

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

A. 510(k) Number:

k063699

B. Purpose for Submission:

New device

C. Measurand:

Opiates, Benzodiazepine, Cocaine, Methadone, and Ethyl Alcohol

D. Type of Test:

Qualitative and semi-quantitative enzyme immunoassay for Opiates, Benzodiazepine, Cocaine and Methadone and a quantitative enzymatic assay for Ethyl Alcohol

E. Applicant:

NOVX Systems Inc.

F. Proprietary and Established Names:

iMDx™ System
iMDxPrep MMT-1 Reagent Plate
iMDxPrep MMT-1 Calibration Plate
iMDxPrep MMT-1 Control

G. Regulatory Information:

1. Regulation section:

21 CFR 862.3650, Opiate test system
21 CFR 862.3040, Alcohol test system
21 CFR 862.3170, Benzodiazepine test system
21 CFR 862.3620, Methadone test system
21 CFR 862.3250, Cocaine and cocaine metabolite test system
21 CFR 862.3200, Clinical toxicology calibrator
21 CFR 862.2160, Discrete photometric chemistry analyzer for clinical use
21 CFR 862.3280 Clinical toxicology control material

2. Classification:

Class II and Class I (reserved)

3. Product code:

DJG, DMT, JXM, DJR, DIO, DKB, JJE and DIF respectively

4. Panel:

Toxicology (91) and Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The iMDx™ System is an in vitro diagnostic device consisting of 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 Opiates (Morphine), Benzodiazepine (Oxazepam) and Cocaine Metabolite (Benzoylcegonine) Assays are an enzyme immunoassay with a 300ng/mL cutoff. These assays are intended for use in the qualitative and semi-quantitative analysis of Opiates, Benzodiazepine and Cocaine Metabolite in human urine. The Methadone Metabolite (EDDP) Assay is an enzyme immunoassay with a 100ng/mL cutoff. The assay is intended for use in the qualitative and semi-quantitative analysis of Methadone Metabolite in human urine. For point of care use semi-quantitative analysis is only for estimation of dilution for confirmation testing.

The Ethyl Alcohol Assay is an enzymatic assay intended for use in quantitative analysis of ethyl alcohol in human urine. Measurements obtained are used in the diagnosis and treatment of alcohol intoxication and poisoning.

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 conditions 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 performed.

For prescription use.

4. Special instrument requirements:

iMDx™ Analyzer

I. Device Description:

The iMDx System contains the following items:

- iMDx Analyzer
- iMDxPrep MMT-1 Reagent plate is a sealed ready to use 96 well microplate that contains the reagents to for perform testing for methadone, cocaine, opiates, benzodiazepine, and alcohol.
- iMDxPrep MMT-1 Calibration Plate is a sealed ready to use 96 well microplate that contains the reagents 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.
- iMDxPrep Reaction Plate is a 96 well microplate that the reagents and samples are pipetted onto where testing is performed.
- iMDxPrep Analyzer Tip Rack is a box of 96 pipet tips.
- iMDxPrep pH Calibrators 4.0 and 7.0 are ready to use liquid calibrator solutions for calibration of the pH electrode.
- iMDxPrep pH Storage solution is a ready to use solution contained in a test tube for the storage and maintenance of the pH electrode.
- iMDxPrep pH Wash solution is a ready to use solution used for washing the pH electrode during a sample run.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Hitachi 911 Analyzer, Boehringer Mannheim (Roche)
CEDIA DAU Opiate Assay, CEDIA DAU Benzodiazepine Assay, CEDIA DAU EDDP Assay, CEDIA DAU Cocaine Assay, Microgenics Corp.
DRI Ethyl Alcohol Assay, Diagnostic Reagents Inc. (now Microgenics Corp)
Drugs of Abuse Urine Calibrators and Controls, Diagnostic Reagents Inc. (now Microgenics Corp)

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

k921661, k945343, k962734, k980746, k945345, k923783 and k983159, respectively

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Cutoff	Methadone-100 ng/mL, Cocaine 300 ng/mL, Opiates 300 ng/mL, Benzodiazepines 300 ng/mL	Methadone-100 ng/mL, Cocaine 300 ng/mL, Opiate 300 ng/mL, Benzodiazepine 300 ng/mL
Assay claims	Qualitative and semi-quantitative for Methadone, Cocaine, Opiates and Benzodiazepine Quantitative for Ethyl Alcohol	Qualitative and semi-quantitative
Method principle drugs-of-abuse	Homogeneous enzyme immunoassay	Homogeneous enzyme immunoassay
Method principle Ethyl Alcohol	Homogeneous enzymatic assay	Homogeneous enzymatic assay
Calibrator/control matrix	Human urine based	Human urine based
Calibrator/control format	Liquid, ready-to-use	Liquid, ready-to-use

Differences		
Item	Device	Predicate
Sample type	Urine	Urine, Plasma, Serum
Sample Volume	1 to 20 uL	3 to 50 uL
Type of reagent	Ready-to-use Liquid	Lyophilized, reconstitution required
Reportable range Ethyl Alcohol	0.6-300 mg/dL (0-64 mM)	0-600 mg/dL
Calibrator/control Analytes	Contains EDDP and ethyl alcohol	Does not contain EDDP and ethyl alcohol

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

CLSI EP5-A: Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline

CLSI EP12-A; User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline

CLSI EP6-A; Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

CLSI EP17-A; Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline

L. Test Principle:

The enzyme immunoassay is used to determine qualitative and semi-quantitative results for drug-of-abuse tests. They are based on the competition between a drug contained within a human urine sample and the drug labeled with the enzyme glucose-6-phosphate dehydrogenase, for a fixed amount of antibody in the reagent. Enzyme activity decreases upon binding to the antibody and the drug concentration is measured spectrophotometrically at 340 nm.

The alcohol assay is a homogeneous enzymatic assay based on the properties of alcohol dehydrogenase (ADH) and is used for the quantitative analysis of alcohol in human urine. ADH converts ethanol in the presence of NAD to acetaldehyde and reduces the NAD to NADH. Ethanol concentration is directly proportional to the ADH activity 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:

Intra-assay and total precision was determined by assaying three levels 75%, 100% and 125% of the cutoff concentration by using a multi-drug calibrator mixture containing (Morphine, EDDP, Oxazepam, Benzoyllecgonine and Ethanol). The precision was assessed by assaying three samples in replicate with four runs per day for ten days. The results are presented below:

25% below the cut-off

	EDDP	BZG	OPI	BZO
Total # determinations	80	80	80	80
Concentration (ng/mL)	75	225	225	225
#NEG/#POS	80/0	80/0	80/0	80/0
Precision	100%	100%	100%	100%

25% above the cut-off

	EDDP	BZG	OPI	BZO
Total # determinations	80	80	80	80
Concentration (ng/mL)	125	375	375	375
#POS/#neg	80/0	80/0	80/0	77/3
Precision	100%	100%	100%	96.3%

Opiate Qualitative

Sample	Mean OD @ 340 nm	Within-run		Total	
		SD	% CV	SD	% CV
225 ng/mL	0.421	0.004	1.04	0.005	1.21
300 ng/mL	0.445	0.004	1.01	0.006	1.26
375 ng/mL	0.461	0.003	0.65	0.003	0.69

Opiates Semi-Quantitative

Sample	Mean ng/mL	Within-run		Total	
		SD	% CV	SD	% CV
225 ng/mL	231.0	15.11	6.54	17.52	7.59
300 ng/mL	321.7	18.35	5.70	22.76	7.08
375 ng/mL	395.9	14.26	3.60	15.06	3.80

Cocaine Qualitative

Sample	Mean OD @ 340 nm	Within-run		Total	
		SD	% CV	SD	% CV
225 ng/mL	0.589	0.005	0.84	0.006	0.96
300 ng/mL	0.621	0.009	1.46	0.009	1.48
375 ng/mL	0.643	0.005	0.78	0.006	0.90

Cocaine Semi-Quantitative

Sample	Mean ng/mL	Within-run		Total	
		SD	% CV	SD	% CV
225 ng/mL	227.7	12.31	5.41	13.99	6.14
300 ng/mL	316.7	27.79	8.77	28.31	8.94
375 ng/mL	389.9	18.01	4.62	20.72	5.31

Benzodiazepine Qualitative

Sample	Mean OD @ 340 nm	Within-run		Total	
		SD	% CV	SD	% CV
225 ng/mL	0.576	0.008	1.32	0.009	1.57
300 ng/mL	0.612	0.006	0.90	0.006	1.01
375 ng/mL	0.630	0.008	1.25	0.009	1.44

Benzodiazepine Semi-Quantitative

Sample	Mean ng/mL	Within-run		Total	
		SD	% CV	SD	% CV
225 ng/mL	230.2	16.95	7.36	20.15	8.75
300 ng/mL	321.5	15.02	4.67	17.02	5.29
375 ng/mL	374.3	24.04	6.42	26.84	7.17

Methadone Qualitative

Sample	Mean OD @ 340 nm	Within-run		Total	
		SD	% CV	SD	% CV
75 ng/mL	0.339	0.006	1.89	0.008	2.27
100 ng/mL	0.375	0.005	1.41	0.006	1.52
125 ng/mL	0.394	0.006	1.46	0.006	1.46

Methadone Semi-Quantitative

Sample	Mean ng/mL	Within-run		Total	
		SD	% CV	SD	% CV
75 ng/mL	69.2	4.68	6.76	5.60	8.09
100 ng/mL	97.5	4.55	4.67	4.89	5.01
125 ng/mL	115.5	5.95	5.15	5.95	5.15

Ethanol Quantitative

Sample	Mean (mg/dL)	Within-run		Total	
		SD	% CV	SD	% CV
Level 1	9.9	0.5	4.70	0.6	6.40
Level 2	42.8	0.7	1.77	0.9	2.21
Level 3	176.9	10.4	5.86	10.5	5.94

Point Of Care (POC) Studies

Precision studies were performed at three POC sites with three trained operators. Two sites were external and one site was in-house at NOVX. A synthetic drug-free urine was spiked to three different concentrations with the following drugs, Morphine, EDDP, Oxazepam, Benzoyllecgonine and Ethanol. All samples were tested twice a day for 3 days for a total 18 samples per drug. The results are summarized in the tables below:

25% below the cut-off

	EDDP	BZG	OPI	BZO
Total # determinations	36	36	36	36
Concentration (ng/mL)	75	225	225	225
#NEG/#POS	36/0	36/0	33/3	36/0
Precision	100%	100%	91.7%	100%

25% above the cut-off

	EDDP	BZG	OPI	BZO
Total # determinations	36	36	36	36
Concentration (ng/mL)	125	375	375	375
#POS/#neg	32/4	36/0	36/0	33/3
Precision	88.9%	100%	100%	91.7%

Ethanol (mg/dL)

Level	Site	Mean	Overall		
			Mean	SD	%CV
Level 1	1	5.5	5.6	0.18	3.5
	2	5.8			
	3	5.4			
Level 2	1	7.6	7.6	0.32	4.3
	2	7.9			
	3	7.3			
Level 3	1	9.4	9.5	0.37	3.8
	2	9.9			
	3	9.2			

b. Linearity/assay reportable range:

The range for each analyte was assessed by diluting a stock drug standard with negative human urine to obtain 7 concentration levels. The dilutions were assayed in duplicate over 2 runs and the percent recovery was calculated. The results are presented below:

Opiate

Expected Conc. (ng/mL)	Mean Observed Conc. (ng/mL)	% Recovery	% CV
100	96	96.0	3.1
150	165	110.2	4.3
200	221	110.5	2.5
300	336	111.0	3.2
500	526	105.2	7.4
750	767	102.2	2.3
1000	1053	105.3	5.4
The linear regression is $y=1.0369x + 7.1677$ ($R^2 = 0.9988$)			

Cocaine

Expected Conc. (ng/mL)	Mean Observed Conc. (ng/mL)	% Recovery	% CV
100	112	97.2	4.7
200	255	109.8	2.2
300	372	106.7	5.3
400	491	106.2	3.4
600	720	103.8	7.7
800	931	100.5	8.3
1000	1142	98.8	7.1
The linear regression is $y=0.9806x + 20.488$ ($R^2 = 0.9984$)			

Benzodiazepine

Expected Conc. (ng/mL)	Mean Observed Conc. (ng/mL)	% Recovery	% CV
100	120	104.2	9.6
200	221	95.5	4.6
300	337	97.2	3.4
400	432	93.6	4.6
600	635	91.7	1.9
800	830	94.8	2.8
1000	1095	89.9	3.1
The linear regression is $y=0.9185x + 8.1215$ ($R^2 = 0.9978$)			

Methadone

Expected Conc. (ng/mL)	Mean Observed Conc. (ng/mL)	% Recovery	% CV
75	80	106.7	3.4
100	101	100.8	5.0
150	127	84.7	4.2
1500	1535	102.4	3.0
1800	1944	108.0	6.9
3000	2997	99.9	1.1
4000	3819	95.5	6.7
The linear regression is $y=0.9728x + 38.071$ ($R^2 = 0.9967$)			

Ethanol

Expected Conc. (mg/dL)	Mean Observed Conc. (mg/dL)	% Recovery	% CV
4.6	5.1	111.2	10.7
9.2	9.7	102.1	3.9
18.9	18.9	101.5	4.6
37.3	37.8	100.2	5.9
74.6	75.1	100.4	5.7
148.8	153.9	103.3	6.2
200.0	197.7	98.9	1.6
250.0	255.6	102.2	1.7
275.0	287.8	104.7	0.7
294.8	339.1	115.0	6.3
The linear regression is $y=0.9215x + 4.0878$ ($R^2 = 0.993$)			

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

Calibrators and controls for Opiates, Cocaine, Benzodiazepine, Methadone and Ethyl Alcohol are traceable to Cerilliant Reference Standards.

The high concentration calibrators for the drugs-of abuse and Ethyl Alcohol are gravimetrically diluted using synthetic urine to various concentrations and confirmed by Gas Chromatography (GC/MS).

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 2-8° C
iMDXPrep Control stability is 3 months at 2-8° C

d. Detection limit:

The detection limit was determined according to protocol recommendations in CLSI EP-17A in one run on a single day. The claimed lower limit was estimated to be 7.8 ng/mL for Methadone assay, 12.6 ng/mL for Benzodiazepine assay, 23.7 ng/mL for Cocaine Metabolite assay, 14.1 ng/mL for Opiate assay and 0.6 mg/dL for Ethanol assay.

e. Analytical specificity:

Various potentially interfering substances were evaluated to determine whether they interfere with assay results. Test compounds were spiked into the drug-free calibrator to various concentrations and evaluated against the cutoff calibrator. The quantity of a compound that produces a value equivalent to the cutoff is listed below:

Opiates

Compound	Quantity equivalent to 300 ng/mL	Approx. % Cross-reactivity
Morphine	300	100%
Codeine	150	200%
Dihydrocodeine	400	75%
Hydrocodone	300	100%
Hydromorphone	600	50%
Levorphanol	600	50%
Morphine-3-glucuronide (in morphine equiv.)	625	48%
Morphine-6-glucuronide	550	54.5%
Norcodeine	7000	4.3%
Oxycodone	2000	15%
Oxymorphone	6000	5%
Thebaine	400	75%

Cocaine

Compound	Quantity equivalent to 300 ng/mL	Approx. % Cross-reactivity
Benzoyllecgonine	300	100%
Cocaine	30000	1%
Norcocaine	60000	0.5%
Ecgonine	163000	<0.2%
Ecgonine, Methyl Ester	350000	<0.1%

Benzodiazepine

Compound	Quantity equivalent to 300 ng/mL	Approx. % Cross-reactivity
Oxazepam	300	100%
Alprazolam	100	300%
Bromazepam	5000	6%
Chlordiazepoxide	125	240%
Clobazam	1300	23.1%
Clonazepam	125	240%
Diazepam	200	150%
Flunitrazepam	70	428.6%
Flurazepam	135	222.2%
Lormetazepam	75	400%
Lorazepam	165	181.8%
Medazepam	70	428.6%
Nitrazepam	220	136.4%
Norfludiazepam	25	1200%
Prazepam	105	285.7%
Temazepam	115	260.9%
Triazolam	105	285.7%
Oxazepam-glucuronide	>10000	<3%
Lorazepam-glucuronide	>10000	<3%
Temazepam-glucuronide	>10000	<3%

Methadone

Compound	Quantity equivalent to 100 ng/mL	Approx. % Cross-reactivity
EDDP	100	100%
EMDP	200000	0.05%
(-) alpha-Methadol	10000	1%
Methadone	40000	0.25%

Ethanol

Compound	Concentration (mg/dL)	% cross reactivity
Acetaldehyde	2000	0
Acetone	2000	0
n-Butanol	2000	1.5
Ethylene glycol	2000	0
Isopropanol	2000	0
Methanol	2000	0
n-Propanol	2000	11

Unrelated compounds were found not to cross-react when tested at various concentrations. The exact concentrations are stated in the package insert including the maximum concentration of compound tested that remained negative.

The following endogenous substances for the following assays Opiates, Cocaine, Benzodiazepine and Methadone were tested and showed at <10% to have no interference: gross hemolysis (800 mg/dL hemoglobin) and icterus (30 mg/dL bilirubin). The following endogenous substances were tested and found to have no interference for the Ethanol assay: gross hemolysis (800 mg/dL hemoglobin), icterus (30 mg/dL bilirubin) and lipemia (1000 mg/dL triglycerides).

The evaluation of urine sample pH on the assay performance was conducted using a drug-free negative urine sample with a pH of 6.4. The sample was aliquoted into two additional samples; one aliquot was adjusted to a pH of 4.0 and the other aliquot was adjusted to a pH of 9.0. All three urine samples were then spiked with the following analytes to their cutoff concentrations; EDDP 100 ng/mL, BZG 300 ng/mL, OPI 300 ng/mL, BZO 300 ng/mL and Ethanol 8 mM and each sample was tested six times. Expected results were obtained for all levels of pH tested.

The evaluation of urine sample specific gravity on the assays performance was conducted using six urine samples with specific gravities of 1.003, 1.005, 1.020, 1.025 and 1.030. Each sample was spiked with the following analytes to their cutoff concentrations; EDDP 100 ng/mL, BZG 300 ng/mL, OPI 300 ng/mL, BZO 300 ng/mL and Ethanol and each sample was tested in duplicate. Expected results were obtained for all levels of specific gravity tested.

f. Assay cut-off:

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:

One hundred and twenty urine samples ranging from 0.5 to 230.3 mg/dL were tested with both a commercially available assay and the iMDxPrep MMT-1 Reagent Plate Ethanol Assay on the iMDxPrep system. The samples were not pre-screened and the sample concentrations tested were distributed over the analytical measurement range. The correlation is as follows:

Slope		Intercept		R ²
Value	95% CI	Value	95% CI	
0.972	0.955 to 0.989	-0.365	-0.776 to 0.046	0.991

Performance for the iMDxPrep MMT-1 Reagent Plate – Opiates, Benzodiazepine, Cocaine and Methadone was evaluated at three Point-of-Care sites and with a total of seven operators. Operators ran from 90 to 120 unaltered clinical samples obtained from NOVX systems. The iMDxPrep System test results were compared to the GC/MS results. Operators were provided instructions from Quick Reference Guide and Package insert.

Opiates

iMDxPrep MMT-1 Reagent Plate Opiate Assay	Low Negative by GC/MS (less than -50%) or negative by Predicate	Near Cutoff Negative (between -50% and cutoff)	Near Cutoff Positive (between cutoff and +50%)	High Positive (greater than +50%)	Percent Agreement with GC/MS
Positive	0	1*	8	37	92%
Negative	31	12	4*	0	97.7%

*Among the five discordant results, all (OPI-6, OPI-44, OPI-45, OPI-48, and OPI-51) have GC/MS morphine concentrations falling close to the cutoff concentration of 300 ng/mL. See table below:

Patient ID#	iMDx Concentration	GC/MS Concentration
OPI-6	430	228 ng/mL Morphine
OPI-44	296	443 ng/mL Morphine
OPI-45	276	411 ng/mL Morphine
OPI-48	232	397 ng/mL Morphine
OPI-51	288	399 ng/mL Morphine

Cocaine (Benzoylecgonine)

iMDxPrep MMT-1 Reagent Plate BZG Assay	Low Negative by GC/MS (less than -50%) or negative by Predicate	Near Cutoff Negative (between -50% and cutoff)	Near Cutoff Positive (between cutoff and +50%)	High Positive (greater than +50%)	Percent Agreement with GC/MS
Positive	0	4*	11	33	100%
Negative	24	18	0	0	91.3%

*Among the four discordant results, all (BZG-2, BZG-3, BZG-4 and BZG-19) have GC/MS BZG concentrations falling close to the cutoff concentration of 300 ng/mL. See table below:

Patient ID#	iMDx Concentration	GC/MS – BZG Concentration
BZG-2	377	254
BZG-3	526	198
BZG-4	407	200
BZG-19	387	286

Benzodiazepines

iMDxPrep MMT-1 Reagent Plate BZO Assay	Low Negative by GC/MS (less than -50%) or negative by Predicate	Near Cutoff Negative (between -50% and cutoff)	Near Cutoff Positive (between cutoff and +50%)	High Positive (greater than +50%)	Percent Agreement with GC/MS
Positive	3*	2*	8	57	92.9%
Negative	35	10	1*	4*	90.0%

*Among the ten discordant results, three (BZO-22, BZO-44 and BZO-60) have GC/MS BZO concentrations falling close to the cutoff concentration of 300 ng/mL. The other seven are largely attributable to the BZO assays cross reactivity with parent or metabolites compounds as listed in the Analytical Specificity and Interference section. See the table below:

Patient ID#	iMDx Concentration	GC/MS – Benzodiazepines Concentration
BZO-10	538	171 ng/mL Oxazepam
BZO-11	592	52 ng/mL Oxazepam
BZO-22	61	300 ng/mL Alprazolam
BZO-34	537	76 ng/mL Oxazepam,

		72 ng/mL Nordiazepam
BZO-38	553	Non detected
BZO-39	70	876 ng/mL Clonazepam
BZO-40	85	800 ng/mL Clonazepam
BZO-41	27	610 ng/mL Clonazepam
BZO-44	219	326 ng/mL Clonazepam
BZO-60	271	692 ng/mL Oxazepam

EDDP

iMDxPrep MMT-1 Reagent Plate EDDP Assay	Low Negative by GC/MS (less than -50%) or negative by Predicate	Near Cutoff Negative (between -50% and cutoff)	Near Cutoff Positive (between cutoff and +50%)	High Positive (greater than +50%)	Percent Agreement with GC/MS
Positive	0	0	6	36	93.3%
Negative	12	33	3*	0	100%

*Among the three discordant results, all (EDDP-47, EDDP-48 and EDDP-50) have GC/MS EDDP concentrations falling close to the cutoff concentration of 100 ng/mL. See table below:

Patient ID#	iMDx Concentration	GC/MS – EDDP Concentration
EDDP-47	96	124
EDDP-48	92	123
EDDP-50	87	148

b. Matrix comparison:

Not applicable. This device is only for use with urine sample.

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. Instrument Name:

iMDx™ System

O. System Descriptions:

1. Modes of Operation:

Batch mode up to 14 samples can be run at one time.

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes X or No

3. Specimen Identification:

A barcode is placed on the sample and read by the analyzer

4. Specimen Sampling and Handling:

Urine Samples should be collected so that testing may be performed within the same day. If testing can not be performed the same day as collection samples can be refrigerated. Refrigerated samples should be brought to room temperature prior to testing.

5. Calibration:

The analyzer requires calibration on a weekly basis. The analyzer will notify the operator that a calibration is due and will not run patient samples until the calibration is completed. A ready to use calibration plate, reagent plate and reaction plate are used to perform the calibration. The ready to use plates are for single use only.

6. Quality Control:

The iMDxPrep control provides a mixture of analytes at concentrations near the cutoff of each assay. The sponsor recommends the Quality Control be run with each batch patient testing.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

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