BECKMAN COULTER®

Emit® II *Plus* Amphetamines Assay

August 2010 9C052.5D_C

Catalog Number	Product Description	Quantity/ Volume
OSR9C229	**Emit® II Plus Amphetamines Assay**	
	OSR9C618 R1 (Antibody/Substrate Reagent 1)	2 x 33 mL
	OSR9C648 R2 (Enzyme Reagent 2)	2 x 16 mL
9A509UL	**Emit® Calibrator/Control Level 0***	1 x 14 mL
9A529UL	**Emit® Calibrator/Control Level 1 (300)***	1 x 14 mL
9A549UL	**Emit® Calibrator/Control Level 2 (500)***	1 x 14 mL
9A569UL	**Emit® Calibrator/Control Level 3 (1000)***	1 x 14 mL
9A609UL	**Emit® Calibrator/Control Level 5 (2000)***	1 x 14 mL

****Required for calibrating the Emit® II Plus Amphetamines 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® Calibrators/Controls for Use in Qualitative or Semiquantitative Analysis

	Qualitative Analysis		Semiquantitative Analysis	
Desired Cutoff Level (ng/mL)	Required Cal/Control Level	Concentration of d-methamphetamine (ng/mL)	Required Cal/Control Level	Concentration of d-methamphetamine (ng/mL)
300	Level 0	0	Level 0	0
	Level 1	300	Level 1	300
	Level 5	2000	Level 2	500
			Level 3	1000
500	Level 0	0		
	Level 2	500		
	Level 5	2000	Level 0	0
			Level 1	300
1000	Level 0	0	Level 2	500
	Level 3	1000	Level 3	1000
	Level 5	2000	Level 5	2000

Note: The Emit® Calibrators/Controls contain the stated concentration of d-methamphetamine 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) are used as controls. See the Emit® Calibrator/Control instructions for use.

1 INTENDED USE

The Emit® II Plus Amphetamines Assay is a homogeneous enzyme immunoassay with a 300 ng/mL, 500 ng/mL or 1000 ng/mL cutoff (SAMHSA initial test cutoff level).[1] The assay is intended for use in the qualitative and semi-quantitative analyses of amphetamines in human urine. These reagents are packaged specifically for use on a variety of AU® Clinical Chemistry Systems.

The Emit® II Plus Amphetamines 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.[2] 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

Amphetamines are central nervous system stimulants that produce wakefulness, alertness, increased energy, reduced hunger, and an overall feeling of well being. The term "amphetamines" refers to a group of drugs that includes d-amphetamine, d-methamphetamine (*N*-methyl derivative of amphetamine), d,l-amphetamine, methylenedioxyamphetamine (MDA) and methylenedioxymethamphetamine (MDMA).[3] Amphetamines can be inhaled, taken orally, intravenously, or by smoking.[3]

Amphetamines are readily absorbed from the gastrointestinal tract and are then either deactivated by the liver or excreted unchanged in the urine. The relative importance of these elimination modes depends on urinary pH. Amphetamine is metabolized to deaminated (hippuric and benzoic acids) and hydroxylated metabolites. Methamphetamine is partially metabolized to amphetamine, its major active metabolite.[3]

Amphetamines appear in urine within three hours after any type of administration[4] and can be detected by this Emit® assay for as long as 24–48 hours after the last dose.[2] The Emit® II Plus Amphetamines Assay detects both d-amphetamine and d-methamphetamine. The assay also detects d,l-amphetamine, d,l-methamphetamine, l-amphetamine, l-methamphetamine, methylenedioxyamphetamine (MDA), methylenedioxymethamphetamine (MDMA) and methylenedioxyethylamphetamine (MDEA) in human urine (see Table 14). The assay contains monoclonal antibodies and is therefore less subject to interferences from amphetamine-like compounds than assays containing polyclonal antibodies. While interferences are reduced with this assay, like any immunological test, some interfering compounds do exist. For this reason, confirmation of preliminary positive results is always recommended.

Methods historically used for detecting amphetamines in biological fluids include liquid chromatography, gas-liquid chromatography, fluorometry, and enzyme immunoassay.[5]

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.[2]

3 METHODOLOGY

The Emit® II Plus Amphetamines Assay is a homogeneous enzyme immunoassay technique used for the analysis of specific compounds in human urine.[6] The assay is based on competition between drug in the specimen and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) 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, 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:

Mouse monoclonal antibodies to d-amphetamine (61 µg/mL) and d-methamphetamine (10 µg/mL), glucose-6-phosphate (5.5 mM), nicotinamide adenine dinucleotide (3.5 mM), bovine serum albumin, amphetamines labeled with bacterial G6PDH (0.72 U/mL), Tris buffer, preservatives and stabilizers.

Precautions

- For *in vitro* diagnostic use
- Reagent 1 contains nonsterile mouse 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.

Preparation of Reagents

The Emit® II Plus Amphetamines 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, reagents must be stored at 2–8°C (36–46°F), upright, 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. Some plastics, other than those listed, can absorb certain drugs.
- If not analyzed immediately, specimens may be stored unrefrigerated for up to 7 days following collection. After 7 days, specimens should be stored frozen at -20°C.[7]
- 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 Amphetamines Assay

Reagent 1
Reagent 2

Materials Required But Not Provided

Emit® Calibrators/Controls
Commercially available controls (see Quality Control, Semiquantitative Analysis)
The use of d-amphetamine controls with the 1000 ng/mL cutoff is not recommended. Recovery and performance of d-amphetamine and d-methamphetamine are not equivalent above 1100 ng/mL.

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

Calibration

Qualitative Analysis

Run the appropriate Emit® Calibrator/Control—Level 1 (300 ng/mL Cutoff), Level 2 (500 ng/mL Cutoff), or Level 3 (1000 ng/mL Cutoff)—in duplicate. Validate the calibration by running controls (see Quality Control). Refer to the analyzer User's Guide for the Application Sheet for instrument settings. Recalibrate as indicated by control results.

Semiquantitative Analysis

Prepare a calibration curve by running the appropriate Emit® Calibrators/Controls: Level 0 (0 ng/mL), Level 1 (300 ng/mL), Level 2 (500 ng/mL), Level 3 (1000 ng/mL), and Level 5 (2000 ng/mL). Validate the calibration by running controls (see Quality Control). Refer to the Emit® 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.

Quality Control

Qualitative Analysis

Validate the calibration by assaying controls. Ensure that the result from Emit® Calibrator/Control level (Level 0 [0 ng/mL] or Level 5 [2000 ng/mL]) relates appropriately to the cutoff calibrator result from the selected cutoff calibrator level (Level 1 [300 ng/mL], Level 2 [500 ng/mL] or Level 3 [1000 ng/mL]). Once calibration is validated, run urine specimens.

Semiquantitative Analysis

For a selected cutoff level (300 ng/mL, 500 ng/mL or 1000 ng/mL), validate the calibration 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.

Evaluation and Interpretation of Results

When the Emit® II Plus Amphetamines 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 contain amphetamines; negative indicating specimens do not contain amphetamines, or amphetamines are present in concentrations below the cutoff level for this assay.

- A specimen that gives a change in rate value 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 Amphetamines Assay yields the approximate concentration of the drug detected by the assay (See Section 8, Specific Performance Chacteristics, 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 only with human urine.
- A positive result from the assay indicates the presence of amphetamines but does not indicate or measure intoxication.
- 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 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.
- Boric acid is not recommended as a preservative for urine.
- Carryover with the reformulated amphetamine was not significant at all 3 cutoffs using up to 100,000 ng/mL of an amphetamine spiked urine sample. Carryover criteria was a change in response < 50% of the negative control (75% of the cutoff concentration).

8 SPECIFIC PERFORMANCE CHARACTERISTICS

The information presented in this section is based on Emit® II Plus Amphetamines 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.

300 ng/mL Cutoff

Accuracy

Clinical urine specimens were analyzed at the 300 ng/mL cutoff on the AU400/AU600 Clinical Chemistry System and on a reference analyzer. Table 2 summarizes the number of positive/negative results identified and the percent agreement with the reference analyzer.

Table 2 — Summary of Comparative Analysis

Assay	Positive	Negative	% Agreement
Amphetamines	69	55	100

Analytical Recovery

Negative human urine specimens were spiked with known concentrations of d-amphetamine and d-methamphetamine. 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 3 and 4 summarize the results on semiquantitative analysis of the specimens.

Table 3 — d-Amphetamine Spiked Sample Semiquantitative Analysis (300 ng/mL cutoff)

Nominal Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
150	88	59
200	167	83
350	332	95
450	396	88

Table 4 — d-Methamphetamine Spiked Sample Semiquantitative Analysis (300 ng/mL cutoff)

Nominal Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
150	82	55
200	145	72
350	332	95
450	429	95

Precision

Within-run precision was determined according to NCCLS Guidelines 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 5 summarizes the findings at the 300 ng/mL cutoff.

Table 5 — Within-Run and Total Precision at 300 ng/mL

	Within-Run Precision			Total Precision		
d-methamphetamine 300 ng/mL Cutoff	**Cutoff Cal**	**Control 75%**	**Control 125%**	**Cutoff Cal**	**Control 75%**	**Control 125%**
Mean (mAU/min)	396	371	431	396	371	431
SD	6.2	5.1	6.6	6.8	6.3	8.5
% CV	1.3	1.2	1.3	1.4	1.4	1.7

500 ng/mL Cutoff

Accuracy

Clinical urine specimens were analyzed at the 500 ng/mL cutoff on the AU400/AU600 Clinical Chemistry System and on a reference analyzer. Table 6 summarizes the number of positive/negative results identified and the percent agreement with the reference analyzer.

Table 6 — Summary of Comparative Analysis

Assay	Positive	Negative	% Agreement
Amphetamines	72	57	99

Analytical Recovery

Negative human urine specimens were spiked with known concentrations of d-amphetamine and d-methamphetamine. 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 7 and 8 summarize the results on semiquantitative analysis of the specimens.

Table 7 — d-Amphetamine Spiked Sample Semiquantitative Analysis (500 ng/mL cutoff)

Nominal Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
200	172	86
350	334	95
450	421	94
600	575	96

Table 8 — d-Methamphetamine Spiked Sample Semiquantitative Analysis (500 ng/mL cutoff)

Nominal Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
200	165	83
350	329	94
450	413	92
600	598	99

Precision

Within-run precision was determined 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 9 summarizes the findings at the 500 ng/mL cutoff.

Table 9 — Within-Run and Total Precision at 500 ng/mL

	Within-Run Precision			Total Precision		
d-methamphetamine 500 ng/mL Cutoff	**Cutoff Cal**	**Control 75%**	**Control 125%**	**Cutoff Cal**	**Control 75%**	**Control 125%**
Mean (mAU/min)	432	393	468	432	393	468
SD	1.3	1.3	1.2	1.9	1.8	2.3
% CV	0.5	0.5	0.4	0.7	0.7	0.8

1000 ng/mL Cutoff

Accuracy

Clinical urine specimens were analyzed at the 1000 ng/mL cutoff on the AU400/AU600 Clinical Chemistry System and on a reference analyzer. Table 10 summarizes the number of positive/negative results identified and the percent agreement with the reference analyzer.

Table 10 — Summary of Comparative Analysis

Assay	Positive	Negative	% Agreement
Amphetamines	57	86	95

Analytical Recovery

Negative human urine specimens were spiked with known concentrations of d-amphetamine and d-methamphetamine. 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 11 and 12 summarize the results on semiquantitative analysis of the specimens.

Table 11 — d-Amphetamine Spiked Sample Semiquantitative Analysis (1000 ng/mL cutoff)

Nominal Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
200	187	94
350	330	94
600	574	96
1200	1077	90

Table 12 — d-Methamphetamine Spiked Sample Semiquantitative Analysis (1000 ng/mL cutoff)

Nominal Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
200	176	88
350	315	90
600	554	92
1200	1260	105

Precision

Within-run precision was determined 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 13 summarizes the findings at the 1000 ng/mL cutoff.

Table 13 — Within-Run and Total Precision at 1000 ng/mL

	Within-Run Precision			Total Precision		
d-methamphetamine 1000 ng/mL Cutoff	**Cutoff Cal**	**Control 75%**	**Control 125%**	**Cutoff Cal**	**Control 75%**	**Control 125%**
Mean (mAU/min)	460	413	497	460	413	497
SD	1.2	1.3	1.3	1.7	2.4	1.6
% CV	0.5	0.5	0.4	0.6	1.0	0.5

Specificity

The Emit® II Plus Amphetamines Assay detects amphetamine compounds in human urine.

Data found in the following tables are representative of the performance of this assay. However, results may vary among reagent lots.

Table 14 lists the concentrations of amphetamine compounds that produce a result that is approximately equivalent to the 300 ng/mL, 500 ng/mL, and 1000 ng/mL calibrator/control cutoffs. Each concentration represents the reactivity level for the stated compound when it is added to a negative urine specimen. These concentrations are within the range of the levels found in urine following use of the compound or, in case of metabolites, the parent compound. If a specimen contains more than one compound detected by the assay, lower concentrations than those listed in Table 14 may combine to produce a rate approximately equivalent to or greater than that of the cutoff calibrator.

Table 14 — Concentrations of Amphetamines that Produce a Result Approximately Equivalent to the 300 ng/mL, 500 ng/mL and 1000 ng/mL Amphetamines Cutoffs

	Concentration (ng/mL) Giving a Response Approximately Equivalent to the Cutoff		
Compound	**300 ng/mL Cutoff**	**500 ng/mL Cutoff**	**1000 ng/mL Cutoff**
d,l-Methamphetamine	519	749	1500
d,l-Amphetamine	545	890	1961
l-Methamphetamine	586	809	1798
l-Amphetamine	2434	3746	8651
MDA	773	1809	3794
MDMA	4195	5109	13037
MDEA	3863	4791	11192

Table 15 lists the concentrations of compounds that produce a result that is approximately equivalent to the 300 ng/mL, 500 ng/mL, and 1000 ng/mL cutoffs. Each concentration represents the reactivity level for the stated compound when it is added to a negative urine specimen. Most of the compounds react at levels much higher than typically found in urine (but which may occasionally occur).[5,8] If a specimen contains more than one compound detected by the assay, lower concentrations than those listed in Table 15 may combine to produce a rate approximately equivalent to or greater than that of the cutoff calibrator.

Table 15 — Concentrations of Compounds that Produce a Result Approximately Equivalent to the 300 ng/mL, 500 ng/mL and 1000 ng/mL Amphetamines Cutoffs

	Concentration (µg/mL) Giving a Response Approximately Equivalent toThe Cutoff		
Compound	**300 ng/mL Cutoff**	**500 ng/mL Cutoff**	**1000 ng/mL Cutoff**
4-Cloramphetamine	2.7	2.5	8.2
Benzphetamine*	0.5	0.8	1.3
Bupropion	193	355	814
Chloroquine	989	1347	3233
l-Ephedrine	443	1369	2240
Fenfluramine	20	57.8	75
Mephentermine	7.8	38.9	22.2
Methoxyphenamine	86	102	231
Nor-pseudoephedrine	59	63	142
Phenmetrazine	2.0	3	6.9
Phentermine	6.9	8.0	16.8
Phenylpropanolamine (PPA)	700	1000	2000
Propranolol	90	117	306
d,l-Pseudoephedrine	1650	1725	4340
Quinacrine	2356	2199	5696
Tranylcypromine	29	36	85
Tyramine	169	173	390

Benzphetamine metabolizes to amphetamine and methamphetamine

Note: Selegiline, a prescription medication used in the treatment of Parkinson's disease, metabolizes to l-amphetamine and l-methamphetamine. Therefore, patients taking Selegiline may test positive by amphetamine assays.

Table 16 lists compounds that produce a negative result by the Emit® II Plus Amphetamines Assay on a reference analyzer. Specificity testing was performed at the 300, 500, and 1000 ng/mL cutoffs. Positive results for compounds structurally unrelated to amphetamines have not been observed.

Table 16 — Concentrations of Compounds Showing a Negative Response

Compound	300 ng/mL Cutoff (µg/mL)	500 ng/mL Cutoff (µg/mL)	1000 ng/mL Cutoff (µg/mL)
Acetaminophen	1000	1000	1000
α-Acetyl-*N,N*-dinormethadol (dinor LAAM)	25	25	25
l-α-Acetylmethadol (LAAM)	25	25	25
N-acetylprocainamide (NAPA)	400	400	400
Acetylsalicylic Acid	1000	1000	1000
Albuterol	1000	1000	1000
p-Aminobenzoic Acid (PABA)	1000	1000	1000
Amitriptyline	1000	1000	1000
Amoxicillin	1000	1000	1000
Atenolol	1000	1000	1000
Benzoylecgonine	1000	1000	1000
Buprenorphine	1000	1000	1000
Caffeine	1000	1000	1000
Carbamazepine	250	250	250
Carisoprodol	1000	1000	1000
Chlorpheniramine	1000	1000	1000
Chlorpromazine	200	200	200
Cimetidine	1000	1000	1000
Clomipramine	2.5	2.5	2.5
Clonidine	1000	1000	1000
Codeine	500	500	500
l-Cotinine	100	100	100
Cyclobenzaprine	1000	1000	1000
Desipramine	300	500	800
Dextromethorphan	1000	1000	1000
Dextrorphan	280	280	280
Diphenhydramine	1000	1000	1000
Doxepin	1000	1000	1000
Doxylamine	1000	1000	1000
l-Epinephrine	1000	1000	1000
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	1000	1000	1000

Table 16 — Concentrations of Compounds Showing a Negative Response (cont.)

Compound	300 ng/mL Cutoff (µg/mL)	500 ng/mL Cutoff (µg/mL)	1000 ng/mL Cutoff (µg/mL)
Fenoprofen	150	150	150
Fluoxetine	500	500	500
Furosemide	1000	1000	1000
Glutethimide	500	500	500
Haloperidol	500	700	1000
Ibuprofen	1000	1000	1000
Imipramine	750	750	750
Isoxsuprine	300	500	500
Ketamine	100	100	100
Ketoprofen	1000	1000	1000
Ketorolac Tromethamine	1000	1000	1000
Labetalol	750	750	750
Lidocaine	1000	1000	1000
LSD	2.5	2.5	2.5
Meperidine	1000	1000	1000
Mescaline	1000	1500	1500
Methadone	1000	1000	1000
Methaqualone	1500	1500	1500
d,l-Methyldopa	1000	1000	1000
l-Methyldopa	1000	1000	1000
Monoethylglycinexylidide (MEGX)	1000	1000	1000
Morphine	1000	1000	1000
Nalmefene	20	20	20
Naloxone	500	500	500
Naproxen	1000	1000	1000
Nicotinic Acid	500	500	500
Noracetylmethadol (nor LAAM)	25	25	25
11-nor-Δ^9-THC-9-COOH	100	100	100
Nortryptyline	750	750	750
Nylidrin	750	750	750
Ofloxacin	100	100	100
Oxazepam	300	300	300
Phencyclidine	1000	1000	1000
Phenelzine	50	100	100
1-Phenylcyclohexylamine (PCA)	50	50	50
Phenytoin (DPH)	1000	1000	1000
Phthalic Acid	1000	1000	1000
1-Piperidinocyclohexane Carbonitrile (PCC)	50	50	50
Procainamide	1000	1000	1000
Promethazine	1000	1000	1000
Propoxyphene	1000	1000	1000
Ranitidine	1000	1000	1000
Scopolamine	500	500	500
Secobarbital	1000	1000	1000
Thioridazine	100	100	100
Tolmetin Sodium	2000	2000	2000
Tramadol	1000	1000	1000
Trazodone	1000	1000	1000
Trifluoperazine	1000	1000	1000
Trimethobenzamide	500	500	500
Trimethoprim	1000	1000	1000
Verapamil	1000	1000	1000
Zidovudine (AZT)	2000	2000	2000
Zolpidem	100	100	100

Table 16 — Concentrations of Compounds Showing a Negative Response (cont.)

Compound	300 ng/mL Cutoff (µg/mL)	500 ng/mL Cutoff (µg/mL)	1000 ng/mL Cutoff (µg/mL)
Sympathomimetic Amines			
Diethylpropion	1000	1000	1000
d,l-Isoproterenol	1000	1000	1000
Metaproterenol	500	500	500
Methylphenidate (Ritalin®)	1000	1000	1000
Phenethylamine	15	20	20
Phenylephrine	1000	1000	1000
Propylhexedrine	20	30	50
3-OH-Tyramine (dopamine)	300	300	300

Sensitivity

The sensitivity level of the Emit® II Plus Amphetamines Assay is 50 ng/mL at the 300 ng/mL cutoff, 75 ng/mL at the 500 ng/mL cutoff and 100 ng/mL at the 1000 ng/mL cutoff. This level represents the lowest concentration of d-methamphetamine 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

2010-07_BC

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