

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

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

k043028

**B. Purpose for Submission:**

New Device

**C. Measurand:**

Methylenedioxymethamphetamine (MDMA)

**D. Type of Test:**

Qualitative and semi-quantitative immunoassay

**E. Applicant:**

Dade Behring, Inc.

**F. Proprietary and Established Names:**

Dade Behring Syva<sup>®</sup> Emit<sup>®</sup> II Plus Ecstasy Assay

**G. Regulatory Information:**

1. Regulation section:

21 CFR 862.3100 (Enzyme Immunoassay, Amphetamine)

21 CFR 862.3200 (Calibrators, Drug Specific)

21 CFR 862.3280 (Clinical Toxicology Control Material)

2. Classification:

Class II

Class II

Class I

3. Product Code:

DKZ

DLJ

DIF

4. Panel:

Toxicology (91)

**H. Intended Use:**

1. Intended use(s):

Refer to Indications for use.

2. Indication(s) for use:

The Emit<sup>®</sup> II Plus Ecstasy Assay is a homogeneous enzyme immunoassay with a 300 ng/mL or 500 ng/mL cutoff. The assay is intended for use in

laboratories for the qualitative and/or semiquantitative analysis of methylenedioxymethamphetamine (MDMA) and closely related drugs in human urine. Emit<sup>®</sup> II Plus Assays are designed for use with a number of chemistry analyzers.

The Emit<sup>®</sup> II Plus Ecstasy Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

The Emit<sup>®</sup> II Plus Ecstasy Calibrators/Controls are used in the calibration of the Emit<sup>®</sup> II Plus Ecstasy Assay. These standards may also be used as quality control materials based upon the Ecstasy assay cutoff.

3. Special condition for use statement(s):

Semi-quantitative results may be helpful in estimating the concentrations of drug(s) in samples. This can aid users when they are preparing dilutions of the samples for further analysis.

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

Certain foods or medications may interfere with tests for methylenedioxymethamphetamine and cause false positive results.

4. Special instrument Requirements:

The device is for use on automated clinical chemistry analyzers. Instruments must be capable of maintaining a constant reaction temperature, pipetting samples and reagents, mixing reagents, timing reactions, and measuring enzyme rates precisely.

Performance was demonstrated in this submission on the SYVA<sup>®</sup>-30R Biochemical System.

## I. **Device Description:**

The device consists of two wet reagents which contain the key components of the immunoassay; **Antibody/Substrate Reagent 1** contains sheep polyclonal antibodies to MDMA, bovine serum albumin, glucose-6-phosphate, nicotinamide adenine dinucleotide, preservatives, and stabilizers. **Enzyme Reagent 2** contains methylenedioxyamphetamine (MDA) labeled with bacterial recombinant glucose-6-phosphate dehydrogenase, Tris buffer, bovine serum albumin, preservatives, and stabilizers.

Five levels of calibrator/control (Level 0 - Level 4) are provided separately:

Desired Cutoff Level (ng/mL)	Additional Recommended Calibrators/Controls for Qualitative Analysis (ng/mL)	Required Calibrators/Controls for Semiquantitative Analysis (ng/mL)
300 (Level 2)	*Level 0 (0) Level 4 (1000)	Level 0 (0) Level 1 (150) Level 2 (300) Level 3 (500) Level 4 (1000)
500 (Level 3)	Level 0 (0) Level 4 (1000)	

For any individual cutoff level, a calibrator/control is used as either a calibrator or as a control when the assay is used for qualitative analysis. When a calibrator/control is used as a calibrator for an individual cutoff level, the other level calibrators/controls (above or below it, as listed above) are used as controls.

\*Emit® Calibrator/Control Level 0 was previously cleared under k993755

#### J. Substantial Equivalence Information:

- Predicate device name(s):  
Microgenics DRI® Ecstasy Enzyme Immunoassay
- Predicate K number(s):  
k012110
- Comparison with predicate:  
Both devices are for measurement of the same analyte in the same matrix and utilize the same test methodology. The predicate device has a single cutoff of 500 ng/mL. The user can choose a cutoff of 300 or 500 ng/mL with the candidate device. Both are for use on automated analyzers.

The reagent formulations vary between the two devices.

Similarities		
Item	Device	Predicate
Intended Use	Same	Qualitative or semi-quantitative determination of MDMA and related drugs in human urine
Principle	Same	Homogeneous enzyme immunoassay

Differences		
Item	Device	Predicate
Cutoff	300 or 500 ng/mL	500 ng/mL
Antibody	Polyclonal	Monoclonal
Components of	Sheep polyclonal antibodies to	Monoclonal anti-MDMA

Antibody/Substrate Reagent	methylenedioxymethamphetamine (MDMA), bovine serum albumin, G6P, NAD, preservatives and stabilizers.	antibody, G6P, NAD in tris buffer with sodium azide as a preservative.
Components of Enzyme Reagent	Methylenedioxymethamphetamine (MDA) labeled with bacterial G6PDH, tris buffer, bovine serum albumin, preservatives and stabilizers.	Methylenedioxymethamphetamine (MDMA) labeled with G6PDH, tris buffer, and sodium azide as a preservative.

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

The sponsor referenced the following guidance document or standards in their submission:

Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests - Draft Guidance for Industry and FDA Staff, published December 2003

NCCLS EP5-A: Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline

**L. Test Principle:**

The test is an enzyme immunoassay for use on automated clinical chemistry analyzers. For qualitative results, two calibrators at 0 and 1000 ng/mL are run with the assay. For semi-quantitative results five calibrators ranging in concentration from 0 to 1000 ng/mL are run with the assay. The assay is based upon competition between drug in the urine specimen and drug labeled with recombinant glucose-6-phosphate dehydrogenase (rG6PDH) for antibody binding sites. Enzyme activity decreases upon binding to the antibody, so the drug concentration in the specimen can be measured in terms of enzyme activity. Active enzyme converts nicotinamide adenine dinucleotide (NAD) to NADH in the presence of glucose-6-phosphate (G6P), resulting in an absorbance change that is measured spectrophotometrically. Endogenous serum G6PDH does not interfere because the coenzyme NAD functions only with the bacterial (*Leuconstoc mesenteroides*) enzyme employed in the assay.

Absorbance measurements are taken at 340 nm. Control and unknown values are read from the calibration curve.

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

All performance was established on the SYVA®-30R Biochemical System.

Specimen description: calibrator/control material consisting of human urine, MDMA, and preservatives.

Number of days: 20

Replicates per day: 4  
 Lots of product used: 1  
 Number of calibrations performed during the study: 1

Results of the studies are presented below.

#### Qualitative Precision

Sample concentration, ng/mL	Mean mA/min	SD	CV%	Sample concentration, ng/mL	Mean mA/min	SD	CV%
Within-Run Imprecision				Total Imprecision			
225	383	1.33	0.35	225	383	2.11	0.55
300	419	2.33	0.56	300	419	3.14	0.75
375	455	2.03	0.45	375	455	2.81	0.62
500	495	3.91	0.79	500	495	4.21	0.85
625	522	2.13	0.41	625	522	4.97	0.95

#### Semi-quantitative Precision

Sample concentration, ng/mL	Mean ng/mL	SD	CV%	Sample concentration, ng/mL	Mean ng/mL	SD	CV%
Within-Run Imprecision				Total Imprecision			
225	220	2.56	1.16	225	220	4.06	1.85
300	291	4.93	1.69	300	291	6.63	2.28
375	375	5.28	1.41	375	375	7.28	1.94
500	502	11.06	2.20	500	502	14.07	2.80
625	638	12.39	1.94	625	638	17.09	2.68

*b. Linearity/assay reportable range:*

Support for the lower limit of the reportable range is characterized by the sensitivity studies and is supported at the high end by the highest calibrator used by the assay.

Recovery studies

Sample description: Negative Human Urine

Number of replicates: 5

Expected Concentration	Mean Observed Concentration	% Recovery	Mean Absorbance Reading	Standard Deviation	Coefficient of Variation (%)
150	144.4	96.3	353.8	1.6	0.5
200	181.5	90.8	372.1	2.1	0.6
225	204.4	90.8	383.7	1.7	0.4
250	230.2	92.1	396.7	1.2	0.3
270	249.1	92.2	406.3	1.1	0.3
300	274.5	91.5	418.8	1.3	0.3
330	315.2	95.5	437.8	2.1	0.5
375	356.8	95.1	455.4	1.4	0.3
450	434.2	96.5	483.0	2.1	0.4
500	492.3	98.5	501.0	1.4	0.3
550	542.4	98.6	513.7	1.6	0.3
625	631.0	101.0	531.9	0.7	0.1
750	740.0	98.7	548.6	0.9	0.2
900	849.0	94.3	560.8	1.3	0.2
1000	891.7	89.2	564.6	2.2	0.4

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

Five levels of calibrator/control material, ranging in concentration from 0 to 1000 ng/mL, are specified in the labeling but are supplied separately. Calibrators/controls are drug free urine based materials spiked with known concentrations of MDMA.

After a master lot of each level of calibrator/control is prepared gravimetrically, the assigned values of the master lot are verified by GC/MS analysis. GC/MS concentrations must be within  $\pm 10\%$  of the target MDMA concentration. Each new calibrator/control lot is prepared in the same manner as the master lot and run as an unknown vs. the master lot. The concentration of the new calibrator lot is adjusted, if needed, to be within  $\pm 5\%$  of the mean value obtained for the corresponding level of the master lot. The value of the new lot is also confirmed by GC/MS.

Stability studies are summarized for the calibrators/controls.

The shelf life of the calibrators/controls will be established based on real-time data from 3 lots. Calibrators/controls stored at 2-8°C are compared to a standard curve generated from calibrators stored at -20°C. The time points tested will be day 0, 7, 14, 21, and 30, and monthly thereafter up to 13 months. Nine replicates will be averaged at each time point. The observed drift of the mean concentration must be within  $\pm 10\%$  of the reference calibrators. Shelf life stability claims at the time of marketing will be based on

real-time data, which is expected to be 8 months. Shelf life will be extended as additional real-time data becomes available.

Opened bottle stability testing will be performed on all levels. At day 0, portions of the bottle will be removed and analyzed. The bottles are then recapped and stored upright at 2-8°C. The process is repeated at 7 months and 13 months. Twenty-five or greater replicates will be averaged at each time point. At each time point, the observed drift of the mean concentration must be within  $\pm 10\%$  of the concentration at day 0. The sponsor states that for opened bottle stability testing, the number of replicate measurements is larger than for closed bottle stability to provide statistically valid results using fewer time points.

*d. Detection limit:*

Sensitivity of the assay is less than 75 ng/mL. To determine analytical sensitivity, the sponsor assayed the negative calibrator 20 times within the same run and extrapolated the value of each measurement from the standard curve. The average and standard deviation of those readings were calculated. The analytical sensitivity was estimated by adding 2 standard deviations to the average of the readings.

*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.

<b>Drug Compound</b>	<b>Concentration in ng/mL producing response equivalent to the 300 cutoff</b>	<b>Response equivalent to the 500 cutoff (ng/mL)</b>
d-amphetamine	>49,000	>265,000
l-amphetamine	>63,000	>300,000
d-methamphetamine	>12,000	>57,000
l-methamphetamine	>9,000	>13,000
3,4-Methylenedioxyethylamphetamine (MDEA)	286	528
N-Methyl-1-(3,4-methylenedioxyphenyl)-2-butanamine hydrochloride (MBDB)	168	365
3,4-Methylenedioxymphetamine (MDA)	284	578
3,4-Methylenedioxyphenyl-2-butanamine hydrochloride (BDB)	152	347
p-Methoxyamphetamine hydrochloride (PMA)	4,933	22,024
p-Methoxymethamphetamine hydrochloride (PMMA)	1,433	3,387

4-Hydroxy-3-methoxymethamphetamine (HMMA)	>40,000	>40,000
d,l-amphetamine	>54,000	>300,000
d,l-methamphetamine	>9,000	>51,000
4-Chloramphetamine	>2,000	>6,000
Benzphetamine	>10,000	>10,000
Bupropion	>500,000	>500,000
Chloroquine	>1,000,000	>1,000,000
l-Ephedrine	>52,000	>384,000
Fenfluramine	>1,000	>6,000
Mephentermine	>15,000	>15,000
Methoxyphenamine	>1,000,000	>1,000,000
Nor-pseudoephedrine	>100,000	>100,000
Phenmetrazine	>300,000	>300,000
Phentermine	>150,000	>150,000
Phenylpropanolamine	>200,000	>200,000
Propanolol	>15,000	>15,000
Pseudoephedrine	>58,000	>411,000
Quinacrine	>1,000,000	>1,000,000
Tranlycypromine	>100,000	>100,000
Tyramine	>100,000	>100,000
Haloperidol	>1,000	>2,500
Isoxsuprine	>2,500	>10,000
Ketorolac Tromethamine	>50,000	>100,000
Labelatol	>10,000	>25,000
Nylidrin	>5,000	>7,500
Trazadone	>1,000	>2,500

The following compounds were evaluated for potential positive interference with the assay. To evaluate for interference the sponsor spiked potentially interfering compounds into drug-free urine. The sponsor recorded the greatest concentration of potential interferent tested that produced a negative result. That concentration appears in the table. Results of the study are presented below:

Potential Interferent	Concentration in µg/mL producing negative response at the 300 cutoff	Concentration in µg/mL producing negative response at the 500 cutoff
Acetaminophen	1000	1000
α -Acetyl- N, N-dinormethadol	25	25
l- α -Acetylmethadol (LAAM)	25	25
N-Acetylprocainamide (NAPA)	400	400



Acetylsalicylic Acid	1000	1000
Albuterol	1000	1000
p-Aminobenzoic Acid (PABA)	1000	1000
Amitriptyline	100	500
Amoxicillin	100	100
Atenolol	1000	1000
Benzoyllecgonine	1000	1000
Buprenorphine	100	100
Caffeine	1000	1000
Carbamazepine	250	250
Carisoprodol	1000	1000
Chlorpheniramine	100	100
Chlorpromazine	200	200
Cimetidine	1000	1000
Clomipramine	2.5	2.5
Clonidine	1000	1000
Codeine	500	500
Cotinine	100	100
Cyclobenzaprine	28	28
Desipramine	800	800
Dextromethorphan	1000	1000
Dextrophan	280	280
Diphenhydramine	1000	1000
Doxepin	10	10
Doxylamine	500	500
Epinephrine	1000	1000
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	1000	1000
Fenoprofen	1000	1000
Fluoxetine	100	500
Furosemide	1000	1000
Glutethimide	500	500
Ibuprofen	1000	1000
Imipramine	100	400
Ketamine	100	100
Ketoprofen	1000	1000
Lidocaine	100	100
LSD	0.15	0.15
Meperidine HCl	1000	1000
Mescaline	1500	1500
Metaclopramide	1000	1000
Methadone	1000	1000
Methaqualone	1500	1500
d,l-Methyldopa	1000	1000

1-Methyldopa	1000	1000
Monoethylglycinexylidide (MEGX)	1000	1000
Morphine	1000	1000
Nalmefene	20	20
Naloxone	500	500
Naproxen	1000	1000
Nicotinic Acid	500	500
Nitroglycerin	1000	1000
Noracetylmethadol	25	25
11-nor-D9-THC-9-COOH	100	100
Nortriptyline	600	750
Ofloxacin	100	100
Oxazepam	300	300
Paroxetine	800	1000
Phencyclidine	1000	1000
Phenelzine	100	100
1-Phenylcyclohexylamine (PCA)	50	50
Phenytoin	1000	1000
Phthalic Acid	1000	1000
1-Piperidinocyclohexane carbonitrile	50	50
Procainamide	1000	1000
Promethazine	1000	1000
Propoxyphene	1000	1000
Ranitidine	900	900
Sertraline	100	300
Scopolamine	500	500
Secobarbital	1000	1000
Thioridazine	100	100
Tolmetin Sodium	2000	2000
Tramadol	100	100
Trifluoperazine	100	100
Trimethobenzamide	500	500
Trimethoprim	500	500
Verapamil	1000	1000
Zidovudine (AZT)	2000	2000
Zolpidem	100	100
Diethylpropion HCl	1000	1000
d,l-Isoproterenol	400	1000
Metaproterenol	200	500
Methylphenidate (Ritalin ® )	1000	1000
Phendimetrazine	400	400
Phenethylamine	20	20
Phenylephrine	400	1000
Propylhexedrine	125	125
3-OH-Tyramine (dopamine)	300	300

To test for potential positive/and or negative interference from endogenous conditions the sponsor spiked each endogenous compound into a negative or positive control. The mean rate of the control with the interferent was compared to the cutoff rate. The criterion applied by the sponsor to conclude that there was or was not interference by the compound was: negative control spiked with endogenous interferents must not produce a positive result and positive control spiked with endogenous interferents must not produce a negative result.

According to these criteria, there was no change in any test samples as compared to the results of the control samples.

#### At the 300 ng/mL cutoff

Negative Control (225 ng/mL) = 385.5 mA/min (without interferent)

300 ng/mL cutoff = 420.5 mA/min

Endogenous Compound	Concentration	Mean Rate of Negative Control plus interferent
Acetone	1.0 g/dL	394 mA/min
Ascorbic Acid	1.5 g/dL	389 mA/min
Bilirubin	2.0 g/dL	388 mA/min
Creatinine	0.5 g/dL	399 mA/min
Ethanol	1.0 g/dL	398 mA/min
Glucose	2.0 g/dL	399 mA/min
Hemoglobin	115 mg/dL	396 mA/min
Human Serum Albumin	0.5 g/dL	398 mA/min
IgG	0.5 g/dL	398 mA/min
Oxalic Acid	0.1 g/dL	395 mA/min
Riboflavin	7.5 mg/dL	390 mA/min
Sodium Chloride	6.0 g/dL	408 mA/min
Urea	6.0 g/dL	394 mA/min

#### At the 300 ng/mL cutoff

Positive Control (375 ng/mL) = 454.6 mA/min (without interferent)

300 ng/mL cutoff = 420.5 mA/min

Endogenous Compound	Concentration	Mean Rate of Positive Control plus interferent
Acetone	1.0 g/dL	466 mA/min
Ascorbic Acid	1.5 g/dL	465 mA/min
Bilirubin	2.0 g/dL	468 mA/min
Creatinine	0.5 g/dL	463 mA/min
Ethanol	1.0 g/dL	464 mA/min
Glucose	2.0 g/dL	467 mA/min
Hemoglobin	115 mg/dL	464 mA/min

Human Serum Albumin	0.5 g/dL	467 mA/min
IgG	0.5 g/dL	467 mA/min
Oxalic Acid	0.1 g/dL	466 mA/min
Riboflavin	7.5 mg/dL	466 mA/min
Sodium Chloride	6.0 g/dL	475 mA/min
Urea	6.0 g/dL	468 mA/min

**At the 500 ng/mL cutoff**

Negative Control (375 ng/mL) = 454.6 mA/min (without interferent)

500 ng/mL cutoff = 494.3 mA/min

Endogenous Compound	Concentration	Mean Rate of Negative Control plus interferent
Acetone	1.0 g/dL	466 mA/min
Ascorbic Acid	1.5 g/dL	465 mA/min
Bilirubin	2.0 g/dL	468 mA/min
Creatinine	0.5 g/dL	463 mA/min
Ethanol	1.0 g/dL	464 mA/min
Glucose	2.0 g/dL	467 mA/min
Hemoglobin	115 mg/dL	464 mA/min
Human Serum Albumin	0.5 g/dL	467 mA/min
IgG	0.5 g/dL	467 mA/min
Oxalic Acid	0.1 g/dL	466 mA/min
Riboflavin	7.5 mg/dL	466 mA/min
Sodium Chloride	6.0 g/dL	475 mA/min
Urea	6.0 g/dL	468 mA/min

**At the 500 ng/mL cutoff**

Positive Control (625 ng/mL) = 523.9 mA/min (without interferent)

500 ng/mL cutoff = 494.3 mA/min

Endogenous Compound	Concentration	Mean Rate of Positive Control plus interferent
Acetone	1.0 g/dL	529 mA/min
Ascorbic Acid	1.5 g/dL	525 mA/min
Bilirubin	2.0 g/dL	529 mA/min
Creatinine	0.5 g/dL	529 mA/min
Ethanol	1.0 g/dL	528 mA/min
Glucose	2.0 g/dL	526 mA/min
Hemoglobin	115 mg/dL	528 mA/min
Human Serum Albumin	0.5 g/dL	531 mA/min
IgG	0.5 g/dL	528 mA/min
Oxalic Acid	0.1 g/dL	526 mA/min
Riboflavin	7.5 mg/dL	526 mA/min
Sodium Chloride	6.0 g/dL	532 mA/min
Urea	6.0 g/dL	527 mA/min

**Testing for pH Interference at the 300 ng/mL cutoff**

Negative Control (225 ng/mL) = 385.7 mA/min

300 ng/mL cutoff = 420.5 mA/min

Positive Control (375 ng/mL) = 454.6 mA/min

pH tested	Mean Rate of the Negative Control (mA/min)	Mean Rate of the Positive Control (mA/min)
3.0	404	465
4.0	402	462
4.5	405	447
8.0	406	468
10.0	411	458
11.0	392	463

**Testing for pH Interference at the 500 ng/mL cutoff**

Negative Control (375 ng/mL) = 454.6 mA/min

500 ng/mL cutoff = 494.1 mA/min

Positive Control (625 ng/mL) = 523.9 mA/min

pH tested	Mean Rate of the Negative Control (mA/min)	Mean Rate of the Positive Control (mA/min)
3.0	465	531
4.0	462	531
4.5	447	547
8.0	468	526
10.0	458	529
11.0	463	521

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 500 ng/mL cutoff concentration of the assay is recommended for use by the Substance Abuse and Mental Health Services Administration (SAMHSA) for screening purposes for MDMA. The user may also choose to use a 300 ng/mL cutoff concentration, as recommended by the United Kingdom Laboratory Guidelines for Legally Defensible Workplace Drug Testing.

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.

To evaluate the 300 ng/mL and 500 ng/mL cutoffs a total of 100 samples were evaluated by the candidate device and by GC/MS.

Sample description: for the evaluation of the 300 ng/mL cutoff, 78 unaltered clinical urine samples were evaluated. 22 additional diluted samples were also included in the study. For the evaluation of the 500 ng/mL cutoff, 77 unaltered clinical urine samples were evaluated plus an additional 23 diluted samples. The diluted samples were prepared by diluting clinical samples with high drug concentrations with drug-free urine. This was done in order to obtain samples near the cutoff concentration of the assay, because the sponsor was not able to obtain unaltered samples near the cutoff.

Sample selection: Samples were chosen such that the MDMA concentration by GC/MS would cover the assay range of the candidate device.

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

Description of the site: Manufacturer's Research and Development facility

Operator description: Manufacturer's Research and Development staff

Number of instruments used: one

Note: due to differences in calibration curves, a semi-quantitative result in ng/mL may not always be in agreement with a qualitative result for the same sample. For example, when using the 300 ng/mL cutoff, the assay might produce a semi-quantitative result of 287 ng/mL and a qualitative result of positive.

### Candidate Device Results vs. GC/MS Values - 300 ng/mL cutoff\*

	Positive by UK Confirmation Cutoff	Negative by UK Confirmation Cutoff
Positive by Candidate Device	55	0
Negative by Candidate Device	2	43

\*Samples are classified as positive or negative based on the United Kingdom Laboratory Guidelines for Legally Defensible Workplace Drug Testing GC/MS confirmation cutoffs, which are: 200 ng/mL MDMA **or** 200 ng/mL MDEA **or** 200 ng/mL MDA.

### Candidate Device Results vs. stratified GC/MS Values - 300 ng/mL cutoff\*

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	7	8	40
Negative	41	3	1	0

\*Samples are classified as positive or negative determined by adding together the GC/MS concentrations for MDMA, MDA, and MDEA

% Agreement among positives is 98%

% Agreement among negatives is 86%

### Candidate Device Results vs. GC/MS Values - 500 ng/mL cutoff\*

	Positive by SAMHSA Confirmation Cutoff	Negative by SAMHSA Confirmation Cutoff
Positive by Candidate Device	53	0
Negative by Candidate Device	4	43

\*Samples are classified as positive or negative based on the Proposed SAMHSA Mandatory Guidelines for Federal Workplace Drug Testing Programs confirmation cutoffs, which are: 250 ng/mL MDMA **or** 250 ng/mL MDEA **or** 250 ng/mL MDA

**Candidate Device Results vs. stratified GC/MS Values - 500 ng/mL cutoff\***

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	8	8	37
Negative	43	1	3	0

\*Samples are classified as positive or negative determined by adding together the GC/MS concentrations for MDMA, MDA, and MDEA

% Agreement among positives is 94%

% Agreement among negatives is 85%

*b. Matrix comparison:*  
Not applicable.

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. 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.