



December 15, 2021

Psychemedics Corporation
Neil Stowe
Principal Scientist
5832 Uplander Way
Culver City, California 90230

Re: K210212

Trade/Device Name: Psychemedics Homogeneous Enzyme Immunoassay for Amphetamines in Hair
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine Test System
Regulatory Class: Class II
Product Code: LAF, DKZ
Dated: September 13, 2021
Received: September 15, 2021

Dear Neil Stowe:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics and Radiological
Health
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH)

Enclosure

Indications for Use

510(k) Number (if known)
k210212

Device Name
Psychemedics Homogeneous Enzyme Immunoassay for Amphetamines in Hair

Indications for Use (Describe)

The Psychemedics homogeneous enzyme immunoassay (HEIA) for amphetamines in hair is an enzyme immunoassay system for the preliminary qualitative detection of methamphetamine in human head and body hair using a methamphetamine calibrator at 3 ng methamphetamine/10 mg hair or 5 ng methamphetamine/10 mg hair for the purpose of identifying methamphetamine use, and for the preliminary qualitative detection of amphetamine in human head and body hair using an amphetamine calibrator at 3 ng amphetamine/10 mg hair for the purpose of identifying amphetamine use.

This is an in vitro diagnostic device intended exclusively for Psychemedics use only and is not for sale to anyone. The Psychemedics HEIA for amphetamines in hair provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Liquid Chromatography/Mass Spectrometry/Mass Spectrometry (LC/MS/MS) is the preferred confirmatory method.

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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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.

The assigned 510(k) number is: k210212

Submitted By: Psychemedics Corporation

5832 Uplander Way

Culver City, CA 90230

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Submission Contact: Neil Stowe

Date Prepared:

Device Trade Name: Psychemedics Homogeneous Enzyme Immunoassay for Amphetamines in Hair

Predicate Device: Psychemedics Microplate EIA for Methamphetamine in Hair, k111927;
Psychemedics Microplate EIA for Amphetamine in Hair, k130811

Product Code: LAF (Methamphetamine Test System), DKZ (Amphetamine Test System)

Device/Classification Name: 21 CFR 862.3610 Methamphetamine Test System, Classification II, 21 CFR 862.3100 Amphetamine Test System, Classification II

Intended Use: The Psychemedics homogeneous enzyme immunoassay (HEIA) for amphetamines in hair is an enzyme immunoassay system for the preliminary qualitative detection of methamphetamine in human head and body hair using a methamphetamine calibrator at 3 ng methamphetamine/10 mg hair or 5 ng methamphetamine/10 mg hair for the purpose of identifying methamphetamine use, and for the preliminary qualitative detection of amphetamine in human head and body hair using an amphetamine calibrator at 3 ng amphetamine/10 mg hair for the purpose of identifying amphetamine use. This is an in vitro diagnostic device intended exclusively for Psychemedics use only and is not for sale to anyone.

The Psychemedics HEIA Amphetamines Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical test result. Liquid Chromatography/Mass Spectrometry/Mass Spectrometry (LC/MS/MS) is the preferred confirmatory method.

Device Description: The test consists of two parts; a pre-analytical hair treatment procedure (to extract amphetamines from the solid hair matrix to a measurable liquid matrix) and the screening assay, the Psychemedics Amphetamines HEIA. The screening portion of the test system is based on competition for antibody binding sites between drug in the measurable liquid matrix and drug-labeled recombinant

glucose-6-phosphate dehydrogenase (G6PDH). As the antibody binds labeled G6PDH, enzyme activity decreases. In the presence of drug, enzyme activity increases in direct proportion to the drug concentration. Active enzyme reduces nicotinamide adenine dinucleotide (NAD) to NADH in the presence of glucose-6-phosphate (G6P), resulting in an absorbance change that is measured spectrophotometrically

The Psychomedics Amphetamines HEIA consists of reagents R1 (anti-methamphetamine monoclonal antibody with substrate) and R2 (methamphetamine labeled recombinant G6PDH) for the detection of methamphetamine, and reagents R1 (anti-amphetamine monoclonal antibody with substrate) and R2 (amphetamine labeled recombinant G6PDH) for the detection of amphetamine.

Sample Collection and Stability: A sample of hair should be cut as close as possible to the skin. The hair is placed in a V-shaped aluminum foil sample holder with the root end of the hair protruding beyond the slanted edge of the foil. The aluminum foil is crimped around the sample, securing the hair specimen firmly into place within the foil. The hair sample, crimped within the foil, is placed in a sample acquisition card envelope and the envelope is sealed with a tamper-evident seal. Hair specimens are kept at ambient temperature in a secure location until they are shipped without refrigeration to the laboratory. Stability of amphetamines in hair samples stored at room temperature has been shown for at least seven months. Amphetamines in samples shipped coast-to-coast twice was stable.

Materials Required: Hair sample collection kit, HEIA for Amphetamines, automated clinical chemistry analyzer, LC/MS/MS for confirmation.

Comparison with Predicate Devices:

Item	Proposed Device	Psychemedics Methamphetamine Assay, k111927
Indications/Intended Use	The Psychemedics HEIA is an enzyme immunoassay system for the preliminary qualitative detection of methamphetamine in human head and body hair using a methamphetamine calibrator of 3 ng methamphetamine/10 mg hair or 5 ng methamphetamine/10 mg hair for the purpose of identifying methamphetamine use. This is an in-vitro diagnostic device intended exclusively for Psychemedics use only and is not for sale to anyone. The enzyme immunoassay system provides only a preliminary analytical test result. To confirm a presumptive screen positive result, a more specific alternate chemical method such as LC/MS/MS (liquid chromatography/mass spectrometry/mass spectrometry) must be used. Clinical consideration and professional judgement must be applied to the interpretation of any drug-of-abuse test result.	The Psychemedics Microplate EIA for Methamphetamine is an enzyme immunoassay (EIA) for the preliminary qualitative detection of methamphetamine in human head and body hair samples using a methamphetamine calibrator at 5 ng/10 mg hair cutoff for the purpose of identifying methamphetamine use. This product is intended exclusively for in-house professional use and not for sale to anyone. The test is not intended for over-the-counter sale to non-professionals. The Psychemedics EIA Methamphetamine Assay provides only a preliminary analytical test result. To confirm a presumptive screen positive result, a more specific alternate chemical method such as LC/MS/MS (liquid chromatography/mass spectrometry/mass spectrometry) must be used. Clinical consideration and professional judgement must be applied to the interpretation of any drug-of-abuse test result.
Product Code	LAF	LAF
Measurand	Methamphetamine	Methamphetamine
Test System	Psychemedics Homogeneous Enzyme Immunoassay for Amphetamines in Hair	Psychemedics Microplate EIA for Methamphetamine in Hair
Sample Matrix	Human Hair	Human Hair
Method of Measurement	Automated Clinical Chemistry Analyzer at 340 nm	Microplate Reader at 450 nm
Type of Test	Enzyme Immunoassay	Enzyme Immunoassay
Extraction Method	Acidic aqueous buffer	Patented Digestion Method
Confirmation Method	LC/MS/MS	LC/MS/MS

Item	Proposed Device	Psychemedics Amphetamine Assay, k130811
Indications/Intended Use	<p>The Psychemedics HEIA is an enzyme immunoassay system for the preliminary qualitative detection of amphetamine in human head and body hair using an amphetamine calibrator of 3 ng/10 mg hair for the purpose of identifying amphetamine use. This is an <i>in vitro</i> diagnostic device intended exclusively for Psychemedics use only and is not for sale to anyone.</p> <p>The enzyme immunoassay system provides only a preliminary analytical test result. To confirm a presumptive screen positive result, a more specific alternate chemical method such as LC/MS/MS (liquid chromatography/mass spectrometry/mass spectrometry) must be used. Clinical consideration and professional judgement must be applied to the interpretation of any drug-of-abuse test result.</p>	<p>The Psychemedics Microplate EIA for Amphetamine is an enzyme immunoassay (EIA) for the preliminary qualitative detection of amphetamine in human head and body hair samples using an amphetamine calibrator at 3 ng/10 mg hair cutoff for the purpose of identifying amphetamine use. This is an <i>in vitro</i> diagnostic device intended exclusively for Psychemedics use only.</p> <p>Psychemedics has not performed an evaluation of reproducibility at different laboratories.</p> <p>The Psychemedics Microplate EIA amphetamine assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or Liquid Chromatography/Double Mass Spectrometry (GC/MS or LC/MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be exercised with any drug of abuse test result, particularly when the result is positive.</p>
Product Code	DKZ	DKZ
Measurand	Amphetamine	Amphetamine
Test System	Psychemedics Homogeneous Enzyme Immunoassay for Amphetamines in Hair	Psychemedics Microplate EIA for Amphetamine in Hair
Sample Matrix	Human Hair	Human Hair
Method of Measurement	Automated Clinical Chemistry Analyzer at 340 nm	Microplate Reader at 450 nm
Type of Test	Enzyme Immunoassay	Enzyme Immunoassay
Extraction Method	Acidic aqueous buffer	Patented Digestion Method
Confirmation Method	LC/MS/MS	LC/MS/MS

Performance Testing Summary: Precision studies were performed by spiking negative hair with previously LC/MS/MS validated calibrator and control solutions to achieve concentrations of negative, the cutoff calibrator of 3 ng methamphetamine/10 mg hair, 5 ng methamphetamine/10 mg hair, or 3 ng amphetamine/10 mg hair, and +/- 75%, +/-50% and +/-25% of the cutoff calibrator.

Methamphetamine Intra-Assay and Inter-Assay Precision Summary, 3 ng Methamphetamine/10 mg Hair Calibrator						
Summary Intra-Assay Precision				Summary Inter-Assay Precision		
Level	NEG	POS		Level	NEG	POS
-100%	8	0		-100%	80	0
-75%	8	0		-75%	80	0
-50%	8	0		-50%	80	0
-25%	8	0		-25%	80	0
+25%	0	8		+25%	0	80
+50	0	8		+50	0	80
+75%	0	8		+75%	0	80
+100%	0	8		+100%	0	80

Methamphetamine Intra-Assay and Inter-Assay Precision Summary, 5 ng Methamphetamine/10 mg Hair Calibrator						
Summary Intra-Assay Precision				Summary Inter-Assay Precision		
Level	NEG	POS		Level	NEG	POS
-100%	8	0		-100%	80	0
-75%	8	0		-75%	80	0
-50%	8	0		-50%	80	0
-25%	8	0		-25%	80	0
+25%	0	8		+25%	0	80
+50	0	8		+50	0	80
+75%	0	8		+75%	0	80
+100%	0	8		+100%	0	80

Amphetamine Intra-Assay and Inter-Assay Precision Summary						
Summary Intra-Assay Precision				Summary Inter-Assay Precision		
Level	NEG	POS		Level	NEG	POS
-100%	8	0		-100%	80	0
-75%	8	0		-75%	80	0
-50%	8	0		-50%	80	0
-25%	8	0		-25%	80	0
+25%	0	8		+25%	0	80
+50	0	8		+50	0	80
+75%	0	8		+75%	0	80
+100%	0	8		+100%	0	80

Cross Reactivity Summary:

The cross reactivity of the following metabolites and amphetamines structural analogs was evaluated by determining the minimum concentration that would result approximately equivalent to the 3.0 ng methamphetamine/10 mg hair and 5.0 ng methamphetamine/10 mg cutoffs.

Cross Reactivities, Methamphetamine 3 ng/10 mg Calibrator, Structurally Related Compounds and Metabolites		
Compound	% Cross Reactivity	Concentration Equivalent to 3.0 ng Methamphetamine/10 mg Hair
MDMA	81	3.7
Para-Methoxy Methamphetamine	50	6.0
1R, 2S Ephedrine	20	15
MDEA	12	25
R-Methamphetamine	2	150
D-Amphetamine	<1	>300
L-Amphetamine	<1	>300
MDA	<1	>300
Para-methoxy Amphetamine	<1	>300

Cross Reactivities, Methamphetamine 5 ng/10 mg Calibrator, Structurally Related Compounds and Metabolites		
Compound	% Cross Reactivity	Concentration Equivalent to 5.0 ng Methamphetamine/10 mg Hair
MDMA	83	6
Para-Methoxy Methamphetamine	50	10
1R, 2S Ephedrine	20	25
MDEA	10	50
R-(-)-Methamphetamine	2	175
D-Amphetamine	<1	>500
L-Amphetamine	<1	>500
MDA	<1	>500
Para-methoxy Amphetamine	<1	>500

The following compounds were shown to have no cross reactivity in the methamphetamine assay using the 3 ng or 5 ng methamphetamine/10 mg hair calibrator.

Lisinopril Dihydrate, Atropine, Bupropion, Cotinine, Cannabinol, Chlorpheniramine Maleate, O-Desmethylvenlafaxine, Desipramine, Doxylamine Succinate, 1S, 2R-Ephedrine, Amitriptyline, Dextromethorphan, Lidocaine, Methocarbamol, Nordoxepin, Pentazocine, Phenylephrine, Triamterene, Naproxen, Nicotine, Nortriptyline, Propoxyphene, R,R-Pseudoephedrine, Thioridazine, Cis-Tramadol, Venlafaxine HCl, 8-(-)11-nor-9-carboxy-delta 9 THC, 11-nor-9-carboxy-delta 9 THC, Amoxicillin, Propranolol, Promethazine, Phenmetrazine, Phendimetrazine, Benzocaine, Dimenhydrinate, Metanephrin, Carbamazepine, Diazepam, Nordiazepam, Oxazepam, Acetaminophen, Caffeine, Dyphylline, Methaqualone, Theophylline, Amphetamine, Cetrizine DiHCl, Imipramine, Phencyclidine, Phenylpropanolamine, Amitriptyline, Bupivacaine HCl, Lidocaine, Methocarbamol, Nordoxepin, Pentazocine, Pheynylephrine, Triamterene, Ethosuximide, Alpha-methyl-alpha-propyl succinimide, Metharbital, Barbitol, Mehsuximide, Phensuximide, N-Normethsuximide, Mephyton, Ethotoin, Mephobarbital, PEMA, Phenobarbital, Methyl PEMA, 10, 11-

Dihydrocarbamazepine, Primidone, 5,5-Diphenylhydantoin, 4-Methylprimidone, Butabarbital, Amobarbital, Secobarbital, Hexobarbital, Azithromycin Dihydrate, Glutethimide, Methaqualone, Diazepam, Chlorpromazine, Flurazepam, AM-2201, JWH-019, JWH-081, JWH-122, CP47,497 (+/-), CP47,497 (+/-), C8 Homologue, HU-211, JWH-200, JWH-250, Ibuprofen, Ephinephrine (+/-), Norephenephine (+/-), Metanephine (+/-), Normetanephine (+/-), Vanilmandelic Acid (+/-), 5-Hydroxyindole-3-acetic acid, Homovanillic acid, Alprazolam, Cimetidine, Citalopram HBr, Clonazepam, Clopidogrel bisulfate, Fluconazole, hydrochlorothiazide, Lamotrigine, L-Thyroxine, Methylphenidate HCl, Omeprazole, Levetiracetam, Sertaline HCl, Topiramate, Zolpidem Tartrate, Zonisamide, Amlodipine Besylate Atorvastatin Calcium Salt

The cross reactivity of the following metabolites and amphetamines structural analogs was evaluated by determining the minimum concentration that would result approximately equivalent to the 3.0 ng amphetamine/10 mg hair cutoff.

Cross Reactivities of Structurally Related Compounds and Metabolites		
Compound	% Cross Reactivity	Concentration Equivalent to 3.0 ng Amphetamine/10 mg Hair
MDA	100	3.0
Phentermine	25	12
D-Methamphetamine	<1	>300
MDMA	<1	>300
Phenmetrazine	<1	>300
1R, 2S Ephedrine	<1	>300

The following compounds were shown to have no cross reactivity in the Amphetamine assay.

Lisinopril Dihydrate, Atropine, Bupropion, Cotinine, Cannabinol, Chlorpheniramine Maleate, O-Desmethylvenlafaxine, Desipiramine, Doxylamine Succinate, 1S, 2R-Ephedrine, Amitriptyline, Dextromethorphan, Lidocaine, Methocarbamol, Nordoxepin, Pentazocine, Phenylephrine, Triamterene, Naproxen, Nicotine, Nortriptyline, Propoxyphene, R,R-Pseudoephedrine, Thioridazine, Cis-Tramadol, Venlafaxine HCl, 8-(-)11-nor-9-carboxy-delta 9 THC, 11-nor-9-carboxy-delta 9 THC, Amoxicillin, Propranolol, Promethazine, Phenmetrazine, Phendimetrazine, Benzocaine, Dimenhydrinate, Metanephine, Carbamazepine, Diazepam, Nordiazepam, Oxazepam, Acetaminophen, Caffeine, Dyphylline, Methaqualone, Theophylline, Cetrizine DiHCl, Imipramine, Methamphetamine, Phencyclidine, Phenylpropanolamine, Amitriptyline, Bupivacaine HCl, Lidocaine, Methocarbamol, Nordoxepin, Pentazocine, Pheynylephrine, Triamterene, Ethosuximide, Alpha-methyl-alpha-propyl succinimide, Metharbital, Barbital, Mehsuximide, Phensuximide, N-Normethsuximide, Mephyton, Ethotoin, Mephobarbital, PEMA, Phenobarbital, Methyl PEMA, 10, 11-Dihydrocarbamazepine, Primidone, 5,5-Diphenylhydantoin, 4-Methylprimidone, Butabarbital, Amobarbital, Secobarbital, Hexobarbital, Azithromycin Dihydrate, Glutethimide, Methaqualone, Diazepam, Chlorpromazine, Flurazepam, AM-2201, JWH-019,

JWH-081, JWH-122, CP47,497 (+/-), CP47, 497 (+/-), C8 Homologue, HU-211, JWH-200, JWH-250, Ibuprofen, Ephinephrine (+/-), Norephenephine (+/-), Metanephine (+/-), Normetanephine (+/-), Vanilmandelic Acid (+/-), 5-Hydroxyindole-3-acetic acid, Homovanillic acid, Alprazolam, Cimetidine, Citalopram HBr, Clonazepam, Clopidogrel bisulfate, Fluconazole, hydrochlorothiazide, Lamotrigine, L-Thyroxine, Methylphenidate HCl, Omeprazole, Levetiracetam, Sertaline HCl, Topiramate, Zolpidem Tartrate, Zonisamide, Amlodipine Besylate Atorvastatin Calcium Salt

Interference:

The following compounds were shown to have no interference in the methamphetamine and amphetamine assays.

Anhydroecgonine Methyl Ester, Atropine, Bupropion, Cotinine, Cannabinol, Chlorpheniramine maleate, O-Desmethylvenlafaxine, Desipramine, Doxylamine Succinate, 1S, 2R-Ephedrine, Naproxen, Nicotine, Nortriptyline, Propoxyphene, R,R-Pseudoephedrine, Thioridazine, Cis-Tramadol, Venlafaxine HCl, 8-(-)-11-nor-9-carboxy-delta-9 THC, 11-nor-9-carboxy-delta-9 THC, Amoxicillin, Propanolol, Promethazine, Phenmetrazine, Phendimetrazine, Benzocaine, Ecgonine, Metanephine, Glutethimide, Meprobamate, Methyprylon, Carbamazepine, Diazepam, Nordiazepam, Oxazepam, Acetaminophen, Caffeine, Dyphylline, Methaqualone, Theophylline, Amitriptyline, Dextromethorphan, Lidocaine, Methocarbamol, Nordoxepin, Pentazocine, Phenylephrine, Triamterene, Ethosuximide, α -Methyl- α -propylsuccinimide, Metharbital, Barbital, Methsuximide, Phensuximide, N-Normethylsuximide, Mephentoin, Ethytion, Mephobarbital, PEMA, Phenobarbital, Methyl PEMA, 10, 11-Dihydrocarbamazepine, Primidone, Carbamazepine, 5,5-Diphenylhydantoin, 4-Methylprimidone, Glutethimide, Methaqualone, Chlorpromazine, Flurazepam, AM-2201, JWH-019, JWH-081, JWH-122, CP47, 497 (\pm), CP 47, 497 (\pm) C8 Homologue, HU-211, JWH-200, JWH-250, Acetaminophen, Caffeine, Chlorpheniramine, Ibuprofen, Naproxen, R,R-(-)-Pseudoephedrine, Epinephrine (\pm), Norepinephrine (\pm), normetanephine (\pm), Alprazolam, Cimetidine, Citalopram HBr, Clonazepam, Clopidogrel Bisulfate, Fluconazole, Hydrochlorothiazide, Lamotrigine, L-Thyroxine, Methylphenidate HCl, Omeprazole, Amlodipine Besylate, Atorvastatin Calcium Salt, Azithromycin Dihydrate, Bupivacaine HCl, Cetirizine Di-HCl, Dimenhydrinate, Lisinopril Dihydrate, Butabarbital, Amobarbital, Secobarbital, Hexobarbital, Medazepam, Lorazepam, Temazepam, Bromazepam, Carbamazepine, Levetiracetam, Metformin HCl, Phenobarbital, Phenytoin, R-(-)-Phenylephrine HCl, Sertraline HCl, Topiramate, Zolpidem Tartrate, Zonisamide, 11-nor-9-carboxy-delta-8 THC, Streptomycin Solution, Procaine, Erythromycin, Penicillin G, Mepivacaine, Vanilmandelic Acid (\pm), 5-Hydroxyindole-3-Acetic Acid, Homovanillic Acid

Calibrator:

Psychomedics prepares calibrators and control materials using drug stocks purchased from a commercial vendor. Each lot of drug is received with its specific certificate of analysis. The commercially obtained stock is made into calibrators and controls to the desired concentrations. The concentrations are confirmed by LC/MS/MS.

**Sample Shipping Stability
During Storage:**

9 methamphetamine positive samples remained positive after approximately 8 months in storage and after shipping twice coast-to-coast. 9 amphetamine positive samples remained positive after approximately 6 months in storage and after shipping twice coast to coast.

Recovery:

The hair sample preparation for the screening HEIA is a phosphate buffer extraction procedure. Recovery of methamphetamine in the method was shown on average to be approximately 100% complete after extraction for 3 hours. Recovery of amphetamine in the method was shown on average to be approximately 100% complete after extraction for 3 hours.

Cosmetic Treatments:

5 methamphetamine-negative head hair samples were treated with perm, dye, shampoo and relaxer and the results compared to the same samples without treatments. In each case of the 5 samples treated with a type of cosmetic treatment, all samples remained negative after the treatments.

4 methamphetamine-positive head hair samples were treated with perm, dye, shampoo and relaxer and the results compared to the same samples without the treatments. In each case, the samples remained positive after the treatments.

5 amphetamine-negative head hair samples were treated with dye, shampoo and relaxer and the results compared to the same samples without treatments. 4 amphetamine-negative head hair samples were treated with perm and the results compared to the same samples without treatments. In each case of the samples treated with a type of cosmetic treatment, all samples remained negative after the treatments.

4 amphetamine-positive head hair samples were treated with perm, dye, shampoo and relaxer and the results compared to the same samples without the treatments. In each case, the samples remained positive after the treatments.

Comparison Studies:

Methamphetamine, 3 ng methamphetamine/10 mg hair calibrator

Samples positive or negative for methamphetamine were identified using the Psychemedics methamphetamine microplate assay (k111927), and then tested with the test device, the Psychemedics HEIA for methamphetamine in hair. The test device (assay) has been validated at the 3 ng methamphetamine/10 mg hair cutoff using 114 individual hair samples collected anonymously from a workplace setting. 58 negative samples and 56 positive samples were identified by the test device.

The stored hair samples were then tested using Psychemedics' LC/MS/MS confirmatory assay, to compare the Psychemedics HEIA results with the LC/MS/MS results. The studies comparing the HEIA with LC/MS/MS documented the source of hair (head or body) and other demographics as available. The comparison of the Psychemedics Methamphetamine HEIA at the 3 ng/10 mg hair calibrator with LC/MS/MS is shown in the following table.

Methamphetamine 3 ng/10 mg hair Calibrator Comparison Study				
HEIA Result	Washed LC/MS/MS Result, ng Methamphetamine/10 mg hair (% of cutoff calibrator)			
	< 1.5 (< 50% below cutoff)	1.50 – 2.99 (≥ 50% below cutoff to cutoff)	3.0 – 4.50 (cutoff to ≥ 50% above cutoff)	> 4.50 (> 50% above cutoff)
Positive	0	2	19	35
Negative	53	5	0	0

Methamphetamine Discordant Results at the 3 ng methamphetamine/10 mg hair calibrator: Positive HEIA/Negative LC/MS/MS

Washing of hair before confirmation: exclusion of potential environmental contamination and/or sweat-derived drug from hair analysis results can result in APPARENT discordant results. Ingested drugs are present in perspiration, which settles on the hair and requires removal if the hair analysis result is to reflect amount of drug ingested rather than exposure to the sweat-derived drug. Drug could also be present as a result of environmental contamination (e.g., powder, smoke). Hair is not washed prior to screening, as it would not be reasonable to wash hundreds of negative hair samples; i.e., samples that are negative without washing. Thus, it is expected that the washing performed before LC/MS/MS confirmation of presumptive positives removes external drug and the confirmation results may then be lower than the screening may have predicted without the consideration of sweat-derived drug and/or drug from environmental contamination.

Methamphetamine, 3 ng/10 mg Hair Calibrator Discordant Results				
Sample	HEIA Result	Unwashed LC/MS/MS Result (ng Meth/10 mg hair)	Washed LC/MS/MS Result (ng Meth/10 mg hair)	Comment
1	POS	4.70	2.43	Samples are screened by HEIA without hair washing. LC/MS/MS is performed only after washing once with isopropanol, 3 times 30 minutes with 90% Ethanol, then 2 times 60 minutes with 90% Ethanol. Thus, it is expected that some samples will be negative by LC/MS/MS after washing.
2	POS	4.80	2.46	

Methamphetamine, 5 ng methamphetamine/10 mg hair calibrator

Samples positive or negative for methamphetamine were identified using the Psychomedics methamphetamine microplate assay (k111927), and then tested with the test device, the Psychomedics HEIA for methamphetamine in hair. The test device (assay) has been validated at the 5 ng methamphetamine/10 mg hair cutoff using 94 individual hair samples collected anonymously from a workplace setting. 49 negative samples and 45 positive samples were identified by the test device.

The stored hair samples were then tested using Psychomedics' LC/MS/MS confirmatory assay, to compare the Psychomedics HEIA results with the

LC/MS/MS results. The studies comparing the HEIA with LC/MS/MS documented the source of hair (head or body) and other demographics as available. The comparison of the Psychomedics Methamphetamine HEIA at the 5 ng/10 mg hair calibrator with LC/MS/MS is shown in the following table.

Methamphetamine 5 ng/10 mg hair Calibrator Comparison Study				
HEIA Result	Washed LC/MS/MS Result, ng Methamphetamine /10 mg hair (% of cutoff calibrator)			
	< 2.5 (< 50% below cutoff)	2.5 – 4.99 (≥ 50% below cutoff to cutoff)	5.0 – 7.50 (cutoff to ≥ 50% above cutoff)	> 7.50 (> 50% above cutoff)
Positive	0	2	6	37
Negative	45	4	0	0

Methamphetamine Discordant Results at the 5 ng methamphetamine/10 mg hair calibrator: Positive HEIA/Negative LC/MS/MS

Washing of hair before confirmation: exclusion of potential environmental contamination and/or sweat-derived drug from hair analysis results can result in APPARENT discordant results. Ingested drugs are present in perspiration, which settles on the hair and requires removal if the hair analysis result is to reflect amount of drug ingested rather than exposure to the sweat-derived drug. Drug could also be present as a result of environmental contamination (e.g., powder, smoke). Hair is not washed prior to screening, as it would not be reasonable to wash hundreds of negative hair samples; i.e., samples that are negative without washing. Thus, it is expected that the washing performed before LC/MS/MS confirmation of presumptive positives removes external drug and the confirmation results may then be lower than the screening may have predicted without the consideration of sweat-derived drug and/or drug from environmental contamination.

Methamphetamine, 5 ng/10 mg Hair Calibrator Discordant Results				
Sample	HEIA Result	Unwashed LC/MS/MS Result (ng Meth/10 mg hair)	Washed LC/MS/MS Result (ng Meth/10 mg hair)	Comment
1	POS	6.18	4.28	Samples are screened by HEIA without hair washing. LC/MS/MS is performed only after washing once with isopropanol, 3 times 30 minutes with 90% Ethanol, then 2 times 60 minutes with 90% Ethanol. Thus, it is expected that some samples will be negative by LC/MS/MS after washing.
2	POS	5.57	4.56	

Amphetamine, 3 ng Amphetamine/10 mg hair calibrator

Samples positive or negative for amphetamine were identified using the Psychomedics methamphetamine microplate assay (k130811), and then tested with the test device, the Psychomedics HEIA for amphetamine in hair. The test device (assay) has been validated using 96 individual hair samples collected

anonymously from a workplace setting. 48 negative samples and 48 positive samples were identified by the test device.

The stored hair samples were then tested using Psychemedics' LC/MS/MS confirmatory assay, to compare the Psychemedics HEIA results with the LC/MS/MS results. The studies comparing the HEIA with LC/MS/MS documented the source of hair (head or body) and other demographics as available. The comparison of the Psychemedics Amphetamine HEIA with LC/MS/MS is shown in the following table.

Amphetamine 3 ng/10 mg hair Calibrator Comparison Study				
HEIA Result	Washed LC/MS/MS Result, ng Amphetamine/10 mg hair (% of cutoff calibrator)			
	< 1.5 (< 50% below cutoff)	1.50 – 2.99 (≥ 50% below cutoff to cutoff)	3.0 – 4.50 (cutoff to ≥ 50% above cutoff)	> 4.50 (> 50% above cutoff)
Positive	0	2	15	31
Negative	42	6	0	0

Amphetamine Discordant Results: Positive HEIA/Negative LC/MS/MS

Washing of hair before confirmation: exclusion of potential environmental contamination and/or sweat-derived drug from hair analysis results can result in APPARENT discordant results. Ingested drugs are present in perspiration, which settles on the hair and requires removal if the hair analysis result is to reflect amount of drug ingested rather than exposure to the sweat-derived drug. Drug could also be present as a result of environmental contamination (e.g., powder, smoke). Hair is not washed prior to screening, as it would not be reasonable to wash hundreds of negative hair samples; i.e., samples that are negative without washing. Thus, it is expected that the washing performed before LC/MS/MS confirmation of presumptive positives removes external drug and the confirmation results may then be lower than the screening may have predicted without the consideration of sweat-derived drug and/or drug from environmental contamination.

Amphetamine, 3 ng/10 mg Hair Calibrator Discordant Results				
Sample	HEIA Result	Unwashed LC/MS/MS Result (ng Amphetamine/10 mg hair)	Washed LC/MS/MS Result (ng Amphetamine/10 mg hair)	Comment
1	POS	3.18	2.51	Samples are screened by HEIA without hair washing. LC/MS/MS is performed only after washing once with isopropanol, 3 times 30 minutes with 90% Ethanol, then 2 times 60 minutes with 90% Ethanol. Thus, it is expected that some samples will be negative by LC/MS/MS after washing.
2	POS	5.82	2.73	

Conclusion:

The Psychomedics HEIA for amphetamines in hair is substantially equivalent based on acceptable performance studies, including precision, specificity and interference (including cosmetic effects).