



Food and Drug Administration
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July 6 2016

ASSURE TECH (HANGZHOU) CO., LTD.
SHISHENG LING
GENERAL MANAGER
BUILDING 1, NO.10, XIYUANSAN ROAD
WESTLAKE ECONOMIC ZONE
HANGZHOU, ZHEJIANG 310030, CHINA

Re: k161044

Trade/Device Name: AssureTech Methamphetamine Strip Test
AssureTech Methamphetamine Cup Test
AssureTech Methamphetamine Dip Card Test
AssureTech Methamphetamine Turn Key Split Cup Test
AssureTech Phencyclidine Strip Test
AssureTech Phencyclidine Cup Test
AssureTech Phencyclidine Dip Card Test
AssureTech Phencyclidine Turn Key Split Cup Test
AssureTech Marijuana Strip Test
AssureTech Marijuana Cup Test
AssureTech Marijuana Dip Card Test
AssureTech Marijuana Turn Key Split Cup Test

Regulation Number: 21 CFR §862.3610

Regulation Name: Methamphetamine Test System

Regulatory Class: II

Product Code: DJC, LCM, LDJ

Dated: April 09, 2016

Received: April 13, 2016

Dear Shisheng Ling:

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

Indications for Use

510(k) Number (if known)

k161044

Device Name

AssureTech Marijuana Strip Test

AssureTech Marijuana Dip Card Test

AssureTech Marijuana Cup Test; AssureTech Marijuana Turn Key Split Cup Test

Indications for Use (Describe)

AssureTech Marijuana Tests are immunochromatographic assays for the qualitative determination of 11-Nor- Δ^9 -Tetrahydrocannabinol-9-COOH in human urine at cut-off concentration of 50 ng/mL. The tests are available in a Strip format, a Cup format, a Dip Card format and a Turn Key Split Cup format.

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

For in vitro diagnostic use only. The 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.

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Indications for Use

510(k) Number (if known)

k161044

Device Name

AssureTech Methamphetamine Strip Test

AssureTech Methamphetamine Dip Card Test

AssureTech Methamphetamine Cup Test; AssureTech Methamphetamine Turn Key Split Cup Test

Indications for Use (Describe)

AssureTech Methamphetamine Tests are immunochromatographic assays for the qualitative determination of d-Methamphetamine in human urine at cut-off concentration of 1000 ng/mL. The tests are available in a Strip format, a Cup format, a Dip Card format and a Turn Key Split Cup format.

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

For in vitro diagnostic use only. The 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)

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Indications for Use

510(k) Number (if known)

k161044

Device Name

AssureTech Phencyclidine Strip Test

AssureTech Phencyclidine Dip Card Test

AssureTech Phencyclidine Cup Test; AssureTech Phencyclidine Turn Key Split Cup Test

Indications for Use (Describe)

AssureTech Phencyclidine Tests are immunochromatographic assays for the qualitative determination of Phencyclidine in human urine at cut-off concentration of 25 ng/mL. The tests are available in a Strip format, a Cup format, a Dip Card format and a Turn Key Split Cup format.

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

For in vitro diagnostic use only. The 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)

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510(k) SUMMARY

1. Date: May 27, 2016
2. Submitter: Assure Tech. (Hangzhou) Co., Ltd.
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Hangzhou, China, 310030
3. Contact person: Shisheng Ling
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4. Device Name: AssureTech Methamphetamine Strip Test
AssureTech Methamphetamine Cup Test
AssureTech Methamphetamine Dip Card Test
AssureTech Methamphetamine Turn Key Split Cup Test
AssureTech Phencyclidine Strip Test
AssureTech Phencyclidine Cup Test
AssureTech Phencyclidine Dip Card Test
AssureTech Phencyclidine Turn Key Split Cup Test
AssureTech Marijuana Strip Test
AssureTech Marijuana Cup Test
AssureTech Marijuana Dip Card Test
AssureTech Marijuana Turn Key Split Cup Test

Classification: Class II

Product Code	CFR #	Panel
DJC	21 CFR, 862.3610 Methamphetamine Test System	Toxicology
LCM	21 CFR, 862.3100 Amphetamine Test System	Toxicology
LDJ	21 CFR, 862.3870 Cannabinoids Test System	Toxicology

5. Predicate Devices: K142396

The Chemtrue® Multi-Panel Drug Screen Dip Card Tests

6. Intended Use

AssureTech Methamphetamine Tests are immunochromatographic assays for the qualitative determination of d-Methamphetamine in human urine at cut-off concentration of 1000 ng/mL. The tests are available in a Strip format, a Cup format, a Dip Card format and a Turn Key Split Cup format.

The tests provide only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

AssureTech Phencyclidine Tests are immunochromatographic assays for the qualitative determination of Phencyclidine in human urine at cut-off concentration of 25 ng/mL. The tests are available in a Strip format, a Cup format, a Dip Card format and a Turn Key Split Cup format.

The tests provide only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

AssureTech Marijuana Tests are immunochromatographic assays for the qualitative determination of 11-Nor- Δ^9 -Tetrahydrocannabinol-9-COOH in human urine at cut-off concentration of 50 ng/mL. The tests are available in a Strip format, a Cup format, a Dip Card format and a Turn Key Split Cup format.

The tests provide only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

7. Device Description

The AssureTech Methamphetamine Tests, AssureTech Phencyclidine Tests, and AssureTech Marijuana Tests are immunochromatographic assays that use a lateral flow system for the qualitative detection of d-Methamphetamine, Phencyclidine and Marijuana (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.

8. Substantial Equivalence Information

A summary comparison of features of the AssureTech Methamphetamine Tests, AssureTech Phencyclidine Tests and AssureTech Marijuana Tests and the predicate devices is provided in following tables.

Table 1: Features Comparison of AssureTech Methamphetamine 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	d-Methamphetamine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Cut-Off Values	1000 ng/mL	Same
Intended Use	For over-the-counter and prescription uses.	Same
Configurations	Strip, Dip Card, Cup, Turn Key Split Cup	Dip Card

Table 2: Features Comparison of AssureTech Phencyclidine 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	Phencyclidine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Cut-Off Values	25 ng/mL	Same
Intended Use	For over-the-counter and prescription uses.	Same
Configurations	Strip, Dip Card, Cup, Turn Key Split Cup	Dip Card

Table 3: Features Comparison of AssureTech Marijuana 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	11-Nor- Δ^9 -Tetrahydrocannabinol-9-COOH	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same

Specimen Type	Human Urine	Same
Cut-Off Values	50 ng/mL	Same
Intended Use	For over-the-counter and prescription uses.	Same
Configurations	Strip, Dip Card, Cup, Turn Key Split Cup	DipCard

9. Test Principle

The AssureTech Methamphetamine Tests, AssureTech Phencyclidine Tests, and AssureTech Marijuana Tests are rapid tests for the qualitative detection of d-Methamphetamine, Phencyclidine and Marijuana 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, cut off, +25% cut off, +50% cut off, +75% cut off and +100% cut off. These samples were prepared by spiking drug in negative samples. Each drug concentration was confirmed by GC/MS. They are 0, 255, 509, 747, 1011, 1265, 1518, 1760 and 2015 ng/mL for Methamphetamine, 0, 7, 13, 20, 27, 33, 39, 45 and 53ng/mL for Phencyclidine, and 0, 14, 28, 39, 53, 61, 73, 90 and 103ng/mL for Marijuana. 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.

AssureTech Methamphetamine Tests

Strip

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	12-/38+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	9-/41+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	9-/41+	50+/0-	50+/0-	50+/0-	50+/0-

Dip Card

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	12-/38+	50+/0-	50+/0-	50+/0-	50+/0-

Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	10-/40+	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-

Tum Key Split Cup

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	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+	12-/38+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	9-/41+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	11-/39+	50+/0-	50+/0-	50+/0-	50+/0-

AssureTech Phencyclidine Tests

Strip

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

Dip Card

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+	10-/40+	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-

Tum Key Split Cup

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	11-/39+	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+	12-/38+	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+	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-

AssureTech Marijuana Tests

Strip

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	11-/39+	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-

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+	11-/39+	50+/0-	50+/0-	50+/0-	50+/0-

Dip Card

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+	10-/40+	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-

Turn Key Split Cup

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	10-/40+	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-

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+	12-/38+	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+	10-/40+	50+/0-	50+/0-	50+/0-	50+/0-

b. Linearity

Not applicable.

c. Stability

The devices are stable at 39.2°F to 86°F (4°C to 30°C) for 24 months based on the accelerated stability study at 45 °C and real time stability determination at both 4 °C and 30 °C.

d. Cut-off

A total of 150 samples of which 25 are native samples and 125 were spiked samples are used in the cut-off study. These samples are equally distributed at concentrations of -50% Cut-Off; -25% Cut-Off; Cut-Off; +25% Cut-Off; +50% Cut-Off were tested using three different lots of each device by three different operators. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for Methamphetamine, Phencyclidine and Marijuana .

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

Calibrator	Cut-off (ng/mL)
d-Methamphetamine	1000
Phencyclidine	25
Marijuana	50

e. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentrations at 25% below and 25% above Cut-Off levels. These urine samples were tested using

three batches of each device. Compounds that showed no interference at a concentration of 100µg/mL are summarized in the following tables. There were no differences observed for different devices.

Methamphetamine:

Acetamidophenol	(+/-)-Ephedrine	Oxymetazoline
Acetaminophen	Erythromycin	Papaverine
Acetophenetidin	β-Estradiol	Penicillin G
N-Acetylprocainamide	Estrone-3-sulfate	Pentobarbital
Acetylsalicylate	Fenoprofen	Perphenazine
Aminopyrine	Furosemide	Phencyclidine
Amitriptyline	Gentisic acid	Phenelzine
Amobarbital	Hemoglobin	Phenobarbital
Amoxicillin	Hydralazine	L-Phenylephrine
Ampicillin	Hydrochlorothiazide	β-Phenylethylamine
D-Amphetamine	Hydrocodone	Phenylpropanolamine
L-Amphetamine	Hydrocortisone	Prednisone
L-Ascorbic Acid	α-Hydroxyhippuric acid	Prednisolone
Apomorphine	3Hydroxytyramine	Procaine
Aspartame	Ibuprofen	D/L-Propranolol
Atropine	Imipramine	D-Propoxyphene
Benzilic acid	(+/-)-Isoproterenol	D-Pseudoephedrine
Benzoic acid	Isoxsuprine	Quinidine
Benzoylcegonine	Ketamine	Quinine
Bilirubin	Ketoprofen	Ranitidine
Caffeine	Labetalol	Salicylic acid
Cannabidiol	Loperamide	Secobarbital
Chloralhydrate	Loxapine succinate	Serotonin (5-Hydroxytyramine)
Chloramphenicol	Maprotiline	Sulfamethazine
Chlordiazepoxide	Meperidine	Sulindac
Chlorothiazide	Meprobamate	Temazepam
Chloroquine	Methadone	Tetracycline
Chlorpromazine	Methoxyphenamine	Tetrahydrocortisone, 3Acetate
Cholesterol	Morphine-3-β-D-glucuronide	Tetrahydrocortisone 3 (β-D-glucuronide)
Clomipramine	Nalidixic acid	Tetrahydrozoline
Clonidine	Nalorphine	Thebaine
Cocaine hydrochloride	Naloxone	Thiamine
Codeine	Naltrexone	Thioridazine
Cortisone	Naproxen	Tolbutamide
Cotinine	Niacinamide	Triamterene
Creatinine	Nifedipine	Trifluoperazine
Deoxycorticosterone	Norcodein	Trimethobenzamide
Dextromethorphan	Norethindrone	Trimethoprim
Diazepam	Noroxymorphone	Trimipramine
Diclofenac	D-Norpropoxyphene	D/ L-Tryptophan
Diflunisal	Noscapine	Tyramine
Digoxin	D/L-Octopamine	D/ L-Tyrosine
Diphenhydramine	Oxalic acid	Uric acid
Doxylamine	Oxazepam	Verapamil
Ecgonine hydrochloride	Oxolinic acid	Zomepirac

Ecgoninemethylester	Oxycodone	
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Phencyclidine

Acetaminophen	(-) Y Ephedrine	Oxycodone
Acetophenetidin	Erythromycin	Oxymetazoline
N-Acetylprocainamide	β -Estradiol	Papaverine
Acetylsalicylic acid	Estrone-3-sulfate	Penicillin-G
Aminopyrine	Ethyl-p-aminobenzoate	Pentazocine hydrochloride
Amitriptyline	Fenoprofen	Pentobarbital
Amobarbital	Furosemide	Perphenazine
Amoxicillin	Gentisic acid	Phenelzine
Ampicillin	Hemoglobin	Phenobarbital
Ascorbic acid	Hydralazine	Phentermine
D,L-Amphetamine	Hydrochlorothiazide	L-Phenylephrine
Apomorphine acid	Hydrocodone	β -Phenylethylamine
Aspartame	Hydrocortisone	Phenylpropanolamine
Atropine	O-Hydroxyhippuric	Prednisolone
Benzilic acid	p-Hydroxymethamphetamine	Prednisone
Benzoic acid	3-Hydroxytyramine	Procaine
Benzoyllecgonine	Ibuprofen	Promazine
Benzphetamine	Imipramine	Promethazine
Bilirubin	Iproniazid	D,L-Propranolol
Brompheniramine	(\pm) - Isoproterenol	D-Propoxyphene
Caffeine	Isoxsuprine	D-Pseudoephedrine
Cannabidiol	Ketamine	Quinidine
Cannabinol	Ketoprofen	Quinine
Chloralhydrate	Labetalol	Ranitidine
Chloramphenicol	Loperamide	Salicylic acid
Chlordiazepoxide	Maprotiline	Secobarbital
Chlorothiazide	Meperidine	Serotonin (5-Hydroxytyramine)
(\pm) Chlorpheniramine	Meprobamate	Sulfamethazine
Chlorpromazine	Methadone	Sulindac
Chloroquine	Methoxyphenamine	Temazepam
Cholesterol	(+) 3,4-Methylenedioxy-	Tetracycline
Clomipramine	(+)3,4-Methylenedioxy-	Tetrahydrocortisone3 (β -D glucuronide)
Clonidine	Morphine-3- β -D glucuronide	Tetrahydrozoline
Cocaine hydrochloride	Morphine Sulfate	Thiamine
Codeine	Nalidixic acid	Thioridazine
Cortisone	Naloxone	D, L-Tyrosine
(-) Cotinine	Naltrexone	Tolbutamide
Creatinine	Naproxen	Triamterene
Deoxycorticosterone	Niacinamide	Trifluoperazine
Dextromethorphan	Nifedipine	Trimethoprim
Diazepam	Norcodein	Trimipramine
Diclofenac	Norethindrone	Tryptamine
Diflunisal	D-Norpropoxyphene	D, L-Tryptophan
Digoxin	Noscapine	Tyramine
Diphenhydramine	D,L-Octopamine	Uric acid
Doxylamine	Oxalic acid	Verapamil

Ecgonine hydrochloride	Oxazepam	Zomepirac
Ecgonine methylester	Oxolinic acid	

Marijuana

Acetamidophenol	β -Estradiol	Papaverine
Acetophenetidin	Estrone-3-sulfate	Penicillin G
N-Acetylprocainamide	Ethyl-p-aminobenzoate	Pentazocine
Acetylsalicylic acid	Fenoprofen	Pentobarbital
Aminopyrine	Furosemide	Perphenazine
Amitriptyline	Gentisic acid	Phencyclidine
Amobarbital	Hemoglobin	Phenelzine
Amoxicillin	Hydralazine	Phenobarbital
Ampicillin	Hydrochlorothiazide	Phentermine
Ascorbic acid	Hydrocodone	L-Phenylephrine
D/L-Amphetamine	Hydrocortisone	β -Phenylethylamine
L-Amphetamine	α -Hydroxyhippuric acid	β -Phenylethylamine
Apomorphine	3-Hydroxytyramine	Phenylpropanolamine
Aspartame	Ibuprofen	Prednisolone
Atropine	Imipramine	Prednisone
Benzilic acid	Iproniazid	Procaine
Benzoic acid	(+/-)-Isoproterenol	Promazine
Benzoyllecgonine	Isoxsuprine	Promethazine
Benzphetamine	Ketamine	D/L-Propranolol
Bilirubin	Labetalol	D-Propoxyphene
Brompheniramine	Levorphanol	D-Pseudoephedrine
Caffeine	Loperamide	Quinidine
Chloralhydrate	Maprotiline	Quinine
Chloramphenicol	Meprobamate	Ranitidine
Chlordiazepoxide	Methadone	Salicylic acid
Chlorothiazide	Methoxyphenamine	Secobarbital
(+/-)-Chlorpheniramine	(+/-)	Serotonin (5-Hydroxytyramine)
Chlorpromazine	(+/-)	Sulfamethazine
Chloroquine	Methylphenidate	Sulindac
Cholesterol	Methyprylon	Temazepam
Clomipramine	Morphine-3- β -D-glucuronide	Tetracycline
Clonidine	Nalorphine	Tetrahydrocortisone3(β -D-glucuronide)
Cocaine hydrochloride	Naloxone	Tetrahydrozoline
Codeine	Nalidixic acid	Thebaine
Cortisone	Naltrexone	Thiamine
(-)-Cotinine	Naproxen	Thioridazine
Creatinine	Niacinamide	D/L-Thyroxine
Deoxycorticosterone	Nifedipine	Tolbutamide
Dextromethorphan	Norcodein	Triamterene
Diazepam	Norethindrone	Trifluoperazine
Diclofenac	D-Norpropoxyphene	Trimethoprim
Diflunisal	Noscapine	Trimipramine
Digoxin	D/L-Octopamine	Tryptamine
Diphenhydramine	Oxalic acid	D/L-Tryptophan
Doxylamine	Oxazepam	Tyramine
Ecgonine hydrochloride	Oxolinic acid	D/ L-Tyrosine

Ecgoninemethylester	Oxycodone	Uric acid
L - Ψ -Ephedrine	Oxymetazoline	Verapamil
Erythromycin	p-Hydroxymethamphetamine	Zomepirac

f. Specificity

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

Methamphetamine (Cutoff=1000 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
D(+)-Methamphetamine	1000	100%
(+/-)3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	10000	10%
D/L-Methamphetamine	1000	100%
p-Hydroxymethamphetamine	10000	10%
D-Amphetamine	Negative at ≤ 100000	< 1%
L-Amphetamine	Negative at ≤ 100000	< 1%
Chloroquine	50000	2%
(+/-)-Ephedrine	4000	25%
L-Methamphetamine	10000	10%
(+/-)3,4-Methylenedioxyamphetamine (MDA)	Negative at ≤ 100000	< 1%
(+/-)3,4-methylenedioxyamphetamine(MDMA)	500	200%
β -Phenylethylamine	7500	13.3%
Trimethobenzamide	20000	5%

Phencyclidine (Cut-off=25 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
Phencyclidine	25	100%
4-Hydroxyphencyclidine	75	33.3%

Marijuana (Cut-off=50 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
11-Nor- Δ^9 -Tetrahydrocannabinol-9-COOH	50	100%
11-Hydroxy- Δ^9 -Tetrahydrocannabinol	50	100%
11-Nor- Δ^8 -Tetrahydrocannabinol-9-COOH	50	100%
Cannabinol	20000	0.25%
Δ^8 -Tetrahydrocannabinol	15000	0.33%
Δ^9 -Tetrahydrocannabinol	15000	0.33%
Cannabidiol	Negative at ≤ 100000	< 0.05%
11-Nor- Δ^9 -THC-carboxy glucuronide	75	66.7%
(-)-11-nor-9-carboxy- Δ^9 -THC	50	100%

g. Effect of Urine Specific Gravity and pH

To investigate the effect of urine specific gravity and urine pH, urine samples, with 1.009 to 1.030 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. Specific gravity from 1.009 to 1.030 does not affect the test results. Similarly, pH from 4 to 9 does not affect

the test result. There were no differences observed for different format of the devices.

2. Comparison Studies

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

Methamphetamine

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

Discordant Results of Methamphetamine Strip

Viewer	Sample Number	GC/MS Result (ng/mL of d-Methamphetamine)	Strip Viewer Results
Viewer A	50368	974	Positive
Viewer C	50368	974	Positive
Viewer A	96378	1045	Negative
Viewer B	79610	1094	Negative
Viewer C	96378	1045	Negative

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

Discordant Results of Methamphetamine Dip Card

Viewer	Sample Number	GC/MS Result (ng/mL of d-Methamphetamine)	Dip Card Viewer Results
Viewer A	50368	974	Positive
Viewer B	50368	974	Positive
Viewer B	96378	1045	Negative

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

Discordant Results of Methamphetamine Turn Key Split Cup

Viewer	Sample Number	GC/MS Result (ng/mL of d-Methamphetamine)	Turn Key Split Cup Viewer Results
Viewer A	50368	974	Positive
Viewer C	50368	974	Positive
Viewer A	96378	1045	Negative
Viewer B	96378	1045	Negative

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

Discordant Results of Methamphetamine Quick Cup

Viewer	Sample Number	GC/MS Result (ng/mL of d-Methamphetamine)	Quick Cup Viewer Results
Viewer A	50368	974	Positive

Viewer A	96378	1045	Negative
Viewer C	79610	1094	Negative

Phencyclidine

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

Discordant Results of Phencyclidine Strip

Viewer	Sample Number	GC/MS Result (ng/mL of Phencyclidine)	Strip Viewer Results
Viewer A	68414	22	Positive
Viewer B	49090	24	Positive
Viewer C	49090	24	Positive
Viewer A	34825	27	Negative
Viewer B	46717	27	Negative

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

Discordant Results of Phencyclidine Dip Card

Viewer	Sample Number	GC/MS Result (ng/mL of Phencyclidine)	Dip Card Viewer Results
Viewer A	49090	24	Positive
Viewer A	68414	22	Positive
Viewer C	68414	22	Positive

Viewer A	34825	27	Negative
Viewer B	61443	27	Negative
Viewer C	46717	27	Negative

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

Viewer	Sample Number	GC/MS Result (ng/mL of Phencyclidine)	Turn Key Split Cup Viewer Results
Viewer A	68414	22	Positive
Viewer B	68414	22	Positive
Viewer C	68414	22	Positive
Viewer A	34825	27	Negative
Viewer B	46717	27	Negative

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

Discordant Results of Phencyclidine Quick Cup

Viewer	Sample Number	GC/MS Result (ng/mL of Phencyclidine)	Quick Cup Viewer Results
Viewer A	68414	22	Positive
Viewer B	68414	22	Positive
Viewer B	49090	24	Positive

Viewer B	46717	27	Negative
Viewer C	46717	27	Negative

Marijuana

Strip		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Viewer B	Positive	0	0	0	13	25
	Negative	10	20	10	2	0
Viewer C	Positive	0	0	1	14	25
	Negative	10	20	9	1	0

Discordant Results of Marijuana Strip

Viewer	Sample Number	GC/MS Result (ng/mL of 11-Nor- Δ 9-Tetrahydrocannabinol-9-COOH)	Strip Viewer Results
Viewer A	87180	46	Positive
Viewer C	87180	46	Positive
Viewer A	97898	52	Negative
Viewer B	97898	52	Negative
Viewer B	32995	53	Negative
Viewer C	32995	53	Negative

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

Discordant Results of Marijuana Dip Card

Viewer	Sample Number	GC/MS Result (ng/mL of 11-Nor- Δ 9-Tetrahydrocannabinol-9-COOH)	Dip Card Viewer Results
Viewer A	38785	44	Positive

Viewer B	87180	46	Positive
Viewer A	97898	52	Negative
Viewer C	32995	53	Negative

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

Viewer	Sample Number	GC/MS Result (ng/mL of 11-Nor- Δ 9-Tetrahydrocannabinol-9-COOH)	Turn Key Split Cup Viewer Results
Viewer A	38785	44	Positive
Viewer B	87180	46	Positive
Viewer A	99015	54	Negative
Viewer B	97898	52	Negative
Viewer C	32995	53	Negative

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

Discordant Results of Marijuana Quick Cup

Viewer	Sample Number	GC/MS Result (ng/mL of 11-Nor- Δ 9-Tetrahydrocannabinol-9-COOH)	Quick Cup Viewer Results
Viewer B	43788	43	Positive

Viewer A	32995	53	Negative
Viewer C	94567	55	Negative

Lay-user study

A lay user study was performed at three intended user sites with 1638 lay persons. The lay users had diverse educational and professional backgrounds and ranged in age from 18 to > 50 years. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample and a device. Each device was tested.

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

% of Cutoff	Number of samples	d-Methamphetamine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	21	0	0	21	100
-75% Cutoff	21	260	0	21	100
-50% Cutoff	21	489	0	21	100
-25% Cutoff	21	769	0	21	100
+25% Cutoff	21	1276	21	0	100
+50% Cutoff	21	1468	21	0	100
+75% Cutoff	21	1795	21	0	100

Comparison between GC/MS and Lay Person Results for Methamphetamine Dip Card

% of Cutoff	Number of samples	d-Methamphetamine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	21	0	0	21	100
-75% Cutoff	21	260	0	21	100
-50% Cutoff	21	489	0	21	100
-25% Cutoff	21	769	1	20	95
+25% Cutoff	21	1276	19	2	90
+50% Cutoff	21	1468	21	0	100
+75% Cutoff	21	1795	21	0	100

Comparison between GC/MS and Lay Person Results for Methamphetamine Turn Key Split Cup

% of Cutoff	Number of samples	d-Methamphetamine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	21	0	0	21	100
-75% Cutoff	21	260	0	21	100
-50% Cutoff	21	489	0	21	100

-25% Cutoff	21	769	1	20	95
+25% Cutoff	21	1276	21	0	100
+50% Cutoff	21	1468	21	0	100
+75% Cutoff	21	1795	21	0	100

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

% of Cutoff	Number of samples	d-Methamphetamine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	21	0	0	21	100
-75% Cutoff	21	260	0	21	100
-50% Cutoff	21	489	0	21	100
-25% Cutoff	21	769	0	21	100
+25% Cutoff	21	1276	20	1	95
+50% Cutoff	21	1468	21	0	100
+75% Cutoff	21	1795	21	0	100

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

% of Cutoff	Number of samples	Phencyclidine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	21	0	0	21	100
-75% Cutoff	21	8	0	21	100
-50% Cutoff	21	12	0	21	100
-25% Cutoff	21	20	0	21	100
+25% Cutoff	21	30	20	1	95
+50% Cutoff	21	39	21	0	100
+75% Cutoff	21	43	21	0	100

Comparison between GC/MS and Lay Person Results for Phencyclidine Dip Card

% of Cutoff	Number of samples	Phencyclidine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	21	0	0	21	100
-75% Cutoff	21	8	0	21	100
-50% Cutoff	21	12	0	21	100
-25% Cutoff	21	20	1	20	95
+25% Cutoff	21	30	20	1	95
+50% Cutoff	21	39	21	0	100
+75% Cutoff	21	43	21	0	100

Comparison between GC/MS and Lay Person Results for Phencyclidine Turn Key Split Cup

% of Cutoff	Number of samples	Phencyclidine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	

% of Cutoff	Number of samples	Phencyclidine Concentration by GC/MS (ng/mL)	No. of Positive	No. of Negative	percentage of correct results (%)
-100% Cutoff	21	0	0	21	100
-75% Cutoff	21	8	0	21	100
-50% Cutoff	21	12	0	21	100
-25% Cutoff	21	20	0	21	100
+25% Cutoff	21	30	19	2	90
+50% Cutoff	21	39	21	0	100
+75% Cutoff	21	43	21	0	100

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

% of Cutoff	Number of samples	Phencyclidine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	21	0	0	21	100
-75% Cutoff	21	8	0	21	100
-50% Cutoff	21	12	0	21	100
-25% Cutoff	21	20	0	21	100
+25% Cutoff	21	30	19	2	90
+50% Cutoff	21	39	21	0	100
+75% Cutoff	21	43	21	0	100

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

% of Cutoff	Number of samples	Marijuana Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	21	0	0	21	100
-75% Cutoff	21	13	0	21	100
-50% Cutoff	21	26	0	21	100
-25% Cutoff	21	39	1	20	95
+25% Cutoff	21	61	20	1	95
+50% Cutoff	21	76	21	0	100
+75% Cutoff	21	86	21	0	100

Comparison between GC/MS and Lay Person Results for Marijuana Dip Card

% of Cutoff	Number of samples	Marijuana Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	21	0	0	21	100
-75% Cutoff	21	13	0	21	100
-50% Cutoff	21	26	0	21	100
-25% Cutoff	21	39	2	19	90
+25% Cutoff	21	61	21	0	100

+50% Cutoff	21	76	21	0	100
+75% Cutoff	21	86	21	0	100

Comparison between GC/MS and Lay Person Results for Marijuana Turn Key Split Cup

% of Cutoff	Number of samples	Marijuana Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	21	0	0	21	100
-75% Cutoff	21	13	0	21	100
-50% Cutoff	21	26	0	21	100
-25% Cutoff	21	39	1	20	95
+25% Cutoff	21	61	20	1	95
+50% Cutoff	21	76	21	0	100
+75% Cutoff	21	86	21	0	100

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

% of Cutoff	Number of samples	Marijuana Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	21	0	0	21	100
-75% Cutoff	21	13	0	21	100
-50% Cutoff	21	26	0	21	100
-25% Cutoff	21	39	1	20	95
+25% Cutoff	21	61	21	0	100
+50% Cutoff	21	76	21	0	100
+75% Cutoff	21	86	21	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 Methamphetamine Tests, AssureTech Phencyclidine Tests and AssureTech Marijuana Tests are substantially equivalent to the predicate.