BECKMAN COULTER®

Emit® II Plus Ecstasy Assay

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See shaded sections:
Updated information from September 2010 version.

Catalog Number	Product Description	Quantity/ Volume
OSR9X229	**Emit® II Plus Ecstasy Assay**	
	OSR9X618 R1 (Antibody/Substrate Reagent 1)	2 x 29 mL
	OSR9X648 R2 (Enzyme Reagent 2)	2 x 14 mL
9A509UL	**Emit® Calibrator/Control Level 0***	1 x 14 mL

Emit® II Plus 6-AM/Ecstasy Calibrators/Controls	OR	Emit® II Plus Ecstasy Calibrators/Controls	Level
9R529UL	OR	9X529UL	Level 1 (150 ng/mL)
9R549UL	OR	9X549UL	Level 2 (300 ng/mL)
9R569UL	OR	9X569UL	Level 3 (500 ng/mL)
9R589UL	OR	9X589UL	Level 4 (1000 ng/mL)

Required for calibrating the Emit® II Plus Ecstasy Assay. Sold separately. To determine the appropriate calibrators required for use, see Table 1.

Note: Reagents and calibrators/controls are shipped ready to use in liquid form. No reconstitution is required.

Note: Reagents 1 and 2 are provided as a matched set. They should not be interchanged with components of kits with different lot numbers.

Note: These reagents are qualified for use with these calibrators only. However, other material may be used for quality control purposes.

Table 1 — Emit® II Plus Ecstasy Calibrators/Controls for Use in Qualitative or Semiquantitative Analysis

	Qualitative Analysis		Semiquantitative Analysis	
Desired Cutoff Level (ng/mL)	Required Cal/ Control Level	Concentration of Methylenedioxy-methamphetamine (ng/mL)	Required Cal/ Control Level	Concentration of Methylenedioxy-methamphetamine (ng/mL)
300	Level 0	0	Level 0	0
	Level 2	300	Level 1	150
	Level 4	1000	Level 2	300
			Level 3	500
500	Level 0	0	Level 1	150
	Level 3	500	Level 2	300
	Level 4	1000	Level 3	500
			Level 4	1000

Note: The Emit® II Plus Ecstasy Calibrators/Controls contain the stated concentration of methylenedioxymethamphetamine (MDMA) listed in Table 1. For any individual cutoff listed, a calibrator/control is used either as 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 calibrator/control (above or below it, as listed above) is used as control. See the Emit® II Plus Ecstasy Calibrator/Control instructions for use.

1 INTENDED USE

The Emit® 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 analyses of methylenedioxymethamphetamine (MDMA) and closely related drugs in human urine. These reagents are packaged specifically for use on a variety of AU® Clinical Chemistry Systems.

The Emit® 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.[1] ***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.***

2 SUMMARY

"Ecstasy" is the popular street name used to refer to methylenedioxymethamphetamine (MDMA).[2] Ecstasy and related drugs, methylenedioxyamphetamine (MDA) and methylenedioxyethamphetamine (MDEA), are amphetamine derivatives. The tablets, as sold illicitly in Europe and North America, may also include amphetamine and methamphetamine in the preparation.[3,4]

Ecstasy drugs are listed by the U.S. Drug Enforcement Administration as Schedule I designating no acceptable medical application with great abuse potential. These compounds are central nervous system stimulants that produce an initial feeling of euphoria and also a feeling of increased well-being, self esteem, with heightened mental and physical capacity.[5,6]

MDMA is readily absorbed from the intestinal track. Peak plasma concentrations occur approximately 2 hours after oral dose and are generally low, since MDMA passes readily into tissues. MDMA is metabolized in the liver and the excretion of the drug occurs with over 95% of the drug cleared in about 2 days.[7] Approximately 65% of the drug is excreted unchanged, with 10–15% of the dose excreted as methylenedioxyamphetamine (MDA) and a similar small amount converted to amphetamine and methamphetamine.[8]

Methods historically used for detecting MDMA in biological fluids include high-performance liquid chromatography, gas-liquid chromatography, and enzyme immunoassay.[9]

While confirmation techniques other than GC/MS may be adequate for some drugs of abuse, GC/MS is generally accepted as a vigorous confirmation technique for all drugs, since it provides the best level of confidence in the result.

3 METHODOLOGY

The Emit® II Plus Ecstasy Assay is a homogeneous enzyme immunoassay technique used for the analysis of specific compounds in human urine. The assay is based on competition between drug in the specimen and drug labeled with the 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 (*Leuconostoc mesenteroides*) enzyme employed in the assay.

4 REAGENTS

Reagents contain the following substances:

Sheep polyclonal antibodies to methylenedioxymethamphetamine (MDMA), bovine serum albumin, glucose-6-phosphate (G6P), nicotinamide adenine dinucleotide (NAD), methylenedioxyamphetamine (MDA) labeled with bacterial rG6PDH, Tris buffer, preservatives, and stabilizers.

Precautions:

- For *in vitro* diagnostic use.
- Reagent 1 contains nonsterile sheep antibodies.
- Reagents 1 and 2 contain nonsterile bovine serum albumin.
- Do not use after expiration date.
- Turbid or yellow reagents may indicate contamination or degradation and must be discarded.
- Contains sodium azide (<0.1%) as a preservative. Sodium azide can react with copper or lead pipes in drain lines to form explosive compounds. Dispose of properly in accordance with local regulations.

Safety data sheets (MSDS/SDS) available on www.siemens.com/diagnostics

Preparation of Reagents

The Emit® II Plus Ecstasy Assay reagents are provided ready to use; no preparation is necessary.

Storage of Assay Components

- Improper storage of reagents can affect assay performance.
- When not in use, store reagents upright at 2–8°C and with screw caps tightly closed.
- Unopened reagents are stable until the expiration date printed on the label, if stored upright at 2–8°C.
- Do not freeze reagents or expose them to temperatures above 32°C.

5 SPECIMEN COLLECTION AND PREPARATION

- Urine specimens may be collected in plastic (i.e., polypropylene, polycarbonate, polyethylene) or glass containers. Other than those listed, some plastics can adsorb certain drugs.
- Internal testing has shown that, if not analyzed immediately, specimens may be stored unrefrigerated for up to 7 days. Specimens may be stored refrigerated for 30 days before analysis. After 7 days unrefrigerated or 30 days refrigerated, samples should be stored frozen.[10]
- Frozen specimens must be thawed and mixed thoroughly prior to analysis.
- Specimens with high turbidity should be centrifuged before analysis.
- Urine specimens within the pH range of 3.0–11.0 do not require prior adjustment of pH.
- Adulteration of the urine specimen may cause erroneous results. If adulteration is suspected, obtain another specimen.
- Human urine specimens should be handled and treated as if they were potentially infectious.

6 PROCEDURE

Materials Provided

Emit® II Plus Ecstasy Assay

Reagent 1
Reagent 2

Materials Required But Not Provided

Emit® Calibrators/Controls
Emit® II Plus Ecstasy Calibrators/Controls
Commercial controls (see Quality Control, Semiquantitative Analysis)

Refer to the Instrument User's Guide for appropriate checks and maintenance instructions.

Calibration

Qualitative Analysis

Calibrate by running the appropriate Emit® II Plus Ecstasy Calibrator/Control—Level 2 (300 ng/mL Cutoff), or Level 3 (500 ng/mL Cutoff)—in duplicate. Validate the calibration by running controls (see Quality Control). Refer to the Emit® II Plus Ecstasy Calibrators/Controls instructions for use, the Application Sheet, and the analyzer User's Guide for additional information and instrument settings. Recalibrate as indicated by control results.

Semiquantitative Analysis

Prepare a calibration curve by running the Emit® Calibrator/Control Level 0 (0 ng/mL) and appropriate Emit® II Plus Ecstasy Calibrators/Controls: Level 1 (150 ng/mL), Level 2 (300 ng/mL), Level 3 (500 ng/mL), and Level 4 (1000 ng mL). Validate the calibration by running controls (see Quality Control). Refer to the Emit® II Plus Ecstasy Calibrators/Controls instructions for use, the Application Sheet, and the analyzer User's Guide for additional information and instrument settings. Recalibrate as indicated by control results.

Note: For semiquantitative analysis there are two curve fitting options: EIA type 1 or Poligonal.

Quality Control

Qualitative Analysis

Validate the calibration by assaying controls. Ensure that the result from Emit® Calibrator/Control Level 0 (0 ng/mL) or Emit® II Plus Ecstasy Calibrator/Control Level 4 (1000 ng/mL) relates appropriately to the result from the selected cutoff calibrator level (Level 2 [300 ng/mL] or Level 3 [500 ng/mL]). Once the calibration is validated, run urine specimens.

Semiquantitative Analysis

For a selected cutoff level (300 ng/mL or 500 ng/mL), validate the calibration curve by assaying commercial controls. Ensure that control results fall within acceptable limits as defined by your laboratory. Once the calibration curve is validated, run urine specimens.

Qualitative and Semiquantitative Analysis

1. Follow government regulations or accreditation requirements for quality control frequency. At least once each day of use, analyze two levels of Quality Control (QC) material with known MDMA concentrations. Follow your laboratory internal QC procedures if the results obtained are outside acceptable limits.
2. Refer to the instrument operator's manual for appropriate instrument checks.

Evaluation and Interpretation of Results

When the Emit® II Plus Ecstasy Assay is used as a qualitative assay, the amount of drugs and metabolites detected by the assay in any given specimen cannot be estimated. The assay results distinguish between positive and negative specimens—positive indicating specimens that contain methylenedioxymethamphetamine (MDMA) and closely related drugs; negative indicating specimens do not contain MDMA and closely related drugs, or that MDMA and closely related drugs are present in concentrations below the cutoff level for this assay.

- A specimen that gives a change in rate equal to or higher than the rate of the selected cutoff calibrator level is interpreted as positive.
- A specimen that gives a change in rate value lower than the rate of the selected cutoff calibrator level is interpreted as negative.

When used semiquantitatively, the Emit® II Plus Ecstasy Assay yields an approximate concentration of the drug detected by the assay (see Section 8, Specific Performance Characteristics, Analytical Recovery). The semiquantitation of positive results enables the laboratory to determine an appropriate dilution of the specimen for confirmation by GC/MS. Semiquantitation also permits the laboratory to establish quality control procedures and assess control performance.

7 LIMITATIONS OF THE PROCEDURE

- The assay is designed for use with human urine only.
- A positive result from the assay indicates the presence of Ecstasy and closely related drugs, but does not indicate or measure intoxication.
- Boric acid is not recommended as a preservative for urine.
- Other substances and/or factors not listed (e.g., technical or procedural errors) may interfere with the test and cause false results.
- Interpretation of results must take into account that urine concentrations of MDMA can vary extensively with fluid intake and other biological variables.
- Immunoassays that produce a single result in the presence of a drug and its metabolites cannot fully quantitate the concentration of individual components.

8 SPECIFIC PERFORMANCE CHARACTERISTICS

The information presented in this section is based on Emit® II Plus Ecstasy Assay studies performed on the AU400®/AU600® Clinical Chemistry System. Positive specimens were confirmed by GC/MS. Refer to the Application Sheets for other AU Clinical Chemistry Systems and for additional information. Results may vary due to analyzer-to-analyzer differences. The following performance characteristics represent total system performance and should not be interpreted to refer only to reagents.

Precision

Within-run precision was calculated according to NCCLS Guideline EP5-A by assaying 2 replicates of each cutoff calibrator/control and positive and negative controls twice a day for 20 days (N=80). Total precision was also calculated from these data. Table 2 summarizes the findings at the 300 ng/mL cutoff; Table 3 summarizes the findings at the 500 ng/mL cutoff.

Table 2 — Within-Run and Total Precision at 300 ng/mL

	Within-Run Precision			Total Precision		
Methylenedioxy-methamphetamine 300 ng/mL Cutoff	**Cutoff Cal**	**Control 75%**	**Control 125%**	**Cutoff Cal**	**Control 75%**	**Control 125%**
Mean (mAU/min)	466	435	500	466	435	500
SD	4.2	5.6	5.6	4.9	6.7	7.5
% CV	0.9	1.3	1.1	1.1	1.5	1.5

Table 3 — Within-Run and Total Precision at 500 ng/mL

	Within-Run Precision			Total Precision		
Methylenedioxy-methamphetamine 500 ng/mL Cutoff	**Cutoff Cal**	**Control 75%**	**Control 125%**	**Cutoff Cal**	**Control 75%**	**Control 125%**
Mean (mAU/min)	585	539	612	585	539	612
SD	2.7	3.1	2.9	3.4	3.3	3.2
% CV	0.8	1.0	0.8	1.0	1.0	0.9

Comparative Analysis

Clinical urine specimens were analyzed on the AU400/AU600 Clinical Chemistry System and on a reference analyzer. Table 4 summarizes the number of positive/negative results identified and the percent agreement between both analyzers.

Table 4 — Summary of Comparative Analysis

Assay	Positive	Negative	% Agreement
Ecstasy 300	56	52	99
Ecstasy 500	51	48	100

Analytical Recovery

Negative human urine specimens were spiked with concentrations of methylenedioxy-methamphetamine (MDMA). Specimens spiked with drug concentrations lower than the cutoff concentration and tested qualitatively were correctly identified as negative 100% of the time. Specimens spiked with drug concentrations greater than the cutoff were correctly identified as positive 100% of the time. Tables 5 and 6 summarize the results on semiquantitative analysis of the specimens.

Table 5 — Semiquantitative Analysis of MDMA Samples – 300 ng/mL Cutoff

Concentration (ng/mL)	EIA Type I Mean (ng/mL)	Poligonal Mean (ng/mL)
100	107	78
250	257	260
375	393	402
450	448	455

Table 6 — Semiquantitative Analysis of MDMA Samples – 500 ng/mL Cutoff

Concentration (ng/mL)	EIA Type I Mean (ng/mL)	Poligonal Mean (ng/mL)
250	259	267
375	404	413
450	485	468
550	613	644
750	791	871

Specificity

The Emit® II Plus Ecstasy Assay detects methylenedioxymethamphetamine (MDMA) and closely related drugs in human urine.

Table 7 lists the concentrations of compounds that produce a result that is approximately equivalent to the 300 ng/mL and 500 ng/mL cutoffs, respectively. Each concentration represents the reactivity level for the stated compound when it is added to a negative urine specimen. If a specimen contains more than one compound detected by the assay, lower concentrations than those listed in Table 7 may combine to produce a rate approximately equivalent to or greater than that of the cutoff calibrator.

Table 7 — Concentrations (µg/mL) of Ecstasy and Related Compounds That Produce a Result Approximately Equivalent to the 300 ng/mL and 500 ng/mL methylenedioxy-methamphetamine (MDMA) Cutoffs

Compounds	Concentration (µg/mL) at the 300 ng/mL Cutoff	Concentration (µg/mL) at the 500 ng/mL Cutoff
MDA	0.33	0.61
MDEA	0.29	0.50
MBDB	0.20	0.43
BDB	0.22	0.78
PMA	13	22.0
PMMA	3.1	9.0
HMMA	1400	2100
D-Amphetamine	160	430
D-Methamphetamine	37	130
D,L-Methamphetamine	18	53
D,L-Amphetamine	93	230
L-Amphetamine	220	310
L-Methamphetamine	30	87
4-Chloramphetamine	9	12
D,L 4-Methylamphetamine	13	—
Benzphetamine	36	88
Buproprion	2000	4400
Chloroquine	6000	6000
L-Ephedrine	230	2200
Fenfluramine	5	10
Mephentermine	180	380
Methoxyphenamine	6900	> 70000
Nor-pseudoephedrine	330	780
Phenmetrazine	3400	7400
Phentermine	700	1700
Phenylpropanolamine (PPA)	700	2200
Propanolol	1000	3200
Pseudoephedrine	220	530
Quinacrine	5000	5000
Tranylcypromine	420	630
Tyramine	1000	1600

Table 8 lists the compounds that produce a positive result by the Emit® II Plus Ecstasy Assay. Specificity testing was performed at the 300 ng/mL and 500 ng/mL cutoffs, which represent the greatest potential for cross-reactivity.

Table 8 — Concentrations of Compounds that Produce a Positive Result Approximately Equivalent to the 300 ng/ml and 500 ng/ml MDMA Cutoffs.

Compound	Concentration (µg/mL) at the 300 ng/mL Cutoff	Concentration (µg/mL) at the 500 ng/mL Cutoff
m-Chlorophenylpiperazine (m-CPP) (Trazodone and Nefazodone metabolite)	41	150
Dobutamine	49	240
Haloperidol	16	85
Isoxsuprine	47	165
Labelatol	35	80
Mebeverine	0.13	0.19
Methylone	24	74
Nylidrin	24	70
Trazodone	7	24

Table 9 lists the compounds that produce a negative result by the Emit® II Plus Ecstasy Assay at both levels.

Table 9 — Concentrations of Compounds Showing a Negative Response

Compound	Concentration (µg/mL) at the 300 ng/mL (0.3 µg/mL) Cutoff	Concentration (µg/mL) at the 500 ng/mL (0.5 µg/mL) 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	1000	1000
Atenolol	1000	1000
Benzoylecgonine	1000	1000
Buprenorphine	1000	1000
Caffeine	1000	1000
Carbamazepine	250	250
Carisoprodol	1000	1000
Chlorpheniramine	500	500
Chlorpromazine	500	500
Cimetidine	1000	1000
Clomipramine	2.5	2.5
Clonidine	1000	1000
Codeine	500	500
L-Cotinine	100	100
Cyclobenzaprine	125	125
Desipramine	800	800
Dextromethorphan	1000	1000
Dextrorphan	280	280
Diphenhydramine	1000	1000
Donepezil	59	170
Doxepin	250	250
Doxylamine	1000	1000
L-Epinephrine	1000	1000
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	1000	1000
Fenoprofen	1000	1000
Fluoxetine	125	500
Furosemide	1000	1000
Glutethimide	500	500
Ibuprofen	1000	1000
Imipramine	750	750
Ketamine	100	100
Ketoprofen	1000	1000
Ketorolac Tromethamine	350	350
Lidocaine	1000	1000
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
L-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

Table 9 — Concentrations of Compounds Showing a Negative Response (cont.)

Compound	Concentration (µg/mL) at the 300 ng/mL (0.3 µg/mL) Cutoff	Concentration (µg/mL) at the 500 ng/mL (0.5 µg/mL) Cutoff
Noracetylmethadol	25	25
11-nor-Δ^9-THC-9-COOH	100	100
Nortriptyline	1000	1000
Ofloxacin	100	100
Oxazepam	300	300
Paroxetine	5	5
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	1000	1000
Sertraline	125	125
Scopolamine	500	500
Secobarbital	1000	1000
Thioridazine	100	100
Tolmetin Sodium	2000	2000
Tramadol	1000	1000
Trifluoperazine	1000	1000
Trimethobenzamide	500	500
Trimethoprim	1000	1000
Verapamil	1000	1000
Zidovudine (AZT)	2000	2000
Zolpidem	100	100
Sympathomimetic Amines		
Diethylpropion HCl	1000	1000
D,L-Isoproterenol	1000	1000
Mephedrone	400	> 600
Metaproterenol	10	10
3,4 Methylendioxypyrovalerone (MDPV)	440	> 800
Methylphenidate (Ritalin®)	1000	1000
Phendimetrazine	400	400
Phenethylamine	20	20
Phenylephrine	20	20
Propylhexedrine	125	125
3-OH-Tyramine (dopamine)	300	300

Non-Interfering Substances

Each of the following compounds when added to urine containing methylenedioxymethamphetamine (MDMA) at ± 25% concentration of the cutoff do not yield a false response relative to the 300 and 500 ng/mL cutoff levels:

Table 10 — Non-Interfering Substances

Compound	Concentration
Acetone	1.0 g/dL
Ascorbic Acid	1.5 g/dL
Bilirubin	2.0 mg/dL
Creatinine	0.5 g/dL
Ethanol	1.0 g/dL
Gamma Globulin	0.5 g/dL
Glucose	2.0 g/dL
Hemoglobin	115 mg/dL
Human Serum Albumin	0.5 g/dL
Oxalic Acid	0.1 g/dL
Riboflavin	7.5 mg/dL
Sodium Chloride	6.0 g/dL
Urea	6.0 g/dL

Sensitivity

The sensitivity level of the Emit® II Plus Ecstasy Assay is less than 75 ng/mL. This level represents the lowest concentration of methylenedioxymethamphetamine (MDMA) that can be distinguished from 0 ng/mL with a confidence level of 95%.

9 REFERENCES

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Symbols Key

	Do not reuse
	Use By
LOT	Batch Code
REF	Catalogue Number
	Caution, consult accompanying documents
	Manufacturer
EC REP	Authorized Representative in the European Community
	Contains sufficient for <n> tests
IVD	*In Vitro* Diagnostic Medical Device
	Temperature Limitation
	Consult Instructions for Use
NON STERILE	Non-sterile
CE	CE Mark
CONTENTS	Contents
	Reconstitution Volume
LEVEL	Level

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