October 31, 2018

Immunalysis Corporation
Wenying (Jessica) Zhu
Regulatory Affairs Specialist III
829 Towne Center Drive
Pomona, CA 91767

Re: k181553
Trade/Device Name: Immunalysis Ethyl Alcohol Enzyme Assay
Regulation Number: 21 CFR 862.3040
Regulation Name: Alcohol test system
Regulatory Class: Class II
Product Code: DIC
Dated: September 19, 2018
Received: September 20, 2018

Dear Wenying (Jessica) Zhu:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k181553

Device Name
Immunalysis Ethyl Alcohol Enzyme Assay

Indications for Use *(Describe)*
The Immunalysis Ethyl Alcohol Enzyme Assay is an in vitro diagnostic device for the quantitative analysis of ethyl alcohol (ethanol) in human urine, serum or plasma with automated clinical chemistry analyzers. The measurement of ethanol is used for the diagnosis and treatment of alcohol intoxication and poisoning. This assay is calibrated against ethyl alcohol. This device is intended for prescription use only.

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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k181553

510(k) SUMMARY

A. GENERAL INFORMATION

Applicant Name:	Immunalysis Corporation 829 Towne Center Drive Pomona, CA 91767 Establishment # 2020952
Company Contact:	Wenying (Jessica) Zhu Regulatory Affairs Specialist III Phone: (909) 451-6697 Email: wzhu@immunalysis.com
Date Prepared:	September 19, 2018

B. DEVICE IDENTIFICATION

Trade or Proprietary Names:	Immunalysis Ethyl Alcohol Enzyme Assay
Common Name:	Ethyl Alcohol Enzyme Assay

C. REGULATORY INFORMATION

Device Classification Name:	Alcohol Test System
Product Codes:	DIC
Regulatory Class:	II
Classification Regulation:	21 CFR 862.3040, Alcohol Test System
Panel:	Toxicology (91)
Predicate Device:	Lin-Zhi Ethyl Alcohol Enzymatic Assay [K032461]

D. DEVICE DESCRIPTION

The Immunalysis Ethyl Alcohol Assay is based on the oxidation of ethyl alcohol to acetaldehyde by alcohol dehydrogenase (ADH) and nicotinamide adenine dinucleotide (NAD) reduced to NADH resulting in an absorbance change measured spectrophotometrically at 340nm. The concentration of ethanol in the sample is directly proportional to the ADH activity.

E. INTENDED USE

The Immunalysis Ethyl Alcohol Enzyme Assay is an *in vitro* diagnostic device for the quantitative analysis of ethyl alcohol (ethanol) in human urine, serum or plasma with automated clinical chemistry analyzers. The measurement of ethanol is used for the diagnosis and treatment of alcohol intoxication and poisoning. This assay is calibrated against ethyl alcohol. This device is intended for prescription use only.

F. COMPARISON WITH PREDICATE

Attribute	Predicate Device Lin-Zhi Ethyl Alcohol Enzymatic Assay [k032461]	Candidate Device Immunalysis Ethyl Alcohol Enzyme Assay
Intended Use	For quantitative analyses of ethyl alcohol in human urine, serum, or plasma.	Same
Sample Matrix	Urine, serum or plasma	Same
Measured Analytes	Ethyl Alcohol (EtOH)	Same
Test Principle	Enzymatic assay	Same
User Environment	For use in laboratories	Same
Test Methodology	In the presence of nicotinamide adenine dinucleotide (NAD), ADH converts ethyl alcohol to acetaldehyde and reduces NAD to NADH. The ethyl alcohol concentration is then directly proportional to the ADH activity. The enzyme activity is measured at 340 nm wavelength.	Same
Instrumentation	Performed on clinical chemistry analyzers	Same
Reagent Storage	2-8°C until expiration date	Same
Assay Range	3-600 mg/dL	Same

G. PERFORMANCE CHARACTERISTICS

The following laboratory performance studies were performed to determine substantial equivalence of the Immunalysis Ethyl Alcohol Enzyme Assay to the predicate device. Assay performance was established using the Olympus AU400e analyzer.

1. Limit of Blank (LoB)/Limit of Detection (LoD)

Sixty (60) blank measurements were taken from unaltered drug free negative human urine, serum and plasma to calculate Limit of blank (LoB). Four samples of each matrix containing concentrations in the range LoB to 4xLoB were tested in replicates of five on two reagent lots over three days to calculate Limit of Detection (LoD). LoB of the assay is 0.481 mg/dL for urine and 0.668 mg/dL for serum and 0.652 mg/dL for plasma. LoD of the assay is 1.3 mg/dL for urine, 1.7 mg/dL for serum and 1.7 mg/dL for plasma.

2. Limit of Quantitation (LoQ)

Limit of Quantitation (LoQ) is selected at a level equal to or higher than LoD. Four independent samples of each matrix spiked at concentration of LoQ were tested on two reagent lots to verify LoQ. Results demonstrated that drug concentration equal to or above LoQ, 2.9 mg/dL, can be quantitatively determined with suitable accuracy.

3. Linearity/Recovery

A linearity study in the quantitative mode was conducted by spiking a drug free urine, serum and plasma pool with a high concentration of EtOH at upper limit of claimed measuring range. Additional pools were made by serially diluting the high concentration specimen with drug free urine, serum and plasma to achieve concentrations ranging from 3 mg/dL to 600 mg/dL. The high value specimen was evaluated with the predicate device to determine initial high-level value. The 0 mg/dL specimen was made from drug free urine, serum and plasma. Each pool was tested in triplicate to calculate the mean concentration values that were used to calculated drug recovery. Linearity test results are presented in **Table 1** to **Table 3**.

Table 1. Linearity/Recovery Test Results - Urine

Expected Concentration (mg/dL)	Mean Observed Concentration (mg/dL)	Recovery (%)
0.0	0.0	N/A
3.0	3.1	102.2
12.0	12.0	100.3
72.0	73.9	102.6
132.0	132.2	100.2
192.0	195.4	101.8
252.0	250.3	99.3
312.0	308.0	98.7
372.0	363.0	97.6
432.0	421.3	97.5
492.0	484.4	98.5
552.0	565.8	102.5
Slope	0.996	
Intercept	-0.172	
r^2	0.999	

Table 2. Linearity/Recovery Test Results - Serum

Expected Concentration (mg/dL)	Mean Observed Concentration (mg/dL)	Recovery (%)
0.0	0.0	N/A
3.0	3.0	101.1
23.2	23.1	99.4
83.2	87.2	104.8
143.2	146.1	102.0
203.2	199.8	98.3
263.2	262.2	99.6
323.2	317.8	98.3
383.2	385.9	100.7

Expected Concentration (mg/dL)	Mean Observed Concentration (mg/dL)	Recovery (%)
443.2	441.4	99.6
503.2	493.6	98.1
563.2	544.3	96.6
Slope	0.978	
Intercept	2.869	
r^2	0.999	

Table 3. Linearity/Recovery Test Results - Plasma

Expected Concentration (mg/dL)	Mean Observed Concentration (mg/dL)	Recovery (%)
0.0	0.0	N/A
3.0	3.0	98.9
9.9	10.5	106.1
69.9	69.7	99.8
129.9	127.5	98.2
189.9	188.4	99.2
249.9	242.3	96.9
309.9	299.9	96.8
369.9	351.9	95.1
429.9	410.0	95.4
489.9	470.4	96.0
549.9	547.0	99.5
Slope	0.970	
Intercept	0.307	
r^2	0.999	

4. Precision

Precision study was performed for 20 days, 2 runs per day in duplicate on drug free urine, serum and plasma (N=80 for each matrix) spiked with EtOH to concentrations of 25 mg/dL, 75 mg/dL, 125 mg/dL, 150 mg/dL, 175 mg/dL and 200 mg/dL and calibrators and controls at concentrations of 50 mg/dL, 100 mg/dL and 300 mg/dL. The spiked concentrations were confirmed by Gas Chromatography – Flame Ionization Detector (GC-FID). The study established assay reproducibility and verified the precision performance in the claimed measuring range. Precision test results are presented in **Table 4** to **Table 6**.

IMMUNALYSIS

Table 4. Precision - Urine

Concentration (mg/dL)	# of Sample	Mean Conc. (mg/dL)	Repeatability		Between Run		Within-Laboratory	
			SD	CV%	SD	CV%	SD	CV%
0	80	0.0	0.1	N/A	0.0	N/A	0.1	N/A
25	80	24.5	0.3	1.2	0.3	1.1	0.5	1.8
50	80	49.0	0.4	0.9	0.6	1.2	0.8	1.5
75	80	74.0	0.7	0.9	1.0	1.3	1.1	1.5
100	80	99.6	0.8	0.8	1.6	1.6	1.6	1.6
125	80	121.3	1.2	1.0	1.5	1.2	1.8	1.5
150	80	146.1	1.3	0.9	1.9	1.3	2.4	1.7
175	80	169.1	1.4	0.9	2.0	1.1	2.7	1.6
200	80	193.9	1.8	0.9	2.6	1.3	3.4	1.7
300	80	292.0	2.2	0.8	3.8	1.3	4.6	1.6

Table 5. Precision – Serum

Concentration (mg/dL)	# of Sample	Mean Conc. (mg/dL)	Repeatability		Between Run		Within-Laboratory	
			SD	CV%	SD	CV%	SD	CV%
0	80	0.4	0.2	N/A	0.1	N/A	0.2	N/A
25	80	25.8	0.2	0.9	0.5	2.0	0.8	3.2
50	80	49.3	0.3	0.7	1.0	2.0	1.0	2.0
75	80	75.7	0.4	0.5	1.4	1.8	2.2	3.0
100	80	99.6	0.5	0.5	2.0	2.1	2.1	2.1
125	80	125.9	0.8	0.6	2.4	1.9	3.9	3.1
150	80	148.4	1.0	0.6	2.6	1.7	3.8	2.6
175	80	172.3	1.0	0.6	3.1	1.8	5.1	3.0
200	80	195.2	1.3	0.7	3.4	1.8	4.9	2.5
300	80	290.4	1.4	0.5	5.5	1.9	6.0	2.1

Table 6. Precision - Plasma

Concentration (mg/dL)	# of Sample	Mean Conc. (mg/dL)	Repeatability		Between Run		Within-Laboratory	
			SD	CV%	SD	CV%	SD	CV%
0	80	0.2	0.1	N/A	0.1	N/A	0.1	N/A
25	80	24.3	0.2	0.7	0.2	1.0	1.2	4.9
50	80	49.9	0.3	0.6	0.5	0.9	0.7	1.5
75	80	69.8	0.4	0.5	0.7	1.0	1.8	2.6

Concentration (mg/dL)	# of Sample	Mean Conc. (mg/dL)	Repeatability		Between Run		Within-Laboratory	
			SD	CV%	SD	CV%	SD	CV%
100	80	100.5	0.5	0.5	1.0	1.0	1.6	1.6
125	80	118.3	0.6	0.5	1.0	0.9	2.7	2.2
150	80	155.8	0.9	0.6	1.2	0.8	4.1	2.6
175	80	170.6	0.9	0.5	1.5	0.9	3.2	1.9
200	80	197.6	1.1	0.6	1.4	0.7	3.9	2.0
300	80	292.7	2.0	0.7	2.7	0.9	5.2	1.8

5. Specificity and Cross-Reactivity

Structurally and functionally similar compounds were spiked into drug free urine, serum and plasma at levels that will yield a result that is equivalent to the concentration of 10 mg/dL and 100 mg/dL. The study verified assay performance relative to the ability of the device to exclusively determine certain drugs, in quantitative mode. Cross-reactivity test results are presented in **Table 7** to **Table 9**.

Table 7. Cross-Reactivity - Urine

Compound	10 mg/dL		100 mg/dL	
	Compound Conc. (mg/dL)	Cross-Reactivity (%)	Compound Conc. (mg/dL)	Cross-Reactivity (%)
Lot #1				
Acetaldehyde	3,000	<0.3	3,000	<3.3
Acetone	3,000	<0.3	3,000	<3.3
n-Butanol	500	2.0	3,000	<3.3
Ethylene Glycol	3,000	<0.3	3,000	<3.3
Isopropanol	3,000	<0.3	3,000	<3.3
Methanol	3,000	<0.3	3,000	<3.3
n-Propanol	60	16.7	1,025	9.8
Propylene Glycol	3,000	<0.3	3,000	<3.3
Lot #2				
Acetaldehyde	3,000	<0.3	3,000	<3.3
Acetone	3,000	<0.3	3,000	<3.3
n-Butanol	500	2.0	3,000	<3.3
Ethylene Glycol	3,000	<0.3	3,000	<3.3
Isopropanol	3,000	<0.3	3,000	<3.3
Methanol	3,000	<0.3	3,000	<3.3
n-Propanol	60	16.7	1,025	9.8
Propylene Glycol	3,000	<0.3	3,000	<3.3
Lot #3				

Compound	10 mg/dL		100 mg/dL	
Acetaldehyde	3,000	<0.3	3,000	<3.3
Acetone	3,000	<0.3	3,000	<3.3
n-Butanol	500	2.0	3,000	<3.3
Ethylene Glycol	3,000	<0.3	3,000	<3.3
Isopropanol	3,000	<0.3	3,000	<3.3
Methanol	3,000	<0.3	3,000	<3.3
n-Propanol	60	16.7	1,025	9.8
Propylene Glycol	3,000	<0.3	3,000	<3.3

Table 8. Cross-Reactivity - Serum

Compound	10 mg/dL		100 mg/dL	
	Compound Conc. (mg/dL)	Cross-Reactivity (%)	Compound Conc. (mg/dL)	Cross-Reactivity (%)
Acetaldehyde	3,000	<0.3	3,000	<3.3
Acetone	3,000	<0.3	3,000	<3.3
n-Butanol	500	2.0	3,000	<3.3
Ethylene Glycol	3,000	<0.3	3,000	<3.3
Isopropanol	3,000	<0.3	3,000	<3.3
Methanol	3,000	<0.3	3,000	<3.3
n-Propanol	90	11.1	900	11.1
Propylene Glycol	3,000	<0.3	3,000	<3.3

Table 9. Cross-Reactivity - Plasma

Compound	10 mg/dL		100 mg/dL	
	Compound Conc. (mg/dL)	Cross-Reactivity (%)	Compound Conc. (mg/dL)	Cross-Reactivity (%)
Acetaldehyde	3,000	<0.3	3,000	<3.3
Acetone	3,000	<0.3	3,000	<3.3
n-Butanol	500	2.0	3,000	<3.3
Ethylene Glycol	3,000	<0.3	3,000	<3.3
Isopropanol	3,000	<0.3	3,000	<3.3
Methanol	3,000	<0.3	3,000	<3.3
n-Propanol	90	11.1	900	11.1
Propylene Glycol	3,000	<0.3	3,000	<3.3

6. Interference – Structurally Unrelated Compounds in Urine

Structurally unrelated compounds were evaluated in quantitative mode by spiking the potential interferent into drug free urine containing EtOH at 10 mg/dL and 100 mg/dL. All potential interferents analyzed verified that assay performance is unaffected by externally ingested

compounds. The levels of structurally unrelated compounds that did not interfere in the assay are presented in **Table 10**.

Table 10. Non-Interfering Structurally Unrelated Compounds in Urine

Compound	Compound Conc. (mg/dL)
Acetaminophen	500,000
6-Acetylcodeine	100,000
6-Acetylmorphine	100,000
Acetylsalicylic Acid	500,000
Alphenal	100,000
Alprazolam	100,000
7-Aminoclonazepam	40,000
7-Aminoflunitrazepam	100,000
7-Aminonitrazepam	100,000
Amitriptyline	100,000
Amobarbital	100,000
S-(+)-Amphetamine	100,000
Aprobarbital	100,000
Barbital	100,000
Benzoylecgonine	100,000
Benzylpiperazine	100,000
Bromazepam	100,000
4-bromo 2-5, dimethoxyphenethylamine	100,000
Buprenorphine	50,000
Bupropion	100,000
Butabarbital	100,000
Butalbital	100,000
Caffeine	500,000
Cannabidiol	100,000
Cannabinol	100,000
Carbamazepine	100,000
Carisoprodol	100,000
Chlordiazepoxide	100,000
Chlorpromazine	100,000
Clobazam	100,000
Clomipramine	100,000
Clonazepam	100,000
Clozapine	100,000
Cocaine	100,000
Codeine	100,000

Compound	Compound Conc. (mg/dL)
Cotinine	100,000
Cyclobenzaprine	100,000
Cyclopentobarbital	100,000
Demoxepam	100,000
Desalkylflurazepam	100,000
Desipramine	100,000
Dextromethorphan	100,000
Diazepam	100,000
Digoxin	100,000
Dihydrocodeine	100,000
Diphenhydramine	500,000
Dehydronorketamine	40,000
delta9 THC	100,000
Doxepin	100,000
Doxylamine	100,000
ecgonine	100,000
ecgonine methyl ester	100,000
EDDP	100,000
EMDP	100,000
1R,2S Ephedrine	100,000
1S,2R Ephedrine	100,000
Ethyl-β-D-Glucuronide	50,000
Ethylmorphine	100,000
Fenfluramine	100,000
Fentanyl	100,000
Flunitrazepam	100,000
Fluoxetine	100,000
Flurazepam	100,000
Haloperidol	100,000
Heroin	100,000
Hexobarbital	100,000
hydrocodone	100,000
hydromorphone	100,000
11-hydroxy-delta9 THC	100,000
Ibuprofen	100,000
Imipramine	100,000
Ketamine	100,000
Lamotrigine	100,000
Levorphanol Tartrate	100,000

Compound	Compound Conc. (mg/dL)
Lidocaine	100,000
Lorazepam	100,000
Lorazepam Glucuronide	50,000
Lormetazepam	100,000
LSD	100,000
Maprotiline	100,000
MDA	100,000
MDEA	100,000
MDMA	100,000
Meperidine	100,000
Meprobamate	100,000
Methamphetamine	100,000
Methadone	500,000
Methaqualone	100,000
Methoxetamine	100,000
Methylone	100,000
Methylphenidate	100,000
Midazolam	100,000
Morphine	100,000
Morphine-3-glucuronide	100,000
Morphine-6-glucuronide	100,000
N-Desmethyltapentadol	100,000
Nalorphine	100,000
Naloxone	100,000
Naltrexone	100,000
Naproxen	100,000
Nitrazepam	100,000
11-nor-9-carboxy-delta9-THC	100,000
Norbuprenorphine	50,000
Norcodeine	100,000
Nordiazepam	100,000
Norketamine	100,000
Normorphine	100,000
Norproxyphene	100,000
Norpseudoephedrine	50,000
Nortriptyline	100,000
N-desmethyltramadol	100,000
N-desmethylvenlafaxine	100,000
O-desmethyltramadol	100,000

Compound	Compound Conc. (mg/dL)
O-desmethylvenlafaxine	100,000
Olanzapine	100,000
Oxycodone	100,000
Oxymorphone	100,000
Oxazepam	100,000
PCP	100,000
Pentazocine	100,000
Pentobarbital	100,000
Phenazepam	100,000
Phenobarbital	100,000
Phentermine	100,000
Phenylephrine	100,000
Phenylpropanolamine	100,000
Phenytoin	100,000
PMA	100,000
Prazepam	100,000
Propranolol	100,000
Propoxyphene	100,000
Protriptyline	100,000
R,R Pseudoephedrine	100,000
S,S Pseudoephedrine	100,000
Ritalinic Acid	100,000
Salicylic Acid	100,000
Sertraline	100,000
Sufentanil Citrate	50,000
Talbutal	50,000
Tapentadol	100,000
Temazepam	100,000
Theophylline	100,000
Thiopental	100,000
Thioridazine	100,000
Tramadol	100,000
Trazadone	100,000
Triazolam	100,000
Trifluoromethylphenyl-piperazine	100,000
Trimipramine	100,000
Venlafaxine	100,000
Verapamil	100,000
Zolpidem Tartrate	100,000

7. Interference – Endogenous Compounds and Urine Preservatives

Endogenous compounds and urine preservatives were evaluated in quantitative mode by spiking the potential interferent into drug free urine containing EtOH at concentration of 10 mg/dL and 100 mg/dL. Assay performance is unaffected by all the internally existing physiological conditions tested. The levels of endogenous compounds and urine preservatives that did not interfere in the assay are presented in **Table 11** to **Table 12**.

Table 11. Non-interfering Endogenous Compounds - Urine

Compound	10 mg/dL and 100 mg/dL
	Compound Conc.
Ascorbic Acid	1.5 g/dL
Bilirubin	0.02 g/dL
Creatinine	0.5 g/dL
Galactose	0.01 g/dL
γ-Globulin	0.5 g/dL
Glucose	2.0 g/dL
Hemoglobin	0.3 g/dL
Human Serum Albumin	0.5 g/dL
Oxalic Acid	0.1 g/dL
Riboflavin	0.0075 g/dL
Sodium Chloride	6.0 g/dL
Urea	6.0 g/dL

Table 12. Non-interfering Urine Preservatives - Urine

Compound	10 mg/dL and 100 mg/dL
	Compound Conc.
Boric Acid	1% w/v
Sodium Azide	1% w/v
Sodium Fluoride	1% w/v

8. Interference – Interferents in Serum and Plasma

Potential interfering substances in serum and plasma matrices were evaluated in quantitative mode by spiking the compound into drug free serum and plasma containing EtOH at concentration of 10 mg/dL and 100 mg/dL, respectively. Additional anticoagulants were evaluated by spiking into drug free plasma containing EtOH at concentration of 10 mg/dL and 100 mg/dL. Assay performance is unaffected by all the internally existing physiological conditions tested. The levels of substances that did not interfere in the assay are presented in **Table 13** and **Table 14**.

Table 13. Non-interfering Substances – Serum and Plasma

Compound	10 mg/dL	100 mg/dL
	Compound Conc.	Compound Conc.
Acetaminophen	20 mg/dL	20 mg/dL
Amikacin	8 mg/dL	8 mg/dL
Ampicillin	5.3 mg/dL	5.3 mg/dL
Ascorbic Acid	6 mg/dL	6 mg/dL
Bilirubin total	60 mg/dL	80 mg/dL
Bilirubin direct	60 mg/dL	80 mg/dL
Caffeine	6 mg/dL	6 mg/dL
Carbamazepine	3 mg/dL	3 mg/dL
Chloramphenicol	5 mg/dL	5 mg/dL
Chlordiazepoxide	1 mg/dL	1 mg/dL
Chlorpromazine	0.2 mg/dL	0.2 mg/dL
Cholesterol	30 mg/dL	503 mg/dL
Cimetidine	2 mg/dL	2 mg/dL
Creatinine	30 mg/dL	30 mg/dL
Dextran	6000 mg/dL	6000 mg/dL
Diazepam	0.51 mg/dL	0.51 mg/dL
Digoxin	6.1 mg/dL	6.1 mg/dL
Erythromycin	6 mg/dL	6 mg/dL
Ethosuximide	25 mg/dL	25 mg/dL
Furosemide	6 mg/dL	6 mg/dL
Gentamicin	1 mg/dL	1 mg/dL
Hemoglobin	62.5 mg/dL	1,000 mg/dL
Heparin	3 U/mL	3 U/mL
Ibuprofen	50 mg/dL	50 mg/dL
IgG	5,000 mg/dL	5,000 mg/dL
Intralipid	187.5 mg/dL	750 mg/dL
Lactate Dehydrogenase	1,000 U/L	237,500 U/L
Lactate	150 mg/dL	901 mg/dL
Lidocaine	1.2 mg/dL	1.2 mg/dL
Lithium	2.2 mg/dL	2.2 mg/dL
Mannitol	500 mg/dL	500 mg/dL
Penicillin	25 U/mL	25 U/mL
Pentobarbital	8 mg/dL	8 mg/dL
Phenobarbital	10 mg/dL	10 mg/dL
Phenytoin	5 mg/dL	5 mg/dL
Primidone	4 mg/dL	4 mg/dL
Propoxyphene	0.16 mg/dL	0.16 mg/dL
HSA (albumin)	37.5 mg/dL	1,250 mg/dL

Compound	10 mg/dL	100 mg/dL
	Compound Conc.	Compound Conc.
Protein (total)	50 mg/dL	1,500 mg/dL
Salicylic Acid	60 mg/dL	60 mg/dL
Theophylline	4 mg/dL	4 mg/dL
Triglycerides	500 mg/dL	500 mg/dL
Urea	500 mg/dL	500 mg/dL
Uric Acid	20 mg/dL	20 mg/dL
Valproic Acid	50 mg/dL	50 mg/dL

Table 14. Non-interfering Anticoagulants –Plasma

Compound	10 mg/dL	100 mg/dL
	Compound Conc.	Compound Conc.
Heparin	3 U/mL	3 U/mL
EDTA	2 mg/mL	2 mg/mL
Oxalic Acid	2 mg/mL	2 mg/mL
Sodium Citrate	3.8 g/dL	3.8 g/dL
Sodium Fluoride	2 mg/mL	2 mg/mL

9. Interference - pH

To evaluate potential interference from the effect of urine pH, device performance in the quantitative mode was tested using a range of urine pH values. All test samples were prepared in drug-free urine containing EtOH at concentration of 10 mg/dL and 100 mg/dL. No interference was observed at urine pH values ranging from 3.0 to 11.0.

10. Interference - Specific Gravity

To evaluate potential interference from the specific gravity of urine, device performance in the quantitative mode was tested using a range of physiologically relevant urine specific gravity values. All test samples were prepared in drug free urine containing EtOH at concentration of 10 mg/dL and 100 mg/dL. No interference was observed at urine specific gravity values ranging from 1.000 to 1.030.

11. Calibration Duration

Drug free negative urine spiked with EtOH at concentration of 10 mg/dL, 100 mg/dL and 300 mg/dL were tested in quantitative mode at time points up to 14 days. At the initial time point, a two-point calibration curve was established. This calibration was used through the duration of this study. The test results met acceptance criteria at each time point. The recommended frequency of calibration is 14 days.

12. Specimen Stability

Drug free negative urine, serum and plasma spiked with EtOH at concentration of 100 mg/dL and 300 mg/dL were stored in industry standard collection containers and tested by assay kit at each time point at 30°C and at 2°C - 8°C. Test results indicated that urine samples containing EtOH are stable for up to 14 days stored at ambient temperature up to 30°C, up to 6 months stored at 2°C - 8°C; serum samples containing EtOH are stable for up to 10 days stored at ambient temperature up to 30°C, up to 14 days stored at 2°C - 8°C; plasma samples containing EtOH are stable for up to 3 day stored at ambient temperature up to 30°C, up to 6 days stored at 2°C - 8°C.

13. Method Comparison

Eighty (80) de-identified, unaltered leftover clinical urine samples, seventy-six (76) de-identified, unaltered leftover clinical serum samples and sixty-four (64) de-identified, unaltered leftover clinical plasma samples obtained from clinical testing laboratories were analyzed for EtOH with the Immunalysis Ethyl Alcohol Enzyme Assay in quantitative mode and compared to results of predicate device. The instruments used were an Olympus AU 400e. Method comparison test results are presented in **Table 15**.

Table 15. Method Comparison Test Results

Matrix	n	Slope	Intercept	r^2	Candidate Device Range (mg/dL)	Predicate Device Range (mg/dL)
Urine	80	1.0284	-2.7848	0.9964	3-600	3-600
Serum	76	1.0067	-5.8802	0.9948	3-600	3-600
Plasma	64	1.0595	-7.3902	0.9932	3-600	3-600

CONCLUSION

The information provided in this pre-market notification demonstrates that the Immunalysis Ethyl Alcohol Enzyme Assay is substantially equivalent to the legally marketed predicate device for its intended use.