DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 28, 2015

OMEGA LABORATORIES, INC.
ROBERT BARD
MANAGING DIRECTOR
400 N. CLEVELAND AVE.
MOGADORE OH 44260

Re: K142855
Trade/Device Name: Omega Laboratories Hair Drug Screening Assay Methamphetamine (Meth) and 3, 4—Methylenedioxymethamphetamine (MDMA)
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine test system
Regulatory Class: II
Product Code: DKZ
Dated: July 01, 2015
Received: July 13, 2015

Dear Robert Bard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k142855

Device Name
Omega Laboratories Hair Drug Screening Assay for Methamphetamine (Meth) and 3,4-Methylenedioxymethamphetamine (MDMA)

Indications for Use *(Describe)*

The Omega Laboratories Hair Drug Screening Assay for Methamphetamine (Meth) and 3,4-Methylenedioxymethamphetamine (MDMA) is an in vitro diagnostic test that is intended for the qualitative detection of Methamphetamine (calibrated with Methamphetamine) and MDMA (calibrated with MDMA) at or above 500 pg/mg in human head and body hair. To confirm a screen positive result, a more specific alternate chemical method, such as Gas Chromatography/Mass Spectrometry (GC/MS) operating in the selected ion monitoring (SIM) mode with deuterated internal standards is the preferred method. Professional judgment should be applied to any drug of abuse test result, particularly when presumptive positive results are obtained.

This test is intended exclusively for single laboratory use only and is not intended for sale to anyone.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

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

510(k) Number: K142855

Date of Summary: July 27, 2015

Applicant:

William R. Corl
Chief Executive Officer

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Correspondent:

Name: ROBERT J BARD, JD, CQE, RAC

Address: Omega Laboratories
400 North Cleveland, Mogadore, OH 44260

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E-mail rbard@reglaw.net

Product Name:

Trade Name: Omega Laboratories Hair Drug Screening Assay Methamphetamine_3, 4-methylenedioxymethamphetamine (Meth_MDMA)

Common Name: Hair Drug Screening Assay Methamphetamine

Regulation Number: CFR 862.3610 (ProCode DKZ)

Classification Name: Methamphetamine Test System

Classification Panel: 91 (Toxicology)

Predicate Device: Omega Laboratories Hair Drug Screening Assay Methamphetamine_3, 4-methylenedioxymethamphetamine (Meth_MDMA) k101973 with the addition of the body hair as an assay matri.;

Product Description: The Omega Laboratories Hair Drug Screening Assays for Methamphetamine_3,4-methylenedioxymethamphetamine (Meth_MDMA) is a test system using ELISA reagents and micro-plate reader for the qualitative detection of Methamphetamine and 3,4-Methylenedioxymethamphetamine (MDMA) in head and body hair samples at or above 500 pg/mg.

Indication for Use: The Omega Laboratories Hair Drug Screening Assay for Methamphetamine (Meth) and 3,4-Methylenedioxymethamphetamine (MDMA) is an in vitro diagnostic test that is intended for the qualitative detection of Methamphetamine (calibrated with Methamphetamine) and MDMA (calibrated with MDMA) at or above 500 pg/mg in human head

and body hair. To confirm a screen positive result, a more specific alternate chemical method, such as Gas Chromatography/Mass Spectrometry (GC/MS) operating in the selected ion monitoring (SIM) mode with deuterated internal standards is the preferred method. Professional judgment should be applied to any drug of abuse test result, particularly when presumptive positive results are obtained.

This test is intended exclusively for single laboratory use only and is not intended for sale to anyone.

Comparison:

All performance studies demonstrated that the Omega assay is in substantial agreement with the predicate products.

Results obtained from donor specimens showed that the qualitative results from the new assays are substantially equivalent to those obtained from the predicate devices.

Table 1: Comparison of Omega Hair Drug Screening Assay for Meth and MDMA

Comparison Element - Similarities	Omega Laboratories Hair Drug Screening Assay Methamphetamine_3, 4-methylenedioxymethamphetamine (Meth_MDMA) (Subject devices)	Omega Laboratories Hair Drug Screening Assay Methamphetamine_3, 4-methylenedioxymethamphetamine (Meth_MDMA) (Predicate device k101973)
Laboratory	Omega Laboratories, Inc.	Same.
Indication for/ Intended Use	The Omega Laboratories Hair Drug Screening Assay for Methamphetamine (Meth) and 3,4-Methylenedioxymethamphetamine (MDMA) is an in vitro diagnostic test that is intended for the qualitative detection of Methamphetamine (calibrated with Methamphetamine) and MDMA (calibrated with MDMA) at or above 500 pg/mg in human head and body hair. To confirm a screen positive result, a more specific alternate chemical method, such as Gas Chromatography/Mass Spectrometry (GC/MS) operating in the selected ion monitoring (SIM) mode with deuterated internal standards is the preferred method. Professional judgment should be applied to any drug of abuse test result, particularly when presumptive positive results are obtained. This test is intended exclusively for single laboratory use only and is not intended for sale to anyone.	The Omega Laboratories Hair Drug Screening Assay Methamphetamine and ,4- Methylenedioxymethamphetamine (MDMA) is a laboratory developed test that is intended to be used for the determination of the presence of Methamphetamine and 3,4-Methylenedioxymethamphetamine (MDMA) in human hair from the crown of the head. The Omega Laboratories Hair Drug Screening Assay (Meth -MDMA) utilizes International Diagnostics Systems Corp One-Step Methamphetamine ELISA for Hair Testing Kit for the qualitative detection of Methamphetamine and MDMA at or above 500 pg/mg of hair for the purpose of identifying the use of Methamphetamine and MDMA. D-Methamphetamine is used as the standard for the assay. 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

Table 1: Comparison of Omega Hair Drug Screening Assay for Meth and MDMA

Comparison Element - Similarities	Omega Laboratories Hair Drug Screening Assay Methamphetamine_3, 4-methylenedioxymethamphetamine (Meth_MDMA) (Subject devices)	Omega Laboratories Hair Drug Screening Assay Methamphetamine_3, 4-methylenedioxymethamphetamine (Meth_MDMA) (Predicate device k101973)
		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.
Method of Measurement	Microplate reader. Read at 450 nm	Same.
Matrix	Head and body hair	Head hair
Cutoff concentration	500 pg /mg hair for both Methamphetamine and MDMA	Same
Assay Principal	ELISA	Same.
Extraction Method	Utilized acid-methanol vs methanol alone to facilitate extraction of drug from hair. Proprietary and patent pending method of pulverizing hair vs cutting the hair into small segments prior to acid-methanol extraction. This improved extraction times without loss of efficiency	Same.

Performance Studies

PRECISION:

Intra-assay precision studies were performed using 11 replicates of negative head hair samples spiked to the following concentrations of Methamphetamine or MDMA: zero drug, -75%, -50%, -25% below the cutoff, and +25%, +50%, +75% and+100% above the cutoff. All samples were treated and analyzed in the same manner as donor hair samples and measured in one run. The results of this study are summarized in the Tables 2a and 2b below.

Table 2a: Intra-Assay Methamphetamine Precision Studies (CO=500 pg/mg head hair)

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

Table 2b: Intra-Assay MDMA Precision Studies (CO=500 pg/mg head hair)

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

Inter-assay precision studies were performed using negative head hair samples spiked to the following concentrations of Methamphetamine and MDMA: zero drug, -75%, -50%, -25% below the cutoff, and +25%, +50%, +75% and+100% above the cutoff. All samples were treated and analyzed in the same manner as donor hair samples. Eleven replicates of these were prepared and analyzed over 20 non-consecutive days for methamphetamine and 10 non-consecutive days for MDMA.

The results of this study are summarized in Tables 3a – 3b below. For the MDMA precision studies, 96 out of the 110 replicates of the -25% solution were positive. This is due to the 166% cross-reactivity of MDMA.

Table 3a: Inter-Assay Methamphetamine Precision Studies (CO=500 pg/mg head hair)

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

Table 3b: Inter-Assay MDMA Precision Studies (CO=500 pg/mg head hair)

Drug	Target Concentration pg/mg (%)	Number of Replicates	Results # Negative	Results # Positive
MDMA	0	110	110	0
MDMA	125 (-75%)	110	110	0
MDMA	250 (-50%)	110	110	0
MDMA	375 (-25%)	110	14	96
MDMA	625 (+25%)	110	0	110
MDMA	750 (+50%)	110	0	110
MDMA	875 (+75%)	110	0	110
MDMA	1000 (+100%)	110	0	110

Conclusion

Evaluation of the precision of the Omega Laboratories, Inc. ELISA Methamphetamine_3, 4-methylenedioxymethamphetamine (Meth_MDMA) Screening Protocol using this study design demonstrated that the intra and inter-assay precision using spiked samples was acceptable (%CV of 10% or less).

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

MDMA samples at a level of 375 pg/mg were positive at the 500 pg/mg methamphetamine cutoff level due the significant cross-reactivity of MDMA. Quantitative GC/MS confirmation is performed on all presumptive positive screening results.

AGREEMENT STUDIES:

A total of 836 head hair samples were tested of which some were positive for both MDMA and Methamphetamine. A total of 138 donor body hair samples were tested (69 Methamphetamine and 69 MDMA)."

The results are listed in Tables 4a-4d below.

Tables 4a – 4b summarize the combined Agreement Studies (head hair and body hair) with results for both Methamphetamine (Table 4a) and MDMA (Table 4b).

Table 4a: Combined Methamphetamine Summary of Agreement Studies Results (n=739) Head and Body Hair

ELISA Methamphetamine Test Result	Negative by GC/MS	Less than half of 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	3	29	47	472
Negative	142	25	20	0	1

Table 4b: Combined MDMA Summary of Agreement Studies Results (n=418) Head and Body Hair

ELISA Methamphetamine Test Result	Negative by GC/MS	Less than half of 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	0	8	260
Negative	142	0	5	2	1

Tables 4c – 4d summarize the discordant results for the combined Studies. Each drug (Meth and MDMA) is broken out to a separate table. All Discordant results are consistent with drug cutoff value of 500 pg/mg. Negative ELISA Discordant results are reported for assays that have GC/MS results of 500 pg/mg or greater. Similarly, Positive ELISA Discordant results are reported for assays that have GC/MS results that are less than 500 pg/mg. The discordant results were found in the head hair samples only.

Table 4c: Methamphetamine GC/MS Summary of Discordant Results

Screening Cutoff (pg/mg)	ELISA Test Result (POS/NEG)	GC/MS Cutoff (pg/mg)	Methamphetamine GC/MS Drug Result (pg/mg)
500	POS	500	Meth 159
500	POS	500	Meth 184
500	POS	500	Meth 248

Table 4c: Methamphetamine GC/MS Summary of Discordant Results

Screening Cutoff (pg/mg)	ELISA Test Result (POS/NEG)	GC/MS Cutoff (pg/mg)	Methamphetamine GC/MS Drug Result (pg/mg)
500	POS	500	Meth 269
500	POS	500	Meth 292
500	POS	500	Meth 296
500	POS	500	Meth 337
500	POS	500	Meth 359
500	POS	500	Meth 367
500	POS	500	Meth 369
500	POS	500	Meth 372
500	POS	500	Meth 373
500	POS	500	Meth 380
500	POS	500	Meth 380
500	POS	500	Meth 390
500	POS	500	Meth 392
500	POS	500	Meth 394
500	POS	500	Meth 397
500	POS	500	Meth 400
500	POS	500	Meth 407
500	POS	500	Meth 413
500	POS	500	Meth 426
500	POS	500	Meth 430
500	POS	500	Meth 440
500	POS	500	Meth 442
500	POS	500	Meth 448
500	POS	500	Meth 470
500	POS	500	Meth 472
500	POS	500	Meth 478
500	POS	500	Meth 480
500	POS	500	Meth 480
500	POS	500	Meth 499
500	NEG	500	Meth 778

Table 4d: MDMA GC/MS Summary of Discordant Results

Screening Cutoff (pg/mg)	ELISA Test Result (POS/NEG)	GC/MS Cutoff (pg/mg)	MDMA GC/MS Drug Result (pg/mg)
500	NEG	500	557
500	NEG	500	563
500	NEG	500	778

Conclusion

Based on the data presented, the effectiveness of the entire process (including the ELISA plates, reagents, and equipment) utilized by the Omega Laboratories, Inc. ELISA Meth_MDMA Screening Protocol has been demonstrated to meet the Acceptance Criteria for differentiating between specimens which are negative or positive for Methamphetamine and/or MDMA at a cut-off level of 500 pg/mg for head and body hair.

Because the Omega Meth_MDMA hair assay reports historical use of drugs and is not intended to be used for application where the results are to be used for contemporaneous drug use-treatment of any disease or condition, there is no issue of safety. The results of the Agreement studies support the effectiveness of the assay for both head and body hair.

Note: All presumptive positive results from a Screening Assay must be confirmed using the recommended method of a GC/MS.

CROSSREACTIVITY:

The Cross-reactivity study was designed to evaluate the specificity of the Omega Laboratories, Inc. ELISA Screening Protocol and the possible effect of interfering compounds.

Cross reactivity with Structurally Similar Compounds:

The specificity of the Methamphetamine ELISA was determined by the generation of inhibition curves for each of compounds listed in Table 5a and 5b. Serial dilutions of each control compound were prepared in negative hair matrix extract. The concentration of the structurally related compound that gave a similar absorbance to the 500pg/mg S(+)methamphetamine Cutoff Control (CO) response was determined and the percent cross reactivity calculated. The percent cross reactivity was calculated by dividing the concentration of the Methamphetamine CO by the extrapolated concentration of the structurally similar compound and then multiplying by 100.

Table 5a. Cross-reactivity of Methamphetamine ELISA with Structurally Similar Compounds (Methamphetamine spike) Head Hair

Compound	Approximate Concentration of Compound (pg/mg) Equivalent to 500 pg/mg S(+)Methamphetamine Cutoff Control (n=3)	Percent Cross reactivity (%)
para-Methoxy-N-methylamphetamine (PMMA)	175	285.7

Table 5a. Cross-reactivity of Methamphetamine ELISA with Structurally Similar Compounds (Methamphetamine spike) Head Hair

Compound	Approximate Concentration of Compound (pg/mg) Equivalent to 500 pg/mg S(+)Methamphetamine Cutoff Control (n=3)	Percent Cross reactivity (%)
(+/-) 3,4-Methylenedioxymethampheta-mine ((+/-) MDMA)	300	166.7
S (+) Methamphetamine	500	100.0
p-Hydroxymethamphetamine	700	71.4
(+/-)1,3-Benzodioxolyl-N-methylbutanamine ((+/-) MBDB)	1000	50.0
(+/-)4-methylenedioxy-N-ethyl-amphetamine ((+/-) MDEA)	2500	20.0
Mephentermine	5500	9.1
(+/-) 4-Hydroxyephedrine	8500	5.9
(+/-) 4-hydroxy-3-methoxymethamphetamine ((+/-) HMMA)	17500	2.9
1R,2S (-) Ephedrine	17500	2.9
(-) Methamphetamine	22500	2.2
para-Methoxyamphetamine, or 4-methoxyamphetamine (PMA)	25000	2.0
(+/-) 3,4-Methylenedioxyamphetamine ((+/-) MDA)	40000	1.3
Fenfluramine	50000	1.0
(+) Pseudoephedrine	50000	1.0
Methoxyphenamine	70000	0.7
(-) Amphetamine	175000	0.3
(+) Amphetamine	300000	0.2
(+/-)2,5-Dimethoxy-4-bromoamphetamine	2,000,000.0	0.03
1S,2R(+) Ephedrine	900,000.0	0.06
Phentermine	600,000.0	0.08
R(+) Methcathinone	900,000.0	0.06
R,R(-) Pseudoephedrine	1,500,000.0	0.03
Diphenhydramine	Not achieved at highest spike concentration. 400000 pg/mg	
Phenylpropanolamine	Not achieved at highest spike concentration. 400000 pg/mg	
Phendimetrazine	Not achieved at highest spike concentration. 400000 pg/mg	
Phentermine	Not achieved at highest spike concentration. 400000 pg/mg	
R (+) Cathinone	Not achieved at highest spike concentration. 400000 pg/mg	

Table 5a. Cross-reactivity of Methamphetamine ELISA with Structurally Similar Compounds (Methamphetamine spike) Head Hair

Compound	Approximate Concentration of Compound (pg/mg) Equivalent to 500 pg/mg S(+)Methamphetamine Cutoff Control (n=3)	Percent Cross reactivity (%)
Labetalol	Not achieved at highest spike concentration. 400000 pg/mg	
(-) Phenylephrine	Not achieved at highest spike concentration. 400000 pg/mg	

Table 5b. Cross-reactivity of Methamphetamine ELISA with Structurally Similar Compounds (MDMA spiked)

Compound	Approximate Concentration of Compound (pg/mg) Equivalent to 500 pg/mg (+/-) MDMA Cutoff Control (n=3)	Percent Cross-reactivity (%)
para-Methoxy-N-methylamphetamine (PMMA)	200	250
(+/-) 3,4-Methylenedioxymethampheta-mine ((+/-) MDMA)	500	100
S (+) Methamphetamine	950	52.6
(+/-)1,3-Benzodioxolyl-N-methylbutanamine ((+/-) MBDB)	1500	33.3
p-Hydroxymethamphetamine	1500	33.3
(+/-)4-methylenedioxy-N-ethyl-amphetamine ((+/-) MDEA)	3000	16.7
Mephentermine	7500	6.7
(+/-) 4-Hydroxyephedrine	10000	5
1R,2S (-) Ephedrine	15000	3.3
(-) Methamphetamine	20000	2.5
(+/-) 4-hydroxy-3-methoxymethamphetamine ((+/-) HMMA)	25000	2
para-Methoxyamphetamine, or 4-methoxyamphetamine (PMA)	35000	1.4
(+/-) 3,4-Methylenedioxyamphetamine ((+/-) MDA)	65000	0.8
Fenfluramine	85000	0.6
(+) Pseudoephedrine	90000	0.6
Methoxyphenamine	150000	0.3
(-) Amphetamine	250000	0.2
(+/-)2,5-Dimethoxy-4-bromoamphetamine	2,000,000.0	0.03
1S,2R(+) Ephedrine	900,000.0	0.06

Table 5a. Cross-reactivity of Methamphetamine ELISA with Structurally Similar Compounds (Methamphetamine spike) Head Hair

Compound	Approximate Concentration of Compound (pg/mg) Equivalent to 500 pg/mg S(+)Methamphetamine Cutoff Control (n=3)	Percent Cross reactivity (%)
Phentermine	600,000.0	0.08
R(+) Methcathinone	900,000.0	0.06
R,R(-) Pseudoephedrine	1,500,000.0	0.03
1S,2R (+) Ephedrine	Not achieved at highest spike concentration. 40000 pg/mg	
(+) Amphetamine	Not achieved at highest spike concentration. 400000 pg/mg	
Diphenhydramine	Not achieved at highest spike concentration. 400000 pg/mg	
Phenylpropanolamine	Not achieved at highest spike concentration. 400000 pg/mg	
R,R (-) Pseudoephedrine	Not achieved at highest spike concentration. 400000 pg/mg	
Phendimetrazine	Not achieved at highest spike concentration. 400000 pg/mg	
R (+) Cathinone	Not achieved at highest spike concentration. 400000 pg/mg	
Labetalol	Not achieved at highest spike concentration. 400000 pg/mg	
(-) Phenylephrine	Not achieved at highest spike concentration. 400000 pg/mg	

In the original Cross-reactivity study, several structurally similar compounds, including R (-) Amphetamine, (-) Methamphetamine, (+) Amphetamine, (+) Pseudoephedrine, (+/-) 2, 5-Dimethoxy-4-Bromoamphetamine, (+/-) MBDB, (+/-) MDA, (+/-) MDEA, 1R, 2S (-) Ephedrine, 1S, 2R (+) Ephedrine, Fenfluramine, (+/-) HMMA, (+/-) 4-Hydroxyephedrine, Mephentermine, Methoxyphenamine, Phentermine, PMA, R (+) Methcathinone, and R, R (-)-Pseudoephedrine, we observed positive test results at -50% of the cut off drug concentration. However, some of these compounds (e.g., (+/-) 2, 5-Dimethoxy-4-Bromoamphetamine , 1S, 2R (+) Ephedrine, Phentermine, R (+) Methcathinone , and R, R (-)-Pseudoephedrine) did not cross react with the assay in it cross reactivity study as a result additional testing was conducted. To better under the observed cross-reactivity of the above identified compounds, the concentration ranges were extended to generate new CR data that could not be seen in the original reported data. The additional test results have been incorporated into the Tables 2a and 2b.

Meth/MDMA cross-reactivity extended testing included (+/-) 2,5-Dimethoxy-4-bromoamphetamine, 1S,2R (+) Ephedrine, Phentermine, R(+) Methcathinone, R,R (-) Pseudoephedrine. The highest concentration tested was 2000000 pg/mg. With the extremely high concentrations, some cross-reactivity was now observable.

The interference tests were also rerun at -50% of cutoffs. There was good correlation with the previous dataset. The calculated equivalents based on the CR curve resulted in a calculated equivalent concentration close to the assay cutoff.

Effect of Interfering Compounds:

A variety of structurally related and unrelated compounds were tested for interference at 10000ng/ml (400000pg/mg) in the Methamphetamine ELISA. Negative hair extracts were spiked with S(+)Methamphetamine at -50% (250pg/mg), +125% (625pg/mg) and +150% (750pg/mg) of the S(+)Methamphetamine Cutoff Concentration (500pg/mg). These were then additionally spiked with 10000ng/ml (400000pg/mg) of the structurally related and unrelated compounds unless otherwise noted. The absorbances were compared to the 500 pg/mg S(+)Methamphetamine Cutoff control (CO). Only compounds that were structurally cross-reactive (Table 6a) interfered in the assay. These structurally related compounds produced a positive response due to significant cross-reactivity. Compounds tested that were not structurally cross-reactive did not interfere with the assay at any of the tested concentrations (Table 6b). No tested samples produced a negative result when expected to be positive. The analysis was performed in triplicate.

Table 6a. Interferences of Structurally Related and Unrelated Compounds on Methamphetamine ELISA (Methamphetamine spike)

Compound (shaded compounds are structurally related)	Concentration of compound ng/ml	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
(-) 11-nor-9-carboxy-delta8-Tetrahydrocannabinol	10000	NEG	POS	POS
(-) 11-nor-9-carboxy-delta9-Tetrahydrocannabinol	10000	NEG	POS	POS
R (-) Amphetamine	10000	POS	POS	POS
(-) Cotinine	10000	NEG	POS	POS
(-) Cotinine-N-oxide	10000	NEG	POS	POS
(-) Isoproterenol	10000	NEG	POS	POS
(-) Methamphetamine	10000	POS	POS	POS
(-) Nicotine	10000	NEG	POS	POS
(-) Phenylephrine	10000	NEG	POS	POS
(-)-Alpha-methadol	10000	NEG	POS	POS
(+) Amphetamine	10000	POS	POS	POS
(+) Isoproterenol	10000	NEG	POS	POS
(+) Methamphetamine	10000	POS	POS	POS
(+) Pseudoephedrine	10000	POS	POS	POS
(+/-) 11-nor-9-carboxy-delta9-Tetrahydrocannabinol	10000	NEG	POS	POS
(+/-) 2,5-Dimethoxy- 4-bromoamphetamine	10000	POS	POS	POS
(+/-) Alphaprodine	10000	NEG	POS	POS
(+/-) Ketamine	10000	NEG	POS	POS
(+/-)1,3-Benzodioxolyl-N-methylbutanamine ((+/-) MBDB)	10000	POS	POS	POS

Table 6a. Interferences of Structurally Related and Unrelated Compounds on Methamphetamine ELISA (Methamphetamine spike)

Compound (shaded compounds are structurally related)	Concentration of compound ng/ml	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
(+/-) 3,4-Methylenedioxyamphetamine ((+/-) MDA)	10000	POS	POS	POS
(+/-)4-methylenedioxy-N-ethyl-amphetamine ((+/-) MDEA)	10000	POS	POS	POS
(+/-) 3,4-Methylenedioxymethampheta-mine ((+/-) MDMA)	10000	POS	POS	POS
(+/-) Metanephrine	10000	NEG	POS	POS
(+/-) Metoprolol	10000	NEG	POS	POS
(+/-) Norcotinine	10000	NEG	POS	POS
(+/-) Propanolol	10000	NEG	POS	POS
(+/-) Trans-3'-Hydroxycotinine	10000	NEG	POS	POS
11-Hydroxy-delta9-Tetrahydrocannabinol	10000	NEG	POS	POS
19-Nortestosterone (Nandrolone)	10000	NEG	POS	POS
1R,2S (-) Ephedrine	10000	POS	POS	POS
1S,2R (+) Ephedrine	10000	POS	POS	POS
2-Oxo-3-hydroxy-LSD	10000	NEG	POS	POS
3-Methoxynaltrexone	10000	NEG	POS	POS
3-Trans-Hydroxy-norcotinine	10000	NEG	POS	POS
4-Acetoamidophenol	10000	NEG	POS	POS
4-Hydroxy-Phencyclidine	10000	NEG	POS	POS
5,5-Diphenylhydantoin	10000	NEG	POS	POS
6-Acetyl-codeine	10000	NEG	POS	POS
6-Monoacetylmorphine	10000	NEG	POS	POS
7-Aminoclonazepam	10000	NEG	POS	POS
7-Aminonitrazepam	10000	NEG	POS	POS
Acebutolol	10000	NEG	POS	POS
Acetophenetidin	10000	NEG	POS	POS
Acetopromazine	10000	NEG	POS	POS
Acetylsalicyclic acid	10000	NEG	POS	POS
Alfentanil	10000	NEG	POS	POS
Alpha-Ergocryptine	10000	NEG	POS	POS
Alprazolam	10000	NEG	POS	POS
7-Aminoflunitrazepam	10000	NEG	POS	POS
Aminorex	10000	NEG	POS	POS
Amitriptyline	10000	NEG	POS	POS

Table 6a. Interferences of Structurally Related and Unrelated Compounds on Methamphetamine ELISA (Methamphetamine spike)

Compound (shaded compounds are structurally related)	Concentration of compound ng/ml	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Amobarbital	10000	NEG	POS	POS
Amoxicillin	10000	NEG	POS	POS
Anhydroecgonine	10000	NEG	POS	POS
Anileridine	10000	NEG	POS	POS
Apomorphine	10000	NEG	POS	POS
Atenolol	10000	NEG	POS	POS
Azaperone	10000	NEG	POS	POS
Benzoylecgonine	10000	NEG	POS	POS
Benzoylecgonine isopropyl ester	10000	NEG	POS	POS
Betamethasone	10000	NEG	POS	POS
Boldenone	10000	NEG	POS	POS
Bumetanide	10000	NEG	POS	POS
Bupivicaine	10000	NEG	POS	POS
Buprenorphine	10000	NEG	POS	POS
Buprenorphine-glucuronide (2500ng/ml)	10000	NEG	POS	POS
Buspirone	10000	NEG	POS	POS
Butabarbital	10000	NEG	POS	POS
Butalbital	10000	NEG	POS	POS
Caffeine	10000	NEG	POS	POS
Cannabidiol	10000	NEG	POS	POS
Cannabinol	10000	NEG	POS	POS
Carbamazepine	10000	NEG	POS	POS
Carisoprodol	10000	NEG	POS	POS
Chlordiazepoxide	10000	NEG	POS	POS
Chlorpromazine	10000	NEG	POS	POS
Cimeterol	10000	NEG	POS	POS
Clenbuterol	10000	NEG	POS	POS
Clomipramine	10000	NEG	POS	POS
Clonazepam	10000	NEG	POS	POS
Clonidine	10000	NEG	POS	POS
Clozapine	10000	NEG	POS	POS
Cocaethylene	10000	NEG	POS	POS
Cocaine	10000	NEG	POS	POS
Codeine	10000	NEG	POS	POS
Corticosterone	10000	NEG	POS	POS
Cortisone	10000	NEG	POS	POS

Table 6a. Interferences of Structurally Related and Unrelated Compounds on Methamphetamine ELISA (Methamphetamine spike)

Compound (shaded compounds are structurally related)	Concentration of compound ng/ml	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Cotinine-N-beta-D-Glucuronide	10000	NEG	POS	POS
Cyclobenzaprine	10000	NEG	POS	POS
d,l-N-Desmethylvenlafaxine	10000	NEG	POS	POS
Delta8-Tetrahydrocannabinol	10000	NEG	POS	POS
Delta9-Tetrahydrocannabinol	10000	NEG	POS	POS
Deoxycorticosterone	10000	NEG	POS	POS
Desalkylflurazepam	10000	NEG	POS	POS
Desipramine	10000	NEG	POS	POS
Desmethyldoxepin (cis/trans)	10000	NEG	POS	POS
Despropionyl-fentanyl	10000	NEG	POS	POS
Dexamethasone	10000	NEG	POS	POS
Dextromethorphan	10000	NEG	POS	POS
Diazepam	10000	NEG	POS	POS
Dibucaine	10000	NEG	POS	POS
Dihydrocodeine	10000	NEG	POS	POS
Dihydroergotamine	10000	NEG	POS	POS
Dihydromorphine	10000	NEG	POS	POS
Diphenhydramine	10000	NEG	POS	POS
Diphenoxylate	10000	NEG	POS	POS
Diprenorphine	10000	NEG	POS	POS
Dothiepin (cis/trans)	10000	NEG	POS	POS
Doxepin	10000	NEG	POS	POS
Doxylamine	10000	NEG	POS	POS
Droperidol	10000	NEG	POS	POS
Ecgonine	10000	NEG	POS	POS
Ecgonine methyl ester	10000	NEG	POS	POS
Ethylidine Dimethyl Diphenyl Pyrrolidine (Metabolite of Methadone) (EDDP)	10000	NEG	POS	POS
Effexor (Venlafaxine)	10000	NEG	POS	POS
2-Ethyl-5-methyl-3,3-diphenylpyrroline (EMDP)	10000	NEG	POS	POS
Ergonovine	10000	NEG	POS	POS
Erythromycin	10000	NEG	POS	POS
Estazolam	10000	NEG	POS	POS
Ethacrynic acid	10000	NEG	POS	POS
Ethopropazine	10000	NEG	POS	POS
Ethylmorphine	10000	NEG	POS	POS

Table 6a. Interferences of Structurally Related and Unrelated Compounds on Methamphetamine ELISA (Methamphetamine spike)

Compound (shaded compounds are structurally related)	Concentration of compound ng/ml	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Fenfluramine	10000	POS	POS	POS
Fentanyl	10000	NEG	POS	POS
Flumethasone	10000	NEG	POS	POS
Flunitrazepam	10000	NEG	POS	POS
Fluphenazine	10000	NEG	POS	POS
Flurazepam	10000	NEG	POS	POS
Furosemide	10000	NEG	POS	POS
Gentamicin	10000	NEG	POS	POS
Gluthimide	10000	NEG	POS	POS
Haloperidol	10000	NEG	POS	POS
Heroin	10000	NEG	POS	POS
Hexobarbital	10000	NEG	POS	POS
(+/-) 4-hydroxy-3-methoxymethamphetamine ((+/-) HMMA)	10000	POS	POS	POS
Hydrochlorothiazide	10000	NEG	POS	POS
Hydrocodone	10000	NEG	POS	POS
Hydrocortisone	10000	NEG	POS	POS
Hydromorphone	10000	NEG	POS	POS
(+/-) 4-Hydroxyephedrine	10000	POS	POS	POS
Hydroxymethamphetamine	10000	POS	POS	POS
Ibogaine	10000	NEG	POS	POS
Ibuprofen	10000	NEG	POS	POS
Imipramine	10000	NEG	POS	POS
Ketoprofen	10000	NEG	POS	POS
Levo-Alpha Acetyl Methadol (LAAM)	10000	NEG	POS	POS
Labetalol	10000	NEG	POS	POS
Levorphanol	10000	NEG	POS	POS
L-Hyoscyamine	10000	NEG	POS	POS
Lidocaine	10000	NEG	POS	POS
Lorazepam	10000	NEG	POS	POS
Lysergic acid diethylamide (LSD/ ISO Lysergic acid diethylamide –(ISO LSD)	10000	NEG	POS	POS
Lysergic acid	10000	NEG	POS	POS
Lysergol	10000	NEG	POS	POS
Maprotiline	10000	NEG	POS	POS
Meperidine	10000	NEG	POS	POS

Table 6a. Interferences of Structurally Related and Unrelated Compounds on Methamphetamine ELISA (Methamphetamine spike)

Compound (shaded compounds are structurally related)	Concentration of compound ng/ml	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Mephentermine	10000	POS	POS	POS
Mepivacaine	10000	NEG	POS	POS
Metaphit	10000	NEG	POS	POS
Metaproterenol	10000	NEG	POS	POS
Metaraminol	10000	NEG	POS	POS
Methadone	10000	NEG	POS	POS
Methohexital	10000	NEG	POS	POS
Methoxyphenamine	10000	POS	POS	POS
Methylergonovine	10000	NEG	POS	POS
Methylphenidate	10000	NEG	POS	POS
m-Hydroxybenzoylecgonine	10000	NEG	POS	POS
Mianserin	10000	NEG	POS	POS
Midazolam	10000	NEG	POS	POS
Monensin	10000	NEG	POS	POS
Morphine	10000	NEG	POS	POS
Morphine-3-betaglucuronide	10000	NEG	POS	POS
Morphine-6-betaglucuronide	10000	NEG	POS	POS
Nadolol	10000	NEG	POS	POS
Nalmefene	10000	NEG	POS	POS
Nalorphine	10000	NEG	POS	POS
Naloxone-3-beta-D-glucuronide	10000	NEG	POS	POS
Naltrexone	10000	NEG	POS	POS
Naltriben	10000	NEG	POS	POS
Naproxen	10000	NEG	POS	POS
N-Desmethylclomipramine	10000	NEG	POS	POS
N-Desmethylflunitrazepam	10000	NEG	POS	POS
N-Desmethyltramadol	10000	NEG	POS	POS
N-Desmethyltrimipramine	10000	NEG	POS	POS
Neomycin	10000	NEG	POS	POS
Nitrazepam	10000	NEG	POS	POS
Norbenzoylecgonine	10000	NEG	POS	POS
Norbuprenorphine	10000	NEG	POS	POS
Norcocaethylene	10000	NEG	POS	POS
Norcocaine	10000	NEG	POS	POS
Norcodeine	10000	NEG	POS	POS
Nordiazepam	10000	NEG	POS	POS

Table 6a. Interferences of Structurally Related and Unrelated Compounds on Methamphetamine ELISA (Methamphetamine spike)

Compound (shaded compounds are structurally related)	Concentration of compound ng/ml	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Norfentanyl	10000	NEG	POS	POS
Nor- Levo-Alpha Acetyl Methadol (Nor-LAAM)	10000	NEG	POS	POS
Nor- Lysergic acid diethylamide (Nor-LSD/Nor-ISO Lysergic acid diethylamide –(Nor-ISO LSD)	10000	NEG	POS	POS
Normeperidine	10000	NEG	POS	POS
Normeperidinic acid	10000	NEG	POS	POS
Normorphine	10000	NEG	POS	POS
Noroxycodone	10000	NEG	POS	POS
Noroxymorphone	10000	NEG	POS	POS
Norpropoxyphene	10000	NEG	POS	POS
Nortriptyline	10000	NEG	POS	POS
Noscapine	10000	NEG	POS	POS
O-Desmethyltramadol	10000	NEG	POS	POS
Oxazepam	10000	NEG	POS	POS
Oxprenolol	10000	NEG	POS	POS
Oxycodone	10000	NEG	POS	POS
Oxymorphone	10000	NEG	POS	POS
p-Acetamidophenyl-beta-D-glucuronide	10000	NEG	POS	POS
Papaverine	10000	NEG	POS	POS
Pemoline	10000	NEG	POS	POS
Penicillin G	10000	NEG	POS	POS
Pentazocine	10000	NEG	POS	POS
Pentobarbital	10000	NEG	POS	POS
Perphenazine	10000	NEG	POS	POS
Phendimetrazine	10000	NEG	POS	POS
Phenelzine	10000	NEG	POS	POS
Phenobarbital	10000	NEG	POS	POS
Phenothiazine	10000	NEG	POS	POS
Phentermine	10000	POS	POS	POS
Phenylbutazone	10000	NEG	POS	POS
Phenylethyamine	10000	NEG	POS	POS
Phenylpropanolamine	10000	NEG	POS	POS
para-Methoxyamphetamine, or 4-methoxyamphetamine (PMA)	10000	POS	POS	POS

Table 6a. Interferences of Structurally Related and Unrelated Compounds on Methamphetamine ELISA (Methamphetamine spike)

Compound (shaded compounds are structurally related)	Concentration of compound ng/ml	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
para-Methoxy-N-methylamphetamine (PMMA)	10000	POS	POS	POS
Prednisolone	10000	NEG	POS	POS
Prilocaine	10000	NEG	POS	POS
Prochlorperazine	10000	NEG	POS	POS
Progesterone	10000	NEG	POS	POS
Promazine	10000	NEG	POS	POS
Promethazine	10000	NEG	POS	POS
Propiomazine	10000	NEG	POS	POS
Propionylpromazine	10000	NEG	POS	POS
Propoxyphene	10000	NEG	POS	POS
Protriptyline	10000	NEG	POS	POS
Quinidine	10000	NEG	POS	POS
R (+) Methcathinone	10000	POS	POS	POS
R (-) Epinephrine	10000	NEG	POS	POS
R (+) Cathinone	10000	NEG	POS	POS
Salbutamol	10000	NEG	POS	POS
Secobarbital	10000	NEG	POS	POS
Sertraline	10000	NEG	POS	POS
Stanazalol	10000	NEG	POS	POS
Streptomycin	10000	NEG	POS	POS
Sulfadimethoxine	10000	NEG	POS	POS
Sulfamethazine	10000	NEG	POS	POS
Sulfathiazole	10000	NEG	POS	POS
Temazepam	10000	NEG	POS	POS
Terbutaline	10000	NEG	POS	POS
Tetracycline	10000	NEG	POS	POS
Thebaine	10000	NEG	POS	POS
Theophylline	10000	NEG	POS	POS
Thioridazine	10000	NEG	POS	POS
Tramadol	10000	NEG	POS	POS
Triamcinolone	10000	NEG	POS	POS
Triazolam	10000	NEG	POS	POS
Trifluoperazine	10000	NEG	POS	POS
Trifluopromazine	10000	NEG	POS	POS
Trimeprazine	10000	NEG	POS	POS
Trimipramine	10000	NEG	POS	POS

Table 6a. Interferences of Structurally Related and Unrelated Compounds on Methamphetamine ELISA (Methamphetamine spike)

Compound (shaded compounds are structurally related)	Concentration of compound ng/ml	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Tylosin	10000	NEG	POS	POS
Tyramine	10000	NEG	POS	POS
Yohimbic acid	10000	NEG	POS	POS
Yohimbine	10000	NEG	POS	POS
Zolpidem	10000	NEG	POS	POS
Zopiclone	10000	NEG	POS	POS
Phencyclidine	10000	NEG	POS	POS
R,R (-)-Pseudoephedrine	10000	POS	POS	POS
Phencyclidine Morpholine	10000	NEG	POS	POS

A variety of structurally related and unrelated compounds were tested for interference at 10000ng/ml (400000pg/mg) unless otherwise noted in the Methamphetamine ELISA. Negative hair extracts were spiked with (±) MDMA at -50% (250pg/mg), +125% (625pg/mg) and +150% (750pg/mg) of the (±)MDMA Cutoff Concentration (500pg/mg). These were then additionally spiked with 10000ng/ml (400000pg/mg) of the structurally related and unrelated compounds unless otherwise noted. The absorbances were compared to the 500 pg/mg (±)MDMA Cutoff control (CO). Compounds that were structurally similar to (±) MDMA (Table 6b) interfered in the assay. These structurally related compounds produced a positive response due to significant cross-reactivity. The remaining compounds which were tested did not interfere with the assay at any of the tested concentrations (Table 6b) except for d,l-desmethyl-Venlafaxine which consistently produced a positive response in the -50% CO interference test at concentrations greater than 7500ng/mL(300000pg/mg). The presence of d,l-desmethyl-Venlafaxine at 10000 ng/mL (400000 pg/mg) did not produce a negative result in the +125% and +150% interference experiments. No tested samples produced a negative result when expected to be positive. The analysis was performed in triplicate.

Table 6b: Interferences of Structurally Related and Unrelated Compounds on Methamphetamine/MDMA ELISA (MDMA spike)

Compound (shaded compounds are structurally related)	Concentration of compound ng/ml	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
(-) 11-nor-9-carboxy-delta8-Tetrahydrocannabinol	1000	NEG	POS	POS
(-) 11-nor-9-carboxy-delta9-Tetrahydrocannabinol	1000	NEG	POS	POS
R (-) Amphetamine	10000	POS	POS	POS
(-) Cotinine	10000	NEG	POS	POS

Table 6b: Interferences of Structurally Related and Unrelated Compounds on Methamphetamine/MDMA ELISA (MDMA spike)

Compound (shaded compounds are structurally related)	Concentration of compound ng/ml	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
(-) Cotinine-N-oxide	10000	NEG	POS	POS
(-) Isoproterenol	10000	NEG	POS	POS
(-) Methamphetamine	10000	POS	POS	POS
(-) Nicotine	10000	NEG	POS	POS
(-) Phenylephrine	10000	NEG	POS	POS
(-)-Alpha-methadol	10000	NEG	POS	POS
(+) Amphetamine	10000	POS	POS	POS
(+) Isoproterenol	10000	NEG	POS	POS
(+) Methamphetamine	10000	POS	POS	POS
(+) Pseudoephedrine	10000	POS	POS	POS
(+/-) 11-nor-9-carboxy-delta9-Tetrahydrocannabinol	1000	NEG	POS	POS
(+/-) 2,5-Dimethoxy- 4-bromoamphetamine	10000	POS	POS	POS
(+/-) Alphaprodine	10000	NEG	POS	POS
(+/-) Ketamine	10000	NEG	POS	POS
(+/-)1,3-Benzodioxolyl-N-methylbutanamine (MBDB)	10000	POS	POS	POS
(+/-) 3,4-Methylenedioxyamphetamine ((+/-) MDA)	10000	POS	POS	POS
(+/-)4-methylenedioxy-N-ethyl-amphetamine ((+/-) MDEA)	10000	POS	POS	POS
(+/-) 3,4-Methylenedioxymethampheta-mine ((+/-)MDMA)	10000	POS	POS	POS
(+/-) Metanephrine	10000	NEG	POS	POS
(+/-) Metoprolol	10000	NEG	POS	POS
(+/-) Norcotinine	10000	NEG	POS	POS
(+/-) Propanolol	10000	NEG	POS	POS

Table 6b: Interferences of Structurally Related and Unrelated Compounds on Methamphetamine/MDMA ELISA (MDMA spike)

Compound (shaded compounds are structurally related)	Concentration of compound ng/ml	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
(+/-) Trans-3'-Hydroxycotinine	10000	NEG	POS	POS
11-Hydroxy-delta9-Tetrahydrocannabinol	1000	NEG	POS	POS
19-Nortestosterone (Nandrolone)	10000	NEG	POS	POS
1R,2S (-) Ephedrine	10000	POS	POS	POS
1S,2R (+) Ephedrine	10000	POS	POS	POS
2-Oxo-3-hydroxy-LSD	1000	NEG	POS	POS
3-Methoxynaltrexone	10000	NEG	POS	POS
3-Trans-Hydroxy-norcotinine	10000	NEG	POS	POS
4-Acetoamidophenol	10000	NEG	POS	POS
4-Hydroxy-Phencyclidine	10000	NEG	POS	POS
5,5-Diphenylhydantoin	10000	NEG	POS	POS
6-Acetyl-codeine	10000	NEG	POS	POS
6-Monoacetylmorphine	1000	NEG	POS	POS
7-Aminoclonazepam	1000	NEG	POS	POS
7-Aminonitrazepam	1000	NEG	POS	POS
Acebutolol	10000	NEG	POS	POS
Acetophenetidin	10000	NEG	POS	POS
Acetopromazine	10000	NEG	POS	POS
Acetylsalicyclic acid	10000	NEG	POS	POS
Alfentanil	10000	NEG	POS	POS
Alpha-Ergocryptine	10000	NEG	POS	POS
Alprazolam	10000	NEG	POS	POS
7-Aminoflunitrazepam	1000	NEG	POS	POS
Aminorex	10000	NEG	POS	POS

Table 6b: Interferences of Structurally Related and Unrelated Compounds on Methamphetamine/MDMA ELISA (MDMA spike)

Compound (shaded compounds are structurally related)	Concentration of compound ng/ml	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Amitriptyline	10000	NEG	POS	POS
Amobarbital	10000	NEG	POS	POS
Amoxicillin	10000	NEG	POS	POS
Anhydroecgonine	10000	NEG	POS	POS
Anileridine	10000	NEG	POS	POS
Apomorphine	10000	NEG	POS	POS
Atenolol	10000	NEG	POS	POS
Azaperone	10000	NEG	POS	POS
Benzoylecgonine	10000	NEG	POS	POS
Benzoylecgonine isopropyl ester	10000	NEG	POS	POS
Betamethasone	10000	NEG	POS	POS
Boldenone	10000	NEG	POS	POS
Bumetanide	10000	NEG	POS	POS
Bupivicaine	10000	NEG	POS	POS
Buprenorphine	1000	NEG	POS	POS
Buprenorphine-glucuronide	2500	NEG	POS	POS
Buspirone	10000	NEG	POS	POS
Butabarbital	10000	NEG	POS	POS
Butalbital	10000	NEG	POS	POS
Caffeine	10000	NEG	POS	POS
Cannabidiol	10000	NEG	POS	POS
Cannabinol	10000	NEG	POS	POS
Carbamazepine	10000	NEG	POS	POS
Carisoprodol	10000	NEG	POS	POS

Table 6b: Interferences of Structurally Related and Unrelated Compounds on Methamphetamine/MDMA ELISA (MDMA spike)

Compound (shaded compounds are structurally related)	Concentration of compound ng/ml	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Chlordiazepoxide	10000	NEG	POS	POS
Chlorpromazine	10000	NEG	POS	POS
Cimeterol	10000	NEG	POS	POS
Clenbuterol	10000	NEG	POS	POS
Clomipramine	10000	NEG	POS	POS
Clonazepam	10000	NEG	POS	POS
Clonidine	10000	NEG	POS	POS
Clozapine	10000	NEG	POS	POS
Cocaethylene	10000	NEG	POS	POS
Cocaine	10000	NEG	POS	POS
Codeine	10000	NEG	POS	POS
Corticosterone	10000	NEG	POS	POS
Cortisone	10000	NEG	POS	POS
Cotinine-N-beta-D-Glucuronide	10000	NEG	POS	POS
Cyclobenzaprine	10000	NEG	POS	POS
d,l-N-Desmethylvenlafaxine	10000	POS	POS	POS
d,l-N-Desmethylvenlafaxine	7500	NEG	Not Tested	Not Tested
Delta8-Tetrahydrocannabinol	10000	NEG	POS	POS
Delta9-Tetrahydrocannabinol	10000	NEG	POS	POS
Deoxycorticosterone	10000	NEG	POS	POS
Desalkylflurazepam	10000	NEG	POS	POS
Desipramine	10000	NEG	POS	POS
Desmethyldoxepin (cis/trans)	10000	NEG	POS	POS
Despropionyl-fentanyl	1000	NEG	POS	POS

Table 6b: Interferences of Structurally Related and Unrelated Compounds on Methamphetamine/MDMA ELISA (MDMA spike)

Compound (shaded compounds are structurally related)	Concentration of compound ng/ml	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Dexamethasone	10000	NEG	POS	POS
Dextromethorphan	10000	NEG	POS	POS
Diazepam	10000	NEG	POS	POS
Dibucaine	10000	NEG	POS	POS
Dihydrocodeine	10000	NEG	POS	POS
Dihydroergotamine	10000	NEG	POS	POS
Dihydromorphine	10000	NEG	POS	POS
Diphenhydramine	10000	NEG	POS	POS
Diphenoxylate	10000	NEG	POS	POS
Diprenorphine	10000	NEG	POS	POS
Dothiepin (cis/trans)	10000	NEG	POS	POS
Doxepin	10000	NEG	POS	POS
Doxylamine	10000	NEG	POS	POS
Droperidol	10000	NEG	POS	POS
Ecgonine	10000	NEG	POS	POS
Ecgonine methyl ester	10000	NEG	POS	POS
Ethylidine Dimethyl Diphenyl Pyrrolidine (Metabolite of Methadone) (EDDP)	10000	NEG	POS	POS
Effexor (Venlafaxine)	10000	NEG	POS	POS
2-Ethyl-5-methyl-3,3-diphenylpyrroline (EMDP)	10000	NEG	POS	POS
Ergonovine	10000	NEG	POS	POS
Erythromycin	10000	NEG	POS	POS
Estazolam	10000	NEG	POS	POS
Ethacrynic acid	10000	NEG	POS	POS

Table 6b: Interferences of Structurally Related and Unrelated Compounds on Methamphetamine/MDMA ELISA (MDMA spike)

Compound (shaded compounds are structurally related)	Concentration of compound ng/ml	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Ethopropazine	10000	NEG	POS	POS
Ethylmorphine	10000	NEG	POS	POS
Fenfluramine	10000	POS	POS	POS
Fentanyl	1000	NEG	POS	POS
Flumethasone	10000	NEG	POS	POS
Flunitrazepam	10000	NEG	POS	POS
Fluphenazine	10000	NEG	POS	POS
Flurazepam	10000	NEG	POS	POS
Furosemide	10000	NEG	POS	POS
Gentamicin	10000	NEG	POS	POS
Gluthimide	10000	NEG	POS	POS
Haloperidol	10000	NEG	POS	POS
Heroin	10000	NEG	POS	POS
Hexobarbital	10000	NEG	POS	POS
(+/-) 4-hydroxy-3-methoxymethamphetamine ((+/-) HMMA)	10000	POS	POS	POS
Hydrochlorothiazide	10000	NEG	POS	POS
Hydrocodone	10000	NEG	POS	POS
Hydrocortisone	10000	NEG	POS	POS
Hydromorphone	10000	NEG	POS	POS
(+/-) 4-Hydroxyephedrine	10000	POS	POS	POS
Hydroxymethamphetamine	10000	POS	POS	POS
Ibogaine	10000	NEG	POS	POS
Ibuprofen	10000	NEG	POS	POS

Table 6b: Interferences of Structurally Related and Unrelated Compounds on Methamphetamine/MDMA ELISA (MDMA spike)

Compound (shaded compounds are structurally related)	Concentration of compound ng/ml	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Imipramine	10000	NEG	POS	POS
Ketoprofen	10000	NEG	POS	POS
Levo-Alpha Acetyl Methadol (LAAM)	10000	NEG	POS	POS
Labetalol	10000	NEG	POS	POS
Levorphanol	10000	NEG	POS	POS
L-Hyoscyamine	10000	NEG	POS	POS
Lidocaine	10000	NEG	POS	POS
Lorazepam	10000	NEG	POS	POS
Lysergic acid diethylamide (LSD/ ISO Lysergic acid diethylamide –(ISO LSD)	10000	NEG	POS	POS
Lysergic acid	10000	NEG	POS	POS
Lysergol	10000	NEG	POS	POS
Maprotiline	10000	NEG	POS	POS
Meperidine	10000	NEG	POS	POS
Mephentermine	10000	POS	POS	POS
Mepivacaine	10000	NEG	POS	POS
Metaphit	10000	NEG	POS	POS
Metaproterenol	10000	NEG	POS	POS
Metaraminol	10000	NEG	POS	POS
Methadone	10000	NEG	POS	POS
Methohexital	10000	NEG	POS	POS
Methoxyphenamine	10000	POS	POS	POS
Methylergonovine	10000	NEG	POS	POS
Methylphenidate	10000	NEG	POS	POS

Table 6b: Interferences of Structurally Related and Unrelated Compounds on Methamphetamine/MDMA ELISA (MDMA spike)

Compound (shaded compounds are structurally related)	Concentration of compound ng/ml	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
m-Hydroxybenzoylecgonine	10000	NEG	POS	POS
Mianserin	10000	NEG	POS	POS
Midazolam	10000	NEG	POS	POS
Monensin	10000	NEG	POS	POS
Morphine (1000ng/ml)	10000	NEG	POS	POS
Morphine-3-betaglucuronide	10000	NEG	POS	POS
Morphine-6-betaglucuronide	1000	NEG	POS	POS
Nadolol	10000	NEG	POS	POS
Nalmefene	10000	NEG	POS	POS
Nalorphine	10000	NEG	POS	POS
Naloxone-3-beta-D-glucuronide	10000	NEG	POS	POS
Naltrexone	10000	NEG	POS	POS
Naltriben	10000	NEG	POS	POS
Naproxen	10000	NEG	POS	POS
N-Desmethylclomipramine	10000	NEG	POS	POS
N-Desmethylflunitrazepam	1000	NEG	POS	POS
N-Desmethyltramadol	10000	NEG	POS	POS
N-Desmethyltrimipramine	10000	NEG	POS	POS
Neomycin	10000	NEG	POS	POS
Nitrazepam	10000	NEG	POS	POS
Norbenzoylecgonine	10000	NEG	POS	POS
Norbuprenorphine (1000ng/ml)	10000	NEG	POS	POS
Norcocaethylene	10000	NEG	POS	POS

Table 6b: Interferences of Structurally Related and Unrelated Compounds on Methamphetamine/MDMA ELISA (MDMA spike)

Compound (shaded compounds are structurally related)	Concentration of compound ng/ml	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Norcocaine	10000	NEG	POS	POS
Norcodeine	10000	NEG	POS	POS
Nordiazepam	10000	NEG	POS	POS
Norfentanyl (1000ng/ml)	10000	NEG	POS	POS
Nor- Levo-Alpha Acetyl Methadol (Nor-LAAM)	1000	NEG	POS	POS
Nor- Lysergic acid diethylamide (Nor-LSD/Nor-ISO Lysergic acid diethylamide – (Nor-ISO LSD)	1000	NEG	POS	POS
Normeperidine	1000	NEG	POS	POS
Normeperidinic acid	10000	NEG	POS	POS
Normorphine	10000	NEG	POS	POS
Noroxycodone	10000	NEG	POS	POS
Noroxymorphone	1000	NEG	POS	POS
Norpropoxyphene	10000	NEG	POS	POS
Nortriptyline	10000	NEG	POS	POS
Noscapine	10000	NEG	POS	POS
O-Desmethyltramadol	10000	NEG	POS	POS
Oxazepam	10000	NEG	POS	POS
Oxprenolol	10000	NEG	POS	POS
Oxycodone	10000	NEG	POS	POS
Oxymorphone	10000	NEG	POS	POS
p-Acetamidophenyl-beta-D-glucuronide	10000	NEG	POS	POS
Papaverine	10000	NEG	POS	POS
Pemoline	10000	NEG	POS	POS

Table 6b: Interferences of Structurally Related and Unrelated Compounds on Methamphetamine/MDMA ELISA (MDMA spike)

Compound (shaded compounds are structurally related)	Concentration of compound ng/ml	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Penicillin G	10000	NEG	POS	POS
Pentazocine	10000	NEG	POS	POS
Pentobarbital	10000	NEG	POS	POS
Perphenazine	10000	NEG	POS	POS
Phendimetrazine	10000	NEG	POS	POS
Phenelzine	10000	NEG	POS	POS
Phenobarbital	10000	NEG	POS	POS
Phenothiazine	10000	NEG	POS	POS
Phentermine	10000	POS	POS	POS
Phenylbutazone	10000	NEG	POS	POS
Phenylethyamine	10000	NEG	POS	POS
Phenylpropanolamine	10000	NEG	POS	POS
para-Methoxyamphetamine, or 4-methoxyamphetamine (PMA)	10000	POS	POS	POS
para-Methoxy-N-methylamphetamine (PMMA)	10000	POS	POS	POS
Prednisolone	10000	NEG	POS	POS
Prilocaine	10000	NEG	POS	POS
Prochlorperazine	10000	NEG	POS	POS
Progesterone	10000	NEG	POS	POS
Promazine	10000	NEG	POS	POS
Promethazine	10000	NEG	POS	POS
Propiomazine	10000	NEG	POS	POS
Propionylpromazine	10000	NEG	POS	POS
Propoxyphene	10000	NEG	POS	POS

Table 6b: Interferences of Structurally Related and Unrelated Compounds on Methamphetamine/MDMA ELISA (MDMA spike)

Compound (shaded compounds are structurally related)	Concentration of compound ng/ml	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Protriptyline	10000	NEG	POS	POS
Quinidine	10000	NEG	POS	POS
R (+) Methcathinone	10000	POS	POS	POS
R (-) Epinephrine	10000	NEG	POS	POS
R (+) Cathinone	10000	NEG	POS	POS
Salbutamol	10000	NEG	POS	POS
Secobarbital	10000	NEG	POS	POS
Sertraline	10000	NEG	POS	POS
Stanazalol	10000	NEG	POS	POS
Streptomycin	10000	NEG	POS	POS
Sulfadimethoxine	10000	NEG	POS	POS
Sulfamethazine	10000	NEG	POS	POS
Sulfathiazole	10000	NEG	POS	POS
Temazepam	10000	NEG	POS	POS
Terbutaline	10000	NEG	POS	POS
Tetracycline	10000	NEG	POS	POS
Thebaine	10000	NEG	POS	POS
Theophylline	10000	NEG	POS	POS
Thioridazine	10000	NEG	POS	POS
Tramadol	10000	NEG	POS	POS
Triamcinolone	10000	NEG	POS	POS
Triazolam	10000	NEG	POS	POS
Trifluoperazine	10000	NEG	POS	POS
Trifluopromazine	10000	NEG	POS	POS

Table 6b: Interferences of Structurally Related and Unrelated Compounds on Methamphetamine/MDMA ELISA (MDMA spike)

Compound (shaded compounds are structurally related)	Concentration of compound ng/ml	-50% CO (250pg/mg)	+125% CO (625pg/mg)	+150% CO (750pg/mg)
Trimeprazine	10000	NEG	POS	POS
Trimipramine	10000	NEG	POS	POS
Tylosin	10000	NEG	POS	POS
Tyramine	10000	NEG	POS	POS
Yohimbic acid	10000	NEG	POS	POS
Yohimbine	10000	NEG	POS	POS
Zolpidem	10000	NEG	POS	POS
Zopiclone	10000	NEG	POS	POS
Phencyclidine	10000	NEG	POS	POS
R,R (-)-Pseudoephedrine	10000	POS	POS	POS
Phencyclidine Morpholine	10000	NEG	POS	POS

CALIBRATOR AND CONTROL:

The Omega Laboratories, Inc. ELISA Meth-MDMA Screening Protocols utilize in-house prepared calibrators and control solutions. The study successfully demonstrated the validation and stability of these solutions and the traceability to NIST standards.

The data demonstrating the stability of Meth-MDMA in methanol for a period of one year when stored refrigerated in an amber bottle was provide as part of K101973. The quantitative values of 512 pg/mg for methamphetamine, after a one year period is within 10% of the target value of 500 pg/mg. The study validated the one 1 year expiration date for the Calibrator Stock Solution.

STABILITY:

Hair samples were taken from the head were packaged (stored) in the Omega Collection Kit (The Hair Collection Kit consists of a poly transport bag, a small piece of foil, a small specimen pouch (envelope). The Collection Kit, containing the hair sample was previously confirmed Positive then stored for an average of 4 years.

A variety of ethnic origin, hair color and curvature were tested.

Table 7: Stability Test Samples

Description of samples	Quantity
Total samples were used in the stability study	100
Previously confirmed Positive for Methamphetamine samples (1 under cutoff of 500pg/mg)	50
previously confirmed Positive for MDMA samples (2 under cutoff of 500pg/mg)	50

Samples Testing

The samples were originally confirmed Positive for Methamphetamine or MDMA using the Omega Confirmation Protocol.

The samples were run a second time using the Omega Confirmation Protocol.

The stability of the samples when stored for an extended period of time will be deemed acceptable if the mean variation in the Methamphetamine or MDMA concentrations is less than 15%. A variance of 15% was chosen since the Uncertainty of Measurement associated with the Omega Laboratories, Inc. GC/MS Confirmation Test process is 13.6% at a 95% confidence level (see the attached Uncertainty Budget completed in accordance with ISO17025 Laboratory Accreditation).

Methamphetamine and MDMA data from this study are shown in the table below.

Table 8: Stability Study Data Summary Ranges

Test Parameter	Value or Range
Meth Stability Study Data Summary Ranges	
Range in concentration pg/mg hair (4 Years Prior)(pg/mg)	271 – 30,262
Range in concentration pg/mg hair (After)(pg/mg)	342- 34,002
Mean Change	4%
% Max and Min Decrease	-10% and -1%
% Max and Min Increase	26% and 1%
Number that increased in concentration	31
Number that decreased in concentration	29
MDMA Stability Study Data Summary Ranges	
Range in concentration pg/mg hair (3.5 Years Prior)(pg/mg)	167 – 12,107

Table 8: Stability Study Data Summary Ranges

Test Parameter	Value or Range
Range in concentration pg/mg hair (After)(pg/mg)	183 – 15,852
Mean Change	10%
% Max and Min Decrease	-7% and 0%
% Max and Min Increase	31% and 0%
Number that increased in concentration	41
Number that decreased in concentration	7
Number that had no change in concentration	2

Conclusion

This Stability Study demonstrated that the mean variance in the concentration of Methamphetamine of 4% or MDMA of 10% in hair samples when stored for an extended period of time was acceptable at less than 15%.

SHIPPING:

200 head hair samples were used in the shipping study; 49 samples previously confirmed Positive for Methamphetamine, 48 -samples previously confirmed positive for MDMA, 100 previously screened negative samples and 3 samples that were just under the cutoff. Each box contained a variety of hair color and curvature. Four separate shipping boxes each containing 25 previously screened negative samples, a minimum of 12 previously confirmed positive samples or close to cutoff were stored in a freezer at approximately -12ºC for approximately 20 hours then heated to approximately 43ºC for a period of approximately seven hours. This represented exposure to extreme temperature. The minimum and maximum temperature and humidity ranges are in Table 9 below. Each box was then shipped to a different location in the United States of America. (Portland, Maine, Anchorage, Alaska, Naples, Florida and Tempe, Arizona). The shipments were held at their respective locations for a period of at least two days then returned to Omega. The returned samples were then confirmed using GC/MS. The comparison of the results prior to shipping and after shipping is summarized below.

All hair samples were taken from the crown of the head and packaged (stored) in the Omega preferred Collection Kit (The Hair Collection Kit consists of a poly transport bag, a small piece of foil, a small specimen pouch/envelope). Collection Kits containing the hair samples were packed in a shipping box (Corrugated box 2.5”X13.5”X11.5”).

Table 9: Shipping Test Samples

Description of Samples	No.
Previously confirmed Methamphetamine Positive samples	49
Previously confirmed MDMA Positive samples	48
Previously screened Negative For Methamphetamine and MDMA samples	100
Samples that confirmed below the 500 pg/mg cutoff level For Methamphetamine	1
Samples that confirmed below the 500 pg/mg cutoff level For MDMA	2
Total Samples used in the shipping study	200

Sample shipping

Each Shipping box contained a "DataLogger" to record humidity and temperature. The DataLogger takes readings every five minutes.

The DataLogger specifications and the raw data generated are attached.

Each box contained hair samples exhibiting a variety color and curvature.

Four separate shipping boxes each containing 25 previously screened negative samples, a minimum of 12 previously confirmed positive samples or close to cutoff were stored in a freezer at approximately -12º C for approximately 20 hours then heated to approximately 43º C for a period of approximately seven hours. This represented exposure to extreme temperature.

Shipping study transport time totaled at least 5 days.

Each box was then shipped to a different location in the United States (Portland, Maine, Anchorage, Alaska, Naples, Florida and Tempe, Arizona). The shipments were held at their respective locations for at least two days and then returned to Omega.

The returned samples were then screened and quantitatively tested using GC/MS.

The minimum and maximum shipping temperature and humidity ranges are shown in Table 10 below.

Table 10 Shipping Temperatures and Humidity Ranges

DataLogger ID	Shipped to Location Then Returned to Omega Laboratories	Min Temp (ºC)	Max Temp (ºC)	Min Humidity (%RH)	Max Humidity (%RH)
7310005629	1. Portland, Maine	-12.7	44.5	10.8	100.0
7310005644	2. Anchorage, Alaska	-12.7	44.9	8.1	96.1
7310005628	3. Naples, Florida	-10.8	43.3	4.4	100.0
7310005627	4. Tempe Arizona	-12.2	42.9	8.9	73.5

Conclusion

This Shipping Study demonstrated that there is no adverse effect on hair samples when exposed to extreme temperatures and variations in humidity that might occur during sample transport. Of the 200 samples screened and confirmed then shipped and returned then screened and confirmed a second time, no samples had discordant screening results.

COSMETIC TREATMENT:

The study was designed to evaluate and document the effects of various cosmetic treatments on the Omega Laboratories, Inc. ELISA Meth_MDMA Screening Protocol

Two Cosmetic Treatment Studies were conducted.

- Study 1 was specific to Methamphetamine and reported MDMA when present.
- Study 2 was specific to MDMA and reported Methamphetamine when present.

Cosmetic Treatment. Studies 1 and 2

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

Study 1

Sixty (60) head hair specimens previously determined to be negative for Meth_MDMA by the screening assay were obtained and the ethnic origin, hair color and curvature were documented.

One hundred and sixteen (116) hair specimens potentially positive for Meth_MDMA by the screening assay were obtained and the ethnic origin, hair color and curvature were documented.

Each specimen was divided into 2 aliquots. One aliquot was analyzed by the ELISA protocol and the GC/MS confirmation method.

The second aliquots were randomly assigned to the hair treatments listed in above and the treatments were performed suggested by the manufacturers.

Treated aliquots were analyzed by the ELISA protocol and the GC/MS confirmation method.

All samples in this study were analyzed by the ELISA protocol and the GC/MS confirmation method before and after cosmetic treatments were applied.

Study 2

Sixty head hair specimens previously determined to be negative for MDMA were obtained and the ethnic origin, hair color and curvature were documented.

One hundred hair specimens potentially positive for MDMA were obtained and the ethnic origin, hair color and curvature were documented.

Each specimen was divided into 2 aliquots. One aliquot was analyzed by the ELISA protocol

The second aliquots were randomly assigned to the hair treatments listed.

Treated aliquots were analyzed by the ELISA protocol

Cosmetic Treatment Study 1 (Methamphetamine)

This effect was negligible for negative samples. The percent difference between the mean normalized absorbance values of the treated and untreated groups was less than 10% for bleaching, perms, dyes, and shampoos. The % change for the hair specimens treated with relaxers was greater at a mean of 14%. However, this only changed the overall positive/negative result for one specimen and the quantitative values before and after treatment was within the standard uncertainty range of the GC/MS confirmation assay as determined in accordance with ISO17025 Accreditation (±12.6% at a 95% confidence interval, equivalent to a range of 437- 563 pg/mg, see attached Uncertainty Budget).

Permanent treatments had the greatest effect on positive samples followed by bleaching resulting in an average decrease in methamphetamine/MDMA concentration of 14% and 11%, respectively. The mean effect of dyes, relaxers, and shampoos was 8%, 8%, and 5% respectively.

Cosmetic Treatment Study 2 (MDMA)

This effect was negligible for negative samples. The percent difference between the mean normalized absorbance values of the treated and untreated groups was 15% or less for permanent, relaxers, dyes, and shampoos. The % change for the hair specimens treated with bleach was greater at a mean of 21%. The overall positive/negative result changed for only one specimen which was due to bleach treatment.

Bleach treatments had the greatest effect on positive resulting in an average decrease in MDMA concentration of 17%. The mean effect of permanents, relaxers, dyes, and shampoos was 13%, 12%, 8%, and 5%, respectively.

The mean change for all treatments except perms, was within the standard uncertainty range of the GC/MS confirmation assay as determined in accordance with ISO17025 Accreditation (±12.6% at a 95% confidence interval).

Table 11: Summary of Effects for Positive GC/MS Confirmation Data

Treatment	Mean change in Meth concentration (pg/mg)	Mean change in MDMA concentration (pg/mg)
Permanent	-14%	-17%

Treatment	Mean change in Meth concentration (pg/mg)	Mean change in MDMA concentration (pg/mg)
Bleach	-11%	-13%
Dyeing	-8%	-12%
Relaxer	-8%	-8%
Shampoo	5%	-5%

ENVIRONMENTAL CONTAMINATION:

Two studies were performed to investigate whether confirmatory testing procedures are able to distinguish between true analytically positive samples and those that have been externally exposed to Meth -MDMA. The focus of the studies was to demonstrate that a 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 Meth - MDMA, 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. Head hair was used for this study.

Evaluating potential environmental contamination and the effectiveness of a methanol wash using this study design, all analytically negative samples tested remained negative after being subjected to Meth - MDMA by the exposure modes described followed by a single methanol wash.

Additionally, all clinically positive samples tested remain positive after the wash steps were performed.

SUMMARY CONCLUSION:

The comparison of results of the proposed assay with the confirmatory GC/MS testing of head and body hair samples showed the results to be substantially equivalent

The candidate Omega Hair Drug Screening Assay for Meth-MDMA (head and body hair) is substantially equivalent to the predicate Omega Hair Drug Screening Assay for Meth - MDMA (K101973 for head hair) based on the design and performance studies discussed in this summary. Supporting Performance Testing presented for review in this document, includes agreement, precision, specificity, interference (including cosmetic effects), removal of environmental contamination, stability and shipping tests.