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

A. 510(k) Number:

k140748

B. Purpose for Submission:

New device

C. Measurand:

Buprenorphine, EDDP (2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine), Morphine, Propoxyphene, and Tricyclic Antidepressants

D. Type of Test:

Qualitative lateral flow immunochromatographic competitive binding assay

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:

1. Regulation section:

Product Code	Classification	Regulation Section	Panel
DJG	Class II	862.3650 Opiate test system	Toxicology (91)
DJR	Class II	862.3620 Methadone test system	Toxicology (91)
DNK	Class II	862.3640 Morphine test system	Toxicology (91)
JXN	Class II	862.3700 Propoxyphene test system	Toxicology (91)
LFG	Class II	862.3910 Tricyclic antidepressant drugs test system	Toxicology (91)

H. Intended Use:

1. Intended use(s):

   Refer to Indications for Use below.

2. Indication(s) for use:

   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	Cutoff Level (ng/mL)
Buprenorphine (BUP)	Buprenorphine	10
2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP)	2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine	300
Morphine (MOP300)	Morphine	300
Propoxyphene (PPX)	Propoxyphene	300
Tri-cyclic Antidepressants (TCA)	Nortriptyline	1000

There are two formats: 1) Test Cup, 2) Test Dipcard. Each format may have from 1 to 5 drugs in any combination. The assays are intended for in vitro diagnostic use. They are intended for prescription use including point of care sites and over-the-counter use.

The tests may yield preliminary positive results even when prescription drugs including Buprenorphine, Propoxyphene, or Tricyclic Antidepressants are ingested, at prescribed doses; it is not intended to distinguish between prescription use or abuse of these drugs. There are no uniformly recognized cutoff concentration levels for Buprenorphine, Propoxyphene, or Tricyclic Antidepressant in urine.

This assay provides only a preliminary analytical test result. Gas Chromatography/Mass spectrometry (GC/MS) or an equivalent analytical method 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):

   These assays are intended for prescription use, including point of care and over the counter use.

4. Special instrument requirements:

   Not applicable; these are visually read single use devices.

I. Device Description:

One Step Single/Multi-drug Test Cup and One Step Single/Multi-drug Test Dipcard are competitive binding, lateral flow immunochromatographic assays for the qualitative detection of Buprenorphine, 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine, Morphine, Propoxyphene, Tricyclic Antidepressants and their metabolites at or above the cut-off levels as indicated. The devices are available in both a test cup and a test card format. 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):

   Advin Multi-Drug Screen Test Dip Card
   Advin Multi-Drug Screen Test Cup
   Advin Multi-Drug Screen Test Cassette

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

   k122809

3. Comparison with predicate:

Similarities		
Item	Candidate Device	Predicate Device (k122809)
Matrix	Same	Urine
Cutoffs	Same	Buprenorphine: 10 ng/mL EDDP: 300 ng/mL Morphine: 300 ng/mL Propoxyphene: 300 ng/mL TCA: 1000 ng/mL
Read time	Same	Five minutes

Methodology	Same	Competitive binding, Lateral flow immunochromatographic assay
Results	Same	Qualitative
Intended Users	Same	Layusers (OTC) and healthcare professionals (prescription point of care)

Differences		
Item	Candidate Device	Predicate Device (k122809)
Available formats	Dipcard and Cup	Cassette, Dip Card and Cup
Number of analytes detected	Five	Sixteen

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

EN13612:2002 Stability testing of in vitro diagnostic reagents

L. Test Principle:

One Step Single/Multi-drug Test Cup and Dip Card are competitive immunoassays used to screen for the presence of various drugs and drug metabolites in urine. They are chromatographic absorbent devices in which drugs or metabolites in a urine sample competitively combine with a limited number of drug monoclonal antibody (mouse) conjugate binding sites.

When the test is activated, the urine is absorbed into each test strip by capillary action, mixes with the respective analyte monoclonal antibody conjugate, and flows across a pre-coated membrane. When drug within the urine sample is at a level below the cutoff of the test, the drug monoclonal antibody conjugate binds to the corresponding drug-protein conjugate immobilized in the Test Region (T) of the test strip. This produces a colored Test line in the Test Region (T) of the strip that, regardless of its intensity, indicates a negative test result.

When sample drug levels are at or above the cutoff of the test, the free drug in the sample binds to the corresponding drug monoclonal antibody conjugate, preventing the respective drug monoclonal antibody conjugate from binding to the corresponding drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a preliminary positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C) of each strip if the volume of sample applied is adequate and the test is operating properly.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Drug free specimens were spiked with the analytes at 0%, -75%, -50%, -25%, cutoff, +25%, +50%, +75%, and +100% of the cutoff. All concentrations were confirmed with GC/MS, LC/MS, or HPLC. Urine specimens at each concentration were divided into aliquots. All aliquots were blindly labeled by a nonparticipant. Separate sets of the blind coded samples were assigned and randomized prior to testing. The study was conducted by three nurses at three Point-of-Care sites.

Buprenorphine - Dipcard Format – Multi

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
2.5	-75	0	60	0	60	0	60
5	-50	0	60	0	60	0	60
7.5	-25	10	50	12	48	8	52
10	Cutoff	38	22	36	24	34	26
12.5	+25	54	6	50	10	52	8
15	+50	56	4	58	2	56	4
17.5	+75	60	0	60	0	60	0
20	+100	60	0	60	0	60	0

Buprenorphine - Dipcard Format – Single

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
2.5	-75	0	60	0	60	0	60
5	-50	0	60	0	60	0	60
7.5	-25	12	48	8	52	10	50
10	Cutoff	34	26	36	24	34	26
12.5	+25	50	10	48	12	50	10
15	+50	54	6	56	4	56	4
17.5	+75	60	0	60	0	60	0
20	+100	60	0	60	0	60	0

Buprenorphine - Cup Format – Multi

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
2.5	-75	0	60	0	60	0	60
5	-50	0	60	0	60	0	60
7.5	-25	10	50	8	52	6	54
10	Cutoff	34	26	32	28	36	24
12.5	+25	54	6	56	4	52	8
15	+50	60	0	58	2	56	4
17.5	+75	60	0	60	0	60	0
20	+100	60	0	60	0	60	0

Buprenorphine - Cup Format – Single

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
0	-75	0	60	0	60	0	60
2.5	-50	0	60	0	60	0	60
5	-25	6	54	8	52	10	50
7.5	Cutoff	32	28	36	24	34	26
10	+25	52	8	50	10	54	6
12.5	+50	58	2	60	0	56	4
15	+75	60	0	60	0	60	0
17.5	+100	60	0	60	0	60	0

EDDP – Dipcard Format – Multi

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	10	50	8	52	6	54
300	Cutoff	32	28	36	24	34	26
375	+25	54	6	52	8	50	10
450	+50	60	0	58	2	56	4
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

EDDP – Dipcard Format – Single

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	10	50	6	54	8	52
300	Cutoff	38	22	36	24	32	28
375	+25	50	10	48	12	52	8
450	+50	56	4	60	0	58	2
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

EDDP – Cup Format – Multi

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	10	50	8	52	12	48
300	Cutoff	36	24	38	22	34	26
375	+25	56	4	54	6	52	8
450	+50	58	2	56	4	58	2
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

EDDP – Cup Format – Single

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	8	52	6	54	10	50
300	Cutoff	34	26	36	24	32	28
375	+25	52	8	54	6	50	10
450	+50	60	0	56	4	58	2
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

Morphine – Dipcard Format – Multi

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	6	54	4	56	8	52
300	Cutoff	36	24	38	22	34	26
375	+25	50	10	48	12	52	8
450	+50	56	4	58	2	60	0
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

Morphine – Dipcard Format – Single

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	8	52	12	48	10	50
300	Cutoff	36	24	34	26	38	22
375	+25	54	6	56	4	52	8
450	+50	58	2	60	0	56	4
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

Morphine – Cup Format – Multi

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	8	52	6	54	4	56
300	Cutoff	34	26	36	24	38	22
375	+25	54	6	50	10	52	8
450	+50	58	2	60	0	56	4
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

Morphine – Cup Format – Single

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	6	54	8	52	4	56
300	Cutoff	34	26	38	22	36	24
375	+25	48	12	50	10	52	8
450	+50	60	0	58	2	56	4
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

Propoxyphene – Dipcard Format – Multi

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	4	56	8	52	6	54
300	Cutoff	36	24	34	26	38	22
375	+25	48	12	52	8	50	10
450	+50	56	4	58	2	58	2
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

Propoxyphene – Dipcard Format – Single

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	6	54	8	52	10	50
300	Cutoff	38	22	34	26	32	28
375	+25	52	8	54	6	50	10
450	+50	56	4	58	2	60	0
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

Propoxyphene – Cup Format – Multi

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	6	54	8	52	6	54
300	Cutoff	34	26	38	22	36	24
375	+25	56	4	52	8	54	6
450	+50	60	0	58	2	50	0
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

Propoxyphene – Cup Format – Single

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	8	52	6	54	4	56
300	Cutoff	38	22	34	26	36	24
375	+25	54	6	50	10	52	8
450	+50	60	0	56	4	58	2
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

TCA – Dipcard Format – Multi

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
250	-75	0	60	0	60	0	60
500	-50	0	60	0	60	0	60
750	-25	4	56	6	54	4	56
1000	Cutoff	36	24	38	22	34	26
1250	+25	54	6	56	4	52	8
1500	+50	58	2	60	0	56	4
1750	+75	60	0	60	0	60	0
2000	+100	60	0	60	0	60	0

TCA – Dipcard Format – Single

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
250	-75	0	60	0	60	0	60
500	-50	0	60	0	60	0	60
750	-25	8	52	6	54	10	50
1000	Cutoff	34	26	35	24	32	28
1250	+25	50	10	52	8	50	10
1500	+50	60	0	56	4	58	2
1750	+75	60	0	60	0	60	0
2000	+100	60	0	60	0	60	0

TCA – Cup Format – Multi

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
250	-75	0	60	0	60	0	60
500	-50	0	60	0	60	0	60
750	-25	8	52	4	56	6	54
1000	Cutoff	34	26	38	22	36	24
1250	+25	50	10	48	12	52	8
1500	+50	56	4	60	0	58	2
1750	+75	60	0	60	0	60	0
2000	+100	60	0	60	0	60	0

TCA – Cup Format – Single

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
250	-75	0	60	0	60	0	60
500	-50	0	60	0	60	0	60
750	-25	4	56	8	52	6	54
1000	Cutoff	38	22	34	26	36	24
1250	+25	52	8	48	12	50	10
1500	+50	58	2	58	2	56	4
1750	+75	60	0	60	0	60	0
2000	+100	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 at analyte concentrations of 0%, -75%, -50%, -25%, cutoff, +25%, +50%, +75%, and +100% of the cutoff. All concentrations were confirmed with GC/MS, LC/MS, or HPLC. Urine specimens at each concentration were divided into aliquots. All aliquots were blindly labeled by a nonparticipant. Separate sets of the blind coded samples were assigned and randomized prior to testing. The study was conducted by three nurses at three Point-of-Care sites.

Buprenorphine - Dipcard Format – Multi

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
2.5	-75	0	60	0	60	0	60
5	-50	0	60	0	60	0	60
7.5	-25	8	52	4	56	6	54
10	Cutoff	34	26	32	28	36	24
12.5	+25	56	4	54	6	52	8
15	+50	60	0	60	0	60	0
17.5	+75	60	0	60	0	60	0
20	+100	60	0	60	0	60	0

Buprenorphine - Dipcard Format – Single

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
2.5	-75	0	60	0	60	0	60
5	-50	0	60	0	60	0	60
7.5	-25	4	56	8	52	6	54
10	Cutoff	34	26	36	24	38	22
12.5	+25	56	4	52	8	54	6
15	+50	60	0	60	0	60	0
17.5	+75	60	0	60	0	60	0
20	+100	60	0	60	0	60	0

Buprenorphine - Cup Format – Multi

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
2.5	-75	0	60	0	60	0	60
5	-50	0	60	0	60	0	60
7.5	-25	6	54	4	56	8	52
10	Cutoff	32	28	34	26	36	24
12.5	+25	54	6	52	8	56	4
15	+50	60	0	60	0	60	0
17.5	+75	60	0	60	0	60	0
20	+100	60	0	60	0	60	0

Buprenorphine - Cup Format – Single

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
0	-75	0	60	0	60	0	60
2.5	-50	0	60	0	60	0	60
5	-25	6	54	8	52	4	56
7.5	Cutoff	32	28	36	24	34	26
10	+25	52	8	54	6	56	4
12.5	+50	60	0	60	0	60	0
15	+75	60	0	60	0	60	0
17.5	+100	60	0	60	0	60	0

EDDP – Dipcard Format – Multi

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	4	56	6	54	8	52
300	Cutoff	36	24	38	22	34	26
375	+25	54	6	52	8	56	4
450	+50	60	0	60	0	60	0
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

EDDP – Dipcard Format – Single

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	8	52	4	56	6	54
300	Cutoff	36	24	38	22	34	26
375	+25	56	4	52	8	54	6
450	+50	60	0	60	0	60	0
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

EDDP – Cup Format – Multi

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	4	56	8	52	6	54
300	Cutoff	36	24	34	26	38	22
375	+25	56	4	52	8	54	6
450	+50	60	0	60	0	60	0
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

EDDP – Cup Format – Single

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	4	56	6	54	8	52
300	Cutoff	36	24	34	26	32	28
375	+25	54	6	56	4	52	8
450	+50	60	0	60	0	60	0
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

Morphine – Dipcard Format – Multi

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	4	56	8	52	6	54
300	Cutoff	36	24	38	22	34	26
375	+25	52	8	56	4	54	6
450	+50	60	0	60	0	60	0
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

Morphine – Dipcard Format – Single

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	6	54	8	52	4	56
300	Cutoff	32	28	36	24	34	26
375	+25	54	6	56	4	52	8
450	+50	60	0	60	0	60	0
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

Morphine – Cup Format – Multi

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	6	54	4	56	6	54
300	Cutoff	38	22	34	26	36	24
375	+25	52	8	54	6	56	4
450	+50	60	0	60	0	60	0
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

Morphine – Cup Format – Single

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	6	54	4	56	8	52
300	Cutoff	36	24	36	24	34	26
375	+25	56	4	54	6	52	8
450	+50	60	0	60	0	60	0
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

Propoxyphene – Dipcard Format – Multi

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	6	54	8	52	4	56
300	Cutoff	36	24	34	26	38	22
375	+25	56	4	52	8	54	6
450	+50	60	0	60	0	60	0
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

Propoxyphene – Dipcard Format – Single

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	4	56	6	54	8	52
300	Cutoff	34	26	32	28	36	24
375	+25	52	8	56	4	54	6
450	+50	60	0	60	0	60	0
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

Propoxyphene – Cup Format – Multi

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	8	52	4	56	6	54
300	Cutoff	34	26	36	24	32	28
375	+25	52	8	56	4	54	6
450	+50	60	0	60	0	60	0
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

Propoxyphene – Cup Format – Single

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
75	-75	0	60	0	60	0	60
150	-50	0	60	0	60	0	60
225	-25	8	52	6	54	4	56
300	Cutoff	32	28	36	24	34	26
375	+25	56	4	54	6	54	6
450	+50	60	0	60	0	60	0
525	+75	60	0	60	0	60	0
600	+100	60	0	60	0	60	0

TCA – Dipcard Format – Multi

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
250	-75	0	60	0	60	0	60
500	-50	0	60	0	60	0	60
750	-25	6	54	6	54	4	56
1000	Cutoff	38	22	34	26	34	26
1250	+25	52	8	54	6	56	4
1500	+50	60	0	60	0	60	0
1750	+75	60	0	60	0	60	0
2000	+100	60	0	60	0	60	0

TCA – Dipcard Format – Single

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
250	-75	0	60	0	60	0	60
500	-50	0	60	0	60	0	60
750	-25	8	52	6	54	4	56
1000	Cutoff	38	22	36	24	34	26
1250	+25	56	4	54	6	52	8
1500	+50	60	0	60	0	60	0
1750	+75	60	0	60	0	60	0
2000	+100	60	0	60	0	60	0

TCA – Cup Format – Multi

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
250	-75	0	60	0	60	0	60
500	-50	0	60	0	60	0	60
750	-25	6	54	8	52	6	54
1000	Cutoff	36	24	38	22	34	26
1250	+25	54	6	56	4	52	8
1500	+50	60	0	60	0	60	0
1750	+75	60	0	60	0	60	0
2000	+100	60	0	60	0	60	0

TCA – Cup Format – Single

Conc (ng/mL)	% of cutoff	Lot 1		Lot 2		Lot 3	
		Pos	Neg	Pos	Neg	Pos	Neg
0	Neg	0	60	0	60	0	60
250	-75	0	60	0	60	0	60
500	-50	0	60	0	60	0	60
750	-25	4	56	8	52	6	54
1000	Cutoff	36	24	34	26	34	26
1250	+25	54	6	52	8	56	4
1500	+50	60	0	60	0	60	0
1750	+75	60	0	60	0	60	0
2000	+100	60	0	60	0	60	0

b. *Linearity/assay reportable range:*

Not applicable. The assays are intended for qualitative use.

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

External control standards are not supplied with this device; labeling states where external control materials can be obtained.

Accelerated and real time studies have been conducted for The One Step Single/Multidrug 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. The assays are intended for qualitative use.

e. Analytical specificity:

Cross reactivity with structurally similar compounds was tested for each device format. Each compound was spiked into drug-free urine to a final concentration of 100 µg/mL. Each sample was tested in 5 replicates. If any positive results were observed, samples were diluted down to the lowest concentration that produced a positive result. Results were as follows:

	Compound tested	Concentration (ng/mL)	% Cross-reactivity
Buprenorphine	Buprenorphine	10	100
	Norbuprenorphine	20	50
	Buprenorphine 3-D-glucuronide	15	66.7
	Norbuprenorphine3-D-glucuronide	200	5

	Compound tested	Concentration (ng/mL)	% Cross-reactivity
EDDP	EDDP	300	100
	Methadone	100,000	0

	Compound tested	Concentration (ng/mL)	% Cross-reactivity
Morphine	Morphine	300	100
	Codeine	300	100
	Hydrocodone	2000	15
	Hydromorphone	1500	20
	6-Monoacetyl morphine (6-MAM)	750	40
	Morphine 3-β-D-glucuronide	300	100
	Ethylmorphine	3500	8.6
	Heroin	300	100
	Levorphanol	5000	6.0
	Norcodeine	7500	4.0
	Oxycodone	100,000	0.3
	Thebain	8000	3.8

	Compound tested	Concentration (ng/mL)	% Cross-reactivity
Propoxyphene	d-Propoxyphene	300	100
	d-Norpropoxyphene	300	100

	Compound tested	Concentration (ng/mL)	% Cross-reactivity
Tricyclic Antidepressants	Nortriptyline	1000	100
	Nordoxepin	1000	100
	Trimipramine	5000	20
	Promazine	3000	33.3
	Desipramine	1000	100
	Imipramine	1000	100
	Chomipramine	12500	8
	Doxepin	2000	50
	Maprotiline	2000	50
	Amitriptyline	1000	100

Interference Study:

The following structurally unrelated compounds were spiked at 100 µg/mL into samples at -50% and +50% of the cutoff for each analyte. Each test format was evaluated. None of these compounds caused any interference at the concentration tested.

Acetaminophen	Digoxin	Nadolol	Tetrahydrozoline
Acetophenetidin	Diphenhydramine	Nalidixic acid	Thiamine
Amoxicillin	Ephedrine	Naproxen	Thioridazine
Ampicillin	β-Estradiol	Niacinamide	d, l-Thyroxine
Aspirin	Estrone-3-sulfate	Nicotine	Tolbutamine
Atenolol	Ethyl-p-aminobenzoate	Nifedipine	Tolbutamide
Atorvastatin	Erythromycin	Norethindrone	Trifluoperazine
Azlocillin	Fenoprofen	Noscapine	Tryptamine
Benzylpenicillin	Flucloxacillin	d,l-Octopamine	Uric acid
Benzoic acid	Fluoxetine	Oxalic acid	Verapamil
Benzilic acid	Furosemide	Oxolinic acid	Zomepirac
Bilirubin	Gentisic acid	Oxymetazoline	
Benzydamine	Hemoglobin	Oxytetracycline	
Caffeine	Hydralazine	Papaverine	
Carbamezepine	Hydrochlorothiazide	Penicillin-G	
Cephalexin	Hydrocortisone	Pentazocine	
Chloralhydrate	o-Hydroxyhippuric acid	Perphenazine	
Chloramphenicol	p-Hydroxytyramine	Phenelzine	
Chlorothiazide	Ibuprofen	Prednisolone	
Chlorpheniramine	Indomethacin	Prednisone	
d,l-Chlorpromazine	Iproniazid	Promethazine	
Cholesterol	d,l-Isoproterenol	d,l-Propanolol	
Clonidine	Isoxsuprine	d-Pseudoephedrine	
Cimetidine	Ketamine	Quinacrine	
Citalopram	Ketoprofen	Quinine	
Cortisone	Labetalol	Quindine	
Creatinine	Lisinopril	Ranitidine	
Deoxycorticosterone	Loperamide	Salicylic acid	
Dexamethasone	Meperidine	Serotonin	
Dextromethorphan	Meprobamate	Sulfamethazine	
Diclofenac	Methoxyphenamine	Sulindac	
Diflunisal	Methylphenidate	Tetracycline	

Each device was also evaluated for interference from pH. Drug-free urine was adjusted to ± 50% cutoffs which were confirmed by GC/MS or LC/MS. Each test format was used for the study. The pH was tested at 3, 4, 5, 6, 7, 8, and 9. No interference from pH was observed.

Each device was evaluated for interference from specific gravity. Drug-free urine was adjusted to ± 50% cutoffs which were confirmed by GC/MS or LC/MS. Each test format was used for the study. Specific gravity was tested at 1.003, 1.010, 1.020, 1.030, and 1.040. No interference from specific gravity was observed.

f. Assay cut-off:

The cut-off characterization study results can be found in the precision section 1.M.1.a above.

2. Comparison studies:

a. Method comparison with predicate device:

Eighty clinical urine samples collected from several hospitals and a drug relief reformatory. All samples were unaltered clinical specimens and the concentrations were confirmed by GC/MS, LC/MS, or HPLC. Each sample was split between two individuals. All aliquots were blindly labeled by a nonparticipant, and randomized prior to testing such that a different sample was used each time testing was performed. Testing was conducted by four nurses at two POC sites.

Buprenorphine - Dipcard Format - Multi

Candidate device result	**Negative**	**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)
Pos	0	*1	5	35
Neg	35	4	0	0

*Analysis of Discordant Results – LC/MS concentration 7.8 ng/mL buprenorphine

Buprenorphine - Dipcard Format - Single

Candidate device result	**Negative**	**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)
Pos	0	*1	5	35
Neg	35	4	0	0

*Analysis of Discordant Results – LC/MS concentration 7.8 ng/mL buprenorphine

Buprenorphine - Cup Format - Multiple

Candidate device result	**Negative**	**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)
Pos	0	*1	5	35
Neg	35	4	0	0

*Analysis of Discordant Results – LC/MS concentration 7.8 ng/mL buprenorphine

Buprenorphine - Cup Format - Single

Candidate device result	**Negative**	**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)
Pos	0	*1	5	35
Neg	35	4	0	0

*Analysis of Discordant Results – LC/MS concentration 7.8 ng/mL buprenorphine

EDDP - Dipcard Format - Multiple

Candidate device result	**Negative**	**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)
Pos	0	*1	7	33
Neg	34	5	0	0

*Analysis of Discordant Results – GC/MS concentration 285 ng/mL EDDP

EDDP - Dipcard Format - Single

Candidate device result	**Negative**	**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)
Pos	0	*1	7	33
Neg	34	5	0	0

*Analysis of Discordant Results – GC/MS concentration 285 ng/mL EDDP

EDDP - Cup Format - Multi

Candidate device result	**Negative**	**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)
Pos	0	*1	7	33
Neg	34	5	0	0

*Analysis of Discordant Results – GC/MS concentration 285 ng/mL EDDP

EDDP - Cup Format - Single

Candidate device result	**Negative**	**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)
Pos	0	*1	7	33
Neg	34	5	0	0

*Analysis of Discordant Results – GC/MS concentration 285 ng/mL EDDP

Morphine - Dipcard Format - Multi

Candidate device result	**Negative**	**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)
Pos	0	*1	5	35
Neg	33	6	0	0

*Analysis of Discordant Results – GC/MS concentration 275 ng/mL Morphine

Morphine - Dipcard Format - Single

Candidate device result	**Negative**	**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)
Pos	0	*1	5	35
Neg	33	6	0	0

*Analysis of Discordant Results – GC/MS concentration 275 ng/mL Morphine

Morphine - Cup Format - multi

Candidate device result	**Negative**	**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)
Pos	0	1	5	35
Neg	33	6	0	0

*Analysis of Discordant Results – GC/MS concentration 275 ng/mL Morphine

Morphine - Cup Format - single

Candidate device result	**Negative**	**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)
Pos	0	1	5	35
Neg	33	6	0	0

*Analysis of Discordant Results – GC/MS concentration 275 ng/mL Morphine

Propoxyphene - Dipcard Format - multi

Candidate device result	**Negative**	**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)
Pos	0	*1	6	34
Neg	34	5	0	0

*Analysis of Discordant Results – GC/MS concentration 269 ng/mL Propoxyphene

Propoxyphene - Dipcard Format - single

Candidate device result	**Negative**	**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)
Pos	0	*1	6	34
Neg	34	5	0	0

*Analysis of Discordant Results – GC/MS concentration 269 ng/mL Propoxyphene

Propoxyphene - Cup Format - multi

Candidate device result	**Negative**	**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)
Pos	0	*1	6	34
Neg	34	5	0	0

*Analysis of Discordant Results – GC/MS concentration 269 ng/mL Propoxyphene

Propoxyphene - Cup Format - single

Candidate device result	**Negative**	**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)
Pos	0	*1	6	34
Neg	34	5	0	0

*Analysis of Discordant Results – GC/MS concentration 269 ng/mL Propoxyphene

TCA - Dipcard Format - multi

Candidate device result	**Negative**	**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)
Pos	0	0	5	34
Neg	35	5	*1	0

*Analysis of Discordant Results – HPLC concentration 1138 ng/mL Nortriptyline

TCA - Dipcard Format - single

Candidate device result	**Negative**	**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)
Pos	0	0	5	34
Neg	35	5	*1	0

*Analysis of Discordant Results – HPLC concentration 1138 ng/mL Nortriptyline

TCA - Cup Format - Multi

Candidate device result	**Negative**	**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)
Pos	0	0	5	34
Neg	35	5	*1	0

*Analysis of Discordant Results – HPLC concentration 1138 ng/mL Nortriptyline

TCA - Cup Format - Single

Candidate device result	**Negative**	**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)
Pos	0	0	5	34
Neg	35	5	*1	0

*Analysis of Discordant Results – HPLC concentration 1138 ng/mL Nortriptyline

b. Matrix comparison:

Not applicable. The assay is intended to be used with urine samples only.

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):

Consumer study:

Three hundred and sixty (360) lay users were divided into two groups to test the multi-version of the test devices. One group tested with the Dipcard format, and the other group tested with the Cup format. Each lay user was provided with the package insert (in English), one blind labeled sample, and a device. Results of the lay user study are presented below.

Buprenorphine

Conc (ng/mL)	% of cutoff	n	Dipcard		Cup	
			Pos	Neg	Pos	Neg
0	Neg	60	0	60	0	60
5	-50%	60	0	60	0	60
7.5	-25%	60	7	53	8	52
12.5	+25%	60	55	5	53	7
15	+50%	60	57	3	58	2
20	+100%	60	60	0	60	0

EDDP

Conc (ng/mL)	% of cutoff	n	Dipcard		Cup	
			Pos	Neg	Pos	Neg
0	Neg	60	0	60	0	60
150	-50%	60	0	60	0	60
225	-25%	60	6	54	5	55
375	+25%	60	57	3	52	8
450	+50%	60	60	0	58	2
600	+100%	60	60	0	60	0

Morphine

Conc (ng/mL)	% of cutoff	n	Dipcard		Cup	
			Pos	Neg	Pos	Neg
0	Neg	60	0	60	0	60
150	-50%	60	0	60	0	60
225	-25%	60	2	58	3	57
375	+25%	60	54	6	52	8
450	+50%	60	59	1	58	2
600	+100%	60	60	0	60	0

Propoxyphene

Conc (ng/mL)	% of cutoff	n	Dipcard		Cup	
			Pos	Neg	Pos	Neg
0	Neg	60	0	60	0	60
150	-50%	60	0	60	0	60
225	-25%	60	5	55	7	53
375	+25%	60	54	6	56	4
450	+50%	60	58	2	60	0
600	+100%	60	60	0	60	0

TCA

Conc (ng/mL)	% of cutoff	n	Dipcard		Cup	
			Pos	Neg	Pos	Neg
0	Neg	60	0	60	0	60
500	-50%	60	0	60	0	60
750	-25%	60	3	57	4	56
1250	+25%	60	55	5	54	6
1500	+50%	60	59	1	60	0
2000	+100%	60	60	0	60	0

The original consumer study data showed some negative results in 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 consumer study protocol to specify a larger sample volume per vial and supplemental consumer studies were conducted to verify that the root cause was correctly identified. Results of the supplemental consumer studies were as follows:

Buprenorphine

Conc (ng/mL)	% of cutoff	n	Dipcard		Cup	
			Pos	Neg	Pos	Neg
0	Neg	60	0	60	0	60
5	-50%	60	0	60	0	60
7.5	-25%	60	4	56	6	54
12.5	+25%	60	57	3	55	5
15	+50%	60	60	0	60	0
20	+100%	60	60	0	60	0

EDDP

Conc (ng/mL)	% of cutoff	n	Dipcard		Cup	
			Pos	Neg	Pos	Neg
0	Neg	60	0	60	0	60
150	-50%	60	0	60	0	60
225	-25%	60	5	55	4	56
375	+25%	60	54	6	57	3
450	+50%	60	60	0	60	0
600	+100%	60	60	0	60	0

Morphine

Conc (ng/mL)	% of cutoff	n	Dipcard		Cup	
			Pos	Neg	Pos	Neg
0	Neg	60	0	60	0	60
150	-50%	60	0	60	0	60
225	-25%	60	4	56	5	55
375	+25%	60	56	4	58	2
450	+50%	60	60	0	60	0
600	+100%	60	60	0	60	0

Propoxyphene

Conc (ng/mL)	% of cutoff	n	Dipcard		Cup	
			Pos	Neg	Pos	Neg
0	Neg	60	0	60	0	60
150	-50%	60	0	60	0	60
225	-25%	60	5	55	3	57
375	+25%	60	56	4	54	6
450	+50%	60	60	0	60	0
600	+100%	60	60	0	60	0

TCA

Conc (ng/mL)	% of cutoff	n	Dipcard		Cup	
			Pos	Neg	Pos	Neg
0	Neg	60	0	60	0	60
500	-50%	60	0	60	0	60
750	-25%	60	6	54	2	58
1250	+25%	60	53	7	55	5
1500	+50%	60	60	0	60	0
2000	+100%	60	60	0	60	0

After testing, each participant was asked to fill out a questionnaire assessing ease of use of the devices. A large majority of the respondents stated that the test was easy to use and that the instructions were clear.

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.