February 7, 2025

Assure Tech LLC
% Jenny Xia
Director
LSI International Inc
504E Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K243996
Trade/Device Name: AssureTech Panel Dip Tests; AssureTech Quick Cup Tests; AssureTech Multi-drug Urine Test Panel; AssureTech Multi-drug Urine Test Cup
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: NFT, PTH, NGL, NFV, NFY, PTG, NGG, NGM, QAW, NFW, QBF
Dated: December 22, 2024
Received: December 26, 2024

Dear Jenny Xia:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joseph A. Kotarek -S

Digitally signed by Joseph A. Kotarek -S
Date: 2025.02.07 09:19:07 -05'00'

Joseph Kotarek, Ph.D.
Branch Chief for Toxicology
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243996

Device Name
AssureTech Panel Dip Tests;
AssureTech Quick Cup Tests;
AssureTech Multi-drug Urine Test Panel; AssureTech Multi-drug Urine Test Cup

Indications for Use *(Describe)*
The AssureTech Panel Dip Tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Fentanyl, Norfentanyl, 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 (AMP)	500 ng/mL
Secobarbital (BAR)	300 ng/mL
Buprenorphine (BUP)	10 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	150 ng/mL
Methadone metabolite (EDDP)	300ng/ml
Fentanyl (FYL)	1 ng/mL
Ecstasy (MDMA)	500 ng/mL
Methamphetamine (MET)	500 ng/mL
Morphine (MOR)	300 ng/mL
Methadone (MTD)	300 ng/mL
Norfentanyl (NFYL)	5 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

The single or multi-test panels can consist of up to seventeen (17) of the above listed analytes in any combination. 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.

The AssureTech Quick Cup Tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Fentanyl, Norfentanyl, 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 (AMP)	500 ng/mL
Secobarbital (BAR)	300 ng/mL
Buprenorphine (BUP)	10 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	150 ng/mL
Methadone metabolite (EDDP)	300ng/ml

Fentanyl (FYL)	1 ng/mL
Ecstasy (MDMA)	500 ng/mL
Methamphetamine (MET)	500 ng/mL
Morphine (MOR)	300 ng/mL
Methadone (MTD)	300 ng/mL
Norfentanyl (NFYL)	5 ng/mL
Oxycodone (OXY)	100 ng/mL
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Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

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For in vitro diagnostic use only.

The AssureTech Multi-drug Urine Test Panel are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Fentanyl, Norfentanyl, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline, d-Propoxyphene and adulterants in human urine at the cutoff concentrations of:

Drug (Identifier)	Cut-off level
Amphetamine (AMP)	500 ng/mL
Secobarbital (BAR)	300 ng/mL
Buprenorphine (BUP)	10 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	150 ng/mL
Methadone metabolite (EDDP)	300ng/ml
Fentanyl (FYL)	1 ng/mL
Ecstasy (MDMA)	500 ng/mL
Methamphetamine (MET)	500 ng/mL
Morphine (MOR)	300 ng/mL
Methadone (MTD)	300 ng/mL
Norfentanyl (NFYL)	5 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

The single or multi-test panel can consist of up to seventeen (17) of the above listed analytes in any combination. It is for in vitro diagnostic use only.
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. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

The AssureTech Multi-drug Urine Test Cup are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Fentanyl, Norfentanyl, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline, d-Propoxyphene and adulterants in human urine at the cutoff concentrations of:

Drug (Identifier)	Cut-off level
Amphetamine (AMP)	500 ng/mL
Secobarbital (BAR)	300 ng/mL
Buprenorphine (BUP)	10 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	150 ng/mL
Methadone metabolite (EDDP)	300ng/ml
Fentanyl (FYL)	1 ng/mL
Ecstasy (MDMA)	500 ng/mL
Methamphetamine (MET)	500 ng/mL
Morphine (MOR)	300 ng/mL
Methadone (MTD)	300 ng/mL
Norfentanyl (NFYL)	5 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

The single or multi-test cups can consist of up to seventeen (17) of the above listed analytes in any combination. It is for in vitro diagnostic use only.
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. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

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
K243996

1. Date: December 22, 2024

2. Submitter:
Assure Tech. LLC.
1521 Concord Pike, Suite 201
Wilmington, DE 19803

3. Contact person:
Jenny Xia
LSI International Inc.
504E Diamond Ave., Suite H
Gaithersburg, MD 20877
Telephone: 301-525-6856
Email: jxia@lsi-consulting.org

4. Device Name:
AssureTech Panel Dip Tests
AssureTech Multi-drug Urine Test Panel
AssureTech Quick Cup Tests
AssureTech Multi-drug Urine Test Cup

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, Opiate 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)
NGL Fentanyl Norfentanyl	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: K181768

   AssureTech Panel Dip Tests and AssureTech Quick Cup Tests

6. Indications for Use

   The AssureTech Panel Dip Tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Fentanyl, Norfentanyl, 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**
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Morphine (MOR)	300 ng/mL
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Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

   The single or multi-test panels can consist of up to seventeen (17) of the above listed analytes in any combination.

   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.

   The AssureTech Quick Cup Tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Fentanyl, Norfentanyl, 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 (AMP)	500 ng/mL
Secobarbital (BAR)	300 ng/mL
Buprenorphine (BUP)	10 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	150 ng/mL
Methadone metabolite (EDDP)	300ng/ml
Fentanyl (FYL)	1 ng/mL
Ecstasy (MDMA)	500 ng/mL
Methamphetamine (MET)	500 ng/mL
Morphine (MOR)	300 ng/mL
Methadone (MTD)	300 ng/mL
Norfentanyl (NFYL)	5 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

The single or multi-test cups can consist of up to seventeen (17) of the above listed analytes in any combination.

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.

The AssureTech Multi-drug Urine Test Panel are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Fentanyl, Norfentanyl, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline, d-Propoxyphene and adulterants in human urine at the cutoff concentrations of:

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Amphetamine (AMP)	500 ng/mL
Secobarbital (BAR)	300 ng/mL
Buprenorphine (BUP)	10 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	150 ng/mL
Methadone metabolite (EDDP)	300ng/ml
Fentanyl (FYL)	1 ng/mL
Ecstasy (MDMA)	500 ng/mL
Methamphetamine (MET)	500 ng/mL
Morphine (MOR)	300 ng/mL
Methadone (MTD)	300 ng/mL
Norfentanyl (NFYL)	5 ng/mL
Oxycodone (OXY)	100 ng/mL

Phencyclidine(PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana(THC)	50 ng/mL

The single or multi-test cups can consist of up to seventeen (17) of the above listed analytes in any combination. It is for *in vitro* diagnostic use only.

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. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

The AssureTech Multi-drug Urine Test Cup are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Fentanyl, Norfentanyl, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline, d-Propoxyphene and adulterants in human urine at the cutoff concentrations of:

Drug (Identifier)	**Cut-off level**
Amphetamine (AMP)	500 ng/mL
Secobarbital (BAR)	300 ng/mL
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Oxazepam (BZO)	300 ng/mL
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Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

The single or multi-test cups can consist of up to seventeen (17) of the above listed analytes in any combination. It is for *in vitro* diagnostic use only.

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. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

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, Fentanyl, Norfentanyl, 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/AssureTech Quick Cup Tests and the Predicate Devices

Item	Device	Predicate - K181768
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 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 Fentanyl (FYL): 1ng/ml Norfentanyl (NFYL): 5ng/ml	Same except that no FYL and NFYL
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 and 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, Fentanyl, Norfentanyl, 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 Fentanyl and Norfentanyl. Data supporting precision for the remaining analytes was reported in K181768.

Fentanyl

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+	49-/1+	28+/22-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	49-/1+	29+/23-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	28+/22-	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+	49-/1+	29+/21-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	27+/23-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	49-/1+	29+/21-	50+/0-	50+/0-	50+/0-	50+/0-

Norfentanyl

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+	49-/1+	27+/23-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	49-/1+	28+/22-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	49-/1+	28+/22-	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+	49-/1+	29+/21-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	49-/1+	27+/23-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	28+/22-	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 50% below and 50% 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 or specified concentrations are summarized in the following table. There were no differences observed for different devices.

11-nor-9 carboxy THC (except for THC)	DL-Tyrosine	Nifedipine
3-Hydroxytyramine	Dopamine	Norethindrone
4-Bromo-2,5,Dimethoxyphenethylamine	Doxepin (except for TCA)	Norpropoxyphene (except for PPX)
7-Aminoflunitrazepam	Ecgonine methyl ester	Norpseudoephedrine
7-Aminonitrazepam	Ephedrine (except for MET)	Nortriptyline (except for TCA)
Acetaminophen	Erythromycin	Noscapine
Acetone (1000 mg/dL)	Estradiol	Octopamine
Acetophenetidin	Estrone	O-Hydroxyhippuric acid
Acetylsalicylic Acid (500 µg/mL)	Ethanol (1%)	Oxalic Acid (100mg/dL)
Albumin (100 mg/dL)	Fenfluramine (except for MET)	Oxazepam (except for BZO)
Albuterol	Fenofibrate	Oxolinic acid
Aminopyrine	Fenoprofen	Oxymetazoline
Amitriptyline (except for TCA)	Fluphenazine	Papaverine
Amlodipine besylate	Fotemustine	Penicillin-G
Amobarbital (except for BAR)	Furosemide	Pentazocine
Amoxicillin	Galactose	Perphenazine
Ampicillin	Gamma Globulin (500mg/dL)	Phencyclidine (except for PCP)
Apomorphine	Gemfibrozil	Phenelzine
Ascorbic Acid	Gentisic acid	Phenobarbital (except for BAR)
Aspartame	Glucose (3000 mg/dL)	Phentermine (except for AMP)
Aspirin	Guaiacolglyceryl ether	Phenylethylamine (except for MET)
Atropine	Hemoglobin	Prednisone
Baclofen	Hexobarbital	Promazine (except for TCA/EDDP)
Benzilic acid	Hydralazine	Promethazine
Benzocaine6	Hydrochlorothiazide	Propoxyphene (except for PPX)
Benzoic Acid	Hydrocortisone	Propranolol
Benzoylecgonine (except for COC)	Hydroxytyramine	Pseudoephedrine
Benzylpiperiazine	Ibuprofen	Pyridoxine
Bilirubin	I-Cotinine	Pyrilamine
Boric Acid (1%)	I-Erythromycin	Pyrogallol
Bupropion	Imipramine (except for TCA)	Quinidine
Caffeine (500 µg/mL)	Isoproterenol	Quinine
Carbamazepine	Isoxsuprine	Quinolinic Acid
Carisoprodol	Ketamine	Ranitidine
Cetirizine	Ketoprofen	r-Globulin
Chloral hydrate	Labetalol	Riboflavin
Chloramphenicol	Lamotrigine	Salicylic Acid
Chlordiazepoxide ((except for BZO)	Lidocaine	Secobarbital (except for BAR)
Chlorothiazide	Lisinopril	Serotonin(5-Hydroxytyramine)
Chlorpheniramine	Loperamide	Sodium Azide
Chlorpromazine	Loratidine	Sufentanil Citrate
Cholesterol	Lorazepam (except for BZO)	Sulfamethazine

Clofibrate	LSD	Sulindac
Clomipramine (except for TCA)	L-thyroxine	Tetracycline
Clonidine	Maprotiline (except for TCA)	Tetrahydrocortisone 3-acetate
Cortisone	Meperidine	Tetrahydrocortisone3-(β-Dglucuronide)
Cotinine	Meprobamate	Tetrahydrozoline
Creatine Hydrate	Metformin	Thiamine
Creatinine	Methapyrilene	Thioridazine
Cyclobenzaprine (except for TCA)	Methaqualone	Triamterene
Cyclodextrin-r	Methoxyphenamine (except for AMP/MET)	Trifluoperazine
Cyproheptadine	Methylphenidate	Trifluoromethylphenyl- piperazine
d,l-Isoproterenol	Metoprolol	Trimethoprim
Demoxepam	Metronidazole (300 ug/mL)	Tryptamine
Deoxycorticosterone	N-Acetylprocainamide	Tyramine
Desipramine (except for TCA)	NaCl (40000 ug/mL)	Urea (2000 mg/dL)
Dextromethorphan	Nalidixic Acid	Uric Acid
Diclofenac	Naloxone (except for OXY)	Valproic acid (250 ug/mL)
Diflunisal	Naltrexone	Venlafaxine
Digoxin	Naproxen	Verapamil
Dimethyl-aminoantipyrine	N-desmethylapentadol	Zolpidem
Diphenhydramine	Niacinamide	Zolpidem Tartrate
Diphenylhydantoin	Nicotine	Zomepirac
DL-Tryptophan	Nicotinic Acid	β-Estradiol
β-Hydroxybutyric Acid		

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 Fentanyl and Norfentanyl. Data supporting specificity for the remaining analytes was reported in K181768. There were no differences observed for different devices.

Fentanyl (Cutoff=1ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
(±) β-hydroxythiofentanyl	5	20
(±)-3-cis-methyl fentanyl	50	2
4-Fluoro-isobutyrylfentanyl	50	2
Acetyl fentanyl	5	20
Acryl fentanyl	5	20
Butyryl fentanyl	25	4
Fentanyl	1	100
Furanyl fentanyl	10	10
Isobutyryl fentanyl	5	20
Ocfentanil	100	1
Para-fluoro fentanyl	25	4
Para-fluorobutyryl fentanyl	25	4
Valeryl fentanyl	50	2
ω-1-Hydroxyfentanyl	50000	0.002
Acetyl norfentanyl	>100000	<0.001
Alfentanil	>100000	<0.001
Norcarfentanil	>10000	<0.01
Norfentanyl	>100000	<0.001
Remifentanil	>10000	<0.01
Sufentanil	>10000	<0.01
Carfentanil	>10000	<0.01

Despropionyl fentanyl (4-ANPP)	>50000	<0.002

Norfentanyl (Cutoff=5ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
(±)-β-Hydroxythiofentanyl	80	6.25
4-Fluoro-isobutyryl Fentanyl	250	2
9-HydroxyRisperidone	10000	0.05
Acetyl Fentanyl	500	1
Acetyl Norfentanyl	50	10
Acryl Fentanyl	100	5
Alfentanil	100000	0.005
Butyryl Fentanyl	500	1
(±)-3-cis-methyl fentanyl	200	2.5
trans-d, l-3-methylfentanyl	200	2.5
Fentanyl	500	1
Furanyl Fentanyl	1000	0.5
Isobutyryl Fentanyl	75	6.67
Labetalol Hydrochloride	100000	0.005
MT-45	8000	0.06
Norfentanyl	5	100
Ocfentanil	5000	0.1
Para-fluorobutyryl fentanyl	100	5
Para-fluoro fentanyl	100	5
Risperidone	800	0.63
Thienyl Fentnayl	100	5
Valeryl Fentanyl	500	1
Carfentanil	>10000	<0.05
Despropionyl fentanyl (4-ANPP)	>50000	<0.01
Norcarfentanil	>10000	<0.05
Remifentanil	>10000	<0.05
Sufentanil	>10000	<0.05
Trazodone	>10000	<0.05
U-47700	>100000	<0.005
ω- 1-Hydroxyfentanyl	>50000	<0.01

Negative results were obtained for all the following opioids compounds tested at 100 µg/mL. There is no cross-reactivity for these compounds.

6-Acetyl morphine	Hydromorphone	Oxycodone
Amphetamine	Levorphanol	Oxymorphone
Buprenorphine	Methadone	Pentazocine (Talwin)
Buprenorphineglucuronide	Morphine	Pipamperone
Codeine	Morphine-3-glucuronide	Tapentadol
Dihydrocodeine	Norbuprenorphine	Tilidine
EDDP	Norcodeine	Tramadol
EMDP	Norketamine	Tramadol-O-Desmethyl

Fluoxetine	Normeperidine	Tramadol-N-Desmethyl
Heroin	Normorphine	
Hydrocodone	Noroxycodone	

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 50% below and 50% above Cut-Off levels. These samples were tested using three lots of each device. Results were all positive for samples at and above +50% Cut-Off and all negative for samples at and below -50% 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 Fentanyl and Norfentanyl. Data supporting method comparison for the remaining analytes was reported in K181768.

FYL

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%)
Operator 1	Positive	0	0	2	19	20
	Negative	1	19	18	1	0
Operator 2	Positive	0	0	2	19	20
	Negative	1	19	18	1	0
Operator 3	Positive	0	0	2	19	20
	Negative	1	19	18	1	0

Discordant Results

Operator	Sample ID	LC/MS Result (ng/mL)	Rapid Test Result
Operator 1, 2, 3	1484	0.78	+
Operator 1	9778	0.95	+
Operator 2, 3	4576	0.97	+
Operator 1	5419	1.05	-
Operator 2, 3	9401	1.00	-

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%)

Operator 1	Positive	0	0	3	19	20
	Negative	1	19	17	1	0
Operator 2	Positive	0	0	2	19	20
	Negative	1	19	18	1	0
Operator 3	Positive	0	0	2	18	20
	Negative	1	19	18	2	0

Discordant Results

Operator	Sample ID	LC/MS Result (ng/mL)	Rapid Test Result
Operator 1, 2, 3	1484	0.78	+
Operator 1, 3	9778	0.95	+
Operator 1, 2	4576	0.97	+
Operator 1, 3	5419	1.05	-
Operator 2, 3	9401	1.00	-

NFYL

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%)
Operator 1	Positive	0	0	3	19	20
	Negative	2	18	18	1	0
Operator 2	Positive	0	0	2	19	20
	Negative	2	18	19	1	0
Operator 3	Positive	0	0	2	18	20
	Negative	2	18	19	2	0

Discordant Results

Operator	Sample ID	LC/MS Result (ng/mL)	Rapid Test Result
Operator 1	4074	4.39	+
Operator 1	1311	4.10	+
Operator 1, 2	0242	4.82	+
Operator 2, 3	5906	4.68	+
Operator 3	2066	4.24	+
Operator 1, 3	0687	5.05	-
Operator 2, 3	8069	5.15	-

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%)
Operator 1	Positive	0	0	2	18	20
	Negative	2	18	18	2	0
Operator 2	Positive	0	0	3	19	20
	Negative	2	18	17	1	0

Operator 3	Positive	0	0	2	19	20
	Negative	2	18	18	1	0

Discordant Results

Operator	Sample ID	LC/MS Result (ng/mL)	Rapid Test Result
Operator 1, 2	4074	4.39	+
Operator 1, 3	0242	4.82	+
Operator 2, 3	2066	4.24	+
Operator 2	5906	4.68	+
Operator 1, 2, 3	0687	5.05	-
Operator 1	8069	5.15	-

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 20 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	124.4	0	20	100
-50% Cutoff	20	246.6	0	20	100
-25% Cutoff	20	377.7	0	20	100
+25% Cutoff	20	621.2	19	1	95
+50% Cutoff	20	756.6	20	0	100
+75% Cutoff	20	870.5	20	0	100

The results summary for FYL:

% 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	0.24	0	20	100
-50% Cutoff	20	0.51	0	20	100
-25% Cutoff	20	0.77	0	19	95
+25% Cutoff	20	1.26	20	0	100
+50% Cutoff	20	1.47	20	0	100
+75% Cutoff	20	1.76	20	0	100

The results summary for NFYL:

% of Cutoff	Number of	Drug	Lay person Results	The percentage

	samples	Concentration by LC/MS(ng/mL)	No. of Positive	No. of Negative	of correct results (%)
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	1.25	0	20	100
-50% Cutoff	20	2.65	0	20	100
-25% Cutoff	20	3.73	0	19	95
+25% Cutoff	20	6.09	20	0	100
+50% Cutoff	20	7.14	20	0	100
+75% Cutoff	20	8.77	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	76.4	0	20	100
-50% Cutoff	20	158.2	0	20	100
-25% Cutoff	20	224.2	2	18	90
+25% Cutoff	20	372.5	19	1	95
+50% Cutoff	20	440.2	20	0	100
+75% Cutoff	20	537.9	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	2.46	0	20	100
-50% Cutoff	20	4.99	0	20	100
-25% Cutoff	20	7.49	1	19	95
+25% Cutoff	20	12.51	19	1	95
+50% Cutoff	20	14.88	20	0	100
+75% Cutoff	20	17.53	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	71.6	0	20	100
-50% Cutoff	20	146.1	0	20	100
-25% Cutoff	20	224.1	2	18	90
+25% Cutoff	20	373.8	20	0	100
+50% Cutoff	20	459.7	20	0	100
+75% Cutoff	20	514.0	20	0	100

The results summary for COC:

% of Cutoff	Number of	Drug	Lay person Results	The percentage

	samples	Concentration by LC/MS(ng/mL)	No. of Positive	No. of Negative	of correct results (%)
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	39.1	0	20	100
-50% Cutoff	20	75.6	0	20	100
-25% Cutoff	20	113.0	1	19	95
+25% Cutoff	20	188.6	19	1	95
+50% Cutoff	20	223.3	20	0	100
+75% Cutoff	20	262.1	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	75.8	0	20	100
-50% Cutoff	20	150.7	0	20	100
-25% Cutoff	20	225.7	1	19	95
+25% Cutoff	20	375.7	19	1	95
+50% Cutoff	20	450.3	20	0	100
+75% Cutoff	20	525.5	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	126.1	0	20	100
-50% Cutoff	20	250.6	0	20	100
-25% Cutoff	20	361.4	1	19	95
+25% Cutoff	20	632.2	20	0	100
+50% Cutoff	20	748.0	20	0	100
+75% Cutoff	20	869.1	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	122.6	0	20	100
-50% Cutoff	20	248.9	0	20	100
-25% Cutoff	20	376.2	0	20	100
+25% Cutoff	20	628.4	19	1	95
+50% Cutoff	20	753.3	20	0	100
+75% Cutoff	20	871.7	20	0	100

The results summary for MOR:

% of Cutoff	Number of	Drug	Lay person Results	The percentage

	samples	Concentration by LC/MS(ng/mL)	No. of Positive	No. of Negative	of correct results (%)
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	76.8	0	20	100
-50% Cutoff	20	150.1	0	20	100
-25% Cutoff	20	225.8	1	19	95
+25% Cutoff	20	376.5	19	1	95
+50% Cutoff	20	449.1	20	0	100
+75% Cutoff	20	526.3	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	75.4	0	20	100
-50% Cutoff	20	157.6	0	20	100
-25% Cutoff	20	225.6	1	19	95
+25% Cutoff	20	374.5	19	1	95
+50% Cutoff	20	451.6	20	0	100
+75% Cutoff	20	524.2	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	26.2	20	0	100
-50% Cutoff	20	50.7	0	20	100
-25% Cutoff	20	75.9	1	19	95
+25% Cutoff	20	125.8	19	1	95
+50% Cutoff	20	146.7	20	0	100
+75% Cutoff	20	173.7	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	6.42	0	20	100
-50% Cutoff	20	12.47	0	20	100
-25% Cutoff	20	19.18	2	18	90
+25% Cutoff	20	31.63	19	1	95
+50% Cutoff	20	37.73	20	0	100
+75% Cutoff	20	43.60	20	0	100

The results summary for PPX:

% of Cutoff	Number of	Drug	Lay person Results	The percentage

	samples	Concentration by LC/MS(ng/mL)	No. of Positive	No. of Negative	of correct results (%)
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	75.0	0	20	100
-50% Cutoff	20	143.7	0	20	100
-25% Cutoff	20	220.6	1	19	95
+25% Cutoff	20	375.2	19	1	95
+50% Cutoff	20	452.5	20	0	100
+75% Cutoff	20	525.3	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	236.9	0	20	100
-50% Cutoff	20	491.6	0	20	100
-25% Cutoff	20	751.3	1	19	95
+25% Cutoff	20	1254.2	20	0	100
+50% Cutoff	20	1493.4	20	0	100
+75% Cutoff	20	1750.5	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	12.3	0	20	100
-50% Cutoff	20	24.1	0	20	100
-25% Cutoff	20	38.3	1	19	95
+25% Cutoff	20	63.3	19	1	95
+50% Cutoff	20	76.1	20	0	100
+75% Cutoff	20	87.4	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, AssureTech Quick Cup Tests, AssureTech Multi-drug Urine Test Panel and AssureTech Multi-drug Urine Test Cup are substantially equivalent to the predicate.