**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION**
**DECISION SUMMARY**
**ASSAY ONLY TEMPLATE**

**A. 510(k) Number:**

k112808

**B. Purpose for Submission:**

New device

**C. Measurand:**

Cocaine

**D. Type of Test:**

Qualitative ELISA Immunoassay

**E. Applicant:**

Omega Laboratories, Inc.

**F. Proprietary and Established Names:**

Omega Laboratories Hair Drug Screening Assay for Cocaine and Cocaine Metabolites

**G. Regulatory Information:**

1. Regulation section:

   21 CFR §862.3250, Cocaine and Cocaine Metabolite Test System

2. Classification:

   Class II

3. Product code:

   DIO – Enzyme Immunoassay, Cocaine and Cocaine Metabolites

4. Panel:

   Toxicology (91)

## H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indications(s) for use:

   The Omega Laboratories Hair Drug Screening Assay for Cocaine and Cocaine Metabolites (Cocaine) is a laboratory developed test that is intended to be used for the qualitative determination of the presence of Cocaine in human hair from the head. The Omega Laboratories Hair Drug Screening Assay Cocaine utilizes the International Diagnostics Systems Corp. One-Step enzyme linked immunosorbent assay (ELISA) for Cocaine Testing Kit, for the qualitative detection of Cocaine at or above 500 pg/mg of hair for the purpose of identifying the use of Cocaine. To confirm a screen positive result, a more specific alternate chemical method, such as Gas Chromatography/Mass Spectrometry (GC/MS) operating in the selected ion monitoring (SIM) mode is the preferred method with deuterated internal standards. Professional judgment should be applied to any drug of abuse test result, particularly when presumptive positive results are obtained.

   This laboratory developed test is intended exclusively for in-house laboratory use only and is not intended for sale to anyone. Omega offers this laboratory developed test as a service to its clients.

3. Special conditions for use statement(s):

   The assay provides only a preliminary analytical test result. A more specific alternative chemical method (e.g. LC/MS/MS) must be used to obtain a confirmed analytical result. Other chemical confirmation methods are available. Clinical consideration and professional judgment must be applied to the interpretation of any drug-of-abuse test result.

4. Special instrument requirements:

   Confirmation testing is performed using an Agilent 6890 Series Gas Chromatograph/Agilent 5973 Mass Spectrometer (GC/MS) operation in the selected ion monitoring mode using a deuterated internal standard. MSD Chemstation™ software is used for data collection and analysis.

## I. Device Description:

Donor samples are collected using the Omega Collection Kit. The Donor Sample is shipped to the Company facility where testing is conducted by trained scientists under the direction of the Laboratory Director. This submission accepts Donor Samples from trained external sources and does not conduct any Point of Care Testing (Home testing) or on-site testing (pre-employment, insurance, court ordered, employment random screening etc.).

The assay consists of two parts; a pre-analytical hair treatment procedure (to extract cocaine from the solid hair matrix to a measurable liquid matrix), and the screening assay. The screening assay is an Enzyme-Linked ImmunoSorbent Assay (ELISA).

The Hair Drug Screening Assay for Cocaine uses the International Diagnostic Systems Corp (IDS) One-Step ELISA Cocaine micro-plate/reagents and a micro-plate reader for the qualitative detection of Cocaine in hair samples. The test system consists of micro strip plates coated with rabbit anti-BE polyclonal antibody, enzyme conjugate (horseradish peroxidase conjugated to cocaine), substrate (containing tetramethylbenzidine), and wash solution. Cut off concentration is 500 pg/mg hair.

## J. Substantial Equivalence Information:

1. Predicate device name(s):

   Quest Diagnostics HairCheck-DT (Cocaine)

2. Predicate 510(k) number(s):

   k023626

3. Comparison with predicate:

| Reagent Similarities and Differences | | |
|---|---|---|
| **Feature** | **Candidate Device: Omega Hair Drug Screening Assay for Cocaine (k112808)** | **Predicate Device: Quest Diagnostic Hair Check-DT (Cocaine) Assay (k023626)** |
| Indication for Use | Intended to be used for the qualitative determination of the presence of Cocaine in human hair from the head. | Same |
| Measureand | Cocaine | Same |
| Micro-plate | International Diagnostics Systems Corp Forensic Human Drugs of Abuse IDS One-Step Cocaine ELISA for Hair Testing Kit | Same |
| Method of Measurement | Microplate Reader, read at 450 nm | Same |
| Matrix | Head Hair | Same |
| Cutoff Concentration | 500 pg Cocaine/mg hair | 300 pg Cocaine/ mg hair |
| Type of Test | ELISA | Same |
| Extraction Method | Utilized acid-methanol vs. methanol alone to facilitate extraction of cocaine from hair. | Methanol |
| Confirmation Method | GC/MS | Same |

**K. Standard/ Guidance Document Referenced (if applicable):**

None were referenced

**L. Test Principle:**

Approximately 10-15 mg of the test sample is used for the assay. The test sample is pulverized and then extracted under heat with acidified methanol. After cooling, the test sample is centrifuged/dried and then reconstituted in 0.1% BSA/BPBS buffer. The resulting solution is applied directly to the IDS ELISA

The prepared hair sample is added to a well of the micro strip plate and enzyme conjugate is added, followed by incubation. During this phase the enzyme-labeled drug conjugate competes with drug in the sample for a limited number of binding sites on the rabbit anti-BE polyclonal antibody-coated micro wells. The two bind in proportion to their concentrations. A wash solution is applied to remove any unbound materials. Enzyme substrate solution containing a chromagen is added. The reaction is stopped with an acid and the absorbance is read using a plate reader at 450 nm. Color intensity is inversely proportional to the amount of drug present in the sample.

The only materials provided to a client (the requestor of the test) is the Sample Collection Kit. None of the laboratory materials, reagents or equipment is shipped or used outside of Omega's laboratory facilities. Specifically, the Calibrator and Controls used in the Cocaine Assay are prepared for in-house use and none are shipped to clients or use by untrained non-professionals.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:
   *a. Precision/Reproducibility:*
   The intra-assay precision study was performed by taking eleven replicates of negative hair samples spiked with ±25%, ±50%, and 100% of the 500 pg/mg hair cut-off value (corresponding to 125, 250, 375, 500, 625, 750, 875, and 1000 pg/mg). The material used to spike the hair sample was commercially available cocaine in methanol. This study was done in one run on one day with one lot of the screening assay. A summary of the results is presented in the tables below.

| [Cocaine] (pg/mg hair) | Percent of Cut-off | Replicate Number | Pos/Neg |
|---|---|---|---|
| 0 | -100% | 11 | 0/11 |
| 125 | -75% | 11 | 0/11 |
| 250 | -50% | 11 | 0/11 |
| 375 | -25% | 11 | 0/11 |
| 625 | +25% | 11 | 11/0 |
| 750 | +50% | 11 | 11/0 |
| 875 | +75% | 11 | 11/0 |
| 1000 | +100% | 11 | 11/0 |

A second study was done using samples from five hair specimens previously found to be positive for cocaine. Each hair specimen was divided into 6 aliquots and three were measured in one run, while the other three were analyzed by GC/MS. The results were as follows:

| Sample | [Cocaine] pg/mg | Replicate Number | Pos/Neg |
|---|---|---|---|
| 1 | 10981 | 3 | 3/0 |
| 2 | 6948 | 3 | 3/0 |
| 3 | 1913 | 3 | 3/0 |
| 4 | 29775 | 3 | 3/0 |
| 5 | 620 | 3 | 3/0 |

The inter-assay precision study was performed by taking eleven replicates of negative hair samples spiked with ±25%, ±50%, 100% of the 500 pg/mg hair cut-off value (corresponding to 125, 250, 375, 500, 625, 750, 875, and 1000 pg/mg). The material used to spike the hair sample was commercially available cocaine in methanol. The study was performed over 20 days. A summary of the results is presented in the tables below.

| [Cocaine] (pg/mg hair) | Percent of Cut-off | Replicate Number | Pos/Neg |
|---|---|---|---|
| 0 | -100% | 220 | 0/220 |
| 125 | -75% | 220 | 0/220 |
| 250 | -50% | 220 | 0/220 |
| 375 | -25% | 220 | 0/220 |
| 625 | +25% | 220 | 220/0 |
| 750 | +50% | 220 | 220/0 |
| 875 | +75% | 220 | 220/0 |
| 1000 | +100% | 220 | 220/0 |

*b. Linearity/assay reportable range:*

Not Applicable, the assay is intended for qualitative use

*c. Traceability, Stability, Expected values (controls, calibrators, or methods):*
Omega laboratories utilized in house prepared calibrator and control solutions. Cocaine in methanol is commercially purchased and used to make stock solutions that are used to prepare working solutions. The assigned values of the calibrator and control stock solutions are verified by GC/MS analysis against a current validated GC/MS calibrator solution each time a batch is prepared. The calibrator and control must fall within 10% of the target concentration. The commercial material is traceable to NIST.

*Stability*
Control Solution: Cocaine in methanol is stable for a period of six months when stored in an amber bottle and refrigerated. The acceptance criteria were that the cocaine value of the control solution had to be within 10% of the target value of 500 pg/mg after six months.

Hair: Storage of hair samples was studied by placing fifty hair samples that were previously tested in a collection kit for 2 years at 14-30°C. A variety of hair color and curvatures were tested. The study showed that the mean variance in cocaine concentration was -23% over two years.

A shipping study was performed to determine whether there were any adverse effects on hair samples when exposed to extreme temperatures and variations in humidity that might occur during sample shipment. Eight shipping boxes containing 25 known positive and negative samples were stored at approximately -13°C for about 15 hours and then were heated to 47°C for about 6 hours. Each box was then shipped to a different location, held for two days and sent back to the lab. The returned samples were screened and quantitatively tested using GC/MS. A variety of hair color and curvatures were tested. No hair samples had discordant results when returned and therefore it was determined

that there were no adverse effects on hair samples when exposed to extreme temperatures and humidity variations when being shipped.

*Expected Values*
The calibrator should be 500 pg/mg and the controls should be 250 pg/mg and 1000 pg/mg of hair.

*d. Detection limit:*

See Precision/Reproducibility section in M1.a above.

*e. Analytical specificity:*

Specificity and cross-reactivity was performed by adding compounds to negative hair samples. 10,000 ng/mL of 270 unrelated compounds were spiked into drug-free hair, -50%, +125%, and +150% of cut-off cocaine-spiked hair. The result was compared to the control which contained 500 pg/mL cocaine (cut-off). The following compounds were found to interfere in the assay.

| Compound | Approximate concentration of Compound (pg/mg) equivalent to 500 pg/mg (cut-off) of cocaine control (n=3) | Cross-reactivity (%) |
|---|---|---|
| Benzoylecgonine isopropyl ester | 300 | 166.7 |
| Cocatheylene | 375 | 133.3 |
| Cocaine | 500 | 100.0 |
| Benzoylecgonine | 600 | 83.3 |
| Meta-hydroxybenzoylecgonine | 700 | 71.4 |
| Ecgonine | 80000 | 0.6 |
| Norbenzoylecgonine | 150000 | 0.3 |
| Norcocaine | 250000 | 0.2 |
| Norcocaethylene | 250000 | 0.2 |
| Ecgonine methyl ester | >400000 | <0.1 |
| Anhydroecgonine methyl ester | >400000 | <0.1 |
| Anydroecgonine | >400000 | <0.1 |
| Atropine | >400000 | <0.1 |

Additionally, inhibition curves for structurally similar compounds were generated. Serial dilutions of each control compound were prepared in negative hair matrix extract. The concentration of the structurally related compound that gave a similar absorbance to the cut-off (500 pg/mg) cocaine control was determined and the percent cross reactivity was calculated. The results were as follows:

benzoylecgonine
benzoylecgonine isopropyl ester
cocaethylene
cocaine
ecgonine
ecgonine methyl ester
m-hydroxybenzoylecgonine
norbenzoylecgonine
norcaethylene
norcocaine

**Cosmetic Treatment**

Studies were performed to determine the effect of various treatments on the Omega Hair Drug Screening Assay for cocaine. Sixty-six specimens previously determined to be negative and 110 specimens determined to be positive for cocaine were treated and analyzed by the ELISA protocol and the GC/MS confirmation method. All samples determined to be negative prior to treatment remained negative post treatment. The following treatments were performed:

| Bleaching Study #1 ELISA Screening Data (n = 12) | | | | | |
|---|---|---|---|---|---|
| | Mean Abs/Range of Abs | # of samples that remained positive | Mean/Range of Abs of all that had a decrease in Abs | # of samples that became negative | Mean/Range of Abs of all that had a increase in Abs |
| Untreated | 0.420 (0.063 – 0.782) | | | | |
| Treated | 0.472 (0.070 – 0.787) | 12 | 0.07 | 0 | 0.509 (0.078 – 0.787) |

| Bleaching Study #2 ELISA Screening Data (n = 12) | | | | | |
|---|---|---|---|---|---|
| | Mean Abs/Range of Abs | # of samples that remained positive | Mean/Range of Abs of all that had a decrease in Abs | # of samples that became negative | Mean/Range of Abs of all that had a increase in Abs |
| Untreated | 0.416 (0.077 – 0.736) | | | | |
| Treated | 0.619 (0.181 – 2.123) | 11 | 0.440 (0.181-0.709) | 1 | 0.679 (0.185-2.123) |

| Hair Permanent Study #1 ELISA Screening Data (n = 13) | | | | | |
|---|---|---|---|---|---|
| | Mean Abs/Range of Abs | # of samples that remained positive | Mean/Range of Abs of all that had a decrease in Abs | # of samples that became negative | Mean/Range of Abs of all that had a increase in Abs |
| Untreated | 0.499 (0.068 – 0.967) | | | | |
| Treated | 0.522 (0.076 – 1.027) | 12 | 0.507 (0.083-0.942) | 1 | 0.532 (0.076 – 1.027) |

| Hair Permanent Study #2 ELISA Screening Data (n = 9) | | | | | |
|---|---|---|---|---|---|
| | Mean Abs/Range of Abs | # of samples that remained positive | Mean/Range of Abs of all that had a decrease in Abs | # of samples that became negative | Mean/Range of Abs of all that had a increase in Abs |
| Untreated | 0.542 (0.066 – 0.915) | | | | |
| Treated | 0.590 (0.067 – 1.022) | 7 | 0.067 | 2 | 0.655 (0.079 – 1.022) |

| Dyeing Study #1 ELISA Screening Data (n = 11) | | | | | |
|---|---|---|---|---|---|
| | Mean Abs/Range of Abs | # of samples that remained positive | Mean/Range of Abs of all that had a decrease in Abs | # of samples that became negative | Mean/Range of Abs of all that had a increase in Abs |
| Untreated | 0.365 (0.097 – 0.874) | | | | |
| Treated | 0.404 (0.095 – 0.876) | 11 | 0.195 (0.095-0.427) | 0 | 0.524 (0.233-0.876) |

| Dyeing Study #1 ELISA Screening Data (n = 12 | | | | | |
|---|---|---|---|---|---|
| | Mean Abs/Range of Abs | # of samples that remained positive | Mean/Range of Abs of all that had a decrease in Abs | # of samples that became negative | Mean/Range of Abs of all that had a increase in Abs |
| Untreated | 0.334 (0.063 0.806) | | | | |
| Treated | 0.356 (0.075 – 0. 768) | 12 | 0.416 (0.075-0.768) | 0 | 0.326 (0.075-0.549) |

| Hair Relaxer Study #1 ELISA Screening Data (n = 11) | | | | | |
|---|---|---|---|---|---|
| | Mean Abs/Range of Abs | # of samples that remained positive | Mean/Range of Abs of all that had a decrease in Abs | # of samples that became negative | Mean/Range of Abs of all that had a increase in Abs |
| Untreated | 0.354 (0.054 – 0.876) | | | | |
| Treated | 0.352 (0.049 – 0.834) | 11 | 0.443 (0.049-0.834) | 0 | 0.300 (0.086-0.702) |

| Hair Relaxer Study #2 ELISA Screening Data (n = 11) | | | | | |
|---|---|---|---|---|---|
| | Mean Abs/Range of Abs | # of samples that remained positive | Mean/Range of Abs of all that had a decrease in Abs | # of samples that became negative | Mean/Range of Abs of all that had a increase in Abs |
| Untreated | 0.334 (0.052 – 0.832) | | | | |
| Treated | 0.347 (0.044 – 0.934) | 11 | 0.33 (0.044-0.746) | 0 | 0.358 (0.074-0.934) |

| Shampoo Study #1 ELISA Screening Data (n = 9) | | | | | |
|---|---|---|---|---|---|
| | Mean Abs/Range of Abs | # of samples that remained positive | Mean/Range of Abs of all that had a decrease in Abs | # of samples that became negative | Mean/Range of Abs of all that had a increase in Abs |
| Untreated | 0.209 (0.042 – 0.428) | | | | |
| Treated | 0.218 (0.082 – 0.480) | 9 | 0.218 (0.15-0.396) | 0 | 0.218 (0.082-0.480) |

| Shampoo Study #2 ELISA Screening Data (n = 10) | | | | | |
|---|---|---|---|---|---|
| | Mean Abs/Range of Abs | # of samples that remained positive | Mean/Range of Abs of all that had a decrease in Abs | # of samples that became negative | Mean/Range of Abs of all that had a increase in Abs |
| Untreated | 0.405 (0.053 – 0.951) | | | | |
| Treated | 0.415 (0.067 – 0.898) | 10 | 0.63 (0.206-0.898) | 0 | 0.322 (0.067-0.687) |

**Environmental Contamination Study**

Preliminary positive hair sample results by the screening method could be due to environmental contamination. All positive should be sent for confirmation testing on a reference method to distinguish between true positive and those samples that were positive due to external exposure.

f. *Assay cut-off:*
The Assay cut-off is 500 pg cocaine/mg hair. Analytical performance of the device around the claimed cutoff is described in the precision section M.1a above.

2. Comparison studies:
   *a. Method comparison with predicate device:*
   The method comparison was performed by testing 345 hair samples with the candidate and comparing to the reference method, GC/MS. Each specimen was divided into two aliquots and one was used fro screening and the other for GC/MS confirmation. The results were:

| IDS ELISA Test Result | GC/MS Negative (<50 pg/mg) | GC/MS Negative (<250 pg/mg) | GC/MS Negative (250-499 pg/mg) | GC/MS Positive (500-750 pg/mg) | GC/MS Positive (>750 pg/mg) |
|---|---|---|---|---|---|
| Positive (Candidate Device) | 0 | 0 | 31 | 23 | 165 |
| Negative (Candidate Device) | 122 | 2 | 32 | 0 | 0 |

The Discordant results are as follows:

| Screening Cutoff (pg/mg) | IDS ELISA Test Result (Pos/neg) | GC/MS Cutoff (pg/mg) | GC/MS Drug Result (Total Cocaine Equivalents pg/mg) |
|---|---|---|---|
| 500 | POS | 500 | 258 |
| 500 | POS | 500 | 264 |
| 500 | POS | 500 | 273 |
| 500 | POS | 500 | 291 |
| 500 | POS | 500 | 293 |
| 500 | POS | 500 | 302 |
| 500 | POS | 500 | 302 |
| 500 | POS | 500 | 318 |
| 500 | POS | 500 | 326 |
| 500 | POS | 500 | 334 |
| 500 | POS | 500 | 335 |
| 500 | POS | 500 | 342 |
| 500 | POS | 500 | 349 |
| 500 | POS | 500 | 358 |

| | | | |
|---|---|---|---|
| 500 | POS | 500 | 372 |
| 500 | POS | 500 | 380 |
| 500 | POS | 500 | 393 |
| 500 | POS | 500 | 399 |
| 500 | POS | 500 | 409 |
| 500 | POS | 500 | 410 |
| 500 | POS | 500 | 450 |
| 500 | POS | 500 | 455 |
| 500 | POS | 500 | 457 |
| 500 | POS | 500 | 461 |
| 500 | POS | 500 | 468 |
| 500 | POS | 500 | 469 |
| 500 | POS | 500 | 471 |
| 500 | POS | 500 | 478 |
| 500 | POS | 500 | 491 |
| 500 | POS | 500 | 491 |
| 500 | POS | 500 | 497 |

*b. Matrix comparison:*

Not applicable.

3. Clinical studies:

*a. Clinical Sensitivity:*

Not Applicable

*b. Clinical specificity:*

Not Applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not Applicable

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range

Not Applicable

**N. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**O. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.