

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

A. 510(k) Number:

k140671

B. Purpose for Submission:

Addition of body hair claim

C. Measurand:

Opiates, Oxycodone and Hydrocodone in hair

D. Type of Test:

Qualitative ELISA Immunoassay

E. Applicant:

Omega Laboratories, Inc.

F. Proprietary and Established Names:

Omega Laboratories, Inc. Hair Drug Screening Assay for Opiates, Oxycodone and Hydrocodone

G. Regulatory Information:

1. Regulation section:

21 CFR §862.3650, Opiate Test System

2. Classification:

Class II

3. Product code:

DJG

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 (Opiates, Oxycodone and Hydrocodone) is an in vitro diagnostic test that is intended for the qualitative detection of opiates (calibrated with morphine) and oxycodone and hydrocodone (calibrated with oxycodone) at or above 300 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):

For Over-the-Counter Use

4. Special instrument requirements:

The screening assay is for use with an automated microplate reader capable of measuring at 450 nm.

For confirmation testing, the sponsor uses an Agilent GC/MS in selected ion monitoring (SIM) mode using deuterated internal standards.

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.

The assay consists of the following:

- Hair sample collection kit
- Micro strip plates coated with either anti-morphine mouse monoclonal or antioxycodone rabbit polyclonal antibody, enzyme conjugate (horseradish peroxidase conjugated to morphine or oxycodone), substrate (containing tetramethylbenzidine), an enzyme diluent, and wash solution

- In-house prepared calibrators and controls are used. These are prepared solutions of morphine and oxycodone added to negative hair matrix tubes.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Omega Laboratories Hair Drug Screening Assay for Opiates, Oxycodone and Hydrocodone

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

k103161

3. Comparison with predicate:

Similarities and Differences		
Item	Device	Predicate
Laboratory	Omega Laboratories	Same
Indication for/Intended Use	Same except for both head and body hair	Intended to be used for the Qualitative determination of the presence of opiates, oxycodone and hydrocodon 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	300 pg Opiates/mg hair 300 pg Oxycodone/mg hair 300 pg Hydrocodone/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 convert the solid matrix of hair 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 antibody-coated micro wells. The two bind in proportion to their concentrations. A wash solution is applied to remove unbound materials. Enzyme substrate solution containing a chromagen is added. The reaction is stopped with a stop solution and absorbance is read using a plate reader at 450 nm. A background reading is also taken at 630 nm. Color intensity is inversely proportional to the amount of drug presented in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

See k103161 for precision/reproducibility information.

b. *Linearity/assay reportable range:*

Not applicable.

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

See k103161 for calibrator and control materials information, hair sample stability, and shipping study information.

d. *Detection limit:*

Not applicable.

e. *Analytical specificity:*

See k103161 for cross reactivity, interference (structurally related and unrelated compounds), hair treatment, and environmental contamination studies.

In addition to studies conducted in k103161, the sponsor performed additional cross reactivity testing on several structurally similar compounds including Buprenorphine, Noroxymorphone, 3-Methoxynaltrexone, Morphine-6-beta-glucuronide, Nalmefene, Nalorphine, Naloxone-3-beta-D-glucuronide, Naltrexone, Naltriben. These compounds appeared to contribute to an Opiate or Oxycodone positive ELISA result

at -50% cutoff, but did not show cross reactivity when tested at concentrations up to 400,000pg/mg.

To investigate this discrepancy, cross reactivity was tested at up to 10 fold higher concentrations. Expected results were obtained. The results are summarized in the tables below. The tables below are also included in the device labeling.

Cross reactivity of Opiates ELISA with Structurally Similar Compounds

Compound	Concentration of Compound (pg/mg) Equivalent to 300 pg/mg Opiates Cutoff Control	Percent Cross-Reactivity (%)
Morphine-6-β-D-glucuronide	800	37.5
Nalorphine	8500	3.5
Buprenorphine	600000	0.050
3-Methoxynaltrexone	900000	0.033
Naltrexone	3000000	0.010
Noroxymorphone	4000000	0.008
Nalmefene	*	0.00
Naloxone-3-β-D-glucuronide	*	0.00
Naltriben	*	0.00

* Unable to generate an assay absorbance equivalent to 300pg/mg Opiates cutoff. Highest concentration tested was 4,000,000pg/mg.

Cross Reactivity of Omega Laboratories, Inc. Oxycodone ELISA with Structurally Similar Compounds

Compound	Concentration of Compound (pg/mg) Equivalent to 300 pg/mg Oxycodone Cutoff Control	Percent Cross-Reactivity (%)
Morphine-6-β-D-glucuronide	31000	0.97
Nalorphine	300000	0.10
Buprenorphine	*	0.00
3-Methoxynaltrexone	380000	0.08
Naltrexone	50000	0.60
Noroxymorphone	58000	0.52
Nalmefene	300000	0.10
Naloxone-3-β-D-glucuronide	680000	0.04
Naltriben	300000	0.10

* Unable to generate an assay absorbance equivalent to 300pg/mg Oxycodone cutoff. Highest concentration tested was 4,000,000pg/mg

f. *Assay cut-off:*

See k103161.

2. Comparison studies:

a. *Method comparison with predicate device:*

Method comparison studies on head hair samples were performed and reported in the predicate submission (k103161). Additional method comparison studies were performed for this current submission with 50 body hair samples. Each tested sample was divided into two aliquots and one was used for screening on the candidate device (ELISA assay) and the other for GC/MS confirmation. Testing was performed on hair samples from different ages, gender, ethnicities and hair color. The combined head hair (performed in k103161) and body hair (this submission) results are shown below:

Opiates Equivalents Summary of Agreement Study Results, Head Hair (N=176) and Body Hair (N=50)

ELISA Test Result	Negative by GC/MS	Less than half the cutoff concentration by GC/MS	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (Greater than 50% above the cutoff concentration)
Positive	0	0	2	24	116
Negative	70	4	9	1	0

GC/MS Summary of Opiates Equivalents Discordant Results (N=3)

Sample No.	Screening Cutoff (pg/mg)	ELISA Test Result (POS/NEG)	GC/MS Cutoff (pg/mg)	GC/MS Drug Result (pg/mg)
16	300	POS	300	HDC 268
150	300	POS	300	HDC 299
29	300	NEG	300	HDC 354

Oxycodone Summary of Agreement Study Results, Head Hair (N=480) and Body Hair (N=50)

ELISA Test Result	Negative by GC/MS	Less than half the cutoff concentration by GC/MS	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (Greater than 50% above the cutoff concentration)
Positive	0	0	6	94	221
Negative	140	6	14	2	0

*Of the 530 samples compared in the Oxycodone assays, 46 ELISA head hair positive samples were negative by GC/MS confirmation for oxycodone but positive for hydrocodone and one head hair test sample was lost during centrifugation reducing the number of test samples reported in the table to 483.

GC/MS Summary of Oxycodone Discordant Results (N=8)

Sample No.	Screening Cutoff (pg/mg)	ELISA Test Result (POS/NEG)	GC/MS Cutoff (pg/mg)	GC/MS Drug Result (pg/mg)
835334	300	NEG	300	OXY 169 HDC 167
EXOP 39	300	POS	300	OXY 131 HDC 83
788840	300	POS	300	OXY 185 HDC 29

Sample No.	Screening Cutoff (pg/mg)	ELISA Test Result (POS/NEG)	GC/MS Cutoff (pg/mg)	GC/MS Drug Result (pg/mg)
787180c	300	POS	300	OXY 229 HDC 68
789526	300	POS	300	OXY 240 HDC 49
872104	300	NEG	300	OXY 130 HDC 221
854976	300	POS	300	OXY 255
800488	300	POS	300	OXY 298

Hydrocodone Summary of Agreement Study Results, Head Hair (N=480), Body Hair (N=50)

ELISA Test Result	Negative by GC/MS	Less than half the cutoff concentration by GC/MS	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (Greater than 50% above the cutoff concentration)
Positive	0	0	8	110	201
Negative	142	8	25	6	0

*Of the 530 samples compared in the HDC assays, 27 ELISA head hair positive samples were negative by GC/MS confirmation for hydrocodone but positive for oxycodone, one head hair test sample was lost during centrifugation and 2 ELISA head hair positive samples were not able to be confirmed by GC/MS which reduced the number of test samples reported here to 500.

GC/MS Summary of Hydrocodone Discordant Results (N=14)

Sample No.	Screening Cutoff (pg/mg)	ELISA Test Result (POS/NEG)	GC/MS Cutoff (pg/mg)	GC/MS Drug Result (pg/mg)
787832	300	NEG	300	HDC 403
89	300	NEG	300	HDC 313
65	300	NEG	300	HDC 334
835334	300	NEG	300	HDC 167 OXY 169
872104	300	NEG	300	HDC 221 OXY 130
835981a	300	NEG	300	HDC 347
788840	300	POS	300	HDC 29 OXY 185
789526	300	POS	300	HDC 49 OXY 240
787180c	300	POS	300	HDC 68 OXY 229
EXOP 39	300	POS	300	HDC 83 OXY 131
790194	300	POS	300	HDC 204
849237	300	POS	300	HDC 256
904316	300	POS	300	HDC 272
780598	300	POS	300	HDC 283

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.