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

A. 510(k) Number:

k122759

B. Purpose for Submission:

New device

C. Measurand:

Cannabinoids (Carboxy-THC) in human hair (body and head)

D. Type of Test:

Qualitative screening test: ELISA Immunoassay
Quantitative confirmatory test: GC-MS-MS

E. Applicant:

Omega Laboratories, Inc.

F. Proprietary and Established Names:

Omega Laboratories Hair Drug Screening Assay for Carboxy-THC (THCA)

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LDJ, Enzyme immunoassay Cannabinoids	Class II	862.3870 Cannabinoid test system	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 Assay for Carboxy-THC (THCA) is an in vitro diagnostic that is intended to be used for the determination of the presence of cannabinoids in human head and body hair samples. The Omega Laboratories Hair Drug Screening Assay for Carboxy-THC utilizes the International Diagnostic Systems Corp. enzyme linked immunosorbant assay (ELISA) for THC Metabolite Testing Kit, for the qualitative detection of THCA at or above 1 pg/mg of hair for the purpose of identifying the use of cannabinoids.

The Omega Laboratories Hair Drug Screening Assay for Carboxy-THC provides only preliminary analytical test results and must be used in combination with a more specific alternate chemical method 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 used as the confirmation method, along with deuterated internal standards.

Omega plans to perform this test at one site. Omega has not performed an evaluation of reproducibility at different laboratories.

3. Special conditions for use statement(s):

For Over-the-Counter Use

The Omega Laboratories Hair Drug Screening Assay for Carboxy-THC (THCA) combines a screening method (immunoassay) with a confirmation method (GC-MS-MS) in one test system.

4. Special instrument requirements:

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

For confirmation testing, Omega uses a GC/MS/MS Agilent 7890a Gas Chromatograph (GC) (Serial Number US 10091018)/ Agilent 7000 MS Triple Quad (MS) (Serial Number US 10026003) in selected ion monitoring (SIM) mode using deuterated internal standards.

I. Device Description:

The assay consists of the following:

- Antibody coated microplate – 5x 96-well microplate coated with rabbit anti-THCA polyclonal high affinity antibody
- Enzyme conjugate concentrate – 1 ml drug analyte conjugated to HRP
- Enzyme diluent – 85 ml to dilute enzyme conjugate
- Wash solution (10x) – 100 ml (Dilute 1:10 with deionized water prior to use)
- K-Blue substrate – 100 ml-3,3',5,5'-Tetramethylbenzidine (TMB)
- Stop solution – 90 ml 1N H_2SO_4
- Hair sample collection kit
- In-house prepared calibrators and controls are used. These are prepared solutions of THCA added to negative hair matrix tubes.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Psychemedics Microplate EIA for Cannabinoids in Hair

2. Predicate K number(s):

   k111929

3. Comparison with predicate:

Item	Device	Psychemedics Microplate EIA for Cannabinoids in Hair k111929
Indications/ Intended Use	The Omega Laboratories Hair Drug Screening Assay for Carboxy-THC (THCA) is an in vitro diagnostic that is intended to be used for the determination of the presence of cannabinoids in human head and body hair samples. The Omega Laboratories Hair Drug Screening Assay for Carboxy-THC utilizes the International Diagnostic Systems Corp. enzyme linked immunosorbant assay (ELISA) for THC Metabolite Testing Kit, for the qualitative detection of THCA at or above 1 pg/mg of hair for the purpose of identifying the use of cannabinoids. The Omega Laboratories Hair Drug	Same

	Screening Assay for Carboxy-THC provides only preliminary analytical test results and must be used in combination with a more specific alternate chemical method 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 used as the confirmation method, along with deuterated internal standards. Omega plans to perform this test at one site. Omega has not performed an evaluation of reproducibility at different laboratories.	
Test System	International Diagnostics Systems Corp Forensic Human Drug of Abuse HTC Metabolite ELISA for Hair Test IDS -4800 and GC-MS-MS confirmation method	Chemiluminscent Microplate EIA for Cannabinoids assay and GC-MS-MS confirmation method
Sample matrix	Head and body hair	Same
Method of measurement	Microplate reader, read at 450 nm	Same
Cutoff	1 pg THCA/mg hair	10 pg THCA/10mg hair
Type of test	ELISA	EIA (Chemiluminescent enzyme immunoassay)
Extraction methods	Utilized acid-methanol vs methanol alone to facilitate extraction of THCA from hair.	Proprietary extraction method

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

None referenced

L. Test Principle:

Screening Assay:

The test consists of two parts; a pre-analytical hair treatment procedure (to remove THCA from 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 unbound materials. Enzyme substrate solution containing a chromagen is added.

The reaction is stopped with an acid 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.

Confirmatory Testing:

Confirmation testing of samples is performed on a 20 mg aliquot of the original specimen. The hair is washed with methylene chloride and then dried under a gentle stream of nitrogen at 40 ºC. After digesting the sodium hydroxide, samples are processed by Solid Phase Extraction (SPE). Extraction retentates are derivatized with PFAA (pentafluoroacetic anhydride)/HFIP (1,1, 1, 3, 3, 3 hexafluoro-2-propanol) and reconstituted with toluene. The samples are analyzed using the GC/MS/MS Agilent 7890A Gas Chromatograph (GC)/ Agilent 7000 GC MS Triple Quad (MS) operating in the selected ion monitoring (SIM) mode using deuterated internal standards.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

   a. Precision/Reproducibility:

   Precision studies were performed by taking commercially available materials consisting of THCA in methanol 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/MS. Each solution was than 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 days. The results are present in the tables below:

Intra-assayTHCA Cutoff = 1 pg/mg (non-normalized data)			
THCA Spiked Samples (Percent of Cutoff)	Mean Abs. (450 nm)	S.D.	CV%
Negative	2.028	0.08143	4.0
0.25 pg/mg (-75%)	1.839	0.05832	3.2

0.50 pg/mg (-50%)	1.621	0.05005	3.1
0.75 pg/mg (-25%)	1.452	0.06416	4.4
1.25 pg/mg (25%)	1.133	0.02243	2.0
1.50 pg/mg (50%)	1.001	0.01421	1.4
1.75 pg/mg (75%)	0.915	0.02788	3.0
2.00 pg/mg (200%)	0.869	0.03985	4.6

Intra-assay THCA Cutoff = 1 pg/mg				
Conc. (pg/mg)	% of Cutoff	Number Tested	Negative	Positive
0	Negative	10	10	0
0.25	75	10	10	0
0.50	50	10	10	0
0.75	25	10	10	0
1.25	125	10	0	10
1.50	150	10	0	10
1.75	175	10	0	10
2.00	200	10	0	10

Inter –assay THCA Cutoff = 1 pg/mg				
Conc. (pg/mg)	% of Cutoff	Number Tested	Negative	Positive
0	Negative	200	200	0
0.25	75	200	200	0
0.50	50	200	200	0
0.75	25	200	200	0
1.25	125	200	0	200
1.50	150	200	0	200
1.75	175	200	0	200
2.00	200	200	0	200

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

GC/MS	Device		
Conc. (pg/mg)	Number Tested	Negative	Positive
1.02	3	0	3
4.92	3	0	3
2.82	3	0	3
1.49	3	0	3
8.59	3	0	3

b. Linearity/assay reportable range:

To assess linearity of the confirmation method, a series of standards were extracted and analyzed and compared to the target concentrations. The Limit of Quantitation (LoQ) was defined as the lowest concentration of analyte that exhibited acceptable chromatography, ion ratios within ± 25% of the calibrator, and a calculated concentration within ± 20% of the target value. The LoQ for carboxy-THC is 0.005 pg/mg.

The highest reportable concentration (upper limit of linearity) was defined as the highest concentration that exhibited acceptable chromatography, ion ratios within ± 25% of the calibrator, and a calculated concentration within ± 20% of the target value. The upper limit of linearity of the confirmation method for Carboxy-THC is 100 pg/mg

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

Commercially purchased materials consisting of (-)-11-nor-9-carboxy THC in methanol are used to prepare stock solutions. Stock solutions are then used to prepare calibrator and control working solutions. The cerillant (-)-11-nor-9-carboxy THC standard is traceable back to NIST.

Assigned values of the prepared calibrator and control working solutions are verified by GC/MS/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 for both the controls and calibrators. Open-vial stability is also 12 months for both.

Shipping Study:

A total number of 201 previously confirmed THCA positive and negative head and body hair samples were used in the study. A variety of hair color and curvatures were tested. Four separate shipping boxes each containing 25 previously screened negative samples , 25 previously confirmed positive

samples were stored in a freezer at approximately -5ºC for approximately 15 hours then heated to approximately 38ºC for a period of approximately six hours. This represented exposure to extreme temperatures.

Each box was then shipped to a different location in the US. The boxes were held for two days at each location than shipped back.

The samples were run on both the screening method and GC/MS before and after shipping. Results from the screening method showed that samples that were positive or negative before shipping remain the same after shipping. The GC/MS average mean % of change in results prior to shipping and after shipping was compared. The results show there is no difference in average mean % change in the results.

Sample Stability:

Fifty head and body hair samples previously confirmed THCA positive or negative were used in the study. A variety of hair color and curvatures were tested. Samples were stored in a climate-controlled space and then analyzed a second time approximately 1 and 2.5 years later. The average mean % of change in results prior from first analysis to second analysis was -30.7% and -47.4%%. The results are shown in the table below:

Measured Value	1 Year	2.5 Year
Average concentration pg/mg hair	1.73	1.53
Mean Change in %	-30.7	-47.4
Range in Concentration (pg/mg)	0.14-13.91	0.24-4.34
% Min and Max Decrease	4.2-69.8	30-65
% Min and Max Increase	2.1	na
Number that decreased in concentration	49	50
Number that increased in concentration	1	0

d. Detection limit:

Please see comments in linearity section M.1.b above.

e. Analytical specificity:

Structurally Related:

Cross-reactivity was established by preparing serial dilutions of each control compound in negative hair matrix extract and evaluated 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 table below and are also included in the package insert:

Compound	Approximate concentration of compound (pg/mg) Equivalent to 1pg/mg (-) 11-nor-9-Carboxy-delta9-THC Cutoff Control n=3	% Cross reactivity
(-) 11-nor-9-Carboxy-delta9-THC	1.0	100
(+/-) 11-nor-9-Carboxy-delta9-THC	1.0	100
(-) 11-nor-9-Carboxy-delta8-THC	0.45	222.2
(-)-delta8-THC	60	1.7
(-)-delta9-THC	50	2.0
(+/-) 11 Hydroxy-delta9-THC	5.0	22.2
Cannabinol	70	1.4
Cannabidiol	3000	<0.03
Nabilone	>400000	<0.01
JWH-018	>40000	<0.01

Structurally unrelated:

Negative head hair extracts were spiked with phencyclidine to -50%, 125% and 150% of the cutoff. Several (270) 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 (-) 11-nor-9-Carboxy-delta9-THC 6 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:

The effects of various head hair treatments (i.e. bleaching, dyeing, relaxer, shampoo, permanent) on the ELISA screening and GC/MS conformation for both positive and negative THCA samples was performed. Study information and results are provided separately below for effects on positive samples and effects on negative samples.

Effect on Positive Samples:

One hundred and twenty hair specimens potentially positive for THCA were obtained. Each sample was divided into 2 aliquots. One aliquot of each sample were randomly assigned into one of 10 groups, 9-14 samples in each group and subjected to the treatment. ELSIA 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 in the Bleaching Study 1 (Normalized data n=13)

ELISA Screening Data					
	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	1.365 (0.724-1.957)				
Treated	1.483 (0.819-2.091)	12	1.579 (1.360-1.718)	1	1.455 (0.819-2.091)
GC/MS Confirmation data					
	Mean/Range of sample concentration (pg/mg)	# of samples that decreased in concentration	Mean/Range of decrease in concentration	# of samples that increased in concentration	Mean/Range of increase in concentration
Untreated	1.76 (0.37-5.40)				
Treated	1.42 (0.26-4.62)	13	0.34 (0.11-0.79)	0	---------

Effects Observed in the Bleaching Study 2 (Normalized data n=12)

ELISA Screening Data					
	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	1.033 (0.707-1.829)				
Treated	1.243 (0.864-2.076)	10	1.057 (1 sample)	2	1.260 (0.864-2.076)
GC/MS Confirmation data					
	Mean/Range of sample	# of samples that	Mean/Range of decrease	# of samples that	Mean/Range of increase in

	concentration (pg/mg)	decreased in concentration	in concentration	increased in concentration	concentration
Untreated	3.54 (0.36-7.08)				
Treated	3.17 (0.24-7.31)	11	0.37 (0.12-0.82)	1	0.23 (1 sample)

Effects Observed in the PERM Study 1 (Normalized data n=12)

ELISA Screening Data					
	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	1.013 (0.605-1.896)				
Treated	1.215 (0.777-2.002)	11	none	1	1.215 (0.777-2.002)
GC/MS Confirmation data					
	Mean/Range of sample concentration (pg/mg)	# of samples that decreased in concentration	Mean/Range of decrease in concentration	# of samples that increased in concentration	Mean/Range of increase in concentration
Untreated	5.40 (0.45-20.67)				
Treated	4.69 (0.39-15.38)	11	0.79 (0.06-5.29)	1	0.18 (1 sample)

Effects Observed in the PERM Study 2 (Normalized data n=12)

ELISA Screening Data					
	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	1.410 (0.737-1.979)				
Treated	1.658 (0.872-2.247)	9	none	3	1.658 (0.872-2.247)
GC/MS Confirmation data					
	Mean/Range of sample	# of samples that	Mean/Range of decrease	# of samples that	Mean/Range of increase in

	concentration (pg/mg)	decreased in concentration	in concentration	increased in concentration	concentration
Untreated	1.87 (0.49-5.85)				
Treated	1.63 (0.34-4.99)	11	0.28 (0.03-0.86)	1	0.34 (1 sample)

Effects Observed in the DYE Study 1 (Normalized data n=11)

ELISA Screening Data					
	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	1.355 (0.821-1.880)				
Treated	1.595 (0.846-2.371)	9	1.363 (0.846-1.732)	2	1.728 (1.101-2.371)
GC/MS Confirmation data					
	Mean/Range of sample concentration (pg/mg)	# of samples that decreased in concentration	Mean/Range of decrease in concentration	# of samples that increased in concentration	Mean/Range of increase in concentration
Untreated	1.46 (0.43-3.55)				
Treated	1.29 (0.34-3.26)	11	0.17 (0.04-0.46)	0	109 (33-239)

Effects Observed in the DYE Study 2 (Normalized data n=9)

ELISA Screening Data					
	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	1.355 (0.670-1.879)				
Treated	1.529 (0.778-	7	1.703 (1 sample)	2	1.508 (0.778-

	2.401)				2.401)
GC/MS Confirmation data					
	Mean/Range of sample concentration (pg/mg)	# of samples that decreased in concentration	Mean/Range of decrease in concentration	# of samples that increased in concentration	Mean/Range of increase in concentration
Untreated	2.38 (0.20-10.49)				
Treated	2.28 (0.08-11.02)	8	0.18 (0.06-0.42)	1	0.53 (1 sample)

Effects Observed in the Relaxer Study 1 (Normalized data n=11)

ELISA Screening Data					
	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	1.254 (0.698-1.799)				
Treated	1.498 (0.696-2.191)	8	0.992 (0.696-1.288)	3	1.611 (0.815-2.191)
GC/MS Confirmation data					
	Mean/Range of sample concentration (pg/mg)	# of samples that decreased in concentration	Mean/Range of decrease in concentration	# of samples that increased in concentration	Mean/Range of increase in concentration
Untreated	3.25 (0.31-12.02)				
Treated	2.68 (0.22-9.85)	11	0.58 (0.09-2.17)	0	

Effects Observed in the Relaxer Study 2 (Normalized data n=13)

ELISA Screening Data					
	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	1.283				

	(0.677-1.973)				
Treated	1.674 (0.853-2.505)	8	none	5	1.674 (0.853-2.505)
GC/MS Confirmation data					
	Mean/Range of sample concentration (pg/mg)	# of samples that decreased in concentration	Mean/Range of decrease in concentration	# of samples that increased in concentration	Mean/Range of increase in concentration
Untreated	2.64 (0.57-10.01)				
Treated	2.30 (0.44-9.50)	13	0.34 (0.10-1.197)	0	

Effects Observed in the Shampoo Study 1 (Normalized data n=13)

ELISA Screening Data					
	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	1.168 (0.687-1.743)				
Treated	1.359 (0.821-2.231)	13	1.497 (1.453-1.558)	0	1.298 (0.821-2.231)
GC/MS Confirmation data					
	Mean/Range of sample concentration (pg/mg)	# of samples that decreased in concentration	Mean/Range of decrease in concentration	# of samples that increased in concentration	Mean/Range of increase in concentration
Untreated	3.06 (0.42-7.65)				
Treated	3.07 (0.33-8.25)	8	0.24 (0.09-0.40)	5	0.41 (0.08-0.60)

Effects Observed in the Shampoo Study 2 (Normalized data n=14)

ELISA Screening Data					
	Mean Abs/Range	# of samples that	Mean/Range of Abs of all	# of samples that became	Mean/Range of Abs of all

	of Abs	remained positive	that had a decrease in Abs	negative	that had a increase in Abs
Untreated	1.412 (0.760-1.954)				
Treated	1.548 (0.873-2.155)	10	1.375 (0.873-1.798)	4	1.539 (0.892-2.155)
GC/MS Confirmation data					
	Mean/Range of sample concentration (pg/mg)	# of samples that decreased in concentration	Mean/Range of decrease in concentration	# of samples that increased in concentration	Mean/Range of increase in concentration
Untreated	2.16 (0.35-11.61)				
Treated	2.17 (0.27-13.27)	11	0.16 (0.03-0.53)	3	0.64 (0.09-1.66)

Effect on Negative Samples:

Fifty two specimens previously confirmed negative for THCA and each sample was divided into 2 aliquots. One aliquot of each sample were randomly assigned into one of 10 groups, 11-14 samples in each group and subjected to the treatment. ELSIA Absorbance readings before and after treatment were compared. GC/MS measurements before and after treatment were also compared. Of the 52 samples 48 samples remained negative after treatment. The percent difference between the mean normalized absorbance values of the treated and untreated groups for all treatments was -19%.

Conclusion:

Bleach and relaxer treatments had the greatest effect on positive samples resulting in an average decrease in THCA concentration of 19%. This was followed by dying and permanents resulting in an average decrease in THCA concentration of 16% and 14%, respectively. The mean effect of shampoos was 6%.

Environmental Contamination:

Twelve head hair specimens of various hair color and texture were contaminated with marijuana smoke. The samples were then split into two additional samples and soaked in either water or saline. The washed and unwashed samples were then analyzed by the confirmation method for THC

and THCA (Carboxy-THC). All samples were? positive by the screening method. For the confirmation test, all of the washed and unwashed samples tested positive for THC parent drug but negative for THCA. The sponsor states that the THCA metabolite (Carboxy-THC) that is confirmed is not known to be present except as a metabolite. Therefore, these samples would have been reported as negative.

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 ELSIA results against the GC/MS results on the same hair sample. A total of 421 donor body and head hair samples were tested (152 negative and 269 positive). The results are presented in the table below:

a. Method comparison with GC/MS:

IDS ELISA THCA Test Result	Negative by GC/MS (less than 50 pg/mg)	Less then 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	47	210
Negative	100	16	28	12	0

Screening Cutoff (pg/mg)	IDS ELSIA THCA Test Results (POS/NEG)	GC/MS Cutoff (pg/mg)	GC/MS Drug Result (pg/mg)
1.0	POS	0.1	0.74
1.0	POS	0.1	0.83
1.0	POS	0.1	0.83
1.0	POS	0.1	0.84

1.0	POS	0.1	0.90
1.0	POS	0.1	0.92
1.0	POS	0.1	0.93
1.0	POS	0.1	0.98
1.0	NEG	0.1	1.00
1.0	NEG	0.1	1.06
1.0	NEG	0.1	1.08
1.0	NEG	0.1	1.09
1.0	NEG	0.1	1.12
1.0	NEG	0.1	1.16
1.0	NEG	0.1	1.16
1.0	NEG	0.1	1.17
1.0	NEG	0.1	1.18
1.0	NEG	0.1	1.22
1.0	NEG	0.1	1.28
1.0	NEG	0.1	1.29

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):

Extraction Recovery Study:

Forty head and body hair samples that previously confirmed positive for THCA were used for these studies. Samples were aliquoted in duplicate; one aliquot was taken through the screening assay acidic-methanol extraction and the other was taken through the 100% recovery extraction.

One aliquot for each hair sample was taken through the screening extraction and assay procedures (described in the Test Principle Section above) up to the point of evaporating the acidic-methanol extract. At this point, GC/MS confirmation Procedure for THCA in hair was followed.
The method representing 100% recovery was accomplished by adding 1.0 ml of 1N NaOH to 20 mg of hair and incubated at 70ºC for 30 minutes. The hair

sample is totally liquefied and the entire drug originally bound to the hair is now dissolved in the base solution. At this point the GC/MS conformation procedure for THCA was followed.

The GC/MS results of the acidic-methanol extraction were compared to the results of the 100% recovery base hydrolysis extraction to determine the relative recovery of THCA using the acidic-methanol incubation. The mean recovery for the acidic-methanol extraction was 84%. The results are in the table below:

Sample	Base Hydrolysis (NaOH) (pg/mg)	1 hr Acidic-methanol (pg/mg)	Recovery
THCP 1	1.82	1.21	66
THCP 4	3.34	2.69	81
THCP 7	1.83	1.12	61
THCP 8	0.36	0.20	56
THCP 9	3.58	2.62	73
THCP 10	13.24	12.10	91
THCP 11	0.26	0.09	35
THCP 12	0.32	0.32	99
THCP 13	0.49	0.43	87
THCP 14	0.45	0.38	84
THCP 15	0.26	0.20	77
THCP 16	0.48	0.45	92
THCP 17	0.50	0.39	78
THCP 18	0.85	0.57	67
THCP 19	1.25	1.69	135
THCP 20	0.52	0.49	94
THCP 21	0.58	0.40	69
THCP 22	1.15	1.35	118
THCP 23	0.63	0.65	103
THCP 25	0.75	0.51	69
THCP 26	0.30	0.16	52
THCP 27	0.30	0.07	22
THCP 28	0.61	0.39	64
THCP 31	0.70	0.62	89
THCP 32	0.64	0.38	59
THCP 34	2.38	1.85	78
THCP 36	3.12	2.34	75
THCP 37	1.65	1.98	120
THCP 38	7.38	6.67	90
THCP 39	2.20	1.73	79
THCP 40	1.71	2.49	146
THCP 41	1.52	1.17	77
THCP 43	9.52	7.22	76

THCP 44	0.53	0.44	83
THCP 45	4.19	3.56	85
THCP 47	1.32	1.80	136
THCP 49	1.05	0.87	83
THCP 50	3.84	2.84	74
THCP 51	2.25	2.55	113
THCP 52	10.24	6.42	63
THCP 53	5.13	5.61	109
THCP 54	4.37	4.14	95
THCP 57	12.65	11.18	88
		Mean Recovery	84

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.