

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

I Background Information:

A 510(k) Number

k191099

B Applicant

Atlas Medical

C Proprietary and Established Names

Atlas Multi-Drugs Screening Test Cup, Atlas Multi-Drugs Screening Test Panel

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
DKZ	Class II	21 CFR 862.3100 Amphetamine Test System	91 (Toxicology)
DIS	Class II	21 CFR 862.3150 Barbiturate test system	91 (Toxicology)
JXM	Class II	21 CFR 862.3170 Benzodiazepine test system	91 (Toxicology)
JXN	Class II	21 CFR 862.3700 Propoxyphene Test System	91 (Toxicology)
DIO	Class II	21 CFR 862.3250 Cocaine and cocaine metabolite test system	91 (Toxicology)
DJC	Class II	21 CFR 862.3610 Methamphetamine test system	91 (Toxicology)
DJR	Class II	21 CFR 862.3620 Methadone test system	91 (Toxicology)
DJG	Class II	21 CFR 862.3650 Opiate test system	91 (Toxicology)
LCM	Unclassified, Enzyme immunoassay, phencyclidine test system		91 (Toxicology)
LDJ	Class II	21 CFR 862.3870 Cannabinoid test system	91 (Toxicology)

Product Code(s)	Classification	Regulation Section	Panel
LFG	Class II	21 CFR 862.3910 Tricyclic antidepressant drugs test system	91 (Toxicology)
DNK	Class II	21 CFR 862.3640 Morphine test system	91 (Toxicology)

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Amphetamine, Methylenedioxymethamphetamine, Morphine, Oxycodone, Cocaine, Nortriptyline, Methamphetamine, Phencyclidine, Marijuana, Secobarbital, Oxazepam, Methadone, Propoxyphene, and Buprenorphine.

C Type of Test:

Lateral flow chromatographic immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

Atlas Multi-Drugs Screening Test Cup and Atlas Multi-Drugs Screening Test Panel are lateral flow chromatographic in vitro diagnostics immunoassays for the qualitative detection of following drugs in urine without the need of instruments:

Drug Name	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	D-Amphetamine	1000
Methylenedioxymethamphetamine (MDMA)	D,LMethylenedioxymethamphetamine	500
Morphine (MOP)	Morphine	300
Morphine (MOP)	Morphine	2000
Oxycodone (OXY)	Oxycodone	100
Cocaine (COC)	Benzoylcegonine	300
Nortriptyline	Nortriptyline	1000
Methamphetamine (MET)	D-Methamphetamine	1000
Phencyclidine (PCP)	Phencyclidine	25
Marijuana (THC)	11-nor- Δ^9 -THC-9 COOH	50
Secobarbital	Secobarbital	300
Oxazepam	Oxazepam	300
Methadone (MTD)	Methadone	300
Propoxyphene (PPX)	Propoxyphene	300
Buprenorphine (BUP)	Buprenorphine	10

The tests are intended for professional use only. The tests will yield preliminary positive results when the prescription drugs Secobarbital, oxazepam, Buprenorphine, Oxycodone, Propoxyphene, and Nortriptyline are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Secobarbital, oxazepam, Buprenorphine, Oxycodone, Propoxyphene, and Nortriptyline in urine. The multi-drugs screening tests (Cup and Panel formats) show the drug was or was not present at the cutoff level. The tests provide only preliminary test results, which must be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated. The tests are not intended to be used in monitoring the drug levels.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use

D. Special Conditions for Use Statement(s):

None

IV Device/System Characteristics:

A Device Description:

The Atlas Multi-Drugs Screening Test Cup and the Atlas Multi-Drugs Screening Test Panel are competitive binding, lateral flow immunochromatographic assays for the qualitative detection of the drugs of abuse, at the indicated cutoffs, stated in the indications for use. The tests can be performed without the use of an instrument. The devices are available in one of two formats: Test Cup and Dipcard. The test configurations consist of single drug screening tests or any combinations of multiple drug screening tests.

B Principle of Operation:

The Atlas Multi-Drugs Screening Test Cup and the Atlas Multi-Drugs Screening Test Panel are immunoassays based on the principle of competitive binding. Drugs present in the urine specimen compete against the drug conjugate for binding sites on the antibody. During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region. A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Rapid Single/Multi-drug Test Cup, Rapid Single/Multi-drug Test Dipcard

B Predicate 510(k) Number(s):

k153050

C Comparison with Predicate(s):

Similarities		
Item	Candidate Device (k191099)	Predicate Device (k153050)
	Atlas Multi-Drugs Screening Test panel Atlas Multi-Drugs Screening Test Cup	Rapid Single/Multi-drug Test Cup Rapid Single/Multi-drug Test Dipcard
Intended use	For the qualitative detection of drugs of abuse	Same
Specimen type (Matrix)	Urine	Same
Methodology	Colloidal Gold Immunoassay (Membrane particle assay)	Same
Test Time	5 minutes	Same
Cut-off (ng/mL)	AMP 1000	Same
	MDMA 500	Same
	Oxazepam 300	Same
	BUP 10	Same
	COC 300	Same
	MET 1000	Same
	MTD 300	Same
	MOP 300	Same
	MOP 2000	Same
	OXY 100	Same
	PCP 25	Same
	PPX 300	Same
	Nortriptyline 1000	Same
	THC 50	Same
Secobarbital 300	Same	

Differences		
Item	Candidate Device (k191099)	Predicate Device (k153050)
	Atlas Multi-Drugs Screening Test panel Atlas Multi-Drugs Screening Test Cup	Rapid Single/Multi-drug Test Cup Rapid Single/Multi-drug Test Dipcard
Intended User	Prescription Use	Prescription and OTC use
Storage	2-30°C	4-30°C

VI Standards/Guidance Documents Referenced:

None referenced.

VII Performance Characteristics (if/when applicable):**A Analytical Performance:**1. Precision/Reproducibility:

A precision study was conducted where three operators tested drug concentrations around the cutoff, using spiked urine samples that were provided blind to the operators. Each operator used devices from 3 different lots of the Atlas Multi-Drugs Screening Test Cup and the Atlas Multi-Drugs Screening Test Panel, and the study was conducted over 2 weeks. For each sample, 45 results were generated for each device. Results are provided in the table below.

Atlas Multi-Drugs Screening Test Panel Test Result:

Amphetamine (AMP) 1,000 ng/ml									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Secobarbital 300 ng/mL									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Oxazepam 300 ng/mL									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Buprenorphine (BUP) 10 ng/ml									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Marijuana (THC) 50 ng/ml									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Methadone (MTD) 300 ng/mL									

Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Methamphetamine (MET) 1,000 ng/mL									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Methylenedioxymethamphetamine (MDMA) 500 ng/mL									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Morphine (MOP 300) 300 ng/mL									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Morphine (MOP 2000) 2000 ng/mL									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Oxycodone (OXY) 100ng/mL									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Phencyclidine (PCP) 25 ng/mL									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Propoxyphene (PPX) 300ng/mL									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-

Nortriptyline 1,000 ng/mL									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Cocaine (COC) 300 ng/mL									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-

Atlas Multi-Drugs Screening Test Cup Test Result:

Amphetamine (AMP) 1,000 ng/ml									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Secobarbital 300 ng/mL									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Oxazepam 300 ng/mL									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Buprenorphine (BUP) 10 ng/ml									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Marijuana (THC) 50 ng/ml									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Methadone (MTD) 300 ng/mL									

Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Methamphetamine (MET) 1,000 ng/mL									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Methylenedioxymethamphetamine (MDMA) 500 ng/mL									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Morphine (MOP 300) 300 ng/mL									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Morphine (MOP 2000) 2000 ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45-/0+	45-/0+	45-/0+	45-/0+	45-/0+
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45-/0+	45-/0+	45-/0+	45-/0+	45-/0+
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45-/0+	45-/0+	45-/0+	45-/0+	45-/0+
Oxycodone (OXY) 100ng/mL									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Phencyclidine (PCP) 25 ng/mL									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Propoxyphene (PPX) 300ng/mL									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/-	45+/-	45+/-	45+/-	45+/-

Nortriptyline 1,000 ng/mL									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Cocaine (COC) 300 ng/mL									
Lot No.	-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 A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-

2. Linearity:
Not applicable.

3. Analytical Specificity/Interference:

Cross-reactivity:

Cross reactivity with structurally similar compounds was tested for each device, and the results for both devices were identical, as provided in the table below. The table below lists the concentrations at which various compounds produced a positive result, or the maximum concentration detected, and these concentrations were used to calculate the percent (%) cross-reactivity.

Drug Name	ng/mL	% of cross reactivity
AMPHETAMINE 1000		
D-Amphetamine	1000	100%
D, L-Amphetamine	2500	40%
L-Amphetamine	50000	2%
(+/-)3,4-Methylenedioxy-amphetamine (MDA)	2000	50%
Ephedrine	> 100000	>1%
3,4-Methylenedioxyethylamphetamine (MDEA)	> 100000	>1%
MDMA	1000	100%
D-Methamphetamine	1500	66.7%
L- Methamphetamine	3500	28.5%

SECOBARBITAL 300	ng/mL	% of cross reactivity
Secobarbital	300	100%
Phenobarbital	2500	12%
Butalbital	500	60%
Pentobarbital	1500	20%
Amobarbital	2500	12%

SECOBARBITAL 300	ng/mL	% of cross reactivity
Cyclopentobarbital	500	60%
Butethal	800	37.5%
Barbital	300	100%
Butabarbital	1500	20%

Buprenorphine 10	ng/mL	% of cross reactivity
Buprenorphine	10	100%
Norbuprenorphine	15	66.7%
Buprenorphine 3-D-Glucuronide	12.5	80%
Norbuprenorphine 3-D-Glucuronide	175	5.7%
Morphine-3-D-glucoronide	100000	0.01%
Morphine	> 100000	>0.01%
Oxymorphone	> 100000	>0.01%
Hydromorphone	> 100000	>0.01%

OXAZEPAM 300	ng/mL	% of cross reactivity
Oxazepam	300	100%
Alprazolam	200	150%
α -Hydroxyalprazolam	1000	30%
Bromazepam	250	120%
Chlordiazepoxide	2500	12%
Clobazam	100	300%
Clonazepam	850	35.3%
Clorazepate	250	120%
Delorazepam	1600	18.75%
Diazepam	200	150%
Estazolam	200	150%
Flunitrazepam	300	100%
Lorazepam	1000	30%
Midazolam	1500	20%
Nitrazepam	100	300%
Nordiazepam	400	75%
Temazepam	150	200%
Triazolam	500	60%

COCAINE 300	ng/mL	% of cross reactivity
Cocaine	> 100000	>0.3%
Benzoylcegonine	300	100%
EcgonineHCl	35000	0.86%
Coethylene	14000	2.14%
Norcocaine	> 100000	>0.3%

METHADONE 300	ng/mL	% of cross reactivity
Methadone	300	100%
(+)-2-Ethyl-1,5-dimethyl-3,3-diphenylpyrrolinium	50000	0.6%
Doxylamine	50000	0.6%
EMDP (2-Ethyl-5-methyl-3,3-diphenylpyrroline)	> 100000	>0.3%
LAAM (1-Alpha-acetylmethadol)	5000	6%
α - Methadol	2000	15%
Disopyramide	8000	3.75%

METHAMPHETAMINES 1000	ng/mL	% of cross reactivity
(+/-)- Methamphetamine	2000	50%
(+)-Methamphetamine	1000	100%
3,4-Methylenedioxythylamphetamine (MDEA)	35000	2.85%
(+/-) 3,4-Methylenedioxymethamphetamine (MDMA)	2000	50%
Ranitidine (Zantac)	> 100000	>1%
3,4-Methylenedioxyamphetamine (MDA)	> 100000	>1%
D-Amphetamine	> 100000	>1%
L-Amphetamine	> 100000	>1%
Ephedrine	> 100000	>1%
L-Methamphetamine	5000	20%

METHYLENEDIOXYMETHAMPHETAMINE (MDMA) 500	ng/mL	% of cross reactivity
(+/-) 3,4-Methylenedioxymethamphetamine (MDMA)	500	100%
D-Amphetamine	> 100000	> 0.5%
L-Methamphetamine	100000	0.5%
3,4-Methylenedioxythylamphetamine (MDEA)	200	250%
3,4-Methylenedioxyamphetamine (MDA)	2000	25%
L-Amphetamine	> 100000	> 0.5%
D-Methamphetamine	> 100000	> 0.5%

MARIJUANA 50	ng/mL	% of cross reactivity
11-nor-D ⁹ -THC-9 COOH	50	100%
11-nor-D ⁸ -THC-9 COOH	50	100%
D ⁸ -THC	8000	0.6%
D ⁹ -THC	10000	0.5%
Cannabinol	100000	0.05%

MORPHINE 2000	ng/mL	% of cross reactivity
Morphine	2000	100%
Codeine	2000	100%
Hydrocodone	10000	20%
Hydromorphone	7000	28.5%
Morphine 3-b-D-glucuronide	2000	100%
6-Monoacetylmorphine	5000	40%
Normorphone	100000	2%
Oxycodone	20000	10%
Oxymorphone	100000	2%
Thebaine	70000	2.8%
Heroin	2500	80%
Ethylmorphine	5000	40%

MORPHINE 300	ng/mL	% of cross reactivity
Morphine	300	100%
Codeine	300	100%
Hydrocodone	2000	15%
Hydromorphone	3500	8.5%
Morphine 3-b-D-glucuronide	300	100%
6-Monoacetylmorphine	600	50%
Normorphone	100000	0.3%
Oxycodone	10000	3%
Oxymorphone	50000	0.6%
Thebaine	7000	4.3%
Heroin	350	85.7%
Ethylmorphine	6000	5%

OXYCODONE 100	ng/mL	% of cross reactivity
Oxycodone	100	100%
Morphine	50000	0.2%
Codeine	25000	0.4%
Morphine 3-b-D-glucuronide	50000	0.2%
Hydrocodone	1600	6.25%
Hydromorphone	15000	0.67%
Normorphone	100000	0.1%
Oxymorphone	1500	6.7%
6-Monoacetylmorphine	>100000	>0.1%
Ethylmorphine	5000	2%

PHENCYCLIDINE 25	ng/mL	% of cross reactivity
Phencyclidine	25	100%
4-Hydroxyphencyclidine	15000	0.17%

PROPOXYPHENE 300	ng/mL	% of cross reactivity
propoxyphene	300	100%
Norpropoxyphene	7500	4%
Methadone	> 100000	0.3%

NORTRIPTYLINE 1000	ng/mL	% of cross reactivity
Nortriptyline	1000	100%
Trimipramine	4500	22.2%
Amitriptyline	1000	100%
Promazine	3000	33.3%
Desipramine	1000	100%
Imipramine	1000	100%
Clomipramine	7500	13.3%
Doxepine	3000	33.3%
Maprotiline	50000	2%

Interference:

Interference from structurally similar and dissimilar compounds was evaluated by spiking these compounds into urine samples containing drugs of abuse at concentrations of +/-25% of the respective cut-offs. The following list of potentially interfering substances showed no interference at a test concentration of 100 ug/ml (albumin was evaluated at 20 mg/mL) when tested with Atlas Multi-Drugs Screening Test Panel and Atlas Multi-Drugs Screening Test cup.

Acetophenetidin	Estrone-3-sulfate	Penicillin-G
Acetone	Ethyl alcohol	Perphenazine
N-Acetylprocainamide	L-ψ-Ephedrine	Phenelzine
Acetylsalicylic acid	Fenoprofen	L-Phenylephrine
Acetaminophen	Furosemide	b-Phenylethylamine
Albumin	Gentisic acid	Pheniramine
Aminopyrine	d-Glucose	Phenothiazine
Amoxicillin	Guaiacol Glyceryl Ether	Prednisolone
Ampicillin	Hemoglobin	Prednisone
L-Ascorbic acid	Hydralazine	Procaine
Apomorphine	Hydrochlorothiazide	DL-Propranolol
Aspartame	Hydrocortisone	D-Pseudoephedrine
Atropine	O-Hydroxyhippuric acid	Quinidine
Benzilic acid	Ibuprofen	Quinine
Benzoic acid	D, L-Isoproterenol	Ranitidine
Bilirubin	Isoxsuprine	Riboflavin
Caffeine	Ketamine	Salicylic acid
Cannabidiol	Ketoprofen	Serotonin
Chloralhydrate	Labetalol	Sodium chloride
Chloramphenicol	Lidocaine	Sulfamethazine
Chlorothiazide	Loperamide	Sulindac
(+) Chlorpheniramine	Meperidine	Tetracycline
Chlorprothixene	Meprobamate	Tetrahydrocortisone, 3-acetate
Chloroquine	Methoxyphenamine	Tetrahydrozoline
Cholesterol	Methylphenidate	Thiamine
Clonidine	Nalidixic acid	Theophylline
Cortisone	Naloxone	Tolbutamide
L- Cotine	Naltrexone	Triamterene
Creatinine	Naproxen	Trifluoperazine
Deoxycorticosterone	Niacinamide	Trimethoprim
Dextromethorphan	Nifedipine	DL-Tryptophan
Dexbrompheniramine	Nicotine	Verapamil
Diclofenac	Norethindrone	Zomepirac
Diffunisal	Noscapine	(R,2S)-(-)-N-Methyl-Ephedrine
Digoxin	Norephedrine	
4-Dimethylaminoantipyrine	d,l-Octopamine	
Diphenhydramine	Oxalic acid	
Dopamine	Oxolinic acid	
Erythromycin	Oxymetazoline	
b-Estradiol	Papaverine	

Effect of pH on the Atlas Multi-Drugs Screening Test Cup and the Atlas Multi-Drugs Screening Test Panel:

The pH of drug-free urine samples was adjusted to be pH 4.5, 5, 6, 7, 8 and 9, and the samples were spiked with drugs of abuse to +/-25% and +/-50% of the respective cutoffs. Each sample was tested using the Atlas Multi-Drugs Screening Test Cup and the Atlas Multi-Drugs Screening Test Panel. The results demonstrated that the pH does not affect the results of the Atlas Multi-Drugs Screening Test Cup and the Atlas Multi-Drugs Screening Test Panels.

Effect of specific gravity on the Atlas Multi-Drugs Screening Test Cup and the Atlas Multi-Drugs Screening Test Panel:

The specific gravity of drug-free urine samples was adjusted to 1.005, 1.010, 1.015, 1.025 and 1.030 and spiked with drugs of abuse to +/-25% and +/-50% of the respective cutoffs. Each sample was tested using the Atlas Multi-Drugs Screening Test Cup and the Atlas Multi-Drugs Screening Test Panel. The results demonstrated that the specific gravity does not affect the results of the Atlas Multi-Drugs Screening Test Cup and the Atlas Multi-Drugs Screening Test Panel.

4. Assay Reportable Range:
Not applicable.
5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):
Not applicable.
6. Detection Limit:
Not applicable.
7. Assay Cut-Off:
See section VII.A.1.

B Comparison Studies:

1. Accuracy
A method comparison study was conducted to demonstrate the accuracy of the Atlas Multi-Drugs Screening Test Cup and the Atlas Multi-Drugs Screening Test Panel with the GC/MS or LC/MS methods. Testing was performed on 80 unaltered clinical specimens for each test analyte (except for PCP samples which were diluted as per the table mentioned below in the study due to difficulty in sourcing PCP native samples). The unaltered clinical samples were quantitated with GC/MS or LC/MS and were also tested using the Atlas Multi-Drugs Screening Test Cup and the Atlas Multi-Drugs Screening Test Panel. Test results per drug analyte are summarized in the table below:

1) Atlas Multi-Drugs Screening Test Panel Test Result:

Tested Drug	Candidate Device Result	Negative samples	Less than half the cutoff concentration by GC/MS	Near cutoff negative (between - 50% below the cutoff and the cutoff concentration)	Near cutoff positive (between the cutoff and +50% Above the cutoff concentration)	High Positive (greater than +50% above the cutoff concentration)
AMP 1000	Positive	0	0	1	4	36
	Negative	16	20	3	0	0
Secobarbital 300	Positive	0	0	1	2	37
	Negative	18	17	4	1	0
Oxazepam 300	Positive	0	0	2	3	36
	Negative	19	17	2	1	0
COC 300	Positive	0	0	1	3	37
	Negative	20	15	4	0	0
THC 50	Positive	0	0	0	2	36
	Negative	21	15	4	2	0
MTD 300	Positive	0	0	1	2	37
	Negative	18	17	4	1	0
MET 1000	Positive	0	0	2	3	36
	Negative	22	14	2	1	0
MDMA 500	Positive	0	0	1	4	36
	Negative	25	11	3	0	0
MOP 300	Positive	0	0	1	2	37
	Negative	21	14	4	1	0
MOP 2000	Positive	0	0	0	4	35
	Negative	20	17	3	1	0
PPX 300	Positive	0	0	1	2	36
	Negative	25	11	3	2	0
OXY 100	Positive	0	0	1	3	37
	Negative	21	14	4	0	0
Nortriptyline 1000	Positive	0	0	0	2	36
	Negative	22	14	4	2	0
BUP 10	Positive	0	0	0	2	36
	Negative	21	15	4	2	0
PCP 25	Positive	0	0	2	3	16
	Negative	20	16	4	0	0

2) Atlas Multi-Drugs Screening Test Cup Test Result:

Tested Drug	Candidate Device Result	Negative samples	Less than half the cutoff concentration by GC/MS	Near cutoff negative (between - 50% below the cutoff and the cutoff concentration)	Near cutoff positive (between the cutoff and +50% Above the	High Positive (greater than +50% above the cutoff concentration)
--------------------	--------------------------------	-------------------------	---	---	--	---

					cutoff concentration)	
AMP 1000	Positive	0	0	1	4	36
	Negative	16	20	3	0	0
Secobarbital 300	Positive	0	0	1	2	37
	Negative	18	17	4	1	0
Oxazepam 300	Positive	0	0	2	3	36
	Negative	19	17	2	1	0
COC 300	Positive	0	0	1	3	37
	Negative	20	15	4	0	0
THC 50	Positive	0	0	0	2	36
	Negative	21	15	4	2	0
MTD 300	Positive	0	0	1	2	37
	Negative	18	17	4	1	0
MET 1000	Positive	0	0	2	3	36
	Negative	22	14	2	1	0
MDMA 500	Positive	0	0	1	4	36
	Negative	25	11	3	0	0
MOP 300	Positive	0	0	1	2	37
	Negative	21	14	4	1	0
MOP 2000	Positive	0	0	0	4	35
	Negative	20	17	3	1	0
PPX 300	Positive	0	0	1	2	36
	Negative	25	11	3	2	0
OXY 100	Positive	0	0	1	3	37
	Negative	21	14	4	0	0
Nortriptyline 1000	Positive	0	0	0	2	36
	Negative	23	13	4	2	0
BUP 10	Positive	0	0	0	2	36
	Negative	21	15	4	2	0
PCP 25	Positive	0	0	2	3	16
	Negative	20	16	4	0	0

The Summary of Discordant Results is listed in the table below:

Tested Drug	Cut-off	Sample Number	LC/MS Result	Atlas Multi – Screening DOA panel Test Results	Atlas Multi – Screening DOA Cup Test Results
AMP	1000	Sample 23	855	Positive	Positive
Secobarbital	300	Sample 51	287	Positive	Positive
Secobarbital	300	Sample 71	348	Negative	Negative
Oxazepam	300	Sample 16	330	Negative	Negative
Oxazepam	300	Sample 37	299	Positive	Positive
Oxazepam	300	Sample 78	198	Positive	Positive

COC	300	Sample 67	294	Positive	Positive
THC	50	Sample 43	55	Negative	Negative
THC	50	Sample 66	56	Negative	Negative
MTD	300	Sample 43	304	Negative	Negative
MTD	300	Sample 80	293	Positive	Positive
MET	1000	Sample 6	1006	Negative	Negative
MET	1000	Sample 34	992	Positive	Positive
MET	1000	Sample 63	989	Positive	Positive
MDMA	500	Sample 43	501	Positive	Positive
MOP	300	Sample 7	318	Negative	Negative
MOP	300	Sample 57	292	Positive	Positive
MOP	2000	Sample 4	2007	Negative	Negative
PCP	25	Sample 10	24	Positive	Positive
PCP	25	Sample 26	22	Positive	Positive
PPX	300	Sample 15	314	Negative	Negative
PPX	300	Sample 42	302	Negative	Negative
PPX	300	Sample 47	289	Positive	Positive
OXY	100	Sample 25	98	Positive	Positive
Nortriptyline	1000	Sample 61	1010	Negative	Negative
Nortriptyline	1000	Sample 78	1013	Negative	Negative
BUP	10	Sample 3	11	Negative	Negative
BUP	10	Sample 78	11	Negative	Negative

2. Matrix Comparison:
Urine is the only matrix

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):
None

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 support a substantial equivalence decision.