510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K250741

B Applicant

Randox Laboratories Limited

C Proprietary and Established Names

Evidence MultiSTAT DOA Urine Multiplex

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
DJG	Class II	21 CFR 862.3650 - Opiate Test System	TX - Clinical Toxicology
DIO	Class II	21 CFR 862.3250 - Cocaine and cocaine metabolite test system	TX - Clinical Toxicology
LDJ	Class II	21 CFR 862.3870 - Cannabinoid test system	TX - Clinical Toxicology
DKZ	Class II	21 CFR 862.3100 - Amphetamine test system	TX - Clinical Toxicology
JXM	Class II	21 CFR 862.3170 - Benzodiazepine test system	TX - Clinical Toxicology
DJC	Class II	21 CFR 862.3610 - Methamphetamine test system	TX - Clinical Toxicology

DJR	Class II	21 CFR 862.3620 - Methadone test system	TX - Clinical Toxicology
DIS	Class II	21 CFR 862.3150 - Barbiturate test system	TX - Clinical Toxicology
LCM	Unclassified		

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Fentanyl, Opiates, Benzoylecgonine/Cocaine, Cannabinoids (THC), Amphetamine, Benzodiazepines 2

C Type of Test:

Chemiluminescent immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Evidence MultiSTAT DOA Urine MultiPlex is intended for use with the Evidence MultiSTAT. The Evidence MultiSTAT is an analyser intended for the qualitative determination of parent drug molecule and metabolites of drugs in human urine at the associated cut offs.

The Evidence MultiSTAT DOA Urine MultiPlex detects the following drugs at the following cut offs:

Analyte	Analyte in Cut Off Material	Cut Off
Methamphetamine	S-(+)-Methamphetamine	500ng/ml
Noroxycodone	Noroxycodone	100ng/ml
Benzodiazepines 1	Oxazepam	200ng/ml
Methadone	(+)-Methadone	300ng/ml
Phenobarbital	Phenobarbital	200ng/ml
Tramadol	Tramadol	200ng/ml
Phencyclidine	Phencyclidine	25ng/ml

Buprenorphine	Norbuprenorphine	5ng/ml
6-Acetylmorphine	6-Acetylmorphine	10ng/ml
Fentanyl	Fentanyl	1ng/ml
Benzodiazepines 2	Lorazepam	200ng/ml
Opiates	Morphine	300ng/ml
Benzoylecgonine/Cocaine	Benzoylecgonine	150ng/ml
Cannabinoids (THC)	(-)-11-nor-9-Carboxy-Δ9-THC	50ng/ml
Amphetamine	S-(+)-Amphetamine	500ng/ml

The Evidence MultiSTAT DOA Urine MultiPlex provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) and/or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) are the preferred confirmatory methods. Other chemical confirmation methods are available. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

For In Vitro Diagnostic use only.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

Evidence MultiSTAT

IV Device/System Characteristics:

A Device Description:

The Evidence MultiSTAT is a benchtop fully automated Biochip Array System analyzer. The Evidence MultiSTAT DOA Urine MultiPlex test kit components include a sealed urine test cartridge which contains materials for the determination of the claimed analytes at the associated cut-off. This submission represents the following claimed analytes and associated cut off concentrations; Fentanyl at 1ng/ml, Opiates at 300ng/ml, Benzoylecgonine/Cocaine at 150ng/ml, Cannabinoids (THC) at 50ng/ml, Amphetamine at 500ng/ml, and Benzodiazepines 2 at 200ng/ml.

The Evidence MultiSTAT DOA Urine MultiPlex test kit will comprise of:
- 12 x Urine Test Cartridges
- 6 x 1mL Urine Cut Off Material (lyophilized)
- 4 x 1mL Urine Positive Control Material (lyophilized)
- 2 x 10mL Reconstitution Buffer
- 1 x Batch Barcodes

Each kit is supplied with the Evidence MutliSTAT Accessory Kit which contains:

• 12 x MultiSTAT Tip Cartridges
• 1 x Tip/Waste Cartridge
• 6 x 1000 µl Pipette Tip
• 1 x Liquid Absorber

The Reagent Composition of the test kit will comprise:

•MultiSTAT DOA Urine MultiPlex Assay Diluent - 20 mM phosphate buffer, pH 7.0 containing protein, detergents, and preservatives. This is contained within the cartridge.
• MultiSTAT DOA Urine MultiPlex Conjugate - 20 mM Tris based buffer, pH 7.0 containing protein, preservatives, and horseradish peroxidase - labelled drug derivatives. This is contained within the cartridge.
• MultiSTAT DOA Urine MultiPlex Biochip - Solid substrate containing immobilized antibody discrete test regions. This is contained within the cartridge.
• MultiSTAT DOA Urine MultiPlex Wash Buffer - 20 mM Tris buffered saline, pH 7.4, containing surfactant and preservatives. This is contained within the cartridge.
• LUM-EV934/PX - Luminol-EV934 and Peroxide are contained within the cartridge and are mixed in a ratio of 1:1 by the analyser to give the working signal reagent
• MultiSTAT DOA Urine MultiPlex Cut Off - Lyophilised, 20 mM phosphate buffer, pH 7.2 containing stabilizers, preservatives and drug concentrations at the assay cut off values.
• MultiSTAT DOA Urine MultiPlex Positive Control - Lyophilised, 20 mM phosphate buffer, pH 7.2 containing stabilizers, preservatives, and drug concentrations at 50% higher than the cutoff values.
• MultiSTAT Reconstitution Buffer – A solution at a neutral pH containing preservatives.

B Principle of Operation:

The candidate device performs simultaneous detection of multiple analytes from a single sample. The core technology is the Randox Biochip, a solid-state device containing an array of discrete test regions containing immobilized antibodies specific to different Drugs of Abuse (DOA) compound classes. A competitive chemiluminescent immunoassay is used for the DOA assays with the drug in the specimen and drug labelled with horseradish peroxidase (HRP) being in direct competition for the antibody binding sites. Increased levels of drug in a specimen will lead to reduced binding of drug labelled with HRP and thus a reduction in chemiluminescence being emitted. The light signal generated from each of the test regions on the biochip is detected by a Charge Coupled Device (CCD) camera in the Evidence MultiSTAT analyzer which, together with the analyzer software, is used to quantify the light output and produce results. The tests employ a qualitative reporting method. Each test sample is assayed against the provided Cut Off material of known concentration, which is used to determine the classification of the samples based on the comparison of the signal output.

The immunoassay processes are performed automatically in a self-contained and sealed biochip cartridge, which holds the biochips, the reagents, wash buffer and other fluids required for the test to be conducted.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Evidence MultiSTAT DOA Urine MultiPlex, Evidence MultiSTAT

B Predicate 510(k) Number(s):
K220451

C Comparison with Predicate(s):

Device & Predicate Device(s):	Candidate Device K250741	K220451
Device Trade Name	Evidence MultiSTAT Urine DOA MultiPlex	Evidence MultiSTAT Urine DOA MultiPlex, Evidence MultiSTAT
General Device Characteristic Similarities		
Intended Use/Indications For Use	Same	For qualitative determination of parent drug molecule and metabolites of drugs in human urine
Sample Matrix	Same	Urine
General Device Characteristic Differences		
Specific Analytes	Fentanyl, Opiates, Benzoylecgonine/Cocaine, Cannabinoids (THC), Amphetamine, Benzodiazepines 2, Phenobarbital, Tramadol, Phencyclidine, Buprenorphine, 6-Acetylmorphine, Methamphetamine, Noroxycodone, Benzodiazepines 1 and Methadone.	Same except no Fentanyl, Opiates, Benzoylecgonine/Cocaine, Cannabinoids (THC), Amphetamine, Benzodiazepines 2, Phenobarbital, Tramadol, Phencyclidine, Buprenorphine and 6-Acetylmorphine.

VI Standards/Guidance Documents Referenced:

CLSI EP12 – A2 – User Protocol for Evaluation of Qualitative Test Performance.

CLSI EP25 – A – Evaluation of Stability of In Vitro Diagnostic Reagents.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

A precision study was conducted using drug free negative urine that was spiked with the appropriate analyte at; -100%, -75%, -50%, -25%, +25%, +50%, +75 %, +100%, of the cut off as well as at the cut off. The test was performed by at least two (2) operators on 3 instruments (1 instrument for Benzodiazepine 2), with 40 replicates per lot. Data for each analyte is represented below. Data for Methamphetamine at 500 ng/ml, Noroxycodone at 100 ng/ml, Benzodiazepines I at 200 ng/ml, and Methadone at 300 ng/ml was reported in K220451 while data for Phenobarbital at 200 ng/ml, Tramadol at 200 ng/ml, Phencyclidine at 25 ng/ml, Buprenorphine at 5 ng/ml, 6-Acetylmorphine at 10 ng/ml was reported in K221550.

Fentanyl								
Concentration (ng/ml)	% of Cut Off	Number of determinations	Lot 1		Lot 2		Lot 3	
			Negative	Positive	Negative	Positive	Negative	Positive
0.00	-100%	40	40	0	40	0	40	0
0.25	-75%	40	40	0	40	0	40	0
0.50	-50%	40	40	0	40	0	40	0
0.75	-25%	40	14	26	23	17	22	18
1.00	Cut Off	40	0	40	6	34	3	37
1.25	+25%	40	0	40	0	40	0	40
1.50	+50%	40	0	40	0	40	0	40
1.75	+75%	40	0	40	0	40	0	40
2.00	+100%	40	0	40	0	40	0	40

Opiates								
Concentration (ng/ml)	% of Cut Off	Number of determinations	Lot 1		Lot 2		Lot 3	
			Negative	Positive	Negative	Positive	Negative	Positive
0	-100%	40	40	0	40	0	40	0
75	-75%	40	40	0	40	0	40	0
150	-50%	40	40	0	40	0	40	0
225	-25%	40	39	1	39	1	39	1
300	Cut Off	40	30	10	22	18	21	19
375	+25%	40	5	35	1	39	3	37
450	+50%	40	0	40	0	40	0	40
525	+75%	40	0	40	0	40	0	40
600	+100%	40	0	40	0	40	0	40

Benzoylecgonine/Cocaine								
Concentration (ng/ml)	% of Cut Off	Number of determinations	Lot 1		Lot 2		Lot 3	
			Negative	Positive	Negative	Positive	Negative	Positive
0.0	-100%	40	40	0	40	0	40	0

37.5	-75%	40	40	0	40	0	40	0
75.0	-50%	40	40	0	40	0	40	0
112.5	-25%	40	37	3	34	6	29	11
150.0	Cut Off	40	17	23	16	24	14	26
187.5	+25%	40	0	40	0	40	1	39
225.0	+50%	40	0	40	0	40	0	40
262.5	+75%	40	0	40	0	40	0	40
300.0	+100%	40	0	40	0	40	0	40

Cannabinoids (THC)								
			Lot 1		Lot 2		Lot 3	
Concentration (ng/ml)	% of Cut Off	Number of determinations	Negative	Positive	Negative	Positive	Negative	Positive
0.0	-100%	40	40	0	40	0	40	0
12.5	-75%	40	40	0	40	0	40	0
25.0	-50%	40	40	0	40	0	40	0
37.5	-25%	40	39	1	40	0	40	0
50.0	Cut Off	40	34	6	38	2	33	7
62.5	+25%	40	10	30	11	29	6	34
75.0	+50%	40	0	40	0	40	0	40
87.5	+75%	40	0	40	0	40	0	40
100.0	+100%	40	0	40	0	40	0	40

Amphetamine								
			Lot 1		Lot 2		Lot 3	
Concentration (ng/ml)	% of Cut Off	Number of determinations	Negative	Positive	Negative	Positive	Negative	Positive
0	-100%	40	40	0	40	0	40	0
125	-75%	40	40	0	40	0	40	0
250	-50%	40	40	0	40	0	40	0
375	-25%	40	36	4	37	3	34	6
500	Cut Off	40	5	35	6	34	2	38
625	+25%	40	0	40	0	40	1	39
750	+50%	40	0	40	0	40	0	40
875	+75%	40	0	40	0	40	0	40
1000	+100%	40	0	40	0	40	0	40

Benzodiazepines 2								
			Lot 1		Lot 2		Lot 3	
Concentration (ng/ml)	% of Cut Off	Number of determinations	Negative	Positive	Negative	Positive	Negative	Positive
0	-100%	40	40	0	40	0	40	0

50	-75%	40	40	0	40	0	40	0
100	-50%	40	40	0	40	0	40	0
150	-25%	40	40	0	39	1	38	2
200	Cut Off	40	6	34	6	34	7	33
250	+25%	40	0	40	0	40	0	40
300	+50%	40	0	40	0	40	0	40
350	+75%	40	0	40	0	40	0	40
400	+100%	40	0	40	0	40	0	40

2. Linearity:

   Not applicable. These devices are intended for qualitative use only.

3. Analytical Specificity/Interference:

   Potential interference from various compounds were tested by spiking the potentially interfering compound into drug-free urine containing the target drug concentrations at 50% below and 50% above the threshold cut off level. If interference was observed, the interferent was titrated down and the concentration at which no interference is observed quoted. The following compounds were found not to interfere with test results when tested up to the concentrations identified in the table below. Data for Methamphetamine at 500 ng/ml, Noroxycodone at 100 ng/ml, Benzodiazepines I at 200 ng/ml, and Methadone at 300 ng/ml was reported in K220451 while data for Phenobarbital at 200 ng/ml, Tramadol at 200 ng/ml, Phencyclidine at 25 ng/ml, Buprenorphine at 5 ng/ml, 6-Acetylmorphine at 10 ng/ml was reported in K221550.

Interference: Fentanyl Assay	
Compound	Concentration Tested
Acetaminophen	1mg/ml
Acetylsalicylic Acid	1mg/ml
Albuterol (salbutamol)	100,000ng/ml
Amitriptyline	10,000ng/ml
Amobarbital	100,000ng/ml
d,l-Amphetamine-D5	500,000ng/ml
Benzoylecgonine	500,000ng/ml
Bupropion	500,000ng/ml
Caffeine	1mg/ml
Carbamazepine 10,11 epoxide	100,000ng/ml
Carbamazepine	100,000ng/ml
Chlorpromazine	10,000ng/ml
Clomipramine	100,000ng/ml
Cyclobenzaprine	25,000ng/ml
Desipramine	10,000ng/ml
Doxepin	10,000ng/ml
Ecgonine	100,000ng/ml
Ephedrine	75,000ng/ml

Fluoxetine	100,000ng/ml
Fluphenazine	100,000ng/ml
Ibuprofen	500,000ng/ml
Imipramine	10,000ng/ml
Ketamine	100,000ng/ml
Lidocaine	500,000ng/ml
Maprotiline	50,000ng/ml
Methaqualone	500,000ng/ml
Metronidazole	300,000ng/ml
(−)-Nicotine	100,000ng/ml
(±)-Norketamine	100,000ng/ml
Nortriptyline	100,000ng/ml
Oxazepam	75,000ng/ml
Phenobarbital	500,000ng/ml
Dextropropoxyphene	100,000ng/ml
D-Norpropoxyphene	10,000ng/ml
Ranitidine	0.5mg/ml
Secobarbital	500,000ng/ml
Valproic acid	500,000ng/ml
Venlafaxine	100,000ng/ml
Acetone	1000mg/dL (10mg/ml)
L-Ascorbic Acid	1500mg/dL (15mg/ml)
Bilirubin	15mg/dL (0.15mg/ml)
Creatinine	500mg/dL (5mg/ml)
Ethanol	1000mg/dL (10mg/ml)
D-(+)-Galactose	10mg/dL (0.1mg/ml)
Gamma globulin	500mg/dL (5mg/ml)
D-(+)-Glucose	3000mg/dL (30mg/ml)
Hemoglobin	500mg/dL (5mg/ml)
Human Serum Allbumin	500mg/dL (5mg/ml)
Oxalic Acid	200mg/dL (2mg/ml)
(−)-Riboflavin	7.5mg/dL (0.075mg/ml)
Sodium Chloride	6000mg/dL (60mg/ml)
Urea	60mg/ml
Boric acid	1% w/v (10mg/ml)
Codeine	100,000ng/ml
Morphine	500,000ng/ml
Naloxone	100,000ng/ml
Naltrexone	100,000ng/ml
*Methapyrilene	10,000ng/ml
*Phencyclidine (PCP)	10,000ng/ml

*Methapyrilene and Phencyclidine (PCP) elicited interference at 10,000ng/ml with the Fentanyl Assay. Cross reactivity was therefore assessed. Assessment of cross reactivity was conducted

using approximate concentrations of 50,000ng/ml (for both compounds) diluted into drug free negative urine. Both compounds generated an approximate % cross reactivity of 0.002.

Interference: Opiates Assay	
Compound	Concentration Tested
Oxazepam	500,000ng/ml
(±)-Lorazepam	500,000ng/ml
Temazepam	500,000ng/ml
Nordiazepam (desmethyldiazepam)	500,000ng/ml
Nitrazepam	500,000ng/ml
Flunitrazepam	500,000ng/ml
nor-9-Carboxy- Δ9-THC	100,000ng/ml
Barbital	500,000ng/ml
Benzoylecgonine	500,000ng/ml
Butalbital	100,000ng/ml
d,l-Amphetamine-D5	500,000ng/ml
d(+)-Amphetamine	300,000ng/ml
(±)-MDA	500,000ng/ml
3,4-MDEA	500,000ng/ml
MDMA	500,000ng/ml
(−)- Methamphetamine	500,000ng/ml
Pentobarbital	500,000ng/ml
Phencyclidine	500,000ng/ml
Phenobarbital	500,000ng/ml
Secobarbital	500,000ng/ml
Acetaminophen	1mg/ml
Acetone	1000mg/dL (10mg/ml)
Acetylsalicylic Acid	1mg/ml
L-Ascorbic Acid	1500mg/dL (15mg/ml)
Caffeine	1mg/ml
Creatinine	500mg/dL (5mg/ml)
Ethanol	1000mg/dL (10mg/ml)
D-(+)-Galactose	10mg/dL (0.1mg/ml)
Gamma globulin	500mg/dL (5mg/ml)
D-(+)-Glucose	3000mg/dL (30mg/ml)
Hemoglobin	500mg/dL (5mg/ml)
Human Serum Allbumin	500mg/dL (5mg/ml)
Ibuprofen	500,000ng/ml
Oxalic Acid	200mg/dL (2mg/ml)
Ranitidine	0.5mg/ml
(−)-Riboflavin	7.5mg/dL (0.075mg/ml)
Sodium Chloride	6000mg/dL (60mg/ml)
Urea	60mg/ml
Naloxone	100,000ng/ml
Naltrexone	100,000ng/ml
Imipramine	100,000ng/ml

Interference: Benzoylecgonine/Cocaine Assay	
Compound	Concentration Tested
Acetaminophen	1mg/ml
Acetone	1000mg/dL (10mg/ml)
L-Ascorbic Acid	1500mg/dL (15mg/ml)
Acetylsalicylic Acid	1mg/ml
Caffeine	1mg/ml
Creatinine	500mg/dL (5mg/ml)
Ethanol	1000mg/dL (10mg/ml)
D-(+)-Galactose	10mg/dL (0.1mg/ml)
Gamma globulin	500mg/dL (5mg/ml)
D-(+)-Glucose	3000mg/dL (30mg/ml)
Hemoglobin	500mg/dL (5mg/ml)
Human Serum Allbumin	500mg/dL (5mg/ml)
Ibuprofen	500,000ng/ml
Oxalic Acid	200mg/dL (2mg/ml)
(−)-Riboflavin	7.5mg/dL (0.075mg/ml)
Sodium Chloride	6000mg/dL (60mg/ml)
Urea	60mg/ml
d,l-Amphetamine-D5	500,000ng/ml
Bupropion	500,000ng/ml
Chlorpheniramine	500,000ng/ml
Fluoxetine	100,000ng/ml
Meperidine (Pethidine)	500,000ng/ml
(±)-Methadone	500,000ng/ml
(−)- Methamphetamine	500,000ng/ml
Methaqualone	500,000ng/ml
Morphine	500,000ng/ml
Nifedipine	100,000ng/ml
Oxazepam	500,000ng/ml
Phencyclidine	500,000ng/ml
Phenobarbital	500,000ng/ml
Dextropropoxyphene	500,000ng/ml
Ranitidine	0.5mg/ml
Secobarbital	500,000ng/ml
Valproic acid	500,000ng/ml

Interference: Cannabinoids (THC) Assay	
Compound	Concentration Tested
Acetaminophen	1mg/ml
Acetylsalicylic acid	500,000ng/ml
Amitriptyline	500,000ng/ml
Amobarbital	500,000ng/ml

d,l-Amphetamine-D5	500,000ng/ml
d(+)-Amphetamine	300,000ng/ml
Benzoylecgonine	500,000ng/ml
Bupropion	500,000ng/ml
Caffeine	1mg/ml
Chlorpheniramine	500,000ng/ml
Chlorpromazine	500,000ng/ml
Cocaine	500,000ng/ml
Codeine	500,000ng/ml
Dextromethorphan	100,000ng/ml
Ecgonine Methyl Ester	500,000ng/ml
(1S,2R)-(+)-Ephedrine	500,000ng/ml
Imipramine	500,000ng/ml
JWH-018	500,000ng/ml
JWH-073	500,000ng/ml
Lidocaine	500,000ng/ml
Meperidine (Pethidine)	500,000ng/ml
(±)-Methadone	500,000ng/ml
(−)- Methamphetamine	500,000ng/ml
Methaqualone	500,000ng/ml
Morphine	500,000ng/ml
Nortriptyline	500,000ng/ml
Oxazepam	500,000ng/ml
Phencyclidine	500,000ng/ml
Pentobarbital	500,000ng/ml
Promethazine	100,000ng/ml
Dextropropoxyphene	500,000ng/ml
D-Norpropoxyphene	500,000ng/ml
Ranitidine	0.5mg/ml
Secobarbital	500,000ng/ml
Valproic acid	500,000ng/ml
Acetone	1000mg/dL (10mg/ml)
L-Ascorbic Acid	500mg/dL (5mg/ml)
Creatinine	500mg/dL (5mg/ml)
Ethanol	1000mg/dL (10mg/ml)
D-(+)-Galactose	10mg/dL (0.1mg/ml)
Gamma globulin	500mg/dL (5mg/ml)
D-(+)-Glucose	3000mg/dL (30mg/ml)
Hemoglobin	500mg/dL (5mg/ml)
Human Serum Allbumin	500mg/dL (5mg/ml)
Oxalic Acid	100mg/dL (1mg/ml)
(−)-Riboflavin	7.5mg/dL (0.075mg/ml)
Sodium Chloride	6000mg/dL (60mg/ml)
Urea	60mg/ml

Interference: Amphetamine Assay	
Compound	Concentration Tested

Creatinine	500mg/dL (5mg/ml)
D-(+)-Glucose	3000mg/dL (30mg/ml)
Human Serum Allbumin	500mg/dL (5mg/ml)
Sodium Chloride	6000mg/dL (60mg/ml)
Oxalic Acid	200mg/dL (2mg/ml)
Urea	60mg/ml
Acetone	1000mg/dL (10mg/ml)
L-Ascorbic Acid	1500mg/dL (15mg/ml)
Ethanol	1000mg/dL (10mg/ml)
Hemoglobin	500mg/dL (5mg/ml)
Bilirubin	15mg/dL (0.15mg/ml)
Acetaminophen	1mg/ml
Acetylsalicylic Acid	1mg/ml
Amitriptyline	100,000ng/ml
Aspartame	100,000ng/ml
Benzocaine	100,000ng/ml
Benzoylecgonine	500,000ng/ml
Caffeine	1mg/ml
Cannabidiol	100,000ng/ml
Cocaine	100,000ng/ml
Codeine	100,000ng/ml
Desipramine	100,000ng/ml
Dextromethorphan	100,000ng/ml
Dextropropoxyphene	500,000ng/ml
Diazepam	100,000ng/ml
Digoxin	100,000ng/ml
Diphenhydramine	100,000ng/ml
Diphenylhydantoin (Phenytoin)	100,000ng/ml
Doxepin	100,000ng/ml
Ecgonine	100,000ng/ml
Ecgonine Methyl Ester	500,000ng/ml
Erythromycin	100,000ng/ml
Furosemide	100,000ng/ml
Guaiacol glyceryl ether	100,000ng/ml
Hydrochlorothiazide	100,000ng/ml
Ibuprofen	500,000ng/ml
Ketamine	100,000ng/ml
L-Thyroxine	100,000ng/ml
LSD	100,000ng/ml
Meperidine (Pethidine)	500,000ng/ml
(±)-Methadone	500,000ng/ml
Methaqualone	500,000ng/ml
Morphine	500,000ng/ml
Naloxone	100,000ng/ml
Naltrexone	100,000ng/ml
Naproxen	100,000ng/ml
Niacinamide (Nicotinamide)	100,000ng/ml

(−)-Nicotine	100,000ng/ml
Nifedipine	100,000ng/ml
Nordiazepam (desmethyldiazepam)	500,000ng/ml
Omeprazole	100,000ng/ml
Oxazepam	500,000ng/ml
Penicillin G	100,000ng/ml
Phencyclidine	500,000ng/ml
Phenobarbital	500,000ng/ml
Quinine	100,000ng/ml
Secobarbital	500,000ng/ml
Tetracycline	100,000ng/ml
Delta-9-THC	100,000ng/ml
(1S,2R)-(+)-Ephedrine	500,000ng/ml

Interference: Benzodiazepines 2 Assay	
Compound	Concentration Tested
Acetone	1000mg/dL
Ethanol	1000mg/dL
Glucose	3000mg/dL
Oxalic Acid	100mg/dL
Sodium Chloride	6000mg/dL
Caffeine	1mg/mL
Ascorbic Acid	1500mg/dL
Galactose	10mg/dL
Haemoglobin	300mg/dL
Riboflavin	7.5mg/dL
Acetaminophen	1mg/mL
Ibuprofen	1mg/mL
Creatinine	5mg/mL
Gamma Globulin	500mg/dL
Human Serum Albumin	500mg/dL
Urea	3500mg/dL
Acetylsalicylic Acid	1mg/mL
Ranitidine	0.9mg/ml
Sodium Fluoride	10g/L
Procaine HCL	100,000ng/ml
Furosemide	100,000ng/ml
Sodium Azide	10mg/ml
Boric Acid	10mg/ml
(1S,2R)-(+)-Ephedrine	500,000ng/ml
(1R,2R)-(-)- Pseudoephedrine	100,000ng/ml
(1S, 2S)-(+)- Pseudoephedrine	100,000ng/ml
(-)-alpha- Acetylmethadol HCL	100,000ng/ml
Chloramphenicol	100,000ng/ml
Labetalol HCL	100,000ng/ml
Atropine Sulfate	100,000ng/ml
(±)-Methadone Hydrochloride	500,000ng/ml

(+) -Methamphetamine Hydrochloride	500,000ng/ml
Bilirubin	0.15mg/ml
Codeine Monohydrate	500,000ng/ml
MDEA HCL	500,000ng/ml
Quinidine	100,000ng/ml
(-)-isoproterenol HCl	100,000ng/ml
(-)-Cotinine	100,000ng/ml
Cocaine Hydrochloride	500,000ng/ml
Benzoylecgonine Tetrahydrate	500,000ng/ml
Morphine Sulfate Salt Pentahydrate	500,000ng/ml
(-)-11-Nor-Δ9-THC Carboxylic Acid	500,000ng/ml
Aspartame	100,000ng/ml
Benzilic Acid	100,000ng/ml
Estrone	100,000ng/ml
Chlorpheniramine	500,000ng/ml
EDDP Perchlorate	100,000ng/ml
Loperamide Hydrochloride	100,000ng/ml
Pentobarbital	500,000ng/ml
Oxycodone Hydrochloride	100,000ng/ml
Heroin	100,000ng/ml
Chloroquine	100,000ng/ml
Ecgonine Methyl Ester	500,000ng/ml
Ketamine HCl	100,000ng/ml
(-) 11-Hydroxy- delta9-THC	100,000ng/ml
(±)-MDMA	100,000ng/ml
Phencyclidine	100,000ng/ml
6-Acetylmorphine	100,000ng/ml
(±)-MDA	100,000ng/ml
Amitriptyline HCl	125,000ng/ml
(±) MBDB	100,000ng/ml
Cannabidiol	100,000ng/ml
EMDP	100,000ng/ml
Secobarbital	100,000 ng/ml
d,l-Amphetamine-D5 HCl	100,000 ng/ml
Amobarbital	100,000ng/ml
(-)-Δ9-THC	100,000ng/ml
Dihydrocodeine	100,000ng/ml
Cocaethylene (Benzoylecgonine ethyl ester)	100,000ng/ml
Perphenazine	100,000ng/ml
Phenethylamine (β- Phenylethylamine)	100,000ng/ml

Analytical Specificity:

To test cross-reactivity, drug metabolites and other compounds that may be present in human urine samples were tested using the candidate device. The sponsor identified the

concentration of each compound prepared in drug free negative urine that would produce a positive response for each assay when analyzed against the cut off material. The following is a summary of the cross-reactivity study. Data for Methamphetamine at 500 ng/ml, Noroxycodone at 100 ng/ml, Benzodiazepines I at 200 ng/ml, and Methadone at 300 ng/ml was reported in K220451 while data for Phenobarbital at 200 ng/ml, Tramadol at 200 ng/ml, Phencyclidine at 25 ng/ml, Buprenorphine at 5 ng/ml, 6-Acetylmorphine at 10 ng/ml was reported in K221550.

Fentanyl Assay Specificity- Unrelated Compounds		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
S(+)-Methamphetamine	Negative at 50,000ng/ml	<0.002
Noroxycodone	Negative at 100,000ng/ml	<0.001
Oxazepam	Negative at 50,000ng/ml	<0.002
(±)-Methadone	Negative at 50,000ng/ml	<0.002
Phenobarbital	Negative at 50,000ng/ml	<0.002
Tramadol	Negative at 100,000ng/ml	<0.001
Norbuprenorphine	Negative at 100,000ng/ml	<0.001
6-Acetylmorphine	Negative at 100,000ng/ml	<0.001
Lorazepam	Negative at 50,000ng/ml	<0.002
Morphine	Negative at 50,000ng/ml	<0.002
Benzoylecgonine	Negative at 100,000ng/ml	<0.001
(-)-11-nor-9-Carboxy-Δ^9-THC	Negative at 100,000ng/ml	<0.001
S(+)-Amphetamine	Negative at 50,000ng/ml	<0.002

Opiates Assay Specificity- Unrelated Compounds		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
S(+)-Methamphetamine	Negative at 50,000ng/ml	<0.6
Noroxycodone	Negative at 100,000ng/ml	<0.3
Oxazepam	Negative at 50,000ng/ml	<0.6
(±)-Methadone	Negative at 50,000ng/ml	<0.6
Phenobarbital	Negative at 50,000ng/ml	<0.6
Tramadol	Negative at 100,000ng/ml	<0.3
Phencyclidine	Negative at 50,000ng/ml	<0.6
Norbuprenorphine	Negative at 100,000ng/ml	<0.3
Fentanyl	Negative at 50,000ng/ml	<0.6
Lorazepam	Negative at 50,000ng/ml	<0.6
Benzoylecgonine	Negative at 100,000ng/ml	<0.3
(-)-11-nor-9-Carboxy-Δ^9-THC	Negative at 100,000ng/ml	<0.3
S(+)-Amphetamine	Negative at 50,000ng/ml	<0.6

Benzoylecgonine/Cocaine Assay Specificity- Unrelated Compounds		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
S(+)-Methamphetamine	Negative at 50,000ng/ml	<0.3
Noroxycodone	Negative at 100,000ng/ml	<0.15

Oxazepam	Negative at 50,000ng/ml	<0.3
(±)-Methadone	Negative at 50,000ng/ml	<0.3
Phenobarbital	Negative at 50,000ng/ml	<0.3
Tramadol	Negative at 100,000ng/ml	<0.15
Phencyclidine	Negative at 50,000ng/ml	<0.3
Norbuprenorphine	Negative at 100,000ng/ml	<0.15
6-Acetylmorphine	Negative at 100,000ng/ml	<0.15
Fentanyl	Negative at 50,000ng/ml	<0.3
Lorazepam	Negative at 50,000ng/ml	<0.3
Morphine	Negative at 50,000ng/ml	<0.3
(-)-11-nor-9-Carboxy-Δ^9-THC	Negative at 100,000ng/ml	<0.15
S(+)-Amphetamine	Negative at 50,000ng/ml	<0.3

Cannabinoids (THC) Assay Specificity- Unrelated Compounds		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
S(+)-Methamphetamine	Negative at 50,000ng/ml	<0.1
Noroxycodone	Negative at 100,000ng/ml	<0.05
Oxazepam	Negative at 50,000ng/ml	<0.1
(±)-Methadone	Negative at 50,000ng/ml	<0.1
Phenobarbital	Negative at 50,000ng/ml	<0.1
Tramadol	Negative at 100,000ng/ml	<0.05
Phencyclidine	Negative at 50,000ng/ml	<0.1
Norbuprenorphine	Negative at 100,000ng/ml	<0.05
6-Acetylmorphine	Negative at 100,000ng/ml	<0.05
Fentanyl	Negative at 50,000ng/ml	<0.1
Lorazepam	Negative at 50,000ng/ml	<0.1
Morphine	Negative at 50,000ng/ml	<0.1
Benzoylecgonine	Negative at 100,000ng/ml	<0.05
S(+)-Amphetamine	Negative at 50,000ng/ml	<0.1

Amphetamine Assay Specificity- Unrelated Compounds		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
S(+)-Methamphetamine	Negative at 50,000ng/ml	<1
Noroxycodone	Negative at 100,000ng/ml	<0.5
Oxazepam	Negative at 50,000ng/ml	<1
(±)-Methadone	Negative at 50,000ng/ml	<1
Phenobarbital	Negative at 50,000ng/ml	<1
Tramadol	Negative at 100,000ng/ml	<0.5
Phencyclidine	Negative at 50,000ng/ml	<1
Norbuprenorphine	Negative at 100,000ng/ml	<0.5
6-Acetylmorphine	Negative at 100,000ng/ml	<0.5
Fentanyl	Negative at 50,000ng/ml	<1
Lorazepam	Negative at 50,000ng/ml	<1

Morphine	Negative at 50,000ng/ml	<1
Benzoylecgonine	Negative at 100,000ng/ml	<0.5
(-)-11-nor-9-Carboxy-Δ9-THC	Negative at 100,000ng/ml	<0.5

Benzodiazepines 2 Assay Specificity- Unrelated Compounds		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
S(+)-Methamphetamine	Negative at 50,000ng/ml	<0.4
S(+)-Amphetamine	Negative at 50,000ng/ml	<0.4
Phenobarbital	Negative at 50,000ng/ml	<0.4
(-)-11-nor-9-Carboxy-Δ9-THC	Negative at 50,000ng/ml	<0.4
Benzoylecgonine	Negative at 50,000ng/ml	<0.4
(±)-Methadone	Negative at 50,000ng/ml	<0.4
Morphine	Negative at 50,000ng/ml	<0.4
Fentanyl	Negative at 50,000ng/ml	<0.4
Noroxycodone	Negative at 50,000ng/ml	<0.4
Tramadol	Negative at 50,000ng/ml	<0.4
Norbuprenorphine	Negative at 50,000ng/ml	<0.4
6-Acetylmorphine	Negative at 50,000ng/ml	<0.4
Phencyclidine (PCP)	Negative at100,000ng/ml	<0.2

Specificity of Structurally Related Compounds:

The following structurally unrelated compounds were tested and were found not to be detected when measuring any of the claimed drugs (Fentanyl, Opiates, Benzoylecgonine/Cocaine, Cannabinoids (THC), Amphetamine, and Benzodiazepines 2). Data for Methamphetamine at 500 ng/ml, Noroxycodone at 100 ng/ml, Benzodiazepines I at 200 ng/ml, and Methadone at 300 ng/ml was reported in K220451 while data for Phenobarbital at 200 ng/ml, Tramadol at 200 ng/ml, Phencyclidine at 25 ng/ml, Buprenorphine at 5 ng/ml, 6-Acetylmorphine at 10 ng/ml was reported in K221550.

Fentanyl Assay Specificity- Related Compounds		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Fentanyl	1	100
Butyryl fentanyl	1	100
ß-hydroxyfentanyl	1.5	66.67
Furanyl fentanyl	2	50
Acrylfentanyl	2.5	40
(±) ß-hydroxythiofentanyl	3	33.33
Isobutyryl fentanyl	4	25
Para-fluorobutyryl fentanyl (p-FBF)	4	25
Norfentanyl	5	20
Para-fluoro fentanyl	5	20
4-Fluoro-isobutyryl fentanyl	10	10
Valeryl fentanyl	12	8.33
Ocfentanil	15	6.67

(±)-3-cis-methyl fentanyl	20	5
ω-1-Hydroxyfentanyl	25	4
Acetyl fentanyl	75	1.33
Acetyl norfentanyl	110	0.91
Remifentanil	300	0.33
Carfentanil	750	0.13
Norcarfentanil	4,500	0.02
Sufentanil	5,000	0.02
Alfentanil	10,000	0.01
Despropionyl fentanyl (4- ANPP)	15,000	0.01
Meperidine	25,000	0.004
Normeperidine	40,000	0.003
Tilidine	50,000	0.002
Methapyrilene	50,000	0.002
Phencyclidine (PCP)	50,000	0.002
6-Acetyl morphine	Negative at 100,000ng/ml	Not Detected
Buprenorphine	Negative at 100,000ng/ml	Not Detected
Buprenorphine glucuronide	Negative at 100,000ng/ml	Not Detected
Dextromethorphan	Negative at 100,000ng/ml	Not Detected
Dihydrocodeine	Negative at 100,000ng/ml	Not Detected
EDDP	Negative at 100,000ng/ml	Not Detected
EMDP	Negative at 100,000ng/ml	Not Detected
Heroin	Negative at 100,000ng/ml	Not Detected
Hydrocodone	Negative at 100,000ng/ml	Not Detected
Hydromorphone	Negative at 100,000ng/ml	Not Detected
9-Hydroxyrisperidone	Negative at 100,000ng/ml	Not Detected
Labetalol	Negative at 100,000ng/ml	Not Detected
Levorphanol	Negative at 100,000ng/ml	Not Detected
M-Chlorophenylpiperazine (m-CPP)	Negative at 100,000ng/ml	Not Detected
Methadone	Negative at 100,000ng/ml	Not Detected
Morphine-3-glucuronide	Negative at 100,000ng/ml	Not Detected
Norbuprenorphine	Negative at 100,000ng/ml	Not Detected
Norcodeine	Negative at 100,000ng/ml	Not Detected
Normorphine	Negative at 100,000ng/ml	Not Detected
Noroxycodone	Negative at 100,000ng/ml	Not Detected
Oxycodone	Negative at 100,000ng/ml	Not Detected
Oxymorphone	Negative at 100,000ng/ml	Not Detected
Pentazocine (Talwin)	Negative at 100,000ng/ml	Not Detected
Pipamperone	Negative at 100,000ng/ml	Not Detected
Quinine	Negative at 100,000ng/ml	Not Detected
Quinidine	Negative at 100,000ng/ml	Not Detected
Risperidone	Negative at 100,000ng/ml	Not Detected
Tapentadol	Negative at 100,000ng/ml	Not Detected
Thioridazine	Negative at 100,000ng/ml	Not Detected
Tramadol	Negative at 100,000ng/ml	Not Detected
Tramadol-O-Desmethyl	Negative at 100,000ng/ml	Not Detected
Tramadol-N-Desmethyl	Negative at 100,000ng/ml	Not Detected

Trazodone	Negative at 100,000ng/ml	Not Detected

Opiates Assay Specificity- Related Compounds		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Morphine	300	100
6-Monoacetylmorphine	35	857.1
6-Acetylcodeine	40	750.0
Heroin	85	352.9
Ethylmorphine	450	66.7
Codeine	480	62.5
Desomorphine	1,500	20.0
Morphine-3-glucuronide	1,700	17.6
Levorphanol	2,200	13.6
Dihydrocodeine	2,700	11.1
Hydromorphone	2,700	11.1
Morphine-6-βD-glucuronide	3,500	8.6
Hydrocodone	3,800	7.9
Thebaine	6,000	5.0
HCl (Meperidine HCl)	200,000	0.2
Nalorphine	220,000	0.1
Dextromethorphan	750,000	0.04
Norcodeine	Negative at 100,000ng/ml	Not Detected
Normorphine	Negative at 100,000ng/ml	Not Detected
Noroxycodone	Negative at 100,000ng/ml	Not Detected
Oxycodone	Negative at 100,000ng/ml	Not Detected
Oxymorphone	Negative at 100,000ng/ml	Not Detected

Benzoylecgonine/Cocaine Assay Specificity- Related Compounds		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Benzoylecgonine	150	100
Cocaethylene	50	300
Cocaine	80	187.5
Ecgonine Methyl Ester	15,000	1
Ecgonine	40,000	0.4
Norcocaine	45,000	0.3
Amobarbital	Negative at 500,000ng/ml	Not Detected
Amoxicillin	Negative at 500,000ng/ml	Not Detected
Atropine	Negative at 500,000ng/ml	Not Detected
Captopril	Negative at 500,000ng/ml	Not Detected
Chlordiazepoxide	Negative at 500,000ng/ml	Not Detected
Chlorpromazine	Negative at 500,000ng/ml	Not Detected
Codeine	Negative at 500,000ng/ml	Not Detected
Dextromethorphan	Negative at 500,000ng/ml	Not Detected
Diazepam	Negative at 500,000ng/ml	Not Detected
Digoxin	Negative at 500,000ng/ml	Not Detected

Enalapril	Negative at 500,000ng/ml	Not Detected
Glyburide	Negative at 500,000ng/ml	Not Detected
Lidocaine	Negative at 500,000ng/ml	Not Detected
Nicotine	Negative at 500,000ng/ml	Not Detected
Salicyluric acid	Negative at 500,000ng/ml	Not Detected
11-nor- THC-COOH	Negative at 500,000ng/ml	Not Detected
Verapamil	Negative at 500,000ng/ml	Not Detected

Cannabinoids (THC) Assay Specificity- Related Compounds		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
(-)-11-nor-9-Carboxy-Δ^9-THC	50	100
8-ß-hydroxy-Δ9-THC	100	50
(+-)-11-Nor-Δ9-THC-Carboxylic Acid	100	50
l-11-Hydroxy-Δ8-THC	200	25
l-11-Hydroxy-Δ9-THC	250	20
exo - THC	350	14.3
(-)-Δ8-THC	800	6.3
Cannabinol	1200	4.2
Nor-Δ9-THC-Carboxylic Acid-glucuronide	14,000	0.4
Δ9-THC	20,000	0.3
Cannabidiol	Negative at 100,000ng/ml	Not Detected

Amphetamine Assay Specificity- Related Compounds		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
S(+)-Amphetamine	500	100
(±) MDA	200	250
BDB	750	66.7
Phentermine	2,800	17.9
(±) MDEA	40,000	1.3
l-Amphetamine	50,000	1
(±) MDMA	100,000	0.5
Tyramine	100,000	0.5
S(+)-Methamphetamine	Negative at 50,000ng/ml	Not Detected
l-Methamphetamine	Negative at 50,000ng/ml	Not Detected
MBDB	Negative at 100,000ng/ml	Not Detected
Phendimetrazine	Negative at 50,000ng/ml	Not Detected
(±) Phenylpropanolamine	Negative at 100,000ng/ml	Not Detected
d-Pseudoephedrine	Negative at 100,000ng/ml	Not Detected

Benzodiazepines 2 Assay Specificity- Related Compounds		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Lorazepam	200	100.0
Phenazepam	180	111.1
Delorazepam	220	90.9

Meclonazepam	300	66.7
Clonazepam	650	30.8
Desalkylflurazepam	750	26.7
Flubromazepam	800	25.0
Nordiazepam	3,000	6.7
Oxazepam	4,000	5.0
Nitrazepam	15,000	1.3
Bromazepam	20,000	1.0
7-Aminoclonazepam	26,000	0.8
Diclazepam	25,000	0.8
Estazolam	50,000	0.4
Benzphetamine	90,000	0.2
Alprazolam	Negative at 20,000ng/ml	Not Detected
alpha-OH-Alprazolam	Negative at 20,000ng/ml	Not Detected
8-Aminoclonazolam	Negative at 20,000ng/ml	Not Detected
Carbamazepine	Negative at 300,000ng/ml	Not Detected
Chlordiazepoxide	Negative at 20,000ng/ml	Not Detected
Clonazolam	Negative at 20,000ng/ml	Not Detected
Clobazam	Negative at 100,000ng/ml	Not Detected
Diazepam	Negative at 20,000ng/ml	Not Detected
Etizolam	Negative at 20,000ng/ml	Not Detected
Flualprazolam	Negative at 20,000ng/ml	Not Detected
α-OH-Flualprazolam	Negative at 20,000ng/ml	Not Detected
Flubromazolam	Negative at 20,000ng/ml	Not Detected
Flunitrazepam	Negative at 20,000ng/ml	Not Detected
Flunitrazolam	Negative at 20,000ng/ml	Not Detected
Flurazepam	Negative at 250,000ng/ml	Not Detected
α-Hydroxytriazolam	Negative at 20,000ng/ml	Not Detected
1' Hydroxy midazolam	Negative at 20,000ng/ml	Not Detected
1' Hydroxy triazolam	Negative at 20,000ng/ml	Not Detected
Lormetazepam	Negative at 75,000ng/ml	Not Detected
Medazepam	Negative at 20,000ng/ml	Not Detected
Midazolam	Negative at 100,000ng/ml	Not Detected
Prazepam	Negative at 100,000ng/ml	Not Detected
Pyrazolam	Negative at 20,000ng/ml	Not Detected
Temazepam	Negative at 20,000ng/ml	Not Detected
Triazolam	Negative at 100,000ng/ml	Not Detected

Specific gravity and pH:

The effect of specific gravity for each analyte was evaluated by testing positive (50% above cutoff) and negative samples (50% below cutoff) at specific gravities ranging from 1.000 to 1.030. No interference was observed for all specific gravities tested.

The sponsor performed a study to evaluate whether low or high pH causes negative or positive interference with the candidate device. Samples containing the claimed drugs at concentrations corresponding to -50% and +50% of the cutoff were adjusted to pH levels

ranging from 3 to 11. Results for Fentanyl, Opiates and Cannabinoids (THC) showed no discrepant results at pH levels from 4-11. Results for Benzoylecgonine /Cocaine showed no discrepant results at pH levels from 3-10. Results Benzodiazepines 2 and Amphetamine showed no discrepant results at pH levels from 3-11. Data for Methamphetamine at 500 ng/ml, Noroxycodone at 100 ng/ml, Benzodiazepines I at 200 ng/ml, and Methadone at 300 ng/ml was reported in K220451 while data for Phenobarbital at 200 ng/ml, Tramadol at 200 ng/ml, Phencyclidine at 25 ng/ml, Buprenorphine at 5 ng/ml, 6-Acetylmorphine at 10 ng/ml was reported in K221550.

4. Assay Reportable Range:

   Not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   The assays are traceable to commercially available standards.

6. Detection Limit:

   Not applicable.

7. Assay Cut-Off:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   A method comparison study was conducted using clinical samples obtained from two sites and tested on the candidate device. Candidate device results were compared to results from a quantitative comparator method (e.g. LC-MS/MS, LC/MS or GC/MS). Results are summarized below. Data for Methamphetamine at 500 ng/ml, Noroxycodone at 100 ng/ml, Benzodiazepines I at 200 ng/ml, and Methadone at 300 ng/ml was reported in K220451 while data for Phenobarbital at 200 ng/ml, Tramadol at 200 ng/ml, Phencyclidine at 25 ng/ml, Buprenorphine at 5 ng/ml, 6-Acetylmorphine at 10 ng/ml was reported in K221550.

Analyte	N	Cut-Off (ng/ml)	Evidence MultSTAT Urine MultiPlex Result	Reference Method Results by GC/MS or LC-MS/MS Value			
				Low Negative Less than 50% below the Cut Off	Near Cut Off Negative Between 50% below the Cut Off	Near Cut Off Positive Between 50% above the Cut Off	High Positive Greater than 50% above the Cut Off
Fentanyl	98	1	Positive	0	20	8	43
			Negative	24	2	1	0

Opiates	84	300	Positive	2*	5	4	39
			Negative	28	6	0	0
Benzoylecogonine/ Cocaine)	87	150	Positive	0	4	4	39
			Negative	37	2	1	0
Cannabinoids (THC)	93	50	Positive	0	2	11	36
			Negative	25	13	6	0
Amphetamine	105	500	Positive	0	1	6	46
			Negative	42	7	3	0
Benzodiazepines 2	151	200	Positive	1**	4	7	31
			Negative	99	6	3	0

Discordant Sample Results:
*These samples contained hydromorphone, hydrocodone and/or codeine at levels shown to cause positive interference in Opiates testing,
**This sample contained oxazepam at levels expected to yield positive results when measured by Benzodiazepines 1, which is always run concurrently with Benzodiazepines 2.

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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