

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

A. 510(k) Number:

k092258

B. Purpose for Submission:

New device

C. Measurand:

Methadone metabolite 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP)

D. Type of Test:

Semi-quantitative and qualitative enzyme immunoassay

E. Applicant:

Radox Laboratories, Limited

F. Proprietary and Established Names:

Radox Methadone Metabolite (EDDP)

G. Regulatory Information:

Regulation section:

Regulation	Regulation Name	Class	Product Code	Panel
21 CFR§862.3620	Methadone test system	II	DJR	(91) Toxicology
21 CFR§862.3200	Clinical toxicology calibrator	II	DKB	(91) Toxicology
21 CFR§862.3280	Clinical toxicology control material	I, reserved	DIF	(91) Toxicology

H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

The Randox Laboratories Ltd. Methadone Metabolite Assay is an *in vitro* diagnostic test for the qualitative and semi-quantitative detection of 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP) in human urine. The cut off for both the qualitative and semi-quantitative modes of the assay is 300 ng/mL for EDDP. Qualitative and semi-quantitative results can be utilized in the diagnosis and treatment of EDDP use or overdose. The Randox Methadone Metabolite Assay has been developed for use on the RX series analyzers, which includes the RX Daytona and RX Imola. This *in vitro* diagnostic device is intended for prescription use only. The semi-quantitative mode is for purposes of

- 1) enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GC/MS, or,
- 2) permitting laboratories to establish quality control procedures.

This assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatograph/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Randox EDDP Calibrator Set

The Randox EDDP Calibrator Set consists of liquid calibrators containing EDDP. There are 5 levels of calibrator. They have been developed for use in the calibration of EDDP assays on the RX series analyzers, which includes the RX Daytona and the RX Imola. This *in vitro* diagnostic device is intended for prescription use only.

Randox EDDP Controls, Level 1 and 2

The Randox EDDP Controls, level 1 and 2 are liquid controls containing EDDP. There are 2 levels of controls. They have been developed for use in the quality control of EDDP assays on the RX series analyzers, which includes the RX Daytona and the RX Imola. This *in vitro* diagnostic device is intended for prescription use only.

3. Special conditions for use statement(s):

Prescription use only

This assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatograph/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment

should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

4. Special instrument requirements:

The Rx Daytona and Rx Imola analyzers were used to conduct performance studies below.

I. Device Description:

The Randox Methadone Metabolite (EDDP) is calibrated against EDDP. The assay is a two reagent system consisting of a murine monoclonal antibody/substrate reagent and the enzyme-drug conjugate reagent. The Randox EDDP Calibrator Set consists of 5 calibrators with EDDP concentrations from 0 to 1,000 ng/mL in human urine. They are ready to use. The Randox EDDP Controls, Level 1 and Level 2, are derived from human urine and are ready to use. The control values are set at approximately \pm 25% of cutoff (300 ng/mL).

J. Substantial Equivalence Information:

1. Predicate device name(s):

DRI® Methadone Metabolite Enzyme Assay

2. Predicate K number(s):

k023617

3. Comparison with predicate:

Similarities		
Item	Device	Predicate (k023617)
Intended Use/ Indications for use	For the qualitative and semi-quantitative determination of Methadone Metabolite, (2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine) EDDP in human urine. The values are utilized in the diagnosis and treatment of EDDP use or overdose	Same
Test Principle	A competitive enzyme immunoassay based on competition between drug in the sample and drug labeled with the enzyme glucose-6-phosphate dehydrogenase	A homogeneous enzyme immunoassay based on competition of an enzyme glucose-6-phosphate dehydrogenase (G6PDH) labeled drug

Similarities		
Item	Device	Predicate (k023617)
	(G6PDH) for a fixed amount of antibody in the reagent. In the absence of drug in the sample the EDDP labeled G6PDH conjugate is bound to antibody and enzyme activity is inhibited. When free drug is present in the sample, antibody binds to the free drug and the unbound EDDP labeled G6PDH exhibits its maximum enzyme activity. Active enzyme converts NAD to NADH resulting in an absorbance change measured spectrophotometrically at 340nm.	and drug from urine sample for a fixed amount of specific antibody binding sites. Direct relationship between drug concentration in urine and the enzyme activity. Enzyme activity is determined spectrophotometrically at 340nm by measuring its ability to convert NAD to NADH.
Sample type	Human urine	Same
Type of reagent	Liquid Ready to use Two reagent assay	Same
Antibody	Monoclonal	Same

Differences		
Item	Device	Predicate
Cutoff	300ng/mL	300ng/mL and 1000ng/mL
Calibrator materials	Liquid ready to use (0, 200, 300, 600, 1000ng/mL)	Liquid ready to use (0, 150, 300, 1000, 2000ng/mL)
Control materials	225, 375ng/ml	75, 125ng/ml

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

None were referenced.

L. Test Principle:

The assay is based on competition between drug in the sample and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for a fixed amount of antibody in the reagent. Enzyme activity decreases upon binding to the antibody, and the drug concentration in the sample is measured in terms of enzyme activity. In the absence of drug in the sample, methadone metabolite-labeled G6PDH conjugate is bound to antibody, and the enzyme activity is inhibited. However, when free drug is present in the sample, antibody would bind to free drug; the

unbound methadone metabolite-labelled G6PDH then exhibits its maximal enzyme activity. Active enzyme converts nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that can be measured spectrophotometrically at 340 nm.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

An EDDP negative urine pool was spiked with EDDP to concentrations of $\pm 25\%$, $\pm 50\%$, $\pm 75\%$ and $\pm 100\%$ of the cutoff of 300 ng/mL as confirmed by GC/MS. Two samples were tested on one RX Daytona and one RX Imola systems twice per day for 20 non-consecutive days (n=80) in the qualitative and semi-quantitative modes. The samples were tested randomly and in a masked order. Two calibrations were performed through the course the studies. A summary of the results is below:

RX Daytona

Sample Concentration % of cutoff	Qualitative Results (#Neg/# Pos)	Semi-Quantitative Results (#Neg/# Pos)
-100%	80 Neg	80 Neg
-75%	80 Neg	80 Neg
-50%	80 Neg	80 Neg
-25%	80 Neg	80 Neg
+25%	80 Pos	80 Pos
+50%	80 Pos	80 Pos
+75%	80 Pos	80 Pos
+100%	80 Pos	80 Pos

RX Imola

Sample Concentration % of cutoff	Qualitative Results (#Neg/# Pos)	Semi-Quantitative Results (#Neg/# Pos)
-100%	80 Neg	80 Neg
-75%	80 Neg	80 Neg
-50%	80 Neg	80 Neg
-25%	80 Neg	80 Neg
+25%	80 Pos	80 Pos
+50%	80 Pos	80 Pos
+75%	80 Pos	80 Pos
+100%	80 Pos	80 Pos

b. *Linearity/assay reportable range:*

A drug free urine pool was spiked with pure EDDP to 1000 ng/mL and

serially diluted in increments of 10% with EDDP negative urine. Each level was tested in triplicate in the semi-quantitative mode on the Rx Daytona and Rx Imola. % recoveries of the target concentrations were calculated for each instrument. Linear regression was also calculated by plotting the observed result against the expected result. See the tables below:

Target (ng/mL)	Rx Daytona		Rx Imola	
	Result (ng/mL)	% Recovery	Result (ng/mL)	% Recovery
0	0.00	0.00	0.00	0.00
10	12.63	126.27	0.00	0.00
20	49.20	246.02	72.84	364.22
30	57.13	197.11	106.34	354.46
40	64.46	161.16	89.40	223.50
50	66.57	133.15	104.25	208.49
60	81.94	136.57	99.63	166.06
70	78.46	112.08	99.71	142.45
80	82.30	102.88	57.88	72.35
90	93.40	103.78	115.55	128.39
100	92.15	92.15	93.66	93.66
200	197.55	98.78	194.74	97.37
300	297.74	99.25	306.86	102.29
400	383.71	95.93	405.18	101.30
500	533.19	106.64	514.53	102.91
600	612.15	102.03	589.23	98.21
700	722.72	103.25	686.34	98.05
800	772.88	96.61	750.34	93.79
900	802.11	89.12	834.48	92.72
1000	983.05	98.31	928.02	92.80

	Rx Daytona	Rx Imola
Slope	0.95	0.91
Intercept	15.91	32.26
R	0.994	0.993
Syx	24.75	25.87

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

Traceability and Value Assignment: The Randox Methadone Metabolite (EDDP) assay has 4 calibrator materials and two control materials. The master calibrator and control stock solutions are gravimetrically prepared using EDDP from an outside supplier and buffered human urine. The purity of the EDDP is determined by GC/FID, HPLC and NMR. The EDDP concentration for the master lot is determined by GC/MS. Value assignment

for control materials and calibrator materials is determined against the current master lot by performing nested testing of the new control materials and the new calibrator materials. The new lots are analyzed in replicates of 10. Results need to meet the sponsor's pre-determined acceptance criteria %CV and % recovery against the current master lot.

Calibrator materials and control materials are sold separately.

Stability: Accelerated and Real-time stability studies were performed with the control and calibrator materials at 2-8° C, 25° C and 37° C on the Rx Imola and Rx Daytona. EDDP recoveries from the stressed material were compared to fresh controls or calibrators stored at 2-8° C. Based on the real time studies, the sponsor determined that calibrators and controls are stable for 18 months at 2-8° C. Open vials of calibrators and controls were stored at 2-8° C and analyzed daily on the Rx Imola and Rx Daytona until the EDDP recovery exceeded the pre-determined acceptance criteria. Open vials of control materials and calibrator materials are stable for 28 days at 2-8° C.

d. Detection limit:

Performance at low drug concentrations in the semi-quantitative assay was characterized by the determination of recovery (see section b above).

e. Analytical specificity:

The cross-reactivity of the parent drug with endogenous compounds, structurally related, and structurally unrelated compounds was evaluated by adding known amounts of each potential interferent to drug-free urine spiked with EDDP to $\pm 25\%$ of the cutoff (300 ng/mL). Samples were assayed in quintuplets for the qualitative and semi-quantitative modes on the RX Daytona and Rx Imola for endogenous and structurally unrelated compounds and in triplicate for structurally related compounds. The results were compared to the appropriate sample containing no interferent. Interference was defined as the concentration of each compound that had a response approximately equal to that of the cutoff calibrator (as positive), or the maximum concentration of the compound tested that remained negative. Any compounds demonstrating interference were retested at lower concentrations of the interferent to determine where interference began.

The interfering concentrations of endogenous, structurally unrelated, and structurally related compounds that were equivalent to the cutoff (300 ng/mL) were determined by comparing the absorbance readings of the samples containing the interferent(s) to the absorbance of the calibrator at the cutoff (300 ng/mL). Results are summarized below:

Structurally Related Compounds Equivalent to the Cutoff--Rx Daytona

		Qualitative		Semi- Quantitative		
Compound	Tested Conc. (ng/mL)	Response equivalent to 300 ng/mL cutoff	Cross-reactivity %	Tested Conc. (ng/mL)	Response equivalent to 300 ng/mL cutoff	Cross-reactivity %
EDDP	300	POS	100.00%	300	POS	100.00%
EMDP	995840	POS	0.03%	857402	POS	0.03%
(-) alpha Methadol	60661	POS	0.49%	40770	POS	0.74%
Methadone	108243	POS	0.28%	89714	POS	0.33%
LAAM	571494	POS	0.05%	506356	POS	0.06%
d, l-Alpha methadol	485119	POS	0.06%	349296	POS	0.09%

Structurally Related Compounds Equivalent to the Cutoff-- Rx Imola

		Qualitative		Semi- Quantitative		
Compound	Tested Conc. (ng/mL)	Response equivalent to 300 ng/mL cutoff	Cross-reactivity %	Tested Conc. (ng/mL)	Response equivalent to 300 ng/mL cutoff	Cross-reactivity %
EDDP	300	POS	100.00%	300	POS	100.00%
EMDP	1210432	POS	0.02%	942693	POS	0.03%
(-) alpha Methadol	117542	POS	0.26%	81334	POS	0.37%
Methadone	103210	POS	0.29%	72649	POS	0.41%
LAAM	929952	POS	0.03%	489669	POS	0.06%
d, l-Alpha methadol	1232051	POS	0.02%	780475	POS	0.04%

Structurally unrelated compounds were tested by spiking each of them into urine samples that contain EDDP at $\pm 25\%$ of cutoff for the Rx Imola and Rx Daytona. The following is the list of compounds tested; 11-hydroxy-delta9-THC, 11-nor9-carboxy-delta9-THC, 6 Acetyl-morphine, Amitriptyline Amobarbital, (+/-)-Amphetamine, Aspirin, Ascorbic acid, Benzoyllecgonine, β -phenylethylamine, Buprenorphine, Caffeine, Cannabidiol, Chlorpheniramine, Cocaethylene, Cocaine, Codeine, Cotinine, delta9-THC, Diazepam, Dihydrocodeine, Doxylamine, Ecgonine methyl ester, D, l-Ephedrine, l-Ephedrine, d-Ephedrine, S,S (+) Pseudoephedrine, R,R (-) Pseudoephedrine, Heroin, MBDB, MDA, MDEA, MDMA, d-Methamphetamine, Morphine, Oxycodone, Paracetamol, Temazepam, Ibuprofen. Results are summarized in the labeling. Interference at the cutoff is summarized below:

Structurally Unrelated Compounds Equivalent to the Cutoff--Rx Daytona

		Response 300 ng/mL	equivalent to cutoff	Cross- reactivity %	
Compound	Tested Conc. (ng/mL)	Qualitative	Semi- quantitative	Qualitative	Semi- quantitative
11-hydroxy- delta9-THC	100,000	NEG	NEG	0%	0%
11-nor9-carboxy- delta9-THC	100,000	NEG	NEG	0%	0%
6 Acetyl- morphine	100,000	NEG	NEG	0%	0%
Amitriptyline	100,000	NEG	NEG	0.10%	0.15%
Amobarbital	100,000	NEG	NEG	0%	0%
(+/-)- Amphetamine	100,000	NEG	NEG	0%	0%
Aspirin	100,000	NEG	NEG	0%	0%
Ascorbic acid	100,000	NEG	NEG	0%	0%
Benzoylcegonine	100,000	NEG	NEG	0%	0%
β- phenylethylamine	100,000	NEG	NEG	0%	0.04%
Buprenorphine	100,000	NEG	NEG	0%	0%
Caffeine	100,000	NEG	NEG	0%	0%
Cannabidiol	100,000	NEG	NEG	0%	0%
Chlorpheniramine	100,000	NEG	NEG	0.22%	0.25%
Cocaehtylene	100,000	NEG	NEG	0.05%	0.12%
Cocaine	100,000	NEG	NEG	0%	0%
Codeine	100,000	NEG	NEG	0%	0%
Cotinine	100,000	NEG	NEG	0%	0%
delta9-THC	100,000	NEG	NEG	0%	0%
Diazepam	100,000	NEG	NEG	0%	0%
Dihydrocodeine	100,000	NEG	NEG	0%	0%
Doxylamine	100,000	NEG	NEG	0.04%	0.08%
Ecgonine methyl ester	100,000	NEG	NEG	0%	0%
D,l-Ephedrine	100,000	NEG	NEG	0%	0%
l-Ephedrine	100,000	NEG	NEG	0%	0%
d-Ephedrine	100,000	NEG	NEG	0%	0%
S,S (+) Pseudoephedrine	100,000	NEG	NEG	0%	0%
R,R (-) Pseudoephedrine	100,000	NEG	NEG	0%	0%
Heroin	100,000	NEG	NEG	0%	0%
MBDB	100,000	NEG	NEG	0%	0%
MDA	100,000	NEG	NEG	0%	0%
MDEA	100,000	NEG	NEG	0%	0%
MDMA	100,000	NEG	NEG	0%	0%
d- Methamphetamine	100,000	NEG	NEG	0.05%	0.08%
Morphine	100,000	NEG	NEG	0%	0%
Oxycodone	100,000	NEG	NEG	0%	0%
Paracetamol	100,000	NEG	NEG	0%	0%
Temazepam	100,000	NEG	NEG	0%	0%
Ibuprofen	100,000	NEG	NEG	0%	0%

Structurally Unrelated Compounds Equivalent to the Cutoff--Rx Imola

		Response equivalent to 300 ng/mL cutoff		Cross- reactivity %	
Compound	Tested Conc. (ng/mL)	Qualitative	Semi- quantitative	Qualitative	Semi- quantitative
11-hydroxy-delta9-THC	100,000	NEG	NEG	0%	0%
11-nor9-carboxy-delta9-THC	100,000	NEG	NEG	0%	0%
6 Acetyl-morphine	100,000	NEG	NEG	0%	0%
Amitriptyline	100,000	NEG	NEG	0.10%	0.15%
Amobarbital	100,000	NEG	NEG	0%	0%
(+/-)-Amphetamine	100,000	NEG	NEG	0%	0%
Aspirin	100,000	NEG	NEG	0%	0%
Ascorbic acid	100,000	NEG	NEG	0%	0%
Benzoylcegonine	100,000	NEG	NEG	0%	0%
β -phenylethylamine	100,000	NEG	NEG	0%	0%
Buprenorphine	100,000	NEG	NEG	0%	0%
Caffeine	100,000	NEG	NEG	0%	0%
Cannabidiol	100,000	NEG	NEG	0%	0%
Chlorpheniramine	100,000	NEG	NEG	0.27%	0.19%
Cocaehtylene	100,000	NEG	NEG	0.04%	0.13%
Cocaine	100,000	NEG	NEG	0%	0%
Codeine	100,000	NEG	NEG	0%	0%
Cotinine	100,000	NEG	NEG	0%	0%
delta9-THC	100,000	NEG	NEG	0%	0%
Diazepam	100,000	NEG	NEG	0%	0%
Dihydrocodeine	100,000	NEG	NEG	0%	0%
Doxylamine	100,000	NEG	NEG	0.04%	0.06%
Ecgonine methyl ester	100,000	NEG	NEG	0%	0%
D,l-Ephedrine	100,000	NEG	NEG	0%	0.03%
l-Ephedrine	100,000	NEG	NEG	0%	0%
d-Ephedrine	100,000	NEG	NEG	0%	0%
S,S (+) Pseudoephedrine	100,000	NEG	NEG	0%	0%
R,R (-) Pseudoephedrine	100,000	NEG	NEG	0%	0%
Heroin	100,000	NEG	NEG	0%	0%
MBDB	100,000	NEG	NEG	0%	0%
MDA	100,000	NEG	NEG	0%	0%
MDEA	100,000	NEG	NEG	0%	0%
MDMA	100,000	NEG	NEG	0%	0%
d- Methamphetamine	100,000	NEG	NEG	0.13%	0.05%
Morphine	100,000	NEG	NEG	0%	0%
Oxycodone	100,000	NEG	NEG	0%	0%
Paracetamol	100,000	NEG	NEG	0%	0%
Temazepam	100,000	NEG	NEG	0%	0%
Ibuprofen	100,000	NEG	NEG	0%	0%

Endogenous interfering compounds were tested at $\pm 25\%$ of cutoff for the Rx Imola and Rx Daytona for Total Bilirubin, Direct Bilirubin, Hemoglobin, Creatinine, Urea, Glucose, H.S.A., Ethanol, Acetone, Gamma globulin, Oxalic acid, Riboflavin, Sodium chloride, Boric acid, Sodium azide, Sodium fluoride. Results are summarized in the labeling. Interference at the cutoff is in the table below. No interference was observed at the cutoff.

Endogenous Interference Equivalent to the Cutoff—Rx Daytona

		Response equivalent to 300 ng/mL cutoff		Cross- reactivity %	
Compound	Tested Conc. (ng/mL)	Qualitative	Semi-quantitative	Qualitative	Semi-quantitative
Total Bilirubin	15	NEG	NEG	0%	0%
Direct Bilirubin	5	NEG	NEG	0%	0%
Haemoglobin	115	NEG	NEG	0%	0%
Creatinine	30	NEG	NEG	0%	0%
Urea	258	NEG	NEG	0%	0%
Glucose	2000	NEG	NEG	0%	0%
H.S.A.	500	NEG	NEG	0%	0%
Ethanol	1000	NEG	NEG	0%	0%
Acetone	1000	NEG	NEG	0%	0%
Gamma globulin	500	NEG	NEG	0%	0%
Oxalic acid	100	NEG	NEG	0%	0%
Riboflavin	7.5	NEG	NEG	0%	0%
Sodium chloride	6000	NEG	NEG	0%	0%
Boric acid	1000	NEG	NEG	0%	0%
Sodium azide	1000	NEG	NEG	0%	0%
Sodium fluoride	1000	NEG	NEG	0%	0%

Endogenous Interference Equivalent to the Cutoff—Rx Imola

		Response equivalent to 300 ng/mL cutoff		Cross- reactivity %	
Compound	Tested Conc. (ng/mL)	Qualitative	Semi-quantitative	Qualitative	Semi-quantitative
Total Bilirubin	15	NEG	NEG	0%	0%
Direct Bilirubin	5	NEG	NEG	0%	0%
Haemoglobin	115	NEG	NEG	0%	0%
Creatinine	30	NEG	NEG	0%	0%
Urea	258	NEG	NEG	0%	0%
Glucose	2000	NEG	NEG	0%	0%
H.S.A.	500	NEG	NEG	0%	0%
Ethanol	1000	NEG	NEG	0%	0%
Acetone	1000	NEG	NEG	0%	0%
Gamma globulin	500	NEG	NEG	0%	0%
Oxalic acid	100	NEG	NEG	0%	0%
Riboflavin	7.5	NEG	NEG	0%	0%
Sodium chloride	6000	NEG	NEG	0%	0%
Boric acid	1000	NEG	NEG	0%	0%
Sodium azide	1000	NEG	NEG	0%	0%
Sodium fluoride	1000	NEG	NEG	0%	0%

Specific Gravity studies were performed on the Rx Daytona and Rx Imola.

Two EDDP negative urine pools were spiked with EDDP to + and – 25% cutoff (300 ng/mL). The pools were further divided and had sodium chloride added to achieve specific gravities of 1.000 (water blank), 1.010, 1.020, 1.030. Specific gravities were confirmed by a commercial method. Each sample was analyzed in replicates of 10 in the semi-quantitative and qualitative modes. Recoveries were compared to the spiked target samples and were expected to be $\leq 10\%$. Specific gravity from 1.000-1.030 had no significant ($\leq 10\%$) effect on EDDP results for the Rx Daytona or Rx Imola.

pH studies were performed using the spiked pools from the specific gravity studies. pH was adjusted by adding either 1M HCl or 1M NaOH to obtain samples with pH levels of 3, 5, 7, 9, 11. pH was confirmed by a pH meter. Each sample was analyzed in replicates of 10 in the semi-quantitative and qualitative modes. Recoveries were compared to the pH 7 sample and were expected to be $\leq 10\%$ of the target values. pH from 3-11 had no significant ($\leq 10\%$) effect on EDDP results for the Rx Daytona or Rx Imola.

f. Assay cut-off:

Analytical performance of the device around the claimed cutoff is described in precision section (1 a.) above.

2. Comparison studies:

a. Method comparison with predicate device:

40 positive and 40 negative unaltered natural samples were analyzed on the Rx Daytona and Rx Imola and by GC/MS. The results with discordant tables are as follows:

RX Daytona Semi-quantitative						
Candidate Device Results	Negative	Less than half the cut-off (concentration by GC/MS analysis)	Near Cutoff Negative (Between 50% below the cut-off and the cut-off concentration)	Near Cutoff Positive (Between the cut-off and 50% above the cut-off concentration)	High Positive (greater than 50% above the cut-off concentration)	% Agreement with GC/MS
Positive	-	-	2	8	32	100.00%
Negative	31	-	7	-	-	95.00%

Cutoff Value	Semi-quantitative EDDP Rx Daytona	Drug/Metabolite GC/MS EDDP (ng/mL)
300 ng/mL	Pos	272
	Pos	290

RX Daytona Qualitative						
Candidate Device Results	Negative	Less than half the cut-off (concentration by GC/MS analysis)	Near Cutoff Negative (Between 50% below the cut-off and the cut-off concentration)	Near Cutoff Positive (Between the cut-off and 50% above the cut-off concentration)	High Positive (greater than 50% above the cut-off concentration)	% Agreement with GC/MS
Positive	-	-	3	8	32	100.00%
Negative	31	-	6	-	-	92.50%

Cutoff Value	Qualitative EDDP Rx Daytona	Drug/Metabolite GC/MS EDDP (ng/mL)
300 ng/mL	Pos	272
	Pos	290
	Pos	292

RX Imola Semi-quantitative						
Candidate Device Results	Negative	Less than half the cut-off (concentration by GC/MS analysis)	Near Cutoff Negative (Between 50% below the cut-off and the cut-off concentration)	Near Cutoff Positive (Between the cut-off and 50% above the cut-off concentration)	High Positive (greater than 50% above the cut-off concentration)	% Agreement with GC/MS
Positive	-	-	4	8	32	100.00%
Negative	31	-	5	-	-	90.00%

Cutoff Value	Qualitative EDDP Rx Imola	Drug/Metabolite GC/MS EDDP (ng/mL)
300 ng/mL	Pos	272
	Pos	283
	Pos	290
	Pos	292

RX Imola Qualitative						
Candidate Device Results	Negative	Less than half the cut-off (concentration by GC/MS analysis)	Near Cutoff Negative (Between 50% below the cut-off and the cut-off concentration)	Near Cutoff Positive (Between the cut-off and 50% above the cut-off concentration)	High Positive (greater than 50% above the cut-off concentration)	% Agreement with GC/MS
Positive	-	-	5	8	32	100.00%
Negative	31	-	4	-	-	87.50%

Cutoff Value	Qualitative EDDP Rx Imola	Drug/Metabolite GC/MS EDDP (ng/mL)
300 ng/mL	Pos	247
	Pos	272
	Pos	283
	Pos	290
	Pos	292

b. Matrix comparison:

Not applicable. This device is for urine 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):

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.