



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

IMMUNALYSIS CORPORATION
JOSEPH GINETE
REGULATORY AFFAIRS SPECIALIST II
829 TOWNE CENTER DRIVE
POMONA CA 91767

July 24, 2015

Re: K151395

Trade/Device Name: Immunalysis EDDP Specific Urine Enzyme Immunoassay,
Immunalysis EDDP Urine Calibrators,
Immunalysis EDDP Urine Control Sets

Regulation Number: 21 CFR 862.3620

Regulation Name: Methadone test system

Regulatory Class: II

Product Code: DJR, DLJ, LAS

Dated: May 22, 2015

Received: May 26, 2015

Dear Joseph Ginete:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
k151395

Device Name

Immunoassay EDDP Specific Urine Enzyme Immunoassay
Immunoassay EDDP Urine Calibrators
Immunoassay EDDP Urine Control Sets

Indications for Use (Describe)

Immunoassay EDDP Specific Urine Enzyme Immunoassay

The Immunoassay EDDP Specific Urine Enzyme Immunoassay is a homogeneous enzyme immunoassay with cutoffs of 100 ng/mL, 300 ng/mL and 1000 ng/mL. The assay is intended for use in laboratories for the qualitative and semiquantitative analysis of EDDP in human urine with automated clinical chemistry analyzers. This assay is calibrated against EDDP. This in-vitro device is for prescription use only.

The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GC-MS or permitting laboratories to establish quality control procedures.

The Immunoassay EDDP Specific Urine Enzyme Immunoassay Kit provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/ Mass Spectrometry (GC-MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC-MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Immunoassay EDDP Urine Calibrators

The Immunoassay EDDP Urine Calibrators are used as calibrators in the Immunoassay EDDP Specific Urine Enzyme Immunoassay for the qualitative and semi-quantitative determination of EDDP in urine on automated clinical chemistry analyzers.

Immunoassay EDDP Urine Control Sets

The Immunoassay EDDP Urine Control Sets are used as control materials in Immunoassay EDDP Specific Urine Enzyme Immunoassay.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

A. Contact Information

1. Manufacturer: Immunalysis Corporation
2. Contact Name: Joseph Ginete
3. Contact Title: Regulatory Affairs Specialist II
4. Address: 829 Towne Center Drive Pomona, CA 91767
5. Phone: (909) 482-0840
6. Fax: (909) 482-0850
7. Email: jginete@immunalysis.com
8. Summary prepared on: July 8, 2015

B. Device Information

1. Trade Name: Immunalysis EDDP Specific Urine Enzyme Immunoassay
Immunalysis EDDP Calibrators and Control Sets
2. Common Name: Immunalysis EDDP Specific Urine Enzyme Immunoassay
Immunalysis EDDP Calibrators and Control Sets

C. Regulatory Information

1. Device Classification: II
I, reserved
2. Regulation Number: 21 CFR862.3250 Enzyme Immunoassay, Methadone
21 CFR 862.3200 Calibrator, Drug Specific
21 CFR 862.3280 Drug Specific Control Materials
3. Panel: Toxicology(91)
4. Product Code: DJR
DLJ
LAS

D. Legally Marketed Device to Which We are Claiming Equivalence (807.92(A)(3))

1. Predicate Device: DRI® Methadone Metabolite Enzyme Immunoassay
2. Predicate Company: Microgenics
3. Predicate K Number: K023617



E. Device Description

1. The assay consists of antibody/ substrate reagent and enzyme conjugate reagent. The antibody/ substrate reagent includes recombinant fab antibodies to EDDP, glucose-6-phosphate (G6P) and nicotinamide adenine dinucleotide (NAD) in Tris buffer with Sodium Azide as a preservative. The enzyme conjugate reagent includes EDDP derivative labeled with glucose-6-phosphate dehydrogenase (G6PDH) in Tris buffer with Sodium Azide as a preservative.
2. All of the Immunalysis EDDP Calibrators and Controls are liquid and ready to use. These calibrators and controls do not have any especially unique technical characteristics. Each contains a known concentration of a specific drug analyte as a mixture.

The negative calibrator is a processed, drug-free synthetic urine matrix with sodium azide as a preservative. The Level 1, 2, 3 and 4 calibrators, as well as the LOW Control 1, HIGH Control 1, LOW Control 2 and HIGH Control 2, and LOW Control 3 and HIGH Control 3 are prepared by spiking known concentrations of EDDP into the negative calibrator matrix. These five calibrators and six controls are sold as individual bottles. The concentration of EDDP in their corresponding calibrators and controls are summarized as follows:

Table 1 Immunalysis EDDP Urine Calibrators and Controls

Analyte	EDDP Calibrators				EDDP Controls		EDDP Controls		EDDP Controls	
	Level 1	Level 2	Level 3	Level 4	LOW Control 1	HIGH Control 1	LOW Control 2	HIGH Control 2	LOW Control 3	HIGH Control 3
EDDP (ng/mL)	100	300	500	1000	75	125	225	375	750	1250

F. Intended Use

1. The Immunalysis EDDP Specific Urine Enzyme Immunoassay is a homogeneous enzyme immunoassay with cutoffs of 100ng/mL, 300ng/mL and 1000ng/mL. The assay is intended for use in laboratories for the qualitative and semi-quantitative analysis of EDDP in human urine with automated clinical chemistry analyzers. The 100ng/mL and 300ng/mL cutoff is for qualitative and semi-quantitative analysis. The 1000ng/mL cutoff is for qualitative analysis only. This assay is calibrated against EDDP. This in-vitro diagnostic device is for prescription use only.

The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GC-MS or permitting laboratories to establish quality control procedures.

The Immunalysis EDDP Specific Urine Enzyme Immunoassay Kit provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas



Chromatography/ Mass Spectrometry (GC-MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC-MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

2. Immunalysis EDDP Urine Controls

The Immunalysis EDDP Urine Controls are used as control materials in Immunalysis EDDP Specific Urine Enzyme Immunoassay.

3. Immunalysis EDDP Urine Calibrators

The Immunalysis EDDP Urine Calibrators are used as calibrators in the Immunalysis EDDP Specific Urine Enzyme Immunoassay for the qualitative and semi-quantitative determination of EDDP in urine on automated clinical chemistry analyzers.

G. Comparison of the new device with the predicate device

Item	EDDP Assay K023617	Immunalysis EDDP Specific Urine EIA
Intended Use	For the qualitative and semi-quantitative determination of the presence of EDDP in human urine at a cutoff of 300ng/mL and 1000ng/mL	For the qualitative and semi-quantitative determination of the presence of EDDP in human urine at a cutoff of 100ng/mL, 300ng/mL and 1000ng/mL
Type of Product	Analytical Reagents	Analytical Reagents
Measured Analytes	EDDP	EDDP
Test Matrix	Urine	Urine
Cutoff Levels	300ng/mL and 1000ng/mL of EDDP	100ng/mL, 300ng/mL and 1000ng/mL of EDDP
Test System	Homogeneous Enzyme Immunoassay	Homogenous Enzyme Immunoassay
Materials	Antibody/Substrate Reagents and Enzyme Labeled Conjugate	Antibody/Substrate Reagents and Enzyme Labeled Conjugate
Mass Spectroscopy Confirmation	Required for preliminary positive analytical results	Required for preliminary positive analytical results
Antibody	Mouse Monoclonal antibodies to EDDP	Recombinant antibody to EDDP
Storage	2 – 8°C until expiration date	2 – 8°C until expiration date
Calibrator Form	Liquid	Liquid
Calibrator Levels	Four (4) Levels	Four (4) Levels
Control Levels	Four (4) Levels	Six (6) Levels

H. The following laboratory performance studies were performed to determine substantial equivalence of the Immunalysis EDDP Specific Urine Enzyme Immunoassay to the predicate

1. Precision/ Cutoff Characterization/ Reproducibility - Precision/Cutoff Characterization – Study was performed for 20 days, 2 runs per day in duplicate (N=80) on concentration of $\pm 25\%$, $\pm 50\%$, $\pm 75\%$, and $\pm 100\%$ of the cutoff. The study verified that the cutoff serves as a boundary between a negative and positive interpretation of a qualitative result. In addition, it also verified that product performance relative to the ability of the device to produce the same value during repeated measurements. The instruments used for this was Beckman Coulter AU 400e.

- a. The following is a summary table of the Qualitative Analysis for the 100ng/mL cutoff test data results.

Table 2 - Qualitative Analysis (for 100ng/mL cutoff)

Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
25	-75%	80	80 Negative
50	-50%	80	80 Negative
75	-25%	80	80 Negative
100	Cutoff	80	43 Negative/37 Positive
125	+25%	80	80 Positive
150	+50%	80	80 Positive
175	+75%	80	80 Positive
200	+100%	80	80 Positive

- b. The following is a summary table of the Qualitative Analysis for the 300ng/mL cutoff test data results.

Table 3 - Qualitative Analysis (for 300 ng/mL cutoff)

Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
75	-75%	80	80 Negative
150	-50%	80	80 Negative
225	-25%	80	80 Negative
300	Cutoff	80	40 Negative / 40 Positive
375	+25%	80	80 Positive
450	+50%	80	80 Positive
525	+75%	80	80 Positive
600	+100%	80	80 Positive

- c. The following is a summary table of the Semi-Quantitative Analysis for the 1000ng/mL cutoff test data results.

Table 4 - Qualitative Analysis (for 1000 ng/mL cutoff)

Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
250	-75%	80	80 Negative
500	-50%	80	80 Negative
750	-25%	80	80 Negative
1000	Cutoff	80	46 Negative / 34 Positive
1250	+25%	80	80 Positive
1500	+50%	80	80 Positive
1750	+75%	80	80 Positive
2000	+100%	80	80 Positive

d. The following is a summary table of the Semi-Quantitative Analysis for the 100ng/mL cutoff test data results.

Table 5 - Semi-Quantitative Analysis (for 100ng/mL cutoff)			
Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
25	-75%	80	80 Negative
50	-50%	80	80 Negative
75	-25%	80	80 Negative
100	Cutoff	80	10 Negative / 70 Positive
125	+25%	80	80 Positive
150	+50%	80	80 Positive
175	+75%	80	80 Positive
200	+100%	80	80 Positive

e. The following is a summary table of the Semi-Quantitative Analysis for the 300ng/mL cutoff test data results.

Table 6 - Semi-Quantitative Analysis (for 300ng/mL cutoff)			
Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
75	-75%	80	80 Negative
150	-50%	80	80 Negative
225	-25%	80	80 Negative
300	Cutoff	80	13 Negative / 67 Positive
375	+25%	80	80 Positive
450	+50%	80	80 Positive
525	+75%	80	80 Positive
600	+100%	80	80 Positive

2. Specificity and Cross-Reactivity - Structurally similar compounds were spiked into drug free urine at levels that will yield a result that is equivalent to the cutoffs. The study verified assay performance relative to the ability of the device to exclusively determine certain drugs. The instrument used for this test was a Beckman Coulter AU 400e.

a. The qualitative result summary table for the 100ng/mL cutoff is outlined below:

Table 7 - Structurally Related Compounds (for 100 ng/mL cutoff) - Qualitative			
Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
EDDP	100	Positive	100
Methadone	700,000	Positive	0.01
EMDP	1,000,000	Negative	<0.01
Chlorpromazine	90,000	Positive	0.11
Diphenhydramine	1,000,000	Positive	0.01
Methylphenidate	100,000	Positive	0.10
Doxylamine	1,000,000	Negative	<0.01
LAAM	1,000,000	Negative	<0.01
(±)-alpha methadol	1,000,000	Positive	0.01

Table 7 - Structurally Related Compounds (for 100 ng/mL cutoff) - Qualitative			
Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
(-)-iso-methadone	100,000	Negative	<0.1

b. The qualitative result summary table for the 300ng/mL cutoff is outlined below:

Table 8 - Structurally Related Compounds (for 300 ng/mL cutoff) - Qualitative			
Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
EDDP	300	Positive	100
Methadone	1,000,000	Negative	<0.03
EMDP	1,000,000	Negative	<0.03
Chlorpromazine	300,000	Positive	0.1
Diphenhydramine	1,000,000	Negative	<0.03
Methylphenidate	360,000	Positive	0.08
Doxylamine	1,000,000	Negative	<0.03
LAAM	1,000,000	Negative	<0.03
(±)-alpha methadol	1,000,000	Negative	<0.03
(-)-iso-methadone	100,000	Negative	<0.3

c. The semi-quantitative result summary table for the 1000ng/mL cutoff is outlined below:

Table 9 - Structurally Related Compounds (for 1000 ng/mL cutoff) - Qualitative			
Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
EDDP	1,000	Positive	100
Methadone	1,000,000	Negative	<0.1
EMDP	1,000,000	Negative	<0.1
Chlorpromazine	1,000,000	Negative	<0.1
Diphenhydramine	1,000,000	Negative	<0.1
Methylphenidate	1,000,000	Negative	<0.1
Doxylamine	1,000,000	Negative	<0.1
LAAM	1,000,000	Negative	<0.1
(±)-alpha methadol	1,000,000	Negative	<0.1
(-)-iso-methadone	100,000	Negative	<1.0

d. The semi-quantitative result summary table for the 100ng/mL cutoff is outlined below:

Table 10 - Structurally Related Compounds (for 100ng/mL cutoff) – Semi-Quantitative			
Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
EDDP	100	Positive	100
Methadone	700,000	Positive	0.01
EMDP	1,000,000	Negative	<0.01
Chlorpromazine	90,000	Positive	0.11
Diphenhydramine	1,000,000	Positive	0.01
Methylphenidate	100,000	Positive	0.10
Doxylamine	1,000,000	Negative	<0.01

Table 10 - Structurally Related Compounds (for 100ng/mL cutoff) – Semi-Quantitative			
Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
LAAM	1,000,000	Negative	<0.01
(±)-alpha methadol	1,000,000	Positive	0.0001
(-)-iso-methadone	100,000	Negative	<0.1

e. The semi-quantitative result summary table for the 300ng/mL cutoff is outlined below:

Table 11 - Structurally Related Compounds (for 300ng/mL cutoff) – Semi-Quantitative			
Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
EDDP	300	Positive	100
Methadone	1,000,000	Negative	<0.03
EMDP	1,000,000	Negative	<0.03
Chlorpromazine	300,000	Positive	0.1
Diphenhydramine	1,000,000	Negative	<0.03
Methylphenidate	360,000	Positive	0.08
Doxylamine	1,000,000	Negative	<0.03
LAAM	1,000,000	Negative	<0.03
(±)-alpha methadol	1,000,000	Negative	<0.03
(-)-iso-methadone	100,000	Negative	<0.3

3. Interference - Structurally non-similar compounds, endogenous compounds, the effect of pH and the effect of specific gravity was evaluated by spiking the potential interferent into drug free urine containing the target analyte at ±25% of the cutoff. All potential interferents analyzed verified that assay performance is unaffected by externally ingested compounds or an internally existing physiological condition. The instrument used for this test was a Beckman Coulter AU 400e.

a. The following is a table of the structurally non-similar compounds for the 100ng/mL cutoff:

Table 12 - Structurally Non-Similar Compounds (for 100ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-25% Cutoff (75ng/mL)		+25% Cutoff (125ng/mL)	
		Result	Interference?	Result	Interference?
4-bromo 2-5, dimethoxyphenethylamine	100,000	Negative	No	Positive	No
Acetaminophen	500,000	Negative	No	Positive	No
Acetylsalicylic Acid	500,000	Negative	No	Positive	No
6-Acetylcodeine	100,000	Negative	No	Positive	No
6-Acetylmorphine	100,000	Negative	No	Positive	No
Alprazolam	100,000	Negative	No	Positive	No
7-Aminoclonazepam	100,000	Negative	No	Positive	No
7-Aminoflunitrazepam	100,000	Negative	No	Positive	No
7-Aminonitrazepam	100,000	Negative	No	Positive	No
Amitriptyline	100,000	Negative	No	Positive	No

Table 12 - Structurally Non-Similar Compounds (for 100ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (75ng/mL)		+25% Cutoff (125ng/mL)	
		Result	Interference?	Result	Interference?
Amobarbital	100,000	Negative	No	Positive	No
S-(+)-Amphetamine	100,000	Negative	No	Positive	No
Benzylpiperazine	100,000	Negative	No	Positive	No
Bromazepam	100,000	Negative	No	Positive	No
Buprenorphine	100,000	Negative	No	Positive	No
Bupropion	100,000	Negative	No	Positive	No
Butabarbital	100,000	Negative	No	Positive	No
Butalbital	100,000	Negative	No	Positive	No
Caffeine	500,000	Negative	No	Positive	No
Cannabidiol	100,000	Negative	No	Positive	No
Cannabinol	75,000	Negative	No	Positive	No
Carbamazepine	100,000	Negative	No	Positive	No
Carisoprodol	100,000	Negative	No	Positive	No
Chlordiazepoxide	100,000	Negative	No	Positive	No
cis-Tramadol	100,000	Negative	No	Positive	No
Clobazam	100,000	Negative	No	Positive	No
Clomipramine	50,000	Negative	No	Positive	No
Clonazepam	100,000	Negative	No	Positive	No
Clozapine	100,000	Negative	No	Positive	No
Codeine	100,000	Negative	No	Positive	No
Cotinine	100,000	Negative	No	Positive	No
Cyclobenzaprine	100,000	Negative	No	Positive	No
Dehydronorketamine	100,000	Negative	No	Positive	No
Demoxepam	100,000	Negative	No	Positive	No
Desipramine	30,000	Negative	No	Positive	No
Desalkylflurazepam	100,000	Negative	No	Positive	No
Dextromethorphan	100,000	Negative	No	Positive	No
Diazepam	100,000	Negative	No	Positive	No
Digoxin	100,000	Negative	No	Positive	No
Dihydrocodeine	100,000	Negative	No	Positive	No
Δ^9 THC	100,000	Negative	No	Positive	No
Doxepin	100,000	Negative	No	Positive	No
1R,2S (-) Ephedrine	100,000	Negative	No	Positive	No
1S,2R (+) Ephedrine	100,000	Negative	No	Positive	No
Ethyl- β -D-Glucuronide	100,000	Negative	No	Positive	No
Ethylmorphine	100,000	Negative	No	Positive	No
Fenfluramine	100,000	Negative	No	Positive	No
Fentanyl	100,000	Negative	No	Positive	No
Flunitrazepam	100,000	Negative	No	Positive	No
Fluoxetine	100,000	Negative	No	Positive	No
Flurazepam	100,000	Negative	No	Positive	No
Haloperidol	100,000	Negative	No	Positive	No
Heroin	100,000	Negative	No	Positive	No

Table 12 - Structurally Non-Similar Compounds (for 100ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (75ng/mL)		+25% Cutoff (125ng/mL)	
		Result	Interference?	Result	Interference?
Hexobarbital	100,000	Negative	No	Positive	No
Hydrocodone	100,000	Negative	No	Positive	No
Hydromorphone	100,000	Negative	No	Positive	No
11-hydroxy- Δ^9 THC	100,000	Negative	No	Positive	No
Ibuprofen	500,000	Negative	No	Positive	No
Imipramine	50,000	Negative	No	Positive	No
Ketamine	100,000	Negative	No	Positive	No
Lamotrigine	100,000	Negative	No	Positive	No
Levorphanol Tartrate	100,000	Negative	No	Positive	No
Lidocaine	100,000	Negative	No	Positive	No
Lorazepam	100,000	Negative	No	Positive	No
Lorazepam Glucuronide	50,000	Negative	No	Positive	No
Lormetazepam	100,000	Negative	No	Positive	No
LSD	100,000	Negative	No	Positive	No
Maprotiline	100,000	Negative	No	Positive	No
(+)-MDA	100,000	Negative	No	Positive	No
MDEA	100,000	Negative	No	Positive	No
MDMA	100,000	Negative	No	Positive	No
Meperidine	50,000	Negative	No	Positive	No
Meprobamate	100,000	Negative	No	Positive	No
S(+)-Methamphetamine	100,000	Negative	No	Positive	No
Methaqualone	100,000	Negative	No	Positive	No
Methoxetamine	100,000	Negative	No	Positive	No
Methylone	100,000	Negative	No	Positive	No
Midazolam	100,000	Negative	No	Positive	No
Morphine	100,000	Negative	No	Positive	No
Morphine-3 β -D-Glucuronide	100,000	Negative	No	Positive	No
Morphine-6 β -D-Glucuronide	50,000	Negative	No	Positive	No
N-Desmethyltapentadol	100,000	Negative	No	Positive	No
Nalorphine	100,000	Negative	No	Positive	No
Naloxone	100,000	Negative	No	Positive	No
Naltrexone	100,000	Negative	No	Positive	No
Naproxen	100,000	Negative	No	Positive	No
Nitrazepam	100,000	Negative	No	Positive	No
11-nor-9-carboxy - Δ^9 -THC	100,000	Negative	No	Positive	No
Norbuprenorphine	50,000	Negative	No	Positive	No
Norcodeine	100,000	Negative	No	Positive	No
Nordiazepam	100,000	Negative	No	Positive	No
Norketamine	100,000	Negative	No	Positive	No
Normorphine	100,000	Negative	No	Positive	No
Norproxyphe	100,000	Negative	No	Positive	No
Norpseudoephedrine	100,000	Negative	No	Positive	No
Nortriptyline	100,000	Negative	No	Positive	No

Table 12 - Structurally Non-Similar Compounds (for 100ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (75ng/mL)		+25% Cutoff (125ng/mL)	
		Result	Interference?	Result	Interference?
Olanzapine	100,000	Negative	No	Positive	No
Oxazepam	100,000	Negative	No	Positive	No
Oxycodone	100,000	Negative	No	Positive	No
Oxymorphone	100,000	Negative	No	Positive	No
PCP	50,000	Negative	No	Positive	No
Pentazocine	100,000	Negative	No	Positive	No
Pentobarbital	100,000	Negative	No	Positive	No
Phenobarbital	100,000	Negative	No	Positive	No
Phentermine	100,000	Negative	No	Positive	No
Phenylephedrine	100,000	Negative	No	Positive	No
Phenylpropanolamine	100,000	Negative	No	Positive	No
Phenytoin	100,000	Negative	No	Positive	No
PMA	100,000	Negative	No	Positive	No
Prazepam	100,000	Negative	No	Positive	No
Propoxyphene	100,000	Negative	No	Positive	No
Propranolol	100,000	Negative	No	Positive	No
Protriptyline	100,000	Negative	No	Positive	No
R,R (+)- Pseudoephedrine	100,000	Negative	No	Positive	No
S,S (-)- Pseudoephedrine	100,000	Negative	No	Positive	No
Ranitidine	100,000	Negative	No	Positive	No
Ritalinic Acid	100,000	Negative	No	Positive	No
Salicylic Acid	100,000	Negative	No	Positive	No
Secobarbital	100,000	Negative	No	Positive	No
Sertraline	100,000	Negative	No	Positive	No
Sufentanil Citrate	50,000	Negative	No	Positive	No
Tapentadol	100,000	Negative	No	Positive	No
Temazepam	100,000	Negative	No	Positive	No
Theophylline	100,000	Negative	No	Positive	No
Thioridazine	30,000	Negative	No	Positive	No
Trazodone	100,000	Negative	No	Positive	No
Triazolam	100,000	Negative	No	Positive	No
Trifluoromethylphenyl-piperazine	100,000	Negative	No	Positive	No
Trimipramine	100,000	Negative	No	Positive	No
Venlafaxine	100,000	Negative	No	Positive	No
Verapamil	100,000	Negative	No	Positive	No
Zolpidem Tartrate	100,000	Negative	No	Positive	No

b. The following is a table of the structurally non-similar compounds for the 300ng/mL cutoff:

Table 13 - Structurally Non-Similar Compounds (for 300ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-25% Cutoff (225ng/mL)		+25% Cutoff (375ng/mL)	
		Result	Interference?	Result	Interference?
4-bromo 2-5, dimethoxyphenethylamine	100,000	Negative	No	Positive	No
Acetaminophen	500,000	Negative	No	Positive	No
Acetylsalicylic Acid	500,000	Negative	No	Positive	No
6-Acetylcodeine	100,000	Negative	No	Positive	No
6-Acetylmorphine	100,000	Negative	No	Positive	No
Alprazolam	100,000	Negative	No	Positive	No
7-Aminoclonazepam	100,000	Negative	No	Positive	No
7-Aminoflunitrazepam	100,000	Negative	No	Positive	No
7-Aminonitrazepam	100,000	Negative	No	Positive	No
Amitriptyline	100,000	Negative	No	Positive	No
Amobarbital	100,000	Negative	No	Positive	No
S-(+)-Amphetamine	100,000	Negative	No	Positive	No
Benzylpiperazine	100,000	Negative	No	Positive	No
Bromazepam	100,000	Negative	No	Positive	No
Buprenorphine	100,000	Negative	No	Positive	No
Bupropion	100,000	Negative	No	Positive	No
Butabarbital	100,000	Negative	No	Positive	No
Butalbital	100,000	Negative	No	Positive	No
Caffeine	500,000	Negative	No	Positive	No
Cannabidiol	100,000	Negative	No	Positive	No
Cannabinol	100,000	Negative	No	Positive	No
Carbamazepine	100,000	Negative	No	Positive	No
Carisoprodol	100,000	Negative	No	Positive	No
Chlordiazepoxide	100,000	Negative	No	Positive	No
cis-Tramadol	100,000	Negative	No	Positive	No
Clobazam	100,000	Negative	No	Positive	No
Clomipramine	100,000	Negative	No	Positive	No
Clonazepam	100,000	Negative	No	Positive	No
Clozapine	100,000	Negative	No	Positive	No
Codeine	100,000	Negative	No	Positive	No
Cotinine	100,000	Negative	No	Positive	No
Cyclobenzaprine	100,000	Negative	No	Positive	No
Dehydronorketamine	100,000	Negative	No	Positive	No
Demoxepam	100,000	Negative	No	Positive	No
Desipramine	100,000	Negative	No	Positive	No
Desalkylflurazepam	100,000	Negative	No	Positive	No
Dextromethorphan	100,000	Negative	No	Positive	No
Diazepam	100,000	Negative	No	Positive	No
Digoxin	100,000	Negative	No	Positive	No
Dihydrocodeine	100,000	Negative	No	Positive	No

Table 13 - Structurally Non-Similar Compounds (for 300ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (225ng/mL)		+25% Cutoff (375ng/mL)	
		Result	Interference?	Result	Interference?
Δ ⁹ THC	100,000	Negative	No	Positive	No
Doxepin	100,000	Negative	No	Positive	No
1R,2S (-) Ephedrine	100,000	Negative	No	Positive	No
1S,2R (+) Ephedrine	100,000	Negative	No	Positive	No
Ethyl-β-D-Glucuronide	100,000	Negative	No	Positive	No
Ethylmorphine	100,000	Negative	No	Positive	No
Fenfluramine	100,000	Negative	No	Positive	No
Fentanyl	100,000	Negative	No	Positive	No
Flunitrazepam	100,000	Negative	No	Positive	No
Fluoxetine	100,000	Negative	No	Positive	No
Flurazepam	100,000	Negative	No	Positive	No
Haloperidol	100,000	Negative	No	Positive	No
Heroin	100,000	Negative	No	Positive	No
Hexobarbital	100,000	Negative	No	Positive	No
Hydrocodone	100,000	Negative	No	Positive	No
Hydromorphone	100,000	Negative	No	Positive	No
11-hydroxy- Δ ⁹ THC	100,000	Negative	No	Positive	No
Ibuprofen	500,000	Negative	No	Positive	No
Imipramine	100,000	Negative	No	Positive	No
Ketamine	100,000	Negative	No	Positive	No
Lamotrigine	100,000	Negative	No	Positive	No
Levorphanol Tartrate	100,000	Negative	No	Positive	No
Lidocaine	100,000	Negative	No	Positive	No
Lorazepam	100,000	Negative	No	Positive	No
Lorazepam Glucuronide	50,000	Negative	No	Positive	No
Lormetazepam	100,000	Negative	No	Positive	No
LSD	100,000	Negative	No	Positive	No
Maprotiline	100,000	Negative	No	Positive	No
(+)-MDA	100,000	Negative	No	Positive	No
MDEA	100,000	Negative	No	Positive	No
MDMA	100,000	Negative	No	Positive	No
Meperidine	100,000	Negative	No	Positive	No
Meprobamate	100,000	Negative	No	Positive	No
S(+)-Methamphetamine	100,000	Negative	No	Positive	No
Methaqualone	100,000	Negative	No	Positive	No
Methoxetamine	100,000	Negative	No	Positive	No
Methylone	100,000	Negative	No	Positive	No
Midazolam	100,000	Negative	No	Positive	No
Morphine	100,000	Negative	No	Positive	No
Morphine-3β-D-Glucuronide	100,000	Negative	No	Positive	No
Morphine-6β-D-Glucuronide	50,000	Negative	No	Positive	No
N-Desmethyltapentadol	100,000	Negative	No	Positive	No
Nalorphine	100,000	Negative	No	Positive	No

Table 13 - Structurally Non-Similar Compounds (for 300ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (225ng/mL)		+25% Cutoff (375ng/mL)	
		Result	Interference?	Result	Interference?
Naloxone	100,000	Negative	No	Positive	No
Naltrexone	100,000	Negative	No	Positive	No
Naproxen	100,000	Negative	No	Positive	No
Nitrazepam	100,000	Negative	No	Positive	No
11-nor-9-carboxy - Δ^9 -THC	100,000	Negative	No	Positive	No
Norbuprenorphine	50,000	Negative	No	Positive	No
Norcodeine	100,000	Negative	No	Positive	No
Nordiazepam	100,000	Negative	No	Positive	No
Norketamine	100,000	Negative	No	Positive	No
Normorphine	100,000	Negative	No	Positive	No
Norproxyphene	100,000	Negative	No	Positive	No
Norpseudoephedrine	100,000	Negative	No	Positive	No
Nortriptyline	100,000	Negative	No	Positive	No
Olanzapine	100,000	Negative	No	Positive	No
Oxazepam	100,000	Negative	No	Positive	No
Oxycodone	100,000	Negative	No	Positive	No
Oxymorphone	100,000	Negative	No	Positive	No
PCP	100,000	Negative	No	Positive	No
Pentazocine	100,000	Negative	No	Positive	No
Pentobarbital	100,000	Negative	No	Positive	No
Phenobarbital	100,000	Negative	No	Positive	No
Phentermine	100,000	Negative	No	Positive	No
Phenylephedrine	100,000	Negative	No	Positive	No
Phenylpropanolamine	100,000	Negative	No	Positive	No
Phenytoin	100,000	Negative	No	Positive	No
PMA	100,000	Negative	No	Positive	No
Prazepam	100,000	Negative	No	Positive	No
Propoxyphene	100,000	Negative	No	Positive	No
Propranolol	100,000	Negative	No	Positive	No
Protriptyline	100,000	Negative	No	Positive	No
R,R (+)- Pseudoephedrine	100,000	Negative	No	Positive	No
S,S (-)- Pseudoephedrine	100,000	Negative	No	Positive	No
Ranitidine	100,000	Negative	No	Positive	No
Ritalinic Acid	100,000	Negative	No	Positive	No
Salicylic Acid	100,000	Negative	No	Positive	No
Secobarbital	100,000	Negative	No	Positive	No
Sertraline	100,000	Negative	No	Positive	No
Sufentanil Citrate	50,000	Negative	No	Positive	No
Tapentadol	100,000	Negative	No	Positive	No
Temazepam	100,000	Negative	No	Positive	No
Theophylline	100,000	Negative	No	Positive	No
Thioridazine	100,000	Negative	No	Positive	No
Trazodone	100,000	Negative	No	Positive	No

Table 13 - Structurally Non-Similar Compounds (for 300ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (225ng/mL)		+25% Cutoff (375ng/mL)	
		Result	Interference?	Result	Interference?
Triazolam	100,000	Negative	No	Positive	No
Trifluoromethylphenyl-piperazine	100,000	Negative	No	Positive	No
Trimipramine	100,000	Negative	No	Positive	No
Venlafaxine	100,000	Negative	No	Positive	No
Verapamil	100,000	Negative	No	Positive	No
Zolpidem Tartrate	100,000	Negative	No	Positive	No

c. The following is a table of the structurally non-similar compounds for the 1000ng/mL cutoff:

Table 14 - Structurally Non-Similar Compounds (for 1000ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (750ng/mL)		+25% Cutoff (1250ng/mL)	
		Result	Interference?	Result	Interference?
4-bromo 2-5, dimethoxyphenethylamine	100,000	Negative	No	Positive	No
Acetaminophen	500,000	Negative	No	Positive	No
Acetylsalicylic Acid	500,000	Negative	No	Positive	No
6-Acetylcodeine	100,000	Negative	No	Positive	No
6-Acetylmorphine	100,000	Negative	No	Positive	No
Alprazolam	100,000	Negative	No	Positive	No
7-Aminoclonazepam	100,000	Negative	No	Positive	No
7-Aminoflunitrazepam	100,000	Negative	No	Positive	No
7-Aminonitrazepam	100,000	Negative	No	Positive	No
Amitriptyline	100,000	Negative	No	Positive	No
Amobarbital	100,000	Negative	No	Positive	No
S-(+)-Amphetamine	100,000	Negative	No	Positive	No
Benzylpiperazine	100,000	Negative	No	Positive	No
Bromazepam	100,000	Negative	No	Positive	No
Buprenorphine	100,000	Negative	No	Positive	No
Bupropion	100,000	Negative	No	Positive	No
Butabarbital	100,000	Negative	No	Positive	No
Butalbital	100,000	Negative	No	Positive	No
Caffeine	500,000	Negative	No	Positive	No
Cannabidiol	100,000	Negative	No	Positive	No
Cannabinol	100,000	Negative	No	Positive	No
Carbamazepine	100,000	Negative	No	Positive	No
Carisoprodol	100,000	Negative	No	Positive	No
Chlordiazepoxide	100,000	Negative	No	Positive	No
cis-Tramadol	100,000	Negative	No	Positive	No
Clobazam	100,000	Negative	No	Positive	No
Clomipramine	100,000	Negative	No	Positive	No
Clonazepam	100,000	Negative	No	Positive	No

Table 14 - Structurally Non-Similar Compounds (for 1000ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (750ng/mL)		+25% Cutoff (1250ng/mL)	
		Result	Interference?	Result	Interference?
Clozapine	100,000	Negative	No	Positive	No
Codeine	100,000	Negative	No	Positive	No
Cotinine	100,000	Negative	No	Positive	No
Cyclobenzaprine	100,000	Negative	No	Positive	No
Dehydronorketamine	100,000	Negative	No	Positive	No
Demoxepam	100,000	Negative	No	Positive	No
Desipramine	100,000	Negative	No	Positive	No
Desalkylflurazepam	100,000	Negative	No	Positive	No
Dextromethorphan	100,000	Negative	No	Positive	No
Diazepam	100,000	Negative	No	Positive	No
Digoxin	100,000	Negative	No	Positive	No
Dihydrocodeine	100,000	Negative	No	Positive	No
Δ^9 THC	100,000	Negative	No	Positive	No
Doxepin	100,000	Negative	No	Positive	No
1R,2S (-) Ephedrine	100,000	Negative	No	Positive	No
1S,2R (+) Ephedrine	100,000	Negative	No	Positive	No
Ethyl- β -D-Glucuronide	100,000	Negative	No	Positive	No
Ethylmorphine	100,000	Negative	No	Positive	No
Fenfluramine	100,000	Negative	No	Positive	No
Fentanyl	100,000	Negative	No	Positive	No
Flunitrazepam	100,000	Negative	No	Positive	No
Fluoxetine	100,000	Negative	No	Positive	No
Flurazepam	100,000	Negative	No	Positive	No
Haloperidol	100,000	Negative	No	Positive	No
Heroin	100,000	Negative	No	Positive	No
Hexobarbital	100,000	Negative	No	Positive	No
Hydrocodone	100,000	Negative	No	Positive	No
Hydromorphone	100,000	Negative	No	Positive	No
11-hydroxy- Δ^9 THC	100,000	Negative	No	Positive	No
Ibuprofen	500,000	Negative	No	Positive	No
Imipramine	100,000	Negative	No	Positive	No
Ketamine	100,000	Negative	No	Positive	No
Lamotrigine	100,000	Negative	No	Positive	No
Levorphanol Tartrate	100,000	Negative	No	Positive	No
Lidocaine	100,000	Negative	No	Positive	No
Lorazepam	100,000	Negative	No	Positive	No
Lorazepam Glucuronide	50,000	Negative	No	Positive	No
Lormetazepam	100,000	Negative	No	Positive	No
LSD	100,000	Negative	No	Positive	No
Maprotiline	100,000	Negative	No	Positive	No
(+)-MDA	100,000	Negative	No	Positive	No
MDEA	100,000	Negative	No	Positive	No
MDMA	100,000	Negative	No	Positive	No

Table 14 - Structurally Non-Similar Compounds (for 1000ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (750ng/mL)		+25% Cutoff (1250ng/mL)	
		Result	Interference?	Result	Interference?
Meperidine	100,000	Negative	No	Positive	No
Meprobamate	100,000	Negative	No	Positive	No
S(+)-Methamphetamine	100,000	Negative	No	Positive	No
Methaqualone	100,000	Negative	No	Positive	No
Methoxetamine	100,000	Negative	No	Positive	No
Methylone	100,000	Negative	No	Positive	No
Midazolam	100,000	Negative	No	Positive	No
Morphine	100,000	Negative	No	Positive	No
Morphine-3 β -D-Glucuronide	100,000	Negative	No	Positive	No
Morphine-6 β -D-Glucuronide	50,000	Negative	No	Positive	No
N-Desmethyltapentadol	100,000	Negative	No	Positive	No
Nalorphine	100,000	Negative	No	Positive	No
Naloxone	100,000	Negative	No	Positive	No
Naltrexone	100,000	Negative	No	Positive	No
Naproxen	100,000	Negative	No	Positive	No
Nitrazepam	100,000	Negative	No	Positive	No
11-nor-9-carboxy - Δ^9 -THC	100,000	Negative	No	Positive	No
Norbuprenorphine	50,000	Negative	No	Positive	No
Norcodeine	100,000	Negative	No	Positive	No
Nordiazepam	100,000	Negative	No	Positive	No
Norketamine	100,000	Negative	No	Positive	No
Normorphine	100,000	Negative	No	Positive	No
Norproxyphe	100,000	Negative	No	Positive	No
Norpseudoephedrine	100,000	Negative	No	Positive	No
Nortriptyline	100,000	Negative	No	Positive	No
Olanzapine	100,000	Negative	No	Positive	No
Oxazepam	100,000	Negative	No	Positive	No
Oxycodone	100,000	Negative	No	Positive	No
Oxymorphone	100,000	Negative	No	Positive	No
PCP	100,000	Negative	No	Positive	No
Pentazocine	100,000	Negative	No	Positive	No
Pentobarbital	100,000	Negative	No	Positive	No
Phenobarbital	100,000	Negative	No	Positive	No
Phentermine	100,000	Negative	No	Positive	No
Phenylephedrine	100,000	Negative	No	Positive	No
Phenylpropanolamine	100,000	Negative	No	Positive	No
Phenytoin	100,000	Negative	No	Positive	No
PMA	100,000	Negative	No	Positive	No
Prazepam	100,000	Negative	No	Positive	No
Propoxyphene	100,000	Negative	No	Positive	No
Propranolol	100,000	Negative	No	Positive	No
Protriptyline	100,000	Negative	No	Positive	No
R,R (+)- Pseudoephedrine	100,000	Negative	No	Positive	No

Table 14 - Structurally Non-Similar Compounds (for 1000ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-25% Cutoff (750ng/mL)		+25% Cutoff (1250ng/mL)	
		Result	Interference?	Result	Interference?
S,S (-)- Pseudoephedrine	100,000	Negative	No	Positive	No
Ranitidine	100,000	Negative	No	Positive	No
Ritalinic Acid	100,000	Negative	No	Positive	No
Salicylic Acid	100,000	Negative	No	Positive	No
Secobarbital	100,000	Negative	No	Positive	No
Sertraline	100,000	Negative	No	Positive	No
Sufentanil Citrate	50,000	Negative	No	Positive	No
Tapentadol	100,000	Negative	No	Positive	No
Temazepam	100,000	Negative	No	Positive	No
Theophylline	100,000	Negative	No	Positive	No
Thioridazine	100,000	Negative	No	Positive	No
Trazodone	100,000	Negative	No	Positive	No
Triazolam	100,000	Negative	No	Positive	No
Trifluoromethylphenyl-piperazine	100,000	Negative	No	Positive	No
Trimipramine	100,000	Negative	No	Positive	No
Venlafaxine	100,000	Negative	No	Positive	No
Verapamil	100,000	Negative	No	Positive	No
Zolpidem Tartrate	100,000	Negative	No	Positive	No

d. Concentrations above the following may result in a falsely low test result for the 100ng/mL cutoff: Cannabinol at 75,000. Concentrations above the following may result in a falsely high test result for the 100ng/mL cutoff: Desipramine at 30,000, Clomipramine and Imipramine at 50,000, Meperidine at 50,000, PCP at 50,000 and Thioridazine at 30,000. The limitations have been added to the labeling regarding these compounds.

e. The following is a table of the endogenous compounds results for the 100ng/mL cutoff:

Table 15 - Endogenous Compounds (for 100ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-25% Cutoff (75ng/mL)		+25% Cutoff (125ng/mL)	
		Result	Interference?	Result	Interference?
Acetone	1.0 g/dL	Negative	No	Positive	No
Ascorbic Acid	1.5 g/dL	Negative	No	Positive	No
Bilirubin	0.002 g/dL	Negative	No	Positive	No
Creatinine	0.5 g/dL	Negative	No	Positive	No
Ethanol	1.0 g/dL	Negative	No	Positive	No
Galactose	0.01 g/dL	Negative	No	Positive	No
γ-Globulin	0.5 g/dL	Negative	No	Positive	No
Glucose	2.0 g/dL	Negative	No	Positive	No
Hemoglobin	0.300 g/dL	Negative	No	Positive	No

Table 15 - Endogenous Compounds (for 100ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (75ng/mL)		+25% Cutoff (125ng/mL)	
		Result	Interference?	Result	Interference?
Human Serum Albumin	0.5 g/dL	Negative	No	Positive	No
Oxalic Acid	0.1 g/dL	Negative	No	Positive	No
Riboflavin	0.0075 g/dL	Negative	No	Positive	No
Sodium Azide	1% w/v	Negative	No	Positive	No
Sodium Chloride	6.0 g/dL	Negative	No	Positive	No
Sodium Fluoride	1% w/v	Negative	No	Positive	No
Urea	6.0 g/dL	Negative	No	Positive	No

f. The following is a table of the endogenous compounds results for the 300ng/mL cutoff:

Table 16 - Endogenous Compounds (for 300ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (225ng/mL)		+25% Cutoff (375ng/mL)	
		Result	Interference?	Result	Interference?
Acetone	1.0 g/dL	Negative	No	Positive	No
Ascorbic Acid	1.5 g/dL	Negative	No	Positive	No
Bilirubin	0.002 g/dL	Negative	No	Positive	No
Creatinine	0.5 g/dL	Negative	No	Positive	No
Ethanol	1.0 g/dL	Negative	No	Positive	No
Galactose	0.01 g/dL	Negative	No	Positive	No
γ-Globulin	0.5 g/dL	Negative	No	Positive	No
Glucose	2.0 g/dL	Negative	No	Positive	No
Hemoglobin	0.300 g/dL	Negative	No	Positive	No
Human Serum Albumin	0.5 g/dL	Negative	No	Positive	No
Oxalic Acid	0.1 g/dL	Negative	No	Positive	No
Riboflavin	0.0075 g/dL	Negative	No	Positive	No
Sodium Azide	1% w/v	Negative	No	Positive	No
Sodium Chloride	6.0 g/dL	Negative	No	Positive	No
Sodium Fluoride	1% w/v	Negative	No	Positive	No
Urea	6.0 g/dL	Negative	No	Positive	No

g. The following is a table of the endogenous compounds results for the 1000ng/mL cutoff:

Table 17 - Endogenous Compounds (for 1000ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (750ng/mL)		+25% Cutoff (1250ng/mL)	
		Result	Interference?	Result	Interference?
Acetone	1.0 g/dL	Negative	No	Positive	No
Ascorbic Acid	1.5 g/dL	Negative	No	Positive	No
Bilirubin	0.002 g/dL	Negative	No	Positive	No
Creatinine	0.5 g/dL	Negative	No	Positive	No
Ethanol	1.0 g/dL	Negative	No	Positive	No
Galactose	0.01 g/dL	Negative	No	Positive	No

Table 17 - Endogenous Compounds (for 1000ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (750ng/mL)		+25% Cutoff (1250ng/mL)	
		Result	Interference?	Result	Interference?
γ-Globulin	0.5 g/dL	Negative	No	Positive	No
Glucose	2.0 g/dL	Negative	No	Positive	No
Hemoglobin	0.300 g/dL	Negative	No	Positive	No
Human Serum Albumin	0.5 g/dL	Negative	No	Positive	No
Oxalic Acid	0.1 g/dL	Negative	No	Positive	No
Riboflavin	0.0075 g/dL	Negative	No	Positive	No
Sodium Azide	1% w/v	Negative	No	Positive	No
Sodium Chloride	6.0 g/dL	Negative	No	Positive	No
Sodium Fluoride	1% w/v	Negative	No	Positive	No
Urea	6.0 g/dL	Negative	No	Positive	No

h. The following is a table of the Boric Acid for the 100ng/mL cutoff results:

Table 18 – Boric Acid (for 100ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (75ng/mL)		+25% Cutoff (125ng/mL)	
		Result	Interference?	Result	Interference?
Boric Acid	1% w/v	Negative	No	Negative	Yes

i. The following is a table of the Boric Acid for the 300ng/mL cutoff results:

Table 19 – Boric Acid (for 300ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (225ng/mL)		+25% Cutoff (375ng/mL)	
		Result	Interference?	Result	Interference?
Boric Acid	1% w/v	Negative	No	Negative	Yes

j. The following is a table of the Boric Acid for the 1000ng/mL cutoff results:

Table 20 – Boric Acid (for 1000ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (750ng/mL)		+25% Cutoff (1250ng/mL)	
		Result	Interference?	Result	Interference?
Boric Acid	1% w/v	Negative	No	Negative	Yes

k. The following is a table of the Boric Acid for the 100ng/mL cutoff results:

Table 21 – Boric Acid (for 100ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-50% Cutoff (50ng/mL)		+50% Cutoff (150ng/mL)	
		Result	Interference?	Result	Interference?
Boric Acid	1% w/v	Negative	No	Positive	No

- l. The following is a table of the Boric Acid for the 300ng/mL cutoff results:

Table 22 – Boric Acid (for 300ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-50% Cutoff (150ng/mL)		+50% Cutoff (450ng/mL)	
		Result	Interference?	Result	Interference?
Boric Acid	1% w/v	Negative	No	Positive	No

- m. The following is a table of the Boric Acid for the 1000ng/mL cutoff results:

Table 23 – Boric Acid (for 1000ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-50% Cutoff (500ng/mL)		+50% Cutoff (1500ng/mL)	
		Result	Interference?	Result	Interference?
Boric Acid	1% w/v	Negative	No	Positive	No

- n. Boric Acid interferes with the assay and the limitations have been added to the labeling regarding this compound.

- o. The following is table of the effect of pH results for the 100ng/mL cutoff:

Table 24 - Effect of pH (for 100ng/mL cutoff)					
Test Parameter	Value	-25% Cutoff (75ng/mL)		+25% Cutoff (125ng/mL)	
		Result	Interference?	Result	Interference?
pH	3.0	NEG	No	POS	No
pH	4.0	NEG	No	POS	No
pH	5.0	NEG	No	POS	No
pH	6.0	NEG	No	POS	No
pH	7.0	NEG	No	POS	No
pH	8.0	NEG	No	POS	No
pH	9.0	NEG	No	POS	No
pH	10.0	NEG	No	POS	No
pH	11.0	NEG	No	POS	No

- p. The following is table of the effect of pH results for the 300ng/mL cutoff:

Table 25 - Effect of pH (for 300ng/mL cutoff)					
Test Parameter	Value	-25% Cutoff (225ng/mL)		+25% Cutoff (375ng/mL)	
		Result	Interference?	Result	Interference?
pH	3.0	NEG	No	POS	No
pH	4.0	NEG	No	POS	No
pH	5.0	NEG	No	POS	No
pH	6.0	NEG	No	POS	No
pH	7.0	NEG	No	POS	No
pH	8.0	NEG	No	POS	No
pH	9.0	NEG	No	POS	No
pH	10.0	NEG	No	POS	No
pH	11.0	NEG	No	POS	No

q. The following is a table of the effect of pH results for the 1000ng/mL cutoff:

Table 26 - Effect of pH (for 1000ng/mL cutoff)					
Test Parameter	Value	-25% Cutoff (750ng/mL)		+25% Cutoff (1250ng/mL)	
		Result	Interference?	Result	Interference?
pH	3.0	NEG	No	POS	No
pH	4.0	NEG	No	POS	No
pH	5.0	NEG	No	POS	No
pH	6.0	NEG	No	POS	No
pH	7.0	NEG	No	POS	No
pH	8.0	NEG	No	POS	No
pH	9.0	NEG	No	POS	No
pH	10.0	NEG	No	POS	No
pH	11.0	NEG	No	POS	No

r. The following is a table of the effect of specific gravity results for the 100ng/mL cutoff:

Table 27 - Effect of Specific Gravity (for 100ng/mL cutoff)					
Test Parameter	Value	-25% Cutoff (75ng/mL)		+25% Cutoff (125ng/mL)	
		Result	Interference?	Result	Interference?
Specific Gravity	1.000	NEG	No	POS	No
Specific Gravity	1.002	NEG	No	POS	No
Specific Gravity	1.005	NEG	No	POS	No
Specific Gravity	1.010	NEG	No	POS	No
Specific Gravity	1.015	NEG	No	POS	No
Specific Gravity	1.020	NEG	No	POS	No
Specific Gravity	1.025	NEG	No	POS	No
Specific Gravity	1.030	NEG	No	POS	No

s. The following is a table of the effect of specific gravity results for the 300ng/mL cutoff:

Table 28 - Effect of Specific Gravity (for 300ng/mL cutoff)					
Test Parameter	Value	-25% Cutoff (225ng/mL)		+25% Cutoff (375ng/mL)	
		Result	Interference?	Result	Interference?
Specific Gravity	1.000	NEG	No	POS	No
Specific Gravity	1.002	NEG	No	POS	No
Specific Gravity	1.005	NEG	No	POS	No
Specific Gravity	1.010	NEG	No	POS	No
Specific Gravity	1.015	NEG	No	POS	No
Specific Gravity	1.020	NEG	No	POS	No
Specific Gravity	1.025	NEG	No	POS	No
Specific Gravity	1.030	NEG	No	POS	No

t. The following is a table of the effect of specific gravity results for the 1000ng/mL cutoff:

Table 29 - Effect of Specific Gravity (for 1000ng/mL cutoff)					
Test Parameter	Value	-25% Cutoff (750ng/mL)		+25% Cutoff (1250ng/mL)	
		Result	Interference?	Result	Interference?
Specific Gravity	1.000	NEG	No	POS	No
Specific Gravity	1.002	NEG	No	POS	No
Specific Gravity	1.005	NEG	No	POS	No
Specific Gravity	1.010	NEG	No	POS	No
Specific Gravity	1.015	NEG	No	POS	No
Specific Gravity	1.020	NEG	No	POS	No
Specific Gravity	1.025	NEG	No	POS	No
Specific Gravity	1.030	NEG	No	POS	No

4. Linearity/ Recovery - A drug free urine pool was spiked with high concentration of the target analyte as a high value specimen. Additional pools were made by serially diluting the high value specimen. The study verified assay linearity in the semi-quantitative mode. The instrument used for this test was a Beckman Coulter AU 400e.

a. The following is a summary table of the linearity/recovery:

Table 30 - Linearity/ Recovery		
Expected Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
0	2.3	N/A
100	109.5	109.5
200	203.8	101.9
300	292.7	97.6
400	413.4	103.4
500	492.2	98.4
600	638.0	106.3
700	746.0	106.6
800	833.7	104.2
900	926.1	102.9
1000	980.0	98.0
1100	1037.8	94.3

b. The Linearity/Recovery study has successfully verified that the product performance can meet the design specifications regarding assay performance in the semi-quantitative mode

5. Method Comparison - Unaltered, anonymous and discarded clinical urine samples obtained from clinical testing laboratories were analyzed with the test device. The study verified that the product performance can be verified by Mass Spectrometry. The instrument used for this test was a Beckman Coulter AU 400e and an Agilent 6430 Liquid Chromatography Tandem Mass Spectrometry.

a. The following is a comparison table of qualitative assay performance for the 100ng/mL cutoff:

Table 31 - Method Comparison (for 100ng/mL cutoff) – Qualitative

		LC/MS Confirmation	
		(+)	(-)
Test Device	(+)	40	1
	(-)	0	39

b. The following is a summary table of qualitative assay performance for the 100ng/mL cutoff:

Table 32 - Assay Performance verified by LC/MS – 100ng/mL Cutoff

Type	EDDP Concentration				Agreement (%)
	< 50ng/mL	50 ~ 99 ng/mL	100 ~ 150 ng/mL	> 150 ng/mL	
Qualitative/ Positive	0	1	4	36	98
Qualitative/ Negative	36	3	0	0	100

c. The following is a summary table of qualitative discordant results for the 100ng/mL cutoff:

Table 33 - Discordant Result Summary – 100ng/mL Cutoff

Sample ID	In-House ID	Qualitative Results 100ng Cutoff	LC/MS Confirmation
		Test Device	EDDP
JM042877	15980	POS	97.0

d. The following is a comparison table of qualitative assay performance for the 300ng/mL cutoff:

Table 34 - Method Comparison (for 300ng/mL cutoff) – Qualitative

		LC/MS Confirmation	
		(+)	(-)
Test Device	(+)	40	0
	(-)	0	40

e. The following is a summary table of the qualitative assay performance for the 300ng/mL cutoff:

Table 35 - Assay Performance verified by LC/MS – 300ng/mL Cutoff

Type	EDDP Concentration				Agreement (%)
	< 150ng/mL	150 ~ 299 ng/mL	300 ~ 450 ng/mL	> 450 ng/mL	
Qualitative/ Positive	0	0	4	36	100
Qualitative/ Negative	36	4	0	0	100

f. The following is a comparison table of qualitative assay performance for the 1000ng/mL cutoff:

Table 36 - Method Comparison (for 1000ng/mL cutoff) – Qualitative

		LC/MS Confirmation	
		(+)	(-)
Test Device	(+)	40	0
	(-)	0	40

g. The following is a summary table of the qualitative assay performance for the 1000ng/mL cutoff:

Table 37 - Assay Performance verified by LC/MS – 1000ng/mL Cutoff					
Type	EDDP Concentration				Agreement (%)
	< 500ng/mL	500 ~ 999 ng/mL	1000 ~ 1500 ng/mL	> 1500 ng/mL	
Qualitative/ Positive	0	0	4	36	100
Qualitative/ Negative	36	4	0	0	100

h. The following is a comparison table of semi-quantitative assay performance for the 100ng/mL cutoff:

Table 38 - Method Comparison (for 100ng/mL cutoff) – Semi-Quantitative

		LC/MS Confirmation	
		(+)	(-)
Test Device	(+)	40	1
	(-)	0	39

i. The following is a summary table of semi-quantitative assay performance for the 100ng/mL cutoff:

Table 39 - Assay Performance verified by LC/MS – 100ng/mL Cutoff					
Type	EDDP Concentration				Agreement (%)
	< 50ng/mL	50 ~ 99 ng/mL	100 ~ 150 ng/mL	> 150 ng/mL	
Semi-Quantitative/ Positive	0	1	4	36	98
Semi-Quantitative / Negative	36	3	0	0	100

j. The following is a summary table of semi-quantitative assay performance for the 100ng/mL:

Table 40 - Discordant Result Summary – 100ng/mL Cutoff – Semi-Quantitative				
Sample ID	In-House ID	Semi-Quantitative Results 100ng Cutoff		LC/MS Confirmation
		Value	Result	EDDP
JM042877	15980	149.5	POS	97.0

k. The following is a comparison table of semi-quantitative assay performance for the 300ng/mL cutoff:

Table 41 - Method Comparison (for 300ng/mL cutoff) – Semi-Quantitative

		LC/MS Confirmation	
		(+)	(-)
Test Device	(+)	40	0
	(-)	0	40

1. The following is a summary table of semi-quantitative assay performance for the 300ng/mL cutoff:

Table 42 - Assay Performance verified by LC/MS – 300ng/mL Cutoff					
Type	EDDP Concentration				Agreement (%)
	< 150ng/mL	150 ~ 299 ng/mL	300 ~ 450 ng/mL	> 450 ng/mL	
Semi-Quantitative/ Positive	0	0	4	36	100
Semi-Quantitative / Negative	36	4	0	0	100

6. Stability -

- a. A closed accelerated stability study was performed on reagents at 25°C to establish the initial expiration dating. The stability study supported an initial expiration date of 1 year at 2 – 8°C for reagents. The instrument used for this test was Beckman Coulter AU 400e. Real stability studies are ongoing.
- b. An open vial stability study was performed on reagents at 25°C to establish the initial expiration dating. The stability study supported an initial expiration date of 1 year at 2 – 8°C for reagents. The instrument used for this test was Beckman Coulter AU 400e. Real stability studies are ongoing.
- c. An open/on-board stability study was performed on reagents to establish expiration dating when reagents are opened and stored on board the instrument at 2°C to 8°C. The stability study supported an initial open vial expiration date of 28 days at 2 – 8°C. The instrument used for this test was Beckman Coulter AU 400e.

7. Calibrator and Control Analytical Performance – Immunalysis EDDP Urine Calibrators and Controls

- a. EDDP Calibrators and Controls Traceability – all components of the calibrators and controls have been traced to a commercially available standard solution.
- b. EDDP Calibrators and Controls Open Vial Stability – An open vial accelerated stability study was performed at 37°C to establish the initial open vial expiration dating. The stability study supported an initial open vial expiration date of 1 year at 2 – 8°C for calibrators and controls. The instrument used for this test was an Agilent 1200 Series Liquid Chromatograph coupled to Agilent 6410 Tandem Mass Spectrometer. All calibrator levels (1, 2, 3, and 4) and all control levels (Low Control 1, 2, and 3 and High Control 1, 2, and 3) for EDDP were within specifications for Day 0, 3, 7, 10, and 13. This stability study was performed to establish initial expiration dating.
- c. EDDP Calibrators and Controls Closed Vial Upright Stability – A closed vial upright accelerated stability study was performed at 37°C to establish the initial vial expiration dating. The stability study supported an initial expiration date of 1 year at 2 – 8°C for calibrators and controls. The instrument used for this test was an Agilent 1200 Series Liquid Chromatograph coupled to Agilent 6410 Tandem Mass Spectrometer. All calibrator levels (1, 2, 3, and 4) and all control levels (Low Control 1, 2,

and 3 and High Control 1, 2, and 3) for EDDP were within specifications for Day 0, 3, 7, 10, and 13. This accelerated stability study was performed to establish initial expiration dating. Real time stability studies are ongoing.

- d. EDDP Calibrators and Controls Closed Vial Inverted Stability – A closed vial inverted accelerated stability study was performed at 37°C to establish the initial vial expiration dating. The stability study supported an initial expiration date of 1 year at 2 – 8°C for calibrators and controls. The instrument used for this test was an Agilent 1200 Series Liquid Chromatograph coupled to Agilent 6410 Tandem Mass Spectrometer. All calibrator levels (1, 2, 3, and 4) and all control levels (Low Control 1, 2, and 3 and High Control 1, 2, and 3) for EDDP were within specifications for Day 0, 3, 7, 10, and 13. This accelerated stability study was performed to establish initial expiration dating. Real time stability studies are ongoing.
- e. EDDP Calibrators and Controls Value Assignment – Calibrators and controls are manufactured and are tested by mass spectrometry. If any of the analytes are not of the acceptable range, then the calibrator and controls is adjusted and re-tested. Values are assigned to the calibrators and controls once the mass spectrometry results are within the acceptable ranges.

I. Conclusion

The information provided in this pre-market notification demonstrates that the Immunalysis EDDP Specific Urine Enzyme Immunoassay is substantially equivalent to the legally marketed predicate device for its general intended use.