



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 31, 2016

ASSURE TECH., INC.
C/O JOE SHIA
REGULATORY CONSULTANT
504 EAST DIAMOND AVE. SUITE I
GAITHERSBURG MD 20877

Re: K153465

Trade/Device Name: AssureTech Amphetamine Tests, AssureTech Cocaine Tests,
AssureTech Morphine Tests

Regulation Number: 21 CFR 862.3100

Regulation Name: Amphetamine Test System

Regulatory Class: Class II

Dated: February 2, 2016

Received: February 17, 2016

Dear Mr. 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 regulation (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" (21CFR 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)
k153465

Device Name

AssureTech Amphetamine Tests
AssureTech Cocaine Tests
AssureTech Morphine Tests

Indications for Use (Describe)

AssureTech Amphetamine Tests are immunochromatographic assays for the qualitative determination of d-Amphetamine 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 Cocaine Tests are immunochromatographic assays for the qualitative determination of Benzoylcegonine in human urine at cut-off concentration of 300 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 Morphine Tests are immunochromatographic assays for the qualitative determination of Morphine in human urine at cut-off concentration of 2000 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.

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510(k) SUMMARY

1. Date: March 26, 2016
2. Submitter: Assure Tech. Co., Ltd.
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3. Contact person: Eric Lin
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4. Device Name: AssureTech Amphetamine Tests
AssureTech Cocaine Tests
AssureTech Morphine Tests

Classification:

Product Code	CFR	Panel
DKZ	21 CFR, 862.3100 Amphetamine Test System	Toxicology
DIO	21 CFR, 862.3250 Cocaine Test System	Toxicology
DJG	21 CFR, 862.3650 Opiate Test System	Toxicology

5. Predicate Devices: K142396

The Chemtrue® Multi-Panel Drug Screen Dip Card Tests

6. Intended Use

AssureTech Amphetamine Tests are immunochromatographic assays for the qualitative determination of d-Amphetamine 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 Cocaine Tests are immunochromatographic assays for the qualitative determination of Benzoyllecgonine in human urine at cut-off concentration of 300 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 Morphine Tests are immunochromatographic assays for the qualitative determination of Morphine in human urine at cut-off concentration of 2000 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 Amphetamine Tests, AssureTech Cocaine Tests, and AssureTech Morphine Tests are immunochromatographic assays that use a lateral flow system for the qualitative detection of d-Amphetamine, Benzoylcegonine and Morphine (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 Amphetamine Tests, AssureTech Cocaine Tests and AssureTech Morphine Tests and the predicate devices is provided in following tables.

Table 1: Features Comparison of AssureTech Amphetamine 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-Amphetamine	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 Cup	Dip Card

Table 2: Features Comparison of AssureTech Cocaine 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	Benzoylcegonine	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	300 ng/mL	Same
Intended Use	For over-the-counter and prescription uses.	Same
Configurations	Strip, Dip Card, Cup, Turn Key Cup	Dip Card

Table 3: Features Comparison of AssureTech Morphine 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	Morphine	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	2000 ng/mL	Same
Intended Use	For over-the-counter and prescription uses.	Same
Configurations	Strip, Dip Card, Cup, Turn Key Cup	DipCard

9. Test Principle

The AssureTech Amphetamine Tests, AssureTech Cocaine Tests, and AssureTech Morphine Tests are rapid tests for the qualitative detection of d-Amphetamine, Benzoylcegonine and Morphine 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 GC/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.

AssureTech Amphetamine 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+	11-/39+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	9-/41+	50+/0-	50+/0-	50+/0-	50+/0-

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+	13-/37+	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-

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+	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+	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-

AssureTech Cocaine 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+	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+	11-/39+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	8-/42+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	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+	11-/39+	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+	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+	13-/37+	50+/0-	50+/0-	50+/0-	50+/0-

AssureTech Morphine 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+	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-

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+	10-/40+	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+	11-/39+	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+	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+	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. Cut-off

A total of 150 samples 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 Amphetamine, Cocaine and Morphine.

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

Calibrator	Cut-off (ng/mL)
d-Amphetamine	1000
Benzoyllecgonine	300
Morphine	2000

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.

Amphetamine:

4-Acetamidophenol	L-Ephedrine	Oxycodone
Acetophenetidin	(-) Y Ephedrine	Oxymetazoline
N-Acetylprocainamide	Erythromycin	Papaverine
Acetylsalicylic acid	β-Estradiol	Penicillin-G
Aminopyrine	Estrone-3-sulfate	Pentazocaine
Amitriptyline	Ethyl-p-aminobenzoate	Pentobarbital
Amobarbital	Fenfluramine	Perphenazine
Amoxicillin	Fenoprofen	Phencyclidine
Ampicillin	Furosemide	Phenelzine
Ascorbic acid	Gentisic acid	Phenobarbital
Aspartame	Hemoglobin	Phenytoin
Atropine	Hydralazine	L-Phenylephrine
Benzilic acid	Hydrochlorothiazide	Phenylpropanolamine

Benzoic acid	Hydrocodone	Prednisolone
Benzoyllecgonine	Hydrocortisone	Prednisone
Bilirubin	O-Hydroxyhippuric acid	Procaine
Brompheniramine	3-Hydroxytyramine	Promazine
Caffeine	Ibuprofen	Promethazine
Cannabidiol	Imipramine	D,L-Propranolol
Cannabinol	(-) Isoproterenol	D-Propoxyphene
Chloralhydrate	Isoxsuprine	Quinidine
Chloramphenicol	Ketamine	Quinine
Chlordiazepoxide	Ketoprofen	Ranitidine
Chlorothiazide	Labetalol	Salicylic acid
(±) Chlorpheniramine	Levorphanol	Secobarbital
Chlorpromazine	Loperamide	Sulfamethazine
Chloroquine	Maprotiline	Sulindac
Cholesterol	Meperidine	Temazepam
Clomipramine	Meprobamate	Tetracycline
Clonidine	Methadone	Tetrahydrocortisone
Cocaine hydrochloride	Methylphenidate	Tetrahydrozoline
Codeine	Morphine-3-Dglucuronide	Δ9-THC-COOH
Cortisone	Nalidixic acid	Thebaine
(-) Cotinine	Naloxone	Thiamine
Creatinine	Naltrexone	Thioridazine
Deoxycorticosterone	Naproxen	D,L-Thyroxine
Dextromethorphan	Niacinamide	Tolbutamide
Diazepam	Nifedipine	Triamterene
Diclofenac	Norcodein	Trifluoperazine
Diflunisal	Norethindrone	Trimethoprim
Digoxin	D-Norpropoxyphene	Trimipramine
Diphenhydramine	Noscapine	Tryptamine
Doxylamine	D,L-Octopamine	D, L-Tyrosine
Ecgonine hydrochloride	Oxalic acid	Uric acid
Ecgonine methylester	Oxazepam	Verapamil
(1R,2S)-(-)-Ephedrine	Oxolinic acid	Zomepirac

Cocaine

Acetaminophen	Estrone-3-sulfate	Oxymetazoline
Acetophenetidin	Ethyl-p-aminobenzoate	Papaverine
N-Acetylprocainamide	Fenoprofen	Penicillin-G
Acetylsalicylic acid	Furosemide	Pentobarbital
Aminopyrine	Gentisic acid	Perphenazine
Amitriptyline	Hemoglobin	Phencyclidine
Amobarbital	Hydralazine	Phenelzine
Amoxicillin	Hydrochlorothiazide	Phenobarbital

Ampicillin	Hydrocodone	Phentermine
L-Ascorbic acid	Hydrocortisone	L-Phenylephrine
DL-Amphetamine	O-Hydroxyhippuric acid	β -Phenylethylamine
Apomorphine	p-Hydroxymethamphetamine	Phenylpropanolamine
Aspartame	3-Hydroxytyramine	Prednisolone
Atropine	Ibuprofen	Prednisone
Benzilic acid	Imipramine	Procaine
Benzoic acid	Iproniazid	Promazine
Benzphetamine	(\pm) - Isoproterenol	Promethazine
(\pm) -Brompheniramine	Isoxsuprine	DL-Propranolol
Caffeine	Ketamine	D-Propoxyphene
Cannabidiol	Ketoprofen	D-Pseudoephedrine
Cannabinol	Labetalol	Quinidine
Chloralhydrate	Levorphanol	Quinine
Chloramphenicol	Loperamide	Ranitidine
Chlordiazepoxide	Maprotiline	Salicylic acid
Chlorothiazide	Meperidine	Secobarbital
(\pm) -Chlorpheniramine	Meprobamate	Serotonin
Chlorpromazine	Methadone	Sulfamethazine
Chloroquine	Methoxyphenamine	Sulindac
Cholesterol	3,4-Methylene dioxymphetamine	Temazepam
Clomipramine	3,4-Methylene-dioxymphetamine	Tetrahydrocortisone 3-(β -D glucuronide)
Clonidine	Morphine-3- β -D glucuronide	Tetracycline
Codeine	Morphine Sulfate	Tetrahydrozoline
Cortisone	Nalidixic acid	Thebaine
(-) Cotinine	Naloxone	Thiamine
Creatinine	Naltrexone	Thioridazine
Deoxycorticosterone	Naproxen	DL-Tyrosine
Dextromethorphan	Niacinamide	Tolbutamide
Diazepam	Nifedipine	Triamterene
Diclofenac	Norcodein	Trifluoperazine
Diflunisal	Norethindrone	Trimethoprim
Digoxin	D-Norpropoxyphene	Trimipramine
Diphenhydramine	Noscapine	Tryptamine
Doxylamine	DL-Octopamine	DL-Tryptophan
Ecgonine methylester	Oxalic acid	Tyramine
(-) - Ψ -Ephedrine	Oxazepam	Uric acid
Erythromycin	Oxolinic acid	Verapamil

β -Estradiol	Oxycodone	Zomepirac
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Morphine

Acebutolol	L - Ψ -Ephedrine	Papaverine
Acetopromazined-6	Erythromycin	Penicillin G
Acetamidophenol	β -Estradiol	Pentazocine
Acetophenetidin	Estrone-3-sulfate	Pentobarbital
Acetylprocainamide	Ethylpaminobenzoate	Perphenazine
Acetylsalicylic acid	Fenoprofen	Phencyclidine
Aminopyrine	Furosemide	Phenelzine
Amitriptyline	Gentisic acid	Phenobarbital
Amobarbital	Hemoglobin	Phentermine
Amoxicillin	Hydralazine	L-Phenylephrine
Ampicillin	Hydrochlorothiazide	β -Phenethylamine
Ascorbic acid	Hydrocortisone	Phenylpropanolamine
D/L-Amphetamine	α -Hydroxyhippuric acid	Prednisolone
L-Amphetamine	3-Hydroxytyramine	Prednisone
Apomorphine	Ibuprofen	Promazine
Aspartame	Imipramine	Promethazine
Atropine	Iproniazid	D/L-Propranolol
Benzilic acid	(+/-)-Isoproterenol	D-Propoxyphene
Benzoic acid	Isoxsuprine	D-Pseudoephedrine
Benzoylecgonine	Ketamine	Quinidine
Benzphetamine	Ketoprofen	Quinine
Bilirubin	Labetalol	Ranitidine
Brompheniramine	Loperamide	Salicylic acid
Caffeine	Maprotiline	Secobarbital
Chloralhydrate	Meprobamate	Serotonin (5-
Chloramphenicol	Methadone	Sulfamethazine
Chlordiazepoxide	Methoxyphenamine	Sulindac
Chlorothiazide	3,4Methylenedioxyamphetamine	Temazepam
Chlorpheniramine	3,4Methylenedioxymethamphetamin	Tetracycline
Chlorpromazine	Methylphenidate	Tetrahydrocortisone
Chloroquine	Methyprylon	Tetrahydrocortisone3 (β -
Cholesterol	Nalorphine	Tetrahydrozoline
Clomipramine	Naloxone	Thiamine
Clonidine	Nalidixic acid	Thioridazine
Cocaine hydrochloride	Naltrexone	D/ L-Thyroxine
Cortisone	Naproxen	Tolbutamide

(-)- Cotinine	Niacinamide	Triamterene
Creatinine	Nifedipine	Trifluoperazine
Deoxycorticosterone	Norcodein	Trimethoprim
Dextromethorphan	Norethindrone	Trimipramine
Diazepam	D-Norpropoxyphene	Tryptamine
Diclofenac	Noscapine	D/L-Tryptophan
Diflunisal	D/L-Octopamine	Tyramine
Digoxin	Oxalic acid	D/L-Tyrosine
Diphenhydramine	Oxazepam	Uric acid
Doxylamine	Oxolinic acid	Verapamil
Ecgonine hydrochloride	Oxymetazoline	Zomepirac
Ecgoninemethylester	p-Hydroxymethamphetamine	

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.

Amphetamine (Cut-off=1000 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
D - Amphetamine	1000	100%
L - Amphetamine	20000	5%
D,L - Amphetamine	3000	33%
Phentermine	30000	3.3%
Hydroxyamphetamine	8000	12.5%
Methylenedioxyamphetamine (MDA)	20000	5%
d-Methamphetamine	Negative at 100000	Not Detected
l-Methamphetamine	Negative at 100000	Not Detected
ephedrine	Negative at 100000	Not Detected
Methylenedioxyethylamphetamine (MDE)	Negative at 100000	Not Detected
3,4-methylenedioxy-methamphetamine (MDMA)	Negative at 100000	Not Detected

Cocaine (Cut-off=300 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
Benzoylcegonine	300	100%
Cocaine HCl	750	40%
Cocaethylene	12500	2.4%
Ecgonine	32000	0.9%
Norcocaine	100000	0.3%

Morphine (Cut-off=2000 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
Morphine	2000	100%
Acetylmorphine	2500	80%

Codeine	1000	200%
Ethyl Morphine	250	800%
Heroin	5000	40%
Hydromorphone	2500	80%
Hydrocodone	5000	40%
Thebaine	13000	15.4%
Morphine-3- β -glucuronide	Negative at 200000	<1%
Oxycodone	Negative at 400000	<0.5%
Oxymorphone	Negative at 400000	<0.5%
Procaine	Negative at 400000	<0.5%
Levorphanol	Negative at 400000	<0.5%

g. 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 Amphetamine Tests, the AssureTech Cocaine Tests and the AssureTech Morphine 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:

Amphetamine

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	13	25
	Negative	10	20	9	2	0

Discordant Results of Amphetamine Strip

Viewer	Sample Number	GC/MS Result	Strip Viewer Results
Viewer A	78081	984	Positive
Viewer B	78081	984	Positive
Viewer C	78081	984	Positive
Viewer A	72430	1083	Negative

Viewer B	79915	1024	Negative
Viewer C	79915	1024	Negative
Viewer C	72430	1083	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	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 Amphetamine Dip Card

Viewer	Sample Number	GC/MS Result	Dip Card Viewer Results
Viewer B	78081	984	Positive
Viewer A	79915	1024	Negative
Viewer C	79915	1024	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	1	20	9	1	0
Viewer B	Positive	0	0	1	13	25
	Negative	1	20	9	2	0
Viewer C	Positive	0	0	0	14	25
	Negative	1	20	10	1	0

Discordant Results of Amphetamine Turn-Key Split Cup

Viewer	Sample Number	GC/MS Result	Turn-Key Split Cup
Viewer A	78081	984	Positive
Viewer B	78081	984	Positive
Viewer A	79915	1024	Negative
Viewer B	79915	1024	Negative
Viewer B	79915	1024	Negative
Viewer C	87184	1257	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	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 Amphetamine Quick Cup

Viewer	Sample Number	GC/MS Result	Quick Cup Viewer Results
Viewer B	78081	984	Positive
Viewer A	79915	1024	Negative
Viewer B	79915	1024	Negative

Cocaine

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	15	25
	Negative	10	20	9	0	0
Viewer B	Positive	0	0	0	14	25
	Negative	10	20	10	1	0
Viewer C	Positive	0	0	2	15	25
	Negative	10	20	8	0	0

Discordant Results of Cocaine Strip

Viewer	Sample Number	GC/MS Result	Strip Viewer Results
Viewer A	38238	285	Positive
Viewer C	58356	280	Positive
Viewer C	38238	285	Positive
Viewer B	71282	312	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	15	25
	Negative	10	20	8	0	0
Viewer B	Positive	0	0	0	15	25
	Negative	10	20	10	0	0
Viewer C	Positive	0	0	1	13	25
	Negative	10	20	9	2	0

Discordant Results of Cocaine Dip Card

Viewer	Sample Number	GC/MS Result	Dip Card Viewer Results
Viewer A	38238	285	Positive
Viewer A	58356	280	Positive
Viewer C	38238	285	Positive
Viewer C	71282	312	Negative
Viewer C	35525	317	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	2	15	25
	Negative	1	20	8	0	0
Viewer B	Positive	0	0	0	14	25
	Negative	1	20	10	1	0
Viewer C	Positive	0	0	0	14	25
	Negative	1	20	10	1	0

Discordant Results of Cocaine Turn-Key Split Cup

Viewer	Sample Number	GC/MS Result	Split Cup Viewer Results
Viewer A	38238	285	Positive
Viewer A	58356	280	Positive
Viewer B	71282	312	Negative
Viewer C	35525	317	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	1	14	25
	Negative	10	20	9	1	0
Viewer C	Positive	0	0	1	14	25
	Negative	10	20	9	1	0

Discordant Results of Cocaine Quick Cup

Viewer	Sample Number	GC/MS Result	Quick Cup Viewer Results
Viewer A	38238	285	Positive
Viewer B	38238	285	Positive
Viewer C	63906	225	Positive
Viewer B	71282	312	Negative
Viewer C	71282	312	Negative

Morphine

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	15	25
	Negative	10	20	9	0	0
Viewer C	Positive	0	0	0	15	25
	Negative	10	20	10	0	0

Discordant Results of Morphine Strip

Viewer	Sample Number	GC/MS Result	Strip Viewer Results
Viewer A	91558	1890	Positive
Viewer B	99379	1917	Positive
Viewer A	65159	2231	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	15	25
	Negative	10	20	8	0	0
Viewer B	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Viewer C	Positive	0	0	0	14	25
	Negative	10	20	10	1	0

Discordant Results of Morphine Dip Card

Viewer	Sample Number	GC/MS Result	Dip Card Viewer Results
Viewer A	99379	1917	Positive
Viewer A	91558	1890	Positive
Viewer B	91558	1890	Positive
Viewer B	62657	2115	Negative
Viewer C	59704	2022	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	1	20	9	1	0
Viewer B	Positive	0	0	1	14	25
	Negative	1	20	9	1	0
Viewer C	Positive	0	0	1	15	25
	Negative	1	20	9	0	0

Discordant Results of Morphine Turn-Key Split Cup

Viewer	Sample Number	GC/MS Result	Split Cup Viewer Results
Viewer A	99379	1917	Positive
Viewer B	49390	1856	Positive
Viewer C	91558	1890	Positive
Viewer A	65159	2231	Negative
Viewer B	62657	2115	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	2	14	25
	Negative	10	20	8	1	0
Viewer B	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Viewer C	Positive	0	0	1	14	25
	Negative	10	20	9	1	0

Discordant Results of Morphine Quick Cup

Viewer	Sample Number	GC/MS Result	Quick Cup Viewer Results
Viewer A	99379	1917	Positive
Viewer A	91558	1890	Positive
Viewer B	91558	1890	Positive
Viewer C	91558	1890	Positive
Viewer A	65159	2231	Negative
Viewer B	59704	2022	Negative
Viewer C	65159	2231	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 Amphetamine Strip

% of Cutoff	Number of samples	d-Amphetamine 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	2.2	0	21	100
-50% Cutoff	21	5.5	0	21	100
-25% Cutoff	21	7.6	1	20	95
+25% Cutoff	21	12.6	20	1	95
+50% Cutoff	21	16.2	21	0	100
+75% Cutoff	21	17.8	21	0	100

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

% of Cutoff	Number of samples	d-Amphetamine 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	2.2	0	21	100
-50% Cutoff	21	5.5	0	21	100
-25% Cutoff	21	7.6	1	20	95
+25% Cutoff	21	12.6	20	1	95
+50% Cutoff	21	16.2	21	0	100
+75% Cutoff	21	17.8	21	0	100

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

% of Cutoff	Number of samples	d-Amphetamine 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	2.2	0	21	100
-50% Cutoff	21	5.5	0	21	100
-25% Cutoff	21	7.6	0	21	100
+25% Cutoff	21	12.6	19	2	90
+50% Cutoff	21	16.2	21	0	100
+75% Cutoff	21	17.8	21	0	100

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

% of Cutoff	Number of samples	d-Amphetamine 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	2.2	0	21	100
-50% Cutoff	21	5.5	0	21	100
-25% Cutoff	21	7.6	2	19	90
+25% Cutoff	21	12.6	20	1	95
+50% Cutoff	21	16.2	21	0	100
+75% Cutoff	21	17.8	21	0	100

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

% of Cutoff	Number of samples	Benzoylcegonine 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	69	0	21	100
-50% Cutoff	21	162	0	21	100
-25% Cutoff	21	251	0	21	100

+25% Cutoff	21	389	20	1	95
+50% Cutoff	21	463	21	0	100
+75% Cutoff	21	510	21	0	100

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

% of Cutoff	Number of samples	Benzoyllecgonine 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	69	0	21	100
-50% Cutoff	21	162	0	21	100
-25% Cutoff	21	251	1	20	95
+25% Cutoff	21	389	20	1	95
+50% Cutoff	21	463	21	0	100
+75% Cutoff	21	510	21	0	100

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

% of Cutoff	Number of samples	Benzoyllecgonine 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	69	0	21	100
-50% Cutoff	21	162	0	21	100
-25% Cutoff	21	251	1	20	95
+25% Cutoff	21	389	19	2	90
+50% Cutoff	21	463	21	0	100
+75% Cutoff	21	510	21	0	100

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

% of Cutoff	Number of samples	Benzoyllecgonine 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	69	0	21	100
-50% Cutoff	21	162	0	21	100
-25% Cutoff	21	251	1	20	95
+25% Cutoff	21	389	20	1	95
+50% Cutoff	21	463	21	0	100
+75% Cutoff	21	510	21	0	100

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

% of Cutoff	Number of samples	Morphine 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	69	0	21	100
-50% Cutoff	21	162	0	21	100
-25% Cutoff	21	251	2	19	90
+25% Cutoff	21	389	20	1	95
+50% Cutoff	21	463	21	0	100
+75% Cutoff	21	510	21	0	100

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

% of Cutoff	Number of samples	Morphine 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	69	0	21	100
-50% Cutoff	21	162	0	21	100
-25% Cutoff	21	251	2	19	90
+25% Cutoff	21	389	21	0	100
+50% Cutoff	21	463	21	0	100
+75% Cutoff	21	510	21	0	100

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

% of Cutoff	Number of samples	Morphine 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	69	0	21	100
-50% Cutoff	21	162	0	21	100
-25% Cutoff	21	251	0	21	100
+25% Cutoff	21	389	20	1	95
+50% Cutoff	21	463	21	0	100
+75% Cutoff	21	510	21	0	100

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

% of Cutoff	Number of samples	Morphine 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	69	0	21	100
-50% Cutoff	21	162	0	21	100
-25% Cutoff	21	251	1	20	95
+25% Cutoff	21	389	21	0	100
+50% Cutoff	21	463	21	0	100
+75% Cutoff	21	510	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 Amphetamine Tests, AssureTech Cocaine Tests and AssureTech Morphine Tests are substantially equivalent to the predicate.