August 20, 2018

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

Re: k181768
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, NFY, NGG, NFW, NGL, NFV, PTH, NGM, PTG, QAW, QBF
Dated: June 29, 2018
Received: July 19, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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)*
k181768

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	500 ng/mL
Oxazepam	300 ng/mL
Cocaine	150 ng/mL
Marijuana	50 ng/mL
Methamphetamine	500 ng/mL
Morphine	300 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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510(k) SUMMARY

1. Date: June 29, 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.
Building 1, No.10, Xiyuansan Road, Westlake Economic Zone
Hangzhou, China, 310030
Telephone: 510-860-4680
Email: customerservice@assurelabs.com.

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: K122809

   The Advin Multi-Drug Screen Tests

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	500 ng/mL
Oxazepam	300 ng/mL
Cocaine	150 ng/mL
Marijuana	50 ng/mL
Methamphetamine	500 ng/mL
Morphine	300 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 - K122809
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): 500 ng/ml Oxazepam (BZO):300 ng/ml Cocaine(COC): 150 ng/ml Marijuana (THC):50 ng/ml Methamphetamine (MET): 500 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 - K122809
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): 500 ng/ml Oxazepam (BZO):300 ng/ml Cocaine(COC): 150 ng/ml Marijuana (THC):50 ng/ml Methamphetamine (MET): 500 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 Amphetamine (AMP500), Cocaine (COC150) and Methamphetamine (MET500). The rest data were reported in the k180349.

AMP500

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+	8-/42+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	11-/39+	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+	7-/43+	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+	8-/42+	50+/0-	50+/0-	50+/0-	50+/0-

COC150

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+	13-/37+	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+	11-/39+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	7-/43+	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-

MET500

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+	12-/38+	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-

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+	11-/39+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	13-/37+	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 lots 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 table. 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 lots of each device. The lowest concentration that caused a positive result for each compound are listed below for Amphetamine (AMP500), Cocaine (COC150) and Methamphetamine (MET500). The rest data were reported in the k180349. There were no differences observed for different devices.

AMP500 (Cut-off=500 ng/mL)	**Result Positive at (ng/mL)**	**% Cross-Reactivity**
D - Amphetamine	500	100%
L - Amphetamine	10000	5%
DL - Amphetamine	1200	42%
Phentermine	15000	3.3%
Hydroxyamphetamine	4000	12.5%
Methylenedioxyamphetamine (MDA)	500	100%
d-Methamphetamine	＞100000	<0.5%
1-Methamphetamine	＞100000	<0.5%
Ephedrine	＞100000	<0.5%
Methylenedioxyethylamphetamine (MDE)	＞100000	<0.5%
3,4-methylenedioxy-methamphetamine (MDMA)	＞100000	<0.5%

Cocaine (Cut-off=150 ng/mL)	**Result Positive at (ng/mL)**	**% Cross-Reactivity**
Benzoylecgonine	150	100%
Cocaine HCl	500	30%
Cocaethylene	7500	2%
Ecgonine	15000	1%
Norcocaine	50000	0.3%

Methamphetamine (Cut-off=500 ng/mL)	**Result Positive at (ng/ml)**	**% Cross-Reactivity**
D(+)-Methamphetamine	500	100%
(+/-)3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	5000	10%
D/L-Methamphetamine	500	100%
p-Hydroxymethamphetamine	5000	10%
D-Amphetamine	＞100000	＜0.5%
L-Amphetamine	＞100000	＜0.5%
Chloroquine	40000	1.25%
(+/-)-Ephedrine	2000	25%
L-Methamphetamine	5000	10%
(+/-)3,4-Methylenedioxyamphetamine (MDA)	＞100000	＜0.5%
(+/-)3,4-methylenedioxymethamphetamine (MDMA)	5000	10%
β-Phenylethylamine	4000	12.5%
Trimethobenzamide	10000	5%

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 GC/MS results. The results are presented in the tables below for Amphetamine (AMP500), Cocaine (COC150) and Methamphetamine (MET500). The rest data were reported in the k180349.

AMP500

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	14	26
	Negative	10	20	9	0	0
Viewer B	Positive	0	0	1	14	26
	Negative	10	20	9	0	0
Viewer C	Positive	0	0	0	14	26
	Negative	10	20	10	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	7042	498	Positive
Viewer B	7042	498	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	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	1	14	25
	Negative	10	20	9	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Quick Cup Viewer Results

Viewer B	7042	498	Positive
Viewer C	7042	498	Positive

COC150

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	14	26
	Negative	10	20	10	0	0
Viewer B	Positive	0	0	0	13	26
	Negative	10	20	10	1	0
Viewer C	Positive	0	0	0	14	26
	Negative	10	20	10	0	0

Discordant Results

Viewer	**Sample Number**	**LC/MS Result**	**Dip Card Viewer Results**
Viewer B	8026	172	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	26
	Negative	10	20	10	0	0
Viewer B	Positive	0	0	0	14	26
	Negative	10	20	10	0	0
Viewer C	Positive	0	0	0	14	26
	Negative	10	20	10	0	0

MET500

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	14	26
	Negative	10	20	10	0	0
Viewer	Positive	0	0	0	13	26

B	Negative	10	20	10	1	0
Viewer C	Positive	0	0	0	13	26
	Negative	10	20	10	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer B	9072	520	Negative
Viewer C	9036	520	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	13	26
	Negative	10	20	10	1	0
Viewer B	Positive	0	0	0	13	26
	Negative	10	20	10	1	0
Viewer C	Positive	0	0	0	14	26
	Negative	10	20	10	0	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Quick Cup Viewer Results
Viewer A	9063	531	Negative
Viewer C	9036	520	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	132	0	20	100
-50% Cutoff	170	262	0	170	100
-25% Cutoff	20	381	0	20	100
+25% Cutoff	20	637	19	1	95
+50% Cutoff	40	765	40	0	100

+75% Cutoff	20	884	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	80	0	20	100
-50% Cutoff	170	160	0	170	100
-25% Cutoff	20	229	2	18	90
+25% Cutoff	20	368	19	1	95
+50% Cutoff	40	447	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	2.4	0	20	100
-50% Cutoff	170	4.6	0	170	100
-25% Cutoff	20	7.7	1	19	95
+25% Cutoff	20	13.2	19	1	95
+50% Cutoff	40	15.2	40	0	100
+75% Cutoff	20	16.9	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	78	0	20	100
-50% Cutoff	170	157	0	170	100
-25% Cutoff	20	220	0	20	100
+25% Cutoff	20	382	20	0	100
+50% Cutoff	40	461	40	0	100
+75% Cutoff	20	531	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	39	0	20	100
-50% Cutoff	170	80	0	170	100
-25% Cutoff	20	115	0	20	100
+25% Cutoff	20	192	19	1	95
+50% Cutoff	40	221	40	0	100

+75% Cutoff	20	268	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	154	0	170	100
-25% Cutoff	20	231	2	18	90
+25% Cutoff	20	376	20	0	100
+50% Cutoff	40	464	40	0	100
+75% Cutoff	20	533	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	122	0	20	100
-50% Cutoff	170	265	0	170	100
-25% Cutoff	20	386	1	19	95
+25% Cutoff	20	633	20	0	100
+50% Cutoff	40	768	40	0	100
+75% Cutoff	20	890	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	134	0	20	100
-50% Cutoff	170	259	0	170	100
-25% Cutoff	20	383	0	20	90
+25% Cutoff	20	637	19	1	95
+50% Cutoff	40	771	40	0	100
+75% Cutoff	20	889	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	78	0	20	100
-50% Cutoff	170	154	0	170	100
-25% Cutoff	20	229	1	19	95
+25% Cutoff	20	369	19	1	95
+50% Cutoff	40	457	40	0	100

+75% Cutoff	20	530	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	146	0	170	100
-25% Cutoff	20	232	0	20	90
+25% Cutoff	20	379	19	1	95
+50% Cutoff	40	446	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	28	20	0	100
-50% Cutoff	170	48	0	170	100
-25% Cutoff	20	79	1	19	95
+25% Cutoff	20	129	19	1	95
+50% Cutoff	40	147	40	0	100
+75% Cutoff	20	179	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	8	0	20	100
-50% Cutoff	170	14	0	170	100
-25% Cutoff	20	21	2	18	90
+25% Cutoff	20	30	19	1	95
+50% Cutoff	40	39	40	0	100
+75% Cutoff	20	48	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	71	0	20	100
-50% Cutoff	170	152	0	170	100
-25% Cutoff	20	228	1	19	95
+25% Cutoff	20	382	20	0	100
+50% Cutoff	40	455	40	0	100

+75% Cutoff	20	522	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	265	0	20	100
-50% Cutoff	170	514	0	170	100
-25% Cutoff	20	763	0	20	100
+25% Cutoff	20	1279	20	0	100
+50% Cutoff	40	1531	40	0	100
+75% Cutoff	20	1782	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	14	0	20	100
-50% Cutoff	170	27	0	170	100
-25% Cutoff	20	39	1	19	95
+25% Cutoff	20	60	19	1	95
+50% Cutoff	40	78	40	0	100
+75% Cutoff	20	84	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.