510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k161044

B. Purpose for Submission:

New Device

C. Measurand:

Methamphetamine, Phencyclidine, Marijuana

D. Type of Test:

Qualitative immunochromatographic assay

E. Applicant:

Assure Tech. Co., Ltd.

F. Proprietary and Established Names:

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

G. Regulatory Information:

1. Regulation section:

   Methamphetamine Test System; 21 CFR 862.3610

   Enzyme Immunoassay, Phencyclidine; Unclassified, 510(k) required

   Cannabinoid Test System; 21 CFR 862.3870

2. Classification:

   Class II

3. Product code:

   DJC, LCM, LDJ

4. Panel:

   91, Toxicology

H. Intended Use:

1. Intended use(s):

   See Indications for Use below.

2. Indication(s) for 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-Δ9-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.

3. Special conditions for use statement(s):

   For over-the-counter use.

4. Special instrument requirements:

   Not applicable; this is a visually read single use device.

I. Device Description:

The AssureTech Methamphetamine Test is for the qualitative determination of d-Methamphetamine in human urine. The AssureTech Phencyclidine Test is for the qualitative determination of Phencyclidine in human urine. The AssureTech Marijuana Test is for the qualitative determination of 11-Nor-Δ9-Tetrahydrocannabinol-9-COOH in human urine. Each test device has four formats: Strip, Dip Card, Quick Cup, Turn-Key Split Cup. The Strip format is comprised of a urine collection cup and a test strip with sample pad with a lateral flow. The Dip Card format is comprised of a urine collection cup and the dip card with a plastic casing as the lateral flow device. The Quick Cup format is comprised of a urine collection cup and a quick cup test with a lateral flow device that will start when the cap is screwed onto cup. The Turn-Key Split Cup is comprised of a urine collection cup and a turn-key Split Cup test with a lateral flow device that will start the test when the cap is screwed onto cup and key is turned 180 degrees.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Chemtrue® Multi-Panel Drug Screen Dip Card Tests

2. Predicate 510(k) number(s):

   k142396

3. Comparison with predicate:

Item	AssureTech Methamphetamine Tests (Candidate Device)	Chemtrue® Multi-Panel Drug Screen Dip Card Tests - k142396 (Predicate Device)
Indication(s) for Use	For the qualitative determination of methamphetamine 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 use.	Same
Configurations	Strip, Dip Card, Cup, Turn Key Split Cup	Dip Card

Item	**AssureTech Phencyclidine Tests (Candidate Device)**	**Chemtrue® Multi-Panel Drug Screen Dip Card Tests - k142396 (Predicate Device)**
Indication(s) for Use	For the qualitative determination of phencyclidine 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 use.	Same
Configurations	Strip, Dip Card, Cup, Turn Key Split Cup	Dip Card

Item	AssureTech Marijuana Tests (Candidate Device)	Chemtrue® Multi-Panel Drug Screen Dip Card Tests - k142396 (Predicate Device)
Indication(s) for Use	For the qualitative determination of marijuana in human urine.	Same (but the number of drugs detected is different)
Calibrator	11-Nor-∆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 use.	Same
Configurations	Strip, Dip Card, Cup, Turn Key Split Cup	DipCard

K. Standard/Guidance Document Referenced (if applicable):

None referenced.

L. Test Principle:

The tests are lateral flow chromatographic immunoassays. During testing, a urine specimen migrates upward by capillary action. If target drug present in the urine specimen is 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 sufficient volume of sample has been applied.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision studies were carried out using samples at analyte 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 urine samples. Each drug concentration was confirmed by GC/MS. The concentration levels used in the study are: 0, 255, 509, 747, 1011, 1265, 1518, 1760 and 2015 ng/mL for Methamphetamine tests; 0, 7, 13, 20, 27, 33, 39, 45 and 53 ng/mL for Phencyclidine tests; and 0, 14, 28, 39, 53, 61, 73, 90 and 103 ng/mL for Marijuana tests. 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. Three lots of each format for each analytes test were used in the study. The results obtained are summarized in the following tables.

AssureTech Methamphetamine Strip Test

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-

AssureTech Methamphetamine Dip Card Test

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-

AssureTech Methamphetamine Turn Key Split Cup Test

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-

AssureTech Methamphetamine Quick Cup Test

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 Strip Test

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-

AssureTech Phencyclidine Dip Card Test

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-

AssureTech Phencyclidine Turn Key Split Cup Test

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-

AssureTech Phencyclidine Quick Cup Test

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 Strip Test

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

AssureTech Marijuana Dip Card Test

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-

AssureTech Marijuana Turn Key Split Cup Test

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-

AssureTech Marijuana Quick Cup Test

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-

b. Linearity/assay reportable range:

Not applicable, these devices are intended for qualitative use only.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

External control materials are not supplied with the devices; however, the package inserts list information on how to obtain control materials.

Sample Storage and Stability - Protocols and acceptance criteria for real time, accelerated and transportation simulation stability studies were described and found to be acceptable. The real time stability data supports the sponsor's claim that the devices are stable at 39.2°F to 86°F (4°C to 30°C) for 24 months.

d. Detection limit:

Not applicable.

e. Analytical specificity:

The potential effect of endogenous and exogenous interferents was tested by spiking the interferents into drug-free urine, and target drug urine with concentrations at 25% below and 25% above the cut-off levels by using three lots and three operators for each format. Compounds that showed no interference at a concentration of 100µg/mL are summarized in the following tables. There were no differences

observed for different device formats for an analyte test.

Methamphetamine

Acetamidophenol	(+/-)-Ephedrine	Oxymetazoline
Acetaminophen	Erythromycin	Papaverine
Acetophenetidin	β-Estradiol	Penicillin G
N-Acetylprocainamide	Estrone-3-sulfate	Pentobarbital
Acetylsalicylate	Fenoprofen	Perphenazine
Aminopyrine	Furosemide	Phencyclidine
Amitryptyline	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-Propanolol
Atropine	Imipramine	D-Propoxyphene
Benzilic acid	(+/-)-Isoproterenol	D-Pseudoephedrine
Benzoic acid	Isoxsuprine	Quinidine
Benzoylecgonine	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	

Phencyclidine

Acetaminophen	(-) Y Ephedrine	Oxycodone
Acetophenetidin	Erythromycin	Oxymetazoline
N-	β-Estradiol	Papaverine
Acetylsalicylic acid	Estrone-3-sulfate	Penicillin-G
Aminopyrine	Ethyl-p-aminobenzoate	Pentazocine hydrochloride
Amitryptyline	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-	Prednisone
Benzoic acid	3-Hydroxytyramine	Procaine
Benzoylecgonine	Ibuprofen	Promazine
Benzphetamine	Imipramine	Promethazine
Bilirubin	Iproniazid	D,L-Propanolol
Brompheniramine	(±) - 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)
(±)	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	Tetrahydrozoline
Cocaine	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	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
Amitryptyline	Gentisic acid	Phencyclidine
Amobarbital	Hemoglobin	Phenelzine
Amoxicillin	Hydralazine	Phenobarbital
Ampicillin	Hydrochlorothiazide	Phentermine
Ascorbic acid	Hydrocodone	L-Phenylephrine
D/L-Amphetamine	Hydrocortisone	β-Phenylethlamine
L-Amphetamine	α-Hydroxyhippuric acid	β-Phenyllethylamine
Apomorphine	3-Hydroxytyramine	Phenylpropanolamine
Aspartame	Ibuprofen	Prednisolone
Atropine	Imipramine	Prednisone
Benzilic acid	Iproniazid	Procaine
Benzoic acid	(+/-)-Isoproterenol	Promazine
Benzoylecgonine	Isoxsuprine	Promethazine
Benzphetamine	Ketamine	D/L-Propanolol
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

To test cross-reactivity, drug metabolites and other components in urine samples that are likely to interfere were tested using three batches of each device format. The lowest concentration that caused a positive result for each compound is listed below. There were no differences observed for different device formats for each analyte test. Results are summarized below:

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-methylenedioxymethamphetamine(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%

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 the cutoff 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 format of each analyte test.

f. Assay cut-off:

Characterization of how the device performs analytically around the claimed cut-off concentration appears in the precision/reproducibility section above.

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison studies for the AssureTech Methamphetamine Tests, the AssureTech Phencyclidine Tests and the AssureTech Marijuana Tests were performed in-house by 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

Viewer	Results	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/mLof 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

Methamphetamine Dip Card

Viewer	Results	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/mLof d-Methamphetamine)	Dip Card Viewer Results
Viewer A	50368	974	Positive
Viewer B	50368	974	Positive
Viewer B	96378	1045	Negative

Methamphetamine Turn Key Split Cup

Viewer	Results	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/mLof 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

Methamphetamine Quick Cup

Viewer	Results	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/mLof d-Methamphetamine)	Quick Cup Viewer Results
Viewer A	50368	974	Positive
Viewer A	96378	1045	Negative
Viewer C	79610	1094	Negative

Phencyclidine Strip

Viewer	Results	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/mLof 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

Phencyclidine Dip Card

Viewer	Results	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/mLof 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

Phencyclidine Turn Key Split Cup

Viewer	Results	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

Phencyclidine Quick Cup

Viewer	Results	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/mLof 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

Viewer	Results	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-∆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

Marijuana Dip Card

Viewer	Results	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-∆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

Marijuana Turn Key Split Cup

Viewer	Results	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-Δ9-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

Marijuana Quick Cup

Viewer	Results	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-Δ9-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	
-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 performed a survey on the ease of understanding of the package insert instructions. Overall the device use instructions were found to easy to follow. All package insert were scored at a reading grade level of 7 using the Flesch-Kincaid reading analysis.

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

*b. Clinical specificity**:***

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.