510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K201630

B Applicant

Assure Tech (Hangzhou) Co., Ltd.

C Proprietary and Established Names

AssureTech DOA Dipstick Screen Panel Tests, AssureTech DOA Integrated Cup Tests

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
DJG	Class II	21 CFR 862.3650 - Opiate Test System	TX - Clinical Toxicology
DKZ	Class II	21 CFR 862.3100 - Amphetamine test system	TX - Clinical Toxicology
LDJ	Class II	21 CFR 862.3870 - Cannabinoid test system	TX - Clinical Toxicology
DIO	Class II	21 CFR 862.3250 - Cocaine and cocaine metabolite test system	TX - Clinical Toxicology
LAF	Class II	21 CFR 862.3610 - Methamphetamine test system	TX - Clinical Toxicology
JXM	Class II	21 CFR 862.3170 - Benzodiazepine test system	TX - Clinical Toxicology
DIS	Class II	21 CFR 862.3150 - Barbiturate test system	TX - Clinical Toxicology
LCM	Unclassified		
DJR	Class II	21 CFR 862.3620 - Methadone test system	TX - Clinical Toxicology
LFG	Class II	21 CFR 862.3910 - Tricyclic antidepressant drugs test system	TX - Clinical Toxicology
JXN	Class II	21 CFR 862.3700 - Propoxyphene test system	TX - Clinical Toxicology

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

6-Monoacetylmorphine, Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline and d-Propoxyphene

C Type of Test:

Qualitative lateral flow immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

AssureTech DOA Dipstick Screen Panel Tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of 6-Monoacetylmorphine, Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline and d-Propoxyphene in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
6-Monoacetylmorphine	10 ng/mL
Amphetamine	500 ng/mL
Oxazepam	300 ng/mL
Cocaine	150 ng/mL
Marijuana	20 ng/mL
Methamphetamine	500 ng/mL
Morphine	300 ng/mL
Oxycodone	100 ng/mL
Secobarbital	300 ng/mL
Buprenorphine	10 ng/mL
Methylenedioxy-methamphetamine	500 ng/mL
Phencyclidine	25 ng/mL
Methadone	300 ng/mL
EDDP	300 ng/mL
Nortriptyline	1000 ng/mL
d-Propoxyphene	300 ng/mL

Configuration of the AssureTech DOA Dipstick Screen Panel Tests can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

For in vitro diagnostic use only.

AssureTech DOA Integrated Cup Tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of 6-Monoacetylmorphine, Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline and d-Propoxyphene in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
6-Monoacetylmorphine	10 ng/mL
Amphetamine	500 ng/mL
Oxazepam	300 ng/mL
Cocaine	150 ng/mL
Marijuana	20 ng/mL
Methamphetamine	500 ng/mL
Morphine	300 ng/mL
Oxycodone	100 ng/mL
Secobarbital	300 ng/mL
Buprenorphine	10 ng/mL
Methylenedioxy-methamphetamine	500 ng/mL
Phencyclidine	25 ng/mL
Methadone	300 ng/mL
EDDP	300 ng/mL
Nortriptyline	1000 ng/mL
d-Propoxyphene	300 ng/mL

Configuration of the AssureTech DOA Integrated Cup Tests can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test

results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

For in vitro diagnostic use only.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

D Special Instrument Requirements:

Not applicable

IV Device/System Characteristics:

A Device Description:

The device is available in a cup and dip card format. With the cup format, the test strips are integrated into the cup provided and the urine sample is collected directly into the cup containing the strips. With the dip card format, the urine is collected into a clean, dry container (not included) and the dip card is dipped into the urine that has been collected. Both formats use the same test strips.

B Principle of Operation:

Immunochromatographic assays of AssureTech DOA Dipstick Screen Panel and the DOA Integrated Cup Tests use a lateral flow, one step system for the qualitative detection of 6-Monoacetylmorphine, Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline and d-Propoxyphene (target analyte) in human urine. Each assay uses a monoclonal antibody-dye conjugate against drugs with gold chloride and fixed drug-protein conjugates and anti-mouse IgG polyclonal antibody in membranes. When the absorb end is immersed into the urine specimen, the urine is absorbed into the device by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cut-off (the detection sensitivity of the test), antibody-dye conjugate binds to the drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that, regardless of its intensity, indicates a negative result. When sample drug levels are at or above the target Cut-Off, the free drug in the sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a potentially positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly because of the antibody-dye conjugate binding to anti-mouse IgG immobilized in the Control Region (C) of the device.

V Substantial Equivalence Information:

A Predicate Device Name(s):
AssureTech Panel Dip Tests, AssureTech Quick Cup Tests, ATTEST Drug Screen Cup, ATTEST Drug Screen Dip Card

B Predicate 510(k) Number(s):
K181768, K182123

C Comparison with Predicate(s):

Device & Predicate Device(s):	K201630	K181768
Device Trade Name	AssureTech DOA Dipstick Screen Panel Tests, AssureTech DOA Integrated Cup Tests	AssureTech Panel Dip Tests, AssureTech Quick Cup Tests
General Device Characteristic Similarities		
Intended Use/Indications For Use	Same, with the addition of 6-MAM	For the qualitative detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline and Propoxyphene in human urine.
General Device Characteristic Differences		
Number of analytes	16	15
Cutoff (THC)	20 ng/mL	50 ng/mL

Device & Predicate Device(s):	K201630	K182123
Device Trade Name	AssureTech DOA Dipstick Screen Panel Tests, AssureTech DOA Integrated Cup Tests	ATTEST Drug Screen Cup, ATTEST Drug Screen Dip Card
General Device Characteristic Similarities		
Intended Use/Indications For Use	Same, different analytes	For the qualitative detection of 6-Acetylmorphine, d-Amphetamine, Benzoylecgonine, Buprenorphine, EDDP, d/l-Methadone, d-Methamphetamine, d/l-Methylenedioxymethamphetamine, Morphine, Nortriptyline, Oxazepam, Oxycodone, Phencyclidine, d-Propoxyphene, Secobarbital and THC-COOH in human urine
General Device Characteristic Differences		
Number of analytes	16	20

VI Standards/Guidance Documents Referenced:

None referenced.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Nine sample pools were prepared by spiking target drugs in drug-free urine samples. Each percentage is % cut-off corresponding to each target drug in each of the nine drug mix samples. The number under drug abbreviation is cut-off value of the drug.

Each sample pools were further aliquoted into 180 individual containers (total 1620 aliquots, 90 aliquots per spiked sample for each test format). All aliquots were blinded labeled by the person who prepared the samples and didn't take part in the sample testing. Drug concentrations of the

sample pools were confirmed by LC/MS/MS. These concentrations were blinded to test operators.

This was a multi-center study to validate the cutoff and precision of the AssureTech DOA Dipstick Screen Screen Panel Tests and the AssureTech DOA Integrated Cup Tests. The three sites represent the intended use settings of the product. Each study site had one test operator for each format to test these samples over a 10-day period. Each operator tested and interpreted 270 specimens over the course of ten days (27 specimens per day, 3 lots × 9 concentrations). Each operator could only test one device format, i.e., the person who tested the cup did not test the panel dip.

Results are summarized below:

AssureTech DOA Integrated Cup Tests

CUP	**6-MAM**			**AMP**			**BAR**		
Drug conc as % of cutoff	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 1**	**Lot 2**	**Lot 3**
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	24+/6-	23+/7-	23+/7-	23+/7-	24+/6-	26+/4-	28+/2-	26+/4-	28+/2-
+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

	BUP			**BZO**			**COC**		
Drug conc as % of cutoff	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 1**	**Lot 2**	**Lot 3**
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	28+/2-	27+/3-	27+/3-	28+/2-	28+/2-	29+/1-	23+/7-	26+/4-	24+/6-
+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

	EDDP			MDMA			MET		
Drug conc as % of cutoff	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 1**	**Lot 2**	**Lot 3**
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	24+/6-	24+/6-	25+/5-	23+/7-	22+/8-	22+/8-	23+/7-	27+/3-	23+/7-
+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

	MOR			MTD			OXY		
Drug conc as % of cutoff	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 1**	**Lot 2**	**Lot 3**
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	22+/8-	24+/6-	23+/7-	26+/4-	27+/3-	27+/3-	27+/3-	28+/2-	28+/2-
+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

	PCP			PPX			TCA		
Drug conc as % of cutoff	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 1**	**Lot 2**	**Lot 3**
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	25+/5-	25+/5-	24+/6-	25+/5-	27+/3-	25+/5-	24+/6-	25+/5-	23+/7-
+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

	THC		
Drug conc as % of cutoff	**Lot 1**	**Lot 2**	**Lot 3**
-100%	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+
cutoff	23+/7-	24+/6-	24+/6-
+25%	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-

AssureTech DOA Dipstick Screen Panel Tests

CARD	**6-MAM**			**AMP**			**BAR**		
Drug conc as % of cutoff	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 1**	**Lot 2**	**Lot 3**
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	24+/6	23+/7-	25+/5-	23+/7-	23+/7-	27+/3-	27+/3-	27+/3-	26+/4-
+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

	BUP			**BZO**			**COC**		
Drug conc as % of cutoff	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 1**	**Lot 2**	**Lot 3**
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	26+/4-	26+/4-	28+/2-	28+/2-	28+/2-	27+/3-	22+/8-	25+/5-	23+/7-
+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

	BUP			BZO			COC		
Drug conc as % of cutoff	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 1**	**Lot 2**	**Lot 3**
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

	EDDP			MDMA			BZO		
Drug conc as % of cutoff	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 1**	**Lot 2**	**Lot 3**
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	24+/6-	24+/6-	24+/6-	24+/6-	24+/6-	22+/8-	25+/5	25+/5-	24+/6-
25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

	MOR			MTD			OXY		
Drug conc as % of cutoff	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 1**	**Lot 2**	**Lot 3**
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	23+/7-	24+/6-	25+/5-	27+/3-	26+/4-	26+/4-	28+/2-	27+/3-	28+/2-
25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

	PCP			PPX			TCA		
Drug conc as % of cutoff	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 1**	**Lot 2**	**Lot 3**
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	25+/5-	25+/5-	24+/6-	25+/5-	25+/5-	26+/4-	23+/7-	23+/7-	24+/6-
25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

	THC		
Drug conc as % of cutoff	**Lot 1**	**Lot 2**	**Lot 3**
-100%	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+
cutoff	24+/6-	22+/8-	22+/8-
25%	30+/0-	30+/0-	30+/0-
50%	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-

2. Linearity:

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

3. Analytical Specificity/Interference:

   The sponsor performed specificity and cross-reactivity studies for the 6-Acetylmorphine (6-MAM) and THC strips only. Please refer to k181768 for the specificity and cross-reactivity performance for the remaining assays.

   The sponsor performed studies to evaluate whether compounds structurally related to 6-MAM and THC cross-react with the assays. The study used three lots and the testing was performed by trained professionals by following the instructions in the package insert.

   Results are summarized below:

6-acetylmorphine (Cut-off=10 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
6-acetylmorphine	10	100%
Acetylcodeine	>10000	<0.1%
Buprenorphine	>10000	<0.1%
Codeine	>10000	<0.1%
Diacetylmorphine	1000	1%
Dihydrocodeine	>10000	<0.1%
Ethylmorphine	>10000	<0.1%
Hydrocodone	>10000	<0.1%
Hydromorphone	5000	0.2%
Morphine	10000	0.1%
Morphine-3-glucuronide	>10000	<0.1%
Nalorphine	5000	0.2%
Thebaine	>20000	<0.05%
Dextromethorphan	>100,000	<0.01%
Heroin	100,000	0.01%
Imipramine	>100,000	<0.01%
LAAM (Levacetylmethadol)	>100,000	<0.01%
Levorphanol	>100,000	<0.01%
Meperidine	>100,000	<0.01%
Methadone	>100,000	<0.01%
Mitragynine (kratom)	>20,000	<0.05%
Morphine 6-D-glucuronide	>100,000	<0.01%
Naloxone	>100,000	<0.01%
Naltrexone	>100,000	<0.01%
Naproxen	>100,000	<0.01%
Norbuprenorphine	>10,000	<0.1%
Norbuprenorphine glucuronide	>100,000	<0.01%
Norcodeine	>100,000	<0.01%
Norhydrocodone	>100,000	<0.01%
Normorphine	>100,000	<0.01%
Noroxycodone	>100,000	<0.01%
Noroxymorphone	>100,000	<0.01%
Norpropoxyphene	>100,000	<0.01%
Oxycodone	>100,000	<0.01%
Oxymorphone	>100,000	<0.01%

6-acetylmorphine (Cut-off=10 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
Oxymorphone-3β-D-glucuronide	>100,000	<0.01%
Tapentadol HCl	>100,000	<0.01%
Tramadol	>100,000	<0.01%

Marijuana (Cut-off=20 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
11-nor-D^9-THC-9 COOH	20	100%
11-nor-D^8-THC-9 COOH	20	100%
Δ^8-Tetrahydrocannabinol	>10000	<0.2%
Δ^9-Tetrahydrocannabinol	>10000	<0.2%
Cannabinol	>10000	<0.2%

To evaluate potential positive or negative interference, non-structurally related compounds were added to drug-free urine and to urine samples containing the claimed analytes at 25% below and 25% above each corresponding cutoff.

Potential interferents were spiked in at a concentration of 100 µg/mL except for albumin at 100 mg/dL and ethanol at 1%.

The following compounds did not cause any positive or negative interference with any of the 16 assays with the candidate device.

Acetaminophen, Acetophenetidin, N-Acetylprocainamide, Acetylsalicylic acid, Albumin (100mg/dL), Aminopyrine, Amoxicillin, Ampicillin, Apomorphine, Ascorbic acid, Aspartame, Atropine, Benzilic acid, Benzoic acid, Bilirubin, Chloral hydrate, Digoxin, Diphenhydramine, Ecgonine methyl ester, β-Estradiol, Erythromycin, Ethanol (1%), Fenoprofen, Furosemide, Gentisic acid, Hemoglobin, Hydralazine, Hydrochlorothiazide, Hydrocortisone, O-Hydroxyhippuric acid, 3-Hydroxytyramine, Ibuprofen, Isoproterenol, Isoxsuprine, Ketamine, Ketoprofen, Labetalol, Loperamide, Meperidine, Meprobamate, Methoxyphenamine, Nalidixic acid, Naloxone, Naltrexone, Naproxen, Niacinamide, Nifedipine, Norethindrone, Noscapine, (±)-Octopamine, Oxalic acid, Oxolinic acid, Oxymetazoline, Papaverine, Penicillin G, Perphenazine, Phenelzine, Prednisone, (±)-Propranolol, Pseudoephedrine, Quinine, Ranitidine, Salicylic acid, Serotonin (5-Hydroxytyramine), Sulfamethazine Sulindac, Tetrahydrocortisone, 3-(β-D glucuronide, Tetrahydrocortisone 3-acetate, Tetrahydrozoline, Thiamine, Thioridazine, Triamterene, Trifluoperazine, Trimethoprim, DL-Tryptophan, Tyramine, DL-Tyrosine, Uric acid, Verapamil, and Zomepirac.

The sponsor also performed studies to evaluate the effect of urine pH and specific gravity on the results. Samples with concentrations of 0 (drug-free), at 25% below and 25% above each corresponding cutoff were adjusted to pH levels of 4, 5, 6, 7, 8, and 9 and at a specific gravity of 1.001, 1.003, 1.005, 1.007, 1.009, 1.010, 1.012, 1.014, 1.015, 1.016, 1.017, 1.020, 1.021, 1.024, 1.025, 1.026, 1.027, 1.029, and 1.030.

There were no deviations from the expected negative or positive results for either pH or specific gravity.

4. Assay Reportable Range:

   Not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   The sponsor's stability protocols were reviewed and found to be acceptable. A shelf-life stability of 24 months from the date of manufacture is claimed.

6. Detection Limit:

   Not applicable.

7. Assay Cut-Off:

   See section VII.A.1 above for a description of how the device performs around the cutoffs.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Method comparison studies for the AssureTech DOA Dipstick Screen Panel Tests and the AssureTech DOA Integrated Cup Tests were performed in-house with three laboratory assistants for each device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples for each drug. The samples were blind labeled and compared to GC/MS results. The results are presented in the tables below for 6-MAM and THC. Please refer to k181768 for the method comparison performance for the remaining assays.

Dip 6-MAM		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer 1	Positive	0	0	0	15	5
	Negative	10	20	10	0	0
Viewer 2	Positive	0	0	0	15	25
	Negative	10	20	10	0	0
Viewer 3	Positive	0	0	0	15	25
	Negative	10	20	10	0	0

Cup 6-MAM		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer 1	Positive	0	0	0	15	25
	Negative	10	20	10	0	0
Viewer 2	Positive	0	0	0	15	25
	Negative	10	20	10	0	0
Viewer 3	Positive	0	0	0	15	25
	Negative	10	20	10	0	0

Dip THC		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer 1	Positive	0	0	0	14	25
	Negative	10	20	10	1	0
Viewer 2	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Viewer 3	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

Cup THC		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer 1	Positive	0	0	0	14	25
	Negative	10	20	10	1	0
Viewer 2	Positive	0	0	0	15	25
	Negative	10	20	10	0	0
Viewer 3	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

2. Matrix Comparison:

Not applicable. The assays are only intended for use with urine samples.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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