

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

**A. 510(k) Number:**

k080347

**B. Purpose for Submission:**

New device

**C. Measurand:**

Methamphetamine, opiates, and THC (tetrahydrocannabinol)

**D. Type of Test:**

Qualitative immunoassay

**E. Applicant:**

Taiwan Unison Biotech Inc.

**F. Proprietary and Established Names:**

mAmp/Opi/THC Panel Test with SUDoA-01 scanner

**G. Regulatory Information:**

1. Regulation section:

21 CFR 862.3610, Methamphetamine test system.

21 CFR 862.3650, Opiate test system.

21 CFR 862.3870, Cannabinoid test system.

2. Classification:

All Class II

3. Product Code:

DJC

DJG

LDJ

4. Panel:  
Toxicology (91)

**H. Intended Use:**

1. Intended use(s):

Refer to Indications for use.

2. Indication(s) for use:

TUBI's UNISCAN-DoA is a system intended for use in Drugs of Abuse Screening Tests.

The mAMP/Opi/THC panel test is a prescription assay intended for use with UNISCAN-DoA Scanner in laboratory by professional personnel. The mAMP/Opi/THC assays were calibrated with d-methamphetamine/morphine/11-nor- $\Delta^9$ -THC-9-COOH, respectively. It provides qualitative screening results for Methamphetamine/ Opiates/ Cannabinoids in human urine at a cutoff concentration of 1000/300/50 ng/mL. For In Vitro Diagnostic Use.

This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC/MS) is the recommended confirmatory method.

3. Special condition for use statement(s):

This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC/MS) is the recommended confirmatory method.

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

Tests for opiates cannot distinguish between abused drugs and certain prescribed medications. Certain foods or medications may interfere with tests for amphetamines and opiates and cause false positive results.

4. Special instrument Requirements:

UNISCAN-DoA Scanner

**I. Device Description:**

The product is a single-use device in a cassette format. Operators add several drops of the sample to the sample well. The test reaction is initiated by movement of the sample through the test strip. At the end of the 25 minute incubation period the user inserts the cartridge into the reader. The reader performs a color signal analysis on the reacted test cassette and produces a result of negative, positive, or invalid. Prior to insertion of the cassette, the operator must enter the correct panel number (which identifies the test cassette) and the strip calibration curve for the specific lot of test cassette.

Description of the test antibodies: monoclonal mouse antibody against d-methamphetamine, morphine, and 11-nor- $\Delta^9$ -THC-9-COOH

Description of the control line antibody: polyclonal goat anti-mouse IgG

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Triage TOX Drug Screen

2. Predicate K number(s):

k043242

3. Comparison with predicate:

Both devices are for the qualitative determination of methamphetamine, opiates, and THC in urine, and utilize the same cutoff concentrations. Both are read by an instrument. The reagent formulations vary between the two devices.

Similarities		
Item	Device	Predicate
Matrix	Same	Urine
Analyte cutoffs	Same	Methamphetamine – 1000 ng/mL Opiates – 300 ng/mL THC – 50 ng/mL
Test principle	Same	Fluorescence immunoassay read by an instrument

Differences		
Item	Device	Predicate
Analytes available	Methamphetamine Opiates THC	Methamphetamine Opiates THC Acetaminophen Barbiturates Benzodiazepines Cocaine PCP Tricyclic antidepressants
Reagent storage temperature	4 – 30° C	2 – 8° C

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

- CLSI EPI2-P; User Protocol for Evaluation of Qualitative Test Performance; Proposed Guidance
- IEC 61010-1 :2001; Safety requirements for electrical equipment for measurement, control, and laboratory use -Part 1: General requirements
- IEC 61010-2-10 1:2002; Safety requirements for electrical equipment for measurement, control and laboratory use -Part 2-101 : Particular requirements for in vitro diagnostic (IVD) medical equipment
- IEC 60601-1-2:2001; Medical Electrical Equipment -Part 1-2: General Requirements for Safety; Electromagnetic Compatibility --Requirements and Tests

**L. Test Principle:**

The test employs lateral flow immunochromatographic technology.

Drug in the sample and drug-labeled conjugate (containing a chromagen) compete for antibody binding sites in the test area of the test strip. Binding of drug in the sample causes the absence of a line at the test area, i.e., a positive result. When drug is not present in the sample, the drug-labeled conjugate binds at the test line, resulting in formation of a line, i.e., a negative result. At the end of the incubation period the user inserts the cartridge into the reader, which produces a result of negative, positive, or invalid.

The device also has an internal process control which indicates that an adequate volume of sample has been added and that the immunochromatographic strip is intact.

**M. Performance Characteristics (if/when applicable):**1. Analytical performance:a. *Precision/Reproducibility:***Within-day precision**

Specimen description: drug free urine spiked with  $\Delta^9$ -THC-COOH, morphine, and d-methamphetamine

Number of days: one

Replicates per day: 25

Lots of product used: one

Number of operators: three

Operator: manufacturer staff

Testing Facility: manufacturer

Results of the study are presented below:

**Cannabinoid (THC) Precision Study Results**

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
0	25	25/0
12.5	25	25/0
25	25	25/0
37.5	25	23/2
50	25	6/19
62.5	25	0/25
75	25	0/25
87.5	25	0/25
100	25	0/25

**Opiates Precision Study Results**

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
0	25	25/0
75	25	25/0
150	25	25/0
225	25	23/2
300	25	8/17
375	25	3/22
450	25	0/25
525	25	0/25
600	25	0/25

## Methamphetamine Precision Study Results

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
0	25	25/0
250	25	25/0
500	25	25/0
750	25	24/1
1000	25	11/14
1250	25	4/21
1500	25	1/24
1750	25	0/25
2000	25	0/25

**Between lot precision**

Specimen description: drug free urine spiked with  $\Delta^9$ -THC-COOH, morphine, and d-methamphetamine

Number of days: one

Replicates per day: 15

Lots of product used: 3

Number of operators: three

Operator: manufacturer staff

Testing Facility: manufacturer

Results of the study are presented below:

Analyte		Methamphetamine							
Conc (ng/mL)		0	250	500	750	1250	1500	1750	2000
n		45	45	45	45	45	45	45	45
Lot 1	# positive	0	0	0	1	12	14	15	15
	# negative	15	15	15	14	3	1	0	0
Lot 2	# positive	0	0	0	2	13	14	15	15
	# negative	15	15	15	13	2	1	0	0
Lot 3	# positive	0	0	0	0	12	15	15	15
	# negative	15	15	15	15	3	0	0	0

Analyte		Opiates							
Conc (ng/mL)		0	75	150	225	375	450	525	600
n		45	45	45	45	45	45	45	45
Lot 1	# positive	0	0	0	1	13	14	15	15
	# negative	15	15	15	14	2	1	0	0
Lot 2	# positive	0	0	0	1	12	15	15	15
	# negative	15	15	15	14	3	0	0	0
Lot 3	# positive	0	0	0	1	12	14	15	15
	# negative	15	15	15	14	3	1	0	0

Analyte		THC							
Conc (ng/mL)		0	12.5	25	37.5	62.5	75	87.5	100
n		45	45	45	45	45	45	45	45
Lot 1	# positive	0	0	0	1	15	15	15	15
	# negative	15	15	15	14	0	0	0	0
Lot 2	# positive	0	0	0	2	14	14	15	15
	# negative	15	15	15	13	1	1	0	0
Lot 3	# positive	0	0	0	0	14	15	15	15
	# negative	15	15	15	15	1	0	0	0

**Between day precision**

Specimen description: drug free urine spiked with  $\Delta^9$ -THC-COOH, morphine, and d-methamphetamine

Number of days: 5

Replicates per day: 3

Lots of product used: 1

Number of operators: three

Operator: manufacturer staff

Testing Facility: manufacturer

Results of the study are presented below:

Analyte		Methamphetamine							
Conc (ng/mL)		0	250	500	750	1250	1500	1750	2000
n		15	15	15	15	15	15	15	15
Day 1	# positive	0	0	0	0	3	3	3	3
	# negative	3	3	3	3	0	0	0	0
Day 2	# positive	0	0	0	1	3	3	3	3
	# negative	3	3	3	2	0	0	0	0
Day 3	# positive	0	0	0	1	2	3	3	3
	# negative	3	3	3	2	1	0	0	0
Day 4	# positive	0	0	0	0	3	3	3	3
	# negative	3	3	3	3	0	0	0	0
Day 5	# positive	0	0	0	0	3	3	3	3
	# negative	3	3	3	3	0	0	0	0

Analyte		Opiates							
Conc (ng/mL)		0	75	150	225	375	450	525	600
n		15	15	15	15	15	15	15	15
Day 1	# positive	0	0	0	0	3	3	3	3
	# negative	3	3	3	3	0	0	0	0
Day 2	# positive	0	0	0	0	2	3	3	3
	# negative	3	3	3	3	1	0	0	0

Day 3	# positive	0	0	0	1	3	3	3	3
	# negative	3	3	3	2	0	0	0	0
Day 4	# positive	0	0	0	1	2	3	3	3
	# negative	3	3	3	2	1	0	0	0
Day 5	# positive	0	0	0	0	3	3	3	3
	# negative	3	3	3	3	0	0	0	0

Analyte		THC							
Conc (ng/mL)		0	12.5	25	37.5	62.5	75	87.5	100
n		15	15	15	15	15	15	15	15
Day 1	# positive	0	0	0	0	3	3	3	3
	# negative	3	3	3	3	0	0	0	0
Day 2	# positive	0	0	0	0	3	3	3	3
	# negative	3	3	3	3	0	0	0	0
Day 3	# positive	0	0	0	0	3	3	3	3
	# negative	3	3	3	3	0	0	0	0
Day 4	# positive	0	0	0	0	3	3	3	3
	# negative	3	3	3	3	0	0	0	0
Day 5	# positive	0	0	0	0	3	3	3	3
	# negative	3	3	3	3	0	0	0	0

b. *Linearity/assay reportable range:*

Not applicable. The assay is intended for qualitative use.

c. *Traceability (controls, calibrators, or method):*

Positive and negative external control materials are required but are not specifically identified in the labeling.

The device has an internal process control. Users are instructed to follow government regulations when determining when to run positive and negative external controls.

d. *Detection limit:*

Sensitivity of this assay is characterized by validating performance around the claimed cutoff concentration of the assay, including a determination of the lowest concentration of drug that is capable of producing a positive result. This information appears in the precision section, above.

e. *Analytical specificity:*

Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into drug-free urine. By analyzing various concentration of each compound the sponsor determined the concentration of the drug that produced a response approximately equivalent to the cutoff concentration of the assay. Results of those studies appear in the table(s) below:

**Methamphetamine**

Drug Compound	Response equivalent to cutoff in ng/mL
d-amphetamine	> 100 µg/mL
l-amphetamine	> 100 µg/mL
d-methamphetamine	1,000
l-methamphetamine	30,000
3,4-Methylenedioxyethylamphetamine(MDEA)	> 100 µg/mL
D,L 3,4-Methylenedioxymethamphetamine (MDMA)	1,000
3,4-Methylenedioxyamphetamine (MDA)	> 100 µg/mL
Ephedrine	> 100 µg/mL
Pseudoephedrine	> 100 µg/mL

**Opiates**

Drug compound	Response equivalent to cutoff in ng/mL
6-monoacetylmorphine	300
Codeine	300
Norcodeine	2,500
Heroin	750
Hydrocodone	1,250
Hydromorphone	1,250

Drug compound	Response equivalent to cutoff in ng/mL
Oxycodone	2,500
Morphine	300
Morphine-3- $\beta$ -glucuronide	375
Nalorphine	750
Ethylmorphine	300

#### Cannabinoids (THC)

Compound	Response equivalent to cutoff in ng/mL
11-Hydroxy- $\Delta^9$ -Tetrahydrocannabinol	5000
11-Nor- $\Delta^8$ -Tetrahydrocannabinol – 9 – carboxylic acid	37.5
11-Nor- $\Delta^9$ -Tetrahydrocannabinol – 9 – carboxylic acid	50
$\Delta^8$ -Tetrahydrocannabinol	15,000
$\Delta^9$ -Tetrahydrocannabinol	25,000

The following compounds were evaluated for potential positive and/or negative interference with the assay. To evaluate for interference the sponsor prepared control samples that consisted of drug-free urine, drug-free urine spiked at 50% of the cutoff, and drug-free urine spiked at 150% of the cutoff:

Analyte	Methamphetamine	Opiates	THC
50% of cutoff	500 (ng/mL)	150 (ng/mL)	12.5 (ng/mL)
150% of cutoff	1500 (ng/mL)	450 (ng/mL)	37.5 (ng/mL)

100  $\mu$ g/mL of each potentially interfering compound was then added to aliquots of the control samples described above and analyzed. There were no deviations from the expected results. None of the compounds exhibited any negative or positive interference with the assay

Acetaminophen	Cortisone	Ibuprofen	Salicylic acid
Acetamidophenol	Deoxyephedrine	Isoproterenol	Tetracycline
Acetylsalicylic acid	Digitoxin	Ketamine	Tetrahydrozoline
Amikacin	Digoxin	Lidocaine	Theophylline
Arterenol	Diphenhydramine	Neomycin	Thioridazine
Ascorbic acid	Epinephrine	Niacinamide	Trifluoperazine
Atropine	Gentisic	Perphenazine	Tryptophan
Caffeine	Guaiacol glycer ester	Penicillin G	Tyramine
Camphor	Histamine	Phenylpropanolamine	Oxazepam

Chloroquine	Hydrochlorothiazine	Promethazine	Chlorpheniramine
Homatrophine	Quinine antidine		

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

To test for potential positive/and or negative interference from endogenous conditions the sponsor prepared the sponsor prepared control samples that consisted of drug-free urine, drug-free urine spiked at 50% of the cutoff, and drug-free urine spiked at 150% of the cutoff and tested the following compounds and physiological conditions:

2000 mg/dL glucose  
 5.0 – 8.5 pH  
 1.004, 1.010, and 1.030 specific gravity  
 2000 mg/dL albumin  
 10 mg/dL hemoglobin  
 4000 mg/dL urea  
 10 mg/dL uric acid

There were no deviations from the expected results.

*f. Assay cut-off:*

The identified cutoff concentrations for methamphetamine and THC are recommended for use by the Substance Abuse and Mental Health Services Administration (SAMHSA). For opiates, SAMHSA recommends a cutoff of 2,000 ng/mL while the sponsor has chosen to use 300 ng/mL.

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section, above.

2. Comparison studies:

*a. Method comparison with predicate device:*

Because the candidate device was compared to a reference method, GC/MS, it was not compared to a predicate device.

Sample description: Unaltered clinical urine samples were evaluated.

The study included an adequate number of samples that contained drugs near to the cutoff concentration of the assay. Approximately

10% of the study samples are evenly distributed between plus and minus 50% of the claimed cutoff concentration.

Number of study sites: one

Type of study site(s): clinical setting

Operator description: manufacturer's staff

### Candidate Device Results vs. stratified GC/MS Values

#### Methamphetamine

Candidate Device Results	Less than half the cutoff concentration by GC/MS analysis	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	2	5	42
Negative	43	4	1	0

GC/MS values used to categorize samples in this table are based on the concentration of methamphetamine found in the sample.

% Agreement among positives is 98%.

% Agreement among negatives is 96%

#### Opiates

Candidate Device Results	Less than half the cutoff concentration by GC/MS analysis	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	3	41
Negative	43	5	2	0

GC/MS values used to categorize samples in this table are determined by adding together the concentration of morphine and codeine found in the sample.

% Agreement among positives is 96%

% Agreement among negatives is 100%

**THC**

Candidate Device Results	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	1	4	41
Negative	43	4	1	0

GC/MS values used to categorize samples in this table are based on the concentration of THC found in the sample.

% Agreement among positives is 98%

% Agreement among negatives is 98%

*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.

*b. Clinical specificity:*

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

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

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

**N. Instrument Name**

UNISCAN –DoA Scanner

**O. System Descriptions**

1. Modes of Operation:

Each test cassette is single use only and must be replaced for each sample.

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes   X   or No \_\_\_\_\_

3. Specimen Identification:

There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

There are no special sampling or handling issues. The sponsor recommends that specimens be brought to room temperature prior to testing and that samples with particulate matter be centrifuged before testing.

5. Calibration:

Calibration parameters are provided for each lot of test cartridges. Prior to testing, the user must enter the test type (referred to as a panel) and the strip calibration curve data.

6. Quality Control:

Each device has internal process controls which run with every sample. A line appearing in the control region confirms that sufficient sample volume and that interpret the test if the control line fails to be detected by the scanner.

Positive and negative external controls are available from commercial sources to ensure proper system performance. In the labeling, the manufacturer recommends that the external control values are within established range and if the values of external control do not fall within established range, the test results are invalid and the sample needs to be repeated.

**P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:**

**Q. Proposed Labeling:**

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

**R. Conclusion:**

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