

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number: K023837

B. Analyte: methamphetamines (methamphetamine or MDMA), cocaine, cannabinoids, opiates.

C. Type of Test: qualitative, visually-read, immunochromatographic assay

D. Applicant: Princeton Biomeditech Corporation

E. Proprietary and Established Names: Lifesign® Home Drug Test (Ecstasy&MET), Status Stik™ MET & MDMA, Accusign® Stik MET and MDMA, Accustik® Met & MDMA, Accusign® MET & MDMA, Status DS™ MET & MDMA, Accustrip Met & MDMA, Lifesign® Home Drug Test (Marijuana, Opiates, Cocaine, Ecstasy&MET), Status Stik™ THC/OPI/COC/MET & MDMA, Accusign® Stik THC/OPI/COC/MET & MDMA, Accustik® DOA 4, Accusign® DOA 4, Status DS™ DOA 4, Accustrip DOA 4

F. Regulatory Information:

1. Regulation section: 21CFR862.3610 Methamphetamine Test System, 21CFR862.3870 Cannabinoid Test System, 21CFR862.3650 Opiate Test System, 21CFR862.3250 Cocaine and Cocaine Metabolite Test System.
2. Classification: Class II
3. Product Code: LAF, LDJ, DJG, DIO
4. Panel: Toxicology (91)

G. Intended Use:

1. Indication(s) for use:
Status Stik™ MET & MDMA, Accusign® Stik MET & MDMA, Accustik® Met & MDMA, Accusign® MET & MDMA, Status DS™ MET & MDMA and Accustrip™ MET & MDMA are immunoassays for the qualitative detection of methamphetamine and 3,4-methylenedioxymethamphetamine (MDMA) at the cutoff of 500 ng/ml in urine to assist in screening of drugs of abuse samples. The devices are for prescription use.

Lifesign Home Drug Test (Ecstasy&MET) is for the qualitative detection of methamphetamine and 3,4-methylenedioxymethamphetamine (MDMA) at the cutoff of 500 ng/ml in urine to assist in screening of drugs of abuse samples at home and workplace.

Status Stik™ THC/OPI/COC/MET & MDMA, Accusign® Stik THC/OPI/COC/MET & MDMA, Accustik® DOA 4, Status DS™ DOA 4, Accusign® DOA 4 and Accustrip™ DOA 4 are immunoassays for the qualitative detection of THC metabolite, opiates, cocaine metabolite, methamphetamine and 3,4-methylenedioxymethamphetamine in urine to assist in screening of drugs of abuse. The detection cutoff concentrations are 50 ng/ml for THC, 2000 ng/ml for morphine, 300 ng/ml for benzylecgonine, 500 ng/ml for methamphetamine, 500 ng/ml for 3,4-methylenedioxymethamphetamine. These devices are for prescription use.

Lifesign Home Drug Test (Marijuana/Opiates/Cocaine/Ecstasy & MET) is an immunoassay for the qualitative detection of THC metabolite, opiates, cocaine metabolite, methamphetamine and 3,4-methylenedioxymethamphetamine in urine to assist in screening of drugs of abuse samples at home or workplace. The detection cutoff concentrations are 50 ng/ml for THC, 2000 ng/ml for morphine, 300 ng/ml for benzylecgonine, 500 ng/ml for methamphetamine, 500 ng/ml for 3,4-methylenedioxymethamphetamine.

2. Special condition for use statement(s): This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/ mass spectrophotometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

The assay detects methamphetamine or MDMA using one test line. (It does not distinguish between the two drugs.)

The Status Stik™, Accusign® Stik, Accustik® , Accusign® , Status DS™ and Accustrip™ tests listed above are indicated for prescription use. The Lifesign Home Drug tests are indicated for home or workplace use.

3. Special instrument Requirements: none

H. Device Description:

The devices are unitized, visually-read immunochromatographic assays in formats of dipstick, dip card or dipstrip. The home use version of the device is in dip card format and also contains material for obtaining GCMS confirmation of preliminary results.

I. Substantial Equivalence Information:

1. Predicate device name(s): Lifesign® Home Drug Test (THC/OPI/COC/MET), Status Stik™ THC/OPI/COC/MET, Accusign® Stik THC/OPI/COC/MET, Accustik™ DOA 4, Accusign® DOA 4, Status DS™ DOA 4, Accustrip™ DOA 4.

Lifesign® Home Drug Test MET, Status Stik™ MET, Accusign® Stik MET, Accustik™ MET, Accusign® MET, Status DS™ MET, Accustrip™ MET.

2. Predicate K number(s): K014192, K014193

3. Comparison with predicate: The operating principle is similar to the predicate device. The change to the device includes changes to an antibody so that it is equally sensitive to both MDMA and methamphetamine and addition of MDMA detection to the indications for use. The cutoff concentration level for both MDMA and methamphetamine are 500 ng/ml for this device. The methamphetamine cutoff level was 1000 ng/ml for the predicate device.

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

K. Test Principle: The test is a visually read lateral flow immunoassay.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Assay cutoff and precision were evaluated for all three formats of the professional use devices. A pooled negative urine solution was spiked with commercial drug material. Three operators each tested 40 samples at each drug level. Testing was conducted over 2 days and included two device lots. A summary of results from that evaluation is shown below:

concentration (ng/ml)	%correct results	%correct results
	methamphetamine	MDMA
0	100	100
250	95-100	98-100
375	75-90	70-90
625	73-93	75-90
750	95-100	95-100
1000	100	100

A lay user consumer study was performed on the Lifesign Home Drug Test to evaluate whether lay users can perform and interpret the test correctly using spiked urine samples. Participants were given a spiked sample (of a concentration unknown to the participant), a test device and a package insert. There were 251 participants ranging in age from 18 to over 45. Education levels of participants ranged from non-high school graduates (n=16) through graduate school graduates (n=81). An additional survey filled out by the participants indicated that users understood how to interpret results, including the description of a preliminary results and how to obtain confirmatory results.

Samples used in the consumer study were prepared by spiking commercial drug standard solution into pooled negative urine. The following were the results of the consumer study for methamphetamine and MDMA using spiked samples:

<u>methamphetamine(ng/ml)</u>	<u># samples tested</u>	<u>% correct answers</u>
125	11	100
250	34	100
375	12	83
625	14	79
750	31	97
875	10	100
1000	10	100

<u>MDMA(ng/ml)</u>	<u># samples tested</u>	<u>% correct answers</u>
125	10	100
250	34	97
375	18	72
625	16	75
750	31	97
875	12	100
1000	11	100

b. Linearity/assay reportable range: Not applicable. This is a qualitative test.

c. Traceability (controls, calibrators, or method): Control materials are available commercially for the professional use test.

d. Detection limit: See assay cutoff section below

e. Analytical specificity: To evaluate cross-reactivity with related drugs, the compounds listed below were added to drug free urine, which was serially diluted (1:1) and tested with the device. Concentrations at which cross-reactivity was observed are shown below:

Compound	Cross-reacting level (ng/ml)
D-amphetamine	100,000
D-,L-Amphetamine	100,000
(-) Ephedrine	100,000
(+/-) Ephedrine	100,000
D-Methamphetamine	500
Methylenedioxyamphetamine	50,000

Methylenedioxymethamphetamine	500
D,L-Methylenedioxyethylamphetamine	10,000

Interference was evaluated by spiking over-the-counter and prescription drugs into drug-free urine to a concentration of 100 ug/ml. The list of drugs tested is included in the package insert. No unusual interference was observed.

The effect of pH (across the range 4.7-8.0) and specific gravity (across the range 1.002-1.04) was evaluated. Urine samples across these ranges were prepared and spiked with methamphetamine or MDMA at levels of 250 and 1000 ng/ml. Variations in pH and specific gravity across these ranges had no effect on the test results observed.

f. Assay cut-off: See precision section above.

2. Comparison studies:

a. Method comparison with predicate device:

Comparison to GCMS was evaluated at the manufacturer's site for more than 50 negative and 40 positive samples. Negative samples were obtained from individuals who had not been taking any medication other than multivitamins. Positive samples were randomly selected retrospective samples from a toxicology laboratory, determined positive by GCMS. Some samples were diluted in order to attain near-cutoff concentrations. Results are shown below for methamphetamine and MDMA:

Method Comparison Tables

GCMS

	+	+ (within 25% above the cutoff concentration)	- (within 25% below the cutoff concentration)	-
+ Status/ MDMA	50	11	2	0
-	0	2	9	50

GCMS

	+	+	-	-
		(within 25% above the cutoff concentration)	(within 25% below the cutoff concentration)	
+	31	8	3	0
-	0	2	7	50

b. Matrix comparison: Not applicable. The device is indicated only for urine specimens.

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. Clinical cutoff data is not typically provided for this device type.

5. Expected values/Reference range: Not applicable

M. Conclusion:

I recommend that the Princeton Biomeditech devices listed above are substantially equivalent to the predicate devices.