



K141406

510(k) SUMMARY

JUL 01 2014

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

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8. Summary prepared on: June 30, 2014

B. Device Information

1. Trade Name: Immunalysis Buprenorphine Urine Enzyme Immunoassay  
Immunalysis Buprenorphine Urine Controls  
Immunalysis Buprenorphine Urine Calibrators
2. Common Name: Immunalysis Buprenorphine Urine Enzyme Immunoassay  
Immunalysis Buprenorphine Urine Controls  
Immunalysis Buprenorphine Urine Calibrators
3. Device Classification: II
4. Regulation Number: CFR 862.3650 Opiate Test System  
CFR 862.3200 Clinical Toxicology Calibrator  
CFR 862.3280 Clinical Toxicology Control Materials
5. Panel: Toxicology(91)
6. Product Code: DJG  
DLJ  
LAS

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

1. Predicate Device: CEDIA Buprenorphine Assay  
CEDIA Buprenorphine Controls  
CEDIA Buprenorphine Calibrators
2. Predicate Company: Microgenics
3. Predicate K Number: K040316

**D. Device Description**

The assay consists of antibody/ substrate reagent and enzyme conjugate reagent. The antibody/ substrate reagent includes rabbit antibodies to Buprenorphine, glucose-6-phosphate (G6P) and nicotinamide adenine dinucleotide (NAD) in Tris buffer with Sodium Azide as a preservative. The enzyme conjugate reagent includes buprenorphine 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

The buprenorphine calibrator and controls consists of a single calibrator at 5ng/mL, a control set containing a LOW control at 3.75ng/mL and a HIGH control at 6.25ng/mL and a calibrator set containing a negative calibrator, a Level 1 calibrator at 5ng/mL, a Level 2 calibrator at 10ng/mL, a Level 3 calibrator at 20ng/mL and a Level 4 calibrator at 40ng/mL.

**E. Intended Use****Immunoanalysis Buprenorphine Urine Enzyme Immunoassay:**

The Immunoanalysis Buprenorphine Urine Enzyme Immunoassay is a homogeneous enzyme immunoassay with a cutoff of 5ng/mL. The assay is intended for use in laboratories for the qualitative and semi-quantitative analysis of Buprenorphine in human urine with automated clinical chemistry analyzers. This assay is calibrated against Buprenorphine. This in-vitro diagnostic device is for prescription use only.

The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GC-MS or permitting laboratories to establish quality control procedures.

The Immunoanalysis Buprenorphine 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 Spectroscopy (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.

**Immunoanalysis Buprenorphine Urine Controls:**

The Immunoanalysis Buprenorphine Urine Controls are used as control materials in the Immunoanalysis Buprenorphine Urine Enzyme Immunoassay.

**Immunoanalysis Buprenorphine Urine Calibrators:**

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

F. Comparison of the new device with the predicate device

| Item                                  | Predicate Device (K040316)   | Test Device  |
|---------------------------------------|--|--|
| <b>Intended Use</b>                   | For the qualitative and semi-quantitative determination of the presence of buprenorphine in human urine at a cutoff of 5 ng/ml | For the qualitative and semi-quantitative determination of the presence of buprenorphine in human urine at a cutoff of 5 ng/ml |
| <b>Type of Product</b>                | Analytical Reagents  | Analytical Reagents  |
| <b>Measured Analytes</b>              | Buprenorphine  | Buprenorphine  |
| <b>Test Matrix</b>                    | Urine  | Urine  |
| <b>Cutoff Levels</b>                  | 5ng/mL of Buprenorphine  | 5ng/mL of Buprenorphine  |
| <b>Test System</b>                    | Homogenous Enzyme Immunoassay  | Homogenous Enzyme Immunoassay  |
| <b>Materials</b>                      | Buffer 1, Buffer 2, Lyophilized Reagent 1a and Lyophilized Reagent   | Antibody/ Substrate Reagents and Enzyme Labeled Conjugate  |
| <b>Mass Spectroscopy Confirmation</b> | Required for preliminary positive analytical results   | Required for preliminary positive analytical results   |
| <b>Antibody</b>                       | Mouse monoclonal anti-buprenorphine derivative   | Rabbit Monoclonal Antibody to Buprenorphine  |
| <b>Storage</b>                        | 2 – 8°C until expiration date  | 2 – 8°C until expiration date  |
| <b>Calibrator Form</b>                | Liquid   | Liquid   |
| <b>Calibrator Levels</b>              | One (1) Level (5ng/mL)   | One (1) Level (5ng/mL)   |
| <b>Control Set Levels</b>             | Two (2) Levels (3ng/mL and 7ng/mL)   | Two (2) Levels (3.75ng/mL and 6.25ng/mL)   |
| <b>Calibrator Set Levels</b>          | Five (5) Levels (0, 5, 20, 50 and 75 ng/mL)  | Five (5) Levels (0, 5, 10, 20 and 40 ng/mL)  |

G. The following laboratory performance studies were performed to determine substantial equivalence of the Immunalysis Buprenorphine 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  $\pm 25\%$ ,  $\pm 50\%$ ,  $\pm 75\%$  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 the product performance relative to the ability of the device to produce the same value during repeated measurements. The instrument used for this test was a Beckman Coulter AU 400e.

a. The following is a summary table of the Qualitative Analysis for the 5ng/mL cutoff test data results.

| <b>Qualitative Analysis (for 5ng/mL cutoff)</b> |             |                     |                         |
|---|-------------|---------------------|-------------------------|
| Concentration (ng/mL)                           | % of cutoff | # of determinations | Result                  |
| 0   | -100%       | 80                  | 80 Negative             |
| 1.25  | -75%        | 80                  | 80 Negative             |
| 2.5   | -50%        | 80                  | 80 Negative             |
| 3.75  | -25%        | 80                  | 80 Negative             |
| 5   | Cutoff      | 80                  | 48 Negative/32 Positive |
| 6.25  | +25%        | 80                  | 80 Positive             |
| 7.5   | +50%        | 80                  | 80 Positive             |
| 8.75  | +75%        | 80                  | 80 Positive             |
| 10  | +100%       | 80                  | 80 Positive             |

b. The following is a summary table of the Semi-Quantitative Analysis for the 5ng/mL cutoff test data results.

| <b>Semi-Quantitative Analysis (for 5ng/mL cutoff)</b> |             |                      |                          |
|---|-------------|----------------------|--------------------------|
| Concentration (ng/mL)                                 | % of cutoff | # of determinations: | Result                   |
| 0   | -100%       | 80                   | 80 Negative              |
| 1.25  | -75%        | 80                   | 80 Negative              |
| 2.5   | -50%        | 80                   | 80 Negative              |
| 3.75  | -25%        | 80                   | 80 Negative              |
| 5   | Cutoff      | 80                   | 33 Negative/ 47 Positive |
| 6.25  | +25%        | 80                   | 80 Positive              |
| 7.5   | +50%        | 80                   | 80 Positive              |
| 8.75  | +75%        | 80                   | 80 Positive              |
| 10  | +100%       | 80                   | 80 Positive              |

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

a. The qualitative result summary table is outlined below:

| <b>Structurally Related Compounds - Qualitative</b> |                              |        |                      |
|---|------------------------------|--------|----------------------|
| Compound  | Concentration Tested (ng/mL) | Result | Cross-Reactivity (%) |
| Buprenorphine                                       | 5                            | N/A    | 100.00               |
| NorBuprenorphine                                    | 5.5                          | POS    | 90.91                |
| Buprenorphine Glucuronide                           | 3,000                        | POS    | 0.17                 |
| NorBuprenorphine Glucuronide                        | 4,000                        | POS    | 0.13                 |
| 6-Acetyl morphine                                   | 100,000                      | NEG    | N.D.                 |
| Codeine   | 100,000                      | NEG    | N.D.                 |
| Dihydrocodeine                                      | 100,000                      | NEG    | N.D.                 |
| EDDP  | 100,000                      | NEG    | N.D.                 |
| EMDP  | 100,000                      | NEG    | N.D.                 |
| Ethyl Morphine                                      | 100,000                      | NEG    | N.D.                 |
| Heroin  | 100,000                      | NEG    | N.D.                 |
| Hydrocodone   | 100,000                      | NEG    | N.D.                 |
| Hydromorphone                                       | 100,000                      | NEG    | N.D.                 |
| LAAM  | 100,000                      | NEG    | N.D.                 |
| Levorphanol   | 100,000                      | NEG    | N.D.                 |
| Methadone   | 100,000                      | NEG    | N.D.                 |
| Meperidine  | 100,000                      | NEG    | N.D.                 |
| Morphine 3 Glucuronide                              | 100,000                      | NEG    | N.D.                 |
| Morphine 6 Glucuronide                              | 100,000                      | NEG    | N.D.                 |
| Morphine  | 100,000                      | NEG    | N.D.                 |
| Nalorphine  | 100,000                      | NEG    | N.D.                 |
| Naloxone  | 100,000                      | NEG    | N.D.                 |
| Naltrexone  | 100,000                      | NEG    | N.D.                 |
| Norpropoxyphene                                     | 100,000                      | NEG    | N.D.                 |
| Oxycodone   | 100,000                      | NEG    | N.D.                 |
| Oxymorphone   | 100,000                      | NEG    | N.D.                 |
| Diacetyl Morphine                                   | 100,000                      | NEG    | N.D.                 |

N.D. = Not Detected (<0.05%)

b. The semi-quantitative result summary table is outlined below:

| <b>Structurally Related Compounds – Semi-Quantitative</b> |                              |                      |
|---|------------------------------|----------------------|
| Compound  | Concentration Tested (ng/mL) | Cross-Reactivity (%) |
| Buprenorphine   | 5                            | 100.00               |
| NorBuprenorphine  | 5.5                          | 90.91                |
| Buprenorphine Glucuronide                                 | 3,000                        | 0.17                 |
| NorBuprenorphine Glucuronide                              | 4,000                        | 0.13                 |
| 6-Acetyl morphine   | 100,000                      | N.D.                 |
| Codeine   | 100,000                      | N.D.                 |
| Dihydrocodeine  | 100,000                      | N.D.                 |
| EDDP  | 100,000                      | N.D.                 |
| EMDP  | 100,000                      | N.D.                 |
| Ethyl Morphine  | 100,000                      | N.D.                 |
| Heroin  | 100,000                      | N.D.                 |
| Hydrocodone   | 100,000                      | N.D.                 |
| Hydromorphone   | 100,000                      | N.D.                 |
| LAAM  | 100,000                      | N.D.                 |
| Levorphanol   | 100,000                      | N.D.                 |
| Methadone   | 100,000                      | N.D.                 |
| Meperidine  | 100,000                      | N.D.                 |
| Morphine 3 Glucuronide                                    | 100,000                      | N.D.                 |
| Morphine 6 Glucuronide                                    | 100,000                      | N.D.                 |
| Morphine  | 100,000                      | N.D.                 |
| Nalorphine  | 100,000                      | N.D.                 |
| Naloxone  | 100,000                      | N.D.                 |
| Naltrexone  | 100,000                      | N.D.                 |
| Norpropoxyphene   | 100,000                      | N.D.                 |
| Oxycodone   | 100,000                      | N.D.                 |
| Oxymorphone   | 100,000                      | N.D.                 |
| Diacetyl Morphine   | 100,000                      | 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. Boric Acid and Riboflavin caused a false negative response at the concentrations tested. All other 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 5ng/mL cutoff

| <b>Structurally Non-Similar Compounds (for: 5ng/mL cutoff)</b> |                              |                                |               |                                |               |
|--|------------------------------|--------------------------------|---------------|--------------------------------|---------------|
| Compound   | Concentration Tested (ng/mL) | <b>-25% Cutoff (3.75ng/mL)</b> |               | <b>+25% Cutoff (6.25ng/mL)</b> |               |
|  |                              | Result                         | Interference? | Result                         | Interference? |
| 4-Bromo-2,5-Dimethoxyphenethylamine                            | 100,000                      | Negative                       | No            | Positive                       | No            |
| 6-Acetylcodeine  | 100,000                      | Negative                       | No            | Positive                       | No            |
| 7-Aminoclonazepam  | 100,000                      | Negative                       | No            | Positive                       | No            |
| 7-Aminoflurazepam  | 100,000                      | Negative                       | No            | Positive                       | No            |
| 7-Aminonitrazepam  | 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            |

| Structurally Non-Similar Compounds (for 5ng/mL cutoff) |                              |                         |               |                         |               |
|--|------------------------------|-------------------------|---------------|-------------------------|---------------|
| Compound   | Concentration Tested (ng/mL) | -25% Cutoff (3.75ng/mL) |               | +25% Cutoff (6.25ng/mL) |               |
|  |                              | Result                  | Interference? | Result                  | Interference? |
| S-(+) Amphetamine                                      | 100,000                      | Negative                | No            | Positive                | No            |
| Benzoyllecgonine                                       | 500,000                      | Negative                | No            | Positive                | No            |
| Benzylpiperazine                                       | 100,000                      | Negative                | No            | Positive                | No            |
| Bromazepam   | 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            |
| 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            |
| 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            |
| 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            |
| Diazepam   | 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            |
| Ecgonine   | 100,000                      | Negative                | No            | Positive                | No            |
| Ecgonine methyl ester                                  | 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            |
| EtG  | 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            |
| Hexobarbital   | 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            |
| Lidocaine  | 100,000                      | Negative                | No            | Positive                | No            |
| Lorazepam  | 100,000                      | Negative                | No            | Positive                | No            |



| Structurally Non-Similar Compounds (for 5ng/mL cutoff) |                              |                         |               |                         |               |
|--|------------------------------|-------------------------|---------------|-------------------------|---------------|
| Compound   | Concentration Tested (ng/mL) | -25% Cutoff (3.75ng/mL) |               | +25% Cutoff (6.25ng/mL) |               |
|  |                              | Result                  | Interference? | Result                  | Interference? |
| 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  | 500,000                      | Negative                | No            | Positive                | No            |
| S(+)-Methamphetamine                                   | 500,000                      | Negative                | No            | Positive                | No            |
| Methaqualone   | 100,000                      | Negative                | No            | Positive                | No            |
| Methylphenidate  | 100,000                      | Negative                | No            | Positive                | No            |
| Midazolam  | 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            |
| Nordiazepam  | 100,000                      | Negative                | No            | Positive                | No            |
| Norcodeine   | 100,000                      | Negative                | No            | Positive                | No            |
| Normorphine  | 100,000                      | Negative                | No            | Positive                | No            |
| Norpseudoephedrine                                     | 100,000                      | Negative                | No            | Positive                | No            |
| Nortriptyline  | 100,000                      | Negative                | No            | Positive                | No            |
| Oxazepam   | 100,000                      | Negative                | No            | Positive                | No            |
| Oxazepam Glucuronide                                   | 50,000                       | 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            |
| Phenylephrine  | 100,000                      | Negative                | No            | Positive                | No            |
| Phenytoine   | 100,000                      | Negative                | No            | Positive                | No            |
| PMA  | 100,000                      | Negative                | No            | Positive                | No            |
| PPA  | 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                                     | 100,000                      | Negative                | No            | Positive                | No            |
| Temazepam  | 100,000                      | Negative                | No            | Positive                | No            |
| 11-hydroxy-delta-9-THC                                 | 100,000                      | Negative                | No            | Positive                | No            |

| Structurally Non-Similar Compounds (for 5ng/mL cutoff) |                              |                         |               |                         |               |
|--|------------------------------|-------------------------|---------------|-------------------------|---------------|
| Compound   | Concentration Tested (ng/mL) | -25% Cutoff (3.75ng/mL) |               | +25% Cutoff (6.25ng/mL) |               |
|  |                              | Result                  | Interference? | Result                  | Interference? |
| 11-nor-9 carboxy THC                                   | 100,000                      | Negative                | No            | Positive                | No            |
| Theophylline   | 100,000                      | Negative                | No            | Positive                | No            |
| Thioridazine   | 100,000                      | Negative                | No            | Positive                | No            |
| 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   | 5,000                        | Negative                | No            | Positive                | No            |
| Venlafaxine  | 100,000                      | Negative                | No            | Positive                | No            |
| Zolpidem Tartrate                                      | 100,000                      | Negative                | No            | Positive                | No            |

b. The following is a summary table of the endogenous compounds results for the 5ng/mL cutoff

| Endogenous Compounds (for 5ng/mL cutoff) |                              |                         |               |                         |               |
|--|------------------------------|-------------------------|---------------|-------------------------|---------------|
| Compound                                 | Concentration Tested (ng/mL) | -25% Cutoff (3.75ng/mL) |               | +25% Cutoff (6.25ng/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            |
| <b>Boric Acid</b>                        | <b>1% w/v</b>                | Negative                | No            | <b>Negative</b>         | <b>Yes</b>    |
| 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            |
| <b>Riboflavin</b>                        | <b>0.0075 g/dL</b>           | Negative                | No            | <b>Negative</b>         | <b>Yes</b>    |
| Sodium Azide                             | 1% w/v                       | Negative                | No            | Positive                | No            |
| Sodium Chloride                          | 6.0 g/dL                     | Negative                | No            | Positive                | No            |
| Sodium Fluoride                          | 1% w/v                       | Negative                | No            | Positive                | No            |
| Urea                                     | 6.0 g/dL                     | Negative                | No            | Positive                | No            |

c. Boric Acid and Riboflavin interfere with the assay and the limitations have been added to the labeling regarding these two compounds.

d. The following is a summary table of the effect of pH results for the 5ng/mL cutoff

| Effect of pH (for 5ng/mL cutoff) |       |                         |               |                         |               |
|----------------------------------|-------|-------------------------|---------------|-------------------------|---------------|
| Test Parameter                   | Value | -25% Cutoff (3.75ng/mL) |               | +25% Cutoff (6.25ng/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 result for the 5ng/mL cutoff:

| Effect of Specific Gravity (for 5ng/mL cutoff) – Qualitative |       |                         |               |                         |               |
|--|-------|-------------------------|---------------|-------------------------|---------------|
| Test Parameter   | Value | -25% Cutoff (3.75ng/mL) |               | +25% Cutoff (6.25ng/mL) |               |
|  |       | Result                  | Interference? | Result                  | Interference? |
| Specific Gravity   | 1.000 | Negative                | No            | Positive                | No            |
| Specific Gravity   | 1.002 | Negative                | No            | Positive                | No            |
| Specific Gravity   | 1.005 | Negative                | No            | Positive                | No            |
| Specific Gravity   | 1.010 | Negative                | No            | Positive                | No            |
| Specific Gravity   | 1.015 | Negative                | No            | Positive                | No            |
| Specific Gravity   | 1.020 | Negative                | No            | Positive                | No            |
| Specific Gravity   | 1.025 | Negative                | No            | Positive                | No            |
| Specific Gravity   | 1.030 | Negative                | No            | Positive                | No            |

4. Linearity/ Recovery – A drug free urine pool was spiked with a 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. Summary results are listed in the following table:

| Linearity/ Recovery            |                            |              |
|--------------------------------|----------------------------|--------------|
| Expected Concentration (ng/mL) | Mean Concentration (ng/mL) | Recovery (%) |
| 5                              | 5.0                        | 100          |
| 10                             | 9.9                        | 99           |
| 15                             | 13.7                       | 91           |
| 20                             | 20.2                       | 101          |
| 25                             | 24.2                       | 97           |
| 30                             | 29.5                       | 98           |
| 35                             | 36.7                       | 105          |
| 40                             | 39.3                       | 98           |
| 45                             | 40.8                       | 91           |
| 50                             | 40.9                       | 82           |
| 55                             | 42.4                       | 77           |

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 5ng/mL cutoff

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

b. The following is a summary table of qualitative assay performance for the 5ng/mL cutoff

| Type                  | Assay Performance verified by LC/MS – 5ng/mL Cutoff |                 |               |             | Agreement (%) |
|-----------------------|---|-----------------|---------------|-------------|---------------|
|                       | Buprenorphine Concentration                         |                 |               |             |               |
|                       | < 2.5ng/mL  | 2.5 ~ 4.9 ng/mL | 5 ~ 7.5 ng/mL | > 7.5 ng/mL |               |
| Qualitative/ Positive | 0   | 0               | 4             | 36          | 100%          |
| Qualitative/ Negative | 36  | 4               | 0             | 0           | 100%          |



c. The following is a comparison table of semi-quantitative assay performance for the 5ng/mL cutoff

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

d. The following is a summary table of semi-quantitative assay performance for the 5ng/mL cutoff

| Assay Performance verified by LC/MS – 5ng/mL Cutoff |                             |                 |               |             |               |
|---|-----------------------------|-----------------|---------------|-------------|---------------|
| Type  | Buprenorphine Concentration |                 |               |             | Agreement (%) |
|   | < 2.5ng/mL                  | 2.5 ~ 4.9 ng/mL | 5 ~ 7.5 ng/mL | > 7.5 ng/mL |               |
| Semi-Quantitative / Positive                        | 0                           | 0               | 4             | 36          | 100%          |
| Semi-Quantitative / Negative                        | 36                          | 4               | 0             | 0           | 100%          |

6. Stability –

a. A closed accelerated stability study was performed on reagents, calibrators and controls at 25°C to establish the initial expiration dating. The stability study supported an initial expiration date of 1 year for reagents. This stability study supported an initial expiration date of 12 months for calibrators and controls. The instrument used for this test was a Beckman Coulter AU 400e.

1. The following is a summary of the qualitative stability data. The 0 and 3.75ng/mL levels were negative in comparison to the 5ng/mL cutoff for Day 0, 2, 8, 16, 24, 32 and 40. The 6.25ng/mL level was positive in comparison to the 5ng/mL cutoff for Day 0, 2, 8, 16, 24, 32 and 40. This accelerated stability study was performed to establish initial expiration dating. Real time stability studies are ongoing.

2. The following is a summary of the semi-quantitative stability data for the 5ng/mL cutoff. The 3.75ng/mL level was negative in comparison to the 5ng/mL cutoff for Day 0, 2, 8, 16, 24, 32 and 40. The 6.25ng/mL level was positive in comparison to the 5ng/mL cutoff for Day 0, 2, 8, 16, 24, 32 and 40. This accelerated stability study was performed to establish initial expiration dating. Real time stability studies are ongoing.

b. An open/ on-board stability study was performed on reagents to establish expiration dating when reagents are opened and stored on board the instrument at 2°C to 8°C. The stability study supported an initial open vial expiration date of 28 days. The instrument used for this test was a Beckman Coulter AU 400e.

1. The following is a summary of the qualitative open/ on-board stability data for the 5ng/mL cutoff. All replicates for the 3.75ng/mL level were negative in comparison to the 5ng/mL cutoff for Day 0, 7, 14, 21 and 28. All replicates of the 6.25ng/mL level were positive in comparison to the 5ng/mL cutoff for Day 0, 7, 14, 21 and 28.

2. The following is a summary of the semi-quantitative open/ on-board stability data for the 5ng/mL cutoff. The mean of the replicates for the 3.75ng/mL level were negative in comparison to the 5ng/mL cutoff for Day 0, 7, 14, 21 and 28. The mean of the replicates of the 6.25ng/mL level were positive in comparison to the 5ng/mL cutoff for Day 0, 7, 14, 21 and 28.

7. Calibrator and Control Traceability – all components of the calibrator and controls have been traced to a commercially available standard solution from Cerilliant Chemicals.

## **IMMUNALYSIS**

8. Calibrator and Control Stability - An open accelerated stability study was performed at 37°C to establish the initial open vial expiration dating. The stability study supported an initial open vial expiration date of 6 months. The instrument used for this test was a Beckman Coulter AU 400e. All calibrator levels (5, 10, 20 and 40ng/mL) and control levels (3.75 and 6.25ng/mL) were within specifications for Day 0, 3, 7, 10 and 13. This accelerated stability study was performed to establish initial expiration dating. Real time stability studies are ongoing.
9. Calibrator and Control Value Assignment – calibrators and controls are manufactured and are tested by mass spectrometry. If any of the analytes are out of the acceptable range, then the calibrator or control is adjusted and re-tested. Values are assigned to the calibrator 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 Buprenorphine Urine Enzyme Immunoassay is substantially equivalent to the legally marketed predicate device for its general intended use.



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

July 1, 2014

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

Re: K141406

Trade/Device Name: Immunalysis Buprenorphine Urine Enzyme Immunoassay  
Immunalysis Buprenorphine Urine Controls  
Immunalysis Buprenorphine Urine Calibrators

Regulation Number: 21 CFR 862.3650

Regulation Name: Opiate test system

Regulatory Class: II

Product Code: DJG, DLJ, LAS

Dated: May 23, 2014

Received: May 28, 2014

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

Page 2—Mr. Ginete

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

**Indications for Use**

510(k) Number (if known)  
K141406

**Device Name**

Immunalysis Buprenorphine Urine Enzyme Immunoassay, Immunalysis Buprenorphine Urine Controls and Calibrators

**Indications for Use (Describe)**

**Immunalysis Buprenorphine Urine Enzyme Immunoassay:**

The Immunalysis Buprenorphine Urine Enzyme Immunoassay is a homogeneous enzyme immunoassay with a cutoff of 5ng/mL. The assay is intended for use in laboratories for the qualitative and semi-quantitative analysis of Buprenorphine in human urine with automated clinical chemistry analyzers. This assay is calibrated against Buprenorphine. This in-vitro diagnostic device is for prescription use only.

The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GC-MS or permitting laboratories to establish quality control procedures.

The Immunalysis Buprenorphine 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 Spectroscopy (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 Buprenorphine Urine Controls:**

The Immunalysis Buprenorphine Urine Controls are used as control materials in the Immunalysis Buprenorphine Urine Enzyme Immunoassay.

**Immunalysis Buprenorphine Urine Calibrators:**

The Immunalysis Buprenorphine Urine Calibrators are used as calibrators in the Immunalysis Buprenorphine Urine Enzyme Immunoassay for the qualitative and semi-quantitative determination of Buprenorphine 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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

**Denise Johnson-Iyles -S**