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

A. 510(k) Number:

k080057

B. Purpose for Submission:

New device

C. Measurands:

Oxycodone, amphetamines, phencyclidine (PCP), and cannabinoids (THC)

D. Type of Test:

Qualitative and semi-quantitative immunoassay

E. Applicant:

NOVX Systems, Inc.

F. Proprietary and Established Names:

iMDx Prep Reagent Plate
iMDx Prep Calibration Plate
iMDx Prep Control

G. Regulatory Information:

1. Regulation section:

   21 CFR § 862.3200 Clinical toxicology calibrator
   21 CFR § 862.3280 Clinical toxicology control material
   21 CFR § 862.3100 Amphetamine test system
   21 CFR § 862.3870 Cannabinoid test system
   21 CFR § 862.3650 Opiate test system
   Unclassified (PCP)

2. Classification:

   All Class II except for 862.3280 Clinical toxicology control material which is Class I (reserved)

3. Product Code:

   DLJ, DIF, DKZ, LDJ, DJG, LCM respectively

4. Panel:

   Toxicology (91)

H. Intended Use:

1. Intended use(s):

   Refer to indications for use below.

2. Indication(s) for use:

   The iMDx™ System is an in vitro diagnostic device consisting of the iMDx™ Analyzer and iMDxPrep™ Assays. The system is an expandable, closed system. All assays are designed for use with automated iMDx™ Analyzer. The system has been designed to be used by practitioners in drug rehabilitation clinics, physician offices, and clinical laboratories.

   The Amphetamines (Methamphetamine), Oxycodone (Oxycodone), Phencyclidine (Phencyclidine), and Cannabinoids (Δ^9-THC-COOH) assays are enzyme immunoassays with cutoffs of 1000 ng/mL, 100 ng/mL, 25 ng/mL, and 50 ng/mL, respectively. These assays are intended for use in the qualitative and semi-quantitative analysis of Amphetamines, Oxycodone, Phencyclidine, and Cannabinoids in human urine. Semi-quantitative analysis is only for estimation of dilution for confirmation testing.

   All assays provide only a preliminary result. Clinical consideration and professional judgment must be applied to a drug test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC/MS) analysis is performed. FOR USE BY TRAINED PERSONNEL ONLY. Only operators trained in the use of the iMDx™ System by NOVX personnel should perform these procedures.

3. Special condition for use statement(s):

   All assays provide only a preliminary result. Clinical consideration and professional judgment must be applied to a drug test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC/MS) analysis is preferred.

For prescription use.

The assay is intended for use in point-of-care settings.

Tests for oxycodone cannot distinguish between abused drugs and certain prescribed medications.

Certain foods or medications may interfere with tests for amphetamines and opiates and cause false positive results.

4. Special instrument Requirements:

iMDx™ Analyzer

I. Device Description:

The device consists of anti-drug monoclonal/polyclonal antibody coated plates and other reagents including enzyme-drug conjugate and substrate solution, stop solution, wash buffer, and calibrators. The specific antibodies are mouse monoclonal against oxycodone, amphetamine/methamphetamine, PCP, and THC.

The iMDx System contains the following items:

- iMDx Analyzer
- iMDxPrep MMT-1 Reagent plate is a sealed ready to use microplate that contains the reagents to perform testing for oxycodone, amphetamines, PCP, and cannabinoids.
- iMDxPrep MMT-1 Calibration Plate is a sealed ready to use microplate that contains calibrator solutions to perform a calibration for each of the analytes contained on the reagent plate.
- iMDxPrep MMT-1 Control is a ready to use human urine based liquid control containing oxycodone, methamphetamine, PCP, and cannabinoids.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Microgenics CEDIA® Amphetamine Assay
Microgenics CEDIA® Cannabinoids Assay
Microgenics DRI® Oxycodone Assay
Microgenics CEDIA® Phencyclidine Assay

2. Predicate k number(s):

k951154, k942337, k040411, k935650

3. Comparison with predicate:

The devices are for measurement of the same analytes in the same matrix, and utilize the same test methodology and cutoff concentrations. The predicate devices are for use on open automated chemistry analyzers, while the new device is a proprietary system that includes calibrators, controls, and reagents.

The reagent formulations vary between the two devices.

Similarities		
Item	**Predicate Devices**	**iMDx™ Analyzer**
Cutoffs	Oxycodone – 100 ng/mL Amphetamines –1000 ng/mL PCP – 25 ng/mL Cannabinoids – 50 ng/mL	Same
Qualitative or semi-quantitative	Both	Same
Method principle	Homogeneous enzyme immunoassay	Same
Calibrator/control matrix	Human urine based	Same

Differences		
Item	**Predicate Devices**	**iMDx™ Analyzer**
Instrument type	Open	Closed
Sample Type	Urine, plasma, serum	Urine
Reagent Type	Lyophilized	Ready to use liquid

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

The sponsor referenced the following guidance documents in their submission:

• CLSI Evaluation Protocols: EP5-A Evaluation of precision performance of clinical chemistry devices

• CLSI Evaluation Protocols: EP6-P Evaluation of the linearity of quantitative analytical methods

• CLSI Evaluation Protocols: EP12-A User protocol for evaluation of qualitative test performance

• Validation of Analytical Procedures: Methodology, Q2B, ICH Harmonized Tripartite Guideline (1996)

• CSA C22.2: Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use

L. Test Principle:

The enzyme immunoassays (EIA) methods are intended for the qualitative and semi-quantitative determination of oxycodone, amphetamine, phencyclidine, and cannabinoids (THC). The EIA assays are 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, drug-labeled G6PDH conjugate is bound to antibody, and the enzyme activity is inhibited. When free drug is present in the sample, antibody binds to the free drug, and the unbound drug-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 on the iMDx Analyzer.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. Precision/Reproducibility:

OXYCODONE

Specimen description: human urine spiked with analyte
Number of days: 5
Replicates per day: 4
Lots of product used: 1
Number of calibrations performed during the study: 2

Note: the precision studies at the cutoff and ± 25% of the cutoff were conducted over ten days, with 4 runs per day and 2 replicates per run, for a total of 80 measurements.

The sponsor states that studies were conducted using CLSI Guidelines (EP5-A) for precision as a guide. Results of the studies are presented below.

Oxycodone – Semi-Quantitative Results

Sample Concentration (ng/mL)	Mean ng/mL	Within-run		Total	
		SD	% CV	SD	% CV
0	0.00	0.00	N/A	0.00	N/A
25	45.80	1.95	4.26	1.97	4.29
50	59.05	1.12	1.89	1.76	2.97
75	82.50	2.89	3.50	3.71	4.49
100	101.61	5.99	5.89	7.71	7.59
125	126.78	10.41	8.21	12.64	9.97
150	121.45	2.01	1.66	3.52	2.90
175	141.55	6.37	4.50	6.48	4.58
200	222.00	28.52	12.85	28.56	12.87

Oxycodone- Qualitative Results

Sample Concentration (ng/mL)	% of Cutoff	Number of Observations	Results #Neg/#Pos
0	-100	20	20/0
25	-75	20	20/0
50	-50	20	20/0
75	-25	80	80/0
100	cutoff	80	31/49
125	25	80	0/80
150	50	20	0/20
175	75	20	0/20
200	100	20	0/20

AMPHETAMINES

Specimen description: human urine spiked with analyte
Number of days: 5
Replicates per day: 4
Lots of product used: 1
Number of calibrations performed during the study: two

Note: the precision studies at the cutoff and ± 25% of the cutoff were conducted over ten days, with 4 runs per day and 2 replicates per run, for a total of 80 measurements.

The sponsor states that studies were conducted using CLSI Guidelines (EP5-A) for precision as a guide. Results of the studies are presented below.

Amphetamines Semi-Quantitative Results

Sample Conc. (ng/mL)	Mean ng/mL	Within-run		Total	
		SD	% CV	SD	% CV
0	0.00	0.00	N/A	0.00	N/A
250	45.80	1.95	4.26	1.97	4.29
500	59.05	1.12	1.89	1.76	2.97
750	82.50	2.89	3.50	3.71	4.49
1000	101.61	5.99	5.89	7.71	7.59
1250	126.78	10.41	8.21	12.64	9.97
1500	121.45	2.01	1.66	3.52	2.90
1750	141.55	6.37	4.50	6.48	4.58
2000	222.00	28.52	12.85	28.56	12.87

Amphetamines - Qualitative Results

Sample Concentration (ng/mL)	% of Cutoff	Number of Observations	Results #Neg/#Pos
0	-100	20	20/0
250	-75	20	20/0
500	-50	20	20/0
750	-25	80	80/0
1000	Cutoff	80	44/36
1250	25	80	0/80
1500	50	20	0/20
1750	75	20	0/20
2000	100	20	0/20

PCP

Specimen description: human urine spiked with analyte
Number of days: 5
Replicates per day: 4
Lots of product used: 1
Number of calibrations performed during the study: 2

Note: the precision studies at the cutoff and ± 25% of the cutoff were conducted over ten days, with 4 runs per day and 2 replicates per run, for a total of 80 measurements.

The sponsor states that studies were conducted using CLSI Guidelines (EP5-A) for precision as a guide. Results of the studies are presented below.

Phencyclidine – Semi-Quantitative Results

Sample Conc. (ng/mL)	Mean ng/mL	Within-run		Total	
		SD	% CV	SD	% CV
0	0.00	0.00	N/A	0.00	N/A
6.25	6.65	1.57	23.54	1.58	23.81
12.5	13.40	1.73	12.93	1.73	12.94
19	19.54	1.72	8.81	1.91	9.77
25	27.53	2.81	10.20	2.85	10.37
32	36.56	3.53	9.65	3.53	9.65
37.5	38.90	1.84	4.74	1.88	4.83
43.75	42.20	3.46	8.21	3.48	8.25
50	50.75	4.53	8.93	4.53	8.93

Phencyclidine- Qualitative Results

Sample Concentration (ng/mL)	% of Cutoff	Number of Observations	Results #Neg/#Pos
0	-100	20	20/0
6.25	-75	20	20/0
12.5	-50	20	20/0
19	-25	80	80/0
25	Cutoff	80	13/67
32	25	80	0/80
37.5	50	20	0/20
43.75	75	20	0/20
50	100	20	0/20

CANNABINOIDS

Specimen description: human urine spiked with analyte
Number of days: 5
Replicates per day: 4
Lots of product used: 1
Number of calibrations performed during the study: 2

Note: the precision studies at the cutoff and ± 25% of the cutoff were conducted over ten days, with 4 runs per day and 2 replicates per run, for a total of 80 measurements.

The sponsor states that studies were conducted using CLSI Guidelines (EP5-A) for precision as a guide. Results of the studies are presented below.

Cannabinoids - Semi-Quantitative Results

Sample Conc. (ng/mL)	Mean ng/mL	Within-run		Total	
		SD	% CV	SD	% CV
0	0.00	0.00	N/A	0.00	N/A
12.5	15.30	1.00	6.54	2.67	17.48
25	32.05	2.59	8.08	2.59	8.08
37.5	42.50	3.44	8.08	3.46	8.14
50	55.04	2.81	5.11	3.46	6.29
62.5	72.14	4.64	6.43	5.22	7.23
75	87.98	5.61	6.37	6.21	7.06
87.5	107.70	8.04	7.47	14.89	13.82
100	126.33	9.03	7.15	11.31	8.95

Cannabinoids- Qualitative Results

Sample Concentration (ng/mL)	% of Cutoff	Number of Observations	Results #Neg/#Pos
0	-100	20	20/0
12.5	-75	20	20/0
25	-50	20	20/0
37.5	-25	80	77/3
50	Cutoff	80	2/78
62.5	25	80	0/80
75	50	20	0/20
87.5	75	20	0/20
100	100	20	0/20

b. Linearity/assay reportable range:

To evaluate linearity, a series of 7 concentration levels were made by diluting a stock solution (traceable back to NIST standard) of oxycodone, methamphetamine, PCP, and THC with negative human urine. The dilutions were assayed in duplicate over 2 runs. The only deviation from this protocol was that six levels were tested for THC instead of seven.

OXYCODONE

Expected Conc. (ng/ml)	Mean Observed Conc. (ng/ml)	% Recovery	%CV
50	58	115.0	3.3%
75	76	101.7	3.3%
100	103	102.5	2.9%
125	126	100.6	2.7%
150	157	104.8	6.1%
200	211	105.6	10.8%
250	239	95.6	12.0%

A linear regression analysis of linear dilution samples gave the following equation: $Y = 0.9582X + 8.4581$ ($R^2 = 0.9907$).

AMPHETAMINES

Expected Conc. (ng/ml)	Mean Observed Conc. (ng/ml)	% Recovery	%CV
200	197	98.3	4.6%
500	474	94.9	4.3%
1000	934	93.4	2.0%
1500	1388	92.5	5.2%
2000	1864	93.2	5.6%
4000	3916	97.9	4.6%
6000	6424	107.1	10.2%

A linear regression analysis of linear dilution samples gave the following equation: $Y = 1.0639X – 139.26$ ($R^2 = 0.9962$).

PCP

Expected Conc. (ng/ml)	Mean Observed Conc. (ng/ml)	% Recovery	%CV
5	4.3	85.0	11.8%
10	9.0	90.0	9.1%
15	14.0	93.3	5.8%
25	22.5	90.0	2.6%
30	28.5	95.0	4.5%
60	63.5	105.8	5.2%
80	88.3	110.3	1.1%

A linear regression analysis of linear dilution samples gave the following equation: $Y = 1.123X - 3.2529$ ($R^2 = 0.9971$).

CANNABINOIDS

Expected Conc. (ng/ml)	Mean Observed Conc. (ng/ml)	% Recovery	%CV
20	18.0	90.0%	11.1%
25	25.0	100.0%	16.0%
37.5	41.0	109.3%	8.7%
50	55.3	110.7%	9.3%
62.5	66.8	106.9%	12.8%
75	75.7	100.9%	6.4%

A linear regression analysis of linear dilution samples gave the following equation: $Y = 1.0632X - 0.8737$ ($R^2 = 0.9882$).

c. Traceability (controls, calibrators, or method):

Calibrators and controls for are traceable to Cerilliant Reference Standards and GC/MS.

An intermediate concentration of calibrators (designated as master calibrator) for each analyte was made by diluting Cerilliant References Standard with synthetic urine. This master calibrator was

value-assigned by GC/MS. The master calibrators are then gravimetrically diluted using synthetic urine to various concentration levels. The concentration values of diluted calibrators/controls are assigned using GC/MS. These calibrators/controls become internal reference standards.

These internal reference standards are aliquoted and stored at below -80°C environments and are used only for testing working calibrators (i.e. calibrators used to produce products). The production protocol for internal reference standards and working calibrators are identical except that the working calibrators are tested against the internal reference standards.

Stability: Real time accelerated stability studies have been conducted. Protocols and acceptance criteria were described and found to be acceptable. The stability is listed below:

iMDXPrep MMT-I Reagent and Calibration plate stability is 3 months at 2-8º C.

iMDXPrep Control stability is 1 month at 2-8º C

Calibrators and one level of control are provided in the kit. The Quality Control section of the labeling also recommends the assaying of commercially available controls at ± 25% of the cutoff. In the labeling the sponsor recommends that users follow federal, state and local guidelines for testing external quality control materials.

Eight levels of calibrator material are provided with the assay at the following concentrations:

Analyte	Calibrator Compound	Concentration (ng/mL)
Oxycodone	Oxycodone	50
		75
		100
		0
		125
		175
		350
		1000

Analyte	Calibrator Compound	Concentration (ng/mL)
Amphetamines	Methamphetamine	200
		500
		750
		0
		1000
		1500
		6000
		16000

Analyte	Calibrator Compound	Concentration (ng/mL)
PCP	PCP	12.5
		18
		25
		0
		32
		50
		100
		285

Analyte	Calibrator Compound	Concentration (ng/mL)
Cannabinoids	(-)-11-nor-9-carboxy-delta9-THC	25
		37.5
		50
		0
		75
		125
		250
		800

d. Detection limit:

Characterization of performance at the low end of the semi-quantitative range was defined as the lowest concentration of analyte that can be distinguished from background and is calculated as twice the standard deviation of results obtained for the zero calibrator. The detection limit for the assays is as follows:

Oxycodone - 16.8 ng/mL

Amphetamine - 73 ng/mL

PCP - 1.21 ng/mL

Cannabinoids - 9.1 ng/mL

e. Analytical specificity:

Cross-reactivity was evaluated by spiking various concentrations of similarly structured drug compounds into drug-free urine. By analyzing various concentrations of each compound the sponsor determined the concentration of the drug that produced a response approximately equivalent to the cutoff concentration of the assay. Results of those studies appear in the table(s) below:

The following parent compounds and metabolites yielded the following percent cross-reactivity results:

Amphetamines

Compound	**Quantity equivalent to cutoff (ng/mL)**	**Approx. % Cross-reactivity**
d-Amphetamine	1000	100
d-Methamphetamine	1000	100
MDA	2800	36
MDMA	2500	40
MDEA	30000	3
d,l-BDB	8000	13
PMMA	2500	40
MBDB	3000	33
PMA	10000	10
HMMA	80000	1

Oxycodone

Compound	**Quantity equivalent to cutoff (ng/mL)**	**Approx. % Cross-reactivity**
Hydrocodone	175	57
Hydromorphone	250	40
Oxycodone	100	100
Oxymorphone	125	80

Cannabinoids (THC)

Compound	Quantity equivalent to cutoff (ng/mL)	Approx. % Cross-reactivity
11-Hydroxy-Δ^9-Tetrahydrocannabinol	80	63
11-Nor-Δ^8-Tetrahydrocannabinol carboxylic acid	70	71
11-Nor-Δ^9-Tetrahydrocannabinol carboxylic acid	50	100
Δ^8-Tetrahydrocannabinol	200	25
Δ^9 – Tetrahydrocannabinol	200	25
Cannabinol	240	21
cannabidiol	9000	0.5
l-9-Carboxyl-11-nor-Δ9-THC-glucuronide	100	100

Phencyclidine

Compound	Quantity equivalent to cutoff (ng/mL)	Approx. % Cross-reactivity
Phencyclidine	25	100
4-hydroxyphencyclidine	64	39
Phencyclidine Morpholine	1250	2

The following compounds were tested with the iMDx Oxycodone assay and gave a negative response when tested at the concentration listed below:

Compound	µg/mL
Acetaminophen	100
Acetylsalicylic acid	250
Amobarbital	100
Benzoylecgonine	100
Bromopheniramine	200

Compound	µg/mL
Bupropion	250
Caffeine	300
Chlorpheniramine	250
Chlorpromazine	150
Codeine	0.5
d,l-Phenylpropanolamine	25
d-Ephedrine	200
l-Ephedrine	60
Dextromethorphan	300
Dihydrocodeine	0.5
D-Methamphetamine	300
Ecgonine	500
Hydromorphine	500
Levorphanol	1.5
Morphine 3-gluco.	1.2
Morphine 6-gluco.	0.3
Meperidine	150
Methadone	150
Morphine	1
Naloxone	0.625
Nicotine	300
Norcodeine	40
Norpropoxphene	100
Phencyclidine	100
Promethiazine	100
Propanol	100
Secobarbital	100
Trazodone	250
Tyramine	50
Valproic	300

Structurally unrelated compounds were tested with the iMDx Amphetamines assay and gave a negative response when tested at the concentration listed below:

Compound	µg/mL
Acetaminophen	3000
Acetylsalicylic Acid	3000
Amorbarbital	3000
l-Amphetamine	24
Benzoylecgonine	3000
Benzphetamine	2000
Bromopheniramine	3000
Bupropion	2000

Compound	µg/mL
Buspirone	3000
Caffeine	3000
Chlorpheniramine	3000
Chorpromazine	3000
Codeine	3000
Dextromethorphen	3000
d-Ephedrine	3000
D,l-Ephedrine	700
l-Ephedrine	400
Fenfluramine	7
3-Hydroxy-Tyramine	1700
Isoxsuprine	3000
l-Methamphetamine	10
Meperidine	3000
Mephentermine	50
Methadone	3000
Methapyrilene	3000
Methaqualone	3000
Morphine	3000
Oxazepam	3000
Phencyclidine	1000
Phendimetrazine	300
Phenethylamine	40
Phenmetrazine	75
Phenobarbital	3000
Phenothiazine	100
Phentermine	40
Phenylephrine	500
d-Phenylpropanolamine	2500
D,l-Phenylpropanolamine	500
I-Phenylpropanolamine	240
Procainamide	800
Promethazine	3000
Propoxyphene	3000
Propranolol	3000
d-Pseudoephedrine	250
l-Pseudoephedrine	2500
Ranitidine	800
Scopolamine	3000
Secobarbital	3000
Sertraline	1000
Thioridazine	3000
Trazodone	2900

Compound	µg/mL
Trifluoperazine	3000
Triflupromazine	3000
Triprolidine	3000
Tyramine	600
Valproic Acid	3000

Structurally unrelated compounds were tested with the iMDx PCP assay and gave a negative response when tested at the concentration listed below:

Compound	µg/mL
Acetaminophen	1000
Acetylsalicylic Acid	1000
Amobarbital	1000
Amphetamine	1000
Benzoylecgonine	3000
Bromopheniramine	100
Bupropion	100
Caffeine	100
Chlorpheniramine	50
Chlorpromazine	100
Codeine	100
Dextromethorphan	1000
Diphenhydramine	1000
Ephedrine	1000
Ketamine	100
Meperidine	100
Methadone	1000
Methamphetamine	1000
Methaqualone	100
Morphine	500
Naloxone	1000
Naltrexone	25
Nicotine	1000
Norpropoxyphene	100
Nortriptyline	100
Oxazepam	1000
Phenobarbital	1000
Phenylpropanolamine	1000
Primidone	1000
Promethazine	100
Propranolol	100
Propoxyphene	1000
Pseudoephedrine	1000

Compound	µg/mL
Ranitidine	1000
Secobarbital	1000
Thioridazine	1000
Triprolidine	150
Tyramine	1000
Valproic Acid	10000

Structurally unrelated compounds were tested with the iMDx THC assay and gave a negative response when tested at the concentration listed below:

Compound	µg/mL
Acetaminophen	1000
Acetylsalicylic Acid	1000
Amitriptyline	1000
Amobarbital	1000
Amphetamine	1000
Benzoylecgonine	1000
Bupropion	1000
Caffeine	1000
Chlorpheniramine	1000
Chlorpromazine	1000
Cocaine	1000
Codeine	1000
Dextromethorphan	1000
Ecgonine	1000
Ephedrine	1000
Imipramine	1000
Lidocaine	1000
Meperidine	1000
Methadone	1000
Methamphetamine	1000
Methaqualone	1000
Morphine	1000
Nortriptyline	1000
Oxazepam	1000
Phencyclidine	1000
Phenobarbital	1000
Promethazine	1000
Propoxyphene	1000
Ranitidine	1000
Secobarbital	1000

Valproic Acid	1000

The effect of sample pH on assay performance was assessed through analyte recovery at their respective cutoff levels with three runs using the iMDx analyzer and associated reagents. During each run, three urine samples containing analytes at cutoff concentration with different pH (pH 4.0, pH 7.3, and pH 9.0) are assayed in duplicate. The average recovery of the concentration at pH 4.0 and pH 9.0 were compared to pH 7.3, the control condition. The results are summarized in the table below.

Analyte	**pH 4.0**	**pH 9.0**
Oxycodone	92.75%	94.10%
Amphetamines	97.06%	102.49%
PCP	96.90%	93.02%
Cannabinoids	91.70%	111.50%

The evaluation of urine sample specific gravity (SG) on assay performance was conducted with two runs for all analytes at their respective cutoff levels. During each run, six urine samples with different specific gravities (SG 1.003, SG 1.005, SG 1.015, SG 1.020, SG 1.025 and SG 1.030) containing cutoff levels of analyte are assayed in duplicate. The average recovery of the concentration is compared to SG 1.020, the control condition. The results are summarized in the table below.

Analyte	**SG 1.003**	**SG 1.005**	**SG 1.015**	**SG 1.025**	**SG 1.03**
Oxycodone	104.90%	102.20%	106.40%	100.50%	100.00%
Amphetamines	100.60%	99.60%	104.00%	102.70%	103.40%
PCP	99.70%	100.70%	99.90%	98.90%	100.00%
THC	89.40%	97.70%	90.30%	94.90%	91.70%

The effect of ascorbic acid, bilirubin and hemoglobin was assessed through analyte recovery at the cutoff levels. Samples were spiked with high levels of the potential interferents and the recovery was compared to a control sample. Recoveries ranged from a low of 90% to a high of 110%.

f. Assay cut-off:

The identified cutoff concentration of the amphetamines, phencyclidine, and cannabinoids assay are recommended for use by the Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA has not made cutoff recommendations for oxycodone assays. Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section, above.

2. Comparison studies:

a. Method comparison with predicate device:

The candidate device was compared to a reference method, GC/MS.

Both negative and positive samples were evaluated by the candidate device and by GC/MS as follows:

Analyte	Positives	Negatives	Total
Oxycodone	53	50	103
Amphetamines	65	50	115
PCP	58	50	108
THC	51	80	131

Unaltered clinical urine samples were evaluated.

The study included an adequate number of samples that contained drugs near to the cutoff concentration of the assay. Approximately 10% of the study samples are evenly distributed between plus and minus 50% of the claimed cutoff concentration.

Number of study sites: three
Description of the site(s): POC setting
Operator description: POC staff
Number of instruments used: Not specified

Candidate Device Results vs. stratified GC/MS Values

OXYCODONE

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	1*	0	3	49
Negative	40	9	1	0

GC/MS values used to categorize samples in this table are based on the concentration of oxycodone found in the sample.

*sample was found to contain 508 ng/mL of hydrocodone

% Agreement among positives is 98%
% Agreement among negatives is 98%

Candidate Device Results vs. stratified GC/MS Values

AMPHETAMINES

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	12	16	49
Negative	32	6	0	0

GC/MS values used to categorize samples in this table are determined by adding together the concentration of amphetamine and methamphetamine.

% Agreement among positives is 100%
% Agreement among negatives is 76%

Candidate Device Results vs. stratified GC/MS Values
PCP

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	1	8	48
Negative	36	13	2	0

GC/MS values used to categorize samples in this table are based on the concentration of PCP found in the sample.

% Agreement among positives is 97%
% Agreement among negatives is 98%

Candidate Device Results vs. stratified GC/MS Values
THC

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff	**High Positive** (greater than 50% above the cutoff concentration)

		concentration)	concentration)	
Positive	1*	11	13	38
Negative	45	23	0	0

GC/MS values used to categorize samples in this table are based on the concentration of THC found in the sample.

*sample was found to contain 20 ng/mL of THC

% Agreement among positives is 100%
% Agreement among negatives is 85%

b. Matrix comparison:
Not applicable. The assay is intended for only one sample matrix.

3. Clinical studies:
   a. Clinical sensitivity:
   Not applicable. Clinical studies are not typically submitted for this device type.
   b. Clinical specificity:
   Not applicable. Clinical studies are not typically submitted for this device type.
   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 809.10.

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