

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

K153465

B. Purpose for Submission:

New Device

C. Measurand:

Amphetamine, Cocaine, Morphine

D. Type of Test:

Qualitative immunochromatographic assay

E. Applicant:

Assure Tech. Co., Ltd.

F. Proprietary and Established Names:

Assure Tech Amphetamine Tests

Assure Tech Cocaine Tests

Assure Tech Morphine Tests

G. Regulatory Information:

1. Regulation section:

21 CFR, 862.3100 Amphetamine Test System

21 CFR, 862.3250 Cocaine Test System

21 CFR, 862.3640 Morphine Test System

2. Classification:

Class II

3. Product code:

DKZ, DIO, DJG

4. Panel:

91, Toxicology

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for 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.

3. Special conditions for use statement(s):

For Prescription and Over-the-counter use

4. Special instrument requirements:

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

I. Device Description:

The Assure Tech Amphetamine Test is for the qualitative determination of d-Amphetamine in human urine.

The device has four formats – Strip, Dip Card, Quick Cup, Turn-Key Split Cup:

-The Strip comprises two items, a urine collection cup and a test strip with sample pad with a lateral flow.

-The Dip Card comprises two items, a urine collection cup and the dip card with a plastic casing as the lateral flow device.

-The Quick Cup comprises 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 comprises 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°.

The Assure Tech Cocaine Test is for the qualitative determination of Benzoyllecgonine in human urine.

The device has four formats – Strip, Dip Card, Quick Cup, turn-key Split Cup:

-The Strip comprises two items, a urine collection cup and a test strip with sample pad with a lateral flow device.

-The Dip Card comprises two items, a urine collection cup and the dip card with a plastic casing as the lateral flow device.

-The Quick Cup comprises 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 comprises 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°.

The Assure Tech Morphine Test is for the qualitative determination of Morphine in human urine.

The device has four formats – Strip, Dip Card, Quick Cup, turn-key Split Cup:

-The Strip comprises two items, a urine collection cup and a test strip with sample pad with a lateral flow device.

-The Dip Card comprises two items, a urine collection cup and the dip card with a plastic casing as the lateral flow device.

-The Quick Cup comprises 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 comprises 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°.

All devices are single-use and visually read.

J. Substantial Equivalence Information:

1. Predicate device name(s):
 Chemtrue® BUP/TCA Single/Multi-Panel Drug Screen Dip Card/Cup/Cassette Tests
 Chemtrue® Multi-Panel Drug Screen Dip Card Tests
 Chemtrue® Multi-Panel Drug Screen Dip Card with OPI 2000 Tests
2. Predicate 510(k) number(s):
 k142396
3. Comparison with predicate:

Similarities		
Item	Candidate Device k153465	Predicate device k142396
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen	Human Urine	Same
Cut-Off Values	Amphetamine: 1000 ng/mL Cocaine: 300 ng/mL Morphine: 2000 ng/mL	Same Same Same
Intended Use	Over-the-counter and prescription use.	Same

Differences		
Item	Candidate Device k153465	Predicate device k142396
Configurations	Strip, Dip Card, Quick Cup Turn-Key Split Cup	Dip Card
Calibrator	d-Amphetamine Benzoylecgonine Morphine	Amphetamine, Cocaine, Marijuana, Morphine, Methamphetamine, Phencyclidine, Benzodiazepines, Barbiturates, Ecstasy, Methadone, Oxycodone and Tricyclic Antidepressants

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

None referenced

L. Test Principle:

The AssureTech Amphetamine Tests, AssureTech Cocaine Tests, and AssureTech Morphine Tests are rapid tests for the qualitative detection of d-Amphetamine, Benzoyllecgonine and Morphine in urine samples. The tests are lateral flow chromatographic immunoassays. During testing, a urine specimen migrates upward by capillary action. If a target drug is 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 onto 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 and no binding sites will be available to allow the antibody coated particles to bind to the immobilized drug conjugate. 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.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision studies were carried out for samples with concentrations of -100%, -75%, -50%, -25%, cutoff, +25%, +50%, +75% and +100% cut off. These samples were prepared by spiking drug into negative urine samples. Each drug concentration was confirmed by GC/MS. These studies were conducted by 3 operators with 3 lots of each device in two runs per day for 25 days (n=50). The results obtained are summarized in the following tables.

Amphetamine:

Assure Tech Amphetamine Strip

Lot #	-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
1	50-/0+	50-/0+	50-/0+	50-/0+	38+/12-	50+/0-	50+/0-	50+/0-	50+/0-
2	50-/0+	50-/0+	50-/0+	50-/0+	39+/11-	50+/0-	50+/0-	50+/0-	50+/0-
3	50-/0+	50-/0+	50-/0+	50-/0+	41+/9-	50+/0-	50+/0-	50+/0-	50+/0-

Assure Tech Amphetamine Dip Card

Lot #	-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
1	50-/0+	50-/0+	50-/0+	50-/0+	39+/11-	50+/0-	50+/0-	50+/0-	50+/0-
2	50-/0+	50-/0+	50-/0+	50-/0+	37+/13-	50+/0-	50+/0-	50+/0-	50+/0-
3	50-/0+	50-/0+	50-/0+	50-/0+	40+/10-	50+/0-	50+/0-	50+/0-	50+/0-

Assure Tech Amphetamine Quick Cup

Lot #	-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
1	50-/0+	50-/0+	50-/0+	50-/0+	37+/13-	50+/0-	50+/0-	50+/0-	50+/0-
2	50-/0+	50-/0+	50-/0+	50-/0+	39+/11-	50+/0-	50+/0-	50+/0-	50+/0-
3	50-/0+	50-/0+	50-/0+	50-/0+	39+/11-	50+/0-	50+/0-	50+/0-	50+/0-

Assure Tech Amphetamine Turn Key Split Cup

Lot #	-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
1	50-/0+	50-/0+	50-/0+	50-/0+	39+/11-	50+/0-	50+/0-	50+/0-	50+/0-
2	50-/0+	50-/0+	50-/0+	50-/0+	39+/11-	50+/0-	50+/0-	50+/0-	50+/0-
3	50-/0+	50-/0+	50-/0+	50-/0+	39+/11-	50+/0-	50+/0-	50+/0-	50+/0-

Cocaine:

Assure Tech Cocaine Strip

Lot #	-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
1	50-/0+	50-/0+	50-/0+	50-/0+	38+/12-	50+/0-	50+/0-	50+/0-	50+/0-
2	50-/0+	50-/0+	50-/0+	50-/0+	40+/10-	50+/0-	50+/0-	50+/0-	50+/0-
3	50-/0+	50-/0+	50-/0+	50-/0+	39+/11-	50+/0-	50+/0-	50+/0-	50+/0-

Assure Tech Cocaine Dip Card

Lot #	-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
1	50-/0+	50-/0+	50-/0+	50-/0+	39+/11-	50+/0-	50+/0-	50+/0-	50+/0-
2	50-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-	50+/0-
3	50-/0+	50-/0+	50-/0+	50-/0+	39+/11-	50+/0-	50+/0-	50+/0-	50+/0-

Assure Tech Cocaine Quick Cup

Lot #	-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
1	50-/0+	50-/0+	50-/0+	50-/0+	38+/12-	50+/0-	50+/0-	50+/0-	50+/0-
2	50-/0+	50-/0+	50-/0+	50-/0+	41+/9-	50+/0-	50+/0-	50+/0-	50+/0-
3	50-/0+	50-/0+	50-/0+	50-/0+	37+/13-	50+/0-	50+/0-	50+/0-	50+/0-

Assure Tech Cocaine Turn Key Split Cup

Lot #	-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
1	50-/0+	50-/0+	50-/0+	50-/0+	39+/11-	50+/0-	50+/0-	50+/0-	50+/0-
2	50-/0+	50-/0+	50-/0+	50-/0+	38+/12-	50+/0-	50+/0-	50+/0-	50+/0-
3	50-/0+	50-/0+	50-/0+	50-/0+	39+/11-	50+/0-	50+/0-	50+/0-	50+/0-

Morphine:

AssureTech Morphine Strip

Lot #	-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
1	50-/0+	50-/0+	50-/0+	50-/0+	41+/9-	50+/0-	50+/0-	50+/0-	50+/0-
2	50-/0+	50-/0+	50-/0+	50-/0+	40+/10-	50+/0-	50+/0-	50+/0-	50+/0-
3	50-/0+	50-/0+	50-/0+	50-/0+	40+/10-	50+/0-	50+/0-	50+/0-	50+/0-

Assure Tech Morphine Dip Card

Lot #	-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
1	50-/0+	50-/0+	50-/0+	50-/0+	39+/11-	50+/0-	50+/0-	50+/0-	50+/0-
2	50-/0+	50-/0+	50-/0+	50-/0+	40+/10-	50+/0-	50+/0-	50+/0-	50+/0-
3	50-/0+	50-/0+	50-/0+	50-/0+	40+/10-	50+/0-	50+/0-	50+/0-	50+/0-

Assure Tech Morphine Quick Cup

Lot #	-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
1	50-/0+	50-/0+	50-/0+	50-/0+	39+/11-	50+/0-	50+/0-	50+/0-	50+/0-
2	50-/0+	50-/0+	50-/0+	50-/0+	40+/10-	50+/0-	50+/0-	50+/0-	50+/0-
3	50-/0+	50-/0+	50-/0+	50-/0+	41+/9-	50+/0-	50+/0-	50+/0-	50+/0-

Assure Tech Morphine Turn Key Split Cup

Lot #	-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
1	50-/0+	50-/0+	50-/0+	50-/0+	39+/11-	50+/0-	50+/0-	50+/0-	50+/0-
2	50-/0+	50-/0+	50-/0+	50-/0+	41+/9-	50+/0-	50+/0-	50+/0-	50+/0-
3	50-/0+	50-/0+	50-/0+	50-/0+	38+/12-	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 2-30 °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(s) urine with concentrations at 25% below and 25% above the cut-off levels by using 3 lots and 3 operators for each format. Compounds that showed no positive or negative interference at a concentration of 100 µg/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	Methylphenidate	Tetrahydrozoline
Codeine	Morphine-3-Dglucuronide	Δ^9 -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	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 Sulfate	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

(±) - 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
(±) - Chlorpheniramine	Meprobamate	Serotonin
Chlorpromazine	Methadone	Sulfamethazine
Chloroquine	Methoxyphenamine	Sulindac
Cholesterol	3,4-Methylene dioxymphetamine	Temazepam
Clomipramine	3,4-Methylene-dioxymethamphetamine	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

Morphine

Acebutolol	L - Ψ -Ephedrine	Papaverine
Acetopromazined-6	Erythromycin	Penicillin G
Acetamidophenol	β -Estradiol	Pentazocine
Acetophenetidin	Estrone-3-sulfate	Pentobarbital
Acetylprocainamide	Ethyl-p-aminobenzoate	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
Benzoyllecgonine	Ketamine	Quinidine
Benzphetamine	Ketoprofen	Quinine
Bilirubin	Labetalol	Ranitidine
Brompheniramine	Loperamide	Salicylic acid
Caffeine	Maprotiline	Secobarbital
Chloralhydrate	Meprobamate	Serotonin (5-Hydroxytyramine)
Chloramphenicol	Methadone	Sulfamethazine
Chlordiazepoxide	Methoxyphenamine	Sulindac
Chlorothiazide	3,4Methylenedioxyamphetamine	Temazepam
Chlorpheniramine	3,4Methylenedioxymethamphetamine	Tetracycline
Chlorpromazine	Methylphenidate	Tetrahydrocortisone
Chloroquine	Methyprylon	Tetrahydrocortisone 3 (β -D-glucuronide)
Cholesterol	Nalorphine	Tetrahydrozoline
Clomipramine	Naloxone	Thiamine

Clonidine	Nalidixic acid	Thioridazine
Cocaine hydrochloride	Naltrexone	D/ L-Thyroxine
Cortisone	Naproxen	Tolbutamidne
(-)- 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
Ecgonine methyl ester	p-Hydroxymethamphetamine	

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 is listed below. There were no differences observed for different devices. Results are summarized below:

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	<1%
l-Methamphetamine	Negative at 100000	<1%
ephedrine	Negative at 100000	<1%
Methylenedioxyethylamphetamine (MDE)	Negative at 100000	<1%
3,4-methylenedioxy-methamphetamine (MDMA)	Negative at 100000	<1%

Cocaine (Cut-off=300 ng/mL)	Result Positive at (ng/mL)	% Cross- Reactivity
Benzoyllecgonine	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%

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 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 formats.

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 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:

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

Amphetamine Dip Card:

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

Amphetamine Turn Key Split Cup:

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	13	25
	Negative	10	20	9	2	0
Viewer C	Positive	0	0	0	14	25
	Negative	10	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

Amphetamine Quick Cup:

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:

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

Cocaine Dip Card:

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

Cocaine Turn Key Split Cup:

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

Cocaine Quick Cup:

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:

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

Morphine Turn Dip Card:

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

Morphine Turn Key Split Cup:

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 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

Morphine Quick Cup:

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 Result for Amphetamine (AMP)/Cocaine (COC)/Morphine (MOR) Strip

% Cutoff	N	Concentration by GC/MS(ng/mL)			Lay person results			Correct results (%)		
		AMP	COC	MOR	AMP	COC	MOR	AMP	COC	MOR
-100%	21	0	0	0	0+/21-	0+/21-	0+/21-	100	100	100
-75%	21	252	70	514	0+/21-	0+/21-	0+/21-	100	100	100
-50%	21	506	165	982	0+/21-	0+/21-	0+/21-	100	100	100
-25%	21	749	255	1487	1+/20-	1+/20-	2+/19-	95	95	90
+25%	21	1253	384	2479	20+/1-	21+/0-	20+/1-	95	100	95
+50%	21	1504	459	3011	21+/0-	21+/0-	21+/0-	100	100	100
+75%	21	1755	517	3518	21+/0-	21+/0-	21+/0-	100	100	100

Comparison between GC/MS and Lay Person Result for Amphetamine (AMP)/Cocaine (COC)/Morphine (MOR) Dip Card

% Cutoff	N	Concentration by GC/MS(ng/mL)			Lay person results			Correct results (%)		
		AMP	COC	MOR	AMP	COC	MOR	AMP	COC	MOR
-100%	21	0	0	0	0+/21-	0+/21-	0+/21-	100	100	100
-75%	21	252	70	514	0+/21-	0+/21-	0+/21-	100	100	100
-50%	21	506	165	982	0+/21-	0+/21-	0+/21-	100	100	100
-25%	21	749	255	1487	1+/20-	1+/20-	2+/19-	95	95	90
+25%	21	1253	384	2479	20+/1-	20+/1-	21+/0-	95	95	100
+50%	21	1504	459	3011	21+/0-	21+/0-	21+/0-	100	100	100
+75%	21	1755	517	3518	21+/0-	21+/0-	21+/0-	100	100	100

Comparison between GC/MS and Lay Person Result for Amphetamine (AMP)/Cocaine (COC)/Morphine (MOR) Quick Cup

% Cutoff	N	Concentration by GC/MS(ng/mL)			Lay person results			Correct results (%)		
		AMP	COC	MOR	AMP	COC	MOR	AMP	COC	MOR
-100%	21	0	0	0	0+/21-	0+/21-	0+/21-	100	100	100
-75%	21	252	70	514	0+/21-	0+/21-	0+/21-	100	100	100
-50%	21	506	165	982	0+/21-	0+/21-	0+/21-	100	100	100
-25%	21	749	255	1487	2+/19-	1+/20-	1+/20-	90	95	90
+25%	21	1253	384	2479	20+/1-	20+/1-	21+/0-	95	95	100
+50%	21	1504	459	3011	21+/0-	21+/0-	21+/0-	100	100	100
+75%	21	1755	517	3518	21+/0-	21+/0-	21+/0-	100	100	100

Comparison between GC/MS and Lay Person Result for Amphetamine (AMP)/Cocaine (COC)/Morphine (MOR) Turn-Key Split Cup

% Cutoff	N	Concentration by GC/MS(ng/mL)			Lay person results			Correct results (%)		
		AMP	COC	MOR	AMP	COC	MOR	AMP	COC	MOR
-100%	21	0	0	0	0+/21-	0+/21-	0+/21-	100	100	100
-75%	21	252	70	514	0+/21-	0+/21-	0+/21-	100	100	100
-50%	21	506	165	982	0+/21-	0+/21-	0+/21-	100	100	100
-25%	21	749	255	1487	0+/21-	0+/21-	0+/21-	100	95	100
+25%	21	1253	384	2479	19+/2-	19+/2-	19+/2-	90	90	95
+50%	21	1504	459	3011	21+/0-	21+/0-	21+/0-	100	100	100
+75%	21	1755	517	3518	21+/0-	21+/0-	21+/0-	100	100	100

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.

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data:

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.