

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

A. 510(k) Number:

k113747

B. Purpose for Submission:

New device

C. Measurand:

Opiates

D. Type of Test:

Qualitative and semi-quantitative immunoassay

E. Applicant:

Radox Laboratories Limited

F. Proprietary and Established Names:

Radox Opiates Assay

Radox Multi Drug Calibrator Set (DOA CAL)

Radox Multidrug Control Level 1 (DOA Control 1)

Radox Multidrug Control Level 2 (DOA Control 2)

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DJG	Class II	21 CFR § 862.3650, Opiates test system	91-Toxicology
DLJ	Class II	21 CFR § 862.3200, Calibrators, Drug specific	91-Toxicology
LAS	Class I, reserved	21 CFR 862.3280 Clinical Toxicology control material	91-Toxicology

H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

Randox Laboratories Ltd. Opiates Assay is an in vitro diagnostic test for the qualitative and semi-quantitative analysis of Opiates in human urine. The cut off for both the qualitative and semi-quantitative application is 2000ng/mL for morphine to which the assay is calibrated. Qualitative and semi-quantitative results can be utilized in the diagnosis and treatment of Opiate use or overdose. The Randox Opiates Assay has been developed for use on the RX series analysers, which includes the RX Daytona and the 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 GCMS

or

(2) Permitting laboratories to establish quality control procedures.

This assay provides only a preliminary analytical test 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.

The Randox Multidrug Calibrator Set is for use on human urine samples. They are liquid calibrators containing Methamphetamine, Secobarbital, Methadone, and Morphine. There are 5 levels of calibrator. They have been developed for use in the calibration of Amphetamine, Barbiturates, Methadone and Opiate assays on the RX series analysers, which includes the RX Daytona and RX Imola. This in vitro diagnostic device is intended for prescription use only.

The Randox Multidrug Controls, Level 1 and 2 are for use on human urine samples. They are liquid controls containing Methamphetamine, Secobarbital, Methadone, and Morphine. There are 2 levels of controls. They have been developed for use in the quality control of Amphetamine, Barbiturates, Methadone and Opiate assays on the RX series analysers, which includes the RX Daytona and RX Imola. This in vitro diagnostic device is intended for prescription use only.

3. Special conditions for use statement(s):

The assay is for prescription use.

4. Special instrument requirements:

Performance studies contained in the 510(k) were carried out on the Rx Daytona and Rx Imola analyzers.

I. Device Description:

Randox Opiates Assay consists of ready to use reagents. Reagent 1 (R1) contains mouse monoclonal anti-morphine antibodies, glucose-6-phosphate, NAD and sodium azide <0.1 % w/v. Reagent 2 (R2) contains morphine labeled G6PDH, buffer and sodium azide <0.1 % w/v.

The calibrators and controls are ready to use human urine-based liquid. Methamphetamine, Secobarbital, and Methadone are previously cleared analytes.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Microgenics DRI Opiate Assay
DRI Multi-Drug Calibrators and Controls
2. Predicate 510(k) number(s):
k011150
k983159
3. Comparison with predicate:

Assay

Similarities		
Item	New Device Randox Opiates Assay Candidate device (k113747)	Predicate Microgenics DRI Opiates Assay (k011150)
Intended Use/ Indications for Use	Qualitative and semi-quantitative analysis of Opiates in human urine.	Same
Cut-off	2000 ng/mL	300 ng/mL or 2000 ng/mL
Sample Type	Human urine	Human urine
Test Principle	A competitive enzyme immunoassay 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. In the absence of drug in the sample the morphine labeled G6PDH conjugate is bound to antibody and enzyme activity is inhibited. When free drug is present in the	A homogenous enzyme immunoassay based on competition of an enzyme glucose-6-phosphate dehydrogenase (G6PDH) labeled drug and drug from urine sample for a fixed amount of specific antibody binding sites. Enzyme activity is determined spectrophotometrically at 340nm by measuring its ability to convert NAD to

Similarities		
Item	New Device Randox Opiates Assay Candidate device (k113747)	Predicate Microgenics DRI Opiates Assay (k011150)
	sample, antibody binds to the free drug and the unbound morphine labeled G6PDH exhibits its maximum enzyme activity. Active enzyme converts NAD to NADH resulting in an absorbance change measured spectrophotometrically at 340nm.	NADH
Type of reagent	Liquid ready to use Two reagent assay	Liquid ready to use Two reagent assay
Methodology	Homogenous enzyme Immunoassay	Homogenous enzyme Immunoassay
Reagents	R1. Antibody/Substrate Reagent: Mouse monoclonal anti-morphine antibodies, glucose-6-phosphate, NAD and sodium azide <0.1% w/v. R2. Enzyme-Drug Conjugate Reagent: Morphine labeled G6PDH and sodium azide <0.1% w/v	R1. Antibody/Substrate Reagent: Monoclonal anti-morphine antibodies, glucose-6-phosphate, NAD and sodium azide <0.1% w/v. R2. Enzyme Conjugate Reagent: Morphine labeled G6PDH and sodium azide <0.1% w/v

Calibrators and Controls

Similarities		
Item	New Device Randox Opiates Assay Candidate device (k113747)	Predicate DRI Multi-Drug Calibrators and Controls (k983159)
Intended Use/ Indications for Use	Same	Calibration and quality control of various drug of abuse Assays.
Analytes	Secobarbital, Methadone, Methamphetamine and Morphine	d-Methamphetamine, Secobarbital, Oxazepam, Benzoylcegonine, Methadone, Methaqualone, Morphine, Phencyclidine and Propoxyphene

Similarities		
Item	New Device Randox Opiates Assay Candidate device (k113747)	Predicate DRI Multi-Drug Calibrators and Controls (k983159)
Calibrators	Liquid ready to use (0, 300, 1000, 2000, 4000 ng/mL)	Liquid ready to use (300, 1000, 2000, 4000, 6000 ng/mL)
Controls	Liquid ready to use 1500, 2500 ng/mL	Liquid ready to use 300, 2000 ng/mL

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

EP7-A2 CLSI Interference Testing in Clinical Chemistry

EP17-A CLSI Protocols for Determination of Limits of Detection & Limits of Quantitation

L. Test Principle:

The Randox Laboratory Ltd. Opiates Assay is an immunoassay with ready to use liquid reagent. 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. In the absence of drug in the sample, morphine-labeled G6PDH conjugate is bound to antibody, and the enzyme activity is inhibited. When free drug is present in the sample, the antibody will bind to the free drug and the unbound morphine-labeled 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:

Precision was determined by spiking Morphine (1 mg/ml solution) into drug free urine at various concentrations (-100%, -75%, -50%, -25%, cut off, +25%, +50%, +75% and +100%). Concentrations were confirmed by GCMS. Intra-assay precision was performed over 20 nonconsecutive days. The between run testing was performed in replicate twice a day for 20 days. The qualitative and semi-quantitative results are presented below:

Rx Daytona and Rx Imola: Total Precision for qualitative mode

Sample concentration	No. observation	Rx Daytona	Rx Imola
-100% cut off	80	80 negative	80 negative
-75% cut off	80	80 negative	80 negative
-50% cut off	80	80 negative	80 negative

-25% cut off	80	80 negative	80 negative
+25% cut off	80	80 positive	80 positive
+50% cut off	80	80 positive	80 positive
+75% cut off	80	80 positive	80 positive
+100% cut off	80	80 positive	80 positive

Rx Daytona and Rx Imola: Total Precision for semi-quantitative mode

Sample concentration	No. observations	Rx Daytona	Rx Imola
-100% cut off	80	80 negative	80 negative
-75% cut off	80	80 negative	80 negative
-50% cut off	80	80 negative	80 negative
-25% cut off	80	80 negative	80 negative
+25% cut off	80	80 positive	80 positive
+50% cut off	80	80 positive	80 positive
+75% cut off	80	80 positive	80 positive
+100% cut off	80	80 positive	80 positive

b. Linearity/assay reportable range:

Recovery across the range was determined by testing a series of samples that were diluted from the high concentration Morphine spiked urine sample. A high urine sample containing around 4000 ng/mL Morphine was serially diluted with analyte-free urine and tested in triplicates in the semi-quantitative mode. The results were averaged and compared to the expected result and the percent recovery was calculated. Results are presented in the tables below.

Rx Imola:

Expected Concentration (ng/mL)	Mean Observed Concentration (ng/mL)	Recovery (%)
0	0.00	Not applicable
40	22.89	57.22
80	61.05	76.31
120	80.83	67.36
160	123.87	77.42
200	193.14	96.57
240	242.39	101.00
280	284.74	101.69
320	342.59	107.06
360	358.97	99.71
400	427.08	106.77
800	848.26	106.03
1200	1200.17	100.01
1600	1554.89	97.18
2000	1949.07	97.45

2400	2328.02	97.00
2800	2923.36	104.41
3200	3219.68	100.61
3600	3543.00	98.42
4000	4161.60	104.04

Rx Daytona:

Expected Concentration (ng/mL)	Mean Observed Concentration (ng/mL)	Recovery (%)
0	0.00	Not applicable
40	0.00	0.00
80	38.00	47.50
120	131.72	109.77
160	196.45	122.78
200	216.18	108.09
240	260.93	108.72
280	283.22	101.15
320	346.30	108.22
360	371.16	103.10
400	429.91	107.48
800	844.61	105.58
1200	1274.79	106.23
1600	1663.39	103.96
2000	1982.23	99.11
2400	2418.72	100.78
2800	2902.23	103.65
3200	3122.82	97.59
3600	3379.54	93.88
4000	4388.57	109.71

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

Traceability and value assignment

The 5 level multi-drug calibrator (0 ng/mL, 300 ng/mL, 1000 ng/mL, 2000 ng/mL, 4000 ng/mL) and 2 level multi-drug control materials (1500 ng/mL, 2500 ng/mL) are both traceable to master lots that have been GC/MS quantified. The master lots were made by spiking morphine, methadone, methamphetamine and secobarbital at the appropriate levels into a buffered human urine matrix that also contains 0.05% sodium azide. The drugs used to make the calibrators and controls are supplied by Cerilliant Corporation the accuracy of which is ensured by purity determinations (GC/FID, HPLC and NMR) and gravimetric preparation using balances calibrated with NIST traceable weights. Each of the Randox calibrator/control level is value assigned using Rx Daytona and Rx Imola. The

target value for each level is the median of the observed values.

Stability

Real time stability testing including shelf-life and on-board stability studies were performed for the assay, controls and calibrators. The acceptance criteria were found to be adequate. The Randox Opiates assay reagents, controls and calibrators are stable for 18 months when stored unopened at 2 – 8° C and 28 days on-board at approximately 10°C.

d. Detection limit:

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

e. Analytical specificity:

The Randox Laboratory Ltd. Opiate Assay was evaluated for interference according to the CLSI Guideline EP7-A2 recommendations. These studies were performed by spiking structurally related and unrelated compounds into drug-free and drug-containing urine samples. Drug-containing urine samples were tested at two different concentrations, +25% and -25% of the cut-off concentration of 2000 ng/mL. Drug-free urine samples were used as controls. Percent cross-reactivity was calculated using the cross-reactant concentration that gives a reaction absorbance which matches the reaction absorbance obtained by the cut-off calibrator. The cut-off calibrator concentration divided by the cross-reactant concentration that achieved the matching reactant absorbance x 100% gives the percent cross reactivity. These studies were performed on both, the Rx Daytona and Rx Imola analyzers. Similar results were obtained with both analyzers and in both qualitative and semi-quantitative modes. The percent cross-reactivity of the tested compounds are presented below:

Structurally related compounds:

Rx Daytona Qualitative

Compound	Tested concentration (ng/mL)	Cross-reactivity (%)
Morphine	2000	100.00
6 Acetyl-morphine	2000	99.98
Ethylmorphine	1872	106.87
Codeine	1785	112.03
Dihydrocodeine	4262	46.93
Morphine-3-β-glucoronide	83642	2.39
Hydromorphone	762735	0.26
Hydrocodone	7780	25.71
Oxycodone	684002	0.29
Heroin	5493	36.41

Rx Imola Qualitative:

Compound	Tested concentration (ng/mL)	Cross-reactivity (%)
Morphine	2000	100.00
6 Acetyl-morphine	1930	103.64
Ethylmorphine	2560	84.75
Codeine	1882	106.26
Dihydrocodeine	5886	33.98
Morphine-3- β -glucuronide	87471	2.29
Hydromorphone	892374	0.22
Hydrocodone	8965	22.31
Oxycodone	871511	0.23
Heroin	7386	27.08

Rx Daytona Semi-Quantitative

Compound	Tested concentration (ng/mL)	Cross-reactivity (%)
Morphine	2000	100.00
6 Acetyl-morphine	2060	97.10
Ethylmorphine	1849	108.19
Codeine	1808	110.60
Dihydrocodeine	4639	43.11
Morphine-3- β -glucuronide	86029	2.32
Hydromorphone	803275	0.25
Hydrocodone	8471	23.61
Oxycodone	712764	0.28
Heroin	6035	33.14

Rx Imola Semi-Quantitative:

Compound	Tested concentration (ng/mL)	Cross-reactivity (%)
Morphine	2000	100.00
6 Acetyl-morphine	1801	111.07
Ethylmorphine	1827	109.48
Codeine	1801	111.05
Dihydrocodeine	4637	43.13
Morphine-3- β -glucuronide	80900	2.47
Hydromorphone	770636	0.26

Hydrocodone	6464	30.94
Oxycodone	752676	0.27
Heroin	5731	30.90

Structurally unrelated compounds:

Rx Daytona:

Compound	Tested Concentration (ng/mL)	-25% of 2000 ng/mL opiate cut-off		+25% of 2000 ng/mL opiate cut-off	
		Qualitative	Semi-Quantitative	Qualitative	Semi-Quantitative
11-hydroxy-delta9-THC	100,000	NEG	NEG	POS	POS
11-nor9-carboxy-delta9-THC	100,000	NEG	NEG	POS	POS
Amitriptyline	100,000	NEG	NEG	POS	POS
Amobarbital	100,000	NEG	NEG	POS	POS
(+/-) Amphetamine D5	100,000	NEG	NEG	POS	POS
Ascorbic acid	100,000	NEG	NEG	POS	POS
Aspirin	100,000	NEG	NEG	POS	POS
Benzoylcegonine	100,000	NEG	NEG	POS	POS
B-phenylethylamine	100,000	NEG	NEG	POS	POS
Caffeine	100,000	NEG	NEG	POS	POS
Cannabidiol	100,000	NEG	NEG	POS	POS
Chlorpheniramine	100,000	NEG	NEG	POS	POS
Cocaehtylene	100,000	NEG	NEG	POS	POS
Cocaine	100,000	NEG	NEG	POS	POS
Cotinine	100,000	NEG	NEG	POS	POS
Delta9-THC	100,000	NEG	NEG	POS	POS
Diazepam	100,000	NEG	NEG	POS	POS
Ecgonine methyl ester	100,000	NEG	NEG	POS	POS
EDDP	100,000	NEG	NEG	POS	POS
EMDP	100,000	NEG	NEG	POS	POS
d,l-Ephedrine	100,000	NEG	NEG	POS	POS
l-Ephedrine	100,000	NEG	NEG	POS	POS
d-Ephedrine	100,000	NEG	NEG	POS	POS
LAAM	100,000	NEG	NEG	POS	POS
MBDB	100,000	NEG	NEG	POS	POS
MDA	100,000	NEG	NEG	POS	POS
MDEA	100,000	NEG	NEG	POS	POS
MDMA	100,000	NEG	NEG	POS	POS
Methadone	100,000	NEG	NEG	POS	POS
d-Methamphetamine	100,000	NEG	NEG	POS	POS
Paracetamol	100,000	NEG	NEG	POS	POS

Methadone	100,000	NEG	NEG	POS	POS
d-Methamphetamine	100,000	NEG	NEG	POS	POS
Paracetamol	100,000	NEG	NEG	POS	POS
S,S (+) Pseudoephedrine	100,000	NEG	NEG	POS	POS
R,R (-) Pseudoephedrine	100,000	NEG	NEG	POS	POS
Temazepam	100,000	NEG	NEG	POS	POS
Ibuprofen	100,000	NEG	NEG	POS	POS
d-amphetamine	100,000	NEG	NEG	POS	POS

Endogenous compounds:

The following endogenous compounds were added into drug-free urine and urine containing Opiate at the concentrations of $\pm 25\%$ surrounding the assay cut-off. These samples were tested using both, the Rx Daytona and Rx Imola analyzers. The substances listed in the table below were determined not to interfere at the concentration shown:

Compound	Tested Concentration
Total bilirubin	15 mg/dL
Direct bilirubin	5 mg/dL
Hemoglobin	115 mg/dL
Creatinine	30 mg/dL
Urea	258 mg/dL
Glucose	2000 mg/dL
HAS	500 mg/dL
Ethanol	1000 mg/dL
Acetone	1000 mg/dL
Gamma globulin	500 mg/dL
Oxalic acid	100 mg/dL
Riboflavin	7.5 mg/dL
Sodium chloride	6000 mg/dL
Boric acid	1000 mg/dL
Sodium azide	1000 mg/dL
Sodium fluoride	1000 mg/dL

In addition, the performance of the assay was evaluated under varying pH levels of: 3, 5, 7, 9 and 11, which had no effect on results. Further, variations in specific gravity between 1.00 and 1.03 also had no effect on results. These studies were performed at concentrations $\pm 25\%$ of the cut-off.

The package insert includes the complete list of all structurally related and unrelated compounds and metabolites tested.

f. *Assay cut-off:*

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

2. Comparison studies:

a. *Method comparison with predicate device:*

One hundred twenty eight unaltered clinical urine samples were evaluated by the Randox Opiate assay and compared to a GC/MS. Results from the study are presented below:

Rx Daytona – Semi-quantitative

	Negative	Less than half the Cut-Off	Near Cut-off Negative (concentration between 50% below the cut-off and the cut-off concentration for Opiates)	Near Cut-off Positive (concentration between 50% above the cut-off and the cut-off concentration for Opiates)	High Positive (concentration > 50% above the cut-off concentration for Opiates)	Percent Agreement with GC/MS for Opiates (based on cross reactivity profile)
GC/MS for opiates (based on cross reactivity profile) →						
2000 ng/mL cut-off Opiate Assay ↓						
Positive	0	0	9	21	41	92.5%
Negative	43	2	7	5	0	85.2%

Rx Daytona Qualitative

	Negative	Less than half the Cut-Off	Near Cut-off Negative (concentration between 50% below the cut-off and the cut-off concentration for Opiates)	Near Cut-off Positive (concentration between 50% above the cut-off and the cut-off concentration for Opiates)	High Positive (concentration > 50% above the cut-off concentration for Opiates)	Percent Agreement with GC/MS for Opiates (based on cross reactivity profile)
GC/MS for opiates (based on cross reactivity profile) →						
2000 ng/mL cut-off Opiate Assay ↓						
Positive	0	0	6	19	42	90.9
Negative	43	2	10	6	0	90.2

Rx Imola – Semi-quantitative

GC/MS for opiate (based on cross reactivity profile) →	Negative	Less than half the Cut-Off	Near Cut-off Negative (concentration between 50% below the cut- off and the cut- off concentration for Opiates)	Near Cut-off Positive (concentration between 50% above the cut-off and the cut-off concentration for Opiates)	High Positive (concentration > 50% above the cut-off concentration for Opiates)	Percent Agreement with GC/MS for Opiates(based on cross reactivity profile)
2000 ng/mL cut-off Opiate Assay ↓						
Positive	0	0	9	22	41	94.0
Negative	43	2	7	4	0	85.2

Rx Imola – Qualitative

GC/MS for Morphine (based on cross reactivity profile) →	Negative	Less than half the Cut-Off	Near Cut-off Negative (concentration between 50% below the cut- off and the cut- off concentration for Opiates)	Near Cut-off Positive (concentration between 50% above the cut-off and the cut-off concentration for Opiates)	High Positive (concentration > 50% above the cut-off concentration for Opiates)	Percent Agreement with GC/MS for Opiates(based on cross reactivity profile)
2000 ng/mL cut-off Opiate Assay ↓						
Positive	0	1	6	22	41	94.0
Negative	43	2	9	4	0	88.5

GC/MS Summary of Discordant Results:

Rx Daytona – Semi-quantitative

Cut-off value (ng/mL) for Morphine	Ranox Opiates Assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL) based on cross reactivity profile
2000	POS	1798 (Morphine)
	POS	1306 (Morphine)
	POS	462 (Morphine) & 629 (Codeine)
	POS	588 (Morphine) & 431 (Codeine)
	POS	728 (Morphine) & 250 (Codeine)
	POS	252 (Morphine) & 784 (Codeine)
	POS	1550 (Morphine)
	POS	1990 (Morphine)
	POS	1550 (Morphine)
	NEG	2313 (Morphine)
	NEG	1967 (Morphine) & 910 (Hydromorphone)
	NEG	2300 (Morphine)

	NEG	2100 (Morphine)
	NEG	2500 (Morphine)

Rx Daytona – Qualitative

Cut-off value (ng/mL) for Morphine	Ranox Opiates Assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL) based on cross reactivity profile
20008	POS	462 (Morphine) & 629 (Codeine)
	POS	588 (Morphine) & 431 (Codeine)
	POS	728 (Morphine) & 250 (Codeine)
	POS	252 (Morphine) & 784 (Codeine)
	POS	1990 (Morphine)
	POS	1550 (Morphine)
	NEG	1967 (Morphine) & 910 (Hydromorphone)
	NEG	2313 (Morphine)
	NEG	2300 (Morphine)
	NEG	2100 (Morphine)
	NEG	2500 (Morphine)
	NEG	2700 (Morphine)

Rx Imola – Semi-quantitative

Cut-off value (ng/mL) for Morphine	Ranox Opiates Assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL) based on cross reactivity profile
2000	POS	1967 (Morphine)
	POS	1306 (Morphine)
	POS	462 (Morphine) & 629 (Codeine)
	POS	588 (Morphine) & 431 (Codeine)
	POS	728 (Morphine) & 250 (Codeine)
	POS	252 (Morphine) & 784 (Codeine)
	POS	1990 (Morphine)
	POS	1550 (Morphine)
	POS	1950 (Morphine)
	NEG	2174 (Morphine)
	NEG	2313 (Morphine)
	NEG	2300 (Morphine)
	NEG	2100 (Morphine)

Rx Imola – Qualitative

Cut-off value (ng/mL) for Morphine	Ranox Opiates Assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL) based on cross reactivity profile
2000	POS	1967 (Morphine)
	POS	462 (Morphine) & 629 (Codeine)
	POS	588 (Morphine) & 431 (Codeine)
	POS	728 (Morphine) & 250 (Codeine)
	POS	252 (Morphine) & 784 (Codeine)
	POS	1990 (Morphine)

	POS	1550 (Morphine)
	NEG	2174 (Morphine)
	NEG	2300 (Morphine)
	NEG	2100 (Morphine)
	NEG	2313 (Morphine)

b. Matrix comparison:

Not applicable. The test is only for urine specimens.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable. Not reviewed for this device type.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are 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.