

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

A. 510(k) Number:

k182738

B. Purpose for Submission:

New device

C. Measurands:

Amphetamine, Secobarbital, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Phencyclidine, Nortriptyline, Oxycodone, and 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine.

D. Type of Test:

Qualitative lateral flow immunoassay

E. Applicant:

Hangzhou AllTest Biotech Co., Ltd

F. Proprietary and Established Names:

Single and Multi-Drug Rapid Test Panel With Adulteration (Urine)

Single and Multi-Drug Rapid Test Panel (Urine)

Single and Multi-Drug Rapid Test Cup With Adulteration (Urine)

Single and Multi-Drug Rapid Test Cup (Urine)

Single Drug Rapid Test Dipstick (Urine)

Single and Multi-Drug Home Rapid Test Panel (Urine)

Single and Multi-Drug Home Rapid Test Cup (Urine)

Single Drug Home Rapid Test Dipstick (Urine)

G. Regulatory Information:

Product Codes	Class	Regulation Section	Regulation Name	Panel
DKZ, NFT	II	862.3100	Amphetamine Test system	Toxicology (91)
DIS, PTH	II	862.3150	Barbiturate Test system	
JXM, NFV	II	862.3170	Benzodiazepines Test System	
DIO, NFY	II	862.3250	Cocaine and metabolites Test System	
DJR, PTG	II	862.3620	Methadone Test system	
LAF, DJC, NGG	II	862.3610	Methamphetamine Test System	
LDJ, NFW	II	862.3870	Cannabinoids Test System	
DNK, NGI	II	862.3640	Morphine Test System	
DJG, NGL	II	862.3650	Opiate Test System	
LCM, NGM	II	Unclassified	Enzyme immunoassay Phencyclidine	
LFG, QAW	II	862.3910	Tricyclic Antidepressant Drugs Test System	

H. Intended Use:

1. Intended use(s):

See indications for use.

2. Indication(s) for use:

Single and Multi-Drug Rapid Test Cup With Adulteration (Urine)

The Single and Multi-Drug Rapid Test Cup With Adulteration (Urine) are rapid chromatographic immunoassay for the qualitative detection of single or multiple drugs and drug metabolites in urine at the following cut-off concentrations: Amphetamine 500ng/mL, Secobarbital 300ng/mL, Benzodiazepines 300ng/mL, Buprenorphine 10ng/mL, Cocaine 150ng/mL, Marijuana 50ng/mL, Methadone 300ng/mL, Methamphetamine 500ng/mL, Methylenedioxymethamphetamine 500ng/mL, Morphine 300ng/mL and 2,000ng/mL, Phencyclidine 25ng/mL, Nortriptyline 1,000ng/mL, Oxycodone 100ng/mL, and 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300ng/mL.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

For Prescription use.

Single and Multi-Drug Rapid Test Cup (Urine)

The Single and Multi-Drug Rapid Test Cup (Urine) are rapid chromatographic immunoassay for the qualitative detection of single or multiple drugs and drug metabolites in urine at the following cut-off concentrations: Amphetamine 500ng/mL, Secobarbital 300ng/mL, Benzodiazepines 300ng/mL, Buprenorphine 10ng/mL, Cocaine 150ng/mL, Marijuana 50ng/mL, Methadone 300ng/mL, Methamphetamine 500ng/mL, Methylenedioxymethamphetamine 500ng/mL, Morphine 300ng/mL and 2,000ng/mL, Phencyclidine 25ng/mL, Nortriptyline 1,000ng/mL, Oxycodone 100ng/mL, and 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300ng/mL.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

For Prescription use.

Single and Multi-Drug Rapid Test Panel With Adulteration (Urine)

The Single and Multi-Drug Rapid Test Panel With Adulteration (Urine) are rapid chromatographic immunoassay for the qualitative detection of single or multiple drugs and drug metabolites in urine at the following cut-off concentrations: Amphetamine 500ng/mL, Secobarbital 300ng/mL, Benzodiazepines 300ng/mL, Buprenorphine 10ng/mL, Cocaine 150ng/mL, Marijuana 50ng/mL, Methadone 300ng/mL, Methamphetamine 500ng/mL, Methylenedioxymethamphetamine 500ng/mL, Morphine 300ng/mL and 2,000ng/mL, Phencyclidine 25ng/mL, Nortriptyline 1,000ng/mL, Oxycodone 100ng/mL, and 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300ng/mL.

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Single and Multi-Drug Rapid Test Panel (Urine)

The Single and Multi-Drug Rapid Test Panel (Urine) are rapid chromatographic immunoassay for the qualitative detection of single or multiple drugs and drug metabolites in urine at the following cut-off concentrations: Amphetamine 500ng/mL,

Secobarbital 300ng/mL, Benzodiazepines 300ng/mL, Buprenorphine 10ng/mL, Cocaine 150ng/mL, Marijuana 50ng/mL, Methadone 300ng/mL, Methamphetamine 500ng/mL, Methylenedioxymethamphetamine 500ng/mL, Morphine 300ng/mL and 2,000ng/mL, Phencyclidine 25ng/mL, Nortriptyline 1,000ng/mL, Oxycodone 100ng/mL, and 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300ng/mL.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

For Prescription use.

Single Drug Rapid Test Dipstick (Urine)

The Single Drug Rapid Test Dipstick (Urine) are rapid chromatographic immunoassay for the qualitative detection of individual drug and drug metabolite(s) in urine at the following cut-off concentrations: Amphetamine 500ng/mL, Secobarbital 300ng/mL, Benzodiazepines 300ng/mL, Buprenorphine 10ng/mL, Cocaine 150ng/mL, Marijuana 50ng/mL, Methadone 300ng/mL, Methamphetamine 500ng/mL, Methylenedioxymethamphetamine 500ng/mL, Morphine 300ng/mL and 2,000ng/mL, Phencyclidine 25ng/mL, Nortriptyline 1,000ng/mL, Oxycodone 100ng/mL, and 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300ng/mL.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

For Prescription use.

Single and Multi-Drug Home Rapid Test Cup (Urine)

The Single and Multi-Drug Home Rapid Test Cup (Urine) are rapid chromatographic immunoassay for the qualitative detection of single or multiple drugs and drug metabolites in urine at the following cut-off concentrations: Amphetamine 500ng/mL, Secobarbital 300ng/mL, Benzodiazepines 300ng/mL, Buprenorphine 10ng/mL, Cocaine 150ng/mL, Marijuana 50ng/mL, Methadone 300ng/mL, Methamphetamine 500ng/mL, Methylenedioxymethamphetamine 500ng/mL, Morphine 300ng/mL and 2,000ng/mL, Phencyclidine 25ng/mL, Nortriptyline 1,000ng/mL, Oxycodone 100ng/mL, and 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300ng/mL.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

For Over-the-Counter Use

Single and Multi-Drug Home Rapid Test Panel (Urine)

The Single and Multi-Drug Home Rapid Test Panel (Urine) are rapid chromatographic immunoassay for the qualitative detection of single or multiple drugs and drug metabolites in urine at the following cut-off concentrations: Amphetamine 500ng/mL, Secobarbital 300ng/mL, Benzodiazepines 300ng/mL, Buprenorphine 10ng/mL, Cocaine 150ng/mL, Marijuana 50ng/mL, Methadone 300ng/mL, Methamphetamine 500ng/mL, Methylenedioxymethamphetamine 500ng/mL, Morphine 300ng/mL and 2,000ng/mL, Phencyclidine 25ng/mL, Nortriptyline 1,000ng/mL, Oxycodone 100ng/mL, and 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300ng/mL.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

For Over-the-Counter Use

Single Drug Home Rapid Test Dipstick (Urine)

The Single Drug Home Drug Rapid Test Dipstick (Urine) are rapid chromatographic immunoassay for the qualitative detection of individual drug and drug metabolite(s) in urine at the following cut-off concentrations: Amphetamine 500ng/mL, Secobarbital 300ng/mL, Benzodiazepines 300ng/mL, Buprenorphine 10ng/mL, Cocaine 150ng/mL, Marijuana 50ng/mL, Methadone 300ng/mL, Methamphetamine 500ng/mL, Methylenedioxymethamphetamine 500ng/mL, Morphine 300ng/mL and 2,000ng/mL, Phencyclidine 25ng/mL, Nortriptyline 1,000ng/mL, Oxycodone 100ng/mL, and 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300ng/mL.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

For Over-the-Counter Use

3. Special conditions for use statement(s):

The Single and Multi-Drug Rapid Test Panel With Adulteration (Urine), Single and Multi-Drug Rapid Test Panel (Urine), Single and Multi-Drug Rapid Test Cup With Adulteration (Urine) Single and Multi-Drug Rapid Test Cup (Urine) and Single Drug Rapid Test Dipstick (Urine) are intended for prescription use.

The Single and Multi-Drug Home Rapid Test Panel (Urine), Single and Multi-Drug Home Rapid Test Cup (Urine) and Single Drug Home Rapid Test Dipstick (Urine) are intended for over the counter use.

4. Special instrument requirements:

Not applicable. These devices are single use and disposable.

I. Device Description:

Single and Multi-Drug Rapid Test Panel With Adulteration (Urine), Single and Multi-Drug Rapid Test Panel (Urine), Single and Multi-Drug Rapid Test Cup With Adulteration (Urine), Single and Multi-Drug Rapid Test Cup (Urine), Single Drug Rapid Test Dipstick (Urine), Single and Multi-Drug Home Rapid Test Panel (Urine), Single and Multi-Drug Home Rapid Test Cup (Urine), and Single Drug Home Rapid Test Dipstick (Urine) are lateral flow-based, competitive immunochromatographic assays for the detection of Amphetamine, Secobarbital, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Phencyclidine, Nortriptyline, Oxycodone, and 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine. The devices are intended for use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs in a urine sample. Information regarding confirmatory testing – the second step in the process is provided in the instructions for use.

The devices have been developed with the following calibrators and cutoffs:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine	d-Amphetamine	500
Secobarbital	Secobarbital	300
Benzodiazepines	Oxazepam	300
Buprenorphine	Buprenorphine	10
Cocaine	Benzoyllecgonine	150

Marijuana	11-nor- Δ^9 -THC-9 COOH	50
Methadone	Methadone	300
Methamphetamine	d-Methamphetamine	500
Methylenedioxymethamphetamine	d,l-Methylenedioxymethamphetamine	500
Morphine	Morphine	300
Morphine	Morphine	2000
Phencyclidine	Phencyclidine	25
Nortriptyline	Nortriptyline	1000
Oxycodone	Oxycodone	100
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300

The Single and Multi-Drug Rapid Test Panel With Adulteration (Urine), the Single and Multi-Drug Rapid Test Panel (Urine) and the Single and Multi-Drug Home Rapid Test Panel (Urine) are dip card format devices that can each accommodate up to 15 drug device test strips, in different test configurations. The Multi-Drug Home Rapid Test Panel (Urine) device has labeling appropriate for OTC users.

The Single and Multi-Drug Rapid Test Cup With Adulteration (Urine), the Single and Multi-Drug Home Rapid Test Cup (Urine) and the Single and Multi-Drug Home Rapid Test Cup (Urine) are cup format devices that can each accommodate up to 15 drug device test strips, in different test configurations. The Multi-Drug Home Rapid Test Cup (Urine) device has labeling appropriate for OTC users.

The Single Drug Rapid Test Dipstick (Urine) and the Single Drug Home Rapid Test Dipstick (Urine) are provided as single test strips (i.e. without a plastic housing), and as such each accommodate only one drug device test strip. The Single Drug Home Rapid Test Dipstick (Urine) device has labeling appropriate for OTC users.

J. Substantial Equivalence Information:

1. Predicate device name(s):
INSTANT-VIEW plus Multi-Drug of Abuse Urine Test - Simple Cup (OTC Use)
INSTANT-VIEW plus Multi-Drug Urine Test - Simple Cup (Prescription Use)
2. Predicate 510(k) number(s):
k173303

3. Comparison with predicate:

Similarities and Differences		
Item	Candidate Device(s) (k182738)	Predicate Device(s) (k173303)
Indication(s) for Use	For the qualitative detection of single or multiple drugs and drug metabolites in urine	Same
Methodology	Lateral flow, competitive binding immunoassay based on the principle of antigen and antibody immunochemistry	Same
Cutoff Levels (ng/mL)	Secobarbital – 300 Benzodiazepines – 300 Buprenorphine – 10 Methylenedioxymethamphetamine – 500 Marijuana – 50 Methadone – 300 Morphine – 300 Morphine – 2000 Oxycodone – 100 Phencyclidine – 25 Nortriptyline – 1000 Amphetamine – 500 Cocaine – 150 Methamphetamine – 500 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine – 300	Amphetamine – 1000 Barbiturates – 200 Benzodiazepines – 300 Buprenorphine – 10 Cocaine – 300 MDMA – 500 Marijuana – 50 Methadone – 300 Methamphetamine – 1000 Morphine – 2000 Oxycodone – 300 Phencyclidine – 25 Tricyclic Antidepressants – 1000
Formats	Cup, Panel and Dipstick	Cup and Panel

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

None referenced

L. Test Principle:

The candidate devices are rapid lateral flow immunoassays in which drug-protein conjugates in the test device compete with drugs or drug metabolites that may be present in urine.

On each test strip, a drug-protein conjugate is added to the test band of the membrane known as the test region (T), and the anti-drug antibody-colloidal gold conjugate pads are placed at the forward end of the membrane. If target drugs are present in the urine specimen

below its cut-off concentration, the solution of the colored antibody-colloidal gold conjugates moves along with the sample solution by capillary action across the membrane to the immobilized drug-protein conjugate zone on the test band region. The colored antibody-gold conjugates then complexes with the drug-protein conjugates to form visible lines.

Therefore, the formation of the visible precipitant in the test band indicates a negative result. Unbound target drug in urine competes with drug protein conjugates on the test band region for the limited antibody on the colored drug antibody-colloidal gold conjugate pad. If target drug is present in excess of the cutoff, the drug will saturate the limited antibody binding sites and the colored antibody-colloidal gold conjugate cannot bind to the drug-protein conjugate at the test region of the test strip. Therefore, absence of the color band on the test region indicates a preliminary positive result. A band should form in the control region (C) of the devices regardless of the presence of drug in the sample to indicate that the test has been performed properly.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

A precision/reproducibility study was performed using 3 lots per device format (cup and panel) five replicates per day for five consecutive days by 3 Point of care (POC) personnel, at 3 POC sites. Blinded, drug-free urine and commercial GC/MS confirmed spiked urine samples at the following concentrations were used: -100%, -75%, -50%, -25%, cutoff, +25%, +50% and +100% of the cutoff level.

Precision performance of the different trade name devices within a format (i.e. within the cup format or within the panel and dipstick formats) is the same (since these different trade name devices differ only by intended user, the presence absence of adulteration strips, or the presence of the plastic housing (in the case of the panel vs. dipstick formats)). Therefore, in the precision studies conducted by the sponsor, the Single and Multi-Drug Rapid Test Panel (Urine) results were found to support performance of the all test panel devices and dipstick devices, and the Single and Multi-Drug Rapid Test Cup (Urine) results are intended to support performance of the all cup devices.

Single and Multi-Drug Rapid Test Panel (Urine):

Amphetamine 500ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	25-/0+	25-/0+	44+/6-	50+/0-	25-/0+	50+/0-
Lot 2	25-/0+	50-/0+	25-/0+	25-/0+	42+/8-	50+/0-	25-/0+	50+/0-
Lot 3	25-/0+	50-/0+	25-/0+	25-/0+	41+/9-	50+/0-	25-/0+	50+/0-

Secobarbital 300ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-
Lot 2	25-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-
Lot 3	25-/0+	50-/0+	50-/0+	50-/0+	41+/1-	50+/0-	50+/0-	50+/0-

Benzodiazepines 300ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-
Lot 2	25-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-
Lot 3	25-/0+	50-/0+	50-/0+	50-/0+	40+/10-	50+/0-	50+/0-	50+/0-

Buprenorphine 10ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	25-/0+	25-/0+	43+/7-	25-/0+	25-/0+	50+/0-
Lot 2	25-/0+	50-/0+	25-/0+	25-/0+	44+/6-	25-/0+	25-/0+	50+/0-
Lot 3	25-/0+	50-/0+	25-/0+	25-/0+	41+/9-	25-/0+	25-/0+	50+/0-

Cocaine 150ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	25-/0+	25-/0+	43+/7-	25-/0+	25-/0+	50+/0-
Lot 2	25-/0+	50-/0+	25-/0+	25-/0+	41+/9-	25-/0+	25-/0+	50+/0-
Lot 3	25-/0+	50-/0+	25-/0+	25-/0+	45+/5-	25-/0+	25-/0+	50+/0-

Marijuana 50ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-
Lot 2	25-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-
Lot 3	25-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-

Methadone 300ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-
Lot 2	25-/0+	50-/0+	50-/0+	50-/0+	41+/9-	50+/0-	50+/0-	50+/0-
Lot 3	25-/0+	50-/0+	50-/0+	50-/0+	40+/10-	50+/0-	50+/0-	50+/0-

Methamphetamine 500ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	25-/0+	25-/0+	44+/6-	50+/0-	25-/0+	50+/0-
Lot 2	25-/0+	50-/0+	25-/0+	25-/0+	42+/8-	50+/0-	25-/0+	50+/0-
Lot 3	25-/0+	50-/0+	25-/0+	25-/0+	42+/8-	50+/0-	25-/0+	50+/0-

MDMA, Methylenedioxymethamphetamine 500ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	25-/0+	25-/0+	41+/9-	25-/0+	25-/0+	50+/0-
Lot 2	25-/0+	50-/0+	25-/0+	25-/0+	38+/12-	25-/0+	25-/0+	50+/0-
Lot 3	25-/0+	50-/0+	25-/0+	25-/0+	37+/13-	25-/0+	25-/0+	50+/0-

Morphine 300ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	25-/0+	25-/0+	25-/0+	24+/1-	25+/0-	25+/0-	25+/0-
Lot 2	25-/0+	25-/0+	25-/0+	25-/0+	23+/2-	25+/0-	25+/0-	25+/0-
Lot 3	25-/0+	25-/0+	25-/0+	25-/0+	23+/2-	25+/0-	25+/0-	25+/0-

Morphine 2,000ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	25-/0+	25-/0+	25-/0+	25-/0+	25+/0-	25+/0-	25+/0-
Lot 2	25-/0+	25-/0+	25-/0+	25-/0+	22+/3-	25+/0-	25+/0-	25+/0-
Lot 3	25-/0+	25-/0+	25-/0+	25-/0+	22+/3-	25+/0-	25+/0-	25+/0-

Phencyclidine 25ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-
Lot 2	25-/0+	50-/0+	50-/0+	50-/0+	38+/12-	50+/0-	50+/0-	50+/0-
Lot 3	25-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-

Nortriptyline 1000ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	50-/0+	50-/0+	41+/9-	50+/0-	50+/0-	50+/0-
Lot 2	25-/0+	50-/0+	50-/0+	50-/0+	40+/10-	50+/0-	50+/0-	50+/0-
Lot 3	25-/0+	50-/0+	50-/0+	50-/0+	40+/10-	50+/0-	50+/0-	50+/0-

Oxycodone 100ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	25-/0+	25-/0+	40+/10-	25-/0+	25-/0+	50+/0-
Lot 2	25-/0+	50-/0+	25-/0+	25-/0+	40+/10-	25-/0+	25-/0+	50+/0-
Lot 3	25-/0+	50-/0+	25-/0+	25-/0+	42+/8-	25-/0+	25-/0+	50+/0-

EDDP, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	25-/0+	25-/0+	40+/10-	25-/0+	25-/0+	50+/0-
Lot 2	25-/0+	50-/0+	25-/0+	25-/0+	37+/13-	25-/0+	25-/0+	50+/0-
Lot 3	25-/0+	50-/0+	25-/0+	25-/0+	39+/11-	25-/0+	25-/0+	50+/0-

Single and Multi-Drug Rapid Test Cup (Urine):

Amphetamine 500ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	25-/0+	25-/0+	45+/5-	50+/0-	25-/0+	50+/0-
Lot 2	25-/0+	50-/0+	25-/0+	25-/0+	43+/7-	50+/0-	25-/0+	50+/0-
Lot 3	25-/0+	50-/0+	25-/0+	25-/0+	40+/10-	50+/0-	25-/0+	50+/0-

Secobarbital 300ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	50-/0+	50-/0+	41+/9-	50+/0-	50+/0-	50+/0-
Lot 2	25-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-
Lot 3	25-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-

Benzodiazepines 300ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-
Lot 2	25-/0+	50-/0+	50-/0+	50-/0+	41+/9-	50+/0-	50+/0-	50+/0-
Lot 3	25-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-

Buprenorphine 10ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	25-/0+	25-/0+	49+/1-	25-/0+	25-/0+	50+/0-
Lot 2	25-/0+	50-/0+	25-/0+	25-/0+	40+/10-	25-/0+	25-/0+	50+/0-
Lot 3	25-/0+	50-/0+	25-/0+	25-/0+	42+/8-	25-/0+	25-/0+	50+/0-

Cocaine 150ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	25-/0+	25-/0+	43+/7-	25-/0+	25-/0+	50+/0-
Lot 2	25-/0+	50-/0+	25-/0+	25-/0+	41+/9-	25-/0+	25-/0+	50+/0-
Lot 3	25-/0+	50-/0+	25-/0+	25-/0+	38+/12-	25-/0+	25-/0+	50+/0-

Marijuana 50ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-
Lot 2	25-/0+	50-/0+	50-/0+	50-/0+	38+/12-	50+/0-	50+/0-	50+/0-
Lot 3	25-/0+	50-/0+	50-/0+	50-/0+	40+/10-	50+/0-	50+/0-	50+/0-

Methadone 300ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-
Lot 2	25-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-
Lot 3	25-/0+	50-/0+	50-/0+	50-/0+	41+/9-	50+/0-	50+/0-	50+/0-

Methamphetamine 500ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	25-/0+	25-/0+	46+/4-	50+/0-	25-/0+	50+/0-
Lot 2	25-/0+	50-/0+	25-/0+	25-/0+	41+/9-	50+/0-	25-/0+	50+/0-
Lot 3	25-/0+	50-/0+	25-/0+	25-/0+	42+/8-	50+/0-	25-/0+	50+/0-

MDMA, Methylenedioxymethamphetamine 500ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	25-/0+	25-/0+	41+/9-	25-/0+	25-/0+	50+/0-
Lot 2	25-/0+	50-/0+	25-/0+	25-/0+	43+/7-	25-/0+	25-/0+	50+/0-
Lot 3	25-/0+	50-/0+	25-/0+	25-/0+	40+/10-	25-/0+	25-/0+	50+/0-

Morphine 300ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	25-/0+	25-/0+	25-/0+	21+/4-	25+/0-	25+/0-	25+/0-
Lot 2	25-/0+	25-/0+	25-/0+	25-/0+	23+/2-	25+/0-	25+/0-	25+/0-
Lot 3	25-/0+	25-/0+	25-/0+	25-/0+	21+/4-	25+/0-	25+/0-	25+/0-

Morphine 2,000ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	25-/0+	25-/0+	25-/0+	21+/4-	25+/0-	25+/0-	25+/0-
Lot 2	25-/0+	25-/0+	25-/0+	25-/0+	24+/1-	25+/0-	25+/0-	25+/0-
Lot 3	25-/0+	25-/0+	25-/0+	25-/0+	23+/2-	25+/0-	25+/0-	25+/0-

Phencyclidine 25ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-
Lot 2	25-/0+	50-/0+	50-/0+	50-/0+	40+/10-	50+/0-	50+/0-	50+/0-
Lot 3	25-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-

Nortriptyline 1000ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	50-/0+	50-/0+	41+/9-	50+/0-	50+/0-	50+/0-
Lot 2	25-/0+	50-/0+	50-/0+	50-/0+	38+/12-	50+/0-	50+/0-	50+/0-
Lot 3	25-/0+	50-/0+	50-/0+	50-/0+	37+/13-	50+/0-	50+/0-	50+/0-

Oxycodone 100ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	25-/0+	25-/0+	41+/9-	25-/0+	25-/0+	50+/0-
Lot 2	25-/0+	50-/0+	25-/0+	25-/0+	37+/13-	25-/0+	25-/0+	50+/0-
Lot 3	25-/0+	50-/0+	25-/0+	25-/0+	38+/12-	25-/0+	25-/0+	50+/0-

EDDP, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300ng/mL

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+100% cut off
Lot 1	25-/0+	50-/0+	25-/0+	25-/0+	40+/10-	25-/0+	25-/0+	50+/0-
Lot 2	25-/0+	50-/0+	25-/0+	25-/0+	38+/12-	25-/0+	25-/0+	50+/0-
Lot 3	25-/0+	50-/0+	25-/0+	25-/0+	40+/10-	25-/0+	25-/0+	50+/0-

b. *Linearity/assay reportable range:*

Not applicable.

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

The devices have internal process controls. A control line appears in the control region confirming that sufficient sample volume has been applied to the test strip and that the sample has migrated correctly on the test strip. Users are informed that the test is invalid if the colored line does not appear in the control region. There are no external controls supplied with the devices.

Accelerated testing demonstrated 36 months shelf-life at room temperature. Real time stability is on-going. Protocol and acceptance criteria were found to be

acceptable.

d. Detection limit:

See precision data in Section M.1.a., above, for assay performance around the claimed cutoff concentrations.

e. Analytical specificity:

The analytical specificity performance of the different trade name devices within a format (i.e. within the cup format or within the panel and dipstick formats) is the same (since these different trade name devices differ only by intended user, the presence absence of adulteration strips, or the presence of the plastic housing (in the case of the panel vs. dipstick formats)). Therefore, in the cross-reactivity, interference and endogenous interferent studies conducted by the sponsor, the Single and Multi-Drug Rapid Test Panel (Urine) results were found to support performance of the all test panel devices and dipstick devices, and the Single and Multi-Drug Rapid Test Cup (Urine) results are intended to support performance of the all cup devices.

Cross-reactivity:

Cross-reactivity was evaluated by spiking various concentration of similarly structured drug compounds into drug-free urine, using 3 lots of each device format (cup and panel). Results are expressed as the lowest concentration producing a positive result (ng/ml).

The cup and panel configurations demonstrate comparable performance. The results of one test configuration (Multi-Drug Rapid Test Cup) are presented in the table below.

Amphetamine 500 ng/mL

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross reactivity
d-Amphetamine	500	100%
Methylenedioxyethylamphetamine (MDEA)	100000	0.5%
d,l-Methamphetamine	>100000	<0.5%
Phenylephrine	>100000	<0.5%
d-Methamphetamine	>100000	<0.5%
l-Methamphetamine	>100000	<0.5%
d,l - Methylenedioxy methamphetamine	100000	0.5%
l-Amphetamine	500	100%
Ephedrine	>100000	<0.5%
Pseudoephedrine	>100000	<0.5%

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross reactivity
d, l-Amphetamine	500	100%
d,l-3,4-Methylenedioxyamphetamine (MDA)	25	2000%
Phentermine	500	100%

Secobarbital 300 ng/mL

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
Secobarbital	300	100%
Pentobarbital	200	150%
Alphenal	300	100%
Amobarbital	300	100%
Aprobarbital	300	100%
Barbital	300	100%
Butabarbital	500	60%
Butalbital	2000	15%
Cyclopentabarbital	500	60%
Phenobarbital	200	150%

Benzodiazepines 300 ng/mL

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
Oxazepam	300	100%
Alprazolam	400	75%
Alpha-Hydroxyalprazolam	300	100%
Bromazepam	300	100%
Chlordiazepoxide	1200	25%
Clobazam	200	150%
Clonazepam	10000	3%
Clorazepate	300	100%
Desalkylflurazepam	>100000	<0.3%
Diazepam	300	100%
Estazolam	100	300%
Flunitrazepam	300	100%
Flurazepam	300	100%
Lorazepam	1000	30%
Lormetazepam	100	300%
Midazolam	1000	30%
Nitrazepam	200	150%
Nordiazepam	200	150%

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
Temazepam	100	300%
Triazolam	300	100%

Buprenorphine 10 ng/mL

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
Buprenorphine	10	100%
Buprenorphine 3- D-Glucuronide	20	50%
Codeine	>100000	<0.01%
Morphine	>100000	<0.01%
Nalorphine	>100000	<0.01%
Norbuprenorphine	20	50%
Norbuprenorphine 3-D-lucuronide	20	50%

Cocaine 150 ng/mL

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
Benzoylcegonine	150	100%
Cocaine HCL	125	120%
Cocaethylene	250	60%
Ecgonine	>100000	<0.15%
Norcocaine	>100000	<0.15%

(EDDP) 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300 ng/mL

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
EDDP	300	100%
Doxylamine	>100000	<0.3%
Methadone	>100000	<0.3%
Methadol	>100000	<0.3%

Methamphetamine 500 ng/mL

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
d-Methamphetamine	500	100%
l -Methamphetamine	10000	5%
d,l-Amphetamine	250	200%
Phentermine	>100000	<0.5%

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
d,l – Methamphetamine	250	200%
d-Amphetamine	100000	0.5%
l-Amphetamine	100000	0.5%
Ephedrine	>100000	<0.5%
Phenylephrine	>100000	<0.5%
Pseudoephedrine	>100000	<0.5%
3,4- Methylenedioxymethamphetamine (MDMA)	1000	50%
d,l- Methylenedioxy ethylamphetamine (MDEA)	6000	8.3%
d,l-3,4-Methylenedioxyamphetamine (MDA)	>100000	<0.5%
d-Methamphetamine	500	100%

Morphine 300 ng/mL

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
Morphine	300	100%
Codeine	250	120%
6-Acetylmorphine	250	120%
Diacetylmorphine (Heroin)	500	60%
Hydrocodone	1000	30%
Hydromorphone	10000	3%
Oxycodone	>100000	<3%
Oxymorphone	>100000	<3%
Procaine	>100000	<3%

Phencyclidine 25 ng/mL

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
Phencyclidine	25	100%
Pheniramine	50000	0.05%

Methadone 300 ng/mL

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
Methadone	300	100%
Doxylamine	>100000	<0.3%

Pheniramine	100000	0.3%
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	>100000	<0.3%

Oxycodone 100 ng/mL

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
Oxycodone	100	100%
Codeine	100000	0.1%
Hydrocodone	50000	0.2%
Oxymorphone	100	100%

Morphine 2000 ng/mL

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
Morphine	2000	100%
Codeine	5000	40%
Diacetylmorphine (Heroin)	>100000	<2%
Hydrocodone	10000	20%
Hydromorphone	5000	40%
Oxycodone	>100000	<2%
6-Acetylmorphine	>100000	<2%
Oxymorphone	>100000	<2%
Normorphine	>100000	<2%
Ethylmorphine	500	400%
Norcodeine	50000	4%

Marijuana 50 ng/mL

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
11-nor- Δ^9 -THC-9-COOH	50	100%
11-nor- Δ^8 -THC-9-COOH	20000	0.25%
Δ^9 -Tetrahydrocannabinol	100000	0.05%
Cannabidiol	>100000	<0.05%
Cannabinol	>100000	<0.05%

(MDMA) Methylenedioxymethamphetamine 500 ng/mL

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
d,l - Methylenedioxymethamphetamine (MDMA)	500	100%
l-Methamphetamine	>100000	<0.5%
Ephedrine	>100000	<0.5%
Pseudoephedrine	>100000	<0.5%
d,l- Amphetamine	>100000	<0.5%
l-Amphetamine	>100000	<0.5%
Phentermine	>100000	<0.5%
d,l- Methamphetamine	>100000	<0.5%
Phenylephrine	>100000	<0.5%
Methylenedioxyethylamphetamine (MDEA)	250	200%
d,l-3,4-Methylenedioxyamphetamine (MDA)	1000	50%
d-Methamphetamine	>100000	<0.5%
d-Amphetamine	>100000	<0.5%

Nortriptyline 1000 ng/mL

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
Nortriptyline	1000	100%
Amitriptyline	2500	40%
Clomipramine	100000	1%
Doxepine	>100000	<1%
Desipramine	800	125%
Imipramine	500	200%
Promethazine	>100000	<1%
Trimipramine	50000	2%

Interference:

Interference was evaluated by spiking the potential interferents below into urine samples having test drug analytes at 25% below and 25% above the cutoff levels for each assay, using 3 lots of each device format (cup and panel). All potential interferents were tested at a concentration of 100 µg/mL, except for ethanol which was tested at a final concentration of 1%.

There were no interferences identified for any of the potential interferents provided in the tables below for each device, for either cup or panel configurations.

Amphetamine 500 ng/mL

Acetylsalicylic Acid	5, 5-Diphenylhydantoin	Octopamine
Amoxicillin	Erythromycin	Papaverine
Ampicillin	Estradiol	Perphenazine
R-(-)-Apomorphine	Estrone	Phenelzine
L-Ascorbic Acid	Ethanol	Phenylethylamine
Aspirin	Fenofibrate	Promazine
Aspartame	Fentanyl	Promethazine
Atropine	Fotemustine	d,l-Propranolol
Baclofen	Furosemide	Pyridoxine
Benzocaine	Gemfibrozil	Pyrilamine
Benzoic Acid	Guaiacol glyceryl ether	Pyrogallol
Carisoprodol	Gentisic acid	Quinine
Chloramphenicol	Hydralazine	Quinolinic Acid
Chlordiazepoxide	Hydrocortisone	Ranitidine
(+)-Chlorpheniramine	3-Hydroxytyramine	Salicylic Acid
Chlorpromazine	(+/-)-Isoproterenol	Sulindac
Clonidine	Ketamine	Tetracycline
Cortisone	Meprobamate	Tetrahydrozoline
(-)-Cotinine	Methylphenidate	Thiamine
Creatine Hydrate	Nalidixic Acid	Thioridazine
Cyclodextrin	Naltrexone	Tramadol
Deoxycorticosterone	(+)-Naproxen	Trifluoperazine
Dextromethorphan	Niacinamide	Tryptamine
Diclofenac	Nicotinic Acid	Zomepirac sodium salt
4-Dimethyl-aminoantipyrine	Nifedipine	19-Norethindrone
Noscapine	Cholesterol	Hemoglobin
Albumin	Creatinine	Uric Acid
Bilirubin	Glucose	Penicillin-G

Secobarbital 300 ng/mL

Acetylsalicylic Acid	5, 5-Diphenylhydantoin	Octopamine
Amoxicillin	Erythromycin	Papaverine
Ampicillin	Estradiol	Perphenazine
R-(-)-Apomorphine	Estrone	Phenelzine
L-Ascorbic Acid	Ethanol	Phenylethylamine
Aspirin	Fenofibrate	Promazine
Aspartame	Fentanyl	Promethazine
Atropine	Fotemustine	d,l-Propranolol
Baclofen	Furosemide	Pyridoxine

Benzocaine	Gemfibrozil	Pyrilamine
Benzoic Acid	Guaiacolglyceryl ether	Pyrogallol
Carisoprodol	Gentisic acid	Quinine
Chloramphenicol	Hydralazine	Quinolinic Acid
Chlordiazepoxide	Hydrocortisone	Ranitidine
(+)-Chlorpheniramine	3-Hydroxytyramine	Salicylic Acid
Chlorpromazine	(+/-)-Isoproterenol	Sulindac
Clonidine	Ketamine	Tetracycline
Cortisone	Meprobamate	Tetrahydrozoline
(-)-Cotinine	Methylphenidate	Thiamine
Creatine Hydrate	Nalidixic Acid	Thioridazine
Cyclodextrin	Naltrexone	Tramadol
Deoxycorticosterone	(+)-Naproxen	Trifluoperazine
Dextromethorphan	Niacinamide	Tryptamine
Diclofenac	Nicotinic Acid	Zomepirac sodium salt
4-Dimethyl-aminoantipyrine	Nifedipine	19-Norethindrone
Noscapine	Cholesterol	Hemoglobin
Albumin	Creatinine	Uric Acid
Bilirubin	Glucose	Penicillin-G

Benzodiazepines 300 ng/mL

Acetylsalicylic Acid	5, 5-Diphenylhydantoin	Octopamine
Amoxicillin	Erythromycin	Papaverine
Ampicillin	Estradiol	Perphenazine
R-(-)-Apomorphine	Estrone	Phenelzine
L-Ascorbic Acid	Ethanol	Phenylethylamine
Aspirin	Fenofibrate	Promazine
Aspartame	Fentanyl	Promethazine
Atropine	Fotemustine	d,l-Propranolol
Baclofen	Furosemide	Pyridoxine
Benzocaine	Gemfibrozil	Pyrogallol
Benzoic Acid	Guaiacolglyceryl ether	Quinine
Carisoprodol	Gentisic acid	Quinolinic Acid
Chloramphenicol	Hydralazine	Ranitidine
Chlordiazepoxide	Hydrocortisone	Salicylic Acid
(+)-Chlorpheniramine	3-Hydroxytyramine	Tetracycline
Chlorpromazine	(+/-)-Isoproterenol	Tetrahydrozoline
Clonidine	Ketamine	Thiamine
Cortisone	Meprobamate	Thioridazine
(-)-Cotinine	Methylphenidate	Tramadol
Creatine Hydrate	Nalidixic Acid	Trifluoperazine
Cyclodextrin	Naltrexone	Tryptamine
Deoxycorticosterone	(+)-Naproxen	Zomepirac sodium salt

Dextromethorphan	Niacinamide	19-Norethindrone
Diclofenac	Nicotinic Acid	Hemoglobin
4-Dimethyl-aminoantipyrine	Nifedipine	Uric Acid
Noscapine	Cholesterol	Penicillin-G
Albumin	Creatinine	Glucose
Bilirubin		

Cocaine 150 ng/mL

Acetylsalicylic Acid	5, 5-Diphenylhydantoin	Octopamine
Amoxicillin	Erythromycin	Papaverine
Ampicillin	Estradiol	Perphenazine
R-(-)-Apomorphine	Estrone	Phenelzine
L-Ascorbic Acid	Ethanol	Phenylethylamine
Aspirin	Fenofibrate	Promazine
Aspartame	Fentanyl	Promethazine
Atropine	Fotemustine	d,l-Propranolol
Baclofen	Furosemide	Pyridoxine
Benzocaine	Gemfibrozil	Pyrilamine
Benzoic Acid	Guaiacolglyceryl ether	Pyrogallol
Carisoprodol	Gentisic acid	Quinine
Chloramphenicol	Hydralazine	Quinolinic Acid
Chlordiazepoxide	Hydrocortisone	Ranitidine
(+)-Chlorpheniramine	3-Hydroxytyramine	Salicylic Acid
Chlorpromazine	(+/-)-Isoproterenol	Sulindac
Clonidine	Ketamine	Tetracycline
Cortisone	Meprobamate	Tetrahydrozoline
(-)-Cotinine	Methylphenidate	Thiamine
Creatine Hydrate	Nalidixic Acid	Thioridazine
Cyclodextrin	Naltrexone	Tramadol
Deoxycorticosterone	(+)-Naproxen	Trifluoperazine
Dextromethorphan	Niacinamide	Tryptamine
Diclofenac	Nicotinic Acid	Zomepirac sodium salt
4-Dimethyl-aminoantipyrine	Nifedipine	19-Norethindrone
Noscapine	Cholesterol	Hemoglobin
Albumin	Creatinine	Uric Acid
Bilirubin	Glucose	Penicillin-G

Marijuana 50 ng/mL

Acetylsalicylic Acid	5, 5-Diphenylhydantoin	Octopamine
Amoxicillin	Erythromycin	Papaverine
Ampicillin	Estradiol	Perphenazine
R-(-)-Apomorphine	Estrone	Phenylethylamine

L-Ascorbic Acid	Fenofibrate	Promazine
Aspirin	Fentanyl	Promethazine
Aspartame	Fotemustine	d,l-Propranolol
Atropine	Furosemide	Pyridoxine
Baclofen	Gemfibrozil	Pyrilamine
Carisoprodol	Guaiacolglyceryl ether	Pyrogallol
Chloramphenicol	Gentisic acid	Quinolinic Acid
Chlordiazepoxide	Hydralazine	Ranitidine
(+)-Chlorpheniramine	Hydrocortisone	Salicylic Acid
Chlorpromazine	3-Hydroxytyramine	Sulindac
Clonidine	(+/-)-Isoproterenol	Tetracycline
Cortisone	Ketamine	Tetrahydrozoline
(-)-Cotinine	Meprobamate	Thiamine
Creatine Hydrate	Methylphenidate	Thioridazine
Cyclodextrin	Nalidixic Acid	Tramadol
Deoxycorticosterone	Naltrexone	Trifluoperazine
Dextromethorphan	(+)-Naproxen	Tryptamine
Diclofenac	Niacinamide	Zomepirac sodium salt
4-Dimethyl-aminoantipyrine	Nicotinic Acid	19-Norethindrone
Albumin	Cholesterol	Hemoglobin
Creatinine	Penicillin-G	Uric Acid
Glucose		

Morphine 2000 ng/mL

Acetylsalicylic Acid	5, 5-Diphenylhydantoin	Octopamine
Amoxicillin	Erythromycin	Papaverine
Ampicillin	Estradiol	Perphenazine
R-(-)-Apomorphine	Estrone	Phenelzine
L-Ascorbic Acid	Ethanol	Phenylethylamine
Aspirin	Fenofibrate	Promazine
Aspartame	Fentanyl	Promethazine
Atropine	Fotemustine	d,l-Propranolol
Baclofen	Furosemide	Pyridoxine
Benzocaine	Gemfibrozil	Pyrilamine
Benzoic Acid	Guaiacolglyceryl ether	Pyrogallol
Carisoprodol	Gentisic acid	Quinine
Chloramphenicol	Hydralazine	Quinolinic Acid
Chlordiazepoxide	Hydrocortisone	Ranitidine
(+)-Chlorpheniramine	3-Hydroxytyramine	Salicylic Acid
Chlorpromazine	(+/-)-Isoproterenol	Sulindac
Clonidine	Ketamine	Tetracycline
Cortisone	Meprobamate	Tetrahydrozoline
(-)-Cotinine	Methylphenidate	Thiamine

Creatine Hydrate	Nalidixic Acid	Thioridazine
Cyclodextrin	Naltrexone	Tramadol
Deoxycorticosterone	(+)-Naproxen	Trifluoperazine
Dextromethorphan	Niacinamide	Tryptamine
Diclofenac	Nicotinic Acid	Zomepirac sodium salt
4-Dimethyl-aminoantipyrine	Nifedipine	19-Norethindrone
Noscapine	Cholesterol	Hemoglobin
Albumin	Creatinine	Uric Acid
Bilirubin	Glucose	Penicillin-G

Morphine 300 ng/mL

Acetylsalicylic Acid	5, 5-Diphenylhydantoin	Octopamine
Amoxicillin	Erythromycin	Papaverine
Ampicillin	Estradiol	Perphenazine
R-(-)-Apomorphine	Estrone	Phenelzine
L-Ascorbic Acid	Ethanol	Phenylethylamine
Aspirin	Fenofibrate	Promazine
Aspartame	Fentanyl	Promethazine
Atropine	Fotemustine	d,l-Propranolol
Baclofen	Furosemide	Pyridoxine
Benzocaine	Gemfibrozil	Pyrilamine
Benzoic Acid	Guaiacolglyceryl ether	Pyrogallol
Carisoprodol	Gentisic acid	Quinine
Chloramphenicol	Hydralazine	Quinolinic Acid
Chlordiazepoxide	Hydrocortisone	Ranitidine
(+)-Chlorpheniramine	3-Hydroxytyramine	Salicylic Acid
Chlorpromazine	(+/-)-Isoproterenol	Sulindac
Clonidine	Ketamine	Tetracycline
Cortisone	Meprobamate	Tetrahydrozoline
(-)-Cotinine	Methylphenidate	Thiamine
Creatine Hydrate	Nalidixic Acid	Thioridazine
Cyclodextrin	Naltrexone	Tramadol
Deoxycorticosterone	(+)-Naproxen	Trifluoperazine
Dextromethorphan	Niacinamide	Tryptamine
Diclofenac	Nicotinic Acid	Zomepirac sodium salt
4-Dimethyl-aminoantipyrine	Nifedipine	19-Norethindrone
Noscapine	Cholesterol	Hemoglobin
Albumin	Creatinine	Uric Acid
Bilirubin	Glucose	Penicillin-G

Methadone 300 ng/mL

Acetylsalicylic Acid	5, 5-Diphenylhydantoin	Octopamine
Amoxicillin	Erythromycin	Papaverine
Ampicillin	Estradiol	Perphenazine
R-(-)-Apomorphine	Estrone	Phenelzine
L-Ascorbic Acid	Ethanol	Phenylethylamine
Aspirin	Fenofibrate	Promazine
Aspartame	Fentanyl	Promethazine
Atropine	Fotemustine	d,l-Propranolol
Baclofen	Furosemide	Pyridoxine
Benzocaine	Gemfibrozil	Pyrilamine
Benzoic Acid	Guaiacolglyceryl ether	Pyrogallol
Carisoprodol	Gentisic acid	Quinine
Chloramphenicol	Hydralazine	Quinolinic Acid
Chlordiazepoxide	Hydrocortisone	Ranitidine
(+)-Chlorpheniramine	3-Hydroxytyramine	Salicylic Acid
Chlorpromazine	(+/-)-Isoproterenol	Sulindac
Clonidine	Ketamine	Tetracycline
Cortisone	Meprobamate	Tetrahydrozoline
(-)-Cotinine	Methylphenidate	Thiamine
Creatine Hydrate	Nalidixic Acid	Thioridazine
Cyclodextrin	Naltrexone	Tramadol
Deoxycorticosterone	(+)-Naproxen	Trifluoperazine
Dextromethorphan	Niacinamide	Tryptamine
Diclofenac	Nicotinic Acid	Zomepirac sodium salt
4-Dimethyl-aminoantipyrine	Nifedipine	19-Norethindrone
Noscapine	Cholesterol	Hemoglobin
Albumin	Creatinine	Uric Acid
Bilirubin	Glucose	Penicillin-G

Methamphetamine 500 ng/mL

Acetylsalicylic Acid	5, 5-Diphenylhydantoin	Octopamine
Amoxicillin	Erythromycin	Papaverine
Ampicillin	Estradiol	Perphenazine
R-(-)-Apomorphine	Estrone	Phenelzine
L-Ascorbic Acid	Ethanol	Phenylethylamine
Aspirin	Fenofibrate	Promazine
Aspartame	Fentanyl	Promethazine
Atropine	Fotemustine	d,l-Propranolol
Baclofen	Furosemide	Pyridoxine
Benzocaine	Gemfibrozil	Pyrilamine
Benzoic Acid	Guaiacolglyceryl ether	Pyrogallol
Carisoprodol	Gentisic acid	Quinine

Chloramphenicol	Hydralazine	Quinolinic Acid
Chlordiazepoxide	Hydrocortisone	Ranitidine
(+)-Chlorpheniramine	3-Hydroxytyramine	Salicylic Acid
Chlorpromazine	(+/-)-Isoproterenol	Sulindac
Clonidine	Ketamine	Tetracycline
Cortisone	Meprobamate	Tetrahydrozoline
(-)-Cotinine	Methylphenidate	Thiamine
Creatine Hydrate	Nalidixic Acid	Thioridazine
Cyclodextrin	Naltrexone	Tramadol
Deoxycorticosterone	(+)-Naproxen	Trifluoperazine
Dextromethorphan	Niacinamide	Tryptamine
Diclofenac	Nicotinic Acid	Zomepirac sodium salt
4-Dimethyl-aminoantipyrine	Nifedipine	19-Norethindrone
Noscapine	Cholesterol	Hemoglobin
Albumin	Creatinine	Uric Acid
Bilirubin	Glucose	Penicillin-G

Nortriptyline 1000 ng/mL

Acetylsalicylic Acid	5, 5-Diphenylhydantoin	Octopamine
Amoxicillin	Erythromycin	Papaverine
Ampicillin	Estradiol	Perphenazine
R-(-)-Apomorphine	Estrone	Phenelzine
L-Ascorbic Acid	Ethanol	Phenylethylamine
Aspirin	Fenofibrate	d,l-Propranolol
Aspartame	Fentanyl	Pyridoxine
Atropine	Fotemustine	Pyrilamine
Baclofen	Furosemide	Pyrogallol
Benzocaine	Gemfibrozil	Quinine
Benzoic Acid	Guaiacolglyceryl ether	Quinolinic Acid
Carisoprodol	Gentisic acid	Ranitidine
Chloramphenicol	Hydralazine	Salicylic Acid
Chlordiazepoxide	Hydrocortisone	Sulindac
(+)-Chlorpheniramine	3-Hydroxytyramine	Tetracycline
Chlorpromazine	(+/-)-Isoproterenol	Tetrahydrozoline
Clonidine	Ketamine	Thiamine
Cortisone	Meprobamate	Thioridazine
(-)-Cotinine	Methylphenidate	Tramadol
Creatine Hydrate	Nalidixic Acid	Trifluoperazine
Cyclodextrin	Naltrexone	Tryptamine
Deoxycorticosterone	(+)-Naproxen	Zomepirac sodium salt
Dextromethorphan	Niacinamide	19-Norethindrone
Diclofenac	Nicotinic Acid	Hemoglobin
4-Dimethyl-	Nifedipine	Uric Acid

aminoantipyrine		
Noscapine	Cholesterol	Penicillin-G
Albumin	Creatinine	Glucose
Bilirubin		

(EDDP) 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300 ng/mL

Acetylsalicylic Acid	5, 5-Diphenylhydantoin	Octopamine
Amoxicillin	Erythromycin	Papaverine
Ampicillin	Estradiol	Perphenazine
R-(-)-Apomorphine	Estrone	Phenelzine
L-Ascorbic Acid	Ethanol	Phenylethylamine
Aspirin	Fenofibrate	Promazine
Aspartame	Fentanyl	Promethazine
Atropine	Fotemustine	d,l-Propranolol
Baclofen	Furosemide	Pyridoxine
Benzoic Acid	Gemfibrozil	Pyrilamine
Carisoprodol	Guaiacolglyceryl ether	Pyrogallol
Chloramphenicol	Gentisic acid	Quinolinic Acid
Chlordiazepoxide	Hydralazine	Ranitidine
(+)-Chlorpheniramine	Hydrocortisone	Salicylic Acid
Chlorpromazine	3-Hydroxytyramine	Sulindac
Clonidine	(+/-)-Isoproterenol	Tetracycline
Cortisone	Ketamine	Tetrahydrozoline
(-)-Cotinine	Meprobamate	Thiamine
Creatine Hydrate	Methylphenidate	Thioridazine
Cyclodextrin	Nalidixic Acid	Tramadol
Deoxycorticosterone	Naltrexone	Trifluoperazine
Dextromethorphan	(+)-Naproxen	Tryptamine
Diclofenac	Niacinamide	Zomepirac sodium salt
4-Dimethyl-aminoantipyrine	Nicotinic Acid	19-Norethindrone
Noscapine	Nifedipine	Hemoglobin
Albumin	Cholesterol	Uric Acid
Bilirubin	Creatinine	Penicillin-G
Glucose		

Phencyclidine 25 ng/mL

Acetylsalicylic Acid	5, 5-Diphenylhydantoin	Papaverine
Ampicillin	Estradiol	Perphenazine
R-(-)-Apomorphine	Estrone	Phenylethylamine
L-Ascorbic Acid	Fenofibrate	d,l-Propranolol
Aspartame	Fentanyl	Pyrilamine
Atropine	Fotemustine	Pyrogallol
Chlordiazepoxide	Furosemide	Quinolinic Acid

(+)-Chlorpheniramine	Gemfibrozil	Ranitidine
Chlorpromazine	Gentisic acid	Salicylic Acid
Clonidine	Hydralazine	Sulindac
Creatine Hydrate	Hydrocortisone	Tetracycline
Cyclodextrin	3-Hydroxytyramine	Thiamine
Deoxycorticosterone	(+/-)-Isoproterenol	Trifluoperazine
Dextromethorphan	Ketamine	19-Norethindrone
4-Dimethyl-aminoantipyrine	Meprobamate	Hemoglobin
Albumin	Naltrexone	Uric Acid
Nicotinic Acid	Creatinine	Glucose

Oxycodone 100 ng/mL

Acetylsalicylic Acid	5, 5-Diphenylhydantoin	Octopamine
Amoxicillin	Erythromycin	Papaverine
Ampicillin	Estradiol	Perphenazine
R-(-)-Apomorphine	Estrone	Phenelzine
L-Ascorbic Acid	Ethanol	Phenylethylamine
Aspirin	Fenofibrate	Promazine
Aspartame	Fentanyl	Promethazine
Atropine	Fotemustine	d,l-Propranolol
Baclofen	Furosemide	Pyridoxine
Benzocaine	Gemfibrozil	Pyrilamine
Benzoic Acid	Guaiacolglyceryl ether	Pyrogallol
Carisoprodol	Gentisic acid	Quinine
Chloramphenicol	Hydralazine	Quinolinic Acid
Chlordiazepoxide	Hydrocortisone	Ranitidine
(+)-Chlorpheniramine	3-Hydroxytyramine	Salicylic Acid
Chlorpromazine	(+/-)-Isoproterenol	Sulindac
Clonidine	Ketamine	Tetracycline
Cortisone	Meprobamate	Tetrahydrozoline
(-)-Cotinine	Methylphenidate	Thiamine
Creatine Hydrate	Nalidixic Acid	Thioridazine
Cyclodextrin	(+)-Naproxen	Tramadol
Deoxycorticosterone	Niacinamide	Trifluoperazine
Dextromethorphan	Nicotinic Acid	Zomepirac sodium salt
Diclofenac	Nifedipine	19-Norethindrone
4-Dimethyl-aminoantipyrine	Cholesterol	Hemoglobin
Noscapine	Creatinine	Uric Acid
Albumin	Glucose	Penicillin-G
Bilirubin		

Methylenedioxymethamphetamine 500 ng/mL

Acetylsalicylic Acid	5, 5-Diphenylhydantoin	Papaverine
Amoxicillin	Estradiol	Perphenazine
Ampicillin	Estrone	Phenylethylamine
R-(-)-Apomorphine	Fenofibrate	Promazine
L-Ascorbic Acid	Fentanyl	Promethazine
Aspirin	Fotemustine	d,l-Propranolol
Aspartame	Furosemide	Pyridoxine
Atropine	Gemfibrozil	Pyrilamine
Baclofen	Guaiacolglyceryl ether	Pyrogallol
Carisoprodol	Gentisic acid	Quinolinic Acid
Chloramphenicol	Hydralazine	Ranitidine
Chlordiazepoxide	Hydrocortisone	Salicylic Acid
(+)-Chlorpheniramine	3-Hydroxytyramine	Sulindac
Chlorpromazine	(+/-)-Isoproterenol	Tetracycline
Clonidine	Ketamine	Tetrahydrozoline
Cortisone	Meprobamate	Thiamine
(-)-Cotinine	Methylphenidate	Thioridazine
Creatine Hydrate	Naltrexone	Tramadol
Cyclodextrin	(+)-Naproxen	Trifluoperazine
Deoxycorticosterone	Niacinamide	Tryptamine
Dextromethorphan	Nicotinic Acid	Zomepirac sodium salt
Diclofenac	Nifedipine	19-Norethindrone
4-Dimethyl-aminoantipyrine	Creatinine	Uric Acid
Albumin	Glucose	Hemoglobin
Bilirubin		

Buprenorphine 10 ng/mL

Acetylsalicylic Acid	5, 5-Diphenylhydantoin	Octopamine
Amoxicillin	Erythromycin	Papaverine
Ampicillin	Estradiol	Perphenazine
R-(-)-Apomorphine	Estrone	Phenelzine
L-Ascorbic Acid	Ethanol	Phenylethylamine
Aspirin	Fenofibrate	Promazine
Aspartame	Fentanyl	Promethazine
Atropine	Fotemustine	d,l-Propranolol
Baclofen	Furosemide	Pyridoxine
Benzocaine	Gemfibrozil	Pyrilamine
Benzoic Acid	Guaiacolglyceryl ether	Pyrogallol
Carisoprodol	Gentisic acid	Quinine
Chloramphenicol	Hydralazine	Quinolinic Acid
Chlordiazepoxide	Hydrocortisone	Ranitidine

(+)-Chlorpheniramine	3-Hydroxytyramine	Salicylic Acid
Chlorpromazine	(+/-)-Isoproterenol	Sulindac
Clonidine	Ketamine	Tetracycline
Cortisone	Meprobamate	Tetrahydrozoline
(-)-Cotinine	Methylphenidate	Thiamine
Creatine Hydrate	Nalidixic Acid	Thioridazine
Cyclodextrin	Naltrexone	Tramadol
Deoxycorticosterone	(+)-Naproxen	Trifluoperazine
Dextromethorphan	Niacinamide	Zomepirac sodium salt
Diclofenac	Nicotinic Acid	19-Norethindrone
4-Dimethyl-aminoantipyrine	Nifedipine	Hemoglobin
Noscapine	Cholesterol	Uric Acid
Albumin	Creatinine	Penicillin-G
Bilirubin	Glucose	

Endogenous Interferents:

The effect of pH was evaluated by preparing samples with test drug analytes at +/-25% of the cutoff for all devices and adjusting the pH to 2.00 to 9.00, in increments of 1 pH unit. There were no interferences observed.

The effect of specific gravity was evaluated by preparing samples with test drug analytes at +/-25% of the cutoff for all devices and adjusting the specific gravity to 1.001, 1.010, 1.015, 1.020, 1.025, and 1.030. There were no interferences observed.

f. Assay cut-off:

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section M.1.a., above.

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison studies were performed at the manufacturer's site using three operators for each device format (cup and panel). Operators tested a minimum of 40 unaltered positive and 40 unaltered negative clinical samples for each drug. The samples were blind labeled and compared to GC/MS results.

Accuracy performance of the different trade name devices within a format (i.e. within the cup format or within the panel and dipstick formats) is the same (since these different trade name devices differ only by intended user, the presence absence of adulteration strips, or the presence of the plastic housing (in the case of the panel vs. dipstick formats)). Therefore, in the method comparison study conducted by the

sponsor, the Single and Multi-Drug Rapid Test Panel (Urine) results were found to support performance of the all test panel devices and dipstick devices, and the Single and Multi-Drug Rapid Test Cup (Urine) results are intended to support performance of the all cup devices. The results are presented in the tables below.

Amphetamine 500 ng/mL Panel Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	6	43
NEG	45	8	0	0

Amphetamine 500 ng/mL Cup Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	1*	6	58
NEG	45	7	0	0

***Discordant Results (Amphetamine) Cup Format**

Specimen	GC/MS Result	Device Results
47	329	Positive

Amphetamine 500 ng/mL Dipstick Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	6	43
NEG	45	8	0	0

Secobarbital 300 ng/mL Panel Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	9	34
NEG	45	7	0	0

Secobarbital 300 ng/mL Cup Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	9	40
NEG	45	9	0	0

Secobarbital 300 ng/mL Dipstick Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	9	34
NEG	45	7	0	0

Benzodiazepines 300 ng/mL: The results for the Panel, Cup, and Dipstick formats were identical and are provided in the table below.

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	28*	11*	2	9
NEG	50	0	0	0

*Discordant Results Benzodiazepines 300 ng/mL

ID	Neg/Pos	GC/MS					
		Oxazepam (ng/mL)	Alprazolam (ng/mL)	Clonazepam (ng/mL)	Nordiazepam (ng/mL)	Lorazepam (ng/mL)	Temazepam (ng/mL)
50	Pos	0	268	NA	NA	NA	NA
51	Pos	0	NA	247	NA	NA	NA
54	Pos	0	507	NA	NA	NA	NA
55	Pos	0	1220	NA	NA	NA	NA
60	Pos	0	938	NA	NA	NA	NA
61	Pos	0	1150	NA	NA	NA	NA
74	Pos	0	NA	NA	NA	NA	195
75	Pos	0	NA	NA	NA	NA	266
80	Pos	0	241	NA	NA	NA	71
81	Pos	0	158	NA	NA	177	87
85	Pos	0	NA	404	NA	NA	NA

ID	Neg/ Pos	GC/MS					
		Oxazepam (ng/mL)	Alprazolam (ng/mL)	Clonazepam (ng/mL)	Nordiazepam (ng/mL)	Lorazepam (ng/mL)	Temazepam (ng/mL)
86	Pos	0	NA	481	NA	NA	NA
88	Pos	0	5169	NA	NA	NA	NA
89	Pos	0	1093	NA	NA	NA	NA
91	Pos	0	NA	1074	NA	NA	NA
92	Pos	0	NA	432	NA	NA	NA
95	Pos	0	554	273	NA	NA	NA
96	Pos	0	NA	1114	NA	NA	NA
97	Pos	0	NA	506	NA	NA	NA
99	Pos	0	196	NA	NA	NA	63
76	Pos	15	NA	NA	NA	NA	462
77	Pos	26	NA	NA	NA	23	864
78	Pos	66	NA	NA	NA	67	1417
53	Pos	78	70	NA	33	NA	61
73	Pos	82	NA	NA	NA	67	3232
72	Pos	118	NA	NA	NA	102	3744
70	Pos	137	NA	NA	NA	212	3117
98	Pos	140	NA	NA	NA	108	2000+
82	Pos	150	99	404	26	111	54
52	Pos	161	NA	481	36	139	62
68	Pos	167	NA	NA	NA	148	3953
69	Pos	190	NA	NA	NA	293	3529
62	Pos	212	NA	NA	50	NA	208
100	Pos	216	NA	NA	50	NA	218
66	Pos	218	NA	NA	NA	138	134
84	Pos	224	NA	NA	49	201	86
83	Pos	246	NA	NA	42	175	85
67	Pos	257	NA	NA	NA	217	>4000
63	Pos	282	268	NA	71	167	181

Cocaine 150 ng/mL Panel Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	4	41
NEG	45	4	0	0

Cocaine 150 ng/mL Cup Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	4	41
NEG	45	4	0	0

Cocaine 150 ng/mL Dipstick Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	4	41
NEG	45	4	0	0

Marijuana 50 ng/mL Panel Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	6	41
NEG	45	7	2*	0

*Discordant Results (Marijuana) Panel Format

Specimen	GC/MS Result	Device Results
53	65.5	Negative
59	55.8	Negative

Marijuana 50 ng/mL Cup Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	9	43
NEG	45	9	0	0

Marijuana 50 ng/mL Dipstick Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	6	41
NEG	45	7	2*	0

*Discordant Results (Marijuana) Dipstick Format

Specimen	GC/MS Result	Device Results
53	65.5	Negative
59	55.8	Negative

Morphine 2000 ng/mL Panel Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	4	41
NEG	45	4	0	0

Morphine 2000 ng/mL Cup Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	4	42
NEG	45	5	0	0

Morphine 2000 ng/mL Dipstick Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	4	41
NEG	45	4	0	0

Morphine 300 ng/mL Panel Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	4	41
NEG	45	4	0	0

Morphine 300 ng/mL Cup Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	4	57
NEG	45	6	0	0

Morphine 300 ng/mL Dipstick Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	4	51
NEG	45	4	0	0

Methamphetamine 500 ng/mL Panel Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	1*	3	50
NEG	45	3	0	0

*Discordant Results (Methamphetamine) Panel Format

Specimen	GC/MS Result	Device Results
47	254	Positive

Methamphetamine 500 ng/mL Cup Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	1*	3	72
NEG	45	3	0	0

*Discordant Results (Methamphetamine) Cup Format

Specimen	GC/MS Result	Device Results
47	254	Positive

Methamphetamine 500 ng/mL Dipstick Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	1*	4	49
NEG	45	3	0	0

*Discordant Results (MET) Dipstick Format

Specimen	GC/MS Result	Device Results
47	254	Positive

Methadone 300 ng/mL Panel Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	3*	13	39
NEG	45	9	0	0

*Discordant Results (Methadone) Format: Panel

Specimen	GC/MS Result	Device Results
50	285	Positive
51	196	Positive
52	291	Positive

Methadone 300 ng/mL Cup Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	3*	13	39
NEG	45	9	0	0

*Discordant Results (Methadone) Format: Cup

Specimen	GC/MS Result	Device Results
50	285	Positive
51	196	Positive
52	291	Positive

Methadone 300 ng/mL Dipstick Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	3*	13	39
NEG	45	9	0	0

*Discordant Results (Methadone) Format: Dipstick

Specimen	GC/MS Result	Device Results
49	285	Positive
50	196	Positive
51	291	Positive

Phencyclidine 25 ng/mL Panel Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	12	42
NEG	45	8	0	0

Phencyclidine 25 ng/mL Cup Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	12	42
NEG	45	8	0	0

Phencyclidine 25 ng/mL Dipstick Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	12	42
NEG	45	8	0	0

Marijuana 1000 ng/mL Panel Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	8	33
NEG	45	9	0	0

Marijuana 1000 ng/mL Cup Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	8	33
NEG	45	9	0	0

Marijuana 1000 ng/mL Dipstick Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	8	33
NEG	45	9	0	0

(EDDP) 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300 ng/mL Panel Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	2*	9	43
NEG	45	8	1*	0

*Discordant Results (EDDP) 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine Panel Format

Specimen	GC/MS Result	Device Results
48	297	Positive
61	188	Positive
56	303	Negative

(EDDP) 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300 ng/mL Cup Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	2*	9	44
NEG	45	8	1*	0

*Discordant Results (EDDP) 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine Cup Format

Specimen	GC/MS Result	Device Results
48	297	Positive
61	188	Positive
56	303	Negative

(EDDP) 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine Dipstick Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	1*	10	43
NEG	45	8	1*	0

*Discordant Results (EDDP) 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine
Dipstick Format

Specimen	GC/MS Result	Device Results
48	297	Positive
56	303	Negative

Oxycodone 100 ng/mL Panel Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	4	37
NEG	45	4	0	0

Oxycodone 100 ng/mL Cup Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	4	37
NEG	45	4	0	0

Oxycodone 100 ng/mL Dipstick Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	4	36
NEG	45	4	0	0

(MDMA) Methylenedioxymethamphetamine 500 ng/mL Panel Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	4	36
NEG	45	4	0	0

(MDMA) Methylenedioxymethamphetamine 500 ng/mL Cup Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	4	36
NEG	45	4	0	0

(MDMA) Methylenedioxymethamphetamine 500 ng/mL Dipstick Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	4	36
NEG	45	4	0	0

Buprenorphine 10 ng/mL Panel Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	8	36
NEG	45	10	0	0

Buprenorphine 10 ng/mL Cup Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	8	36
NEG	45	10	0	0

Buprenorphine 10 ng/mL Dipstick Format

Candidate Device Result	Concentration Range by GC/MS (ng/mL)			
	≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 50%)	High Positive (≥50% cutoff)
POS	0	0	8	36
NEG	45	10	0	0

b. Matrix comparison:

Not applicable.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

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

A lay user study using the cup format of the device was performed by 245 lay persons at three intended user sites. An additional lay user study using the panel format of the device was performed by 65 lay persons at three intended user sites. The lay users were recruited to ensure a representative and demographically diverse population. Urine samples were prepared with test drug analytes at the following concentrations; -100%, -50%, -25%, +25%, +50% and +100% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into an individual blind-labeled container. Each lay-user was provided with a package insert in English only, one blind-labeled sample for cup format testing and two blind-labeled samples for panel format testing.

Amphetamine 500 ng/mL Format: Cup

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	198	0	0	198	100%
-50% Cutoff	8	242	0	8	100%
-25% Cutoff	8	359	1	7	87.5%
+25% Cutoff	8	628	8	0	100%
+50% Cutoff	8	782	8	0	100%
+100% Cutoff	15	1523	15	0	100%

Amphetamine 500 ng/mL Format: Panel

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	79	0	0	79	100%
-50% Cutoff	7	242	0	7	100%
-25% Cutoff	7	359	1	6	85.7%
+25% Cutoff	7	628	6	1	85.7%
+50% Cutoff	7	782	7	0	100%
+100% Cutoff	23	1523	23	0	100%

Secobarbital 300 ng/mL Format: Cup

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	202	0	0	198	100%
-50% Cutoff	7	153	0	8	100%
-25% Cutoff	7	218	0	7	100%
+25% Cutoff	7	384	7	0	100%
+50% Cutoff	7	442	7	0	100%
+100% Cutoff	15	889	15	0	100%

Secobarbital 300 ng/mL Format: Panel

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	79	0	0	79	100%
-50% Cutoff	7	153	0	7	100%
-25% Cutoff	7	218	1	6	85.7%
+25% Cutoff	7	384	6	1	85.7%
+50% Cutoff	7	442	7	0	100%
+100% Cutoff	23	889	23	0	100%

Benzodiazepines ng/mL 300 Format: Cup

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	202	0	0	202	100%
-50% Cutoff	7	148	0	7	100%
-25% Cutoff	7	216	1	6	85.7%
+25% Cutoff	7	361	6	1	85.7%
+50% Cutoff	7	468	7	0	100%
+100% Cutoff	15	873	15	0	100%

Benzodiazepines ng/mL 300 Format: Panel

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	72	0	0	72	100%
-50% Cutoff	7	148	0	7	100%
-25% Cutoff	7	216	1	6	85.7%
+25% Cutoff	7	361	6	1	85.7%
+50% Cutoff	7	468	7	0	100%
+100% Cutoff	30	873	30	0	100%

Cocaine 150 ng/mL Format: Cup

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	198	0	0	198	100%
-50% Cutoff	8	78	0	8	100%
-25% Cutoff	8	111	0	8	100%
+25% Cutoff	8	179	8	0	100%
+50% Cutoff	8	221	8	0	100%
+100% Cutoff	15	447	15	0	100%

Cocaine 150 ng/mL Format: Panel

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	86	0	0	86	100%
-50% Cutoff	7	78	0	7	100%
-25% Cutoff	7	111	1	6	85.7%
+25% Cutoff	7	179	6	1	85.7%
+50% Cutoff	7	221	7	0	100%
+100% Cutoff	16	447	16	0	100%

(MDMA) Methylenedioxymethamphetamine 500 ng/mL Format: Cup

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	198	0	0	198	100%
-50% Cutoff	8	247	0	8	100%
-25% Cutoff	8	388	0	8	100%
+25% Cutoff	8	636	7	1	87.5%
+50% Cutoff	8	763	8	0	100%
+100% Cutoff	15	1563	15	0	100%

(MDMA) Methylenedioxymethamphetamine 500 ng/mL Format: Panel

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	79	0	0	79	100%
-50% Cutoff	7	247	0	7	100%
-25% Cutoff	7	388	1	6	85.7%
+25% Cutoff	7	636	5	2	71.4%
+50% Cutoff	7	763	7	0	100%
+100% Cutoff	23	1563	23	0	100%

(EDDP) 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300 ng/mL Format: Cup

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	198	0	0	198	100%
-50% Cutoff	8	156	0	8	100%
-25% Cutoff	8	216	0	8	100%
+25% Cutoff	8	372	8	0	100%
+50% Cutoff	8	443	8	0	100%
+100% Cutoff	15	925	15	0	100%

(EDDP) 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300 ng/mL Format: Panel

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	86	0	0	86	100%
-50% Cutoff	7	156	0	7	100%
-25% Cutoff	7	216	1	6	85.7%
+25% Cutoff	7	372	6	1	85.7%
+50% Cutoff	7	443	7	0	100%
+100% Cutoff	16	925	16	0	100%

Morphine 2000 ng/mL Format: Cup

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	202	0	0	202	100%
-50% Cutoff	7	1000	0	7	100%
-25% Cutoff	7	1398	0	7	100%
+25% Cutoff	7	2368	6	1	85.7%
+50% Cutoff	7	2935	7	0	100%
+100% Cutoff	15	6200	15	0	100%

Morphine 2000 ng/mL Format: Panel

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	94	0	0	94	100%
-50% Cutoff	7	1000	0	7	100%
-25% Cutoff	7	1398	1	6	85.7%
+25% Cutoff	7	2368	6	1	85.7%
+50% Cutoff	7	2935	7	0	100%
+100% Cutoff	8	6200	8	0	100%

Morphine 300 ng/mL Format: Cup

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	159	0	0	159	100%
-50% Cutoff	7	156	0	7	100%
-25% Cutoff	7	236	0	7	100%
+25% Cutoff	7	369	7	0	100%
+50% Cutoff	7	443	7	0	100%
+100% Cutoff	58	854	58	0	100%

Morphine 300 ng/mL Format: Panel

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	58	0	0	58	100%
-50% Cutoff	7	156	0	7	100%
-25% Cutoff	7	236	2	5	71.4%
+25% Cutoff	7	369	6	1	85.7%
+50% Cutoff	7	443	7	0	100%
+100% Cutoff	44	854	44	0	100%

Methamphetamine ng/mL 500 Format: Cup

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	198	0	0	198	100%
-50% Cutoff	8	246	0	8	100%
-25% Cutoff	8	386	1	7	87.5%
+25% Cutoff	8	638	8	0	100%
+50% Cutoff	8	737	8	0	100%
+100% Cutoff	15	1672	15	0	100%

Methamphetamine 500 ng/mL Format: Panel

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	72	0	0	72	100%
-50% Cutoff	7	246	0	7	100%
-25% Cutoff	7	386	1	6	85.7%
+25% Cutoff	7	638	6	1	85.7%
+50% Cutoff	7	737	7	0	100%
+100% Cutoff	30	1672	30	0	100%

Phencyclidine 25 ng/mL Format: Cup

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	202	0	0	202	100%
-50% Cutoff	7	12.7	0	7	100%
-25% Cutoff	7	17.8	1	7	87.5%
+25% Cutoff	7	32.2	7	0	100%
+50% Cutoff	7	37.3	7	0	100%
+100% Cutoff	15	78.4	15	0	100%

Phencyclidine 25 ng/mL Format: Panel

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	72	0	0	72	100%
-50% Cutoff	7	12.7	0	7	100%
-25% Cutoff	7	17.8	1	6	85.7%
+25% Cutoff	7	32.2	6	1	85.7%
+50% Cutoff	7	37.3	7	0	100%
+100% Cutoff	30	78.4	30	0	100%

Nortriptyline 1000 ng/mL Format: Cup

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	202	0	0	202	100%
-50% Cutoff	7	482	0	7	100%
-25% Cutoff	7	719	1	6	85.7%
+25% Cutoff	7	1223	6	1	85.7%
+50% Cutoff	7	1425	7	0	100%
+100% Cutoff	15	2900	15	0	100%

Nortriptyline 1000 ng/mL Format: Panel

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	79	0	0	79	100%
-50% Cutoff	7	482	0	7	100%
-25% Cutoff	7	719	1	6	85.7%
+25% Cutoff	7	1223	6	1	85.7%
+50% Cutoff	7	1425	7	0	100%
+100% Cutoff	23	2900	23	0	100%

Marijuana 50 ng/mL Format: Cup

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	202	0	0	202	100%
-50% Cutoff	7	23	0	7	100%
-25% Cutoff	7	37	0	7	100%
+25% Cutoff	7	59	7	0	100%
+50% Cutoff	7	73	7	0	100%
+100% Cutoff	15	154	15	0	100%

Marijuana 50 ng/mL Format: Panel

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	86	0	0	86	100%
-50% Cutoff	7	23	0	7	100%
-25% Cutoff	7	37	1	6	85.7%
+25% Cutoff	7	59	6	1	85.7%
+50% Cutoff	7	73	7	0	100%
+100% Cutoff	16	154	16	0	100%

Oxycodone 100 ng/mL Format: Cup

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	198	0	0	198	100%
-50% Cutoff	8	47	0	8	100%
-25% Cutoff	8	69	0	8	100%
+25% Cutoff	8	127	8	0	100%
+50% Cutoff	8	141	8	0	100%
+100% Cutoff	15	315	15	0	100%

Oxycodone 100 ng/mL Format: Panel

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	79	0	0	79	100%
-50% Cutoff	7	47	0	7	100%
-25% Cutoff	7	69	1	6	85.7%
+25% Cutoff	7	127	6	1	85.7%
+50% Cutoff	7	141	7	0	100%
+100% Cutoff	23	315	23	0	100%

Methadone 300 ng/mL Format: Cup

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	202	0	0	202	100%
-50% Cutoff	7	145	0	7	100%
-25% Cutoff	7	215	0	7	100%
+25% Cutoff	7	382	7	0	100%
+50% Cutoff	7	461	7	0	100%
+100% Cutoff	15	826	15	0	100%

Methadone 300 ng/mL Format: Panel

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	79	0	0	79	100%
-50% Cutoff	7	145	0	7	100%
-25% Cutoff	7	215	2	5	71.4%
+25% Cutoff	7	382	6	1	85.7%
+50% Cutoff	7	461	7	0	100%
+100% Cutoff	23	826	23	0	100%

Buprenorphine 10 ng/mL Format: Cup

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	198	0	0	198	100%
-50% Cutoff	8	4.8	0	8	100%
-25% Cutoff	8	7.2	0	8	87.5%
+25% Cutoff	8	11.8	8	0	100%
+50% Cutoff	8	14.8	8	0	100%
+100% Cutoff	15	28	15	0	100%

Buprenorphine 10 ng/mL Format: Panel

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	86	0	0	86	100%
-50% Cutoff	7	4.8	0	7	100%
-25% Cutoff	7	7.2	2	5	71.4%
+25% Cutoff	7	11.8	6	1	87.5%
+50% Cutoff	7	14.8	7	0	100%
+100% Cutoff	16	28	16	0	100%

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.9-8.0.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

O. Conclusion:

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