%	20	530	176	20+/0-	20+/0-	100	100

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

3. Clinical Studies

Not applicable.

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity, method comparison, and lay-user studies of the devices, it's concluded that the AssureTech Secobarbital Strip, AssureTech Oxycodone Strip, AssureTech Secobarbital/Oxycodone Panel Dip, AssureTech Secobarbital/Oxycodone Quick Cup and AssureTech Secobarbial/Oxycodone Turn Key-Split Cup are substantially equivalent to the predicate.