

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k060810

B. Purpose for Submission:

New 510(k)

C. Measurand:

Amphetamine, Methamphetamine, Cannabinoids, Cocaine, and Morphine in urine

D. Type of Test:

Qualitative visually read immunochromatographic assay

E. Applicant:

IND Diagnostics, Inc.

F. Proprietary and Established Names:

One Step Amphetamine, Methamphetamine, Cocaine, Morphine, and Marijuana Tests

G. Regulatory Information:

1. Regulation section:

862.3100, Enzyme Immunoassay, Amphetamine
862.3870, Enzyme Immunoassay, Cannabinoids
862.3250, Enzyme Immunoassay, Cocaine and Cocaine Metabolites
862.3610, Thin Layer Chromatography, Methamphetamine
862.3640, Liquid Chromatography, Morphine

2. Classification:

Class II

3. Product code:

DKZ, LDJ, DIO, DJC, and DPK, respectively

4. Panel:
91 (Toxicology)

H. Intended Use:

1. Intended use(s):

See indications for use.

2. Indication(s) for use:

The One Step Drugs of Abuse Test is a prescription lateral flow competitive immunoassay panel or single test intended for professional central laboratory use by trained users. It provides qualitative visual screening results for Marijuana, Cocaine, Morphine, Amphetamine and Methamphetamine at cutoff concentrations of 50 ng/mL Marijuana, 300 ng/mL Cocaine, 300 ng/mL Morphine, 1000 ng/mL Amphetamine and 1000 ng/mL Methamphetamine in urine in combinations (Multi-Panel) or separately (Single). It is not intended for over the counter sales to the lay person.

For *in vitro* diagnostic use only.

As with all qualitative tests, this assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used. To obtain a confirmed analytical result, a more specific alternative chemical method is needed. Gas chromatography/Mass spectrometry is the recommended confirmatory method.

3. Special conditions for use statement(s):

The assay is for prescription use. The assay is not designated for use in point-of-care settings.

4. Special instrument requirements:

Not applicable. The device is a visually read single-use device.

I. Device Description:

The product may be sold as a single test or as part of a panel, and may be packaged in either a strip or a cassette format. Operators dip the test strip into the urine, or add drops of urine to the cassette test well to initiate the test reaction. Results are visually read.

The sponsor indicates the device has no human source material.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Princeton Biomeditech Accusign DOA 5

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

k962353

3. Comparison with predicate:

Both devices have the same intended use, utilize the same test methodology and have the same cutoff concentrations. The reagent formulations vary between the two devices, as do the manufacturers.

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

The sponsor did not reference any standards in this submission.

L. Test Principle:

The test is based on the principle of a competitive inhibition immunoassay, in which a chemically labeled drug (drug conjugate) competes with the drug which may be present in urine, for limited antibody binding sites. The test device consists of a membrane strip, which is pre-coated with DOA-BSA conjugate on the test band region, and a colored anti-DOA monoclonal antibody-colloid gold conjugate pad, which is placed at the end of the membrane.

In the absence of drug in the urine, the colored antibody-colloid gold conjugate moves with the sample by capillary action along the membrane until it reaches the immobilized drug conjugate in the test band region. At this point, the antibody-colloid gold conjugate reacts with the pre-coated drug conjugate and forms a visible pink colored line as the antibodies form complexes with the drug conjugate. Therefore, formation of a visible pink color line on the test band region is interpreted as a negative test result.

When the drug is present in the urine, the drug/metabolite antigen will compete with the drug conjugate coated in the test band region for the limited antibody sites. When a sufficient concentration of drug is present, it will fill the limited antibody binding sites, and will prevent attachment of the colored antibody-colloid gold conjugate to drug conjugates pre-coated in the test band region. Therefore, absence of the pink color band on the test region indicates a positive result for the specified drug. A control line indicates that an adequate volume of sample was added and that the test membrane is intact.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision of the test was characterized at the sponsor's facility by two trained technicians. Replicates of drug-free urine were tested, as well as drug-free urine spiked to the cutoff concentration, 25% above the cutoff concentration, and 25% below the cutoff concentration. Testing was performed on strip, cassette, and multi-panel test formats. Results are presented below.

Marijuana

Marijuana	0 ng / mL	37.5 ng / mL	50 ng / mL	62.5 ng / mL
Negative	60	54	0	0
Positive	0	6	60	60

Cocaine

Benzoylcegonine	0 ng / mL	225 ng /mL	300 ng / mL	375 ng / mL
Negative	60	54	0	0
Positive	0	6	60	60

Methamphetamine

D-MET	0 ng / mL	750 ng / mL	1000 ng / mL	1250 ng / mL
Negative	60	54	0	0
Positive	0	4	60	60

Amphetamine

D-AMP	0 ng / mL	750 ng / mL	1000 ng / mL	1250 ng / mL
Negative	60	54	0	0
Positive	0	6	60	60

Morphine

Morphine	0 ng / mL	225 ng /mL	300 ng / mL	375 ng / mL
Negative	60	54	0	0
Positive	0	6	60	60

b. Linearity/assay reportable range:

Not applicable. The assay is intended for qualitative use.

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

Controls are required with this assay but are not specifically identified in the labeling. The sponsor did not indicate any degree of traceability for their devices. Users are instructed to follow federal, state, and local guidelines concerning QC practices.

d. Detection limit:

Sensitivity of a qualitative assay may be characterized by validating performance around the claimed cutoff concentration of the assay, and demonstrating the lowest concentration of drug that is capable of or consistently producing a positive result. This information appears in the precision section, above.

e. Analytical specificity:

An extensive list of compounds were tested for positive interference. Each compound was dissolved in drug-free control urine to a concentration of 100 µg / mL. Samples were adjusted to 3 pH levels (5, 7, 9) and 3 specific gravity levels (low, normal, high). All test results were negative.

Cross-reactivity of structurally related compounds was estimated by testing various amounts of drug or drug metabolite added to a drug-free urine control. Results are expressed as the lowest concentration required to produce a positive result.

Cross-reactivity of One-Step Marijuana

Compounds	Concentration (ng/ml)
11-nor- Δ -9-Tetrahydrocannabinol-COOH	50
11-nor-- Δ -8-Tetrahydrocannabinol-COOH	440
Δ -9-Tetrahydrocannabinol	20,000
Δ -8-Tetrahydrocannabinol	17,500
Canabinol	50,000
Cannabidiol	100,000

Cross-reactivity of One-Step Cocaine

Compounds	Concentration (ng/ml)
Cocaine	300
Benzoylecgonine	300

Cross-reactivity of One-Step Morphine test

Compounds	Concentration (ng/ml)
Morphine	300
Codeine	300
Ethyl morphine	300
Hydrocodone	400
Hydromorphone	400
Levophanol	5,000
Meperidine	70,000
Morphine-3-glucuronide	500
Naporphine	2,000
Norcodeine	30,000
Oxycodone	13,125
Oxymorphone	50,000
Thebaine	26,250

Cross Reactivity of One Step Amphetamine

Compounds	Concentration (ng/ml)
D-Amphetamine	1000
D/L-Amphetamine	2000
3,4-Methylenedioxyamphetamine	2500
L-Amphetamine	30,000
D-(+) Methamphetamine	43,750
D,L 3,4-Methylenedioxymethamphetamine	43,750

Cross-Reactivity of One Step Methamphetamine

Compounds	Concentration (ng/ml)
D-(+) Methamphetamine	1000
3,4-Methylenedioxyethylamphetamine(MDEA)	1000
d-Amphetamine	50,000
l-Amphetamine	50,000
3,4-Methylenedioxyamphetamine (MDA)	50,000

There is the possibility that other substances and/or factors not listed above may interfere with the test and cause false results, e.g., technical or procedural errors.

f. Assay cut-off:

The identified cutoff concentration(s) of the assay(s) are consistent with other cleared DOA assays.

2. Comparison studies:

a. Method comparison with predicate device:

Clinical samples were purchased from a laboratory in order to characterize performance of the One-Step assays against GC/MS. Samples were selected in order to obtain adequate distribution of the targeted drug around the claimed cutoff concentration. Results of the studies are presented below:

Comparison of One-step THC Test with GC/MS

THC Metabolite	Low Negative (< 50% cutoff)	Near Cutoff Negative (between -50% + cutoff)	Near Cutoff Positive (between cutoff + 50%)	High Positive (> 50% cutoff)
Positive	0	0	11	22
Negative	31	8	3	0

Comparison of One-step Cocaine Test with GC/MS

Benzoyl-ecgonine	Low Negative (< 50% cutoff)	Near Cutoff Negative (between -50% + cutoff)	Near Cutoff Positive (between cutoff + 50%)	High Positive (> 50% cutoff)
Positive	0	0	5	30
Negative	30	8	2	0

Comparison of One-step Methamphetamine Test with GC/MS

D-Meth	Low Negative (< 50% cutoff)	Near Cutoff Negative (between -50% + cutoff)	Near Cutoff Positive (between cutoff + 50%)	High Positive (> 50% cutoff)
Positive	0	1	11	23
Negative	31	9	0	0

Comparison of One-step Amphetamine Test with GC/MS

D-Amph	Low Negative (< 50% cutoff)	Near Cutoff Negative (between -50% + cutoff)	Near Cutoff Positive (between cutoff + 50%)	High Positive (> 50% cutoff)
Positive	0	2	9	26
Negative	31	7	0	0

Comparison of One-step Morphine Test with GC/MS

Morphine	Low Negative (< 50% cutoff)	Near Cutoff Negative (between -50% + cutoff)	Near Cutoff Positive (between cutoff + 50%)	High Positive (> 50 % cutoff)
Positive	0	1	7	28
Negative	31	7	1	0

b. Matrix comparison:

Not applicable. The assay is intended for only one sample matrix.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable. Clinical studies are not typically submitted for this device type and matrix.

b. Clinical specificity:

Not applicable. Clinical studies are not typically submitted for this device type and matrix.

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

4. Clinical cut-off:

Validation of the clinical appropriateness of the cutoff is not typically submitted for this device type and matrix.

5. Expected values/Reference range:

Not applicable. No elicited drugs should be present in urine.

O. Proposed Labeling:

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

P. Conclusion:

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