DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 18, 2016

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

Re: K153693
Trade/Device Name: Immunalysis Methamphetamine Urine Enzyme Immunoassay, Immunalysis Multi-drug Calibrators
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine test system
Regulatory Class: II
Product Code: LAF, DKB
Dated: December 21, 2015
Received: December 23, 2015

Dear Mr. 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Immunalysis Methamphetamine Urine Enzyme Immunoassay and Immunalysis Multi-Drug Calibrators

Indications for Use *(Describe)*
The Immunalysis Methamphetamine Urine Enzyme Immunoassay is a homogeneous enzyme immunoassay with a dual cutoff of 500ng/mL and 1000ng/mL. The assay is intended for use in laboratories for the qualitative and semi-quantitative analysis of Methamphetamine in human urine with automated clinical chemistry analyzers. This assay is calibrated against Methamphetamine. 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 Gas Chromatography/ Mass Spectrometry (GC-MS) or permitting laboratories to establish quality control procedures.

The Immunalysis Methamphetamine 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. GC-MS or Liquid Chromatography / Mass Spectrometry (LC/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.

The Immunalysis Multi-Drug Calibrators are intended for in vitro diagnostic use for the calibration of assays for the analytes currently listed in the package insert: Benzoylecgonine, Methamphetamine, Morphine, PCP and Oxazepam. The calibrators are designed for prescription use with immunoassays.

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.

IMMUNALYSIS

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: February 17, 2016

B. Device Information

1. Trade Name: Immunalysis Methamphetamine Urine Enzyme Immunoassay
   Immunalysis Multi-Drug Calibrators
2. Common Name: Immunalysis Methamphetamine Urine Enzyme Immunoassay
   Immunalysis Multi-Drug Calibrators

C. Regulatory Information

1. Device Classification: II
2. Regulation Number: 21 CFR 862.3100 Enzyme Immunoassay, Methamphetamine
   21 CFR 862.3200 Clinical Toxicology Calibrator
3. Panel: Toxicology(91)
4. Product Code: DKZ
   DKB

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

1. Predicate Device: DRI® Methamphetamines Assay
   LZI Multiple Analyte Drugs of Abuse Calibrators and Controls
2. Predicate Company: Microgenics, Inc.
   Lin-Zhi International, Inc.
3. Predicate K Number: K093114
   K051088

E. Device Description

1. The assay consists of antibody/ substrate reagent and enzyme conjugate reagent. The antibody/ substrate reagent includes monoclonal antibodies to Methamphetamine, glucose-6-phosphate (G6P) and nicotinamide adenine dinucleotide (NAD) in Tris buffer with Sodium Azide as a preservative. The enzyme conjugate reagent includes Methamphetamine derivative labeled with glucose-6-phosphate dehydrogenase (G6PDH) in Tris buffer with Sodium Azide as a preservative.

2. All of the Immunalysis Multi-Drug Calibrators are liquid and ready to use. 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 are prepared by spiking known concentrations of drug analyte into the negative calibrator matrix. These five calibrators (negative, Level 1, 2, 3 and 4) are sold as individual bottles. The concentration of drug analyte in the corresponding calibrators is summarized as follows:

Table 1 Immunalysis Multi-Drug Calibrators

Analyte	Multi-Drug Calibrators			
	Level 1	Level 2	Level 3	Level 4
Benzoylecgonine	150ng/mL	300ng/mL	500ng/mL	1000ng/mL
Methamphetamine	500ng/mL	1000ng/mL	1500ng/mL	2000ng/mL
Morphine	100ng/mL	300ng/mL	500ng/mL	1000ng/mL
PCP	12.5ng/mL	25ng/mL	50ng/mL	100ng/mL
Oxazepam	100ng/mL	200ng/mL	500ng/mL	1000ng/mL

F. Intended Use

1. The Immunalysis Methamphetamine Urine Enzyme Immunoassay is a homogeneous enzyme immunoassay with a dual cutoff of 500ng/mL and 1000ng/mL. The assay is intended for use in laboratories for the qualitative and semi-quantitative analysis of Methamphetamine in human urine with automated clinical chemistry analyzers. This assay is calibrated against Methamphetamine. 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 Methamphetamine 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 / Mass Spectrometry (LC/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 Multi-Drug Calibrators

The Immunalysis Multi-Drug Calibrators are intended for in vitro diagnostic use for the calibration of assays for the analytes currently listed in the package insert: Benzoylecgonine, Methamphetamine, Morphine, PCP and Oxazepam. The calibrators are designed for prescription use with immunoassays.

G. Comparison of the new device with the predicate device

Item	**Methamphetamine Assay K093114**	**Immunalysis Methamphetamine Urine EIA**
Intended Use	For the qualitative and semi-quantitative determination of the presence of Methamphetamine in human urine at a cutoff of 500ng/mL and 1000ng/mL	For the qualitative and semi-quantitative determination of the presence of Methamphetamine in human urine at a cutoff of 500ng/mL and 1000ng/mL
Type of Product	Analytical Reagents	Analytical Reagents
Measured Analytes	Methamphetamine and Amphetamine	Methamphetamine
Test Matrix	Urine	Urine
Cutoff Levels	500ng/mL and 1000ng/mL of Methamphetamine/Amphetamine	500ng/mL and 1000ng/mL of Methamphetamine
Test System	Homogeneous Enzyme Immunoassay	Homogeneous Enzyme Immunoassay
Materials	Liquid Ready-to-Use Two Reagent Assay (R1 and R2)	Antibody/Substrate Reagents and Enzyme Labeled Conjugate
Mass Spectroscopy Confirmation	Required for preliminary positive analytical results	Required for preliminary positive analytical results
Antibody	Monoclonal antibodies to Methamphetamine and/or Amphetamine	Monoclonal antibody to Methamphetamine
Storage	2 – 8°C until expiration date	2 – 8°C until expiration date

Item	**LZI Multiple Analyte** K051088	**Immunalysis Multi-Drug Calibrator**
Analyte	benzoylecgonine, d-methamphetamine, methadone, morphine, oxazepam, secobarbital, phencyclidine, propoxyphene	benzoylecgonine, methamphetamine, morphine, PCP, oxazepam
Matrix	Urine	Urine
Calibrator Levels	5 Levels – See Table 2 Below	5 Levels (Negative and Level 1, 2, 3 and 4) - See Device Description Table 1
Storage	2 – 8°C until expiration date	2 – 8°C until expiration date

Table 2 LZI Multiple Analyte DAU Calibrators and Controls				
Analyte	Multiple Analyte Calibrators			
	Low	Cutoff	Intermediate	High
d-Methamphetamine	250ng/mL	500ng/mL	750ng/mL	1000ng/mL
Morphine	1000ng/mL	2000ng/mL	4000ng/mL	6000ng/mL
Phencyclidine	12.5ng/mL	25ng/mL	50ng/mL	100ng/mL
Benzoylecgonine	75ng/mL	150ng/mL	300ng/mL	1000ng/mL
Oxazepam	100ng/mL	200ng/mL	500ng/mL	1000ng/mL
Secobarbital	100ng/mL	200ng/mL	500ng/mL	1000ng/mL
Propoxyphene	150ng/mL	300ng/mL	600ng/mL	1000ng/mL
Methadone	150ng/mL	300ng/mL	600ng/mL	1000ng/mL

H. The following laboratory performance studies were performed to determine substantial equivalence of the Immunalysis Methamphetamine 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 on drug free urine (N=80) spiked with methamphetamine to concentrations of ±25%, ±50%, ±75%, and ±100% of the cutoff. The spiked concentrations were confirmed by mass spectrometry (MS). The study verified that the cutoff serves as a boundary between a negative and positive interpretation of a qualitative result. The instruments used for this was Beckman Coulter AU 400e.

    a. The following is a summary table of the Qualitative Analysis for the 500ng/mL cutoff test data results.

Table 3 - Qualitative Analysis (for 500ng/mL cutoff)			
Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
125	-75%	80	80 Negative
250	-50%	80	80 Negative
375	-25%	80	80 Negative
500	Cutoff	80	41 Negative/39 Positive
625	+25%	80	80 Positive
750	+50%	80	80 Positive
875	+75%	80	80 Positive
1000	+100%	80	80 Positive

b. The following is a summary table of the Qualitative 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	44 Negative/36 Positive
1250	+25%	80	80 Positive
1500	+50%	80	80 Positive
1750	+75%	80	80 Positive
2000	+100%	80	80 Positive

c. The following is a summary table of the Semi-Quantitative Analysis for the 500ng/mL cutoff test data results.

Table 5 - Semi-Quantitative Analysis (for 500ng/mL cutoff)			
Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
125	-75%	80	80 Negative
250	-50%	80	80 Negative
375	-25%	80	80 Negative
500	Cutoff	80	35 Negative/45 Positive
625	+25%	80	80 Positive
750	+50%	80	80 Positive
875	+75%	80	80 Positive
1000	+100%	80	80 Positive

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

Table 6 - Semi-Quantitative Analysis (for 1000ng/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	37 Negative/43 Positive
1250	+25%	80	80 Positive
1500	+50%	80	80 Positive
1750	+75%	80	80 Positive
2000	+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, in both the qualitative and semi-

quantitative modes. The instrument used for this test was a Beckman Coulter AU 400e.

a. The qualitative result summary table for the 500ng/mL cutoff is outlined below:

Table 7 - Structurally Related Compounds (for 500 ng/mL cutoff) - Qualitative			
Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
(+) Methamphetamine	500	Positive	100.00
(-) Methamphetamine	90,000	Positive	0.56
(+) Amphetamine	20,000	Positive	2.50
(-) Amphetamine	900,000	Positive	0.06
Methylenedioxyamphetamine (MDA)	18,000	Positive	2.78
Methoxyamphetamine (PMA)	15,000	Positive	3.33
Methylenedioxymethamphetamine (MDMA)	800	Positive	62.50
MDEA	3,000	Positive	16.67
Fenfluramine	7,000	Positive	7.14
(+) Pseudoephedrine	75,000	Positive	0.67
(-) Pseudoephedrine	300,000	Positive	0.17
(-) Ephedrine	65,000	Positive	0.77
(+) Ephedrine	1,000,000	Negative	<0.05
Phentermine	500,000	Positive	0.10
Tyramine	850,000	Positive	0.06
Phenylephrine	800,000	Positive	0.06
Diphenhydramine	1,000,000	Negative	<0.050
Phenypropanolamine	1,000,000	Negative	<0.05

b. The qualitative result summary table for the 1000ng/mL cutoff is outlined below:

Table 8 - Structurally Related Compounds (for 1000 ng/mL cutoff) - Qualitative			
Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
(+) Methamphetamine	1,000	Positive	100.00
(-) Methamphetamine	200,000	Positive	0.44
(+) Amphetamine	60,000	Positive	2.50
(-) Amphetamine	1,000,000	Negative	<0.10
Methylenedioxyamphetamine (MDA)	40,000	Positive	2.50
Methoxyamphetamine (PMA)	40,000	Positive	3.33
Methylenedioxymethamphetamine (MDMA)	1,000	Positive	71.43
MDEA	5,000	Positive	14.29
Fenfluramine	10,000	Positive	6.06
(+) Pseudoephedrine	200,000	Positive	0.67
(-) Pseudoephedrine	1,000,000	Positive	0.13
(-) Ephedrine	200,000	Positive	0.57
(+) Ephedrine	1,000,000	Negative	<0.10

Table 8 - Structurally Related Compounds (for 1000 ng/mL cutoff) - Qualitative			
Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
Phentermine	1,000,000	Negative	<0.10
Tyramine	1,000,000	Negative	<0.10
Phenylephrine	1,000,000	Negative	<0.10
Diphenhydramine	1,000,000	Negative	<0.10
Phenypropanolamine	1,000,000	Negative	<0.10

c. The semi-quantitative result summary table for the 500ng/mL cutoff is outlined below:

Table 9 - Structurally Related Compounds (for 500 ng/mL cutoff) – Semi-Quantitative			
Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
(+) Methamphetamine	500	Positive	100.00
(-) Methamphetamine	90,000	Positive	0.56
(+) Amphetamine	20,000	Positive	2.50
(-) Amphetamine	900,000	Positive	0.06
Methylenedioxyamphetamine (MDA)	18,000	Positive	2.78
Methoxyamphetamine (PMA)	15,000	Positive	3.33
Methylenedioxymethamphetamine (MDMA)	800	Positive	62.50
MDEA	3,000	Positive	16.67
Fenfluramine	7,000	Positive	7.14
(+) Pseudoephedrine	75,000	Positive	0.67
(-) Pseudoephedrine	300,000	Positive	0.17
(-) Ephedrine	65,000	Positive	0.77
(+) Ephedrine	1,000,000	Negative	<0.05
Phentermine	500,000	Positive	0.10
Tyramine	850,000	Positive	0.06
Phenylephrine	800,000	Positive	0.06
Diphenhydramine	1,000,000	Negative	<0.050
Phenypropanolamine	1,000,000	Negative	<0.05

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

Table 10 - Structurally Related Compounds (for 1000 ng/mL cutoff) - Qualitative			
Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
(+) Methamphetamine	1,000	Positive	100.00
(-) Methamphetamine	200,000	Positive	0.44
(+) Amphetamine	60,000	Negative	2.50
(-) Amphetamine	1,000,000	Positive	<0.10
Methylenedioxyamphetamine (MDA)	40,000	Positive	2.50
Methoxyamphetamine (PMA)	40,000	Positive	3.33
Methylenedioxymethamphetamine (MDMA)	1,000	Positive	71.43
MDEA	5,000	Positive	14.29

Table 10 - Structurally Related Compounds (for 1000 ng/mL cutoff) - Qualitative			
Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
Fenfluramine	10,000	Positive	6.06
(+) Pseudoephedrine	200,000	Positive	0.67
(-) Pseudoephedrine	1,000,000	Positive	0.13
(-) Ephedrine	200,000	Positive	0.57
(+) Ephedrine	1,000,000	Negative	<0.10
Phentermine	1,000,000	Negative	<0.10
Tyramine	1,000,000	Negative	<0.10
Phenylephrine	1,000,000	Negative	<0.10
Diphenhydramine	1,000,000	Negative	<0.10
Phenypropanolamine	1,000,000	Negative	<0.10

3. Interference – Structurally unrelated compounds were evaluated in qualitative and semi-quantitatyive modes by spiking the potential interferent into drug free urine containing methamphetamine at ±25% of the cutoff. All potential interferents analyzed verified that assay performance is unaffected by externally ingested compounds. The instrument used for this test was a Beckman Coulter AU 400e.
    a. The following is a summary table of the structurally unrelated compounds for the 500ng/mL cutoff :

Table 11 - Structurally Unrelated Compounds (for 500ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (375ng/mL)**		**+25% Cutoff (625ng/mL)**	
		Qualitative	Semi-Quantitative	Qualitative	Semi-Quantitative
4-Bromo-2,5,Dimethoxyphenethylamine	100,000	Negative	Negative	Positive	Positive
6-Acetylmorphine	100,000	Negative	Negative	Positive	Positive
7-Aminoclonazepam	100,000	Negative	Negative	Positive	Positive
Acetaminophen	500,000	Negative	Negative	Positive	Positive
Acetylsalicylic Acid	500,000	Negative	Negative	Positive	Positive
Alprazolam	100,000	Negative	Negative	Positive	Positive
Amitriptyline	100,000	Negative	Negative	Positive	Positive
Amobarbital	100,000	Negative	Negative	Positive	Positive
Benzoylecgonine	500,000	Negative	Negative	Positive	Positive
Benzylpiperazine	100,000	Negative	Negative	Positive	Positive
Bromazepam	100,000	Negative	Negative	Positive	Positive
Buprenorphine	100,000	Negative	Negative	Positive	Positive
Bupropion	100,000	Negative	Negative	Positive	Positive
Butabarbital	100,000	Negative	Negative	Positive	Positive
Caffeine	500,000	Negative	Negative	Positive	Positive
Carbamazepine	100,000	Negative	Negative	Positive	Positive
Chlordiazepoxide	100,000	Negative	Negative	Positive	Positive
Chlorpromazine	100,000	Negative	Negative	Positive	Positive
cis-Tramadol	100,000	Negative	Negative	Positive	Positive

Table 11 - Structurally Unrelated Compounds (for 500ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (375ng/mL)**		**+25% Cutoff (625ng/mL)**	
		Qualitative	Semi-Quantitative	Qualitative	Semi-Quantitative
Clobazam	100,000	Negative	Negative	Positive	Positive
Clomipramine	100,000	Negative	Negative	Positive	Positive
Clonazepam	100,000	Negative	Negative	Positive	Positive
Cocaine	100,000	Negative	Negative	Positive	Positive
Codeine	100,000	Negative	Negative	Positive	Positive
Cyclobenzaprine	100,000	Negative	Negative	Positive	Positive
N-Demethyltapentadol	100,000	Negative	Negative	Positive	Positive
Delta-9-THC	100,000	Negative	Negative	Positive	Positive
Desipramine	100,000	Negative	Negative	Positive	Positive
Dextromethorphan	100,000	Negative	Negative	Positive	Positive
Diazepam	100,000	Negative	Negative	Positive	Positive
Dihydrocodeine	100,000	Negative	Negative	Positive	Positive
Doxepin	100,000	Negative	Negative	Positive	Positive
EDDP	100,000	Negative	Negative	Positive	Positive
Ethyl β-D-glucuronide	100,000	Negative	Negative	Positive	Positive
Ethylmorphine	100,000	Negative	Negative	Positive	Positive
Fentanyl	100,000	Negative	Negative	Positive	Positive
Flunitrazepam	100,000	Negative	Negative	Positive	Positive
Fluoxetine	100,000	Negative	Negative	Positive	Positive
Flurazepam	100,000	Negative	Negative	Positive	Positive
Heroin	100,000	Negative	Negative	Positive	Positive
Hexobarbital	100,000	Negative	Negative	Positive	Positive
Hydrocodone	100,000	Negative	Negative	Positive	Positive
Hydromorphone	100,000	Negative	Negative	Positive	Positive
11-hydroxy-delta-9-THC	100,000	Negative	Negative	Positive	Positive
Ibuprofen	100,000	Negative	Negative	Positive	Positive
Imipramine	100,000	Negative	Negative	Positive	Positive
Ketamine	100,000	Negative	Negative	Positive	Positive
Levorphanol Tartrate	100,000	Negative	Negative	Positive	Positive
Lidocaine	100,000	Negative	Negative	Positive	Positive
Lorazepam	100,000	Negative	Negative	Positive	Positive
LSD	100,000	Negative	Negative	Positive	Positive
Maprotiline	100,000	Negative	Negative	Positive	Positive
Meperidine	100,000	Negative	Negative	Positive	Positive
Meprobamate	100,000	Negative	Negative	Positive	Positive
Methadone	100,000	Negative	Negative	Positive	Positive
Methaquolone	100,000	Negative	Negative	Positive	Positive
Methylphenidate	100,000	Negative	Negative	Positive	Positive
Morphine	100,000	Negative	Negative	Positive	Positive
Morphine-3β-glucuronide	100,000	Negative	Negative	Positive	Positive
Morphine-6β-glucuronide	100,000	Negative	Negative	Positive	Positive
Nalorphine	100,000	Negative	Negative	Positive	Positive

Table 11 - Structurally Unrelated Compounds (for 500ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (375ng/mL)**		**+25% Cutoff (625ng/mL)**	
		Qualitative	Semi-Quantitative	Qualitative	Semi-Quantitative
Naloxone	100,000	Negative	Negative	Positive	Positive
Naltrexone	100,000	Negative	Negative	Positive	Positive
Nitrazepam	100,000	Negative	Negative	Positive	Positive
Norbuprenorphine	100,000	Negative	Negative	Positive	Positive
Norcodeine	100,000	Negative	Negative	Positive	Positive
Nordiazepam	100,000	Negative	Negative	Positive	Positive
Normorphine	100,000	Negative	Negative	Positive	Positive
Norpropoxyphene	100,000	Negative	Negative	Positive	Positive
Nortriptyline	100,000	Negative	Negative	Positive	Positive
Oxazepam	100,000	Negative	Negative	Positive	Positive
Oxycodone	100,000	Negative	Negative	Positive	Positive
Oxymorphone	100,000	Negative	Negative	Positive	Positive
PCP	100,000	Negative	Negative	Positive	Positive
Pentazocine	100,000	Negative	Negative	Positive	Positive
Pentobarbital	100,000	Negative	Negative	Positive	Positive
Phenobarbital	100,000	Negative	Negative	Positive	Positive
Phentermine	100,000	Negative	Negative	Positive	Positive
Phenytoin	100,000	Negative	Negative	Positive	Positive
Prazepam	100,000	Negative	Negative	Positive	Positive
Propranolol	100,000	Negative	Negative	Positive	Positive
Protriptyline	100,000	Negative	Negative	Positive	Positive
Ranitidine	100,000	Negative	Negative	Positive	Positive
Ritalinic Acid	100,000	Negative	Negative	Positive	Positive
Secobarbital	100,000	Negative	Negative	Positive	Positive
Sufentanil Citrate	100,000	Negative	Negative	Positive	Positive
Temazepam	100,000	Negative	Negative	Positive	Positive
11-nor-9 carboxy THC	100,000	Negative	Negative	Positive	Positive
Thioridazine	100,000	Negative	Negative	Positive	Positive
Triazolam	100,000	Negative	Negative	Positive	Positive
Trifluoromethylphenyl-piperazine	100,000	Negative	Negative	Positive	Positive
Trimipramine	100,000	Negative	Negative	Positive	Positive
Venlafaxine	100,000	Negative	Negative	Positive	Positive

b. The following is a summary table of the structurally unrelated compounds for the 1,000ng/mL cutoff:

Table 12 - Structurally Non-Similar Compounds (for 1,000ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (750ng/mL)**		**+25% Cutoff (1250ng/mL)**	
		Qualitative	Semi-Quantitative	Qualitative	Semi-Quantitative
4-Bromo-2,5,Dimethoxyphenethylamine	100,000	Negative	Negative	Positive	Positive
6-Acetylmorphine	100,000	Negative	Negative	Positive	Positive
7-Aminoclonazepam	100,000	Negative	Negative	Positive	Positive
Acetaminophen	500,000	Negative	Negative	Positive	Positive
Acetylsalicyclic Acid	500,000	Negative	Negative	Positive	Positive
Alprazolam	100,000	Negative	Negative	Positive	Positive
Amitriptyline	100,000	Negative	Negative	Positive	Positive
Amobarbital	100,000	Negative	Negative	Positive	Positive
Benzoylecgonine	500,000	Negative	Negative	Positive	Positive
Benzylpiperazine	100,000	Negative	Negative	Positive	Positive
Bromazepam	100,000	Negative	Negative	Positive	Positive
Buprenorphine	100,000	Negative	Negative	Positive	Positive
Bupropion	100,000	Negative	Negative	Positive	Positive
Butabarbital	100,000	Negative	Negative	Positive	Positive
Caffeine	500,000	Negative	Negative	Positive	Positive
Carbamazepine	100,000	Negative	Negative	Positive	Positive
Chlordiazepoxide	100,000	Negative	Negative	Positive	Positive
Chlorpromazine	100,000	Negative	Negative	Positive	Positive
cis-Tramadol	100,000	Negative	Negative	Positive	Positive
Clobazam	100,000	Negative	Negative	Positive	Positive
Clomipramine	100,000	Negative	Negative	Positive	Positive
Clonazepam	100,000	Negative	Negative	Positive	Positive
Cocaine	100,000	Negative	Negative	Positive	Positive
Codeine	100,000	Negative	Negative	Positive	Positive
Cyclobenzaprine	100,000	Negative	Negative	Positive	Positive
N-Demethyltapentadol	100,000	Negative	Negative	Positive	Positive
Delta-9-THC	100,000	Negative	Negative	Positive	Positive
Desipramine	100,000	Negative	Negative	Positive	Positive
Dextromethorphan	100,000	Negative	Negative	Positive	Positive
Diazepam	100,000	Negative	Negative	Positive	Positive
Dihydrocodeine	100,000	Negative	Negative	Positive	Positive
Doxepin	100,000	Negative	Negative	Positive	Positive
EDDP	100,000	Negative	Negative	Positive	Positive
Ethyl β-D-glucuronide	100,000	Negative	Negative	Positive	Positive
Ethylmorphine	100,000	Negative	Negative	Positive	Positive
Fentanyl	100,000	Negative	Negative	Positive	Positive
Flunitrazepam	100,000	Negative	Negative	Positive	Positive
Fluoxetine	100,000	Negative	Negative	Positive	Positive

Table 12 - **Structurally Non-Similar Compounds** (for 1,000ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (750ng/mL)**		**+25% Cutoff (1250ng/mL)**	
		Qualitative	Semi-Quantitative	Qualitative	Semi-Quantitative
Flurazepam	100,000	Negative	Negative	Positive	Positive
Heroin	100,000	Negative	Negative	Positive	Positive
Hexobarbital	100,000	Negative	Negative	Positive	Positive
Hydrocodone	100,000	Negative	Negative	Positive	Positive
Hydromorphone	100,000	Negative	Negative	Positive	Positive
11-hydroxy-delta-9-THC	100,000	Negative	Negative	Positive	Positive
Ibuprofen	100,000	Negative	Negative	Positive	Positive
Imipramine	100,000	Negative	Negative	Positive	Positive
Ketamine	100,000	Negative	Negative	Positive	Positive
Levorphanol Tartrate	100,000	Negative	Negative	Positive	Positive
Lidocaine	100,000	Negative	Negative	Positive	Positive
Lorazepam	100,000	Negative	Negative	Positive	Positive
LSD	100,000	Negative	Negative	Positive	Positive
Maprotiline	100,000	Negative	Negative	Positive	Positive
Meperidine	100,000	Negative	Negative	Positive	Positive
Meprobamate	100,000	Negative	Negative	Positive	Positive
Methadone	100,000	Negative	Negative	Positive	Positive
Methaquolone	100,000	Negative	Negative	Positive	Positive
Methylphenidate	100,000	Negative	Negative	Positive	Positive
Morphine	100,000	Negative	Negative	Positive	Positive
Morphine-3β-glucuronide	100,000	Negative	Negative	Positive	Positive
Morphine-6β-glucuronide	100,000	Negative	Negative	Positive	Positive
Nalorphine	100,000	Negative	Negative	Positive	Positive
Naloxone	100,000	Negative	Negative	Positive	Positive
Naltrexone	100,000	Negative	Negative	Positive	Positive
Nitrazepam	100,000	Negative	Negative	Positive	Positive
Norbuprenorphine	100,000	Negative	Negative	Positive	Positive
Norcodeine	100,000	Negative	Negative	Positive	Positive
Nordiazepam	100,000	Negative	Negative	Positive	Positive
Normorphine	100,000	Negative	Negative	Positive	Positive
Norpropoxyphene	100,000	Negative	Negative	Positive	Positive
Nortriptyline	100,000	Negative	Negative	Positive	Positive
Oxazepam	100,000	Negative	Negative	Positive	Positive
Oxycodone	100,000	Negative	Negative	Positive	Positive
Oxymorphone	100,000	Negative	Negative	Positive	Positive
PCP	100,000	Negative	Negative	Positive	Positive
Pentazocine	100,000	Negative	Negative	Positive	Positive
Pentobarbital	100,000	Negative	Negative	Positive	Positive
Phenobarbital	100,000	Negative	Negative	Positive	Positive
Phentermine	100,000	Negative	Negative	Positive	Positive
Phenytoin	100,000	Negative	Negative	Positive	Positive
Prazepam	100,000	Negative	Negative	Positive	Positive

Table 12 - **Structurally Non-Similar Compounds** (for 1,000ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (750ng/mL)**		**+25% Cutoff (1250ng/mL)**	
		Qualitative	Semi-Quantitative	Qualitative	Semi-Quantitative
Propranolol	100,000	Negative	Negative	Positive	Positive
Protriptyline	100,000	Negative	Negative	Positive	Positive
Ranitidine	100,000	Negative	Negative	Positive	Positive
Ritalinic Acid	100,000	Negative	Negative	Positive	Positive
Secobarbital	100,000	Negative	Negative	Positive	Positive
Sufentanil Citrate	100,000	Negative	Negative	Positive	Positive
Temazepam	100,000	Negative	Negative	Positive	Positive
11-nor-9 carboxy THC	100,000	Negative	Negative	Positive	Positive
Thioridazine	100,000	Negative	Negative	Positive	Positive
Triazolam	100,000	Negative	Negative	Positive	Positive
Trifluoromethylphenyl-piperazine	100,000	Negative	Negative	Positive	Positive
Trimipramine	100,000	Negative	Negative	Positive	Positive
Venlafaxine	100,000	Negative	Negative	Positive	Positive

4. Interference – Endogenous compounds were evaluated in qualitative and semi-quantitatyive modes by spiking the potential interferent into drug free urine containing methamphetamine at ±25% of the cutoff. All potential interferents analyzed verified that assay performance is unaffected by internally existing physiological conditions. The instrument used for this test was a Beckman Coulter AU 400e.
    a. The following is a summary table of the endogenous compounds results for the 500ng/mL cutoff:

Table 13 - **Endogenous Compounds** (for 500ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (375ng/mL)**		**+25% Cutoff (625ng/mL)**	
		Qualitative	Semi-Quantitative	Qualitative	Semi-Quantitative
Acetone	1.0 g/dL	Negative	Negative	Positive	Positive
Ascorbic Acid	1.5 g/dL	Negative	Negative	Positive	Positive
Bilirubin	0.002 g/dL	Negative	Negative	Positive	Positive
Creatinine	0.5 g/dL	Negative	Negative	Positive	Positive
Ethanol	1.0 g/dL	Negative	Negative	Positive	Positive
Galactose	0.01 g/dL	Negative	Negative	Positive	Positive
γ-Globulin	0.5 g/dL	Negative	Negative	Positive	Positive
Glucose	2.0 g/dL	Negative	Negative	Positive	Positive
Hemoglobin	0.150 g/dL	Negative	Negative	Positive	Positive
Human Serum Albumin	0.5 g/dL	Negative	Negative	Positive	Positive
Oxalic Acid	0.1 g/dL	Negative	Negative	Positive	Positive
Riboflavin	0.0075 g/dL	Negative	Negative	Positive	Positive
Sodium Azide	1% w/v	Negative	Negative	Positive	Positive
Sodium Chloride	6.0 g/dL	Negative	Negative	Positive	Positive

Table 13 - Endogenous Compounds (for 500ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (375ng/mL)**		**+25% Cutoff (625ng/mL)**	
		Qualitative	Semi-Quantitative	Qualitative	Semi-Quantitative
Sodium Fluoride	1% w/v	Negative	Negative	Positive	Positive
Urea	6.0 g/dL	Negative	Negative	Positive	Positive

b. The following is a summary table of the endogenous compounds results for the 1,000ng/mL cutoff:

Table 14 - Endogenous Compounds (for 500ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (375ng/mL)**		**+25% Cutoff (625ng/mL)**	
		Qualitative	Semi-Quantitative	Qualitative	Semi-Quantitative
Acetone	1.0 g/dL	Negative	Negative	Positive	Positive
Ascorbic Acid	1.5 g/dL	Negative	Negative	Positive	Positive
Bilirubin	0.002 g/dL	Negative	Negative	Positive	Positive
Creatinine	0.5 g/dL	Negative	Negative	Positive	Positive
Ethanol	1.0 g/dL	Negative	Negative	Positive	Positive
Galactose	0.01 g/dL	Negative	Negative	Positive	Positive
γ-Globulin	0.5 g/dL	Negative	Negative	Positive	Positive
Glucose	2.0 g/dL	Negative	Negative	Positive	Positive
Hemoglobin	0.150 g/dL	Negative	Negative	Positive	Positive
Human Serum Albumin	0.5 g/dL	Negative	Negative	Positive	Positive
Oxalic Acid	0.1 g/dL	Negative	Negative	Positive	Positive
Riboflavin	0.0075 g/dL	Negative	Negative	Positive	Positive
Sodium Azide	1% w/v	Negative	Negative	Positive	Positive
Sodium Chloride	6.0 g/dL	Negative	Negative	Positive	Positive
Sodium Fluoride	1% w/v	Negative	Negative	Positive	Positive
Urea	6.0 g/dL	Negative	Negative	Positive	Positive

5. Interference – Boric Acid at a concentration of 1% w/v was evaluated in qualitative and semi-quantitatyive modes by spiking the potential interferent into drug free urine containing methamphetamine at ±25% and ±50% of the cutoff. The instrument used for this test was a Beckman Coulter AU 400e.
    a. The following is a summary table of Boric Acid for the 500ng/mL cutoff results:

Table 15 – Boric Acid (for 500ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (375ng/mL)**		**+25% Cutoff (625ng/mL)**	
		Qualitative	Semi-Quantitative	Qualitative	Semi-Quantitative
Boric Acid	1% w/v	Negative	Negative	**Negative**	**Negative**

b. The following is a summary table of the Boric Acid for the 1,000ng/mL cutoff results:

Table 16 – Boric Acid (for 1000ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (750ng/mL)**		**+25% Cutoff (1250ng/mL)**	
		Qualitative	Semi-Quantitative	Qualitative	Semi-Quantitative
Boric Acid	1% w/v	Negative	Negative	**Negative**	Positive

c. The following is a summary table of the Boric Acid for the 500ng/mL cutoff results:

Table 17 – Boric Acid (for 500ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-50% Cutoff (250ng/mL)**		**+50% Cutoff (750ng/mL)**	
		Qualitative	Semi-Quantitative	Qualitative	Semi-Quantitative
Boric Acid	1% w/v	Negative	Negative	**Negative**	N/A

d. The following is a summary table of the Boric Acid for the 1,000ng/mL cutoff results:

Table 18 – Boric Acid (for 1000ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-50% Cutoff (250ng/mL)**		**+50% Cutoff (750ng/mL)**	
		Qualitative	Semi-Quantitative	Qualitative	Semi-Quantitative
Boric Acid	1% w/v	Negative	Negative	**Negative**	**Negative**

6. Interference – To evaluate potential interference from the pH of urine, device performance in the qualitative and semi-quantitative modes was tested using a range of urine pH values (3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0 and 11.0). All test samples were prepared in drug free urine containing methamphetamine at ±25% of the cutoff. No positive or negative interference was observed at urine pH values ranging from 3.0 to 11.0 for each test mode. The instrument used for this test was a Beckman Coulter AU 400e.
   a. The following is a summary table of the effect of pH results for the 500ng/mL cutoff:

Table 19 - Effect of pH (for 500ng/mL cutoff)					
Test Parameter	Value	**-25% Cutoff (375ng/mL)**		**+25% Cutoff (625ng/mL)**	
		Qualitative	Semi-Quantitative	Qualitative	Semi-Quantitative
pH	3.0	Negative	Negative	Positive	Positive
pH	4.0	Negative	Negative	Positive	Positive
pH	5.0	Negative	Negative	Positive	Positive
pH	6.0	Negative	Negative	Positive	Positive
pH	7.0	Negative	Negative	Positive	Positive
pH	8.0	Negative	Negative	Positive	Positive
pH	9.0	Negative	Negative	Positive	Positive

Table 19 - Effect of pH (for 500ng/mL cutoff)					
Test Parameter	Value	**-25% Cutoff (375ng/mL)**		**+25% Cutoff (625ng/mL)**	
		Qualitative	Semi-Quantitative	Qualitative	Semi-Quantitative
pH	10.0	Negative	Negative	Positive	Positive
pH	11.0	Negative	Negative	Positive	Positive

b. The following is a summary table of the effect of pH results for the 1,000ng/mL cutoff:

Table 20 - Effect of pH (for 1000ng/mL cutoff)					
Test Parameter	Value	**-25% Cutoff (750ng/mL)**		**+25% Cutoff (1250ng/mL)**	
		Qualitative	Semi-Quantitative	Qualitative	Semi-Quantitative
pH	3.0	Negative	Negative	Positive	Positive
pH	4.0	Negative	Negative	Positive	Positive
pH	5.0	Negative	Negative	Positive	Positive
pH	6.0	Negative	Negative	Positive	Positive
pH	7.0	Negative	Negative	Positive	Positive
pH	8.0	Negative	Negative	Positive	Positive
pH	9.0	Negative	Negative	Positive	Positive
pH	10.0	Negative	Negative	Positive	Positive
pH	11.0	Negative	Negative	Positive	Positive

7. Interference - To evaluate potential interference from the specific gravity of urine, device performance in the qualitative and semi-quantitative modes was tested using a range of physiologically relevant urine specific gravity values (1.000, 1.002, 1.005, 1.010, 1.015, 1.020, 1.025 and 1.030). All test samples were prepared in drug free urine containing methamphetamine at ±25% of the cutoff. No positive or negative interference was observed at urine specific gravity values ranging from 1.000 to 1.030 for each test mode.
    a. The following is a summary table of the effect of specific gravity results for 500ng/mL cutoff:

Table 21 - Effect of Specific Gravity (for 500ng/mL cutoff)					
Test Parameter	Value	**-25% Cutoff (375ng/mL)**		**+25% Cutoff (625ng/mL)**	
		Qualitative	Semi-Quantitative	Qualitative	Semi-Quantitative
Specific Gravity	1.000	Negative	Negative	Positive	Positive
Specific Gravity	1.002	Negative	Negative	Positive	Positive
Specific Gravity	1.005	Negative	Negative	Positive	Positive
Specific Gravity	1.010	Negative	Negative	Positive	Positive
Specific Gravity	1.015	Negative	Negative	Positive	Positive
Specific Gravity	1.020	Negative	Negative	Positive	Positive
Specific Gravity	1.025	Negative	Negative	Positive	Positive
Specific Gravity	1.030	Negative	Negative	Positive	Positive

b. The following is a summery table of the effect of specific gravity results for 1,000ng/mL cutoff:

Table 22 - Effect of Specific Gravity (for 1000ng/mL cutoff)					
Test Parameter	Value	**-25% Cutoff (750ng/mL)**		**+25% Cutoff (1250ng/mL)**	
		Qualitative	Semi-Quantitative	Qualitative	Semi-Quantitative
Specific Gravity	1.000	Negative	Negative	Positive	Positive
Specific Gravity	1.002	Negative	Negative	Positive	Positive
Specific Gravity	1.005	Negative	Negative	Positive	Positive
Specific Gravity	1.010	Negative	Negative	Positive	Positive
Specific Gravity	1.015	Negative	Negative	Positive	Positive
Specific Gravity	1.020	Negative	Negative	Positive	Positive
Specific Gravity	1.025	Negative	Negative	Positive	Positive
Specific Gravity	1.030	Negative	Negative	Positive	Positive

8. Linearity/ Recovery - A linearity study in the semi-quantitative mode was conducted by spiking a drug free urine pool with a high concentration of methamphetamine as a high value specimen. Additional pools were made by serially diluting the high value specimen with drug free urine to achieve concentrations ranging from 200ng/mL to 2200ng/mL. Each pool was tested in triplicate to calculate the mean concentration values that were used to calculate drug recovery. The instrument used for this test was a Beckman Coulter AU 400e.
   a. The following is a summary table of the linearity/recovery:

Table 23 - Linearity/ Recovery		
Expected Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
200	272.7	136.4
400	436.8	109.2
600	674.6	112.4
800	830.0	103.8
1000	1107.6	110.8
1200	1247.0	103.9
1400	1481.2	105.8
1600	1711.5	107.0
1800	1917.4	106.5
2000	2080.7	104.0
2200	2226.4	101.2

9. Method Comparison – Eighty unaltered, anonymous and discarded clinical urine samples obtained from clinical testing laboratories were analyzed for methamphetamine with the candidate test device on a Beckman Coulter AU 400e clinical chemitrsy analyzer and verified by Mass Spectrometry (LC-MS/MS). Results were obtained in both qualitative and semi-quantitative modes. The instruments used for this test was a Beckman Coulter AU 400e and an Agilent 6430 Liquid Chromatography Tandem Mass Spectrometer.

   a. The following is a comparison table of qualitative assay performance for the 500ng/mL cutoff:

Table 24 - Method Comparison (for 500ng/mL cutoff) - Qualitative

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

   b. The following is a summary table of qualitative assay performance for the 500ng/mL cutoff:

Table 25 - Assay Performance verified by LC/MS – 500ng/mL Cutoff

Type	Methamphetamine Concentration				Agreement (%)
	< 250ng/mL	250 ~ 499 ng/mL	500 ~ 750 ng/mL	> 750 ng/mL	
Qualitative/ Positive	0	0	4	36	100
Qualitative/ Negative	36	4	0	0	100

   c. The following is a comparison table of qualitative assay performance for the 1,000ng/mL cutoff:

Table 26 - Method Comparison (for 1000ng/mL cutoff) - Qualitative

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

   d. The following is a summary table of qualitative assay performance for the 1,000ng/mL

Table 27 - Assay Performance verified by LC/MS – 1000ng/mL Cutoff

Type	Methamphetamine Concentration				Agreement (%)
	< 500ng/mL	500 ~ 999 ng/mL	1000 ~ 1500 ng/mL	> 1500 ng/mL	
Qualitative/ Positive	0	0	16	24	100
Qualitative/ Negative	36	4	0	0	100

   e. The following is a comparison table of semi-quantitative assay performance for the 500ng/mL cutoff:

Table 28 - Method Comparison (for 500ng/mL cutoff) – Semi-Quantitative

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

f. The following is a summary table of semi-quantitative assay performance for the 500ng/mL cutoff:

Table 29 - Assay Performance verified by LC/MS – 500ng/mL Cutoff					
Type	Methamphetamine Concentration				Agreement (%)
	< 250ng/mL	250 ~ 499 ng/mL	500 ~ 750 ng/mL	> 750 ng/mL	
Semi-Quantitative/ Positive	0	1	4	36	98
Semi-Quantitative / Negative	36	3	0	0	100

g. The following is a summary table of semi-quantitative discordant results for the 500ng/mL cutoff:

Table 30 - Discordant Result Summary – 500ng/mL Cutoff – Semi-Quantitative				
Sample ID	In-House ID	Semi-Quantitative Results 500ng Cutoff		LC/MS Confirmation
		Value	Result	
358433ZA	**16559**	**544.9**	**Positive**	**494**

h. The following is a comparison table of semi-quantitative assay performance for the 1,000ng/mL cutoff:

Table 31 - Method Comparison (for 1000ng/mL cutoff) – Semi-Quantitative

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

i. The following is a summary table of semi-quantitative assay performance for the 1,000ng/mL cutoff:

Table 32 - Assay Performance verified by LC/MS – 500ng/mL Cutoff					
Type	Methamphetamine Concentration				Agreement (%)
	< 500ng/mL	500 ~ 999 ng/mL	1000 ~ 1500 ng/mL	> 1500 ng/mL	
Semi-Quantitative/ Positive	0	0	3	36	100
Semi-Quantitative / Negative	36	4	1	0	98

j. The following is a summary table of semi-quantitative discordant results for the 1000ng/mL cutoff

Table 33 - Discordant Result Summary – 1000ng/mL Cutoff – Semi-Quantitative				
Sample ID	In-House ID	Semi-Quantitative Results 1000ng Cutoff		LC/MS Confirmation
		Value	Result	
358429ZA	**16597**	**998.5**	**Negative**	**1017**

10. Immunalysis Multi-Drug Calibrators Analytical Performance

a. Traceability – all components of the calibrators have been traced to a commercially available methamphetamine solution.

b. Closed Vial Stability (Accelerated) – A closed vial stability study was performed at 25ºC to establish the initial vial expiration dating. All calibrator levels (1, 2, 3, and 4) were within specifications for Day 0, 8, 16, 24, 32, and 40. This accelerated stability study was performed to establish initial expiration dating. The stability study supported an initial expiration date of 12 months after testing on LC/MS. Real time stability studies are ongoing.

c. Open Vial Stability – An open vial stability study was performed at 5ºC to establish the initial open vial expiration dating on LC/MS. All calibrator levels (1, 2, 3, and 4) were within specifications for Day 0, 19, 26, 33, 41, and 60. This stability study supported an initial open vial expiration date of 60 days.

d. Value Assignment – Calibrators are manufactured and are tested by mass spectrometry. The negative calibrator is a processed, drug free urine matrix. The standard is compared to a reference negative standard to ensure that it is free of analyte. The non-zero calibrators are prepared by spiking a known concentration of oxazepam in the negative calibrator matrix. If any of the analytes are not of the acceptable range, then the calibrator is adjusted and re-tested. Values are assigned to the calibrators once the mass spectrometry results are within the acceptable ranges.

I. Proposed Labeling

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

J. Conclusion

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