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

A. 510(k) Number:

k142885

B. Purpose for Submission:

Addition of body hair claim to a previously cleared test

C. Measurand:

Methamphetamine (Meth) and 3,4-Methylenedioxymethamphetamine (MDMA) in hair

D. Type of Test:

Qualitative ELISA Immunoassay

E. Applicant:

Omega Laboratories, Inc.

F. Proprietary and Established Names:

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

G. Regulatory Information:

1. Regulation section:

   21 CFR §862.3610, Methamphetamine Test System

2. Classification:

   Class II

3. Product code:

   DKZ – Enzyme Immunoassay, Methamphetamine

4. Panel:

   Toxicology (91)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   The Omega Laboratories Hair Drug Screening Assay for 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.

3. Special conditions for use statement(s):

   The assay provides only a preliminary analytical test 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.

4. Special instrument requirements:

   The screening assay is for use with an automated microplate reader capable of measuring at 450 and 630 nm.

I. Device Description:

The assay consists of two parts; a pre-analytical hair treatment procedure (to extract methamphetamine and MDMA from the solid hair matrix to a measurable liquid matrix), and the screening assay. The screening assay is an Enzyme-Linked ImmunoSorbent Assay (ELISA).

The Hair Drug Screening Assay for Methamphetamine (Meth) and 3,4-Methylenedioxymethamphetamine (MDMA) uses the International Diagnostic Systems Corp

(IDS) One-Step ELISA Methamphetamine micro-plate/reagents and a micro-plate reader for the qualitative detection of Methamphetamine in hair samples. The test system consists of micro strip plates coated with rabbit anti-BE polyclonal antibody, enzyme conjugate (horseradish peroxidase conjugated to Methamphetamine substrate (containing tetramethylbenzidine), and wash solution. Cut off concentration is 500 pg/mg hair.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Omega Laboratories Hair Drug Screening Assay for Methamphetamine and 3, 4-Methylenedioxymethamphetamine

2. Predicate 510(k) number(s):

   k101973

3. Comparison with predicate:

Similarities and Differences		
Item	Device	k101973 Predicate
Laboratory	Omega Laboratories	Same
Indication for/Intended Use	Same except for head and body hair	Intended to be used for the qualitative determination of the presence of Methamphetamine and 3,4-Methylenedioxymethamphetamine (MDMA) in human hair from the head.
Method of Measurement	Same	Microplate Reader read at 450 nm
Matrix	Head and body hair	Head hair
Cut-off Concentration	Same	500 pg Methamphetamine and MDMA /mg hair
Assay Principal	Same	ELISA
Extraction Method	Same	Acid-methanol to facilitate extraction of Methamphetamine and 3,4-Methylenedioxymethamphetamine (MDMA from hair. Hair is pulverized into small segments prior to acid-methanol extraction, which improves extraction times without loss of efficiency

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

None referenced

L. Test Principle:

The test consists of two parts; a pre-analytical hair treatment procedure (to remove Methamphetamine and MDMA from the solid hair matrix to a measurable liquid matrix), and the screening assay. The screening assay is an Enzyme-Linked ImmunoSorbent Assay (ELISA). Sample is added to a well of the micro strip plate and enzyme conjugate is added, followed by incubation. During this phase the enzyme-labeled drug conjugate competes with drug in the sample for a limited number of binding sites on the rabbit antibody-coated micro wells. The two bind in proportion to their concentrations. A wash solution is applied to remove any unbound materials.

Enzyme substrate solution containing a chromagen is added. The reaction is stopped with an acid and the absorbance is read using a plate reader at 450 nm and a background reading is also taken at 630 nm. Color intensity is inversely proportional to the amount of drug present in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   See k101973

   b. Linearity/assay reportable range:

   Not applicable

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

   See k101973 for control stability, hair sample stability, and shipping stability information.

   d. Detection limit:

   See k101973

   e. Analytical specificity:

   See k101973 for cross reactivity, interference (structurally related and unrelated compounds), hair treatment, and environmental contamination studies.

In addition to studies conducted in k101973, the sponsor performed additional cross reactivity testing on several structurally similar compounds including ((+/-) 2, 5-Dimethoxy-4-Bromoamphetamine, 1S, 2R (+) Ephedrine, Phentermine, R(+) Methcathinone, and R, R (-)-Pseudoephedrine). These compounds appeared to contribute to a Methamphetamine or MDMA positive ELISA result at -50% cutoff, but did not show cross reactivity when tested at concentrations up to 400,000 pg/mg.

To investigate this discrepancy, cross reactivity was tested at up to 10 fold higher concentrations. Expected results were obtained. The results are summarized in the tables below. The tables below are also included in the device labeling.

Compound	Concentration of Compound (pg/mg) Equivalent to 500 pg/mg Methamphetamine Cutoff Control	Percent Cross-Reactivity (%)
S(+) Methamphetamine	500.0	100.0
(+/-)2,5-Dimethoxy-4bromoamphetamine	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

f. Assay cut-off:

See k101973

2. Comparison studies:

a. Method comparison with predicate device:

A total of 138 body hair samples (69 each of Methamphetamine and MDMA samples) were tested and compared to the results from GC/MS drug analysis. These

samples included samples near the cutoff concentration, and positive samples for both MDMA and Methamphetamine. Results were acceptable.

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.