K101059

JUL 12 2010

SUMMARY OF SAFETY AND EFFECTIVENESS

April 12, 2010

Trade Name: Hair Drug Screening Assay (PCP)

Common Name: Hair Drug Screening Assay (PCP)

Applicant:

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Classification Name:

Classification Panel: Clinical Chemistry

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1.0 ASSAY SUMMARY

The Assay is an enzyme immunoassay for the qualitative detection of phencyclidine in hair.

Phencyclidine (PCP), the hallucinogen commonly referred to as Angel Dust, can be detected in hair. Human head hair grows at approximately ½ inch per month, and has been measured using various biomarkers (1,2). Hair, due to its growth rate and stability, offers a much longer history of drug usage than any other matrix. Hair has been increasingly chosen as a workplace test specimen, since, in contrast to urine, the collection is observed, and the possibility of adulteration or substitution of the specimens is reduced. PCP itself is incorporated into the growing hair shaft. For the screening of PCP in hair, an enzyme linked immunosorbent assay (ELISA) procedure has been established; and for confirmatory analysis, gas chromatography with mass spectrometric detection is the preferred laboratory procedure.

1.1 Classification Information

Classification or descriptor	Name or designation
Trade Name	Hair Drug Screening Assay for Phencyclidine (PCP)
Common Name	Hair Drug Screening Assay for Phencyclidine (PCP)
Classification Name	Enzyme immunoassay, phencyclidine
Classification Panel	91 (Toxicology)
Product Code	LCM
Regulation Number	Unclassified, Enzyme Immunoassay, PCP

2.0 PREDICATE DEVICES

2.1 Quest Diagnostics HairCheck-DT (PCP)

2.1.1 510(k) Number: k042726

2.2 Psychemedics Corporation RIA Phencyclidine (PCP) Assay

2.2.1 510(k) Number: k011275

3.0 INTENDED USE AND INDICATIONS FOR USE

3.1 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 Systems Corp (IDS) One-Step enzyme linked immunosorbent 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. The Omega Laboratories Hair Drug Screening Assay (PCP) screening test provides only a preliminary qualitative test result. 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.

4.0 ASSAY DESCRIPTIONS

4.1 The Omega Laboratories Hair Drug Screening Assay (PCP) is a test system that utilizes the International Diagnostic Systems Corp (IDS) One-Step ELISA PCP reagents and a micro-plate reader for the qualitative detection of Phencyclidine in hair samples at or above 300 pg/mg. It is an assay intended exclusively for in-house use by trained laboratory personnel only and is not intended for sale to anyone.

4.2 The Omega Laboratories Hair Drug Screening Assay (PCP) screening test provides only a preliminary analytical test result. To confirm a screen positive result, a more specific alternate chemical method must be used.

4.3 Assay

4.3.1 The test consists of two parts; a pre-analytical proprietary and patent pending hair treatment procedure (to convert the solid matrix of hair to a measurable liquid matrix), and the screening assay.

4.4 Specifications

4.4.1 Donor Sample Collection

4.4.1.1 Donor samples are collected using the Omega Collection Kit or a similar system that are equivalent to the Omega Collection Kit specifications. Hair samples stored in the Kit have a one year shelf life.

4.4.2 IDS One-Step ELISA PCP (microplate format)

4.4.2.1 The IDS PCP utilizes an enzyme-linked immunosorbent assay technology (ELISA). ELISA utilizes highly sensitive and specific antibodies onto a solid-phase surface such as a microwell plate. The sample to be tested competes with an enzyme solution for the binding sites of the antibody. If the enzyme binds to the antibody, a

color change occurs after the addition of substrate. The darker the color, the lower the amount of analyte in the sample.

4.5 Materials

4.5.1 Sample Collection Kit

4.5.2 IDS One-Step ELISA PCP Kit

4.5.3 Micro Plate Read

4.5.4 GC/MS for Confirmation Testing

.0 COMPARISON OF BASESENS SYSTEM AND ITS PREDICATES

5.1 Comparison of Omega Laboratories PCP Assay vs Quest Diagnostic Hair Check-DT (PCP) Assay

Comparison Element	Hair Drug Screening Assay for Phencyclidine (PCP). (Subject devices)	Hair Drug Screening Assay for Phencyclidine (PCP). (Predicate device k042726)	Psychemedics RIA Phencyclidine Assay (Predicate device k011275),
Laboratory	Omega Laboratories, Inc.	Quest Diagnostics, Inc.	Psychemedics Corp
Indication for/ Intended 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. The Omega Laboratories Hair Drug Screening Assay (PCP) utilizes the International Diagnostic Systems Corp (IDS) One-Step enzyme linked immunosorbent 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.	The Quest Diagnostics Hair Check-DT (PCP) is a test system that utilizes the IDS One-Step ELISA PCP Kit for the qualitative detection of Phencyclidine at or above 300 pg/mg in head hair samples. This test system has not been evaluated for use in specific user populations or with hair specimens other than the head. It is an in vitro diagnostic device intended exclusively for in-house professional use only and is not intended for sale to anyone. The Quest Diagnostics Hair Check-DT (PCP) screening test provides only a preliminary analytical test result. 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 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. (From FDA Published Statement of Indications for Use)	The Psychemedics PCP Assay is a radioimmunoassay (RIA) for the preliminary qualitative and semi-quantitative detection of phencyclidine (PCP) in hair using a 3 ng/l10 mg hair cutoff for the purpose of identifying PCP use. For a quantitative analytical result or to confirm positive results via the presence of PCP. a more specific alternate chemical method must be used in order to obtain a confirmed analytical result. (From FDA Published Statement of Indications for Use)

Product Code	LCM	LCM	LCL
Measurand	Phencyclidine (PCP) in hair	Phencyclidine (PCP) in hair	Phencyclidine (PCP) in hair
Test system	International Diagnostics Systems Corp Forensic Human Drugs of Abuse One-Step ELISA for Hair Testing Kit – IDS part# PCP-480-OM.	International Diagnostics Systems Corp Forensic Human Drugs of Abuse One-Step ELISA for Hair Testing Kit – IDS part# PCP-480-OM.	Polyclonal primary antibody; isotopically labeled PCP; double antibody precipitation
Method of Measurement	Microplate reader. Read at 450 nm	Microplate reader. Read at 450 nm	
Matrix	Head hair	Head hair	Hair/Head hair
Cutoff concentration	300 pg PCP/mg hair	300 pg PCP/mg hair	3 ng PCP/10 mg hair
Type of Test	ELISA	ELISA	Radioimmunoassay (RIA)
Extraction Method	Utilized acid-methanol vs methanol alone to facilitate extraction of PCP 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	Methanol	Proprietary The hair sample preparation for the assay is a 2-hour, pH = 9.5, enzymatic dilation of the hair.
Confirmation methods	GC/MS	GC/MS	GC/MS
Produces radioactive waste	No	No	Yes

6.0 SUMMARY OF PERFORMANCE TESTING

6.1 Precision Study

6.1.1 The Screening Protocol was studied to evaluate its precision/reproducibility. The Precision Study was performed to evaluate the intra and inter-assay precision/reproducibility of the Protocol.

Inter-Assay Precision using Spiked Samples (normalized data)

PCP Spiked Sample	negative	75 pg/mg -75%	150 pg/mg -50%	225 pg/mg -25%	375 pg/mg +25%	450 pg/mg +50%	525 pg/mg +75%	600 pg/mg +100%
Mean Abs. (450 nm)	1.926	1.203	0.865	0.697	0.505	0.437	0.398	0.348
S.D.	0.05531	0.08171	0.03957	0.03382	0.02465	0.02637	0.02467	0.02157
%CV	2.9	3.8	4.6	4.9	4.9	6.0	6.2	6.2

Intra-assay Precision of PCP using Individual Hair Specimens

Accession #	A	B	C	D	E
	0.521	0.486	0.282	0.115	0.058
	0.534	0.492	0.342	0.113	0.073
	0.466	0.527	0.256	0.105	0.053
Mean	0.507	0.502	0.293	0.111	0.061
S.D.	0.03609709	0.0221	0.0441	0.0053	0.0104
%CV	7.1	4.4	15.0	4.8	17.0
95% CI	0.041	0.025	0.050	0.006	0.012
95% CI Lower	0.466	0.477	0.243	0.105	0.050
95% CI Upper	0.548	0.527	0.343	0.117	0.073

GC/MS Analysis of Intra-assay Precision of PCP using Individual Hair Specimens

Accession #	A (pg/mg)	B (pg/mg)	C (pg/mg)	D (pg/mg)	E (pg/mg)
	379	568	1334	4749	7493
	406	542	1552	4134	6754
	411	571	1418	4702	7040
Mean	399	560	1435	4528	7096
S.D.	17.2143	15.9478	109.952	342.31	372.632
%CV	4.3	2.8	7.7	7.6	5.3
95% CI	19.5	18.0	124.4	387.4	421.7

95% CI Lower	379	542	1310	4141	6674
95% CI Upper	418	578	1559	4916	7517

6.1.2 Evaluation of the precision of the Omega Laboratories, Inc. ELISA PCP Screening Protocol demonstrated that the intra and inter-assay precision using spiked samples was acceptable (%CV of 10% or less).

6.1.3 Evaluation of the precision of the Omega Laboratories, Inc. ELISA PCP Screening Protocol using this study design demonstrated that the intra-assay precision using individual donor sample replicates was acceptable (%CV of 15% or less).

6.2 Agreement Study

6.2.1 The Agreement Study was performed by comparing ELISA results against quantitative GC/MS confirmatory results on the same hair specimens. A total of 352 donor hair samples were tested in this study (Negative n=176 and Positive n=176).

Summary of Agreement Study Results

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

6.2.2 Evaluation of the agreement of the Omega Laboratories, Inc. ELISA PCP Screening Protocol vs quantitative GC/MS results demonstrated the false detection rate of samples containing PCP at levels higher than 50% above cutoff concentration is 0% and the false detection rate of PCP at levels less than 50% of the cutoff concentration is 0.6%.

6.3 Cosmetic Treatment Study

6.3.1 The Cosmetic Treatment study documented the absence of effects of various cosmetic treatments on the Omega Laboratories, Inc. ELISA PCP Screening Protocol.

Hair Treatment Assignment

BLEACH 1	Salon Care Blue Flash Professional Powder Lightener
BLEACH 2	Loreal Super Oreal Blanc® Professional Powder Bleach
PERM 1	Naturelle Natural Curls Alkiline Perm
PERM 2	Natural Apple Self-Timing Perm
DYE 1	Revlon® Colorsilk™ Black

DYE 2	Garnier Herbashine Soft Mahogany Dark Brown
RELAXER 1	Silk Elements™ No-Lye Sensitive Scalp Relaxer System
RELAXER 2	Ultra Precise No-Lye Conditioning Relaxer
SHAMPOO 1	After Burner drug removing shampoo
SHAMPOO 2	Ultra Cleanse drug removing shampoo

Summary of Effects for Positive GC/MS Confirmation Data

Treatment	Mean change in concentration (pg/mg)
Bleach	-28%
Permanent	-36%
Dyeing	-5%
Relaxer	-9%
Shampoo	-4%

6.3.2 Permanent treatments had the greatest effect on positive samples followed by bleaching resulting in an average decrease in PCP concentration of 36% and 28%, respectively. The mean effect of relaxer or shampoo treatments was negligible i.e. the mean change was within the standard uncertainty range of the GC/MS confirmation assay

6.4 Cross reativities

Cross Reactivity and Interference was studied were conducted to evaluate the specificity of the Omega Laboratories, Inc. ELISA PCP Screening Protocol and the possible effect of interfering compounds.

6.4.1 The study demonstrated that the presence of the structurally similar compounds metaphit, 4-hydroxyphencyclidine, and phencyclidine morpholine may contribute to a PCP positive ELISA result when utilizing this protocol. None of the other (270) compounds demonstrated interference with the ELISA PCP protocol. Since a GC/MS confirmation is performed on all presumptive positive screening results, these interfering compounds will not confirm as a positive PCP result report.

6.5 Environmental Contamination

6.5.1 Two studies were conducted. The first study involved exposing drug-free hair to PCP, washing the hair with methanol three times, performing confirmation testing on the samples and the washes, and observing the final test result. The second study involved performing confirmation testing on known positive samples and observing whether the methanol washes change the final result.

6.5.2 The studies examined the following potential exposure modes. Dry Contact, Dry Contact plus Liquid, Dry Contact ply Saline (NaCl) Solution and Smoke.

6.5.3 Based on the study results, the proposed testing procedures are able to distinguish between true analytically positive samples and those that have been externally exposed to PCP.

6.6 Calibrator and Control

6.6.1 The in-house calibrator and control solutions are prepared solely for use within Omega and only at its laboratories in Mogadore, OH.

6.6.2 The study demonstrated the stability of PCP in methanol for a period of one year when stored refrigerated in an amber bottle is also attached. This validates the one 1 year expiration date for the PCP Calibrator Stock Solution

6.7 Recovery Study

6.7.1 The Extraction Recovery Study evaluated the effectiveness of the extraction method utilized by the Omega Laboratories, Inc. ELISA PCP Screening Protocol.

6.7.2 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%.

6.8 Shipping Study

6.8.1 The Shipping Study was conducted to determine whether there is any adverse effect on donor hair samples when exposed to extreme temperatures and variations in humidity that might occur during sample shipments.

6.8.2 The average mean % of change in result prior to shipping and after shipping was 0% for all locations combined. The study demonstrated that because a hair sample is a solid matrix, it is not susceptible to the same temperature constraints as a urine sample.

6.9 Stability Study

6.9.1 The Stability Study was conducted to determine whether there are any adverse effects on the level of PCP contained in a hair sample when it is placed in storage for an extended period of time.

Table 16: Stability values

Measured value	**Value or range**
Range in concentration pg/mg hair (Before)	110 - 4999
Range in concentration pg/mg hair (After)	115 - 5102
Mean Change	-8%

% Max and Min Decrease	-32% and -2%
% Max and Min Increase	9% and 2%
Number that increased in concentration	8
Number that decreased in concentration	12

Based on the 8 % mean percent change over the 2.5 year storage, donor sample PCP drug stability is maintained at value well within the Acceptance Criteria of less 15% and is consider acceptable for use in the Protocol. Shelf life for the hair samples has been set at 1 year after collection.

Conclusion:

The Omega Laboratory Hair Drug Screening Assay for Phencyclidine (PCP) does not raise any new safety and efficacy concerns when compared to the cleared Quest Diagnostics HairCheck-DT (PCP).

Based on the design and performance test results, the Omega assay is substantially equivalent to the Quest Diagnostic HairCheck-DT (PCP).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Omega Laboratories, Inc.
c/o Mr. Robert J Bard JD
Managing Director
PO Box 506
South Lyon, Michigan 48178

JUL 12 2010

Re: k101059
Trade Name: Omega Laboratories Hair Drug Screening Assay for Phencyclidine
Regulation Number: Unclassified
Regulatory Class: Class II
Product Codes: LCM
Dated: April 11, 2010
Received: April 15, 2010

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k): K101059

Device Name: Omega Laboratories Hair Drug Screening Assay Phencyclidine (PCP)

Indication 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 Systems Corp (IDS) One-Step enzyme linked immunosorbent 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.

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Prescription Use _____	And/Or	Over the Counter Use __X__
(21 CFR Part 801 Subpart D)		(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 Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101059