

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

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

k131128

**B. Purpose for Submission:**

Addition of body hair claim

**C. Measurand:**

Cocaine and cocaine metabolites in hair

**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. Indication(s) for use:

The Omega Laboratories Hair Drug Screening Assay for Cocaine and Cocaine Metabolites (Cocaine) is an in vitro diagnostic test that is intended for the qualitative detection of Cocaine at or above 500 pg/mg in human head and body hair. 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 test is intended exclusively for single laboratory use only and is not intended for sale to anyone.

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 head and body hair 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 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):  
Omega Laboratories Hair Drug Screening Assay for Cocaine and Cocaine Metabolites
2. Predicate 510(k) number(s):  
  
k112808
3. Comparison with predicate:

<b>Similarities and Differences</b>		
Item	Device	Predicate
Laboratory	Omega Laboratories	Same
Indication for/Intended Use	Same except for head and body hair	Intended to be used for the qualitative determination of the presence of Cocaine in human hair from the head.
Method of Measurement	Same	Microplate Reader read at 450 nm
Matrix	Head and body hair	Head hair
Cut-off Concentration	Same	500 pg Cocaine /mg hair
Assay Principal	Same	ELISA
Extraction Method	Same	Acid-methanol to facilitate extraction of Cocaine from hair. Hair is pulverized into small segments prior to acid-methanol extraction, which improves extraction times without loss of efficiency

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

None referenced

**L. Test Principle:**

The test consists of two parts; a pre-analytical hair treatment procedure (to remove 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). 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 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 and a background reading is also taken at 630 nm. Color intensity is inversely proportional to the amount of drug present in the sample.

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

1. Analytical performance:

*a. Precision/Reproducibility:*

See k112808

*b. Linearity/assay reportable range:*

Not applicable

*c. Traceability, Stability, Expected values (controls, calibrators, or methods):*

See k112808 for control stability, hair storage, and shipping study information.

*d. Detection limit:*

See k112808

*e. Analytical specificity:*

Cross-reactivity of structurally similar (test) compounds was assessed by performing serial dilutions of each test compound in negative head hair matrix. The concentration of the test compound that gave a similar absorbance to the 500 pg/mg cocaine cut-off

control was determined and percent cross reactivity was calculated. The results are shown below:

**Cross reactivity of Cocaine ELISA with Structurally Similar Compounds**

<b>Compound</b>	<b>Approximate Concentration of Compound (pg/mg) Equivalent to 500 pg/mg Cocaine Cutoff Control (n=3)</b>	<b>Percent Cross-Reactivity (%)</b>
Benzoylecgonine isopropyl ester	300	166.7
Cocaethylene	375	133.3
Cocaine	500	100
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	105000	0.48
Anhydroecgonine methyl ester	250000	0.2
Anhydroecgonine	No cross-reactivity achieved at highest spike concentration tested (4,000,000 pg/mg).	
Atropine	No cross-reactivity achieved at highest spike concentration tested (4,000,000 pg/mg).	

Specificity was tested for several related and unrelated (test) compounds at 10,000 ng/mL (400,000 pg/mg). Negative head hair extracts were spiked with cocaine at -50% (250 pg/mg), +125% (625 pg/mg), and +150% (750 pg/mg) of the cocaine cut-off concentration (500 pg/mg). The samples were additionally spiked with the test compounds and compared to the control containing the 500 pg/mL cocaine cut-off concentration. All compounds were found to interfere at the +125% (625 pg/mg), and +150% (750 pg/mg) cut-off concentrations. The following compounds were found to interfere in the assay at the -50% (250 pg/mg) cut-off concentration (if combined equivalent cocaine concentration > 500 pg/mg)\*:

- Anhydroecgonine methyl ester
- Benzoylecgonine
- Benzoylecgonine isopropyl ester
- Cocaethylene
- Cocaine
- Ecgonine
- Ecgonine methyl ester
- m-Hydroxybenzoylecgonine
- Norbenzoylecgonine
- Norcocaethylene

Norcocaine

Note: \* (% Cross-Reactivity/100) X (400,000 pg/mg tested concentration) = X pg/mg cocaine equivalents. X pg/mg cocaine equivalents + 250 mg/pg cocaine (-50% cocaine cut-off)= combined equivalent cocaine concentration.

**Cosmetic treatment and environmental contamination**

See k112808 for cosmetic treatment and environmental contamination study information

f. Assay cut-off:

See k112808

2. Comparison studies:

a. *Method comparison with predicate device:*

In the first of three agreement studies, 345 head hair specimens (including 100 negative specimens) were analyzed utilizing the ELISA technique described above. An additional 30 head hair negative specimens were analyzed in a second study and 49 body hair specimens were analyzed in the third study. Each specimen was divided into 2 aliquots for screening and GC/MS confirmation to verify the quantitative value of cocaine compared to the 500 pg/mg cut-off. The combined results (n=424) are shown below:

<b>ELISA Test Result</b>	<b>GC/MS Negative (&lt;50 pg/mg)</b>	<b>GC/MS Negative (&lt;250 pg/mg)</b>	<b>GC/MS Negative (250-499 pg/mg)</b>	<b>GC/MS Positive (500-750 pg/mg)</b>	<b>GC/MS Positive (&gt;750 pg/mg)</b>
Positive (Candidate Device)	0	0	31	24	210
Negative (Candidate Device)	122	3	34	0	0

<b>Screening Cutoff (pg/mg)</b>	<b>ELISA Test Result (POS/NEG)</b>	<b>Drug</b>			<b>GC/MS Drug Result</b>
		Cocaine	Benzoylecgonine	Cocaethylene	
500	Positive	189	83	0	272
500	Positive	227	44	0	271
500	Positive	273	0	0	273
500	Positive	219	87	0	306
500	Positive	251	50	0	301
500	Positive	260	50	0	310
500	Positive	230	87	0	317
500	Positive	278	48	0	326

500	Positive	272	65	0	337
500	Positive	334	0	0	334
500	Positive	238	116	0	354
500	Positive	342	0	0	342
500	Positive	313	43	0	356
500	Positive	335	28	0	363
500	Positive	284	106	0	390
500	Positive	294	103	0	397
500	Positive	354	47	0	401
500	Positive	333	79	0	412
500	Positive	364	54	0	418
500	Positive	328	98	0	426
500	Positive	265	118	65	448
500	Positive	424	37	0	461
500	Positive	393	77	0	470
500	Positive	390	85	0	475
500	Positive	433	42	0	475
500	Positive	469	0	0	469
500	Positive	444	32	0	476
500	Positive	336	32	94	462
500	Positive	491	0	0	491
500	Positive	453	46	0	499
500	Positive	497	0	0	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.