

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

510(k) Number: K131128

Date of Summary: Nov. 8, 2013

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Product Name:
Trade Name: Omega Laboratories Hair Drug Screening Assay for Cocaine and Cocaine Metabolites

Common Name: Hair Drug Screening Assay Cocaine and Cocaine Metabolites

Regulation Number: CFR 862.3250 (ProCode DIO)

Classification Name: Cocaine and cocaine metabolite test system

Classification Panel: 91 (Toxicology)

Predicate Device: Omega Laboratories Hair Drug Screening Assay for Cocaine and Cocaine Metabolites (k112808);

Indication 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.

Comparison: When used to qualitatively detect Cocaine and Cocaine Metabolites in head hair specimens collected with the Omega Specimen Collection Device, the Omega assays yield results in substantial agreement with the predicate device (see Table 1 below).

Comparison Performance Data: All performance studies demonstrated that the Omega assay is in substantial agreement with the predicate products. Results obtained from donor specimens showed that the qualitative results from the new assays are substantially equivalent to those obtained from the predicate devices.

Table 1: Comparison of Omega Laboratories Cocaine Assay vs Omega Laboratories Cocaine Assay

Comparison Element - Similarities	Hair Drug Screening Assay for Cocaine. (Subject devices)	Hair Drug Screening Assay (Cocaine). (Predicate device)
Laboratory	Omega Laboratories, Inc.	Same.
Indication for/ Intended Use	<p>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.</p> <p>This test is intended exclusively for single laboratory use only and is not intended for sale to anyone.</p>	Same.
Method of Measurement	Microplate reader. Read at 450 nm	Same.
Matrix	Head and body hair	Head hair
Cutoff concentration	500 pg Cocaine /mg hair	Same.
Assay Principal	ELISA	Same.

Table 1: Comparison of Omega Laboratories Cocaine Assay vs Omega Laboratories Cocaine Assay

Comparison Element - Similarities	Hair Drug Screening Assay for Cocaine. (Subject devices)	Hair Drug Screening Assay (Cocaine). (Predicate device)
Extraction Method	Utilized acid-methanol vs methanol alone to facilitate extraction of Cocaine from hair. Proprietary and patent pending method of pulverizing hair vs cutting the hair into small segments prior to acid-methanol extraction. This improved extraction times without loss of efficiency	Same.

Performance Studies

PRECISION : Intra-assay precision studies were performed using 11 replicates of negative head hair samples spiked to the following concentrations of cocaine: zero drug, -75%, -50%, -25% below the cutoff, and +25%, +50%, +75% and +100% above the cutoff. All samples were treated and analyzed in the same manner as donor hair samples and measured in one run. Head hair was used in this study.

Table 2: Intra-Assay Cocaine Precision Studies (11 replicates/8 concentrations n= 88)

Drug	Concentration of Sample (pg/mg)	Number of Replicates	Results # Negative	Results # Positive
Cocaine	0 (Negative)	11	11	0
Cocaine	125 (-75%)	11	11	0
Cocaine	250 (-50%)	11	11	0
Cocaine	375 (-25%)	11	11	0
Cocaine	625 (+25%)	11	0	11
Cocaine	750 (+50%)	11	0	11
Cocaine	875 (+75%)	11	0	11
Cocaine	1000 (+100%)	11	0	11

Inter-assay precision studies were performed using negative head hair samples spiked to the following concentrations of cocaine: zero drug, -75%, -50%, -25% below the cutoff, and +25%, +50%, +75% and +100% above the cutoff. All samples were treated and analyzed in the same manner as donor hair samples. Eleven replicates of these were prepared and analyzed over 20 non-consecutive. The precision of the assay was deemed to be acceptable if the %CV was less than 15%.

Table 3: Inter-Assay Cocaine Precision Studies (CO=500 pg/mg)
(11 replicates/8 concentrations over 20 n= 1760)

Drug	Concentration of Sample (pg/mg)	Number of Replicates	Results # Negative	Results # Positive
Cocaine	0 (Negative)	220	220	0
Cocaine	125 (-75%)	220	220	0
Cocaine	250 (-50%)	220	220	0
Cocaine	375 (-25%)	220	220	0
Cocaine	625 (+25%)	220	0	220
Cocaine	750 (+50%)	220	0	220
Cocaine	875 (+75%)	220	0	220
Cocaine	1000 (+100%)	220	0	220

AGREEMENT: The method comparison was performed by testing 424 hair samples in three studies with the candidate assay and comparing to the reference method, GC/MS. Each specimen was divided into two aliquots and one was used for screening and the other for GC/MS confirmation. Testing was performed on body and head hair samples from different ages, gender, ethnicities and hair color. The results were:

Table 4a: Cocaine Agreement Studies (n=424)

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	0	0	31	24	210
Negative	122	3	34	0	0

Table 4b: GC/MS Summary of Discordant Results

Screening Cutoff (pg/mg)	ELISA Test Result (POS/NEG)	Drug			GC/MS Drug Result (pg/mg)
		Cocaine	Benzoylcegonine	Cocaethylene	
500	POS	189	83	0	272
500	POS	227	44	0	271

Table 4b: GC/MS Summary of Discordant Results

Screening Cutoff (pg/mg)	ELISA Test Result (POS/NEG)	Drug			GC/MS Drug Result (pg/mg)
		Cocaine	Benzoyllecgonine	Cocaethylene	
500	POS	273	0	0	273
500	POS	219	87	0	306
500	POS	251	50	0	301
500	POS	260	50	0	310
500	POS	230	87	0	317
500	POS	278	48	0	326
500	POS	272	65	0	337
500	POS	334	0	0	334
500	POS	238	116	0	354
500	POS	342	0	0	342
500	POS	313	43	0	356
500	POS	335	28	0	363
500	POS	284	106	0	390
500	POS	294	103	0	397
500	POS	354	47	0	401
500	POS	333	79	0	412
500	POS	364	54	0	418
500	POS	328	98	0	426
500	POS	265	118	65	448
500	POS	424	37	0	461
500	POS	393	77	0	470
500	POS	390	85	0	475

Table 4b: GC/MS Summary of Discordant Results

Screening Cutoff (pg/mg)	ELISA Test Result (POS/NEG)	Drug			GC/MS Drug Result (pg/mg)
		Cocaine	Benzoyllecgonine	Cocaethylene	
500	POS	433	42	0	475
500	POS	469	0	0	469
500	POS	444	32	0	476
500	POS	336	32	94	462
500	POS	491	0	0	491
500	POS	453	46	0	499
500	POS	497	0	0	497

CROSSREACTIVITY: The Crossreactivity Study demonstrated that the presence of the structurally similar compounds Anhydroecgonine methyl ester, Benzoyllecgonine, Benzoyllecgonine isopropyl ester, Meta-Hydroxybenzoyllecgonine, Cocaine, Cocaethylene, Ecgonine, Ecgonine methyl ester, Norbenzoyllecgonine, Norcocaine, and Norcocaehtylene may contribute to a Cocaine positive ELISA result when utilizing this protocol. Since a GC/MS confirmation is performed on all presumptive positive screening results, these compounds will not confirm as a positive result report. None of the other compounds studied demonstrated any interference with the protocol. Head hair was used in this study.

Table 5a: Cross reactivity of Omega Laboratories, Inc. Cocaine ELISA with Structurally Similar Compounds

Compound	Approximate Concentration of Compound (pg/mg) Equivalent to 500pg/mg Cocaine Cutoff Control (n=3)	Percent Crossreactivity (%)
Benzoyllecgonine isopropyl ester	300	166.7
Cocaethylene	375	133.3
Cocaine	500	100.0
Benzoyllecgonine	600	83.3
Meta-Hydroxybenzoyllecgonine	700	71.4
Ecgonine	80000	0.6
Norbenzoyllecgonine	150000	0.3

Table 5a: Cross reactivity of Omega Laboratories, Inc. Cocaine ELISA with Structurally Similar Compounds

Compound	Approximate Concentration of Compound (pg/mg) Equivalent to 500pg/mg Cocaine Cutoff Control (n=3)	Percent Crossreactivity (%)
Norcocaine	250000	0.2
Norcocaethylene	250000	0.2
Ecgonine methyl ester	105000	0.48
Anhydroecgonine methyl ester	250000	0.2
Anhydroecgonine	Not achieved at highest spike concentration. 4000000 pg/mg	
Atropine	Not achieved at highest spike concentration. 4000000 pg/mg	

Although the percent cross-reactivity for Ecognine, Norbenzoylecgonine, Norcocaine, Norcocaethylene, Ecgonine methyl ester and Anhydroecgonine methyl ester could be considered "low", they have been validated and are sufficiently high enough to produce a "positive" result at these testing concentrations. With the levels of cross-reactivity presented in the table above, these compounds demonstrate positive interference at -50%, +125% and +150% of the cut-off. To demonstrate that these drugs are sufficiently cross-reactive, the table below mathematically re-expresses the percent cross-reactivities as cocaine equivalent concentrations at -50% of the cut-off (250 pg/mg), using Anhydroecgonine methyl ester as an example. This was accomplished by multiplying the (Observed Cross-reactivity) by the (Tested Concentration pg/mg) and adding the 250 pg/mg cocaine present in the sample at -50% of the cut-off.

Example: Anhydroecgonine methyl ester spiked at 400,000 pg/mg into -50% of the cut-off cocaine control sample.

For this calculation we used 0.2% for the Anhydroecgonine methyl ester percent cross-reactivity.

$(0.2/100) \times (400,000 \text{ pg/mg tested concentration}) = 800 \text{ pg/mg cocaine equivalents.}$

800 pg/mg cocaine equivalents + 250 pg/mg Cocaine present at -50% of the cut-off = 1050 pg/mg combined equivalent cocaine concentration.

This observed concentration is greater than the 500 pg/mg cocaine cutoff control. Similar calculations can be made for +125% and 150% of the cut-off.

Effect of Interfering Compounds: A variety of structurally related and unrelated compounds were tested for interference at 10000ng/ml (400000pg/mg) in the Omega Laboratories, Inc. ELISA Cocaine Screening Protocol. Negative hair extracts were spiked with Cocaine at -50% (250pg/mg), +125% (625pg/mg) and +150% (750pg/mg) of the Cocaine Cutoff Concentration (500pg/mg). These were then additionally spiked with 10000ng/ml (400000pg/mg) of the structurally related and unrelated compounds unless otherwise noted. The absorbances were compared to the 500 pg/mg Cocaine cutoff control (CO). Only those compounds that were structurally cross reactive interfered in the assay. These structurally related compounds produced a positive response due to significant cross-reactivity. Compounds tested that were not structurally cross-reactive did not interfere with the assay at any of the tested concentrations. No tested samples produced a negative result when expected to be positive. The analysis was performed in triplicate. Head hair was used for this study.

Table 5b: Interferences of Structurally Related and Unrelated Compounds on the Omega Laboratories, Inc. Cocaine ELISA Assay

Compound	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
(-) 11-nor-9-carboxy-delta8-Tetrahydrocannabinol	NEG	POS	POS
(-) 11-nor-9-carboxy-delta9-Tetrahydrocannabinol	NEG	POS	POS
R (-) Amphetamine	NEG	POS	POS
(-) Cotinine	NEG	POS	POS
(-) Cotinine -N-oxide	NEG	POS	POS
(-) Isoproterenol	NEG	POS	POS
(-) Methamphetamine	NEG	POS	POS
(-) Nicotine	NEG	POS	POS
(-) Phenylephrine	NEG	POS	POS
(-)-Alpha-methadol	NEG	POS	POS
(+) Amphetamine	NEG	POS	POS
(+) Isoproterenol	NEG	POS	POS
(+) Methamphetamine	NEG	POS	POS
(+) Pseudoephedrine	NEG	POS	POS
(+/-) 11-nor-9-carboxy-delta9-Tetrahydrocannabinol	NEG	POS	POS
(+/-) 2,5-Dimethoxy- 4-	NEG	POS	POS

Table 5b: Interferences of Structurally Related and Unrelated Compounds on the Omega Laboratories, Inc. Cocaine ELISA Assay

Compound	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
bromoamphetamine			
(+/-) Alphaprodine	NEG	POS	POS
(+/-) Ketamine	NEG	POS	POS
(+/-) MBDB	NEG	POS	POS
(+/-) MDA	NEG	POS	POS
(+/-) MDEA	NEG	POS	POS
(+/-) MDMA	NEG	POS	POS
(+/-) Metanephrine	NEG	POS	POS
(+/-) Metoprolol	NEG	POS	POS
(+/-) Norcotinine	NEG	POS	POS
(+/-) Propanolol	NEG	POS	POS
(+/-) Trans-3'-Hydroxycotinine	NEG	POS	POS
11-Hydroxy-delta9-Tetrahydrocannabinol	NEG	POS	POS
19-Nortestosterone (Nandrolone)	NEG	POS	POS
1R,2S (-) Ephedrine	NEG	POS	POS
1S,2R (+) Ephedrine	NEG	POS	POS
2-Oxo-3-hydroxy-LSD	NEG	POS	POS
3-methoxynaltrexone	NEG	POS	POS
3-Trans-Hydroxy-norcotinine	NEG	POS	POS
4-Acetoamidophenol	NEG	POS	POS
4-Hydroxy-Phencyclidine	NEG	POS	POS
5,5-Diphenylhydantoin	NEG	POS	POS

Table 5b: Interferences of Structurally Related and Unrelated Compounds on the Omega Laboratories, Inc. Cocaine ELISA Assay

Compound	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
6-Acetyl-codeine	NEG	POS	POS
6-Monoacetylmorphine	NEG	POS	POS
7-Aminoclonazepam	NEG	POS	POS
7-Aminonitrazepam	NEG	POS	POS
Acebutolol	NEG	POS	POS
Acetophenetidin	NEG	POS	POS
Acetopromazine	NEG	POS	POS
Acetylsalicylic acid	NEG	POS	POS
Alfentanil	NEG	POS	POS
Alpha-Ergocryptine	NEG	POS	POS
Alprazolam	NEG	POS	POS
7-Aminoflunitrazepam	NEG	POS	POS
Aminorex	NEG	POS	POS
Amitriptyline	NEG	POS	POS
Amobarbital	NEG	POS	POS
Amoxicillin	NEG	POS	POS
Anhydroecgonine	NEG	POS	POS
Anhydroecgonine methyl ester	POS	POS	POS
Anileridine	NEG	POS	POS
Apomorphine	NEG	POS	POS
Atenolol	NEG	POS	POS
Atropine	NEG	POS	POS
Azaperone	NEG	POS	POS

Table 5b: Interferences of Structurally Related and Unrelated Compounds on the Omega Laboratories, Inc. Cocaine ELISA Assay

Compound	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Benzoylcegonine	POS	POS	POS
Benzoylcegonine isopropyl ester	POS	POS	POS
Betamethasone	NEG	POS	POS
Boldenone	NEG	POS	POS
Bumetanide	NEG	POS	POS
Bupivacaine	NEG	POS	POS
Buprenorphine	NEG	POS	POS
Buspirone	NEG	POS	POS
Butabarbital	NEG	POS	POS
Butalbital	NEG	POS	POS
Caffeine	NEG	POS	POS
Cannabidiol	NEG	POS	POS
Cannabinol	NEG	POS	POS
Carbamazepine	NEG	POS	POS
Carisoprodol	NEG	POS	POS
Chlordiazepoxide	NEG	POS	POS
Chlorpromazine	NEG	POS	POS
Cimeterol	NEG	POS	POS
Clenbuterol	NEG	POS	POS
Clomipramine	NEG	POS	POS
Clonazepam	NEG	POS	POS
Clonidine	NEG	POS	POS

Table 5b: Interferences of Structurally Related and Unrelated Compounds on the Omega Laboratories, Inc. Cocaine ELISA Assay

Compound	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Clozapine	NEG	POS	POS
Cocaethylene	POS	POS	POS
Cocaine	POS	POS	POS
Codeine	NEG	POS	POS
Corticosterone	NEG	POS	POS
Cortisone	NEG	POS	POS
Cotinine-N-beta-D-Glucuronide	NEG	POS	POS
Cyclobenzaprine	NEG	POS	POS
d,l-N-Desmethylvenlafaxine	NEG	POS	POS
Delta8-Tetrahydrocannabinol	NEG	POS	POS
Delta9-Tetrahydrocannabinol	NEG	POS	POS
Deoxycorticosterone	NEG	POS	POS
Desalkylflurazepam	NEG	POS	POS
Desipramine	NEG	POS	POS
Desmethyldoxepin (cis/trans)	NEG	POS	POS
Despropionyl-fentanyl	NEG	POS	POS
Dexamethasone	NEG	POS	POS
Dextromethorphan	NEG	POS	POS
Diazepam	NEG	POS	POS
Dibucaine	NEG	POS	POS
Dihydrocodeine	NEG	POS	POS
Dihydroergotamine	NEG	POS	POS

Table 5b: Interferences of Structurally Related and Unrelated Compounds on the Omega Laboratories, Inc. Cocaine ELISA Assay

Compound	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Dihydromorphine	NEG	POS	POS
Diphenhydramine	NEG	POS	POS
Diphenoxylate	NEG	POS	POS
Diprenorphine	NEG	POS	POS
Dothiepin (cis/trans)	NEG	POS	POS
Doxepin	NEG	POS	POS
Doxylamine	NEG	POS	POS
Droperidol	NEG	POS	POS
Ecgonine	POS	POS	POS
Ecgonine methyl ester	POS	POS	POS
EDDP	NEG	POS	POS
Effexor (Venlafaxine)	NEG	POS	POS
EMDP	NEG	POS	POS
Ergonovine	NEG	POS	POS
Erythromycin	NEG	POS	POS
Estazolam	NEG	POS	POS
Ethacrynic acid	NEG	POS	POS
Ethopropazine	NEG	POS	POS
Ethylmorphine	NEG	POS	POS
Fenfluramine	NEG	POS	POS
Fentanyl	NEG	POS	POS
Flumethasone	NEG	POS	POS
Flunitrazepam	NEG	POS	POS

Table 5b: Interferences of Structurally Related and Unrelated Compounds on the Omega Laboratories, Inc. Cocaine ELISA Assay

Compound	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Fluphenazine	NEG	POS	POS
Flurazepam	NEG	POS	POS
Furosemide	NEG	POS	POS
Gentamicin	NEG	POS	POS
Gluthimide	NEG	POS	POS
Haloperidol	NEG	POS	POS
Heroin	NEG	POS	POS
Hexobarbital	NEG	POS	POS
HMMA	NEG	POS	POS
Hydrochlorothiazide	NEG	POS	POS
Hydrocodone	NEG	POS	POS
Hydrocortisone	NEG	POS	POS
Hydromorphone	NEG	POS	POS
(+/-) 4-Hydroxyephedrine	NEG	POS	POS
Hydroxymethamphetamine	NEG	POS	POS
Ibogaine	NEG	POS	POS
Ibuprofen	NEG	POS	POS
Imipramine	NEG	POS	POS
Ketoprofen	NEG	POS	POS
LAAM	NEG	POS	POS
Labetalol	NEG	POS	POS
LAMPA (1000ng/ml)	NEG	POS	POS
Levorphanol	NEG	POS	POS

Table 5b: Interferences of Structurally Related and Unrelated Compounds on the Omega Laboratories, Inc. Cocaine ELISA Assay

Compound	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
L-Hyoscyamine	NEG	POS	POS
Lidocaine	NEG	POS	POS
Lorazepam	NEG	POS	POS
LSD	NEG	POS	POS
Lysergic acid	NEG	POS	POS
Lysergol	NEG	POS	POS
Maprotiline	NEG	POS	POS
Meperidine	NEG	POS	POS
Mephentermine	NEG	POS	POS
Mepivacaine	NEG	POS	POS
Metaphit	NEG	POS	POS
Metaproterenol	NEG	POS	POS
Metaraminol	NEG	POS	POS
Methadone	NEG	POS	POS
Methohexital	NEG	POS	POS
Methoxyphenamine	NEG	POS	POS
Methylergonovine	NEG	POS	POS
Methylphenidate	NEG	POS	POS
m-Hydroxybenzoylecgonine	POS	POS	POS
Mianserin	NEG	POS	POS
Midazolam	NEG	POS	POS
Monensin	NEG	POS	POS
Morphine	NEG	POS	POS

Table 5b: Interferences of Structurally Related and Unrelated Compounds on the Omega Laboratories, Inc. Cocaine ELISA Assay

Compound	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Morphine-3-betaglucuronide	NEG	POS	POS
Morphine-6-betaglucuronide	NEG	POS	POS
Nadolol	NEG	POS	POS
Nalmefene	NEG	POS	POS
Nalorphine	NEG	POS	POS
Naloxone-3-beta-D-glucuronide	NEG	POS	POS
Naltrexone	NEG	POS	POS
Naltriben	NEG	POS	POS
Naproxen	NEG	POS	POS
N-Desmethyldomipramine	NEG	POS	POS
N-Desmethyflunitrazepam	NEG	POS	POS
N-Desmethyltramadol	NEG	POS	POS
N-Desmethyltrimipramine	NEG	POS	POS
Neomycin	NEG	POS	POS
Nitrazepam	NEG	POS	POS
Norbenzoylecgonine	POS	POS	POS
Norbuprenorphine	NEG	POS	POS
Norcocaethylene	POS	POS	POS
Norcocaine	POS	POS	POS
Norcodeine	NEG	POS	POS
Nordiazepam	NEG	POS	POS
Norfentanyl	NEG	POS	POS

Table 5b: Interferences of Structurally Related and Unrelated Compounds on the Omega Laboratories, Inc. Cocaine ELISA Assay

Compound	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Nor-LAAM	NEG	POS	POS
Nor-LSD/Nor-ISO-LSD	NEG	POS	POS
Normeperidine	NEG	POS	POS
Normeperidinic acid	NEG	POS	POS
Normorphine	NEG	POS	POS
Noroxycodone	NEG	POS	POS
Noroxymorphone	NEG	POS	POS
Norpropoxyphene	NEG	POS	POS
Nortriptyline	NEG	POS	POS
Noscapine	NEG	POS	POS
O-Desmethyltramadol	NEG	POS	POS
Oxazepam	NEG	POS	POS
Oxprenolol	NEG	POS	POS
Oxycodone	NEG	POS	POS
Oxymorphone	NEG	POS	POS
p-Acetamidophenyl-beta-D-glucuronide	NEG	POS	POS
Papaverine	NEG	POS	POS
Pemoline	NEG	POS	POS
Penicillin G	NEG	POS	POS
Pentazocine	NEG	POS	POS
Pentobarbital	NEG	POS	POS
Perphenazine	NEG	POS	POS

Table 5b: Interferences of Structurally Related and Unrelated Compounds on the Omega Laboratories, Inc. Cocaine ELISA Assay

Compound	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Phendimetrazine	NEG	POS	POS
Phenelzine	NEG	POS	POS
Phenobarbital	NEG	POS	POS
Phenothiazine	NEG	POS	POS
Phentermine	NEG	POS	POS
Phenylbutazone	NEG	POS	POS
Phenylethylamine	NEG	POS	POS
Phenylpropanolamine	NEG	POS	POS
Phencyclidine	NEG	POS	POS
R,R (-)-Pseudoephedrine	NEG	POS	POS
Phencyclidine Morpholine	NEG	POS	POS
PMA	NEG	POS	POS
PMMA	NEG	POS	POS
Prednisolone	NEG	POS	POS
Prilocaine	NEG	POS	POS
Prochlorperazine	NEG	POS	POS
Progesterone	NEG	POS	POS
Promazine	NEG	POS	POS
Promethazine	NEG	POS	POS
Propiomazine	NEG	POS	POS
Propionylpromazine	NEG	POS	POS
Propoxyphene	NEG	POS	POS
Protriptyline	NEG	POS	POS

Table 5b: Interferences of Structurally Related and Unrelated Compounds on the Omega Laboratories, Inc. Cocaine ELISA Assay

Compound	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Quinidine	NEG	POS	POS
R (+) Methcathinone	NEG	POS	POS
R (-) Epinephrine	NEG	POS	POS
R (+) Cathinone	NEG	POS	POS
Salbutamol	NEG	POS	POS
Secobarbital	NEG	POS	POS
Sertraline	NEG	POS	POS
Stanzalol	NEG	POS	POS
Streptomycin	NEG	POS	POS
Sulfadimethoxine	NEG	POS	POS
Sulfamethazine	NEG	POS	POS
Sulfathiazole	NEG	POS	POS
Temazepam	NEG	POS	POS
Terbutaline	NEG	POS	POS
Tetracycline	NEG	POS	POS
Thebaine	NEG	POS	POS
Theophylline	NEG	POS	POS
Thioridazine	NEG	POS	POS
Tramadol	NEG	POS	POS
Triamcinolone	NEG	POS	POS
Triazolam	NEG	POS	POS
Trifluoperazine	NEG	POS	POS
Trifluopromazine	NEG	POS	POS

Table 5b: Interferences of Structurally Related and Unrelated Compounds on the Omega Laboratories, Inc. Cocaine ELISA Assay

Compound	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Trimeprazine	NEG	POS	POS
Trimipramine	NEG	POS	POS
Tylosin	NEG	POS	POS
Tyramine	NEG	POS	POS
Yohimbic acid	NEG	POS	POS
Yohimbine	NEG	POS	POS
Zolpidem	NEG	POS	POS
Zopiclone	NEG	POS	POS

CALIBRATOR AND CONTROL: The Omega Laboratories, Inc. ELISA Cocaine Screening Protocol utilizes in-house prepared calibrator and control solutions. This study successfully demonstrated the validation and stability of these solutions and the traceability to NIST standards.

While the typical urine drugs of abuse controls challenge the cutoff calibrator with concentrations of \pm 25% of the cutoff calibrator in nanograms, the hair testing industry utilizes -50% and +100% in picograms. Example -25% of a nanogram is larger than -50% of a picogram. Head hair was used in this study.

STABILITY: The Stability Study demonstrated that the mean variance on the concentration of combined cocaine+ cocaine metabolites in 50 head hair samples when stored for an extended period of approximately 2 years was -23%.

Additionally, the largest decrease and increase for combined cocaine+ cocaine metabolites was -46% and 17%, respectively. The general trend of decreasing cocaine and increasing benzoylecgonine may be consistent with non-enzymatic hydrolysis of cocaine to benzoylecgonine. Head hair was used in this study.

Table 6: Cocaine Stability Study Summary of Results

Study Observation	Cocaine	Benzoylecgonine	Norcocaine	Cocaethylene
Average Concentration (pg/mg)	5123	1262	287	438
Mean Change in %	-23	5	5	2
Range in Concentration	369 - 35666	36 - 9499	39 - 1963	24 - 2101

Study Observation	Cocaine	Benzoyllecgonine	Norcocaine	Cocaethylene
(pg/mg)				
% Max and Min decrease	-50% and -5%	-47% and -2%	-30% and -0.4%	-41% and 0%
% Max and Min increase	18% and 4%	59% and 1%	47% and 2%	135% and 0%
Number that decreased in concentration	45	18	16	17
Number that increased in concentration	5	32	20	16

SHIPPING: A total of 200 hair samples were use in the study; 100 positive samples and 100 negative samples. Head hair was used in this study.

The Shipping Study demonstrated that there was no adverse effect on head hair samples that would affect the screening assay when samples are exposed to extreme temperatures and variations in humidity that might occur during sample transport. The average percent change in Positive Cocaine sample GC/MS results prior to shipping and after shipping was +5% for all locations combined.

Additionally, there were no discordant results pre- and post-shipping (as confirmed by GC/MS).

COSMETIC TREATMENT: Numerous studies have demonstrated that the use of cosmetic treatments can reduce the amount of drugs and metabolites detected in hair specimens. This effect is completely dependent upon the nature of the hair specimen and the treatment used, and is independent of the method of analysis. This study demonstrates that the Omega Laboratories, Inc. ELISA Cocaine Screening Assay is not an exception to this phenomenon.

Sixty six hair specimens previously determined to be negative for cocaine were obtained and the ethnic origin, hair color and curvature were documented. One hundred and ten hair specimens potentially positive for cocaine were obtained and the ethnic origin, hair color and curvature were documented. Each specimen was divided into 2 aliquots. One aliquot was analyzed by the ELISA protocol and by the GC/MS confirmation method.

Of the 176 treated specimens, four initially POSITIVE ELISA assays (one bleach and three permanent) reported NEG ELISA results after treatment.

ENVIRONMENTAL CONTAMINATION: Preliminary positive hair sample results by the screening method could be due to environmental contamination. All positive samples should be sent for confirmation testing on a reference method to distinguish between true positives and those samples that were positive due to external exposure. Head hair was used for this study.

CONCLUSION:

The comparison of results of the proposed assay and GC/MS for Cocaine and Cocaine metabolites in head and body hair samples showed the results to be substantially equivalent

The candidate Omega Laboratories Hair Drug Screening Assay for Cocaine and Cocaine Metabolites is substantially equivalent to the predicate Omega Laboratories Hair Drug Screening Assay for Cocaine and

Cocaine Metabolites (Cocaine) predicate device based on acceptable performance studies, including precision, specificity, interference (including cosmetic effects) and removal of environmental contamination.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 13, 2013

Omega Laboratories, Inc.
C/O Robert J. Bard, JD
400 North Cleveland
MOGADORE OH 44260

Re: K131128

Trade/Device Name: Omega Laboratories Hair Drug Screening Assay for Cocaine and Cocaine Metabolites
Regulation Number: 21 CFR 862.3250
Regulation Name: Cocaine and cocaine metabolite test system
Regulatory Class: II
Product Code: DIO
Dated: September 18, 2013
Received: October 1, 2013

Dear Mr. Bard:

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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2—Mr. Bard

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: k131128

Device Name: Omega Laboratories Hair Drug Screening Assay for Cocaine and Cocaine Metabolites

Indications 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.

Prescription Use _____
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use x
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k): k131128