April 5, 2018

Assure Tech (Hangzhou) Co., Ltd.
% Joe Shia
Manager
LSI International
504 E Diamond Ave, Suite I
Gaithersburg, MD 20877

Re: K180349
Trade/Device Name: AssureTech Panel Dip Tests, AssureTech Quick Cup Tests
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: NFT, NFW, NFY, NGG, NGL, NFV, PTH, NGM, PTG, QAW, QBF
Dated: February 5, 2018
Received: February 8, 2018

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 Part 801 and Part 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -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

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)*
k180349

Device Name
AssureTech Panel Dip Tests
AssureTech Quick Cup Tests

Indications for Use *(Describe)*
AssureTech Panel Dip Tests and AssureTech Quick Cup Tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline and d-Propoxyphene in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine	1000 ng/mL
Oxazepam	300 ng/mL
Cocaine	300 ng/mL
Marijuana	50 ng/mL
Methamphetamine	1000 ng/mL
Morphine	300 ng/mL or 2000 ng/mL
Oxycodone	100 ng/mL
Secobarbital	300 ng/mL
Buprenorphine	10 ng/mL
Methylenedioxy-methamphetamine	500 ng/mL
Phencyclidine	25 ng/mL
Methadone	300 ng/mL
EDDP	300 ng/mL
Nortriptyline	1000 ng/mL
d-Propoxyphene	300 ng/mL

Configuration of the AssureTech Panel Dip Tests and the AssureTech Quick Cup Tests can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.
For in vitro diagnostic use only.

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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k180349
510(k) SUMMARY

1. Date: March 13, 2018

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

3. Contact person: Eric Lin
Assure Tech. Co., Ltd.
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Hangzhou, China, 310030
Telephone: 510-860-4680
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4. Device Name: AssureTech Panel Dip Tests
AssureTech Quick Cup Tests

Classification: Class 2

Product Code	Classification	Regulation Section	Panel
NFT Amphetamine	II	21 CFR § 862.3100, Amphetamine Test System	Toxicology (91)
NFW Cannabinoids	II	21 CFR § 862.3870, Cannabinoids Test System	Toxicology (91)
NFY Cocaine	II	21 CFR § 862.3250, Cocaine and Cocaine Metabolites Test System	Toxicology (91)
NGG Methamphetamine	II	21 CFR § 862.3610, Methamphetamine Test System	Toxicology (91)
NGL Morphine	II	21 CFR § 862.3650, Morphine Test System	Toxicology (91)
NFV Oxazepam	II	21 CFR § 862.3170, Benzodiazepine Test System	Toxicology (91)
NGL Oxycodone	II	21 CFR § 862.3650, Opiate Test System	Toxicology (91)
PTH Secobarbital	II	21 CFR § 862.3150, Barbiturate Test System	Toxicology (91)
NGL Buprenorphine	II	21 CFR § 862.3650, Opiate Test System	Toxicology (91)
NGG Methylenedioxy-methamphetamine	II	21 CFR § 862.3610, Methamphetamine Test System	Toxicology (91)
NGM Phencyclidine	unclassified	Enzyme Immunoassay Phencyclidine	Toxicology (91)
PTG Methadone	II	21 CFR § 862.3620, Methadone Test System	Toxicology (91)

PTG 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP)	II	21 CFR § 862.3620, Methadone Test System	Toxicology (91)
QAW Nortriptyline	II	21 CFR, 862.3910 Tricyclic Antidepressant Drugs Test System	Toxicology (91)
QBF Propoxyphene	II	21 CFR, 862.3700 Propoxyphene Test System	Toxicology (91)

5. Predicate Devices: K153050

   The CO-INNOVATION BIOTECH Rapid Multi-Drug Test Dip Card and Rapid Multi-Drug Test Cup

6. Indications for Use

   AssureTech Panel Dip Tests and AssureTech Quick Cup Tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline and d-Propoxyphene in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine	1000 ng/mL
Oxazepam	300 ng/mL
Cocaine	300 ng/mL
Marijuana	50 ng/mL
Methamphetamine	1000 ng/mL
Morphine	300 ng/mL or 2000 ng/mL
Oxycodone	100 ng/mL
Secobarbital	300 ng/mL
Buprenorphine	10 ng/mL
Methylenedioxy-methamphetamine	500 ng/mL
Phencyclidine	25 ng/mL
Methadone	300 ng/mL
EDDP	300 ng/mL
Nortriptyline	1000 ng/mL
d-Propoxyphene	300 ng/mL

Configuration of the AssureTech Panel Dip Tests and the AssureTech Quick Cup Tests can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

For in vitro diagnostic use only.

7. Device Description

The AssureTech Panel Dip Tests and AssureTech Quick Cup Tests are immunochromatographic assays that use a lateral flow system for the qualitative detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline and Propoxyphene (target analytes) in human urine. The products are single-use in vitro diagnostic devices, which come in the formats of Panel Dip Cards or Cups. Each test kit contains a Test Device (in one of the two formats), a package insert and a urine cup for sample collection. Each test device is sealed with a desiccant in an aluminum pouch

8. Substantial Equivalence Information

A summary comparison of features of the AssureTech Panel Dip Tests and AssureTech Quick Cup Tests and the predicate devices is provided in following tables.

Table 1: Features Comparison of AssureTech Panel Dip Tests and the Predicate Devices

Item	Device	Predicate - K153050
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 and Cut-Off Values	Amphetamine (AMP): 1,000 ng/ml Oxazepam (BZO):300 ng/ml Cocaine(COC): 300 ng/ml Marijuana (THC):50 ng/ml Methamphetamine (MET): 1,000 ng/ml Morphine (MOR): 300ng/mL or 2000 ng/ml Oxycodone(OXY) : 100 ng/ml Secobarbital (BAR): 300 ng/ml Buprenorphine (BUP): 10 ng/ml Methylenedioxy-methamphetamine(MDMA): 500 ng/ml Phencyclidine (PCP): 25 ng/ml Methadone (MTD): 300 ng/ml 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP): 300 ng/ml Nortriptyline (TCA): 1000 ng/ml Propoxyphene (PPX): 300 ng/ml	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
Intended Use	For over-the-counter	Same

Configurations	Dip Card	Same

Table 2: Features Comparison of AssureTech Quick Cup Tests and the Predicate Devices

Item	Device	Predicate - K153050
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 and Cut-Off Values	Amphetamine (AMP): 1,000 ng/ml Oxazepam (BZO):300 ng/ml Cocaine(COC): 300 ng/ml Marijuana (THC):50 ng/ml Methamphetamine (MET): 1,000 ng/ml Morphine (MOR): 300ng/mL or 2000 ng/ml Oxycodone(OXY) : 100 ng/ml Secobarbital (BAR): 300 ng/ml Buprenorphine (BUP): 10 ng/ml Methylenedioxy-methamphetamine(MDMA): 500 ng/ml Phencyclidine (PCP): 25 ng/ml Methadone (MTD): 300 ng/ml 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP): 300 ng/ml Nortriptyline (TCA): 1000 ng/ml Propoxyphene (PPX): 300 ng/ml	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
Intended Use	For over-the-counter	Same
Configurations	Cup	Same

9. Test Principle

The AssureTech Panel Dip Tests, and AssureTech Quick Cup Tests are rapid tests for the qualitative detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline and Propoxyphene 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 LC/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 for 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP), Nortriptyline (TCA) and Propoxyphene (PPX). The rest data were reported in the k170049.

EDDP

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+	9-/41+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	10-/40+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	9-/41+	50+/0-	50+/0-	50+/0-	50+/0-

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+	10-/40+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	9-/41+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	9-/41+	50+/0-	50+/0-	50+/0-	50+/0-

Nortriptyline

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+	10-/40+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	9-/41+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	10-/40+	50+/0-	50+/0-	50+/0-	50+/0-

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+	9-/41+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	8-/42+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	8-/42+	50+/0-	50+/0-	50+/0-	50+/0-

Propoxyphene

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+	12-/38+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	9-/41+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	11-/39+	50+/0-	50+/0-	50+/0-	50+/0-

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+	9-/41+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	8-/42+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	9-/41+	50+/0-	50+/0-	50+/0-	50+/0-

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. 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 (albumin was tested at 100 mg/dL) are summarized in the following tables. There were no differences observed for different devices.

Acetaminophen	β-Estradiol	Oxalic acid
Acetophenetidin	Erythromycin	Oxolinic acid
N-Acetylprocainamide	Fenoprofen	Oxymetazoline
Acetylsalicylic acid	Furosemide	Papaverine
Albumin (100 mg/dL)	Gentisic acid	Penicillin G
Aminopyrine	Hemoglobin	Perphenazine
Amoxicillin	Hydralazine	Phenelzine
Ampicillin	Hydrochlorothiazide	Prednisone
Apomorphine	Hydrocortisone	(±)-Propranolol
Ascorbic acid	O-Hydroxyhippuric acid	Pseudoephedrine
Aspartame	3-Hydroxytyramine	Quinine
Atropine	Ibuprofen	Ranitidine
Benzilic acid	Isoproterenol	Salicylic acid
Benzoic acid	Isoxsuprine	Serotonin (5- Hydroxytyramine)
Bilirubin	Ketamine	Sulfamethazine
Chloral hydrate	Ketoprofen	Sulindac
Chloramphenicol	Labetalol	Tetrahydrocortisone 3-(β-Dglucuronide)
Chlorothiazide	Loperamide	Tetrahydrocortisone 3-acetate
Chlorpromazine	Meperidine	Tetrahydrozoline
Cholesterol	Meprobamate	Thiamine
Clonidine	Methoxyphenamine	Thioridazine
Cortisone	Nalidixic acid	Triamterene
(-)-Cotinine	Naloxone	Trifluoperazine
Creatinine	Naltrexone	Trimethoprim
Deoxycorticosterone	Naproxen	DL-Tryptophan
Dextromethorphan	Niacinamide	Tyramine

Diclofenac	Nifedipine	DL-Tyrosine
Diflunisal	Norethindrone	Uric acid
Digoxin	Noscapine	Verapamil
Diphenhydramine	(±)-Octopamine	Zomepirac
Ecgonine methyl ester		

e. 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 for 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP), Nortriptyline (TCA) and Propoxyphene (PPX). The rest data were reported in the k170049. There were no differences observed for different devices.

EDDP (Cut-off=300 ng/mL)	**Result Positive at (ng/mL)**	**% Cross-Reactivity**
EDDP(2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine)	300	100%
EMDP (2-Ethyl-5-methyl-3,3-diphenylpyrroline)	＞100000	<0.3%
Disopyramide	75	400%
Methadone	＞100000	<0.3%
LAAM (Levo-alpha-acetylmethadol) HCl	＞100000	<0.3%
Alpha Methadol	＞100000	<0.3%
Doxylamine	＞100000	<0.3%

Nortriptyline (Cut-off=1000 ng/mL)	**Result Positive at (ng/mL)**	**% Cross-Reactivity**
Nortriptyline	1000	100%
Amitriptyline	750	133.3%
Clomipramine	10000	10%
Desipramine	200	500%
Doxepin	1250	80%
Imipramine	625	160%
Maprotiline	2000	50%
Nordoxepin	1000	100%
Promazine	1500	66.7%
Promethazine	25000	4%
Trimipramine	3000	33.3%
Cyclobenzaprine Hydrochloride	5000	20%
Norclomipramine	3000	33.3%

Propoxyphene (Cut-off=300 ng/mL)	**Result Positive at (ng/ml)**	**% Cross-Reactivity**
d-Propoxyphene	300	100%
Norpropoxyphene	333	90.1%

f. 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 lots 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 AssureTech Panel Dip Tests and the AssureTech Quick Cup Tests were performed in-house with three laboratory assistants for each device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples for each drug. The samples were blind labeled and compared to LC/MS results. The results are presented in the tables below for 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP), Nortriptyline (TCA) and Propoxyphene (PPX). The rest data were reported in the k170049.

EDDP

Panel Dip		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	14	25
	Negative	10	20	8	1	0
Viewer B	Positive	0	0	0	15	25
	Negative	10	20	10	0	0
Viewer C	Positive	0	0	1	14	25
	Negative	10	20	9	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	86905	295	Positive
Viewer A	36355	290	Positive
Viewer C	63254	295	Positive
Viewer A	24973	308	Negative
Viewer C	24082	307	Negative

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

Discordant Results

Viewer	Sample Number	LC/MS Result	Quick Cup Viewer Results
Viewer A	47796	296	Positive
Viewer B	63254	295	Positive
Viewer C	36355	290	Positive
Viewer B	24082	307	Negative
Viewer C	24973	308	Negative

Nortriptyline

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

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer B	50313	942	Positive
Viewer B	77063	1081	Negative
Viewer C	77063	1081	Negative

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

Viewer	Sample Number	LC/MS Result	Quick Cup Viewer Results
Viewer C	50313	942	Positive
Viewer A	77063	1081	Negative

Viewer B	54803	1130	Negative

Propoxyphene

Panel Dip		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/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	0	15	25
	Negative	10	20	10	0	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	31727	294	Positive
Viewer B	34150	298	Positive

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

Discordant Results

Viewer	Sample Number	LC/MS Result	Quick Cup Viewer Results
Viewer B	66995	287	Positive
Viewer C	34150	298	Positive
Viewer A	27051	359	Negative
Viewer C	27051	359	Negative

Lay-user study

A lay user study was performed at three intended user sites with 310 lay persons for each device format. 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 drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by LC/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. Typical results are shown below.

The results summary for AMP:

% of Cutoff	Number of samples	Drug Concentration by LC/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	248	0	20	100
-50% Cutoff	170	508	0	170	100
-25% Cutoff	20	752	1	19	95
+25% Cutoff	20	1255	19	1	95
+50% Cutoff	40	1506	40	0	100
+75% Cutoff	20	1748	20	0	100

The results summary for BAR:

% of Cutoff	Number of samples	Drug Concentration by LC/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	170	151	0	170	100
-25% Cutoff	20	223	1	19	95
+25% Cutoff	20	378	19	1	95
+50% Cutoff	20	456	40	0	100
+75% Cutoff	20	521	20	0	100

The results summary for COC:

% of Cutoff	Number of samples	Drug Concentration by LC/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	76	0	20	100
-50% Cutoff	170	154	0	170	100
-25% Cutoff	20	222	2	18	90
+25% Cutoff	20	377	19	1	95
+50% Cutoff	40	452	40	0	100
+75% Cutoff	20	528	20	0	100

The results summary for BUP:

% of Cutoff	Number of samples	Drug Concentration by LC/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	2.6	0	20	100
-50% Cutoff	170	4.8	0	170	100

-25% Cutoff	20	7.2	1	19	95
+25% Cutoff	20	12.6	19	1	95
+50% Cutoff	40	15.4	40	0	100
+75% Cutoff	20	17.3	20	0	100

The results summary for MET:

% of Cutoff	Number of samples	Drug Concentration by LC/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	255	0	20	100
-50% Cutoff	170	496	0	170	100
-25% Cutoff	20	757	2	18	90
+25% Cutoff	20	1258	19	1	95
+50% Cutoff	40	1504	40	0	100
+75% Cutoff	20	1744	20	0	100

The results summary for MTD:

% of Cutoff	Number of samples	Drug Concentration by LC/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	170	155	0	170	100
-25% Cutoff	20	228	1	19	95
+25% Cutoff	20	377	19	1	95
+50% Cutoff	40	454	40	0	100
+75% Cutoff	20	528	20	0	100

The results summary for MOR:

% of Cutoff	Number of samples	Drug Concentration by LC/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	77	0	20	100
-50% Cutoff	170	155	0	170	100
-25% Cutoff	20	227	2	18	90
+25% Cutoff	20	371	18	2	90
+50% Cutoff	40	447	40	0	100
+75% Cutoff	20	521	20	0	100

The results summary for OXY:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	20	0	100
-75% Cutoff	20	23	20	0	100
-50% Cutoff	170	53	0	170	100

-25% Cutoff	20	72	1	19	95
+25% Cutoff	20	128	19	1	95
+50% Cutoff	40	154	40	0	100
+75% Cutoff	20	171	20	0	100

The results summary for PCP:

% of Cutoff	Number of samples	Drug Concentration by LC/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	7	0	20	100
-50% Cutoff	170	11	0	170	100
-25% Cutoff	20	18	1	19	95
+25% Cutoff	20	32	19	1	95
+50% Cutoff	40	39	40	0	100
+75% Cutoff	20	44	20	0	100

The results summary for THC:

% of Cutoff	Number of samples	Drug Concentration by LC/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	13	0	20	100
-50% Cutoff	170	24	0	170	100
-25% Cutoff	20	38	1	19	95
+25% Cutoff	20	64	19	1	95
+50% Cutoff	40	77	40	0	100
+75% Cutoff	20	86	20	0	100

The results summary for BZO:

% of Cutoff	Number of samples	Drug Concentration by LC/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	170	146	0	170	100
-25% Cutoff	20	228	2	18	90
+25% Cutoff	20	377	20	0	100
+50% Cutoff	40	452	40	0	100
+75% Cutoff	20	519	20	0	100

The results summary for MDMA:

% of Cutoff	Number of samples	Drug Concentration by LC/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	121	0	20	100
-50% Cutoff	170	253	0	170	100

-25% Cutoff	20	371	1	19	95
+25% Cutoff	20	628	19	1	95
+50% Cutoff	40	756	40	0	100
+75% Cutoff	20	879	20	0	100

The results summary for TCA:

% of Cutoff	Number of samples	Drug Concentration by LC/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	254	0	20	100
-50% Cutoff	170	505	0	170	100
-25% Cutoff	20	755	1	19	95
+25% Cutoff	20	1258	18	2	90
+50% Cutoff	40	1508	40	0	100
+75% Cutoff	20	1745	20	0	100

The results summary for EDDP:

% of Cutoff	Number of samples	Drug Concentration by LC/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	170	148	0	170	100
-25% Cutoff	20	228	1	19	95
+25% Cutoff	20	373	19	1	95
+50% Cutoff	40	454	40	0	100
+75% Cutoff	20	523	20	0	100

The results summary for PPX:

% of Cutoff	Number of samples	Drug Concentration by LC/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	170	154	0	170	100
-25% Cutoff	20	228	0	20	100
+25% Cutoff	20	378	19	1	95
+50% Cutoff	40	453	40	0	100
+75% Cutoff	20	523	20	0	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 Panel Dip Tests and AssureTech Quick Cup Tests are substantially equivalent to the predicate.