



Food and Drug Administration
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IMMUNALYSIS CORPORATION
JOSEPH GINETE
REGULATORY AFFAIRS SPECIALIST II
829 TOWNE CENTER DRIVE
POMONA CA 91767

June 29, 2015

Re: K150925

Trade/Device Name: Immunalysis Benzoylcegonine Urine Enzyme Immunoassay,
Immunalysis Benzoylcegonine Urine Calibrators,
Immunalysis Benzoylcegonine Urine Control Set

Regulation Number: 21 CFR 862.3250

Regulation Name: Cocaine and cocaine metabolite test system

Regulatory Class: II

Product Code: DIO, DLJ, LAS

Dated: April 2, 2015

Received: April 6, 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

Indications for Use

510(k) Number (if known)
K150925

Device Name

Immunalysis Benzoylcegonine Urine Enzyme Immunoassay
Immunalysis Benzoylcegonine Urine Calibrators
Immunalysis Benzoylcegonine Urine Control Set

Indications for Use (Describe)

Immunalysis Benzoylcegonine Urine Enzyme Immunoassay

The Immunalysis Benzoylcegonine Urine Enzyme Immunoassay is a homogeneous enzyme immunoassay with a dual cutoff of 150ng/mL and 300ng/mL. The assay is intended for use in laboratories for the qualitative and semi-quantitative analysis of Benzoylcegonine in human urine with automated clinical chemistry analyzers. This assay is calibrated against Benzoylcegonine. 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 Benzoylcegonine 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 Benzoylcegonine Urine Calibrators

The Immunalysis Benzoylcegonine Urine Calibrators are intended for in vitro diagnostic use for the calibration of assays for the analytes currently listed in the package insert: Benzoylcegonine. The calibrators are designed for prescription use with homogenous enzyme immunoassays on automated clinical chemistry analyzers.

Immunalysis Benzoylcegonine Urine Control Set

The Immunalysis Benzoylcegonine Urine Control Set is intended for in vitro diagnostic use to monitor the performance of assays for the analyte currently listed in the package insert: Benzoylcegonine. The controls are designed for prescription use with homogenous enzyme immunoassays 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 26, 2015

B. Device Information

1. Trade Name: Immunalysis Benzoyllecgonine Urine Enzyme Immunoassay
Immunalysis Benzoyllecgonine Urine Calibrators
Immunalysis Benzoyllecgonine Urine Control Set
2. Common Name: Immunalysis Benzoyllecgonine Urine Enzyme Immunoassay
Immunalysis Benzoyllecgonine Urine Calibrators
Immunalysis Benzoyllecgonine Urine Control Set

C. Regulatory Information

1. Device Classification: II
2. Regulation Number: 21 CFR862.3250 Cocaine and Cocaine Metabolite System
21 CFR 862.3200 Clinical Toxicology Calibrator
21 CFR 862.3280 Clinical Toxicology Control Material
3. Panel: Toxicology(91)
4. Product Code: DIO
DLJ
LAS

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

1. Predicate Devices: Radox Cocaine Metabolite Assay
Radox Multidrug Calibrator Set
Radox Multidrug Controls, Level 1 and 2
2. Predicate Company: Radox Laboratories, Ltd.
3. Predicate K Number: K113751



E. Device Descriptions

1. The assay consists of antibody/ substrate reagent and enzyme conjugate reagent. The antibody/ substrate reagent includes polyclonal sheep antibodies to Benzoyllecgonine, glucose-6-phosphate (G6P) and nicotinamide adenine dinucleotide (NAD) in HEPES buffer with Sodium Azide as a preservative. The enzyme conjugate reagent includes Benzoyllecgonine derivative labeled with glucose-6-phosphate dehydrogenase (G6PDH) in HEPES buffer with Sodium Azide as a preservative.
2. All of the Immunalysis Benzoyllecgonine 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 1, HIGH Control 1, LOW Control 2 and HIGH Control 2 are prepared by spiking known concentrations of benzoyllecgonine into the negative calibrator matrix. These five calibrators and four controls are sold as individual bottles. The concentration of benzoyllecgonine in their corresponding calibrators and controls are summarized as follows:

Analyte	Benzoyllecgonine Urine Calibrators				
	Negative	Level 1	Level 2	Level 3	Level 4
	0ng/mL	150ng/mL	300ng/mL	500ng/mL	1000ng/mL
Benzoyllecgonine	Benzoyllecgonine Urine Control Set				
	LOW Control 1	HIGH Control 1	LOW Control 2	HIGH Control 2	
	112.5ng/mL	187.5ng/mL	225ng/mL	375ng/mL	

F. Intended Use

1. Immunalysis Benzoyllecgonine Urine Enzyme Immunoassay:
The Immunalysis Benzoyllecgonine Urine Enzyme Immunoassay is a homogeneous enzyme immunoassay with a dual cutoff of 150ng/mL and 300ng/mL. The assay is intended for use in laboratories for the qualitative and semi-quantitative analysis of Benzoyllecgonine in human urine with automated clinical chemistry analyzers. This assay is calibrated against Benzoyllecgonine. 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 Benzoyllecgonine 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. **Immunoanalysis Benzoylcegonine Urine Calibrators:**
The Immunoanalysis Benzoylcegonine Urine Calibrators are intended for in vitro diagnostic use for the calibration of assays for the analytes currently listed in the package insert: Benzoylcegonine. The calibrators are designed for prescription use with homogenous enzyme immunoassays on automated clinical chemistry analyzers.
3. **Immunoanalysis Benzoylcegonine Urine Control Set:**
The Immunoanalysis Benzoylcegonine Control Set is intended for in vitro diagnostic use to monitor the performance of assays for the analytes currently listed in the package insert: Benzoylcegonine. The controls are designed for prescription use with homogenous enzyme immunoassays on automated clinical chemistry analyzers

G. Comparison of the new device with the predicate device

Item	Cocaine Metabolite Assay K113751	Immunoanalysis Benzoylcegonine Urine EIA
Intended Use	For the qualitative and semi-quantitative determination of the presence of benzoylcegonine in human urine at a cutoff of 300ng/mL	For the qualitative and semi-quantitative determination of the presence of benzoylcegonine in human urine at a cutoff of 150ng/mL and 300ng/mL
Type of Product	Analytical Reagents	Same
Test Matrix	Urine	Same
Cutoff Levels	300 ng/mL of Benzoylcegonine	150 ng/mL and 300 ng/mL of Benzoylcegonine
Test System	Homogeneous Enzyme Immunoassay	Same
Materials	Liquid Ready-to-Use Two Reagent Assay	Antibody/Substrate Reagents and Enzyme
Antibody	Mouse Monoclonal antibodies to Benzoylcegonine	Polyclonal Sheep antibody to Benzoylcegonine
Storage	2 – 8°C until expiration date	Same
Calibrator and Control Matrix	Urine	Same
Calibrator Levels	Five levels 0, 150, 300, 500, and 1000 ng/mL	Five levels 0, 150, 300, 500, and 1000 ng/mL
Control Levels	Two levels 225 and 375 ng/mL	Four levels 112.5, 187.5, 225, and 375 ng/mL
Calibrator and Control Storage	2 – 8 C until expiration date	Same

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

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

- a. The following is a summary table of the Qualitative Analysis for the 150ng/mL cutoff test data results.

Table 2 - Qualitative Analysis (for 150ng/mL cutoff)			
Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
37.5	-75%	80	80 Negative
75	-50%	80	80 Negative
112.5	-25%	80	80 Negative
150	Cutoff	80	36 Neg / 44 Pos
187.5	+25%	80	80 Positive
225	+50%	80	80 Positive
262.5	+75%	80	80 Positive
300	+100%	80	80 Positive

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

Table 3 - Qualitative Analysis (for 300 ng/mL cutoff)			
Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
75	-75%	80	80 Negative
150	-50%	80	80 Negative
225	-25%	80	80 Negative
300	Cutoff	80	37 Neg / 43 Pos
375	+25%	80	80 Positive
450	+50%	80	80 Positive
525	+75%	80	80 Positive
600	+100%	80	80 Positive

- c. The following is a summary table of the Semi-Quantitative Analysis for the 150ng/mL cutoff test data results.

Table 4 - Semi-Quantitative Analysis (for 150ng/mL cutoff)			
Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
37.5	-75%	80	80 Negative
75	-50%	80	80 Negative
112.5	-25%	80	80 Negative

Concentration (ng/mL)	% of cutoff	# of determinations	Result
150	Cutoff	80	25 Neg / 55 Pos
187.5	+25%	80	80 Positive
225	+50%	80	80 Positive
262.5	+75%	80	80 Positive
300	+100%	80	80 Positive

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

Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
75	-75%	80	80 Negative
150	-50%	80	80 Negative
225	-25%	80	80 Negative
300	Cutoff	80	24 Neg / 56 Pos
375	+25%	80	80 Positive
450	+50%	80	80 Positive
525	+75%	80	80 Positive
600	+100%	80	80 Positive

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

a. The qualitative result summary table for the 150ng/mL cutoff is outlined below:

Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
Benzoylecgonine	150	POS	100.00
m-Hydroxybenzoylecgonine	150	POS	100.00
Cocaine	100,000	POS	0.15
Ecgonine	59,000	POS	0.25
Ecgonine Methyl Ester	100,000	NEG	N.D.
Cocaethylene	100,000	NEG	N.D.
Norcocaine	100,000	NEG	N.D.

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

Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
Benzoylecgonine	300	POS	100.00
m-Hydroxybenzoylecgonine	300	POS	100.00
Cocaine	100,000	NEG	N.D.
Ecgonine	100,000	NEG	N.D.
Ecgonine Methyl Ester	100,000	NEG	N.D.
Cocaethylene	100,000	NEG	N.D.

Table 7 - Structurally Related Compounds (for 300 ng/mL cutoff) - Qualitative

Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
Norcocaine	100,000	NEG	N.D.

c. The semi-quantitative result summary table for the 150ng/mL cutoff is outlined below:

Table 8 - Structurally Related Compounds (for 150ng/mL cutoff) – Semi-Quantitative

Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
Benzoylecgonine	150	POS	100.00
m-Hydroxybenzoylecgonine	150	POS	100.00
Cocaine	100,000	POS	0.15
Ecgonine	59,000	POS	0.25
Ecgonine Methyl Ester	100,000	NEG	N.D.
Cocaethylene	100,000	NEG	N.D.
Norcocaine	100,000	NEG	N.D.

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

Table 9 - Structurally Related Compounds (for 300ng/mL cutoff) – Semi-Quantitative

Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
Benzoylecgonine	300	POS	100.00
m-Hydroxybenzoylecgonine	300	POS	100.00
Cocaine	100,000	NEG	N.D.
Ecgonine	100,000	NEG	N.D.
Ecgonine Methyl Ester	100,000	NEG	N.D.
Cocaethylene	100,000	NEG	N.D.
Norcocaine	100,000	NEG	N.D.

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 $\pm 25\%$ 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 150ng/mL cutoff:

Table 10 - Structurally Non-Similar Compounds (for 150ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (112.5ng/mL)		+25% Cutoff (187.5ng/mL)	
		Result	Interference?	Result	Interference?
4-Bromo-2,5-Dimethoxyphenethylamine	100,000	Negative	No	Positive	No
6-Acetylcodeine	100,000	Negative	No	Positive	No
6-Acetylmorphine	100,000	Negative	No	Positive	No
7-Aminoclonazepam	100,000	Negative	No	Positive	No
7-Aminoflunitrazepam	100,000	Negative	No	Positive	No
7-Aminonitrazepam	100,000	Negative	No	Positive	No
11-hydroxy-delta-9-THC	100,000	Negative	No	Positive	No

Table 10 - Structurally Non-Similar Compounds (for 150ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (112.5ng/mL)		+25% Cutoff (187.5ng/mL)	
		Result	Interference?	Result	Interference?
11-nor-9 carboxy-delta-THC	100,000	Negative	No	Positive	No
Acetaminophen	500,000	Negative	No	Positive	No
Acetylsalicylic Acid	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
Benzylpiperazine	100,000	Negative	No	Positive	No
Bromazepam	100,000	Negative	No	Positive	No
Buprenorphine	100,000	Negative	No	Positive	No
Bupropion	100,000	Negative	No	Positive	No
Butabarbital	100,000	Negative	No	Positive	No
Butalbital	100,000	Negative	No	Positive	No
Caffeine	500,000	Negative	No	Positive	No
Cannabidiol	100,000	Negative	No	Positive	No
Cannabinol	100,000	Negative	No	Positive	No
Carbamazepine	100,000	Negative	No	Positive	No
Carisoprodol	100,000	Negative	No	Positive	No
Chlordiazepoxide	100,000	Negative	No	Positive	No
Chlorpromazine	100,000	Negative	No	Positive	No
cis-Tramadol	100,000	Negative	No	Positive	No
Clobazam	100,000	Negative	No	Positive	No
Clomipramine	100,000	Negative	No	Positive	No
Clonazepam	100,000	Negative	No	Positive	No
Clozapine	100,000	Negative	No	Positive	No
Codeine	100,000	Negative	No	Positive	No
Cotinine	100,000	Negative	No	Positive	No
Cyclobenzaprine	100,000	Negative	No	Positive	No
Dehydronorketamine	100,000	Negative	No	Positive	No
Delta-9-THC	100,000	Negative	No	Positive	No
Demoxepam	100,000	Negative	No	Positive	No
Desakylflurazepam	100,000	Negative	No	Positive	No
Desipramine	100,000	Negative	No	Positive	No
Dextromethorphan	100,000	Negative	No	Positive	No
Diazepam	100,000	Negative	No	Positive	No
Digoxin	100,000	Negative	No	Positive	No
Dihydrocodeine	100,000	Negative	No	Positive	No
Diphenhydramine	500,000	Negative	No	Positive	No
Doxepin	100,000	Negative	No	Positive	No
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

Table 10 - Structurally Non-Similar Compounds (for 150ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (112.5ng/mL)		+25% Cutoff (187.5ng/mL)	
		Result	Interference?	Result	Interference?
Ethylmorphine	100,000	Negative	No	Positive	No
Fenfluramine	100,000	Negative	No	Positive	No
Fentanyl	100,000	Negative	No	Positive	No
Flunitrazepam	100,000	Negative	No	Positive	No
Fluoxetine	100,000	Negative	No	Positive	No
Flurazepam	100,000	Negative	No	Positive	No
Haloperidol	100,000	Negative	No	Positive	No
Heroin	100,000	Negative	No	Positive	No
Hexobarbital	100,000	Negative	No	Positive	No
Hydrocodone	100,000	Negative	No	Positive	No
Hydromorphone	100,000	Negative	No	Positive	No
Ibuprofen	500,000	Negative	No	Positive	No
Imipramine	100,000	Negative	No	Positive	No
Ketamine	100,000	Negative	No	Positive	No
Lamotrigine	100,000	Negative	No	Positive	No
Levorphanol Tartrate	100,000	Negative	No	Positive	No
Lidocaine	100,000	Negative	No	Positive	No
Lorazepam	100,000	Negative	No	Positive	No
Lorazepam Glucuronide	50,000	Negative	No	Positive	No
Lormetazepam	100,000	Negative	No	Positive	No
LSD	100,000	Negative	No	Positive	No
Maprotiline	100,000	Negative	No	Positive	No
MDA	100,000	Negative	No	Positive	No
MDEA	100,000	Negative	No	Positive	No
MDMA	100,000	Negative	No	Positive	No
Meperidine	100,000	Negative	No	Positive	No
Meprobamate	100,000	Negative	No	Positive	No
Methadone	100,000	Negative	No	Positive	No
Methamphetamine	100,000	Negative	No	Positive	No
Methaqualone	100,000	Negative	No	Positive	No
Methoxetamine	100,000	Negative	No	Positive	No
Methylone	100,000	Negative	No	Positive	No
Methylphenidate	100,000	Negative	No	Positive	No
Midazolam	100,000	Negative	No	Positive	No
Morphine	100,000	Negative	No	Positive	No
Morphine 3-D-glucuronide	100,000	Negative	No	Positive	No
Morphine 6-D-glucuronide	50,000	Negative	No	Positive	No
Nalorphine	100,000	Negative	No	Positive	No
Naloxone	100,000	Negative	No	Positive	No
Naltrexone	100,000	Negative	No	Positive	No
Naproxen	100,000	Negative	No	Positive	No
N-desmethyltapentadol	100,000	Negative	No	Positive	No
Nitrazepam	100,000	Negative	No	Positive	No

Table 10 - Structurally Non-Similar Compounds (for 150ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (112.5ng/mL)		+25% Cutoff (187.5ng/mL)	
		Result	Interference?	Result	Interference?
Norbuprenorphine	50,000	Negative	No	Positive	No
Norcodeine	100,000	Negative	No	Positive	No
Nordiazepam	100,000	Negative	No	Positive	No
Norketamine	100,000	Negative	No	Positive	No
Normorphine	100,000	Negative	No	Positive	No
Norproxyphene	100,000	Negative	No	Positive	No
Norpseudoephedrine	100,000	Negative	No	Positive	No
Nortriptyline	100,000	Negative	No	Positive	No
Olanzapine	100,000	Negative	No	Positive	No
Oxazepam	100,000	Negative	No	Positive	No
Oxycodone	100,000	Negative	No	Positive	No
Oxymorphone	100,000	Negative	No	Positive	No
PCP	100,000	Negative	No	Positive	No
Pentazocine	100,000	Negative	No	Positive	No
Pentobarbital	100,000	Negative	No	Positive	No
Phenobarbital	100,000	Negative	No	Positive	No
Phentermine	100,000	Negative	No	Positive	No
Phenylephedrine	100,000	Negative	No	Positive	No
Phenylpropanolamine	100,000	Negative	No	Positive	No
Phenytoin	100,000	Negative	No	Positive	No
PMA	100,000	Negative	No	Positive	No
Prazepam	100,000	Negative	No	Positive	No
Propoxyphene	100,000	Negative	No	Positive	No
Propranolol	100,000	Negative	No	Positive	No
Protriptyline	100,000	Negative	No	Positive	No
R,R(-)-Pseudoephedrine	100,000	Negative	No	Positive	No
S,S(+)-Pseudoephedrine	100,000	Negative	No	Positive	No
Ranitidine	100,000	Negative	No	Positive	No
Ritalinic Acid	100,000	Negative	No	Positive	No
Salicylic Acid	100,000	Negative	No	Positive	No
Secobarbital	100,000	Negative	No	Positive	No
Sertraline	100,000	Negative	No	Positive	No
Sufentanil Citrate	50,000	Negative	No	Positive	No
Tapentadol	100,000	Negative	No	Positive	No
Temazepam	100,000	Negative	No	Positive	No
Theophylline	100,000	Negative	No	Positive	No
Thioridazine	100,000	Negative	No	Positive	No
Trazodone	100,000	Negative	No	Positive	No
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

Table 10 - Structurally Non-Similar Compounds (for 150ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (112.5ng/mL)		+25% Cutoff (187.5ng/mL)	
		Result	Interference?	Result	Interference?
Verapamil	100,000	Negative	No	Positive	No
Zolpidem Tartrate	100,000	Negative	No	Positive	No

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

Table 11 - Structurally Non-Similar Compounds (for 300ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (225ng/mL)		+25% Cutoff (375ng/mL)	
		Result	Interference?	Result	Interference?
4-Bromo-2,5-Dimethoxyphenethylamine	100,000	Negative	No	Positive	No
6-Acetylcodeine	100,000	Negative	No	Positive	No
6-Acetylmorphine	100,000	Negative	No	Positive	No
7-Aminoclonazepam	100,000	Negative	No	Positive	No
7-Aminoflunitrazepam	100,000	Negative	No	Positive	No
7-Aminonitrazepam	100,000	Negative	No	Positive	No
11-hydroxy-delta-9-THC	100,000	Negative	No	Positive	No
11-nor-9 carboxy-delta-THC	100,000	Negative	No	Positive	No
Acetaminophen	500,000	Negative	No	Positive	No
Acetylsalicylic Acid	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
Benzylpiperazine	100,000	Negative	No	Positive	No
Bromazepam	100,000	Negative	No	Positive	No
Buprenorphine	100,000	Negative	No	Positive	No
Bupropion	100,000	Negative	No	Positive	No
Butabarbital	100,000	Negative	No	Positive	No
Butalbital	100,000	Negative	No	Positive	No
Caffeine	500,000	Negative	No	Positive	No
Cannabidiol	100,000	Negative	No	Positive	No
Cannabinol	100,000	Negative	No	Positive	No
Carbamazepine	100,000	Negative	No	Positive	No
Carisoprodol	100,000	Negative	No	Positive	No
Chlordiazepoxide	100,000	Negative	No	Positive	No
Chlorpromazine	100,000	Negative	No	Positive	No
cis-Tramadol	100,000	Negative	No	Positive	No
Clobazam	100,000	Negative	No	Positive	No
Clomipramine	100,000	Negative	No	Positive	No
Clonazepam	100,000	Negative	No	Positive	No
Clozapine	100,000	Negative	No	Positive	No
Codeine	100,000	Negative	No	Positive	No

Table 11 - Structurally Non-Similar Compounds (for 300ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (225ng/mL)		+25% Cutoff (375ng/mL)	
		Result	Interference?	Result	Interference?
Cotinine	100,000	Negative	No	Positive	No
Cyclobenzaprine	100,000	Negative	No	Positive	No
Dehydronorketamine	100,000	Negative	No	Positive	No
Delta-9-THC	100,000	Negative	No	Positive	No
Demoxepam	100,000	Negative	No	Positive	No
Desakylflurazepam	100,000	Negative	No	Positive	No
Desipramine	100,000	Negative	No	Positive	No
Dextromethorphan	100,000	Negative	No	Positive	No
Diazepam	100,000	Negative	No	Positive	No
Digoxin	100,000	Negative	No	Positive	No
Dihydrocodeine	100,000	Negative	No	Positive	No
Diphenhydramine	500,000	Negative	No	Positive	No
Doxepin	100,000	Negative	No	Positive	No
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
Fluoxetine	100,000	Negative	No	Positive	No
Flurazepam	100,000	Negative	No	Positive	No
Haloperidol	100,000	Negative	No	Positive	No
Heroin	100,000	Negative	No	Positive	No
Hexobarbital	100,000	Negative	No	Positive	No
Hydrocodone	100,000	Negative	No	Positive	No
Hydromorphone	100,000	Negative	No	Positive	No
Ibuprofen	500,000	Negative	No	Positive	No
Imipramine	100,000	Negative	No	Positive	No
Ketamine	100,000	Negative	No	Positive	No
Lamotrigine	100,000	Negative	No	Positive	No
Levorphanol Tartrate	100,000	Negative	No	Positive	No
Lidocaine	100,000	Negative	No	Positive	No
Lorazepam	100,000	Negative	No	Positive	No
Lorazepam Glucuronide	50,000	Negative	No	Positive	No
Lormetazepam	100,000	Negative	No	Positive	No
LSD	100,000	Negative	No	Positive	No
Maprotiline	100,000	Negative	No	Positive	No
MDA	100,000	Negative	No	Positive	No
MDEA	100,000	Negative	No	Positive	No
MDMA	100,000	Negative	No	Positive	No
Meperidine	100,000	Negative	No	Positive	No

Table 11 - Structurally Non-Similar Compounds (for 300ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (225ng/mL)		+25% Cutoff (375ng/mL)	
		Result	Interference?	Result	Interference?
Meprobamate	100,000	Negative	No	Positive	No
Methadone	100,000	Negative	No	Positive	No
Methamphetamine	100,000	Negative	No	Positive	No
Methaqualone	100,000	Negative	No	Positive	No
Methoxetamine	100,000	Negative	No	Positive	No
Methylone	100,000	Negative	No	Positive	No
Methylphenidate	100,000	Negative	No	Positive	No
Midazolam	100,000	Negative	No	Positive	No
Morphine	100,000	Negative	No	Positive	No
Morphine 3-D-glucuronide	100,000	Negative	No	Positive	No
Morphine 6-D-glucuronide	50,000	Negative	No	Positive	No
Nalorphine	100,000	Negative	No	Positive	No
Naloxone	100,000	Negative	No	Positive	No
Naltrexone	100,000	Negative	No	Positive	No
Naproxen	100,000	Negative	No	Positive	No
N-desmethyltapentadol	100,000	Negative	No	Positive	No
Nitrazepam	100,000	Negative	No	Positive	No
Norbuprenorphine	50,000	Negative	No	Positive	No
Norcodeine	100,000	Negative	No	Positive	No
Nordiazepam	100,000	Negative	No	Positive	No
Norketamine	100,000	Negative	No	Positive	No
Normorphine	100,000	Negative	No	Positive	No
Norproxyphe	100,000	Negative	No	Positive	No
Norpseudoephedrine	100,000	Negative	No	Positive	No
Nortriptyline	100,000	Negative	No	Positive	No
Olanzapine	100,000	Negative	No	Positive	No
Oxazepam	100,000	Negative	No	Positive	No
Oxycodone	100,000	Negative	No	Positive	No
Oxymorphone	100,000	Negative	No	Positive	No
PCP	100,000	Negative	No	Positive	No
Pentazocine	100,000	Negative	No	Positive	No
Pentobarbital	100,000	Negative	No	Positive	No
Phenobarbital	100,000	Negative	No	Positive	No
Phentermine	100,000	Negative	No	Positive	No
Phenylephedrine	100,000	Negative	No	Positive	No
Phenylpropanolamine	100,000	Negative	No	Positive	No
Phenytoin	100,000	Negative	No	Positive	No
PMA	100,000	Negative	No	Positive	No
Prazepam	100,000	Negative	No	Positive	No
Propoxyphene	100,000	Negative	No	Positive	No
Propranolol	100,000	Negative	No	Positive	No
Protriptyline	100,000	Negative	No	Positive	No
R,R(-)-Pseudoephedrine	100,000	Negative	No	Positive	No

Table 11 - Structurally Non-Similar Compounds (for 300ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (225ng/mL)		+25% Cutoff (375ng/mL)	
		Result	Interference?	Result	Interference?
S,S(+)-Pseudoephedrine	100,000	Negative	No	Positive	No
Ranitidine	100,000	Negative	No	Positive	No
Ritalinic Acid	100,000	Negative	No	Positive	No
Salicylic Acid	100,000	Negative	No	Positive	No
Secobarbital	100,000	Negative	No	Positive	No
Sertraline	100,000	Negative	No	Positive	No
Sufentanil Citrate	50,000	Negative	No	Positive	No
Tapentadol	100,000	Negative	No	Positive	No
Temazepam	100,000	Negative	No	Positive	No
Theophylline	100,000	Negative	No	Positive	No
Thioridazine	100,000	Negative	No	Positive	No
Trazodone	100,000	Negative	No	Positive	No
Triazolam	100,000	Negative	No	Positive	No
Trifluoromethylphenyl-piperazine	100,000	Negative	No	Positive	No
Trimipramine	100,000	Negative	No	Positive	No
Venlafaxine	100,000	Negative	No	Positive	No
Verapamil	100,000	Negative	No	Positive	No
Zolpidem Tartrate	100,000	Negative	No	Positive	No

c. The following is a summary table of the endogenous compounds results for the 150ng/mL cutoff:

Table 12 - Endogenous Compounds (for 150ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (112.5ng/mL)		+25% Cutoff (187.5ng/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	0.300 g/dL	Negative	No	Positive	No
Human Serum Albumin	0.5 g/dL	Negative	No	Positive	No
Oxalic Acid	0.1 g/dL	Negative	No	Positive	No
Riboflavin	0.0075 g/dL	Negative	No	Positive	No
Sodium Azide	1% w/v	Negative	No	Positive	No
Sodium Chloride	6.0 g/dL	Negative	No	Positive	No
Sodium Fluoride	1% w/v	Negative	No	Positive	No
Urea	6.0 g/dL	Negative	No	Positive	No

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

Table 13 - Endogenous Compounds (for 300ng/mL cutoff)

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

e. The following is a summary table of the Boric Acid for the 150ng/mL cutoff results:

Table 14 – Boric Acid (for 150ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-25% Cutoff (112.5ng/mL)		+25% Cutoff (187.5ng/mL)	
		Result	Interference?	Result	Interference?
Boric Acid	1% w/v	Negative	No	Negative	Yes

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

Table 15 – Boric Acid (for 300ng/mL cutoff)

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

g. The following is a summary table of the Boric Acid for the 150ng/mL cutoff results:

Table 16 – Boric Acid (for 150ng/mL cutoff)

Compound	Concentration Tested (ng/mL)	-50% Cutoff (75ng/mL)		+50% Cutoff (225ng/mL)	
		Result	Interference?	Result	Interference?
Boric Acid	1% w/v	Negative	No	Negative	Yes

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

Table 17 – Boric Acid (for 300ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-50% Cutoff (150ng/mL)		+50% Cutoff (450ng/mL)	
		Result	Interference?	Result	Interference?
Boric Acid	1% w/v	Negative	No	Negative	Yes

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

j. The following is a summary table of the effect of pH results for the 150ng/mL cutoff:

Table 18 - Effect of pH (for 150ng/mL cutoff)					
Test Parameter	Value	-25% Cutoff (112.5ng/mL)		+25% Cutoff (187.5ng/mL)	
		Result	Interference?	Result	Interference?
pH	3.0	NEG	No	POS	No
pH	4.0	NEG	No	POS	No
pH	5.0	NEG	No	POS	No
pH	6.0	NEG	No	POS	No
pH	7.0	NEG	No	POS	No
pH	8.0	NEG	No	POS	No
pH	9.0	NEG	No	POS	No
pH	10.0	NEG	No	POS	No
pH	11.0	NEG	No	POS	No

k. The following is a summary table of the effect of pH results for the 300ng/mL cutoff:

Table 19 - Effect of pH (for 300ng/mL cutoff)					
Test Parameter	Value	-25% Cutoff (225ng/mL)		+25% Cutoff (375ng/mL)	
		Result	Interference?	Result	Interference?
pH	3.0	NEG	No	POS	No
pH	4.0	NEG	No	POS	No
pH	5.0	NEG	No	POS	No
pH	6.0	NEG	No	POS	No
pH	7.0	NEG	No	POS	No
pH	8.0	NEG	No	POS	No
pH	9.0	NEG	No	POS	No
pH	10.0	NEG	No	POS	No
pH	11.0	NEG	No	POS	No

l. The following is a summary table of the effect of specific gravity results for the 150ng/mL cutoff:

Table 20 - Effect of Specific Gravity (for 150ng/mL cutoff)					
Test Parameter	Value	-25% Cutoff (112.5ng/mL)		+25% Cutoff (187.5ng/mL)	
		Result	Interference?	Result	Interference?
Specific Gravity	1.000	NEG	No	POS	No
Specific Gravity	1.002	NEG	No	POS	No
Specific Gravity	1.005	NEG	No	POS	No
Specific Gravity	1.010	NEG	No	POS	No
Specific Gravity	1.015	NEG	No	POS	No
Specific Gravity	1.020	NEG	No	POS	No
Specific Gravity	1.025	NEG	No	POS	No
Specific Gravity	1.030	NEG	No	POS	No

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

Table 21 - Effect of Specific Gravity (for 300ng/mL cutoff)					
Test Parameter	Value	-25% Cutoff (225ng/mL)		+25% Cutoff (375ng/mL)	
		Result	Interference?	Result	Interference?
Specific Gravity	1.000	NEG	No	POS	No
Specific Gravity	1.002	NEG	No	POS	No
Specific Gravity	1.005	NEG	No	POS	No
Specific Gravity	1.010	NEG	No	POS	No
Specific Gravity	1.015	NEG	No	POS	No
Specific Gravity	1.020	NEG	No	POS	No
Specific Gravity	1.025	NEG	No	POS	No
Specific Gravity	1.030	NEG	No	POS	No

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

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

Table 22 - Linearity/ Recovery		
Expected Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
100	98.9	98.9
150	162.9	108.6
200	194.7	97.4
300	304.5	101.5
400	419.7	104.9
500	489.9	98.0
600	602.8	100.5
700	736.4	105.2
800	803.1	100.4
900	946.0	105.1
1000	996.0	99.6

Table 22 - Linearity/ Recovery		
Expected Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
1100	1003.1	91.2

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 150ng/mL cutoff:

Table 23 - Method Comparison (for 150ng/mL cutoff) – Qualitative

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

b. The following is a summary table of qualitative assay performance for the 150ng/mL cutoff:

Table 24 - Assay Performance verified by LC/MS – 150ng/mL Cutoff					
Type	Benzoylecgonine Concentration				Agreement (%)
	< 75ng/mL	75 ~ 149 ng/mL	150 ~ 225 ng/mL	> 225 ng/mL	
Qualitative/ Positive	0	1*	4	36	98
Qualitative/ Negative	36	3	0	0	100

*Sample contained 124ng/mL Benzoylecgonine by LC-MS/MS

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

Table 25 - Method Comparison (for 300ng/mL cutoff) – Qualitative

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

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

Table 26 - Assay Performance verified by LC/MS – 300ng/mL Cutoff					
Type	Benzoylecgonine Concentration				Agreement (%)
	< 150ng/mL	150 ~ 299 ng/mL	300 ~ 450 ng/mL	> 450 ng/mL	
Qualitative/ Positive	0	0	4	36	100
Qualitative/ Negative	36	4	0	0	100

e. The following is a comparison table of semi-quantitative assay performance for the 150ng/mL cutoff:

Table 27 - Method Comparison (for 150ng/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 150ng/mL cutoff:

Table 28 - Assay Performance verified by LC/MS – 150ng/mL Cutoff					
Type	Benzoylcegonine Concentration				Agreement (%)
	< 75ng/mL	75 ~ 149 ng/mL	150 ~ 225 ng/mL	> 225 ng/mL	
Semi-Quantitative/ Positive	0	1*	4	36	98
Semi-Quantitative / Negative	36	3	0	0	100

*Sample contained 124ng/mL Benzoylcegonine by LC-MS/MS

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

Table 29 - Method Comparison (for 300ng/mL cutoff) – Semi-Quantitative

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

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

Table 30 - Assay Performance verified by LC/MS – 300ng/mL Cutoff					
Type	Benzoylcegonine Concentration				Agreement (%)
	< 150ng/mL	150 ~ 299 ng/mL	300 ~ 450 ng/mL	> 450 ng/mL	
Semi-Quantitative/ Positive	0	0	4	36	100
Semi-Quantitative / Negative	36	4	0	0	100

6. Calibrator and Control Analytical Performance – Immunalysis Benzoylcegonine Urine Calibrators and Controls

- a. Benzoylcegonine Urine Calibrators and Controls Traceability – all components of the calibrators and controls have been traced to a commercially available standard solution.
- b. Benzoylcegonine Urine Calibrators and Controls Stability – A closed vial stability study was performed at 25°C 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 1 and 2 and High Control 1 and 2) for Benzoylcegonine



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. Benzoyllecgonine Urine Calibrators and Controls Stability – An open vial stability study was performed at 5°C 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 1 and 2 and High Control 1 and 2) for Benzoyllecgonine were within specifications for Day 0, 19, 26, 33, 41, and 60. This stability study was performed to establish initial expiration dating.

d. Benzoyllecgonine Urine Calibrators and Controls Value Assignment – Calibrators and controls are manufactured and are tested by mass spectrometry. If any of the analytes are not of the acceptable range, then the calibrator and controls is adjusted and re-tested. Values are assigned to the calibrators and controls once the mass spectrometry results are within the acceptable ranges.

I. Conclusion

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