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

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

September 4, 2015

Re: K152176
Trade/Device Name: Immunalysis PCP Urine Enzyme Immunoassay and Immunalysis Multi-Drug Calibrators
Regulation Number: 21 CFR 862.3100
Regulatory Class: Unclassified
Product Code: LCM, DKB
Dated: August 3, 2015
Received: August 4, 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,

Katherine Serrano -S

For: 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)*K152176

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

Indications for Use *(Describe)*
The Immunalysis PCP Urine Enzyme Immunoassay is a homogeneous enzyme immunoassay with a cutoff of 25ng/mL. The assay is intended for use in laboratories for the qualitative and semi-quantitative analysis of PCP in human urine with automated clinical chemistry analyzers. This assay is calibrated against PCP. 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 PCP 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, Morphine and PCP. 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.

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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:	September 3, 2015

B. Device Information

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

C. Regulatory Information

1. 510(k) Number:	K152176
2. Device Classification:	Unclassified
3. Regulation Section:	Enzyme Immunoassay, Phencyclidine CFR 862.3200 Clinical Toxicology Calibrator
4. Panel:	Toxicology(91)
5. Product Code:	LCM DKB

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

1. Predicate Device:	DRI Phencyclidines Assay LZI Multiple Analyte Drugs of Abuse Calibrators and Controls
2. Predicate Company:	Diagnostic Reagents Inc. Lin-Zhi International, Inc.
3. Predicate K Number:	K935320 K051088

E. Device Description

1. The assay consists of antibody/ substrate reagent and enzyme conjugate reagent. The antibody/ substrate reagent includes recombinant antibodies to Phencyclidine, glucose-6-phosphate (G6P) and nicotinamide adenine dinucleotide (NAD) in Tris buffer with Sodium Azide as a preservative. The enzyme conjugate reagent includes phencyclidine 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 are 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
Morphine	100ng/mL	300ng/mL	500ng/mL	1000ng/mL
PCP	12.5ng/mL	25ng/mL	50ng/mL	100ng/mL

F. Intended Use

1. Immunalysis PCP Urine Enzyme Immunoassay
   The Immunalysis PCP Urine Enzyme Immunoassay is a homogeneous enzyme immunoassay with a cutoff of 25ng/mL. The assay is intended for use in laboratories for the qualitative and semi-quantitative analysis of PCP in human urine with automated clinical chemistry analyzers. This assay is calibrated against PCP. 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 PCP 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.
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, Morphine and PCP. The calibrators are designed for prescription use with immunoassays.

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G. Comparison of the new device with the predicate device

Item	**PCP Assay K935320**	**Immunalysis PCP Urine EIA**
Intended Use	For the qualitative and semi-quantitative determination of the presence of PCP in human urine at a cutoff of 25ng/mL	Same
Type of Product	Analytical Reagents	Same
Measured Analytes	PCP	Same
Test Matrix	Urine	Same
Cutoff Levels	25ng/mL of PCP	Same
Test System	Homogeneous Enzyme Immunoassay	Same
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	Same
Antibody	Monoclonal antibodies to PCP	Recombinant antibody to PCP
Storage	2 – 8°C until expiration date	Same

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

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

1. Precision/Cutoff Characterization – Study was performed for 20 days, 2 runs per day in duplicate (N=80) on concentration of ±25%, ±50%, ±75%, and ±100% of the cutoff. 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 25ng/mL cutoff test data results

Table 3 – Qualitative Analysis (for 25ng/mL cutoff)			
Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
6.25	-75%	80	80 Negative
12.5	-50%	80	80 Negative
19	-25%	80	80 Negative
25	Cutoff	80	35 Negative/45 Positive
31	+25%	80	80 Positive
37.5	+50%	80	80 Positive
43.75	+75%	80	80 Positive
50	+100%	80	80 Positive

    b. The following is a summary table of the Semi-Quantitative Analysis for the 25ng/mL cutoff test data results

Table 4 - Semi-Quantitative Analysis (for 25ng/mL cutoff)			
Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
6.25	-75%	80	80 Negative
12.5	-50%	80	80 Negative
19	-25%	80	80 Negative
25	Cutoff	80	30 Negative/50 Positive
31	+25%	80	80 Positive
37.5	+50%	80	80 Positive
43.75	+75%	80	80 Positive
50	+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 cutoff. 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 25ng/mL cutoff is outlined below:

Table 5 - Structurally Related Compounds (for 25 ng/mL cutoff) - Qualitative			
Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
PCP	25	Positive	100
Chlorpromazine	140,000	Positive	0.01785
Clomipramine	350,000	Positive	0.00714
Cyclobenzaprine	25,000	Positive	0.10000
Dextromethorphan	80,000	Positive	0.03125
Diphenhydramine	220,000	Positive	0.01136
Doxepin	90,000	Positive	0.02777
4 – Hydroxyphencyclidine	3,500	Positive	0.71429
Imipramine	200,000	Positive	0.01250
Methoxetamine	36,000	Positive	0.06944
Thioridazine	140,000	Positive	0.01785
Venlafaxine	1,000,000	Positive	0.00250

    b. The semi-quantitative result summary table for the 25ng/mL cutoff is outlined below:

Table 6 - Structurally Related Compounds (for 25ng/mL cutoff) – Semi-Quantitative			
Compound	Concentration Tested (ng/mL)	Mean Value	Cross-Reactivity (%)
PCP	25	26.7	100
Chlorpromazine	140,000	25.9	0.01785
Clomipramine	350,000	24.8	0.00714
Cyclobenzaprine	25,000	24.9	0.10000
Dextromethorphan	80,000	24.1	0.03125
Diphenhydramine	220,000	26.6	0.01136
Doxepin	90,000	27.1	0.02777
4 – Hydroxyphencyclidine	3,500	25.6	0.71429
Imipramine	200,000	26.4	0.01250
Methoxetamine	36,000	25.9	0.06944
Thioridazine	140,000	25.4	0.01785
Venlafaxine	1,000,000	23.9	0.00250

3. Interference - Structurally non-similar compounds, endogenous compounds, the effect of pH, the effect of specific gravity and boric acid 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 25ng/mL cutoff

Table 7 - Structurally Non-Similar Compounds (for 25ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (19ng/mL)**		**+25% Cutoff (31ng/mL)**	
		Result	Interference?	Result	Interference?
Acetaminophen	500000	Negative	No	Positive	No
6-Acetylcodeine	100000	Negative	No	Positive	No
6-Acetylmorphine	100000	Negative	No	Positive	No
Acetylsalicylic Acid	500000	Negative	No	Positive	No
Alprazolam	100000	Negative	No	Positive	No
7-Aminoclonazepam	100000	Negative	No	Positive	No
7-Aminoflurnitrazepam	100000	Negative	No	Positive	No
7-Aminonitrazepam	100000	Negative	No	Positive	No
Amitriptyline	70000	Negative	No	Positive	No
Amobarbital	100000	Negative	No	Positive	No
S-(+)-Amphetamine	100000	Negative	No	Positive	No
Benzylpiperzine	100000	Negative	No	Positive	No
Bromazepam	100000	Negative	No	Positive	No
4-bromo 2-5, dimethoxyphenethylamine	100000	Negative	No	Positive	No
Buprenorphine	100000	Negative	No	Positive	No
Bupropion	100000	Negative	No	Positive	No
Butabarbital	100000	Negative	No	Positive	No
Butalbital	100000	Negative	No	Positive	No
Caffeine	500000	Negative	No	Positive	No
Cannabidiol	100000	Negative	No	Positive	No
Cannabinol	100000	Negative	No	Positive	No
Carbamazepine	100000	Negative	No	Positive	No
Carisoprodol	100000	Negative	No	Positive	No
Chlordiazepoxide	100000	Negative	No	Positive	No
cis-Tramadol	100000	Negative	No	Positive	No
Clobazam	100000	Negative	No	Positive	No
Clonazepam	100000	Negative	No	Positive	No
Clozapine	100000	Negative	No	Positive	No
Codeine	100000	Negative	No	Positive	No
Cotinine	100000	Negative	No	Positive	No
Demoxepam	100000	Negative	No	Positive	No
Desalkyflurazepam	100000	Negative	No	Positive	No
Desipramine	100000	Negative	No	Positive	No
Diazepam	100000	Negative	No	Positive	No
Digoxin	100000	Negative	No	Positive	No
Dihydrocodeine	100000	Negative	No	Positive	No
Dehydronorketamine	100000	Negative	No	Positive	No
Δ^9 THC	100000	Negative	No	Positive	No

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Table 7 - Structurally Non-Similar Compounds (for 25ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (19ng/mL)**		**+25% Cutoff (31ng/mL)**	
		Result	Interference?	Result	Interference?
EDDP	100000	Negative	No	Positive	No
EDMP	100000	Negative	No	Positive	No
1R,2S Ephedrine	100000	Negative	No	Positive	No
1S,2R Ephedrine	100000	Negative	No	Positive	No
Ethyl-β-D-Glucuronide	100000	Negative	No	Positive	No
Ethylmorphine	100000	Negative	No	Positive	No
Fenfluramine	100000	Negative	No	Positive	No
Fentanyl	100000	Negative	No	Positive	No
Flunitrazepam	100000	Negative	No	Positive	No
Fluoxetine	100000	Negative	No	Positive	No
Flurazepam	100000	Negative	No	Positive	No
Haloperidol	100000	Negative	No	Positive	No
Heroin	100000	Negative	No	Positive	No
Hexobarbital	100000	Negative	No	Positive	No
Hydrocodone	100000	Negative	No	Positive	No
Hydromorphone	100000	Negative	No	Positive	No
11-hydroxy-Δ^9 THC	100000	Negative	No	Positive	No
Ibuprofen	500000	Negative	No	Positive	No
Ketamine	100000	Negative	No	Positive	No
Lamotrigine	100000	Negative	No	Positive	No
Levorphanol Tartrate	100000	Negative	No	Positive	No
Lidocaine	100000	Negative	No	Positive	No
Lorazepam	100000	Negative	No	Positive	No
Lorazepam Glucuronide	50000	Negative	No	Positive	No
Lormetazepam	100000	Negative	No	Positive	No
LSD	100000	Negative	No	Positive	No
Maprotiline	100000	Negative	No	Positive	No
MDA	100000	Negative	No	Positive	No
MDEA	100000	Negative	No	Positive	No
MDMA	100000	Negative	No	Positive	No
Meperidine	100000	Negative	No	Positive	No
Meprobamate	100000	Negative	No	Positive	No
Methadone	100000	Negative	No	Positive	No
Methylphenidate	100000	Negative	No	Positive	No
R(-)-Methamphetamine	100000	Negative	No	Positive	No
S(+)-Methamphetamine	100000	Negative	No	Positive	No
Methaquolone	100000	Negative	No	Positive	No
Methylone	100000	Negative	No	Positive	No
Midazolam	100000	Negative	No	Positive	No
Morphine	100000	Negative	No	Positive	No
Morphine-3- β-Glucuronide	100000	Negative	No	Positive	No
Morphine-6β-D-Glucuronide	50000	Negative	No	Positive	No

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Table 7 - Structurally Non-Similar Compounds (for 25ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (19ng/mL)**		**+25% Cutoff (31ng/mL)**	
		Result	Interference?	Result	Interference?
N-Desmethyltapentadol	100000	Negative	No	Positive	No
Nalorphine	100000	Negative	No	Positive	No
Naloxone	100000	Negative	No	Positive	No
Naltrexone	100000	Negative	No	Positive	No
Naproxen	100000	Negative	No	Positive	No
Nitrazepam	100000	Negative	No	Positive	No
11-nor-9-carboxy-Δ^9-THC	100000	Negative	No	Positive	No
Norbuprenorphine	50000	Negative	No	Positive	No
Norcodeine	100000	Negative	No	Positive	No
Nordiazepam	100000	Negative	No	Positive	No
Norketamine	100000	Negative	No	Positive	No
Normorphine	100000	Negative	No	Positive	No
Norproxyphene	100000	Negative	No	Positive	No
Norpseudoephedrine	100000	Negative	No	Positive	No
Nortriptyline	100000	Negative	No	Positive	No
Olanzapine	100000	Negative	No	Positive	No
Oxazepam	100000	Negative	No	Positive	No
Oxycodone	100000	Negative	No	Positive	No
Oxymorphone	100000	Negative	No	Positive	No
Pentazocine	100000	Negative	No	Positive	No
Pentobarbital	100000	Negative	No	Positive	No
Phenobarbital	100000	Negative	No	Positive	No
Phentermine	100000	Negative	No	Positive	No
Phenylephrine	100000	Negative	No	Positive	No
Phenylpropanolamine	100000	Negative	No	Positive	No
Phenytoin	100000	Negative	No	Positive	No
PMA	100000	Negative	No	Positive	No
Prazepam	100000	Negative	No	Positive	No
Propoxyphene	100000	Negative	No	Positive	No
Propranolol	100000	Negative	No	Positive	No
Protripyline	100000	Negative	No	Positive	No
R,R Pseudoephedrine	100000	Negative	No	Positive	No
S,S Pseudoephedrine	100000	Negative	No	Positive	No
Ranitidine	100000	Negative	No	Positive	No
Ritalinic Acid	100000	Negative	No	Positive	No
Salicylic Acid	100000	Negative	No	Positive	No
Secobarbital	100000	Negative	No	Positive	No
Sertraline	100000	Negative	No	Positive	No
Sufentanil Citrate	50000	Negative	No	Positive	No
Tapentadol	100000	Negative	No	Positive	No
Temazepam	100000	Negative	No	Positive	No
Theophylline	100000	Negative	No	Positive	No
Trazodone	100000	Negative	No	Positive	No

Table 7 - Structurally Non-Similar Compounds (for 25ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (19ng/mL)**		**+25% Cutoff (31ng/mL)**	
		Result	Interference?	Result	Interference?
Triazolam	100000	Negative	No	Positive	No
Trifluoromethylphenyl-piperazine	100000	Negative	No	Positive	No
Trimipramine	100000	Negative	No	Positive	No
Verapamil	60000	Negative	No	Positive	No
Zolpidem Tartrate	100000	Negative	No	Positive	No

b. The following is a table of the endogenous compounds results for the 25ng/mL cutoff

Table 8 - Endogenous Compounds (for 25ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (19ng/mL)**		**+25% Cutoff (31ng/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	0.115 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

c. The following is a table of the boric acid for the 25ng/mL cutoff results

Table 9 – Boric Acid (for 25ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (19ng/mL)**		**+25% Cutoff (31ng/mL)**	
		Result	Interference?	Result	Interference?
Boric Acid	1% w/v	NEG	No	**NEG**	**Yes**

d. The following is a table of the boric acid for the 25ng/mL cutoff results

Table 10 – Boric Acid (for 25ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-50% Cutoff (13ng/mL)**		**+50% Cutoff (38ng/mL)**	
		Result	Interference?	Result	Interference?
Boric Acid	1% w/v	NEG	No	**NEG**	**Yes**

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

f. The following is a table of the effect of pH results for the 25ng/mL cutoff

Table 11 - Effect of pH (for 25ng/mL cutoff)					
Test Parameter	Value	**-25% Cutoff (19ng/mL)**		**+25% Cutoff (31ng/mL)**	
		Result	Interference?	Result	Interference?
pH	3.0	Negative	No	Positive	No
pH	4.0	Negative	No	Positive	No
pH	5.0	Negative	No	Positive	No
pH	6.0	Negative	No	Positive	No
pH	7.0	Negative	No	Positive	No
pH	8.0	Negative	No	Positive	No
pH	9.0	Negative	No	Positive	No
pH	10.0	Negative	No	Positive	No
pH	11.0	Negative	No	Positive	No

g. The following is a summary table of the effect of specific gravity results for the 25ng/mL cutoff

Table 12 - Effect of Specific Gravity (for 25ng/mL cutoff)					
Test Parameter	Value	**-25% Cutoff (19ng/mL)**		**+25% Cutoff (31ng/mL)**	
		Result	Interference?	Result	Interference?
Specific Gravity	1.000	Negative	No	Positive	No
Specific Gravity	1.002	Negative	No	Positive	No
Specific Gravity	1.005	Negative	No	Positive	No
Specific Gravity	1.010	Negative	No	Positive	No
Specific Gravity	1.015	Negative	No	Positive	No
Specific Gravity	1.020	Negative	No	Positive	No
Specific Gravity	1.025	Negative	No	Positive	No
Specific Gravity	1.030	Negative	No	Positive	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 instrument used for this test was a Beckman Coulter AU 400e.

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

Table 13 - Linearity/ Recovery		
Expected Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
10	9.5	94.7
20	19.6	98.2
25	27.0	108.1
30	32.4	108.0
40	42.2	105.6
50	52.4	104.9
60	64.6	107.6
70	78.3	111.9
80	85.4	106.8
90	94.6	105.1

Table 13 - Linearity/ Recovery		
Expected Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
100	100.8	100.8
110	110.0	100.0

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 25ng/mL cutoff:

Table 14 – Method Comparison for the 25ng/mL - Qualitative

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

   b. The following is a summary table of the qualitative assay performance for the 25ng/mL cutoff

Table 15 - Assay Performance verified by LC/MS – 25ng/mL Cutoff					
Type	PCP Concentration				Agreement (%)
	< 12.5ng/mL	12.5 ~ 24 ng/mL	25 ~ 37.5 ng/mL	> 37.5 ng/mL	
Qualitative/ Positive	0	0	6	34	100
Qualitative/ Negative	36	4	0	0	100

   c. The following is a comparison table of semi-quantitative assay performance for the 25ng/mL cutoff

Table 16 – Method Comparison for the 25ng/mL – Semi-Quantitative

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

   d. The following is a summary table of semi-quantitative assay performance for the 25ng/mL cutoff

Table 16 - Assay Performance verified by LC/MS – 25ng/mL Cutoff					
Type	PCP Concentration				Agreement (%)
	< 12.5ng/mL	21.5 ~ 24 ng/mL	25 ~ 37.5 ng/mL	> 37.5 ng/mL	
Semi-Quantitative/ Positive	0	0	6	34	100
Semi-Quantitative / Negative	36	4	0	0	100

6. Calibrator and Control Analytical Performance – Immunalysis Multi-Drug Calibrators
   a. Immunalysis Multi-Drug Calibrators Traceability – all components of the calibrators and controls have been traced to a commercially available PCP solution.
   b. Immunalysis Multi-Drug Calibrators Closed Vial Stability – A closed vial stability study was performed at 25ºC to establish the initial vial expiration

dating. The stability study supported an initial expiration date of 12 months. 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) for PCP were within specifications for Day 0, 8, 16, 24, 32, and 40. This accelerated stability study was performed to establish initial expiration dating. Real time stability studies are ongoing.

7.

a. Immunalysi Multi-Drug Calibrators Open Vial Stability – An open vial stability study was performed at 5ºC to establish the initial open vial expiration dating. The stability study supported an initial open vial expiration date of 60 days. 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) for PCP were within specifications for Day 0, 19, 26, 33, 41, and 60. This stability study was performed to establish initial expiration dating.
b. Immunalysis Multi-Drug Calibrators Value Assignment – Calibrators are manufactured and are tested by mass spectrometry. 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. Conclusion

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