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

A. 510(k) Number:

k103161

B. Purpose for Submission:

New device

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 Hair Drug Screening Assays for Opiates, Oxycodone and Hydrocodone

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DJG, Enzyme immunoassay Opiates	Class II	862.3650	91-Toxicology

H. Intended Use:

1. Intended use(s):

   See Indications for use below.

2. Indication(s) for use:

The Omega Laboratories Hair Drug Screening Assays are test systems that utilize ELISA assays for the qualitative detection of morphine and related opiates (calibrated with morphine) and oxycodone and hydrocodone (calibrated with oxycodone) at or above 300 pg/mg in head hair samples.

The Omega Laboratories Hair Drug Screening Assay for Opiates, Oxycodone and Hydrocodone provide only preliminary analytical test results. A more specific alternate chemical method must be used in order to obtain a confirmed result. Gas Chromatograph– Mass Spectrometry operating in the selected ion monitoring (SIM) mode or GC/MS/MS in selected reaction mode (SRM) is the preferred method with deuterated internal standards. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

These tests are intended exclusively for in-house use only and are not intended for sale to anyone. Omega offers these tests as services to its clients.

3. Special conditions for use statement(s):

The assay is 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:

The assay consists of the following:

- Hair sample collection kit
- Micro strip plates coated with either anti-morphine mouse monoclonal or anti-oxycodone 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):

Quest Diagnostic HairCheck-DT (Opiates)
American BioMedica Corporation, RapidOne–OXY Test (Oxycodone)

2. Predicate K number(s):

   k042725
   k014101

3. Comparison with predicate:

Item	Proposed Device	Quest Hair Drug Screening k042725	RapidOne – OXY Test K014101
Indications/ Intended Use	The Omega Laboratories Hair Drug Screening Assays are test systems that utilize ELISA assays for the qualitative detection of morphine and related opiates, oxycodone and hydrocodone at or above 300 pg/mg in head hair samples. The Omega Laboratories Hair Drug Screening Assay for Opiates, Oxycodone and Hydrocodone provide only preliminary analytical test results. A more specific alternate chemical method must be used in order to obtain a confirmed result. Gas Chromatography – Mass Spectrometry operating in the selected ion monitoring (SIM) mode or GC/MS/MS in selected reaction mode (SRM) is the preferred method with deuterated internal standards. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when	Quest Diagnostics HairCheck-DT (Opiates) is a test system that utilizes the IDS One step ELISA Opiates Kit for the qualitative detection of opiates at concentrations at or above 300 pg/mg hair for the purpose of identifying chronic use of heroine. This test system has not been evaluated for use with other populations or with hair specimens other than head. It is an in vitro diagnostic device intended exclusively for in-house professional use only and not intended for sale to anyone. The Quest Diagnostics HairCheck-DT (Opiates) provides only preliminary analytical test results. A more specific alternate chemical method must be used in order to obtain a confirmed result. Gas Chromatography – Mass Spectrometry operating in the selected ion monitoring (SIM) mode or GC/MS/MS in selected reaction mode (SRM) is the preferred method with deuterated internal standards. Other	RapidOne-OXY Test is a one-step, lateral flow immunoassay for the detection of oxycodone in urine. RapidOne-OXY Test is intended for the qualitative detection of oxycodone inhuman urine at 100 ng/mL. RapidOne-OXY Test is intended for professional use. It is not intended for over the counter sales to nonprofessionals. RapidOne-OXY provides only preliminary analytical test results. A more specific alternate chemical method must be used in order to obtain a confirmed result GC/MS is the preferred confirmatory method

	preliminary positive results are obtained.	chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.	
Product Code	DJG	Same as the proposed device	Same as the proposed device
Measurand	Opiates, Oxycodone and Hydrocodone in hair	Opiates in hair	Oxycodone in urine
Test System	International Diagnostics Systems Corp Forensic Human Drugs of Abuse One-Step Morphine and Oxycodone ELISA for Hair Testing Kits	International Diagnostics Systems Corp Forensic Human Drugs of Abuse IDS One-Step Opiates ELISA for Hair Testing Kit	American Bio Medica Corp. 'RapidOne--OXY' Test
Sample matrix	Head Hair	Same as the proposed device	Urine
Method of measurement	Microplate reader, read at 450 nm	Same as the proposed device	Lateral flow immunoassay, visually read endpoint
Cutoff	300 pg Opiates/mg hair 300 pg Oxycodone/mg hair 300 pg Hydrocodone/mg hair	500 pg Opiates/mg hair	100 ng Oxycodone/mL urine
Type of test	ELISA	Same as the proposed device	Immunoassay
Extraction methods	Acid-methanol	Methanol	Not Applicable
Confirmation method	GC/MS	Same as the proposed device	Same as the proposed device

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

None were referenced

L. Test Principle:

Screening Assay:

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:

Precision studies were performed by taking commercially available materials consisting of morphine in methanol, oxycodone in methanol and hydrocodone in methanol (all with a Certificate of Analysis traceable to NIST) to prepare spiking solutions at the following concentrations; negative, ±75%, ±50%, ±25% and 200% of the cutoff. The concentration of each sample was confirmed by GC/MS. The morphine and oxycodone solutions were then used to spike 11 replicates of negative hair samples. The hydrocodone solution was used to spike 10 replicates of negative hair samples. Intra-assay precision was performed in one run and inter-assay precision was performed over 20 non-consecutive days (10 non-consecutive days for hydrocodone). The results are presented in the tables below:

Intra-assay Morphine Cutoff = 300 pg/mg				
Conc. (pg/mg)	% of Cutoff	Number Tested	Negative	Positive
0	Negative	11	11	0
75	-75	11	11	0
150	-50	11	11	0
225	-25	11	11	0
375	125	11	0	11
450	150	11	0	11
525	175	11	0	11
600	200	11	0	11

Intra-assay Oxycodone Cutoff = 300 pg/mg				
Conc. (pg/mg)	% of Cutoff	Number Tested	Negative	Positive
0	Negative	11	11	0
75	-75	11	11	0
150	-50	11	11	0
225	-25	11	11	0
375	125	11	0	11
450	150	11	0	11
525	175	11	0	11
600	200	11	0	11

Intra-assay Hydrocodone Cutoff = 300 pg/mg				
Conc. (pg/mg)	% of Cutoff	Number Tested	Negative	Positive
0	Negative	10	10	0
75	-75	10	10	0
150	-50	10	10	0
225	-25	10	9	1
375	125	10	0	10
450	150	10	0	10
525	175	10	0	10
600	200	10	0	10

Inter–assay Morphine Cutoff = 300 pg/mg				
Conc. (pg/mg)	% of Cutoff	Number Tested	Negative	Positive
0	Negative	220	220	0
75	-75	220	220	0
150	-50	220	220	0
225	-25	220	220	0
375	125	220	0	220
450	150	220	0	220
525	175	220	0	220
600	200	220	0	220

Inter–assay Oxycodone Cutoff = 300 pg/mg				
Conc. (pg/mg)	% of Cutoff	Number Tested	Negative	Positive
0	Negative	220	220	0
75	-75	220	220	0
150	-50	220	220	0
225	-25	220	220	0
375	125	220	0	220
450	150	220	0	220

525	175	220	0	220
600	200	220	0	220

Inter–assay Hydrocodone Cutoff = 300 pg/mg				
Conc. (pg/mg)	% of Cutoff	Number Tested	Negative	Positive
0	Negative	100	100	0
75	-75	100	100	0
150	-50	100	100	0
225	-25	100	61	39
375	125	100	0	100
450	150	100	0	100
525	175	100	0	100
600	200	100	0	100

The sponsor also performed an intra-assay precision for morphine, oxycodone and hydrocodone using 5 hair specimens for each drug analyte previously found to be positive. Each specimen was divided into 6 aliquots. Three aliquots were treated and analyzed on the device in one run. Additionally, three aliquots were analyzed by GC/MS. The results are presented below:

GC/MS	Device		
Morphine Conc. (pg/mg)	Number Tested	Negative	Positive
794	3	0	3
1530	3	0	3
2636	3	0	3
745	3	0	3
2296	3	0	3

GC/MS	Device		
Oxycodone Conc. (pg/mg)	Number Tested	Negative	Positive
2424	3	0	3
561	3	0	3
4785	3	0	3
1532	3	0	3
4560	3	0	3

GC/MS	Device		
Hydrocodone Conc. (pg/mg)	Number Tested	Negative	Positive
439	3	0	3
600	3	0	3
3290	3	0	3
7867	3	0	3
9922	3	0	3

b. Linearity/assay reportable range:

Not applicable. This is a qualitative assay.

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

Commercially purchased materials consisting of morphine in methanol, oxycodone in methanol and hydrocodone in methanol are used to prepare stock solutions. Stock solutions of each are then used to prepare calibrator and control working solutions. The Cerilliant morphine, oxycodone and hydrocodone standards are traceable back to NIST.

Assigned values of the prepared calibrator and control working solutions are verified by GC/MS analysis each time a new batch is prepared. The calibrator must fall with 10% of the targeted concentration.

Protocols and acceptance criteria were described and found to be acceptable. When stored refrigerated in an amber bottle the shelf life is 12 months.

Shipping Study:

260 samples were used in the shipping study which were tested for opiates, oxycodone and hydrocodone: 155 previously confirmed positive samples, 100 previously screened negative samples, and 5 samples that were confirmed below the 300 pg/mg cutoff. A variety of hair color and curvatures were tested.

Four separate shipping boxes each containing 25 previously screened negative samples were stored in a freezer at approximately -11^{o}C for approximately 17 hours then heated to approximately 44^{o}C for a period of approximately 4 hours. Four separate shipping boxes each containing 40 previously screened positive samples were stored in a freezer at approximately -13^{o}C for approximately 18 hours then heated to approximately 47^{o}C for a period of approximately 4 hours.

Locations and minimum and maximum temperature and relative humidities are presented in the tables below:

Negative Samples

Shipped to Location then Returned to Omega Laboratories	Min Temp (^{o}C)	Max Temp (^{o}C)	Min Humidity (%RH)	Max Humidity (%RH)
Portland, Maine	-12.7	44.4	10.8	100
Anchorage, Alaska	-9.4	44.9	8.1	96.1
Naples, Florida	-10.8	43.3	4.4	100
Tempe, Arizona	-12.2	42.9	8.9	73.5

Positive Samples

Shipped to Location then Returned to Omega Laboratories	Min Temp (^{o}C)	Max Temp (^{o}C)	Min Humidity (%RH)	Max Humidity (%RH)
Portland, Maine	-12.8	50.8	0	97.8
Anchorage, Alaska	-13.8	47.6	0	100
Naples, Florida	-11.6	51.3	0	100
Tempe, Arizona	-15.3	41.9	3.2	100

This represented exposure to extreme temperatures and humidities. Each box was then shipped to a different location in the US. The boxes were held for two days at each location then shipped back to the laboratory.

The samples were run on both the screening method and GC/MS before and after shipping. Results from the screening method showed that 256 of the 260 samples that were positive or negative before shipping remained the same after shipping. There were 4 discordant results, where 2 samples that screened positive prior to shipping screened negative after shipping and 2 samples that screened negative prior to shipping screened positive after shipping. The GC/MS concentrations of the samples prior to shipping and after shipping were within +/-25% of the cutoff.

Sample Stability:

Fifty-four samples varying in ethnic origin, hair color and curvature that previously confirmed positive were used in the study. Two different aliquots of hair were used to perform the testing. Samples were stored in a temperature-controlled room that averages 14^{o}C to 30^{o}C year round for periods of time varying between 2.1 and 3.2 years. The average mean % of change in results from first analysis to second analysis was 1% for morphine, -4% Oxycodone and -5% for Hydrocodone. Morphine hair samples can be stored up to 3 years and Oxycodone and Hydrocodone up to 2 years. The results are shown in the table below:

Morphine Measured Value	Value or range
Range in concentration pg/mg hair (Before)	520 – 1690
Range in concentration pg/mg hair (After)	530 – 1588
Mean Change	1%
% Max and Min Decrease	-20% and -3%
% Max and Min Increase	35% and 1%
Number that increased in concentration	5
Number that decreased in concentration	7

Codeine Measured Value	Value or range
Range in concentration pg/mg hair (Before)	480 – 1150
Range in concentration pg/mg hair (After)	539 – 1132
Mean Change	7%
% Max and Min Decrease	-2%
% Max and Min Increase	18% and 1%
Number that increased in concentration	8
Number that decreased in concentration	2

6-Acetylmorphine Measured Value	Value or range
Range in concentration pg/mg hair (Before)	600 – 2140
Range in concentration pg/mg hair (After)	636 – 1987
Mean Change	4%
% Max and Min Decrease	-8% and -7%
% Max and Min Increase	16% and 1%
Number that increased in concentration	5
Number that decreased in concentration	2

Oxycodone Measured Value	Value or range
Range in concentration pg/mg hair (Before)	157 – 5174
Range in concentration pg/mg hair (After)	156 – 4638
Mean Change	-4%
% Max and Min Decrease	-16% and -1%
% Max and Min Increase	15% and 3%
Number that increased in concentration	4
Number that decreased in concentration	8

Hydrocodone Measured Value	Value or range
Range in concentration pg/mg hair (Before)	196 – 2524
Range in concentration pg/mg hair (After)	207– 2359
Mean Change	-5%
% Max and Min Decrease	-23% and -1%
% Max and Min Increase	6% and 5%
Number that increased in concentration	3
Number that decreased in concentration	10

d. *Detection limit:*
Sensitivity of this assay is characterized by validating performance around the claimed cutoff concentration of the assay, including a determination of the lowest concentration of drug that is capable of producing a positive result. This information appears in the precision section, above.

e. *Analytical specificity:*

Cross-reactivity was established by preparing serial dilutions of each control compound in negative hair matrix extract and evaluating against the cutoff control.

Results are expressed as a minimum concentration of compound required to produce a response approximately equivalent to the cutoff concentration of the assay. The results are presented in the tables below:

Compound	Approximate concentration of compound (pg/mg) Equivalent to 300 pg/mg Morphine Cutoff Control n=3	% Cross reactivity
Morphine	300	100
Heroin	200	150
Codeine	250	120
6-Acetylcodeine	275	109
Ethylmorphine	200	150
Dihydrocodeine	700	43
6-Monoacetyl-morphine	200	150
Morphine-3-Beta-Glucuronide	700	43
Thebaine	1250	24
Morphine-6-Beta-Glucuronide	600	50
Dihydromorphine	1500	20
Hydrocodone	1250	24

Hydromorphone	2000	15
Nalorphine	7000	4.3
Levorphanol	4000	7.5
Norcodeine	250,000	0.1
Oxycodone	225,000	0.1
Normorphine	175,000	0.2
Diprenorphine	225,000	0.1
Dextromethorphan	>1,000,000	<0.1
Naltrexone	>1,000,000	<0.1
Norbuprenorphine	>1,000,000	<0.1
Buprenorphine	>1,000,000	<0.1
Oxymorphone	200,000	0.2
Naltriben	>1,000,000	<0.1
Nalmefene	>1,000,000	<0.1
Apomorphine	>1,000,000	<0.1
Naloxone	>1,000,000	<0.1
Noroxymorphone	>1,000,000	<0.1
Noroxycodone	>1,000,000	<0.1
3-Methoxy-naltrexone	>1,000,000	<0.1

Compound	Approximate concentration of compound (pg/mg) Equivalent to 300 pg/mg Oxycodone Cutoff Control n=3	% Cross reactivity
Hydrocodone	250	120
Oxycodone	300	100
Oxymorphone	1500	20
Dihydrocodeine	2500	12
6-Acetylcodeine	4000	7.5
Codeine	4500	6.7
Ethylmorphine	5000	6
Hydromorphone	6000	5
Heroin	15,000	2
Dihydromorphine	15,000	2
Levorphanol	15,000	2
6-Monoacetyl-morphine	20,000	1.5
Morphine	30,000	1
Noroxycodone	30,000	1
Thebaine	40,000	0.75
Morphine-3-Beta-Glucuronide	150,000	0.2

Naloxone	250,000	0.12
Norcodeine	400,000	0.07
Morphine-6-Beta-Glucuronide	>40,000	<1.5
Norbuprenorphine	>40,000	<1.5
Buprenorphine	>40,000	<1.5
Noroxymorphone	>40,000	<1.5
Nalorphine	>400,000	<0.2
Normorphine	>400,000	<0.2
Diprenorphine	>400,000	<0.2
Dextromethorphan	>400,000	<0.2
Naltrexone	>400,000	<0.2
Naltriben	>400,000	<0.2
Nalmefene	>400,000	<0.2
Apomorphine	>400,000	<0.2
3-Methoxy-naltrexone	>400,000	<0.2

Structurally related and unrelated:

Negative hair extracts were spiked with morphine or oxycodone to -50%, 125% and 150% of the cutoff. Several (269) structurally related and unrelated compounds were added to methanol to a concentration of 10,000 ng/mL then added to the hair matrix tubes. Samples were evaluated in triplicate and the listed compounds can be found in the package insert. Compounds that are not structurally similar to morphine or oxycodone have not been observed to produce an interference with the assay. There is the possibility that other substances and/or factors not listed above may interfere with the test and cause false results.

Hair Treatment:

Tests were performed to determine the effects of various hair treatments (i.e. bleaching, dyeing, relaxer, shampoo, permanent) on samples tested using the ELISA Opiates, Oxycodone and Hydrocodone screening test.

Effect on Positive Samples:

111 specimens were identified as positive for opiates, oxycodone and/or hydrocodone. The ethnic origin, hair color and curvature were documented. The study was conducted with two different hair treatments for each product. Two different aliquots of hair from the same individual were used to perform the testing. Each sample was divided into 2 aliquots. One aliquot was analyzed by the ELISA protocol and GC/MS confirmatory tests. The second aliquot of each sample was randomly assigned to the hair treatments groups (bleach, permanent, dye, relaxer, shampoo). ELISA absorbance readings before and

after treatment were compared. GC/MS measurements before and after treatment were also compared. The data is presented in the tables below:

Effects Observed for Morphine in the Bleaching Study 1 and 2

ELISA Screening Data (n = 18)					
	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	0.274 0.075 – 0.529				
Treated	0.207 0.027 – 0.530	18	0.140 0.027 – 0.291	0	0.407 0.335 – 0.530

Effects Observed for Oxycodone and Hydrocodone in the Bleaching Study 1 and 2

ELISA Screening Data (n = 8)					
	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	0.218 0.046 – 0.349				
Treated	0.233 0.048 – 0.339	8	0.339 0.339	0	0.218 0.048 – 0.319

Effects Observed for Morphine in the Permanent Study 1 and 2

ELISA Screening Data (n = 17)					
	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	0.212 0.056 – 0.571				
Treated	0.206 0.017 – 0.514	17	0.127 0.017 – 0.359	0	0.396 0.317 – 0.514

Effects Observed for Oxycodone and Hydrocodone in the Permanent Study 1 and 2

ELISA Screening Data (n = 6)					
	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	0.199 0.101 – 0.274				
Treated	0.245 0.114 – 0.387	6	None	0	0.245 0.114 – 0.387

Effects Observed on Morphine in the Dye Study 1 and 2

ELISA Screening Data (n = 23)					
	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	0.279 0.050 – 0.879				
Treated	0.246 0.022 – 0.654	22	0.153 0.22 – 0.545	1	0.458 0.038 – 0.654

Effects Observed on Oxycodone and Hydrocodone in the Dye Study 1 and 2

ELISA Screening Data (n = 5)					
	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	0.172 0.061 – 0.255				
Treated	0.217 0.054 – 0.504	4	0.054 0.054	1	0.258 0.132 – 0.344

Effects Observed on Morphine in the Relaxer Study 1 and 2

ELISA Screening Data (n = 14)					
	Mean Abs/Range of	# of samples that	Mean/Range of Abs of all	# of samples that became	Mean/Range of Abs of all

	Abs	remained positive	that had a decrease in Abs	negative	that had a increase in Abs
Untreated	0.256 0.073 – 0.553				
Treated	0.190 0.024 – 0.585	14	0.110 0.024 – 0.252	0	0.483 0.343 – 0.585

Effects Observed on Oxycodone and Hydrocodone in the Relaxer Study 1 and 2

ELISA Screening Data (n = 8)					
	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	0.220 0.043 – 0.541				
Treated	0.230 0.117 – 0.403	8	0.437 0.437	0	0.200 0.053 – 0.403

Effects Observed on Morphine in the Shampoo Study 1 and 2

ELISA Screening Data (n = 22)					
	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	0.255 0.046 – 0.534				
Treated	0.193 0.026 – 0.722	22	0.139 0.026 – 0.421	0	0.435 0.215 – 0.722

Effects Observed on Oxycodone and Hydrocodone in the Shampoo Study 1 and 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	0.258				

	0.111 – 0.499				
Treated	0.387 0.050 – 1.086	10	0.108 0.108	0	0.417 0.050 – 1.086

Effect on Negative Samples:

Sixty five negative hair samples were each divided into 2 aliquots. One aliquot of each sample was assigned randomly to the hair treatments. ELISA absorbance readings before and after treatment were compared. GC/MS measurements before and after treatment were also compared.
For negative samples the percent difference between the mean normalized absorbance values of the treated and untreated groups was 10% or less for the permanent, dye, and shampoo treatments.
The % change for the hair specimens treated with bleach and relaxer was greater at a mean of 26% and 22%, respectively.

Environmental Contamination:

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:

Analytical performance of the device around the claimed cutoff is described in precision section M.1a above.

2. Comparison studies:

The study was performed by comparing ELISA results against the GC/MS results on the same hair sample. A total of 176 donor hair samples were tested for opiates. Those 176 samples plus 304 additional samples were tested for oxycodone and hydrocodone. The hydrocodone showed two samples that tested positive on the immunoassay however the GC/MS was unable to confirm due to sampling error and they are excluded from the table below. The results are presented in the tables below:

a. Method comparison with GC/MS:

IDS ELISA Opiate Test Result	Negative by GC/MS (less than 50 pg/mg)	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	14	78
Negative	70	4	7	1	0

Discrepant Results:

Screening Cutoff (pg/mg)	IDS ELISA Opiate Test Results (POS/NEG)	GC/MS Cutoff (pg/mg)	GC/MS Drug Result (pg/mg)
300	POS	300	HDC 268
300	POS	300	HDC 299
300	NEG	300	HDC 354

IDS ELISA Oxycodone Test Result	Negative by GC/MS (less than 50 pg/mg)	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	5	93	191
Negative	140	6	14	2	0

Discrepant Results:

Screening Cutoff (pg/mg)	IDS ELISA Oxycodone Test Results (POS/NEG)	GC/MS Cutoff (pg/mg)	GC/MS Drug Result (pg/mg)
300	POS	300	OXY 240
300	POS	300	OXY 229
300	POS	300	OXY 185
300	POS	300	OXY 255
300	POS	300	OXY 298
300	NEG	300	OXY 169/ HDC 167
300	NEG	300	OXY 130/ HDC 221

IDS ELISA Hydrocodone Test Result	Negative by GC/MS (less than 50 pg/mg)	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	7	107	159
Negative	142	8	25	6	0

Discrepant Results:

Screening Cutoff (pg/mg)	IDS ELISA Hydrocodone Test Results (POS/NEG)	GC/MS Cutoff (pg/mg)	GC/MS Drug Result (pg/mg)
300	POS	300	HDC 204
300	POS	300	HDC 214
300	POS	300	HDC 289
300	POS	300	HDC 297
300	POS	300	HDC 256
300	POS	300	HDC 272
300	POS	300	HDC 283
300	NEG	300	HDC 313
300	NEG	300	HDC 334
300	NEG	300	HDC 403
300	NEG	300	HDC 167/ OXY 169
300	NEG	300	HDC 221/ OXY 130
300	NEG	300	HDC 347

b. Matrix comparison:

Not applicable. The assay is intended for only one sample matrix.

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.