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

June 5, 2015

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

Re: K151203
Trade/Device Name: Immunalysis Cannabinoids Urine Enzyme Immunoassay,
Immunalysis cTHC Urine Calibrators,
Immunalysis cTHC Urine Control Set
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: II
Product Code: LDJ, DLJ, LAS
Dated: May 4, 2015
Received: May 5, 2015

Dear Mr. 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

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)*

K151203

Device Name

Immunalysis Cannabinoids Urine Enzyme Immunoassay
Immunalysis cTHC Urine Control Set
Immunalysis cTHC Urine Calibrators

Indications for Use *(Describe)*

The Immunalysis Cannabinoids Urine Enzyme Immunoassay is a homogeneous enzyme immunoassay with a cutoff of 50ng/mL. The assay is intended for use in laboratories for the qualitative and semi-quantitative analysis of Cannabinoids in human urine with automated clinical chemistry analyzers. This assay is calibrated against 11-nor-9-carboxy-Δ9-THC (cTHC). 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 Immunalysis Cannabinoids 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.

Immunalysis cTHC Urine Control Set: The Immunalysis cTHC Urine Control Set is used as control materials in the Immunalysis Cannabinoids Urine Enzyme Immunoassay.

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

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: June 03, 2015

B. Device Information

1. Trade Name: Immunalysis Cannabinoids Urine Enzyme Immunoassay
   Immunalysis cTHC Urine Control Set
   Immunalysis cTHC Urine Calibrators
2. Common Name: Immunalysis Cannabinoids Urine Enzyme Immunoassay
   Immunalysis cTHC Urine Control Set
   Immunalysis cTHC Urine Calibrators
3. Device Classification: II
4. Regulation Number: CFR 862.3870 Enzyme Immunoassay, Cannabinoids
   CFR 862.3200 Calibrator, Drug Specific
   CFR 862.3280 Clinical Toxicology Control Materials
5. Panel: Toxicology(91)
6. Product Code: LDJ
   DLJ
   LAS

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

1. Predicate Device: LZI Cannabinoids (cTHC) Enzyme Immunoassay
   LZI Cannabinoids (cTHC) Drugs of Abuse (DAU) Calibrators
   LZI Cannabinoids (cTHC) Drugs of Abuse (DAU) Controls
2. Predicate Company: Lin-Zhi Internationals, Inc.
3. Predicate K Number: K110239

D. Device Description

1. The assay consists of antibody/ substrate reagent and enzyme conjugate reagent. The antibody/ substrate reagent includes monoclonal and polyclonal antibodies to Cannabinoids, glucose-6-phosphate (G6P) and nicotinamide adenine dinucleotide (NAD) in Tris buffer with Sodium Azide as a preservative. The enzyme conjugate reagent includes Cannabinoids derivative labeled with glucose-6-phosphate dehydrogenase (G6PDH) in Tris buffer with Sodium Azide as a preservative. Calibrators and controls are sold separately. Reagents are liquid, ready to use

2. All of the Immunalysis cTHC Urine Calibrators and Controls 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, as well as the LOW Control and HIGH Control are prepared by spiking known concentrations of 11-nor-9-carboxy-Δ^9-THC (cTHC) into the negative calibrator matrix. The negative calibrator, Level 1 calibrator, Level 2 calibrator, Level 3 calibrator, Level 4 calibrator and two controls are sold as individual bottles. The concentration of cTHC in their corresponding calibrators and controls are summarized as follows:

Table 1 Immunalysis cTHC Urine Calibrators and Controls

Analyte	cTHC Calibrators				cTHC Controls	
	Level 1	Level 2	Level 3	Level 4	LOW Control 1	HIGH Control 1
cTHC	20ng/mL	50ng/mL	100ng/mL	2000ng/mL	37.5ng/mL	62.5ng/mL

E. Intended Use

1. The Immunalysis Cannabinoids Urine Enzyme Immunoassay is a homogeneous enzyme immunoassay with a cutoff of 50ng/mL. The assay is intended for use in laboratories for the qualitative and semi-quantitative analysis of Cannabinoids in human urine with automated clinical chemistry analyzers. This assay is calibrated against cTHC. 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 Immunalysis Cannabinoids 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 cTHC Urine Control: The Immunalysis cTHC Urine Controls are used as control materials in Immunalysis Cannabinoids Urine Enzyme Immunoassay.

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

F. Comparison of the new device with the predicate device

Item	**Cannabinoids Assay K110239**	**Immunalysis Cannabinoids Urine EIA**
Intended Use	For the qualitative and semi-quantitative determination of the presence of Cannabinoids in human urine at a cutoff of 25ng/mL, 50ng/mL and 100ng/mL	For the qualitative and semi-quantitative determination of the presence of Cannabinoids in human urine at a cutoff of 50ng/mL
Type of Product	Analytical Reagents	Analytical Reagents
Measured Analytes	Cannabinoids	Cannabinoids
Test Matrix	Urine	Urine
Cutoff Levels	25ng/mL, 50ng/mL and 100ng/mL of Cannabinoids	50ng/mL of Cannabinoids
Test System	Homogeneous Enzyme Immunoassay	Homogenous 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	Mouse Monoclonal antibodies to Cannabinoids	Monoclonal and polyclonal antibodies to Cannabinoids
Storage	2 – 8°C until expiration date	2 – 8°C until expiration date
Calibrator Form	Liquid	Liquid
Calibrator Levels	Three sets of Five (5) Levels	Five (5) Levels (including negative)
Control Levels	Three sets of Two (2) Levels	Two (2) Levels

G. The following laboratory performance studies were performed to determine substantial equivalence of the Immunalysis Cannabinoids Urine 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 50ng/mL cutoff test data results.

Table 2 - Qualitative Analysis (for 50ng/mL cutoff)

Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
12.5	-75%	80	80 Negative
25	-50%	80	80 Negative
37.5	-25%	80	80 Negative
50	Cutoff	80	40 Negative/40 Positive
62.5	+25%	80	80 Positive
75	+50%	80	80 Positive
87.5	+75%	80	80 Positive
100	+100%	80	80 Positive

   b. The following is a summary table of the Semi-Quantitative Analysis for the 50ng/mL cutoff test data results.

Table 3 - Semi-Quantitative Analysis (for 50ng/mL cutoff)

Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
12.5	-75%	80	80 Negative
25	-50%	80	80 Negative
37.5	-25%	80	80 Negative
50	Cutoff	80	38 Negative/42 Positive
62.5	+25%	80	80 Positive
75	+50%	80	80 Positive
87.5	+75%	80	80 Positive
100	+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 50ng/mL cutoff is outlined below:

Table 4 - Structurally Related Compounds (for 50 ng/mL cutoff) - Qualitative			
Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
11-nor-9-carboxy- Δ^9-THC	50	Positive	100.0
(±) 11-Hydroxy- Δ^9-THC	100	Positive	50.0
11-nor- Δ^8-carboxy-THC	40	Positive	125.0
Cannabinol	75	Positive	66.7
Cannabidiol	1,000,000	Negative	<0.005
Δ^9-THC	50	Positive	100.0

b. The semi-quantitative result summary table for the 50ng/mL cutoff is outlined below:

Table 5 - Structurally Related Compounds (for 50ng/mL cutoff) – Semi-Quantitative		
Compound	Concentration Tested (ng/mL)	Cross-Reactivity (%)
11-nor-9-carboxy- Δ^9-THC	50	100.0
(±) 11-Hydroxy- Δ^9-THC	100	50.0
11-nor- Δ^8-carboxy-THC	40	125.0
Cannabinol	75	66.7
Cannabidiol	1,000,000	<0.005
Δ^9-THC	50	100.0

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 summary table of the structurally non-similar compounds for the 50ng/mL cutoff :

Table 6 - Structurally Non-Similar Compounds (for 50ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (37.5ng/mL)**		**+25% Cutoff (62.5ng/mL)**	
		Result	Interference?	Result	Interference?
6-Acetylmorphine	100,000	Negative	No	Positive	No
7-Aminoclonazepam	100,000	Negative	No	Positive	No
Acetaminophen	500,000	Negative	No	Positive	No
Alprazolam	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
Benzoylecgonine	500,000	Negative	No	Positive	No
Benzylpiperazine	100,000	Negative	No	Positive	No
4-Bromo-2,5,Dimethoxyphenethylamine	100,000	Negative	No	Positive	No

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Table 6 - Structurally Non-Similar Compounds (for 50ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (37.5ng/mL)**		**+25% Cutoff (62.5ng/mL)**	
		Result	Interference?	Result	Interference?
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
Caffeine	500,000	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
Chlorpromazine	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
Cocaine	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
N-Desmethyltapentadol	100,000	Negative	No	Positive	No
Despiramine	100,000	Negative	No	Positive	No
Dextromethorphan	100,000	Negative	No	Positive	No
Diazepam	100,000	Negative	No	Positive	No
Dihydrocodeine	100,000	Negative	No	Positive	No
Diphenhydramine (DPH)	500,000	Negative	No	Positive	No
Doxepin	100,000	Negative	No	Positive	No
Ecgonine	100,000	Negative	No	Positive	No
Ecgonine methyl ester	100,000	Negative	No	Positive	No
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	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
Flurazepam	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
Ibuprofen	100,000	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

Table 6 - **Structurally Non-Similar Compounds** (for 50ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (37.5ng/mL)**		**+25% Cutoff (62.5ng/mL)**	
		Result	Interference?	Result	Interference?
Levorphanol Tartrate	100,000	Negative	No	Positive	No
Lidocaine	100,000	Negative	No	Positive	No
Lorazepam	100,000	Negative	No	Positive	No
Lysergic acid diethylamide (LSD)	100,000	Negative	No	Positive	No
Maprotiline	100,000	Negative	No	Positive	No
(+)-3,4-Methylenedioxyamphetamine (MDA)	100,000	Negative	No	Positive	No
3,4-methylenedioxy-*N*-ethyl-amphetamine (MDEA)	100,000	Negative	No	Positive	No
3,4-methylenedioxy-methamphetamine (MDMA)	100,000	Negative	No	Positive	No
Meperidine	100,000	Negative	No	Positive	No
Meprobamate	100,000	Negative	No	Positive	No
Methadone	500,000	Negative	No	Positive	No
S(+)-Methamphetamine	100,000	Negative	No	Positive	No
Methaquolone	100,000	Negative	No	Positive	No
Methylphenidate	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	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
Nitrazepam	100,000	Negative	No	Positive	No
Norbuprenorphine	100,000	Negative	No	Positive	No
Norcodeine	100,000	Negative	No	Positive	No
Nordiazepam	100,000	Negative	No	Positive	No
Normorphine	100,000	Negative	No	Positive	No
Norpropoxyphene	100,000	Negative	No	Positive	No
Nortriptyline	100,000	Negative	No	Positive	No
Oxezepam	100,000	Negative	No	Positive	No
Oxycodone	100,000	Negative	No	Positive	No
Oxymorphone	100,000	Negative	No	Positive	No
Phencyclidine (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
Phenylepherine	100,000	Negative	No	Positive	No
Phenylpropanolamine	100,000	Negative	No	Positive	No
Pheytoin	100,000	Negative	No	Positive	No
para-Methoxyamphetamine	100,000	Negative	No	Positive	No

Table 6 - Structurally Non-Similar Compounds (for 50ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-25% Cutoff (37.5ng/mL)		+25% Cutoff (62.5ng/mL)	
		Result	Interference?	Result	Interference?
(PMA)					
Prazepam	100,000	Negative	No	Positive	No
Propoxyphene	100,000	Negative	No	Positive	No
Propranolol	100,000	Negative	No	Positive	No
Protripyline	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
Salicyclic Acid	100,000	Negative	No	Positive	No
Secobarbial	100,000	Negative	No	Positive	No
Sertraline	100,000	Negative	No	Positive	No
Sufentanil Citrate	100,000	Negative	No	Positive	No
Temazepam	100,000	Negative	No	Positive	No
Theophylline	100,000	Negative	No	Positive	No
Thiordazine	100,000	Negative	No	Positive	No
cis-Tramadol	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
Zolpidem	100,000	Negative	No	Positive	No

b. The following is a summary table of the endogenous compounds results for the 50ng/mL cutoff:

Table 7 - Endogenous Compounds (for 50ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-25% Cutoff (37.5ng/mL)		+25% Cutoff (62.5ng/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	300 mg/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

Table 7 - **Endogenous Compounds** (for 50ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (37.5ng/mL)**		**+25% Cutoff (62.5ng/mL)**	
		Result	Interference?	Result	Interference?
Sodium Fluoride	1% w/v	Negative	No	Positive	No
Urea	6.0 g/dL	Negative	No	Positive	No

c. The following is a summary table of Boric Acid for the 50ng/mL cutoff results:

Table 8 – Boric Acid (for 50ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (37.5ng/mL)**		**+25% Cutoff (62.5ng/mL)**	
		Result	Interference?	Result	Interference?
Boric Acid	1% w/v	Negative	No	Positive	No

d. The following is a summary table of the effect of pH results for the 50ng/mL cutoff:

Table 9 - Effect of pH (for 50ng/mL cutoff)					
Test Parameter	Value	**-25% Cutoff (37.5ng/mL)**		**+25% Cutoff (62.5ng/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

e. The following is a summary table of the effect of specific gravity results for 50ng/mL cutoff:

Table 10 - Effect of Specific Gravity (for 50ng/mL cutoff)					
Test Parameter	Value	**-25% Cutoff (37.5ng/mL)**		**+25% Cutoff (62.5ng/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. 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 11 - Linearity/ Recovery		
Expected Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
20	19.3	96.3
40	40.4	101.0
50	52.1	104.3
60	64.4	107.4
80	77.8	97.3
100	101.2	101.2
120	128.4	107.0
140	144.5	103.2
160	156.1	97.5
180	173.1	96.2
200	219.4	109.7
220	223.7	101.7

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 50ng/mL cutoff:

Table 12 - Method Comparison (for 50ng/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 50ng/mL cutoff:

Table 13 - Assay Performance verified by LC/MS – 50ng/mL Cutoff					
Type	Cannabinoids Concentration				Agreement (%)
	< 25ng/mL	25 ~ 49 ng/mL	50 ~ 75 ng/mL	> 75 ng/mL	
Qualitative/ Positive	0	0	10	30	100
Qualitative/ Negative	36	4	0	0	100

c. The following is a comparison table of semi-quantitative assay performance for the 50ng/mL cutoff:

Table 14 - Method Comparison (for 50ng/mL cutoff) – 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 50ng/mL cutoff:

Table 15 - Assay Performance verified by LC/MS – 50ng/mL Cutoff

Type	Cannabinoids Concentration				Agreement (%)
	< 25ng/mL	25 ~ 49 ng/mL	50 ~ 75 ng/mL	> 75 ng/mL	
Semi-Quantitative/ Positive	0	0	10	30	100
Semi-Quantitative / Negative	36	4	0	0	100

6. Calibrator and Control Analytical Performance – Immunalysis cTHC Urine Calibrators and Controls
   a. cTHC Calibrator and Control Traceability – all components of the calibrator and controls have been traced to a commercially available standard solution
   b. cTHC Calibrators and Controls 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) and all control levels (Low Control and High Control) for cTHC 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.
   c. cTHC Calibrators and Controls 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) and all control levels (Low Control and High Control) for cTHC were within specifications for Day 0, 7, 14, 21, 30, 45 and 60. This stability study was performed to establish initial expiration dating.
   d. cTHC Calibrator and Control 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.

H. Conclusion

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