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

A. 510(k) Number:

k140215

B. Purpose for Submission:

New Device

C. Measurand:

Barbiturates, Benzodiazepine, Methamphetamine, Methadone, Opiate, and Phencyclidine.

D. Type of Test:

Qualitative lateral flow chromatographic immunoassay.

E. Applicant:

Co-Innovation Biotech Co., Ltd.

F. Proprietary and Established Names:

One Step Single/Multi-drug Test Cup

One Step Single/Multi-drug Test Dipcard

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DIS	Class II	21 CFR part 862.3150 Barbiturate test system	Toxicology (91)
JXM	Class II	21 CFR part 862.3170 Benzodiazepine test system	Toxicology (91)
DJC	Class II	21 CFR part 862.3610 Methamphetamine test system	Toxicology (91)
DJR	Class II	21 CFR part 862.3620 Methadone test system	Toxicology (91)
DJG	Class II	21 CFR part 862.3650 Opiate test system	Toxicology (91)
LCM	Unclassified	Phencyclidine	Toxicology (91)

H. Intended Use:

1. Intended use(s):

   See Indications for Use below.

2. Indication(s) for use:

   The One Step Single/Multi-drug Test Cup and One Step Single/Multi-drug Test Dipcard are lateral flow chromatographic immunoassays designed to qualitatively detect the presence of drugs and drug metabolites in human urine at the following cut-off concentrations:

Test	Calibrator	Cut-off level
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Methylenedioxymeth-amphetamine (MDMA)	3,4-Methylenedioxy-methamphetamine	500 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL

   The tests are available in one of two formats: 1) Test Cup, 2) Test Dipcard, The test configuration comes with a single drug screening test or any combinations of multiple drug screening tests. The test is intended for in vitro diagnostics use. They are intended for prescription use in clinical laboratories only and not for point-of-care use.

   This assay provides only a preliminary analytical test 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.

3. Special conditions for use statement(s):

   For Prescription Use in Clinical Laboratories.

4. Special instrument requirements:

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

I. Device Description:

The One Step Single/Multi-drug Test Cup and One Step Single/Multi-drug Test Dipcard are competitive binding, lateral flow immunochromatographic assays for qualitative detection of Barbiturates, Benzodiazepines, Methylenedioxymethamphetamine, Methadone, Oxycodone, Phencyclidine and their metabolites in human urine at or above the cut-off levels as indicated. The devices are available in one of two formats: 1) Test Cup, 2) Test Dipcard. The test configuration comes with single drug screening test or any combinations of multiple drug screening tests. The tests are visually read.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   UCP Home Drug Screening Test Cards
   UCP Home Drug Screening Test Cup

2. Predicate 510(k) number(s):

   k091588

3. Comparison with predicate:

Similarities		
Item	Candidate Device	Predicate
Indication for use	Qualitative detection of drugs-of-abuse in urine （Barbiturates, Benzodiazepines, Methylenedioxymethamphetamine, Methadone, Oxycodone, Phencyclidine)	Same
Intended Users	Prescription Use	Over the Counter (OTC) Use and Prescription Use
Specimen	Urine	Same
Cutoff	Barbiturates:300 ng/mL Benzodiazepines:300 ng/mL Methylenedioxymethamphetamine:500 ng/mL Methadone:300 ng/mL Oxycodone:100 ng/mL Phencyclidine:25 ng/mL	Same
Read time	5 minutes	Same
Results	Qualitative	Same

Methodology	Competitive binding, Lateral flow immunochromatographic assay based on the principle of antigen antibody immunochemistry	Same
Configuration	Dipcard and Cup	Same
Differences		
Item	Candidate Device	Predicate
The number of analytes in each device	6 analytes	12 analytes

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

None were referenced.

L. Test Principle:

The One Step Single/Multi-drug Test Cup and the One Step Single/Multi-drug Test Dipcard employ lateral flow immunochromatographic technology based on the principle of competitive binding. Drugs, if present in concentrations below the cutoff level, will not saturate the binding sites of monoclonal antibody (mouse) coated particles in the device. The antibody-coated particles will then be captured by immobilized drug-specific conjugate and a colored line will appear in the test line region indicating a negative result. The colored line will not form if the sample contains drug in excess of the cutoff level because the drug will saturate all the binding sites of the drug-specific antibody, indicating a positive result. Each strip in the device contains a procedural control that appears in the control line region regardless of the presence of drug, indicating that the sample has migrated properly on the test strip.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Initial precision studies were performed using the single drug and multi-drug test formats. For these studies, drug free urine specimens were spiked with drug analyte at different concentrations containing 0, +/- 75% cutoff, +/- 50% cutoff, +/- 25% cutoff, +100% cutoff and cutoff of drug. The concentrations of the target drug were confirmed with GC/MS. In both the single drug test precision study and the multi-drug test precision study each concentration of urine specimen was divided into aliquots. Each aliquot was blindly labeled with a separate number by a nonparticipant and each aliquot was tested with one test format only (test dipcard or test cup). The study was conducted at 3 hospital laboratories. Two operators per location tested 3 aliquots at each concentration for each lot per day (3runs/day) for 10 non-consecutive days using one device lot per location. One operator tested the test dipcard format and

the second operator tested the test cup format. Results from these initial studies are presented in the following tables:

Precision data of One Step Single-drug (BAR) Test (Dipcard)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
75ng/ml	-75%cutoff	60	0	60	0	60	0	60
150ng/ml	-50%cutoff	60	0	60	0	60	0	60
225ng/ml	-25%cutoff	60	6	54	8	52	4	56
300ng/ml	cutoff	60	38	22	36	24	38	22
375ng/ml	+25%cutoff	60	52	8	54	6	52	8
450ng/ml	+50%cutoff	60	58	2	60	0	56	4
525ng/ml	+75%cutoff	60	60	0	60	0	60	0
600ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Single-drug (BAR) Test (Cup)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
75ng/ml	-75%cutoff	60	0	60	0	60	0	60
150ng/ml	-50%cutoff	60	0	60	0	60	0	60
225ng/ml	-25%cutoff	60	6	54	8	52	6	54
300ng/ml	cutoff	60	36	24	36	24	36	24
375ng/ml	+25%cutoff	60	54	6	54	6	52	8
450ng/ml	+50%cutoff	60	60	0	60	0	56	4
525ng/ml	+75%cutoff	60	60	0	60	0	60	0
600ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Multi-drug Test Dipcard (For BAR)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
250ng/ml	-75%cutoff	60	0	60	0	60	0	60
500ng/ml	-50%cutoff	60	0	60	0	60	0	60
750ng/ml	-25%cutoff	60	4	56	6	54	8	52
1000ng/ml	cutoff	60	36	24	38	22	36	24
1250ng/ml	+25%cutoff	60	52	8	54	6	54	6
1500ng/ml	+50%cutoff	60	56	4	58	2	60	0
1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
2000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Multi-drug Test Cup (For BAR)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
250ng/ml	-75%cutoff	60	0	60	0	60	0	60
500ng/ml	-50%cutoff	60	0	60	0	60	0	60
750ng/ml	-25%cutoff	60	6	54	4	56	4	56
1000ng/ml	cutoff	60	38	22	36	24	36	24
1250ng/ml	+25%cutoff	60	52	8	54	6	56	4
1500ng/ml	+50%cutoff	60	58	2	56	4	60	0
1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
2000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Single-drug (BZO) Test (Dipcard)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
75ng/ml	-75%cutoff	60	0	60	0	60	0	60
150ng/ml	-50%cutoff	60	0	60	0	60	0	60
225ng/ml	-25%cutoff	60	8	52	4	56	6	54
300ng/ml	cutoff	60	38	22	34	26	36	24
375ng/ml	+25%cutoff	60	54	6	52	8	52	8
450ng/ml	+50%cutoff	60	56	4	58	2	60	0
525ng/ml	+75%cutoff	60	60	0	60	0	60	0
600ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Single-drug (BZO) Test (Cup)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
75ng/ml	-75%cutoff	60	0	60	0	60	0	60
150ng/ml	-50%cutoff	60	0	60	0	60	0	60
225ng/ml	-25%cutoff	60	10	50	6	54	8	52
300ng/ml	cutoff	60	34	26	36	24	36	24
375ng/ml	+25%cutoff	60	52	8	54	6	56	4
450ng/ml	+50%cutoff	60	56	4	60	0	60	0
525ng/ml	+75%cutoff	60	60	0	60	0	60	0
600ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Multi-drug Test Dipcard (For BZO)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	60	0	60	0	60	0
250ng/ml	-75%cutoff	60	60	0	60	0	60	0
500ng/ml	-50%cutoff	60	0	60	0	60	0	60
750ng/ml	-25%cutoff	60	4	56	4	56	6	54
1000ng/ml	cutoff	60	34	26	34	26	38	22
1250ng/ml	+25%cutoff	60	54	6	54	6	52	8
1500ng/ml	+50%cutoff	60	58	2	56	4	58	2
1750ng/ml	+75%cutoff	60	60	60	0	60	0	60
2000ng/ml	+100%cutoff	60	60	60	0	60	0	60

Precision data of One Step Multi-drug Test Cup (For BZO)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
250ng/ml	-75%cutoff	60	0	60	0	60	0	60
500ng/ml	-50%cutoff	60	0	60	0	60	0	60
750ng/ml	-25%cutoff	60	6	54	8	52	6	54
1000ng/ml	cutoff	60	38	22	34	26	36	24
1250ng/ml	+25%cutoff	60	56	4	54	6	54	6
1500ng/ml	+50%cutoff	60	60	0	56	4	58	2
1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
2000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Single-drug (MDMA) Test (Dipcard)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
125ng/ml	-75%cutoff	60	0	60	0	60	0	60
250ng/ml	-50%cutoff	60	0	60	0	60	0	60
375ng/ml	-25%cutoff	60	10	50	8	52	8	52
500ng/ml	cutoff	60	34	26	32	28	36	24
625ng/ml	+25%cutoff	60	48	12	52	8	50	10
750ng/ml	+50%cutoff	60	56	4	54	6	54	6
875ng/ml	+75%cutoff	60	60	0	60	0	60	0
1000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Single drug (MDMA) Test (Cup)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
125ng/ml	-75%cutoff	60	0	60	0	60	0	60
250ng/ml	-50%cutoff	60	0	60	0	60	0	60
375ng/ml	-25%cutoff	60	6	54	8	52	10	50
500ng/ml	cutoff	60	36	24	34	26	32	28
625ng/ml	+25%cutoff	60	52	8	50	10	48	12
750ng/ml	+50%cutoff	60	58	2	56	4	54	6
875ng/ml	+75%cutoff	60	60	0	60	0	60	0
1000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Multi-drug Test Dipcard (For MDMA)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
250ng/ml	-75%cutoff	60	0	60	0	60	0	60
500ng/ml	-50%cutoff	60	0	60	0	60	0	60
750ng/ml	-25%cutoff	60	8	52	10	50	10	50
1000ng/ml	cutoff	60	34	26	36	24	32	28
1250ng/ml	+25%cutoff	60	52	8	48	12	50	10
1500ng/ml	+50%cutoff	60	54	6	56	4	58	2
1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
2000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Multi-drug Test Cup (For MDMA)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
250ng/ml	-75%cutoff	60	0	60	0	60	0	60
500ng/ml	-50%cutoff	60	60	0	60	0	60	0
750ng/ml	-25%cutoff	60	60	10	50	8	52	6
1000ng/ml	cutoff	60	60	36	24	32	28	34
1250ng/ml	+25%cutoff	60	60	50	10	54	6	52
1500ng/ml	+50%cutoff	60	60	56	4	58	2	58
1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
2000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Single-Drug (MTD) Test (Dipcard)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
75ng/ml	-75%cutoff	60	0	60	0	60	0	60
150ng/ml	-50%cutoff	60	0	60	0	60	0	60
225ng/ml	-25%cutoff	60	6	54	8	52	10	50
300ng/ml	cutoff	60	32	28	34	26	36	24
375ng/ml	+25%cutoff	60	50	10	52	8	54	6
450ng/ml	+50%cutoff	60	56	4	54	6	58	2
525ng/ml	+75%cutoff	60	60	0	60	0	60	0
600ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Single-Drug (MTD) Test (Cup)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
75ng/ml	-75%cutoff	60	0	60	0	60	0	60
150ng/ml	-50%cutoff	60	0	60	0	60	0	60
225ng/ml	-25%cutoff	60	8	52	6	54	6	54
300ng/ml	cutoff	60	36	24	34	26	36	24
375ng/ml	+25%cutoff	60	54	6	52	8	54	6
450ng/ml	+50%cutoff	60	58	2	56	4	58	2
525ng/ml	+75%cutoff	60	60	0	60	0	60	0
600ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Multi-drug Test Dipcard (For MTD)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
250ng/ml	-75%cutoff	60	0	60	0	60	0	60
500ng/ml	-50%cutoff	60	0	60	0	60	0	60
750ng/ml	-25%cutoff	60	6	54	10	50	8	52
1000ng/ml	cutoff	60	32	28	36	24	34	26
1250ng/ml	+25%cutoff	60	54	6	50	10	52	8
1500ng/ml	+50%cutoff	60	60	0	58	2	56	4
1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
2000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Multi-drug Test Cup (For MTD)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
250ng/ml	-75%cutoff	60	0	60	0	60	0	60
500ng/ml	-50%cutoff	60	0	60	0	60	0	60
750ng/ml	-25%cutoff	60	6	54	8	52	6	54
1000ng/ml	cutoff	60	36	24	34	26	34	26
1250ng/ml	+25%cutoff	60	52	8	54	6	54	6
1500ng/ml	+50%cutoff	60	56	4	58	2	56	4
1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
2000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Single-drug (OXY) Test (Dipcard)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
25ng/ml	-75%cutoff	60	0	60	0	60	0	60
50ng/ml	-50%cutoff	60	0	60	0	60	0	60
75ng/ml	-25%cutoff	60	6	54	2	58	4	56
100ng/ml	cutoff	60	34	26	38	22	36	24
125ng/ml	+25%cutoff	60	56	4	56	4	58	2
150ng/ml	+50%cutoff	60	58	2	58	2	60	0
175ng/ml	+75%cutoff	60	60	0	60	0	60	0
200ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Single-drug (OXY) Test (Cup)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
25ng/ml	-75%cutoff	60	0	60	0	60	0	60
50ng/ml	-50%cutoff	60	0	60	0	60	0	60
75ng/ml	-25%cutoff	60	4	56	4	56	6	54
100ng/ml	cutoff	60	38	22	36	24	38	22
125ng/ml	+25%cutoff	60	58	2	56	4	56	4
150ng/ml	+50%cutoff	60	60	0	58	2	58	2
175ng/ml	+75%cutoff	60	60	0	60	0	60	0
200ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Multi-drug Test Dipcard (For OXY)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
250ng/ml	-75%cutoff	60	0	60	0	60	0	60
500ng/ml	-50%cutoff	60	0	60	0	60	0	60
750ng/ml	-25%cutoff	60	2	58	6	54	4	56
1000ng/ml	cutoff	60	36	24	38	22	34	26
1250ng/ml	+25%cutoff	60	56	4	58	2	58	2
1500ng/ml	+50%cutoff	60	58	2	60	0	60	0
1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
2000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Multi-drug Test Cup (For OXY)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
250ng/ml	-75%cutoff	60	0	60	0	60	0	60
500ng/ml	-50%cutoff	60	0	60	0	60	0	60
750ng/ml	-25%cutoff	60	6	54	4	56	6	54
1000ng/ml	cutoff	60	38	22	36	24	36	24
1250ng/ml	+25%cutoff	60	58	2	58	2	56	4
1500ng/ml	+50%cutoff	60	60	0	60	0	58	2
1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
2000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Single-drug (PCP) Test (Dipcard)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
6.3ng/ml	-75%cutoff	60	0	60	0	60	0	60
12.5ng/ml	-50%cutoff	60	0	60	0	60	0	60
18.8ng/ml	-25%cutoff	60	4	56	2	58	4	56
25ng/ml	cutoff	60	34	26	36	24	32	28
31.3ng/ml	+25%cutoff	60	52	8	54	6	54	6
37.5ng/ml	+50%cutoff	60	56	4	60	0	58	2
43.8ng/ml	+75%cutoff	60	60	0	60	0	60	0
50ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Single-drug (PCP) Test (Cup)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
6.3ng/ml	-75%cutoff	60	0	60	0	60	0	60
12.5ng/ml	-50%cutoff	60	0	60	0	60	0	60
18.8ng/ml	-25%cutoff	60	4	56	4	56	2	58
25ng/ml	cutoff	60	38	22	36	24	38	22
31.3ng/ml	+25%cutoff	60	56	4	54	6	58	2
37.5ng/ml	+50%cutoff	60	58	2	58	2	60	0
43.8ng/ml	+75%cutoff	60	60	0	60	0	60	0
50ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Multi-drug Test Dipcard (For PCP)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
250ng/ml	-75%cutoff	60	0	60	0	60	0	60
500ng/ml	-50%cutoff	60	0	60	0	60	0	60
750ng/ml	-25%cutoff	60	2	58	4	56	2	58
1000ng/ml	cutoff	60	38	22	32	28	34	26
1250ng/ml	+25%cutoff	60	54	6	52	8	56	4
1500ng/ml	+50%cutoff	60	60	0	60	0	58	2
1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
2000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Multi-drug Test Cup (For PCP)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
250ng/ml	-75%cutoff	60	0	60	0	60	0	60
500ng/ml	-50%cutoff	60	0	60	0	60	0	60
750ng/ml	-25%cutoff	60	2	58	2	58	4	56
1000ng/ml	cutoff	60	36	24	38	22	34	26
1250ng/ml	+25%cutoff	60	58	2	54	6	56	4
1500ng/ml	+50%cutoff	60	60	0	58	2	60	0
1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
2000ng/ml	+100%cutoff	60	60	0	60	0	60	0

The original precision study data showed numerous negative results in the specimens containing drug concentrations at +50% above the cutoff. A root cause analysis was conducted by the sponsor to determine the cause of these results. The root cause was identified to be inconsistent and inadequate volume of aliquoted samples. The sponsor revised the precision study protocol to specify a sample volume per vial and supplemental precision studies were conducted to verify that the root cause was

correctly identified.

Supplemental precision studies were conducted for the single drug and multi-drug test formats using drug free urine specimens spiked with one drug analyte at different concentrations containing 0, +/- 75% cutoff, +/- 50% cutoff, +/- 25% cutoff, +100% cutoff and cutoff of drug. The concentrations of the target drug were confirmed with GC/MS. In both the single drug test precision study and the multi-drug test precision study each concentration of urine specimen was divided into aliquots. Each aliquot was blindly labeled with a separate number by a nonparticipant and each aliquot was tested with one test format only (test dipcard or test cup). The study was conducted at 3 hospital laboratories. Two operators per location tested 3 aliquots at each concentration for each lot per day (3runs/day) for 10 non-consecutive days using one device lot per location. One operator tested the test dipcard format and the second operator tested the test cup format. Results from these supplemental precision studies are presented in the following tables:

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Precision data of One Step Single-drug (BAR) Test (Dipcard)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
75ng/ml	-75%cutoff	60	0	60	0	60	0	60
150ng/ml	-50%cutoff	60	0	60	0	60	0	60
225ng/ml	-25%cutoff	60	6	54	4	56	6	54
300ng/ml	cutoff	60	36	24	38	22	38	22
375ng/ml	+25%cutoff	60	54	6	56	4	54	6
450ng/ml	+50%cutoff	60	60	0	60	0	60	0
525ng/ml	+75%cutoff	60	60	0	60	0	60	0
600ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Single-drug (BAR) Test (Cup)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
75ng/ml	-75%cutoff	60	0	60	0	60	0	60
150ng/ml	-50%cutoff	60	0	60	0	60	0	60
225ng/ml	-25%cutoff	60	6	54	4	56	6	54
300ng/ml	cutoff	60	36	24	38	22	38	22
375ng/ml	+25%cutoff	60	54	6	56	4	54	6
450ng/ml	+50%cutoff	60	60	0	60	0	60	0
525ng/ml	+75%cutoff	60	60	0	60	0	60	0
600ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Multi-drug Test Dipcard (For BAR)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
250ng/ml	-75%cutoff	60	0	60	0	60	0	60
500ng/ml	-50%cutoff	60	0	60	0	60	0	60
750ng/ml	-25%cutoff	60	6	54	4	56	4	56
1000ng/ml	cutoff	60	38	22	36	24	36	24
1250ng/ml	+25%cutoff	60	56	4	54	6	56	4
1500ng/ml	+50%cutoff	60	60	0	60	0	60	0
1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
2000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Multi-drug Test Cup (For BAR)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
250ng/ml	-75%cutoff	60	0	60	0	60	0	60
500ng/ml	-50%cutoff	60	0	60	0	60	0	60
750ng/ml	-25%cutoff	60	6	54	4	56	4	56
1000ng/ml	cutoff	60	38	22	36	24	36	24
1250ng/ml	+25%cutoff	60	56	4	54	6	56	4
1500ng/ml	+50%cutoff	60	60	0	60	0	60	0
1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
2000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Single-drug (BZO) Test (Dipcard)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
75ng/ml	-75%cutoff	60	0	60	0	60	0	60
150ng/ml	-50%cutoff	60	0	60	0	60	0	60
225ng/ml	-25%cutoff	60	6	54	4	56	4	56
300ng/ml	cutoff	60	38	22	40	20	36	24
375ng/ml	+25%cutoff	60	54	6	54	6	56	4
450ng/ml	+50%cutoff	60	60	0	60	0	60	0
525ng/ml	+75%cutoff	60	60	0	60	0	60	0
600ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Single-drug (BZO) Test (Cup)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
75ng/ml	-75%cutoff	60	0	60	0	60	0	60
150ng/ml	-50%cutoff	60	0	60	0	60	0	60
225ng/ml	-25%cutoff	60	6	54	8	52	4	56
300ng/ml	cutoff	60	36	24	36	24	38	22
375ng/ml	+25%cutoff	60	56	4	54	6	58	2
450ng/ml	+50%cutoff	60	60	0	60	0	60	0
525ng/ml	+75%cutoff	60	60	0	60	0	60	0
600ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Multi-drug Test Dipcard (For BZO)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	60	0	60	0	60	0
250ng/ml	-75%cutoff	60	60	0	60	0	60	0
500ng/ml	-50%cutoff	60	60	0	60	0	60	0
750ng/ml	-25%cutoff	60	60	4	56	6	54	8
1000ng/ml	cutoff	60	60	36	24	38	22	34
1250ng/ml	+25%cutoff	60	60	56	4	54	6	54
1500ng/ml	+50%cutoff	60	60	60	0	60	0	60
1750ng/ml	+75%cutoff	60	60	60	0	60	0	60
2000ng/ml	+100%cutoff	60	60	60	0	60	0	60

Precision data of One Step Multi-drug Test Cup (For BZO)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
250ng/ml	-75%cutoff	60	0	60	0	60	0	60
500ng/ml	-50%cutoff	60	0	60	0	60	0	60
750ng/ml	-25%cutoff	60	6	54	4	56	4	56
1000ng/ml	cutoff	60	36	24	38	22	36	24
1250ng/ml	+25%cutoff	60	56	4	54	6	58	2
1500ng/ml	+50%cutoff	60	60	0	60	0	60	0
1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
2000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Single-drug (MDMA) Test (Dipcard)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
125ng/ml	-75%cutoff	60	0	60	0	60	0	60
250ng/ml	-50%cutoff	60	0	60	0	60	0	60
375ng/ml	-25%cutoff	60	8	52	6	54	4	56
500ng/ml	cutoff	60	34	26	34	26	36	24
625ng/ml	+25%cutoff	60	56	4	54	6	58	2
750ng/ml	+50%cutoff	60	60	0	60	0	60	0
875ng/ml	+75%cutoff	60	60	0	60	0	60	0
1000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Single drug (MDMA) Test (Cup)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
125ng/ml	-75%cutoff	60	0	60	0	60	0	60
250ng/ml	-50%cutoff	60	0	60	0	60	0	60
375ng/ml	-25%cutoff	60	6	54	4	56	8	52
500ng/ml	cutoff	60	36	24	38	22	34	26
625ng/ml	+25%cutoff	60	56	4	58	2	54	6
750ng/ml	+50%cutoff	60	60	0	60	0	60	0
875ng/ml	+75%cutoff	60	60	0	60	0	60	0
1000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Multi-drug Test Dipcard (For MDMA)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
250ng/ml	-75%cutoff	60	0	60	0	60	0	60
500ng/ml	-50%cutoff	60	0	60	0	60	0	60
750ng/ml	-25%cutoff	60	6	54	8	52	6	54
1000ng/ml	cutoff	60	36	24	34	26	34	26
1250ng/ml	+25%cutoff	60	58	2	56	4	54	6
1500ng/ml	+50%cutoff	60	60	0	60	0	60	0
1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
2000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Multi-drug Test Cup (For MDMA)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
250ng/ml	-75%cutoff	60	0	60	0	60	0	60
500ng/ml	-50%cutoff	60	0	60	0	60	0	60
750ng/ml	-25%cutoff	60	6	54	4	56	8	52
1000ng/ml	cutoff	60	36	24	38	22	34	26
1250ng/ml	+25%cutoff	60	56	4	58	2	54	6
1500ng/ml	+50%cutoff	60	60	0	60	0	60	0
1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
2000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Single-Drug (MTD) Test (Dipcard)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
75ng/ml	-75%cutoff	60	0	60	0	60	0	60
150ng/ml	-50%cutoff	60	0	60	0	60	0	60
225ng/ml	-25%cutoff	60	6	54	6	54	8	52
300ng/ml	cutoff	60	34	26	32	28	36	24
375ng/ml	+25%cutoff	60	52	8	54	6	56	4
450ng/ml	+50%cutoff	60	60	0	60	0	60	0
525ng/ml	+75%cutoff	60	60	0	60	0	60	0
600ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Single-Drug (MTD) Test (Cup)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
75ng/ml	-75%cutoff	60	0	60	0	60	0	60
150ng/ml	-50%cutoff	60	0	60	0	60	0	60
225ng/ml	-25%cutoff	60	6	54	4	56	6	54
300ng/ml	cutoff	60	36	24	34	26	38	22
375ng/ml	+25%cutoff	60	56	4	58	2	56	4
450ng/ml	+50%cutoff	60	60	0	60	0	60	0
525ng/ml	+75%cutoff	60	60	0	60	0	60	0
600ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Multi-drug Test Dipcard (For MTD)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
250ng/ml	-75%cutoff	60	0	60	0	60	0	60
500ng/ml	-50%cutoff	60	0	60	0	60	0	60
750ng/ml	-25%cutoff	60	4	56	8	52	6	54
1000ng/ml	cutoff	60	38	22	34	26	36	24
1250ng/ml	+25%cutoff	60	58	2	54	6	56	4
1500ng/ml	+50%cutoff	60	60	0	60	0	60	0
1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
2000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Multi-drug Test Cup (For MTD)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
250ng/ml	-75%cutoff	60	0	60	0	60	0	60
500ng/ml	-50%cutoff	60	0	60	0	60	0	60
750ng/ml	-25%cutoff	60	6	54	6	54	4	56
1000ng/ml	cutoff	60	36	24	34	26	38	22
1250ng/ml	+25%cutoff	60	56	4	54	6	58	2
1500ng/ml	+50%cutoff	60	60	0	60	0	60	0
1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
2000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Single-drug (OXY) Test (Dipcard)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
25ng/ml	-75%cutoff	60	0	60	0	60	0	60
50ng/ml	-50%cutoff	60	0	60	0	60	0	60
75ng/ml	-25%cutoff	60	6	54	4	56	2	58
100ng/ml	cutoff	60	36	24	38	22	36	24
125ng/ml	+25%cutoff	60	56	4	58	2	58	2
150ng/ml	+50%cutoff	60	60	0	60	0	60	0
175ng/ml	+75%cutoff	60	60	0	60	0	60	0
200ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Single-drug (OXY) Test (Cup)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
25ng/ml	-75%cutoff	60	0	60	0	60	0	60
50ng/ml	-50%cutoff	60	0	60	0	60	0	60
75ng/ml	-25%cutoff	60	2	58	4	56	6	54
100ng/ml	cutoff	60	38	22	36	24	36	24
125ng/ml	+25%cutoff	60	58	2	56	4	58	2
150ng/ml	+50%cutoff	60	60	0	60	0	60	0
175ng/ml	+75%cutoff	60	60	0	60	0	60	0
200ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Multi-drug Test Dipcard (For OXY)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
250ng/ml	-75%cutoff	60	0	60	0	60	0	60
500ng/ml	-50%cutoff	60	0	60	0	60	0	60
750ng/ml	-25%cutoff	60	2	58	4	56	4	56
1000ng/ml	cutoff	60	38	22	38	22	36	24
1250ng/ml	+25%cutoff	60	58	2	56	4	56	4
1500ng/ml	+50%cutoff	60	60	0	60	0	60	0
1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
2000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Multi-drug Test Cup (For OXY)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
250ng/ml	-75%cutoff	60	0	60	0	60	0	60
500ng/ml	-50%cutoff	60	0	60	0	60	0	60
750ng/ml	-25%cutoff	60	4	56	2	58	2	58
1000ng/ml	cutoff	60	38	22	40	20	36	24
1250ng/ml	+25%cutoff	60	58	2	56	4	58	2
1500ng/ml	+50%cutoff	60	60	0	60	0	60	0
1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
2000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Single-drug (PCP) Test (Dipcard)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
6.3ng/ml	-75%cutoff	60	0	60	0	60	0	60
12.5ng/ml	-50%cutoff	60	0	60	0	60	0	60
18.8ng/ml	-25%cutoff	60	2	58	4	56	2	58
25ng/ml	cutoff	60	38	22	36	24	36	24
31.3ng/ml	+25%cutoff	60	54	6	56	4	58	2
37.5ng/ml	+50%cutoff	60	60	0	60	0	60	0
43.8ng/ml	+75%cutoff	60	60	0	60	0	60	0
50ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Single-drug (PCP) Test (Cup)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
6.3ng/ml	-75%cutoff	60	0	60	0	60	0	60
12.5ng/ml	-50%cutoff	60	0	60	0	60	0	60
18.8ng/ml	-25%cutoff	60	4	56	2	58	4	56
25ng/ml	cutoff	60	36	24	38	22	38	22
31.3ng/ml	+25%cutoff	60	56	4	58	2	58	2
37.5ng/ml	+50%cutoff	60	60	0	60	0	60	0
43.8ng/ml	+75%cutoff	60	60	0	60	0	60	0
50ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Multi-drug Test Dipcard (For PCP)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
250ng/ml	-75%cutoff	60	0	60	0	60	0	60
500ng/ml	-50%cutoff	60	0	60	0	60	0	60
750ng/ml	-25%cutoff	60	4	56	2	58	4	56
1000ng/ml	cutoff	60	36	24	38	22	38	22
1250ng/ml	+25%cutoff	60	56	4	56	4	58	2
1500ng/ml	+50%cutoff	60	60	0	60	0	60	0
1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
2000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Precision data of One Step Multi-drug Test Cup (For PCP)

Approximate concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/ml	Negative	60	0	60	0	60	0	60
250ng/ml	-75%cutoff	60	0	60	0	60	0	60
500ng/ml	-50%cutoff	60	0	60	0	60	0	60
750ng/ml	-25%cutoff	60	6	54	4	56	2	58
1000ng/ml	cutoff	60	36	24	36	24	38	22
1250ng/ml	+25%cutoff	60	58	2	56	4	54	6
1500ng/ml	+50%cutoff	60	60	0	60	0	60	0
1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
2000ng/ml	+100%cutoff	60	60	0	60	0	60	0

b. *Linearity/assay reportable range:*

Not Applicable.

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

External controls are not supplied with this device. The labeling provides information on where external controls can be obtained.

Stability
Accelerated and real time studies have been conducted for The One Step Single/Multi-drug Test Cup and the One Step Single/Multi-drug Test Dipcard devices. Protocols and acceptance criteria were reviewed and found to be acceptable. The information supports the following expiration date for the unopened (shelf-life) stability: 24 months under 4 ~ 30° C for both the Test Cup and Dipcard formats.

d. *Detection limit:*

Not applicable these are qualitative devices.

e. *Analytical specificity:*

I. Cross Reactivity with related substances
Analytical Cross-reactivity (specificity) studies were conducted. Drugs and drug metabolites within the same class of drugs, or with similar molecular structures that may cross-react were studied. When a positive result from a compound was observed, the interferent was serially diluted with a drug-free specimen until a

negative result was obtained. The concentration of the compounds that produced a response approximately equivalent to the cutoff concentrations of the assay was identified as the cross-reactive concentration and the percent (%) cross reactivity was determined. The study results for both formats (dipcard and cup) were the same and are reported in the tables below.

Barbiturates (BAR) Test

Compound	Concentration equivalent to cutoff(ng/mL)	% Cross-Reactivity
Secobarbital	300	100%
Amobarbital	500	60%
Alphenol	150	200%
Aprobarbital	200	150%
Butabarbital	75	400%
Butalbital	1,500	20%
Butethal	100	300%
Cyclopentobarbital	600	50%
Pentobarbital	700	42.9%
Phenobarbital	300	100%

Benzodiazepines (BZO) Test

Compound	Concentration equivalent to cutoff(ng/mL)	% Cross-Reactivity
Oxazepam	300	100%
Alprazolam	200	150%
α-Hydroxyalprazolam	1100	27.3%
Bromazepam	1000	30%
Chlordiazepoxide	2000	15%
Clobazam	100	300%
Clonazepam	800	37.5%
Clorazepate	200	150%
Delorazepam	1600	18.8%
Desalkylflurazepam	400	75%
Diazepam	200	150%

Estazolam	1000	30%
Flunitrazepam	350	85.7%
Lorazepam	1200	25%
Midazolam	2500	12%
Nitrazepam	100	300%
Nordiazepam	400	75%
Temazepam	120	250%
Triazolam	1000	30%

Methylenedioxymethamphetamine (MDMA) Test

Compound	Concentration equivalent to cutoff(ng/mL)	% Cross- Reactivity
(+/-)3,4Methylenedi-oxymethamphetamine (MDMA)	500	100%
3,4-methylenedioxy-amphetamine (MDA)	2200	22.7%
3,4-Methylenedioxy ethylamphetamine (MDEA)	240	208.3%
D-methamphetamine (MAMP)	100000	0.5%
The compound (D-Amphetamine) showed no cross-reactivity in the assay at a concentration of 100000 ng/mL.		

Methadone (MTD) Test

Compound	Concentration equivalent to cutoff(ng/mL)	% Cross- Reactivity
Methadone	300	100%
(+/-)2-Ethylidene-1,5-dimethyl- 3,3-diphenylpyrrolinium	50000	0.6%
Doxylamine	50000	0.6%

Oxycodone (OXY) Test

Compound	Concentration equivalent to cutoff(ng/mL)	% Cross-Reactivity
Oxycodone	100	100%
Naloxone	50000	0.2%
Naltrexone	50000	0.2%
Morphine 3-β-D-curonide	50000	0.2%
Hydrocodone	3000	3.3%
Hydromorphone	75000	0.1%
Oxymorphone	1000	10%

Phencyclidine (PCP) Test

Compound	Concentration equivalent to cutoff(ng/mL)	% Cross-Reactivity
Phencyclidine	25	100%
4-Hydroxyphencycli-dine	15000	0.2%

II. Exogenous Interference

Drug free specimens containing drug concentrations at +/- 50% of the cutoff were spiked with each compound at a concentration of 100 ug/mL. The concentrations of target drug were confirmed with GC/MS. Each sample was tested in 3 replicates. The common compounds listed in this table were found not to interfere with test results at a test concentration of 100µg/mL.

Acetaminophen	β-Estradiol	Norethindrone
Acetophenetidin	Estrone-3-sulfate	Noscapine
Amoxicillin	Ethyl-p-aminobenzoate	d,l-Octopamine
Ampicillin	Erythromycin	Oxalic acid
Aspirin	Fenoprofen	Oxolinic acid
Atenolol	Flucloxacillin	Oxymetazoline
Atorvastatin	Fluoxetine	Oxytetracycline
Azlocillin	Furosemide	Papaverine
Benzilic acid	Gentisic acid	Penicillin-G
Benzylpenicillin	Hemoglobin	Pentazocine
Benzoic acid	Hydralazine	Perphenazine

Bilirubin	Hydrochlorothiazide	Phenelzine
Benzydamine	Hydrocortisone	Prednisolone
Caffeine	o-Hydroxyhippuric acid	Prednisone
Carbamazepine	p-Hydroxytyramine	d,l-Propanolol
Cephalexin	Ibuprofen	d-Pseudoephedrine
Chloralhydrate	Indomethacin	Quinacrine
Chloramphenicol	Iproniazid	Quinine
Chlorothiazide	d,l-Isoproterenol	Quindine
Chlorpheniramine	Isoxsuprine	Ranitidine
d,l-Chlorpromazine	Ketamine	Salicylic acid
Cholesterol	Ketoprofen	Serotonin
Clonidine	Labetalol	Sulindac
Cimetidine	Lisinopril	Tetracycline
Citalopram	Loperamide	Tetrahydrozoline
Cortisone	Meperidine	Thioridazine
Creatinine	Meprobamate	d, l-Thyroxine
Deoxycorticosterone	Methoxyphenamine	Tolbutamine
Dexamethasone	Methylphenidate	Tolbutamide
Dextromethorphan	Nadolol	Trifluoperazine
Diclofenac	Nalidixic acid	Tryptamine
Diflunisal	Naproxen	Uric acid
Digoxin	Niacinamide	Verapamil
Diphenhydramine	Nicotine	Zomepirac
Ephedrine	Nifedipine	

pH and specific gravity conditions:

To evaluate the effects of variable range of pH and specific gravity conditions that might exist within the body, two pools of specimen were altered to reflect the physiological conditions. One pool was altered to contain a drug concentration +50% of the cutoff and the other pool was altered to contain a drug concentration -50% of the cutoff. The performances of the test device under varying pH (3-9) and specific gravity (0.900-1.050 g/mL) conditions were studied and it was observed that pH ranges from pH 3 to pH 9 and specific gravity ranges from 1.002 – 1.040 g/mL did not affect the expected testing results.

f. Assay cut-off:

The test cut-off was determined according to the precision study. See precision studies above in section 1.M.1.a.

2. <u>Comparison studies:</u>

   a. *Method comparison with predicate device:*

   The study was performed using unaltered clinical urine specimens compared to GC/MS. Samples were divided by concentration into five categories as stated in the tables below. The samples were further divided into 2 sets, one for cup format testing and one for dipcard format testing. All aliquots were blindly labeled by a nonparticipant and samples were randomized prior to testing. Tests were performed at two hospital laboratories by 4 lab technicians (2 operators per site). One site tested the dipcard format and the other site tested the test cup format. For each drug analyte, a total of 80 specimens were tested using the single-drug and multi-drug test dipcard and the test cup formats. The results are presented below:

Comparison Data of One Step Single drug Test Cup

One Step Single drug Test Cup		GC/MS					Total
		Drug free by GC/MS analysis	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative Between 50% below the cutoff and the cutoff concentration	Near Cutoff Positive Between the cutoff and 50% above the cutoff concentration	High Positive greater than 50% above the cutoff concentration	
BAR	+	0	0	0	6	34	80
	–	33	0	7	0	0	
BZO	+	0	0	1	7	33	80
	–	31	0	8	0	0	
MDMA	+	0	0	0	5	34	80
	–	32	3	5	1	0	
MTD	+	0	0	1	5	35	80
	–	32	2	5	0	0	
OXY	+	0	0	0	6	34	80
	–	35	0	5	0	0	
PCP	+	0	0	1	5	35	80
	–	35	0	4	0	0	

Analysis of Discordant Results with One Step Single drug Test Cup

One Step Single drug Test Cup			GC/MS Analysis	
Drug Test	Cutoff (ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
BZO	300	Positive	188	Oxazepam
MDMA	500	Negative	715	3,4-Methylenedioxy-methamphetamine
MTD	300	Positive	209	Methadone
PCP	25	Positive	23	Phencyclidine

Comparison Data of One Step Single drug Test Dipcard

One Step Single drug Test Dipcard		GC/MS					Total
		Drug free by GC/MS analysis	Less than half the cutoff concentration by GC/MS	Near Cutoff Negative Between 50% below the cutoff and the cutoff	Near Cutoff Positive Between the cutoff and 50% above the cutoff concentration	High Positive greater than 50% above the cutoff concentration	
BAR	+	0	0	0	6	34	80
	–	33	0	7	0	0	
BZO	+	0	0	1	7	33	80
	–	31	0	8	0	0	
MDMA	+	0	0	0	5	34	80
	–	32	3	5	1	0	
MTD	+	0	0	1	5	35	80
	–	32	2	5	0	0	
OXY	+	0	0	0	6	34	80
	–	35	0	5	0	0	
PCP	+	0	0	1	5	35	80
	–	35	0	4	0	0	

Analysis of Discordant Results with One Step Single drug Test Dipcard

One Step Single drug Test Dipcard			GC/MS Analysis	
Drug Test	Cutoff (ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
BZO	300	Positive	188	Oxazepam
MDMA	500	Negative	715	3,4-Methylenedioxy-methamphetamine
MTD	300	Positive	209	Methadone
PCP	25	Positive	23	Phencyclidine

Comparison Data of One Step Multi drug Test Cup

One Step Multi drug Test Cup		GC/MS					Total
		Drug free by GC/MS analysis	Less than half the cutoff concentration by GC/MS	Near Cutoff Negative Between 50% below the cutoff and the cutoff	Near Cutoff Positive Between the cutoff and 50% above the cutoff concentration	High Positive greater than 50% above the cutoff concentration	
BAR	+	0	0	0	6	34	80
	–	33	0	7	0	0	
BZO	+	0	0	1	7	33	80
	–	31	0	8	0	0	
MDMA	+	0	0	0	5	34	80
	–	32	3	5	1	0	
MTD	+	0	0	1	5	35	80
	–	32	2	5	0	0	
OXY	+	0	0	0	6	34	80
	–	35	0	5	0	0	
PCP	+	0	0	1	5	35	80
	–	35	0	4	0	0	

Analysis of Discordant Results with One Step Multi drug Test Cup

One Step Multi-drug Test Cup			GC/MS Analysis	
Drug Test	Cutoff (ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
BZO	300	Positive	188	Oxazepam
MDMA	500	Negative	715	3,4-Methylenedioxy-methamphetamine
MTD	300	Positive	209	Methadone
PCP	25	Positive	23	Phencyclidine

Comparison Data of One Step Multi drug Test Dipcard

One Step Multi drug Test Dipcard		GC/MS					Total
		Drug free by GC/MS analysis	Less than half the cutoff concentration by GC/MS	Near Cutoff Negative Between 50% below the cutoff and the cutoff	Near Cutoff Positive Between the cutoff and 50% above the cutoff concentration	High Positive greater than 50% above the cutoff concentration	
BAR	+	0	0	0	6	34	80
	–	33	0	7	0	0	
BZO	+	0	0	1	7	33	80
	–	31	0	8	0	0	
MDMA	+	0	0	0	5	34	80
	–	32	3	5	1	0	
MTD	+	0	0	1	5	35	80
	–	32	2	5	0	0	
OXY	+	0	0	0	6	34	80
	–	35	0	5	0	0	
PCP	+	0	0	1	5	35	80
	–	35	0	4	0	0	

Analysis of Discordant Results with One Step Multi-drug Test Dipcard

One Step Multi-drug Test Dipcard			GC/MS Analysis	
Drug Test	Cutoff (ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
BZO	300	Positive	188	Oxazepam
MDMA	500	Negative	715	3,4-Methylenedioxy-methamphetamine
MTD	300	Positive	209	Methadone
PCP	25	Positive	23	Phencyclidine

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):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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