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

May 2, 2017

ASSURE TECH (HANGZHOU) CO., LTD.
C/O JOE SHIA
LSI INTERNATIONAL. INC
504 E DIAMOND AVE.
SUITE I
GAITHERSBURG MD 20877

Re: k170049
Trade/Device Name: AssureTech Panel Dip Tests,
AssureTech Quick Cup Test
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: II
Product Code: NFT, NFW, NFY, NGG, NGL, NFV, PTH, NGM, PTG
Dated: March 18, 2017
Received: March 24, 2017

Dear Joe Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling 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,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

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, Cannabinoids, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine and Methadone 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
Cannabinoids	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

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, Oxazepam, Secobarbital 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.
The tests are 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

1. Date: April 21, 2017

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)

5. Predicate Devices: K142396

The Chemtrue® Multi-Panel Drug Screen Dip Card Tests

6. Intended 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 and Methadone 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

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, Oxazepam, Secobarbital 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.

The tests are intended for over-the-counter and for prescription use.

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 and Methadone (target analytes) in human urine. 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.

The AssureTech Panel Dip Tests comprise two items, a urine collection cup and the dip card with a plastic casing as the lateral flow device. The AssureTech Quick Cup Tests comprise a urine collection cup and a quick cup test with a lateral flow device that will start when the cap is screwed onto cup.

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 - K142396
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	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 and prescription uses.	Same
Configurations	Dip Card, Cup	Dip Card

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

Item	Device	Predicate - K142396
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	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 and prescription uses.	Same
Configurations	Dip Card, Cup	Dip Card

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 and Methadone 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 Oxazepam, Methylenedioxy-methamphetamine and Morphine. The rest data were reported in k153465, k151211, k152025 and k161044.

Oxazepam

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+	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+	8-/42+	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-

Methylenedioxy-methamphetamine

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+	13-/37+	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+	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+	11-/39+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	12-/38+	50+/0-	50+/0-	50+/0-	50+/0-

Morphine (300 ng/mL Cut-off)

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+	11-/39+	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+	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+	8-/42+	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-

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

Acetominophen	Ecgonine methyl ester	D,L-Octopamine
Acetophenetidin	EMDP	Oxalic acid
N-Acetylprocainamide	Erythromycin	Oxolinic acid
Acetylsalicylic acid	β-Estradiol	Oxymetazoline
Albumin (100mg/dL)	Fenoprofen	Papaverine
Aminopyrine	Furosemide	Penicillin-G
Amoxicillin	Gentisic acid	Perphenazine
Ampicillin	Hemoglobin	Phenelzine
Apomorphine	Hydralazine	Prednisone
Ascorbic acid	Hydrochlorothiazide	DL-Propranolol
Aspartame	Hydrocortisone	D-Pseudoephedrine
Atropine	O-Hydroxyhippuric acid	Quinine
Benzilic acid	3-Hydroxytyramine	Ranitidine
Benzoic acid	Ibuprofen	Salicylic acid
Bilirubin	D,L-Isoproterenol	Serotonin (5- Hydroxytyramine)
Chloralhydrate	Isoxsuprine	Sulfamethazine
Chloramphenicol	Ketamine	Sulindac
Chlorothiazide	Ketoprofen	Tetrahydrocortisone, 3-acetate
Chlorpromazine	Labetalol	Tetrahydrocortisone 3-(β-Dglucuronide)
Cholesterol	Loperamide	Tetrahydrozoline
Clonidine	Maprotiline	Thiamine
Cortisone	Meperidine	Thioridazine
(-) Cotinine	Meprobamate	Triamterene
Creatinine	Methoxyphenamine	DL-Tyrosine
Deoxycorticosterone	Nalidixic acid	Trifluoperazine
Dextromethorphan	Naloxone	Trimethoprim
Diclofenac	Naltrexone	D L-Tryptophan
Diflunisal	Naproxen	Tyramine
Digoxin	Niacinamide	Uric acid
Diphenhydramine	Nifedipine	Verapamil
Disopyramide	Norethindrone	Zomepirac
EDDP	Noscapine	

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 Oxazepam, Methylenedioxy-methamphetamine and Morphine. The rest data were reported in k153465, k151211, k152025 and k161044. There were no differences observed for different devices.

Oxazepam (Cut-off=300 ng/mL)	**Result Positive at (ng/mL)**	**% Cross-Reactivity**
Oxazepam	300	100%
Alprazolam	150	200%
a-Hydroxyalprazolam	1000	30%
Bromazepam	1000	30%
Chiordiazepoxide	63	476.2%
Clonazepam	2500	12%
Clobazam	75	400%
Clorazepate dipotassium	100	300%
Desalkylflurazepam	500	60%
Diazepam	500	60%
Estazolam	500	60%
Flunitrazepam	＞50000	＜0.6%
D,L-Lorazepam	10000	3%
Midazolam	10000	3%
Nitrazepam	75	400%
Norchiordiazepoxide	62.5	480%
Nordiazepam	125	240%
Temazepam	75	400%
Trazolam	1000	30%

Ecstasy (Cut-off=500 ng/mL)	**Result Positive at(ng/ml)**	**% Cross-Reactivity**
Methylenedioxymethamphetamine (MDMA)	500	100%
3,4-Methylenedioxyamphetamine (MDA)	5,000	10%
3,4-Methylenedioxyethylamphetamine (MDEA)	300	166.7%
d-methamphetamine	>50000	＜1%
d-amphetamine	>50000	＜1%
l-amphetamine	>50000	＜1%
l-methamphetamine	>50000	＜1%

Morphine (Cut-off=300 ng/mL)	**Result Positive at(ng/ml)**	**% Cross-Reactivity**
Morphine	300	100%
Codeine	300	100%
Ethylmorphine	310	96.8%
Hydrocodone	25000	1.2%
Hydromorphine	10000	3%
Levorphanol	>100000	＜0.3%
6-Acetylmorphine	250	120%
Morphine 3-β-D-glucuronide	10000	3%
Normorphine	100000	0.3%
Oxycodone	>100000	＜0.3%
Oxymorphone	>100000	＜0.3%
Procaine	>100000	＜0.3%
Thebaine	>100000	＜0.3%
Heroine	500	60%

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 Oxazepam, Methylenedioxy-methamphetamine and Morphine. The rest data were reported in k153465, k151211, k152025 and k161044.

Oxazepam

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	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	Dip Card Viewer Results
Viewer C	41261	289.61	Positive
Viewer A	35578	310.69	Negative
Viewer B	35578	310.69	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	Positive	0	0	1	15	25

C	Negative	10	20	9	0	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Quick Cup Viewer Results
Viewer C	41261	289.6	Positive
Viewer A	73291	311.7	Negative
Viewer B	35578	310.6	Negative

Methylenedioxy-methamphetamine

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	25
	Negative	10	20	9	1	0
Viewer B	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Viewer C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	37623	491.17	Positive
Viewer B	37623	491.17	Positive
Viewer C	37623	491.17	Positive
Viewer A	61074	508.34	Negative
Viewer B	61074	508.34	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	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	14	25
	Negative	10	20	9	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Quick Cup Viewer Results

Viewer A	37623	491.17	Positive
Viewer B	37623	491.17	Positive
Viewer C	37623	491.17	Positive
Viewer A	61074	508.34	Negative
Viewer C	61074	508.34	Negative

Morphine

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	25
	Negative	10	20	9	1	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 A	90003	278.16	Positive
Viewer B	80161	280.75	Positive
Viewer A	59386	322.85	Negative
Viewer B	98199	306.08	Negative
Viewer C	98199	306.08	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	0	15	25
	Negative	10	20	10	0	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Quick Cup Viewer Results
Viewer A	80161	280.75	Positive
Viewer B	80161	280.75	Positive

Viewer B	59386	322.85	Negative

Lay-user study

A lay user study was performed at three intended user sites with 280 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	
			No. of Positive	No. of Negative
-100% Cutoff	20	0	0	20
-75% Cutoff	20	248	0	20
-50% Cutoff	140	508	0	140
-25% Cutoff	20	752	1	19
+25% Cutoff	20	1255	19	1
+50% Cutoff	40	1506	40	0
+75% Cutoff	20	1748	20	0

The results summary for BAR:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results	
			No. of Positive	No. of Negative
-100% Cutoff	20	0	0	20
-75% Cutoff	20	73	0	20
-50% Cutoff	140	151	0	140
-25% Cutoff	20	223	1	19
+25% Cutoff	20	378	20	0
+50% Cutoff	40	456	40	0
+75% Cutoff	20	521	20	0

The results summary for COC:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results	
			No. of Positive	No. of Negative
-100% Cutoff	20	0	0	20
-75% Cutoff	20	76	0	20
-50% Cutoff	140	154	0	140
-25% Cutoff	20	222	1	19
+25% Cutoff	20	377	20	0
+50% Cutoff	40	452	40	0
+75% Cutoff	20	528	20	0

The results summary for BUP:

% of Cutoff	Number of	Drug Concentration by	Lay person Results

	samples	LC/MS(ng/mL)	No. of Positive	No. of Negative
-100% Cutoff	20	0	0	20
-75% Cutoff	20	2.6	0	20
-50% Cutoff	140	4.8	0	140
-25% Cutoff	20	7.2	2	18
+25% Cutoff	20	12.6	20	0
+50% Cutoff	40	15.4	40	0
+75% Cutoff	20	17.3	20	0

The results summary for MET:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results	
			No. of Positive	No. of Negative
-100% Cutoff	20	0	0	20
-75% Cutoff	20	255	0	20
-50% Cutoff	140	496	0	140
-25% Cutoff	20	757	1	19
+25% Cutoff	20	1258	20	0
+50% Cutoff	40	1504	40	0
+75% Cutoff	20	1744	20	0

The results summary for MTD:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results	
			No. of Positive	No. of Negative
-100% Cutoff	20	0	0	20
-75% Cutoff	20	73	0	20
-50% Cutoff	140	155	0	140
-25% Cutoff	20	228	0	20
+25% Cutoff	20	377	19	1
+50% Cutoff	40	454	40	0
+75% Cutoff	20	528	20	0

The results summary for MOR:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results	
			No. of Positive	No. of Negative
-100% Cutoff	20	0	0	20
-75% Cutoff	20	77	0	20
-50% Cutoff	140	155	0	140
-25% Cutoff	20	227	1	19
+25% Cutoff	20	371	20	0
+50% Cutoff	40	447	40	0
+75% Cutoff	20	521	20	0

The results summary for OXY:

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

-50% Cutoff	140	53	0	140
-25% Cutoff	20	72	1	19
+25% Cutoff	20	128	19	1
+50% Cutoff	40	154	40	0
+75% Cutoff	20	171	20	0

The results summary for PCP :

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results	
			No. of Positive	No. of Negative
-100% Cutoff	20	0	0	20
-75% Cutoff	20	7	0	20
-50% Cutoff	140	11	0	140
-25% Cutoff	20	18	2	18
+25% Cutoff	20	32	20	0
+50% Cutoff	40	39	40	0
+75% Cutoff	20	44	20	0

The results summary for THC:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results	
			No. of Positive	No. of Negative
-100% Cutoff	20	0	0	20
-75% Cutoff	20	13	0	20
-50% Cutoff	140	24	0	140
-25% Cutoff	20	38	1	19
+25% Cutoff	20	64	19	1
+50% Cutoff	40	77	40	0
+75% Cutoff	20	86	20	0

The results summary for BZO:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results	
			No. of Positive	No. of Negative
-100% Cutoff	20	0	0	20
-75% Cutoff	20	73	0	20
-50% Cutoff	140	146	0	140
-25% Cutoff	20	228	1	19
+25% Cutoff	20	377	20	0
+50% Cutoff	40	452	40	0
+75% Cutoff	20	519	20	0

The results summary for MDMA:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results	
			No. of Positive	No. of Negative
-100% Cutoff	20	0	0	20
-75% Cutoff	20	121	0	20
-50% Cutoff	140	253	0	140
-25% Cutoff	20	371	0	20
+25% Cutoff	20	628	19	1
+50% Cutoff	40	756	40	0

+75% Cutoff	20	879	20	0

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.