



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

I Background Information:

A 510(k) Number

K240698

B Applicant

Guangzhou Decheng Biotechnology Co., Ltd.

C Proprietary and Established Names

Dochek® Multi-Drug Urine Test Dipcard Rx; Dochek® Multi-Drug Urine Test Dipcard

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NFT	Class II	21 CFR 862.3100 - Amphetamine Test System	TX - Clinical Toxicology
DKZ	Class II	21 CFR 862.3100 - Amphetamine test system	TX - Clinical Toxicology
PTH	Class II	21 CFR 862.3150 - Barbiturate test system	TX - Clinical Toxicology
DIS	Class II	21 CFR 862.3150 - Barbiturate test system	TX - Clinical Toxicology
NGL	Class II	21 CFR 862.3650 - Opiate test system	TX - Clinical Toxicology
DJG	Class II	21 CFR 862.3650 - Opiate test system	TX - Clinical Toxicology
NFV	Class II	21 CFR 862.3170 - Benzodiazepine test system	TX - Clinical Toxicology

JXM	Class II	21 CFR 862.3170 - Benzodiazepine test system	TX - Clinical Toxicology
NFY	Class II	21 CFR 862.3250 - Cocaine and cocaine metabolite test system	TX - Clinical Toxicology
DIO	Class II	21 CFR 862.3250 - Cocaine and cocaine metabolite test system	TX - Clinical Toxicology
PTG	Class II	21 CFR 862.3620 - Methadone test system	TX - Clinical Toxicology
DJR	Class II	21 CFR 862.3620 - Methadone test system	TX - Clinical Toxicology
NGG	Class II	21 CFR 862.3610 - Methamphetamine test system	TX - Clinical Toxicology
DJC	Class II	21 CFR 862.3610 - Methamphetamine test system	TX - Clinical Toxicology
NGM	Unclassified		
LCM	Unclassified		
QBF	Class II	21 CFR 862.3700 - Propoxyphene test system	TX - Clinical Toxicology
JXN	Class II	21 CFR 862.3700 - Propoxyphene test system	TX - Clinical Toxicology
QAW	Class II	21 CFR 862.3910 - Tricyclic antidepressant drugs test system	TX - Clinical Toxicology
LFG	Class II	21 CFR 862.3910 - Tricyclic antidepressant drugs test system	TX - Clinical Toxicology
NFW	Class II	21 CFR 862.3870 - Cannabinoid test system	TX - Clinical Toxicology
LDJ	Class II	21 CFR 862.3870 - Cannabinoid test system	TX - Clinical Toxicology

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, d-Propoxyphene, Nortriptyline, Cannabinoids and 6-Acetylmorphine

C Type of Test:

Qualitative lateral flow immunochromatographic assay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

Dochek® Multi-Drug Urine Test Dipcard Rx is an immunoassay for the qualitative determination of single or multiple drugs in human urine at the following cutoff concentrations:

Drug (Identifier)	Cut-off level
Amphetamine (AMP)	1000 or 500 ng/mL
Secobarbital (BAR)	300 ng/mL
Buprenorphine (BUP)	10 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300 or 150 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Methamphetamine (MET)	1000 or 500 ng/mL
Morphine (MOP300/OPI2000)	2000 or 300 ng/mL
Methadone (MTD)	300 ng/mL

Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Cannabinoids (THC)	50 ng/mL
6-Monoacetylmorphine (6-MAM)	10 ng/mL

Dochek® Multi-Drug Urine Test Dipcard Rx offers any combinations from 1 to 16 drugs but only one cutoff concentration under same drug condition will be included per device. It is intended for prescription use. For in vitro diagnostic use only.

The test provides only preliminary results. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. GC/MS or LC/MS is the recommended confirmatory method.

Dochek® Multi-Drug Urine Test Dipcard is an immunoassay for the qualitative determination of single or multiple drugs in human urine at the following cutoff concentrations:

Drug (Identifier)	Cut-off level
Amphetamine (AMP)	1000 or 500 ng/mL
Secobarbital (BAR)	300 ng/mL
Buprenorphine (BUP)	10 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300 or 150 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Methamphetamine (MET)	1000 or 500 ng/mL
Morphine (MOP300/OPI2000)	2000 or 300 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL

Nortriptyline (TCA)	1000 ng/mL
Cannabinoids (THC)	50 ng/mL
6-Monoacetylmorphine (6-MAM)	10 ng/mL

Dochek® Multi-Drug Urine Test Dipcard offers any combinations from 1 to 16 drugs but only one cutoff concentration under same drug condition will be included per device. It is intended for over-the-counter (OTC) use. For in vitro diagnostic use only.

The test provides only preliminary results. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. GC/MS or LC/MS is the recommended confirmatory method.

C Special Conditions for Use Statement(s):

Rx and OTC

D Special Instrument Requirements:

Not applicable.

IV Device/System Characteristics:

A Device Description:

Dochek® Multi-Drug Urine Test Dipcard Rx and Dochek® Multi-Drug Urine Test Dipcard are immunochromatographic assays that use a lateral flow system for the qualitative detection of single or multiple drugs in human urine.

This device is a dipcard format in which the test strips are integrated into the plastic dipcard. After removing the cap of the dipcard, the absorbent end of the test strips is exposed and can be in direct contact with the urine sample. The device is in a ready-to-use format and no longer requires assembly before use. The products are single-use in vitro diagnostic devices.

B Principle of Operation:

The candidate device is a competitive immunoassay that is used to screen for the presence of various drugs and drug metabolites in urine. It is a chromatographic absorbent device in which, drugs within a urine sample, competitively combined to a limited number of drug monoclonal antibody (mouse) conjugate binding sites. When the test is activated, the urine is absorbed into each test strip by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across a pre-coated membrane. When drug within the urine sample is below the detection level of the test, respective drug monoclonal antibody conjugate binds to the respective drug-protein conjugate immobilized in the Test Region (T) of the test strip. This produces a colored Test line in the Test Region (T) of the strip, which, regardless of its intensity, indicates a negative test result.

When sample drug levels are at or above the detection level of the test, the free drug in the sample binds to the respective drug monoclonal antibody conjugate, preventing the respective drug monoclonal antibody conjugate from binding to the respective 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 preliminary positive result. To serve as a procedure control, a colored line will appear at the Control Region (C) of each strip, if the test has been performed properly.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Dochek® Multi-Drug Urine Test Cup Rx, Dochek® Multi-Drug Urine Test Cup

B Predicate 510(k) Number(s):

K232659

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K240698</u>	<u>K232659</u>
Device Trade Name	Dochek® Multi-Drug Urine Test Dipcard Rx and Dochek® Multi-Drug Urine Test Dipcard	Dochek® Multi-Drug Urine Test Cup Rx Dochek® Multi-Drug Urine Test Cup
General Device Characteristic Similarities		
Intended Use/Indications For Use	Qualitative detection of drugs of abuse in urine	Same
Specimen	Human Urine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assay based on antigen-antibody reaction	Same
Intended Users	Over the Counter (OTC) Use and Prescription Use	Same
General Device Characteristic Differences		
Format	Test dipcard	Test cup

VI Standards/Guidance Documents Referenced:

None referenced.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Precision studies were performed in-house for samples with concentrations of +100% cutoff, +75% cutoff, +50% cutoff, +25% cutoff, cutoff, -25% cutoff, -50% cutoff, -75% cut off and -100% cutoff. Samples were prepared by spiking target drug into drug-free urine samples. Each drug concentration was confirmed by LC-MS/MS. Two configurations of samples were tested, as listed below. For each configuration, testing was performed over two runs per day for 25 days using three lots with one operator per lot.

Configuration 1 consisted of:

Target Drug	Cutoff value
Amphetamine (AMP)	1000 ng/mL
Secobarbital (BAR)	300 ng/mL
Buprenorphine (BUP)	10 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Methamphetamine (MET)	1000 ng/mL
Morphine (OPI)	2000 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Cannabinoids (THC)	50 ng/mL
6-Monoacetylmorphine (6-MAM)	10 ng/mL

Configuration 2 consisted of:

Target Drug	Cutoff value
Amphetamine (AMP)	500 ng/mL
Secobarbital (BAR)	300 ng/mL
Buprenorphine (BUP)	10 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	150 ng/mL

Target Drug	Cutoff value
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methylenedioxyamphetamine (MDMA)	500 ng/mL
Methamphetamine (MET)	500 ng/mL
Morphine (MOP)	300 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Cannabinoids (THC)	50 ng/mL
6-Monoacetylmorphine (6-MAM)	10 ng/mL

The results obtained are summarized in the following tables:

Analyte	% of cutoff	Number of Determinations per lot	Result					
			Lot 1		Lot 2		Lot 3	
			+	-	+	-	+	-
AMP 500	Negative	50	0	50	0	50	0	50
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	Cutoff	50	38	12	38	12	38	12
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0
AMP 1000	Negative	50	0	50	0	50	0	0
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	Cutoff	50	37	13	36	14	37	13
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0

Analyte	% of cutoff	Number of Determinations per lot	Result					
			Lot 1		Lot 2		Lot 3	
			+	-	+	-	+	-
BAR 300	Negative	50	0	50	0	50	0	50
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	Cutoff	50	36	14	38	12	36	14
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0
BUP 10	Negative	50	0	50	0	50	0	50
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	Cutoff	50	36	16	35	15	35	15
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0
BZO 300	Negative	50	0	50	0	50	0	50
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	Cutoff	50	39	11	37	13	38	12
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0

Analyte	% of cutoff	Number of Determinations per lot	Result					
			Lot 1		Lot 2		Lot 3	
			+	-	+	-	+	-
COC 150	Negative	50	0	50	0	50	0	50
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	Cutoff	50	35	15	36	14	36	14
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0
COC 300	Negative	50	0	50	0	50	0	50
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	Cutoff	50	38	12	37	13	38	12
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0
EDDP 300	Negative	50	0	50	0	50	0	0
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	Cutoff	50	37	13	38	12	38	12
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0

Analyte	% of cutoff	Number of Determinations per lot	Result					
			Lot 1		Lot 2		Lot 3	
			+	-	+	-	+	-
MDMA 500	Negative	50	0	50	0	50	0	50
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	Cutoff	50	10	10	40	10	39	11
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0
MET 500	Negative	50	0	50	0	50	0	50
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	Cutoff	50	38	12	37	13	38	12
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0
MET 1000	Negative	50	0	50	0	50	0	50
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	Cutoff	50	39	11	40	10	39	11
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0

Analyte	% of cutoff	Number of Determinations per lot	Result					
			Lot 1		Lot 2		Lot 3	
			+	-	+	-	+	-
MOP 300	Negative	50	0	50	0	50	0	50
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	Cutoff	50	36	14	35	15	36	14
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0
OPI 2000	Negative	50	0	50	0	50	0	50
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	Cutoff	50	40	10	41	9	40	10
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0
MTD 300	Negative	50	0	50	0	50	0	50
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	Cutoff	50	36	14	35	15	36	14
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0

Analyte	% of cutoff	Number of Determinations per lot	Result					
			Lot 1		Lot 2		Lot 3	
			+	-	+	-	+	-
OXY 100	Negative	50	0	50	0	50	0	0
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	Cutoff	50	37	13	35	15	35	15
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0
PCP 25	Negative	50	0	50	0	50	0	50
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	Cutoff	50	35	15	34	16	36	14
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0
PPX 300	Negative	50	0	50	0	50	0	50
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	Cutoff	50	38	12	38	12	38	12
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0

Analyte	% of cutoff	Number of Determinations per lot	Result					
			Lot 1		Lot 2		Lot 3	
			+	-	+	-	+	-
TCA 1000	Negative	50	0	50	0	50	0	50
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	Cutoff	50	38	12	39	11	39	11
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0
THC 50	Negative	50	0	50	0	50	0	50
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	Cutoff	50	36	14	37	13	36	14
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0
6-AM 10	Negative	50	0	50	0	50	0	0
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	Cutoff	50	36	14	35	15	35	15
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0

2. Linearity:

Not Applicable.

3. Analytical Specificity/Interference:

Cross-Reactivity:

To test cross-reactivity, drug metabolites and other structurally related compounds that are likely to cross-react were spiked into negative urine and were tested using three lots of each device. The lowest concentration that caused a positive result for each compound is listed below along with the corresponding % cross-reactivity. If no cross-reactivity was observed, the highest concentration tested is listed below along with the cross-reactivity as a “<” concentration.

Drug/Cutoff	Cross-reacting compound	Lowest concentration causing a positive result (ng/mL)	% Cross- Reactivity
AMP 1000	d-Amphetamine	1,000	100%
	d/l-Amphetamine	3,000	33.3%
	l-Amphetamine	50,000	2%
	(+/-) 3,4-methylenedioxyamphetamine (MDA)	5,000	20%
	Phentermine	3,000	33.3%
	Hydroxyamphetamine	10,000	10%
	d-Methamphetamine	100,000	<1%
	l-Methamphetamine	100,000	<1%
	(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	100,000	<1%
	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	100,000	<1%
	(1R,2S)-(-)-Ephedrine	100,000	<1%
	β-Phenylethylamine	100,000	1%
	Tyramine	100,000	1%
	p-Hydroxynorephedrine	100,000	1%
	Phenylpropanolamine	100,000	<1%
	(±)Phenylpropanolamine	100,000	<1%
	p-Hydroxyamphetamine	100,000	1%
	d/l-Norephedrine	100,000	1%

Drug/Cutoff	Cross-reacting compound	Lowest concentration causing a positive result (ng/mL)	% Cross- Reactivity
	Benzphetamine	100,000	<1%
	l-Epinephrine	100,000	<1%
	d/l-Epinephrine	100,000	<1%
BAR 300	Secobarbital	300	100%
	Amobarbital	1,000	30%
	Alphenal	75	400%
	Aprobarbital	250	120%
	Butobarbital	100	300%
	Butalbital	5,000	6%
	Butethal	500	60%
	Cyclopentobarbital	500	60%
	Pentobarbital	200	150%
	Phenobarbital	300	100%
BUP 10	Buprenorphine	10	100%
	Norbuprenorphine	50	20%
	Buprenorphine 3-D-glucuronide	10	100%
	Norbuprenorphine 3-D-glucuronide	10	100%
	Morphine	100,000	<0.1%
	Oxymorphone	100,000	<0.1%
	Hydromorphone	100,000	<0.1%
	Oxazepam	300	100%
	Alprazolam	150	200%
	α -Hydroxyalprazolam	1,500	20%
	Bromazepam	100	300%
	Chlordiazepoxide	500	60%
	Clobazam	750	40%
	Clonazepam	1,500	20%
	Clorazepate dipotassium	100	300%

Drug/Cutoff	Cross-reacting compound	Lowest concentration causing a positive result (ng/mL)	% Cross- Reactivity
BZO 300	Diazepam	500	60%
	Estazolam	500	60%
	Flunitrazepam	2,500	12%
	Midazolam	2,000	15%
	Nitrazepam	2,000	15%
	Nordiazepam	500	60%
	Temazepam	250	120%
	Triazolam	1,000	30%
	Desalkylflurazepam	500	60%
	Lorazepam	5,000	6%
	Norchlordiazepoxide	500	60%
	Nordazepam	1,000	30%
	Delorazepam	2,000	15%
	Demoxepam	5,000	6%
	Flurazepam	500	60%
COC 300	Benzoylecgonine	300	100%
	Cocaine HCl	750	40%
	Cocaethylene	12,500	2.4%
	Ecgonine	30,000	1%
	Ecgonine methyl ester	100,000	<0.3%
	Norcocaine	100,000	<0.3%
EDDP 300	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300	100%
	Methadone	100,000	<0.3%
	EMDP	100,000	<0.3%
	Doxylamine	100,000	<0.3%
	Levacetylmethadol (LAAM)	100,000	<0.3%
	Disopyramide	100,000	<0.3%
	Alpha Methadol	100,000	<0.3%

Drug/Cutoff	Cross-reacting compound	Lowest concentration causing a positive result (ng/mL)	% Cross- Reactivity
MDMA 500	(+/-) 3,4-Methylenedioxymethamphetamine HCl (MDMA)	500	100%
	(+/-) 3,4-Methylenedioxyamphetamine HCl (MDA)	3,000	17%
	(+/-) 3,4-Methylenedioxyethylamphetamine (MDEA)	300	167%
	d-Methamphetamine	100,000	<0.5%
	d-Amphetamine	100,000	<0.5%
	l-Methamphetamine	100,000	<0.5%
	l-Amphetamine	100,000	<0.5%
MET 1000	d-Methamphetamine	1,000	100%
	d-Amphetamine	50,000	2%
	Chloroquine	50,000	2%
	(1R,2S)-(-)-Ephedrine	50,000	2%
	(-)-Methamphetamine	25,000	4%
	(+/-)3,4-methylenedioxumethamphetamine (MDMA)	4,000	25%
	β-Phenylethylamine	50,000	2%
	Trimethobenzamide	10,000	10%
	l-Amphetamine	75,000	1.3%
	(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	30,000	3.3%
	Mephentermine	50,000	2%
	Methoxyphenamine	50,000	2%
	Fenfluramine	75,000	1.3%

Drug/Cutoff	Cross-reacting compound	Lowest concentration causing a positive result (ng/mL)	% Cross- Reactivity
	Procaine	100,000	<1%
	d/l-Amphetamine	100,000	<1%
	p-Hydroxymethamphetamine	30,000	3.3%
	l-Phenylephrine	100,000	<1%
	d/l-Methamphetamine	1,000	100%
	(+/-) 3,4-Methylenedioxyamphetamine (MDA)	100,000	<1%
OPI 2000	Morphine	2,000	100%
	Codeine	2,000	100%
	Hydrocodone	12,500	16%
	Hydromorphone	5,000	40%
	6-Monoacetylmorphine	1,500	133%
	Morphine 3-β-D-glucuronide	2,000	100%
	Ethylmorphine	1,500	133%
	Diacetylmorphine (heroin)	2,000	100%
	Levorphanol	75,000	2.7%
	Norcodeine	12,500	16%
	Oxycodone	100,000	<2%
	Thebaine	5,000	40%
	Normorphine	50,000	4%
	Oxymorphone	100,000	<2%
	Procaine	100,000	<2%
	Codeine-6-β-D-glucuronide	3,000	67%
d-Norpropoxyphene hydrochloride	5,000	40%	
MTD 300	Methadone	300	100%
	EDDP	100,000	<0.3%
	Doxylamine	50,000	0.6%
	Levacetylmethadol (LAAM)	100,000	<0.3%

Drug/Cutoff	Cross-reacting compound	Lowest concentration causing a positive result (ng/mL)	% Cross- Reactivity
	EMDP	100,000	<0.3%
	Alpha Methadol	100,000	<0.3%
OXY 100	Oxycodone	100	100%
	Hydrocodone	5,000	2%
	Hydromorphone	50,000	0.2%
	Oxymorphone	1,000	10%
	Codeine	100,000	<0.1%
	Ethylmorphine	100,000	<0.1%
	Dihydrocodeine	20,000	0.5%
	Oxymorphone-3 β -D- glucuronide	5,000	2%
	Morphine	100,000	<0.1%
	6-Monoacetylmorphine	100,000	<0.1%
	Buprenorphine	100,000	<0.1%
	Thebaine	100,000	<0.1%
PCP 25	Phencyclidine	25	100%
	4-Hydroxy Phencyclidine	1500	1.7%
PPX 300	d-Propoxyphene	300	100%
	d-Norpropoxyphene	300	100%
TCA 1000	Notriptyline	1,000	100%
	Nordoxepin	1,000	100%
	Trimipramine	3,000	33.3%
	Promazine	1,500	66.7%
	Desipramine	200	500%
	Imipramine	750	133%
	Clomipramine	10,000	10%
	Doxepin	1,250	80%
	Maprotiline	2,000	50%
	Amitriptyline	1,500	66.7%
	Promethazine	25,000	4%

Drug/Cutoff	Cross-reacting compound	Lowest concentration causing a positive result (ng/mL)	% Cross- Reactivity
	Cyclobenzaprine	1,000	100%
	Norclomipramine	12,500	8%
THC 50	11-nor- Δ 9-THC-9-COOH	50	100%
	11-nor- Δ 8-THC-9-COOH	30	167%
	(\pm)-11-Hydroxy- Δ 9-THC	2,500	2%
	Δ 8- Tetrahydrocannabinol	2,000	2.5%
	Δ 9- Tetrahydrocannabinol	5,000	1%
	Cannabinol	10,000	0.5%
	Cannabidiol(CBD)	100,000	0.05%
	(\pm)-11-nor-9-carboxy- Δ 9-THC	100	50%
	11-nor- Δ 9-THC-carboxy glucuronide	100	50%
6-MAM 10	6-Monoacetylmorphine	10	100%
	Codeine	100,000	<0.01%
	Ethylmorphine	100,000	<0.01%
	Hydrocodone	50,000	0.02%
	Hydromorphone	10,000	0.1%
	Levorphanol	100,000	<0.01%
	Morphine 3- β -D-glucuronide	100,000	<0.01%
	Morphine	100,000	0.01%
	Norcodeine	100,000	<0.01%
	Normorphine	100,000	<0.01%
	Oxycodone	100,000	<0.01%
	Oxymorphone	10,000	0.1%
	Procaine	50,000	0.02%
	Thebaine	10,000	0.1%
	Diacetylmorphine (heroin)	25	40%
	Acetylcodeine	10,000	<0.1%
Buprenorphine	10,000	<0.1%	

Drug/Cutoff	Cross-reacting compound	Lowest concentration causing a positive result (ng/mL)	% Cross- Reactivity
6-MAM 10 (cont)	Dihydrocodeine	10,000	<0.1%
	Nalorphine	5,000	0.02%
	Dextromethorphan	100,000	<0.01%
	Imipramine	100,000	<0.01%
	Levacetylmethadol (LAAM)	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%
	Norhydrocodone	100,000	<0.01%
	Noroxycodone	100,000	<0.01%
	Noroxymorphone	100,000	<0.01%
	Norpropoxyphene	100,000	<0.01%
	Oxymorphone-3 β -D- glucuronide	100,000	<0.01%
	Tapentadol HCl	100,000	<0.01%
Tramadol	100,000	<0.01%	
	d-Amphetamine	500	100%
	d/l-Amphetamine	1,500	33.3%
	l-Amphetamine	25,000	2%
	(+/-) 3,4-methylenedioxyamphetamine (MDA)	2,500	20%
	Phentermine	1,500	33.3%
	Hydroxyamphetamine	5,000	10%

Drug/Cutoff	Cross-reacting compound	Lowest concentration causing a positive result (ng/mL)	% Cross- Reactivity
AMP 500	d-Methamphetamine	100,000	<0.5%
	l-Methamphetamine	100,000	<0.5%
	(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	100,000	<0.5%
	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	100,000	<0.5%
	(1R,2S)-(-)-Ephedrine	100,000	<0.5%
	β-Phenylethylamine	100,000	0.5%
	Tyramine	100,000	0.5%
	p-Hydroxynorephedrine	100,000	0.5%
	Phenylpropanolamine	100,000	<0.5%
	(±)Phenylpropanolamine	100,000	<0.5%
	p-Hydroxyamphetamine	100,000	0.5%
	d/l-Norephedrine	100,000	0.5%
	Benzphetamine	100,000	<0.5%
	l-Epinephrine	100,000	<0.5%
	d/l-Epinephrine	100,000	<0.5%
COC 150	Benzoylcegonine	150	100%
	Cocaine HCl	500	30%
	Cocaethylene	5,000	3%
	Ecgonine	15,000	1%
	Ecgonine methyl ester	100,000	<0.15%
	Norcocaine	100,000	<0.15%
	d-Methamphetamine	500	100%
	d-Amphetamine	25,000	2%
	Chloroquine	25,000	2%
	(1R,2S)-(-)-Ephedrine	25,000	2%
	(-)-Methamphetamine	12,500	4%

Drug/Cutoff	Cross-reacting compound	Lowest concentration causing a positive result (ng/mL)	% Cross- Reactivity
MET 500	(+/-)3,4-methylenedioxymethamphetamine (MDMA)	2,000	25%
	β-Phenylethylamine	25,000	2%
	Trimethobenzamide	5,000	10%
	l-Amphetamine	50,000	1%
	(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	15,000	3.3%
	Mephentermine	25,000	2%
	Methoxyphenamine	25,000	2%
	Fenfluramine	37,500	1.3%
	Procaine	100,000	<0.5%
	d/l-Amphetamine	75,000	0.7%
	p-Hydroxymethamphetamine	15,000	3.3%
	l-Phenylephrine	100,000	<0.5%
	d/l-Methamphetamine	500	100%
	(+/-) 3,4-Methylenedioxyamphetamine (MDA)	75,000	0.7%
MOP 300	Morphine	300	100%
	Codeine	300	100%
	Hydrocodone	5,000	6%
	Hydromorphone	1,000	30%
	6-Monoacetylmorphine	150	200%
	Morphine 3-β-D-glucuronide	1,000	30%
	Ethylmorphine	100	300%
	Diacetylmorphine (heroin)	300	100%
	Levorphanol	10,000	3%
	Norcodeine	5,000	6%

Drug/Cutoff	Cross-reacting compound	Lowest concentration causing a positive result (ng/mL)	% Cross- Reactivity
	Oxycodone	75,000	0.4%
	Thebaine	3,000	10%
	Normorphine	3,000	10%
	Oxymorphone	25,000	1.2%
	Procaine	100,000	<0.3%
	Codeine-6-β-D-glucuronide	500	60%
	d-Norpropoxyphene hydrochloride	300	100%

Interfering substances:

To evaluate potential interference, non-structurally related compounds were added to drug-free urine and to urine samples containing the target drugs at 25% below and 25% above each corresponding cutoff. Compounds that showed no interference at a concentration of 100 µg/mL are summarized in the following table.

3-Hydroxytyramine	Diflunisal	Oxalic Acid
Acetaminophen	Digoxin	Oxolinic Acid
Acetylsalicylic Acid	Diphenhydramine	Oxymetazoline
Acyclovir	Dopamine HCl	Paliperidone
Albumin (100 mg/dL)	D-Pseudoephedrine	Papaverine
Albuterol sulfate (Proair HFA)	Duloxetine	Penicillin-G
Aminophylline	Erythromycin	PenicillinV Potassium
Aminopyrine	Esomeprazole Magnesium	Phenacetin (Acetophenetidin)
Amoxicillin	Ethanol (1%)	Phenelzine
Ampicillin	Fenoprofen	Prednisone
Apomorphine	Fluoxetine Hydrochloride	Pregablin

Aripiprazole	Furosemide	Quinine
Aspartame	Gabapentin	Ranitidine
Atomoxetine	Gentisic Acid	Rifampicin
Atorvastatin Calcium	Glucose	Risperidone
Atropine	Hemoglobin	Salicylic Acid
Azithromycin	Hydralazine	Serotonin
Benzilic acid	Hydrochlorothiazide	Sertraline Hydrochloride
Benzocaine	Hydrocortisone	Sildenafil Citrate
Benzoic acid	Ibuprofen	Simvastatin
Bilirubin	Isoxsuprine	Sulfamethazine
Bupropion	Ketamine	Sulindac
Captopril	Ketoprofen	Tetrahydrozoline
Carbamazepine	Labetalol	Theophylline
Cefradine	Levofloxacin Hydrochloride	Thiamine
Cephalexin	Levonorgestrel	Thioridazine
Chloral Hydrate	Levothyroxine Sodium	Tramadol Hydrochloride
Chloramphenicol	Lidocaine Hydrochloride	Trazodone Hydrochloride
Chlorothiazide	Lisinopril	Triamterene
chlorpheniramine	Loperamide	Trifluoperazine
Cholesterol	Loratadine	Trimethoprim
Ciprofloxacin Hydrochloride	Magnesium	Uric Acid
Citalopram	Meperidine	Venlafaxine HCl

Clarithromycin	Meprobamate	Verapamil
Clonidine	Metoprolol Tartrate	Vitamin B2
Clozapine	Mifepristone	Vitamin C (Ascorbic acid)
Conjugated Estrogens	N-Acetylprocainamide	Zomepirac
Cortisone	Nalidixic Acid	β -Estradiol
Cotinine	Naproxen	Chlorpromazine
Creatinine	Niacinamide	Perphenazine
D,L- Isoproterenol	Nicotine	Tetrahydrocortisone 3-(β -D-glucuronide)
D,L-Octopamine	Nifedipine	Tetrahydrocortisone 3-acetate
D,L-Propranolol	Nitroglycerin	Ecgonine methyl ester
D,L-Tryptophan	Norethindrone	Methoxyphenamine (except MET test)
D,L-Tyrosine	Noscapine	Naloxone
Deoxycorticosterone	O-Hydroxyhippuric Acid	Naltrexone
Dextromethorphan	Omeprazole	Tyramine (except AMP test)
Diclofenac		

Effect of Urinary Specific Gravity and pH:

To investigate the effect of urine specific gravity and urine pH, urine samples with specific gravity at 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030, and 1.035 and urine samples with pH at 4, 5, 6, 7, 8, and 9 were spiked with the target drugs to concentrations at 25% below and 25% above the cutoff level for each drug. These samples were tested using three lots with two configurations. The results demonstrated that pH levels of 4 to 9 and specific gravity levels of 1.000 to 1.035 do not affect the results of the assays.

4. Assay Reportable Range:

Not applicable.

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

The device is traceable to commercially available materials.

6. Detection Limit:

Not applicable.

7. Assay Cut-Off:

Refer to Section VII.A.1

B Comparison Studies:

1. Method Comparison with Predicate Device:

Method comparison studies were performed in-house by three operators. Eighty (80) unaltered clinical samples were run for each target drug. The samples were tested in a blinded fashion and compared to LC/MS results. The results are presented in the tables below:

AMP 1000	Candidate Device Result	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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	0	7	31
	Negative	15	8	17	2	0
Viewer B	Positive	0	0	0	6	31
	Negative	15	8	17	3	0
Viewer C	Positive	0	0	0	6	31
	Negative	15	8	17	3	0

Discordant Results

Viewer	Sample number	LC-MS result (ng/mL)	Candidate device result
A, B, C	0955	1014.625	Negative
A, B, C	0936	1056.71	Negative
B, C	0903	1141.794	Negative

AMP 500	Candidate Device Result	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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	0	8	30
	Negative	15	12	13	2	0
Viewer B	Positive	0	0	0	8	30
	Negative	15	12	13	2	0
Viewer C	Positive	0	0	0	8	30
	Negative	15	12	13	2	0

Discordant Results

Viewer	Sample number	LC-MS result (ng/mL)	Candidate device result
A, B, C	1345	513	Negative
A, B, C	1297	546	Negative

BAR	Candidate Device Result	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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	0	16	22
	Negative	15	18	7	2	0
Viewer B	Positive	0	0	0	16	22
	Negative	15	18	7	2	0
Viewer C	Positive	0	0	0	15	22
	Negative	15	18	7	3	0

Discordant Results

Viewer	Sample number	LC-MS result (ng/mL)	Candidate device result
A, B, C	0221	302.963	Negative
C	0238	304.207	Negative
A, B, C	0173	312.828	Negative

BUP	Candidate Device Result	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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	29	10
	Negative	15	13	10	1	0
Viewer B	Positive	0	0	2	29	10
	Negative	15	13	10	1	0
Viewer C	Positive	0	0	1	29	10
	Negative	15	13	11	1	0

Discordant Results

Viewer	Sample number	LC-MS result (ng/mL)	Candidate device result
A, B, C	0136	8.76	Positive
A, B	0137	8.785	Positive
A, B, C	0141	10.761	Negative

BZO	Candidate Device Result	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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	8	31
	Negative	15	11	13	1	0
Viewer B	Positive	0	0	2	7	31
	Negative	15	11	12	2	0
Viewer C	Positive	0	0	1	7	31
	Negative	15	11	13	2	0

Discordant Results

Viewer	Sample number	LC-MS result (ng/mL)	Candidate device result
B	0405	269.424	Positive
A, B, C	0428	290.449	Positive
B, C	0422	301.512	Negative
A, B, C	0409	301.586	Negative

COC 300	Candidate Device Result	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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	11	27
	Negative	15	13	10	2	0
Viewer B	Positive	0	0	1	11	27
	Negative	15	13	11	2	0
Viewer C	Positive	0	0	2	11	27
	Negative	15	13	10	2	0

Discordant Results

Viewer	Sample number	LC-MS result (ng/mL)	Candidate device result
A, B, C	0632	284.614	Positive
A, C	0602	295.071	Positive
A, B, C	0620	307.773	Negative
A, B, C	0630	308.012	Negative

COC 150	Candidate Device Result	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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	13	25
	Negative	15	12	12	2	0
Viewer B	Positive	0	0	1	13	25
	Negative	15	12	12	2	0
Viewer C	Positive	0	0	1	13	25
	Negative	15	12	12	2	0

Discordant Results

Viewer	Sample number	LC-MS result (ng/mL)	Candidate device result
A, B, C	1446	138.9	Positive
A, B, C	1512	156.5	Negative
A, B, C	1505	162.1	Negative

EDDP	Candidate Device Result	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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	11	29
	Negative	15	6	18	0	0
Viewer B	Positive	0	0	0	11	29
	Negative	15	6	19	0	0
Viewer C	Positive	0	0	1	11	29
	Negative	15	6	18	0	0

Discordant Results

Viewer	Sample number	LC-MS result (ng/mL)	Candidate device result
A, C	1591	296.944	Positive

MDMA	Candidate Device Result	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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	9	30
	Negative	15	14	10	1	0
Viewer B	Positive	0	0	0	9	30
	Negative	15	14	11	1	0
Viewer C	Positive	0	0	1	9	30
	Negative	15	14	10	1	0

Discordant Results

Viewer	Sample number	LC-MS result (ng/mL)	Candidate device result
A, C	0762	458.975	Positive
A, B, C	0750	565.340	Negative

MET 1000	Candidate Device Result	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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	0	8	30
	Negative	15	8	17	2	0
Viewer B	Positive	0	0	0	8	30
	Negative	15	8	17	2	0
Viewer C	Positive	0	0	0	8	30
	Negative	15	8	17	2	0

Discordant Results

Viewer	Sample number	LC-MS result (ng/mL)	Candidate device result
A, B, C	0972	1002.105	Negative
A, B, C	1025	1026.596	Negative

MET 500	Candidate Device Result	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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	0	10	30
	Negative	15	14	11	0	0
Viewer B	Positive	0	0	0	9	30
	Negative	15	14	11	1	0
Viewer C	Positive	0	0	0	9	30
	Negative	15	14	11	1	0

Discordant Results

Viewer	Sample number	LC-MS result (ng/mL)	Candidate device result
B, C	1403	508	Negative

OPI 2000	Candidate Device Result	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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	9	29
	Negative	15	9	14	2	0
Viewer B	Positive	0	0	2	9	29
	Negative	15	9	14	2	0
Viewer C	Positive	0	0	2	9	29
	Negative	15	9	14	2	0

Discordant Results

Viewer	Sample number	LC-MS result (ng/mL)	Candidate device result
A, B, C	0817	1872.771	Positive
A, B, C	0855	1996.034	Positive
A, B, C	0879	2022.484	Negative
A, B, C	0880	2137.854	Negative

MOP 300	Candidate Device Result	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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	18	21
	Negative	15	12	11	1	0
Viewer B	Positive	0	0	2	19	21
	Negative	15	12	11	0	0
Viewer C	Positive	0	0	2	18	21
	Negative	15	12	11	1	0

Discordant Results

Viewer	Sample number	LC-MS result (ng/mL)	Candidate device result
A, B, C	1279	249	Positive
A, B, C	1259	250	Positive
A, C	1264	309	Negative

MTD	Candidate Device Result	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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	9	30
	Negative	15	12	11	1	0
Viewer B	Positive	0	0	2	8	30
	Negative	15	12	11	2	0
Viewer C	Positive	0	0	2	9	30
	Negative	15	12	11	1	0

Discordant Results

Viewer	Sample number	LC-MS result (ng/mL)	Candidate device result
A, B, C	1159	271	Positive
A, B, C	1185	273	Positive
A, B, C	1129	309	Negative
B	1123	325	Negative

OXY	Candidate Device Result	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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	10	29
	Negative	15	12	11	1	0
Viewer B	Positive	0	0	2	9	29
	Negative	15	12	11	2	0
Viewer C	Positive	0	0	2	10	29
	Negative	15	12	11	1	0

Discordant Results

Viewer	Sample number	LC-MS result (ng/mL)	Candidate device result
A, B, C	0379	85	Positive
A, B, C	0375	88	Positive
B	0397	107	Negative
A, B, C	0340	109	Negative

PCP	Candidate Device Result	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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	0	27	12
	Negative	15	13	12	1	0
Viewer B	Positive	0	0	0	28	12
	Negative	15	13	12	0	0
Viewer C	Positive	0	0	0	27	12
	Negative	15	13	12	1	0

Discordant Results

Viewer	Sample number	LC-MS result (ng/mL)	Candidate device result
A, C	0053	25.9	Negative

PPX	Candidate Device Result	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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	11	28
	Negative	15	13	10	1	0
Viewer B	Positive	0	0	1	12	28
	Negative	15	13	11	0	0
Viewer C	Positive	0	0	1	10	28
	Negative	15	13	11	2	0

Discordant Results

Viewer	Sample number	LC-MS result (ng/mL)	Candidate device result
A, B, C	0504	286	Positive
A	0487	296	Positive
A, C	0536	347	Negative
C	0551	356	Negative

TCA	Candidate Device Result	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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	0	6	32
	Negative	15	13	12	2	0
Viewer B	Positive	0	0	0	6	32
	Negative	15	13	12	2	0
Viewer C	Positive	0	0	0	6	32
	Negative	15	13	12	2	0

Discordant Results

Viewer	Sample number	LC-MS result (ng/mL)	Candidate device result
A, B, C	0688	1051	Negative
A, B, C	0653	1136	Negative

THC	Candidate Device Result	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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	9	30
	Negative	15	13	10	1	0
Viewer B	Positive	0	0	1	9	30
	Negative	15	13	11	1	0
Viewer C	Positive	0	0	1	9	30
	Negative	15	13	11	1	0

Discordant Results

Viewer	Sample number	LC-MS result (ng/mL)	Candidate device result
A, C	0300	41.2	Positive
A, B	0317	49.4	Positive
A, B, C	0312	55.6	Negative

6-MAM	Candidate Device Result	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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	3	28	10
	Negative	15	13	9	2	0
Viewer B	Positive	0	0	3	28	10
	Negative	15	13	9	2	0
Viewer C	Positive	0	0	3	28	10
	Negative	15	13	9	2	0

Discordant Results

Viewer	Sample number	LC-MS result (ng/mL)	Candidate device result
A, B, C	1091	9.006	Positive
A, B, C	1081	9.465	Positive
A, B, C	1053	9.967	Positive
A, B, C	1048	10.237	Negative
A, B, C	1052	10.257	Negative

2. Lay user study:

A lay user study was performed using configuration 1 and configuration 2 at three intended use sites with the results read by 280 lay persons. The lay users had diverse ages and educational and professional backgrounds. Urine samples were prepared at multiple concentrations (Negative (-100%), +/-75%, +/-50%, +/-25% of the cutoff) by spiking drugs into drug free pooled urine specimens. The concentrations of the samples were confirmed by LC/MS. Each sample was aliquoted into individual containers and tested in a blinded fashion. Each participant was provided with the package insert, one blind-labeled sample and a dipcard device, and with no assistance. Summary results are shown below:

Configuration 1

Analyte	% of Cut-off	Number of samples	Lay person results		Percentage of correct results (%)
			No. of Positive	No. of Negative	
AMP 1000	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	0	20	100
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100

Analyte	% of Cut-off	Number of samples	Lay person results		Percentage of correct results (%)
			No. of Positive	No. of Negative	
	+75% Cut-off	20	20	0	100
BAR 300	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	1	19	95
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
BUP 10	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	2	18	90
	+25% Cut-off	20	19	1	95
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
BZO 300	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	1	19	95
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
COC 300	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	1	19	95
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
EDDP 300	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	1	19	95
	+25% Cut-off	20	20	0	100

Analyte	% of Cut-off	Number of samples	Lay person results		Percentage of correct results (%)
			No. of Positive	No. of Negative	
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
	-100% Cut-off	20	0	20	100
MDMA 500	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	0	20	100
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
	-100% Cut-off	20	0	20	100
MET 1000	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	1	19	95
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
	-100% Cut-off	20	0	20	100
OPI 2000	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	0	20	100
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
	-100% Cut-off	20	0	20	100
MTD 300	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	1	19	95
	+25% Cut-off	20	19	1	95
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
	-100% Cut-off	20	0	20	100
OXY 100	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	1	19	95
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
	-100% Cut-off	20	0	20	100
PCP 25	-100% Cut-off	20	0	20	100

Analyte	% of Cut-off	Number of samples	Lay person results		Percentage of correct results (%)
			No. of Positive	No. of Negative	
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	2	18	90
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
	PPX 300	-100% Cut-off	20	0	20
-75% Cut-off		20	0	20	100
-50% Cut-off		20	0	20	100
-25% Cut-off		20	0	20	100
+25% Cut-off		20	20	0	100
+50% Cut-off		20	20	0	100
+75% Cut-off		20	20	0	100
TCA 1000	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	0	20	100
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
THC 50	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	1	19	95
	+25% Cut-off	20	19	1	95
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
6-AM 10	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	0	20	100
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100

Configuration 2

Analyte	% of Cut-off	Number of samples	Lay person results		Percentage of correct results (%)
			No. of Positive	No. of Negative	
AMP 500	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	19	1	20	95
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
BAR 300	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	1	19	95
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
BUP 10	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	0	20	100
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
BZO 300	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	1	19	95
	+25% Cut-off	20	19	1	95
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
COC 150	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	2	18	90

Analyte	% of Cut-off	Number of samples	Lay person results		Percentage of correct results (%)
			No. of Positive	No. of Negative	
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
EDDP 300	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	1	19	95
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
MDMA 500	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	1	19	95
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
MET 500	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	0	20	100
	+25% Cut-off	20	19	1	95
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
MOP 300	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	1	19	95
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
MTD 300	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	0	20	100
	+25% Cut-off	20	19	1	95
	+50% Cut-off	20	20	0	100

Analyte	% of Cut-off	Number of samples	Lay person results		Percentage of correct results (%)
			No. of Positive	No. of Negative	
	+75% Cut-off	20	20	0	100
OXY 100	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	2	18	90
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
PCP 25	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	1	19	95
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
PPX 300	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	2	18	90
	+25% Cut-off	20	19	1	95
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
TCA 1000	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	1	19	95
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
THC 50	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	2	18	90
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100
6-AM 10	-100% Cut-off	20	0	20	100
	-75% Cut-off	20	0	20	100

Analyte	% of Cut-off	Number of samples	Lay person results		Percentage of correct results (%)
			No. of Positive	No. of Negative	
	-50% Cut-off	20	0	20	100
	-25% Cut-off	20	1	19	95
	+25% Cut-off	20	20	0	100
	+50% Cut-off	20	20	0	100
	+75% Cut-off	20	20	0	100

3. Matrix Comparison:

Not applicable.

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):

Read Time: The sponsor provided data to support the recommendation for read time. The sponsor recommends that the results should be read 5-60 minutes after testing.

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.