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

A. 510(k) Number:

k101059

B. Purpose for Submission:

New device

C. Measurand:

Phencyclidine (PCP) in hair

D. Type of Test:

Qualitative ELISA Immunoassay

E. Applicant:

Omega Laboratories, Inc.

F. Proprietary and Established Names:

Omega Laboratories Hair Drug Screening Assay for Phencyclidine (PCP)

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LCM, Enzyme immunoassay Phencyclidine	Class II	Unclassified	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 Phencyclidine (PCP) is a laboratory developed test that is intended to be used for the determination of the presence of PCP in human hair from the head. The Omega Laboratories Hair Drug Screening Assay (PCP) utilizes the International Diagnostic System Corp (IDS) One-Step enzyme linked immunosorbant assay (ELISA) for PCP, for the qualitative detection of PCP at or above 300 pg/mg of hair for the purpose of identifying the use of PCP. 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 laboratory developed test is intended exclusively for in-house laboratory use only and is not intended for sale to anyone. Omega offers this laboratory developed test as a service to its clients.

3. Special conditions for use statement(s):

   The assay is for Prescription Use

4. Special instrument requirements:

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

I. Device Description:

The assay consists of the following:

- Antibody coated microplate – 5x 96-well microplate coated with goat anti-PCP 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
- Calibrators and controls. These are prepared solutions of PCP added to negative hair matrix tubes.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Quest Diagnostic HairCheck-DT (PCP)

2. Predicate K number(s):

k042726

3. Comparison with predicate:

Item	Device	Quest Hair Drug Screening k042726
Indications/Intended Use	Intended to be used for the determination of the presence of PCP in human Hair	Same
Test System	International Diagnosticx Systems Corp Forensic Human Drug of Abuse One-Step ELISA for Hair Testing Kit – IDS part # PCP-480-OM	Same
Sample matrix	Head Hair	Same
Method of measurement	Microplate reader, read at 450 nm	Same
Cutoff	300 pg/mg	Same
Type of test	ELISA	Same
Extraction methods	Utilized acid-methanol vs methanol alone to facilitate extraction of PCP from hair.	Methanol
Confirmation method	GC/MS	Same
Measurand	Phencyclidine (PCP) in hair	Same

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), 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 PCP in methanol (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. Each solution was than used to spike 11 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-assay PCP 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

Inter –assay PCP 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

The sponsor also performed an intra-assay precision using 5 hair specimens previously found to be positive for PCP. 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
399	3	0	3
560	3	0	3
1435	3	0	3
4528	3	0	3
7096	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 PCP in methanol are used to prepare stock solutions. Stock solutions are then used to prepare calibrator and control working solutions. The cerillant PCP standard is 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 for stability testing were described and found to be acceptable. When stored refrigerated in an amber bottle the shelf life is 12 months.

d. Detection limit:

Performance at low concentrations was evaluated in the precision studies above. This is a qualitative assay.

e. Analytical specificity:

Structurally Related:

Cross-reactivity to structurally-related compounds was evaluated 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:

Compound	Approximate concentration of compound (pg/mg) Equivalent to 300 pg/mg Phencyclidine Cutoff Control n=3	% Cross reactivity
Phencyclidine	300	100
Metaphit	500	60
4-Hydroxy-Phencyclidine	6000	5.0
Doxylamine	>40000	<0.8
Phencyclidine Morpholine	1500	20

Structurally unrelated:

Negative 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 PCP have not been observed to produce an interference with the assay. Only those compounds that are structurally similar (metaphit, 4-hydroxyphencyclidine and phencyclidine morpholine) were shown to contribute to a PCP positive ELSIA screening result.

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 hair treatments (i.e. bleaching, dyeing, relaxer, shampoo, permanent) on the ELISA screening and GC/MS conformation for both positive and negative PCP samples was performed.

Effect on Positive Samples:

One hundred and thirty nine hair specimens potentially positive for PCP were obtained. Of these 139 samples 90 were confirmed positive for PCP. Each sample was divided into 2 aliquots. One aliquot of each sample were randomly assigned into one of 10 groups, 9 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

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	0.359 (0.093-0.660)				
Treated	0.354 (0.075-0.635)	9	0.253 (0.075-0.583)	0	0.557 (0.494-0.635)
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	2751 (334-6778)				
Treated	2257 (298-6381)	9	494 (37-1330)	0	---------

Effects Observed in the Bleaching Study 2

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	0.331 (0.074-0.509)				
Treated	0.326 (0.074-0.560)	9	0.286 (0.074-0.399)	0	0.376 (0.150-0.560)
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	1941 (612-7304)				
Treated	1534 (525-5195)	9	407 (87-2109)	0	---------

Effects Observed in the PERM Study 1

ELISA Screening Data					
	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	0.250 (0.121-0.449)				
Treated	0.279 (0.136-0.564)	9	0.257 (0.161-0.353)	0	0.285 (0.136-0.564)
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	2178 (717-3421)				
Treated	1545 (438-2660)	9	633 (154-1102)	0	---------

Effects Observed in the PERM Study 2

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	0.465 (0.104-0.702)				
Treated	0.526 (0.132-0.819)	6	0.334 (only 1 sample)	3	0.550 (0.132-0.819)
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	1465 (301-5244)				
Treated	1261 (177-4291)	9	203 (17-786)	0	---------

Effects Observed in the DYE Study 1

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	0.468				

	(0.178-0.674)				
Treated	0.485 (0.186-0.779)	8	0.500 (0.402-0.599)	1	0.480 (0.186-0.779)
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	876 (206-2100)				
Treated	900 (281-2185)	4	82 (11-151)	5	109 (33-239)

Effects Observed in the DYE Study 2

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	0.442 (0.123-0.688)				
Treated	0.456 (0.099-0.777)	8	0.313 (0.099-0.608)	1	0.636 (0.414-0.777)
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	1575 (307-4954)				
Treated	2257 (298-6381)	5	44 (6-102)	4	182 (9-312)

Effects Observed in the Relaxer Study 1

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	0.417 (0.129-0.678)				
Treated	0.441 (0.132-0.709)	9	0.387 (0.146-0.672)	0	0.467 (0.132-0.709)
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	1409 (313-4031)				
Treated	1401 (280-4251)	6	58 (4-152)	3	91 (16-220)

Effects Observed in the Relaxer Study 2

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	0.505 (0.163-0.691)				
Treated	0.547 (0.150-0.835)	8	0.471 (0.150-0.636)	1	0.642 (0.555-0.835)
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	758 (305-2764)				
Treated	758 (275-2783)	6	59 (12-141)	3	28 (15-51)

Effects Observed in the Shampoo Study 1

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	0.451 (0.320-0.685)				
Treated	0.473 (0.274-0.686)	9	0.319 (0.274-0.390)	0	0.597 (0.475-0.686)
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	766 (311-1430)				
Treated	744 (267-1447)	6	41 (7-77)	3	18 (15-21)

Effects Observed in the Shampoo Study 2

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	0.417 (0.275-0.620)				
Treated	0.445 (0.263-0.683)	9	0.275 (0.263-0.297)	0	0.547 (0.432-0.683)
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	827 (305-1784)				
Treated	820 (287-1709)	6	56 (18-125)	3	90 (77-114)

Effect on Negative Samples:

Eighty six hair specimens (37 previously confirmed negative for PCP and 49 from the 139). Each sample was divided into 2 aliquots. One aliquot of each sample were randomly assigned into one of 10 groups, 9 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. For the bleaching, perming and dyeing there was a small change in the percent difference between the mean absorbance values of the treated and untreated groups. The difference was not enough to change the result. No effect was observed for the relaxer and shampoo treatments.

Conclusion:

Permanent treatments had the greatest effect on positive samples followed by bleaching resulting which causes a decrease in PCP concentration potentially having a PCP result as negative instead of positive.

Environmental Contamination:

Two studies were performed to investigate whether confirmatory testing procedures (methanol wash procedure) are able to distinguish between true analytically positive samples and those that have been externally exposed to PCP. The study focused on demonstrating that the methanol wash procedure mitigates the risk of false positive results while maintaining true analytical positive results.

The first study involved exposing drug-free hair to PCP, washing the hair with methanol, performing confirmation testing on the samples and the washes and observing the final result.

Ten hair specimens that had previously screened negative for PCP were selected in order to represent two hair types, listed below:

Hair Types

Category	Hair Color	Hair Texture
A	Black	Curly
B	Blonde	Straight

Five hair specimen aliquots of each hair type were exposed to PCP (in separate experiments) according to the exposure modes listed below. Approximately 20 mg aliquot of each hair sample were then analyzed by GC/MS. Results are presented for each exposure mode and according to the drug and category of hair type.

Exposure Modes

Type of Exposure	How performed
Dry Contact	Exactly 1.0 mg of phencyclidine hydrochloride was weighed and then combined with 10 grams of dextrose with maltodextrin, aspartame (Splenda®). The powdered mixture was mixed thoroughly for homogeneity using a mortar and pestle. Exactly 5 grams of powder was added to the bottom of a 1 liter beaker. A lid containing both hair types attached to hair clips was affixed to the top and sealed with parafilm. The powder at the bottom of the beaker was disturbed by applying a burst of compressed gas with a compressed gas canister. The lid only allowed the small tube to deliver compressed gas, allowing powder to become airborne and distribute as a cloud inside the 1 liter container. The hair bundles remained in the container for 30 minutes of exposure to the airborne powder. The PCP powder-exposed hair were then taken out of the beaker and shaken to remove excess power. Separate 20 mg aliquots of each hair specimen were weighed and placed into individual test tubes.
Dry Contact plus Liquid	After dry contact exposure as described above, 20 mg aliquots of each hair specimen were weighed out and 2.0 mL of water was added and then quickly removed to simulate rinsing the hair, as in

	a shower or bathing. An additional 2.0 mL of water was added and the tube was allowed to stand for 30 minutes at ambient temperature. The water was then removed and the hair was allowed to dry overnight. Separate 20 mg aliquots of each hair specimen were weighed and placed into individual test tubes.
Dry Contact plus Saline	After dry contact exposure as described above 20 mg aliquots of hair were weighed out and 0.3 mL of saline (0.9% sodium chloride solution) was added. The saline solution was sufficient to saturate the hair specimen and also expose a fraction of the hair with constant soaking, to simulate sweating close to the scalp. The tube was allowed to stand for 30 minutes at ambient temperature. The saline solution was then removed and the hair was allowed to dry overnight. Separate 20 mg aliquots of each hair specimen were weighed and placed into individual test tubes.
Smoke Contact	A total of 10 hair specimens known to be drug-free were exposed to PCP smoke by burning a tobacco cigarette soaked in 3.0 mg of PCP in an enclosed 5 gallon bucket. The ten hair specimens attached to hair clips on a string were hung inside the bucket. A cigarette was lit first, and a pipette was used to apply 300 uL of a 10 mg/mL PCP solution on the cigarette. It was then placed in an aluminum foil tray, and the cigarette was allowed to completely burn with the specimens remaining in the bucket overnight. After exposure to the PCP smoke, separate 20 mg aliquots of each hair specimen were weighed into two and placed into individual test tubes.

Dry Contact Exposure

Specimen	1st Methanol Wash (PCP pg/mg)	2nd Methanol Wash (PCP pg/mg)	3rd Methanol Wash (PCP pg/mg)	Hair Specimen (PCP pg/mg)
A1	617	67	None detected	None detected
A2	1028	247	None detected	None detected
A3	944	77	None detected	None detected
A4	792	48	None detected	None detected
A5	256	None detected	None detected	None detected
B1	619	50	None detected	None detected
B2	697	89	None detected	None detected
B3	551	75	None detected	None detected
B4	631	84	None detected	None detected
B5	876	95	None detected	None detected

Dry Contact with Liquid Exposure

Specimen	1st Methanol Wash (PCP pg/mg)	2nd Methanol Wash (PCP pg/mg)	3rd Methanol Wash (PCP pg/mg)	Hair Specimen (PCP pg/mg)
A1	670	67	None detected	None detected

A2	933	83	None detected	None detected
A3	1918	81	None detected	None detected
A4	1027	33	None detected	None detected
A5	993	61	None detected	None detected
B1	628	20	None detected	None detected
B2	686	37	None detected	None detected
B3	974	25	None detected	None detected
B4	768	51	None detected	None detected
B5	775	20	None detected	None detected

Dry Contact with Saline Exposure

Specimen	1st Methanol Wash (PCP pg/mg)	2nd Methanol Wash (PCP pg/mg)	3rd Methanol Wash (PCP pg/mg)	Hair Specimen (PCP pg/mg)
A1	666	26	None detected	None detected
A2	447	51	None detected	None detected
A3	857	68	None detected	None detected
A4	627	104	None detected	None detected
A5	997	20	None detected	None detected
B1	2035	41	None detected	None detected
B2	871	84	None detected	None detected
B3	442	32	None detected	None detected
B4	826	20	None detected	None detected
B5	708	44	None detected	None detected

Smoke Exposure

Specimen	1st Methanol Wash (PCP pg/mg)	2nd Methanol Wash (PCP pg/mg)	3rd Methanol Wash (PCP pg/mg)	Hair Specimen (PCP pg/mg)
A1	314	25	None detected	None detected
A2	269	42	None detected	None detected
A3	281	82	None detected	None detected
A4	318	57	None detected	None detected
A5	343	84	None detected	None detected
B1	466	33	None detected	None detected
B2	465	55	None detected	None detected
B3	377	95	None detected	None detected
B4	439	38	None detected	None detected
B5	291	42	None detected	None detected

The second study involved performing confirmation testing on known positive samples and observing whether the methanol washes change the final result. Five clinically positive hair samples were selected for the study. All samples were previously screened and confirmed positive. Results are presented below:

Specimen	1st Methanol Wash (PCP pg/mg)	2nd Methanol Wash (PCP pg/mg)	3rd Methanol Wash (PCP pg/mg)	Hair Specimen (PCP pg/mg)
H1	None detected	None detected	None detected	327
H2	None detected	None detected	None detected	521
H3	None detected	None detected	None detected	1154
H4	34	None detected	None detected	2892
H5	50	None detected	None detected	6847

Conclusions of the study:

Evaluating potential external contamination using this study design, all analytically negative samples tested remained negative after being subjected to PCP and exposure modes described. All clinically positive samples tested remained positive.

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 352 donor hair samples were tested (176 negative and 176 positive). The results are presented in the table below:

a. Method comparison with GC/MS:

IDS ELSIA PCP 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	1	14	33	128
Negative	150	15	7	4	0

Discrepant Results:

Screening Cutoff (pg/mg)	IDS ELSIA PCP Test Results (POS/NEG)	GC/MS Cutoff (pg/mg)	GC/MS Drug Result (pg/mg)
300	POS	300	122
300	POS	300	166
300	POS	300	184

300	POS	300	264
300	POS	300	267
300	POS	300	272
300	POS	300	280
300	POS	300	286
300	POS	300	287
300	POS	300	287
300	POS	300	288
300	POS	300	290
300	POS	300	291
300	POS	300	293
300	POS	300	298
300	NEG	300	301
300	NEG	300	301
300	NEG	300	305
300	NEG	300	313

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:

Five hair samples that previously confirmed positive for PCP 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 PCP 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 PCP 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 PCP using the acidic-methanol incubation. The mean recovery for the acidic-methanol extraction was 102%. The results are in the table below:

Sample	Acidic-methanol (pg/mg)	Base Hydrolysis (pg/mg)	Recovery
176160	418	457	91%
176161	250	233	107%
176163	126	104	121%
254474	261	251	104%
406560	300	337	89%

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.