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ADVIA® 1800
ADVIA® 2400
Chemistry Systems

Ecstasy (XTC)

Current Revision and Date[a]	Rev. F, 2019-09	
Product Name	ADVIA® Chemistry Ecstasy (XTC) Reagents	REF 10378735
Systems	ADVIA 1800 Chemistry System ADVIA 2400 Chemistry System	
Materials Required but Not Provided	Emit® Calibrators/Controls Level 0 (0 ng/mL) REF 9A509UL	
	Emit II Plus 6-AM/Ecstasy Calibrators/Controls Level 1 (150 ng/mL) 9R529UL Level 2 (300 ng/mL) 9R549UL Level 3 (500 ng/mL) 9R569UL Level 4 (1000 ng/mL) 9R589UL	
	Reagent container adapters Commercially available controls	
Specimen Types	Urine	
Assay Principle	Enzyme multiplied immunoassay technique (EMIT)	
Assay Range	**Cutoff**	**Range**
	300 ng/mL 500 ng/mL	75–500 ng/mL 75–1000 ng/mL
Reagent Storage	2–8°C	
Reagent On-System Stability	30 days	
Reagent Code	74831	

[a] In Rev. E or later, a vertical bar in the margin indicates a technical update to the previous version.

Intended Use

For *in vitro* diagnostic use in the qualitative and semiquantitative analyses of methylenedioxymethamphetamine (MDMA) and closely related drugs in human urine on ADVIA® Chemistry systems.

The ADVIA Chemistry Ecstasy (XTC) 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 judgement should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.

Summary and Explanation

Ecstasy is a synonym for methylenedioxymethamphetamine (MDMA).[1] Ecstasy and related drugs, methylenedioxyamphetamine (MDA) and methylenedioxyethylamphetamine (MDEA), are amphetamine derivatives. The tablets, as sold illicitly in Europe and North America, may also include amphetamine and methamphetamine in the preparation.[2,3]

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 and self esteem, with heightened mental and physical capacity.[4,5]

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.[6] Approximately 65% of the drug is excreted unchanged, with 10–15% of the dose excreted as MDA and a similar small amount converted to amphetamine and methamphetamine.[7]

Assays historically used to detect MDMA in biological fluids include high-performance liquid chromatography, gas-liquid chromatography, and enzyme immunoassay.[8]

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

Principles of the Procedure

The ADVIA Chemistry XTC assay is a homogeneous immunoassay that is used for the qualitative or semiquantitative analysis of MDMA in human urine. The ADVIA Chemistry XTC assay uses the Syva® Emit® II Plus Ecstasy reagents in ADVIA Chemistry containers.

This assay is based on competition between drug in the 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 reduced nicotinamide adenine dinucleotide (NADH) in the presence of glucose-6-phosphate (G6P), resulting in an absorbance change that is measured spectrophotometrically at 340/410 nm. Endogenous G6PDH does not interfere because the coenzyme NAD functions only with the bacterial (*Leuconostoc mesenteroides*) enzyme employed in this assay.

Reagents

Reagent	Description	Storage	Reagent Stability
REF 10378735	**ADVIA Chemistry Ecstasy (XTC) Reagents**		
Ecstasy Reagent 1 XTC R1	20.0 mL in 20-mL containers Sheep polyclonal antibodies to methylenedioxymethamphetamine (MDMA) (5.3 µg/mL)[a] Glucose-6-phosphate (G6P) (5.5 mM) Nicotinamide Adenine Dinucleotide (NAD) (3.5 mM) Bovine serum albumin Preservatives and stabilizers including Methylisothiazolinone (MIT) < 0.1%	2–8°C	**Unopened:** Stable until the expiration date on product. **On-system:** 30 days
Ecstasy Reagent 2 XTC R2	10.5 mL in 20-mL containers Methylenedioxyamphetamine (MDA) labeled with recombinant glucose-6-phosphate dehydrogenase (rG6PDH) (0.26 U/mL)[a] Tris buffer Bovine serum albumin Preservatives and stabilizers including Methylisothiazolinone (MIT) < 0.1% NaN_3 (< 0.1%)	2–8°C	**Unopened:** Stable until the expiration date on product. **On-system:** 30 days

[a] The antibody titer and enzyme conjugate activity may vary from lot to lot.

Warnings and Precautions

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

Caution

This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

Contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent the buildup of azides. Disposal into drain systems must be in compliance with prevailing regulatory requirements.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner, and in compliance with prevailing regulatory requirements.

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

For *in vitro* diagnostic use.

Preparing Reagents

All reagents are liquid and ready to use.

Before use, gently invert the capped reagent to disrupt bubbles and ensure homogeneity. If bubbles still exist or foam is present, use a clean transfer pipette to aspirate them from the reagent container prior to use.

Storing and Stability

Unopened reagents are stable until the expiration date printed on the product label when stored at 2–8°C. Do not freeze reagents.

Specimen Collection and Handling

Siemens Healthcare Diagnostics validated urine for the ADVIA Chemistry XTC assay.

The purpose of handling and storage information is to provide guidance to users. It is the responsibility of the individual laboratory to use all available references and/or its own studies when establishing alternate stability criteria to meet specific needs.

Collecting the Specimen

Follow these guidelines for specimens used for this assay:

- Urine specimens may be collected in plastic (such as polypropylene, polycarbonate, or polyethylene) or glass containers. Some plastics can adsorb certain drugs.
- Specimens with high turbidity should be centrifuged before analysis.
- Urine specimens within the pH range of 3.0 to 11.0 do not require prior pH adjustment.
- 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 are potentially infectious.
- Frozen specimens must be thawed and mixed thoroughly prior to analysis.

Storing the Specimen

Follow these guidelines for specimens used for this assay:

- 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.

Procedure

Materials Provided

The following materials are provided:

Item	Contents	Number of Tests
REF 10378735	Reagent 1: 4 × 20-mL containers Reagent 2: 4 × 20-mL containers	4 × 190

Materials Required but Not Provided

The following materials are required to perform this assay, but are not provided:

Item	Description
REF 9A509UL	Emit Calibrators/Controls Level 0 (0 ng/mL)
REF 9R529UL	Emit II Plus 6-AM/Ecstasy Calibrators/Controls Level 1 (150 ng/mL)
REF 9R549UL	Emit II Plus 6-AM/Ecstasy Calibrators/Controls Level 2 (300 ng/mL)
REF 9R569UL	Emit II Plus 6-AM/Ecstasy Calibrators/Controls Level 3 (500 ng/mL)
REF 9R589UL	Emit II Plus 6-AM/Ecstasy Calibrators/Controls Level 4 (1000 ng/mL)
REF 02404085	20-mL reagent container adapter for 40-mL slot (ADVIA 1800)
REF 00771668	20-mL reagent container adapter for 70-mL slot (ADVIA 2400)
	Commercially available control materials

Assay Procedure

Sampling, reagent delivery, mixing, and processing are automatically performed by the ADVIA Chemistry system.

For detailed information on performing the procedure, refer to the system operating instructions.

Preparing the System

For detailed information on preparing the system, refer to the system operating instructions.

Preparing the Samples

Before placing samples on the system, ensure that samples have the following characteristics:

- Samples are free of particulate matter.
- Samples are free of bubbles.

On-System Stability

The ADVIA Chemistry XTC reagents are stable on the system for 30 days.

Do not use reagents beyond the expiration date.

Performing Calibration

To calibrate the ADVIA Chemistry XTC assay, use the Emit Calibrators/Controls Level 0 (REF 9A509UL) and the following Emit II Plus 6-AM/Ecstasy Calibrators/Controls:

- Level 1 (9R529UL)
- Level 2 (9R549UL)
- Level 3 (9R569UL)
- Level 4 (9R589UL)

For both qualitative and semiquantitative analyses, a calibrator is used either as a calibrator or as a control for any individual cutoff level. When a calibrator/control is used as a calibrator for an individual cutoff level, the other levels of calibrators/controls above and below it (as listed in Table 1) are used as controls.

Calibration Frequency

Calibrate the assay every 15 days.

Calibrate the assay after the following events:

- When the reagent lot number changes
- When a reagent pack is replaced by a new reagent pack with the same lot number, and the previous reagent pack was recalibrated during use
- After replacing critical optical or hydraulic components
- When indicated by quality control procedures

Individual laboratory quality control programs and procedures may require more frequent calibration.

Reagent Blank (RBL) Frequency

The ADVIA Chemistry system measures the RBL during assay calibration.

Run an additional RBL on the same reagent pack every day.

Run an additional RBL when a reagent pack is replaced by a new reagent pack with the same lot number, and an additional reagent blank was run during use.

Note Use Emit Calibrator/Control - Level 0 as the sample for the RBL in the ADVIA Chemistry XTC_2 assay.

For more information on running daily reagent blanks for multiple standard methods on the ADVIA Chemistry systems, refer to the Customer Bulletin entitled: *Performing Reagent Blank (RBL) on Multi Standard (MSTD) Assays* (PN 073D0483, latest revision).

Qualitative Analysis

For qualitative analysis, run the appropriate Emit II Plus 6-AM/Ecstasy Calibrators/Controls in duplicate for the 300 ng/mL or 500 ng/mL cutoff listed in Table 1. Validate the calibration by assaying controls. Recalibrate as indicated by the quality control results.

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

Semiquantitative Analysis

For semiquantitative analysis, run the Emit Calibrator/Control Level 0 or the appropriate Emit II Plus 6-AM/Ecstasy Calibrators/Controls. Validate the calibration by assaying controls. Recalibrate as indicated by the quality control results.

Table 1: Emit Calibrator/Control Level 0 and Emit II Plus 6-AM/Ecstasy Calibrators/Controls for Use in Qualitative or Semiquantitative Analysis

Calibrators/Controls for Qualitative Analysis at the 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)[a] Level 4 (1000)	Level 0 (0)[a] Level 1 (150) Level 2 (300) Level 3 (500)
500 (Level 3)	Level 0 (0)[a] Level 4 (1000)	Level 0 (0)[a] Level 1 (150) Level 2 (300) Level 3 (500) Level 4 (1000)

[a] Emit Calibrator/Control Level 0

Refer to the package insert supplied with the Emit Calibrators/Controls and Emit II Plus 6-AM/Ecstasy Calibrators/Controls for handling instructions and values, or to the *Calibration* chapter of the operator's guide for more information.

Test Definitions (TDEFs)

Adjust the test definition (TDEF) parameter settings to run the ADVIA Chemistry XTC assay as a qualitative or semiquantitative assay, and to change the drug cutoff level.

The TDEF parameters for the ADVIA Chemistry XTC assay that are installed in your ADVIA Chemistry system contain the correct settings to run the ADVIA Chemistry XTC assay in qualitative mode at the 500 ng/mL cutoff level. To run a test in semiquantitative mode, or to change the cutoff level, adjust the TDEF parameters as listed in Table 2.

For more information on adjusting the parameters to run in the Semiquantitative Mode on the ADVIA Chemistry systems, refer to the Customer Bulletin entitled: *ADVIA Chemistry System EMIT Drugs of Abuse, Customizing the Software for Qualitative and Semiquantitative DAU Testing* (PN 073D0484, latest revision).

The following table provides settings to configure the assay type and cutoff level.

Table 2: ADVIA Chemistry XTC Assay TDEF Parameters for Available Assay Modes

		Qualitative		Semiquantitative	
Setting	**TDEF Parameter**	**XTC300**	**XTC500**	**XTC300**	**XTC500**
Sub Analytical Conditions	Name	XTC300	XTC500	XTC300	XTC500
Analytical Conditions	Serum reac s. vol.	23	16	23	16
	Urine reac. s. vol.	23	16	23	16
Sub Param. #1	Calc. method	STD	STD	MSTD	MSTD
	Qualit. judge	Do	Do	Not Do	Not Do
One-Point Cal Setting	FV	300	500	[a]	[a]

		Qualitative		Semiquantitative	
Setting	**TDEF Parameter**	**XTC300**	**XTC500**	**XTC300**	**XTC500**
Multipoint Cal Setting	Formula	[a]	[a]	Logit Log 2	Logit Log 2
	Points	[a]	[a]	4	5
	FV1	[a]	[a]	150	150
	FV2	[a]	[a]	300	300
	FV3	[a]	[a]	500	500
	FV4	[a]	[a]		1000
Qualitative Judgement Set	Urine setting range	300, 99999	500, 99999	[a]	[a]
Standards Setting	Abnml (serum) H	[a]	[a]	500	1000
	Abnml (serum) L	[a]	[a]	75	75
	Abnml (urine) H	[a]	[a]	500	1000
	Abnml (urine) L	[a]	[a]	75	75
	FV	[a]	[a]	300	500

[a] Setting values are ignored by the system for these cases.

Performing Quality Control

Follow government regulations or accreditation requirements for quality control frequency.

A satisfactory level of performance is achieved when the analyte values obtained are within the expected control range for the system or within your range, as determined by an appropriate internal laboratory quality control scheme.

The actual frequency of control in a laboratory is based on many factors, such as workflow, system experience, and government regulation. Each laboratory should evaluate the controls based on the frequency established by their laboratory guidelines.

Also, assay controls under the following conditions:

- Whenever you use a new reagent lot
- Following any system maintenance, cleaning, or troubleshooting procedure
- After performing a new calibration or an additional reagent blank

Follow your laboratory internal QC procedures if the results obtained are outside acceptable limits.

Qualitative Analysis

For qualitative analysis, Siemens recommends the use of Emit Calibrator/Control Level 0 (0 ng/mL) and Emit II Plus 6-AM/Ecstasy Calibrators/Controls of at least 2 levels (low and high).

Ensure that the result from Emit Calibrator/Control Level 0 (0 ng/mL) and Emit II Plus 6-AM/ Ecstasy Calibrator/Control Level 4 (1000 ng/mL) relates appropriately to the result from the cutoff calibrator chosen from column 1 in Table 1.

If the Emit Calibrator/Control Level 0 (0 ng/mL) was run, ensure that the result is negative relative to the selected cutoff calibrator level.

If Emit II Plus 6-AM/Ecstasy Calibrator/Control Level 4 (1000 ng/mL) was run, ensure that the result is positive relative to the selected cutoff calibrator level.

Once the calibration is validated, run urine specimens.

Semiquantitative Analysis

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.

Taking Corrective Action

If the quality control results do not fall within the expected control range or within the laboratory's established values, do not report results. Take the following actions:

1. Determine and correct the cause of the unacceptable control results:
    a. Verify that the assay was performed according to the instructions for use.
    b. Verify that the materials are not expired.
    c. Verify that required maintenance was performed.
    d. Rerun the assay with fresh quality control samples, and confirm that quality control results are within acceptable limits before running patient samples.
    e. If the quality control results are not within acceptable limits, recalibrate the assay, and repeat the prior step.
    f. If necessary, contact your local technical support provider or distributor for assistance.
2. After corrective action is complete, repeat required testing of patient samples before reporting results.

Perform corrective actions in accordance with your established laboratory protocol.

Results

Calculation of Results

The system calculates and reports results based on the absorbance measurements of the test sample during the test, and of the calibrator(s) from calibration.

The instrument provides qualitative analysis results as positive (+) or negative (-), and semiquantitative analysis results in ng/mL (common units or SI units).

Qualitative Analysis

Refer to Table 1 for the appropriate cutoff for the Emit II Plus 6-AM/Ecstasy Calibrators/Controls. Table 1 contains the MDMA concentration present in the Emit II Plus 6-AM/Ecstasy Calibrators/Controls selected as a cutoff, and used to distinguish positive from negative specimens.

Positive Results: A specimen that gives a change in rate value greater than or equal to the Emit II Plus 6-AM/Ecstasy Calibrator/Control cutoff rate value is interpreted as positive (the specimen contains MDMA).

Negative Results: A specimen that gives a change in rate value less than the Emit II Plus 6-AM/Ecstasy Calibrator/Control cutoff rate value is interpreted as negative. Either the specimen does not contain MDMA or MDMA is present in concentrations below the cutoff level for this assay.

Semiquantitative Analysis

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. Refer to the *Analytical Measuring Range* section for the semiquantitative range.

Using the ADVIA Chemistry XTC assay, it is possible to make semiquantitative determinations of methylenedioxymethamphetamine (MDMA). An estimate of relative total drug concentrations may be obtained by running the appropriate Calibrators/Controls: Levels 0 (0 ng/mL), 1 (150 ng/mL), 2 (300 ng/mL), 3 (500 ng/mL), or 4 (1000 ng/mL). Refer to Table 1 for requirements.

Limitations

The ADVIA Chemistry XTC procedure has the following limits:

- 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.
- There is a possibility that substances and/or factors not listed (such as 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.

A number of substances cause physiological changes in urine analyte concentrations. A comprehensive discussion of possible interfering substances, their urine concentrations, and their possible physiological involvements is beyond the scope of this document. Consult the listed reference for specific details on known potential interfering substances.[9]

As with any chemical reaction, you must be alert to the possible effect on results of unknown interferences from medications or endogenous substances. The laboratory and physician must evaluate all patient results in light of the total clinical status of the patient.

Siemens has determined that there is a possibility for certain reagents to interact with the ADVIA Chemistry XTC assay when run on the same system. To mitigate these carryover events, the ADVIA Chemistry system software provides a Contamination Avoidance process. For further information and instructions to establish this process on your systems, refer to the Customer Bulletin entitled: *Consolidated Directory of Contamination Avoidance Settings for ADVIA Chemistry Systems* (PN 073D0354, latest revision).

Expected Values

When the ADVIA Chemistry XTC assay is used as a qualitative method, 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 MDMA and closely related drugs.

When run as a semiquantitative assay, the ADVIA Chemistry XTC assay yields approximate, cumulative concentrations above the cutoff level of MDMA and closely related drugs (refer to the *Results* section).

Performance Characteristics

Analytical Measuring Range

When run as a semiquantitative method, the ADVIA Chemistry XTC assay measures the ecstasy concentration in urine ranging from the Limit of Detection (LoD) to the ecstasy concentrations in the highest level of the calibrator, as listed in the following table.

Cutoff	Range
300 ng/mL	75–500 ng/mL
500 ng/mL	75–1000 ng/mL

Specificity

The ADVIA Chemistry XTC assay detects MDMA and closely related drugs in human urine.

The specificity of the assay was evaluated by assaying compounds whose chemical structure or concurrent usage could potentially interfere with the ADVIA Chemistry XTC assay. These data were collected on an automated chemistry system using method parameters equivalent to those used on the ADVIA Chemistry systems.[10]

MDA and MDMA recover according to the proposed SAMHSA mandatory guidelines of ± 50% of each respective cutoff value. Tables 3, 4, and 5 list the concentrations of compounds that produce a result equivalent to the 300 ng/mL and 500 ng/mL cutoffs. If a specimen contains more than one compound detected by the assay, lower concentrations than those listed in Table 4 may combine to produce a rate equal to or greater than that of the cutoff calibrator. Data presented are representative of typical performance of this method.

Table 3: Concentrations of Structurally Related Compounds that Produce a Positive Result Equivalent to the 300 ng/mL and 500 ng/mL MDMA Cutoffs

Compound	Concentration Tested (µg/mL) at the 300 ng/mL Cutoff	Concentration Tested (µg/mL) at the 500 ng/mL Cutoff
Methylenedioxyamphetamine (MDA)	0.0247	0.495
Methylenedioxyethylamphetamine (MDEA)	0.250	0.435
N-methyl-1-(1,3-benzodioxol-5-yl)-2-aminobutane (MBDB)	0.2	0.43
3,4-(methylenedioxyphenyl)-2-butanamine (BDB)	0.22	0.78
Para-methoxyamphetamine (PMA)	13	22
Para-methoxymethamphetamine (PMMA)	3.1	9.0
4-Hydroxy-3-methoxymethamphetamine (HMMA)	182.63	377.214

Table 4: Concentrations of Structurally Related Compounds that Produce a Positive Result Equivalent to the 300 ng/mL and 500 ng/mL MDMA Cutoffs

Compound	Concentration Tested (µg/mL) at the 300 ng/mL Cutoff	Concentration Tested (µg/mL) at the 500 ng/mL Cutoff
d-Amphetamine	41	80
d,l-Amphetamine	28	62
l-Amphetamine	28	48
4-Chloramphetamine	9	12
Benzphetamine	5	11
Buproprion	108	214
l-Ephedrine	56	106
Fenfluramine	5	10
Mephentermine	26	64
d-Methamphetamine	9.1	18
d,l-Methamphetamine	7	14.5
d,l-4-Methylamphetamine	5.3	12.9
l-Methamphetamine	8	13.8
Methoxyphenamine	162	385
Nor-pseudoephedrine	330	780
Phenmetrazine	262	477
Phentermine	79	207
Phenylpropanolamine (PPA)	269	565
Propanolol	98	148
d-Pseudoephedrine	46	83
Tranylcypromine	102	224

Table 5: Concentrations of Structurally Unrelated Compounds that Produce a Positive Result Equivalent to the 300 ng/mL and 500 ng/mL MDMA Cutoffs

Compound	Concentration Tested (µg/mL) at the 300 ng/mL Cutoff	Concentration Tested (µg/mL) at the 500 ng/mL Cutoff
m-Chlorophenylpiperazine (m-CPP) (Trazodone and Nefazodone metabolite)	7.4	14
Dobutamine	86.7	240
Haloperidol	77	138.8
Isoxsuprine	92	165
Labelatol	16.1	29
Mebeverine	2.426	4.858

Compound	Concentration Tested (µg/mL) at the 300 ng/mL Cutoff	Concentration Tested (µg/mL) at the 500 ng/mL Cutoff
Methylone	6	12
Nylidrin	24	70
Trazodone	7	24

Table 6 lists the compounds that produce a negative result by the ADVIA Chemistry XTC assay. Specificity testing was performed at the 300 ng/mL and the 500 ng/mL cutoffs.

Table 6: Concentrations of Compounds that Show a Negative Response

Compound	Concentration Tested (µg/mL) at the 300 ng/mL Cutoff	Concentration Tested (µg/mL) at the 500 ng/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	10	10
Amoxicillin	1000	1000
Atenolol	1000	1000
Benzoylecgonine	1000	1000
Buprenorphine	1000	1000
Caffeine	1000	1000
Carbamazepine	250	250
Carisoprodol	1000	1000
Chloroquine	10,125	10,125
Chlorpheniramine	333	500
Chlorpromazine	500	500
Cimetidine	1000	1000
Clomipramine	2.5	2.5
Clonidine	1000	1000
Codeine	500	500
Cotinine	100	100
Cyclobenzaprine	125	125
Desipramine	800	800

Compound	Concentration Tested (µg/mL) at the 300 ng/mL Cutoff	Concentration Tested (µg/mL) at the 500 ng/mL Cutoff
Dextromethorphan	1000	1000
Dextrorphan	280	280
Diphenhydramine	1000	1000
Donepezil	20	113
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

Compound	Concentration Tested (µg/mL) at the 300 ng/mL Cutoff	Concentration Tested (µg/mL) at the 500 ng/mL Cutoff
Nitroglycerin	1000	1000
Noracetylmethadol	25	25
11-nor-Δ^9-THC-9-COOH	100	100
Nortryptyline	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	334	1000
Propoxyphene	1000	1000
Quinacrine	6630	6630
Ranitidine	1000	1000
Scopolamine	500	500
Secobarbital	1000	1000
Sertraline	42	83
Thioridazine	100	100
Tolmetin Sodium	2000	2000
Tramadol	1000	1000
Trifluoperazine	1000	1000
Trimethobenzamide	500	500
Trimethoprim	1000	1000
Tyramine	856	3608
Verapamil	149	667
Zidovudine (AZT)	2000	2000
Zolpidem	100	100
Sympathomimetic Amines		

Compound	Concentration Tested (µg/mL) at the 300 ng/mL Cutoff	Concentration Tested (µg/mL) at the 500 ng/mL Cutoff
Diethylpropion HCl	334	334
d,l-Isoproterenol	1000	1000
Mephedrone	38	210
Metaproterenol	10	10
3,4-Methylenedioxypyrovalerone (MDPV)	33	119
Methylphenidate (Ritalin)	1000	1000
Phendimetrazine	267	400
Phenethylamine	20	20
Phenylephrine	20	20
Propylhexedrine	50	125
3-OH-Tyramine (dopamine)	300	300

Precision

The precision of the ADVIA Chemistry XTC assay was analyzed as described in CLSI protocol EP5-A2.[11] Each sample was assayed 2 times per run, 1 or 2 runs per day, for at least 10 days.

Qualitative Analysis: 300 ng/mL Cutoff

ADVIA 1650/1800

MDMA Concentration in Urine	Mean (mA/min)	Within-Run SD[a] (mA/min)	Within-Run CV[b] (%)	Total SD[a] (mA/min)	Total CV[b] (%)
225 ng/mL	414	2.7	0.7	3.4	0.8
300 ng/mL	438	1.6	0.4	2.3	0.5
375 ng/mL	458	2.0	0.4	3.8	0.8

[a] SD = standard deviation
[b] CV = coefficient of variation

ADVIA 2400

MDMA Concentration in Urine	Mean (mA/min)	Within-Run SD[a] (mA/min)	Within-Run CV[b] (%)	Total SD[a] (mA/min)	Total CV[b] (%)
225 ng/mL	410	0.9	0.2	1.9	0.5
300 ng/mL	435	1.0	0.2	1.6	0.4
375 ng/mL	457	0.7	0.1	1.7	0.4

[a] SD = standard deviation
[b] CV = coefficient of variation

Qualitative Analysis: 500 ng/mL Cutoff

ADVIA 1650/1800

MDMA Concentration in Urine	Mean (mA/min)	Within-Run SD[a] (mA/min)	Within-Run CV[b] (%)	Total SD[a] (mA/min)	Total CV[b] (%)
375 ng/mL	449	2.8	0.6	3.1	0.7
500 ng/mL	478	2.8	0.6	3.7	0.8
625 ng/mL	493	4.5	0.9	5.3	1.1

[a] SD = standard deviation
[b] CV = coefficient of variation

ADVIA 2400

MDMA Concentration in Urine	Mean (mA/min)	Within-Run SD[a] (mA/min)	Within-Run CV[b] (%)	Total SD[a] (mA/min)	Total CV[b] (%)
375 ng/mL	445	1.1	0.2	2.0	0.5
500 ng/mL	476	0.6	0.1	2.0	0.4
625 ng/mL	493	0.7	0.1	1.9	0.4

[a] SD = standard deviation
[b] CV = coefficient of variation

Semiquantitative Analysis: 300 ng/mL Cutoff

ADVIA 1650/1800

MDMA Concentration in Urine	Mean (mA/min)	Within-Run SD[a] (mA/min)	Within-Run CV[b] (%)	Total SD[a] (mA/min)	Total CV[b] (%)
225 ng/mL	235	6.01	2.6	7.65	3.3
300 ng/mL	301	5.29	1.8	7.37	2.4
375 ng/mL	382	8.80	2.3	16.93	4.4

[a] SD = standard deviation
[b] CV = coefficient of variation

ADVIA 2400

MDMA Concentration in Urine	Mean (mA/min)	Within-Run SD[a] (mA/min)	Within-Run CV[b] (%)	Total SD[a] (mA/min)	Total CV[b] (%)
225 ng/mL	239	2.01	0.8	4.38	1.8
300 ng/mL	306	3.06	1.0	5.09	1.7
375 ng/mL	389	3.09	0.8	8.05	2.1

[a] SD = standard deviation
[b] CV = coefficient of variation

Semiqualitative Analysis: 500 ng/mL Cutoff

ADVIA 1650/1800

MDMA Concentration in Urine	Mean (mA/min)	Within-Run SD[a] (mA/min)	Within-Run CV[b] (%)	Total SD[a] (mA/min)	Total CV[b] (%)
375 ng/mL	380	10.86	2.9	11.92	3.1
500 ng/mL	516	16.49	3.2	21.69	4.2
625 ng/mL	628	31.54	5.0	38.02	6.1

[a] SD = standard deviation
[b] CV = coefficient of variation

ADVIA 2400

MDMA Concentration in Urine	Mean (mA/min)	Within-Run SD[a] (mA/min)	Within-Run CV[b] (%)	Total SD[a] (mA/min)	Total CV[b] (%)
375 ng/mL	387	3.92	1.0	7.39	1.9
500 ng/mL	528	3.45	0.7	11.92	2.3
625 ng/mL	655	6.51	1.0	17.79	2.7

[a] SD = standard deviation
[b] CV = coefficient of variation

Actual results will vary depending on the study design, and on the sample and sample population used. Results obtained at individual laboratories may vary from the data provided.

Accuracy / Method Comparison

Qualitative Analysis: 300 ng/mL cutoff

One hundred and seven (107) samples were analyzed by the ADVIA Chemistry Ecstasy method on the ADVIA 1650/1800, and 2400 Chemistry systems and by the Emit II Plus assay on the Syva®-30R Biochemical System.

For all ADVIA Chemistry systems: Fifty-three (53) samples showed positive results by both methods and fifty-one (51) samples showed negative results by both methods. Two samples were negative by the ADVIA method and positive by the reference method. One sample was positive by the ADVIA method and negative by the reference method. The ADVIA rates for these discrepant samples were within 7.5% of the cutoff rate.

Table 7: Qualitative Results for the 300 ng/mL Cutoff for the ADVIA 1650/1800 Chemistry System

		ADVIA 1650/1800 (n = 107) +	ADVIA 1650/1800 (n = 107) -
Reference Method SYVA-30R	+	53	2
	-	1	51

Table 8: Qualitative Results for the 300 ng/mL Cutoff for the ADVIA 2400 Chemistry System

		ADVIA 2400 (n = 107)	
		+	-
Reference Method SYVA-30R	+	53	2
	-	1	51

Qualitative Analysis: 500 ng/mL cutoff

One hundred and one (101) samples were analyzed by the ADVIA Chemistry Ecstasy method on the ADVIA 1650/1800, and 2400 Chemistry systems and by the Emit II Plus assay on the Syva-30R Biochemical System.

For ADVIA 1650/1800 Chemistry systems: Forty-seven (47) samples showed positive results by both methods and fifty-two (52) samples showed negative results by both methods. One sample was positive by the ADVIA method and negative by the reference method, and one sample was negative by the ADVIA method and positive by the reference method. The ADVIA rates for these samples were within 7.5% of the cutoff rate.

For ADVIA 2400 Chemistry system: Forty-seven (47) samples showed positive results by both methods and fifty three (53) samples showed negative results by both methods. One sample was negative by the ADVIA method and positive by the reference method. The ADVIA rate for this sample was within 7.5% of the cutoff rate.

Table 9: Qualitative Results for the 500 ng/mL Cutoff for the ADVIA 1650/1800 Chemistry System

		ADVIA 1650/1800 (n = 101)	
		+	-
Reference Method SYVA-30R	+	47	1
	-	1	52

Table 10: Qualitative Results for the 500 ng/mL Cutoff for the ADVIA 2400 Chemistry System

		ADVIA 2400 (n = 101)	
		+	-
Reference Method SYVA-30R	+	47	1
	-	0	53

Analytical Recovery

Negative human urine was spiked with concentrations of MDMA at levels from 100–500 ng/mL for the 300 ng/mL cutoff, and at levels from 100–1000 ng/mL for the 500 ng/mL cutoff.

Qualitative Results

In qualitative spike analysis, the ADVIA Chemistry XTC assay correctly identified the mean rate from replicate analysis of spiked specimens that contained less than the cutoffs listed in Tables 11–12 as negative, and the mean rate from replicate analysis of spiked specimens that contained more than the cutoffs listed in Tables 11–12 as positive.

Semiquantitative Results

For each known drug concentration, drug recovery was calculated using the average concentration obtained from replicate analysis by the ADVIA Chemistry XTC assay. Semiquantitative results are shown in Tables 11–12.

Table 11: Analytical Recovery of Semiquantitative Results (300 ng/mL Cutoff)

Nominal Methylenemethamphetamine (MDMA) Concentration (ng/mL)	Mean Methylenemethamphetamine (MDMA) Concentration by the ADVIA Chemistry XTC Assay (ng/mL)	Recovery (%)
100	108.3	108.3
150	154.2	102.8
200	205.4	102.7
225	234.5	104.2
250	265.4	106.2
275	294.2	107.0
300	319.1	106.4
330	349.9	106.0
375	392.7	104.7
450	459.3	102.1
500	492.8	98.6

Table 12: Analytical Recovery of Semiquantitative Results (500 ng/mL Cutoff)

Nominal Methylenemethamphetamine (MDMA) Concentration (ng/mL)	Mean Methylenemethamphetamine (MDMA) Concentration by the ADVIA Chemistry XTC Assay (ng/mL)	Recovery (%)
100	111.7	111.7
150	153.6	102.4
200	205.1	102.6
225	230.3	102.3
250	260.4	104.2
275	296.0	107.6
300	323.0	107.7
330	352.7	106.9
375	408.3	108.9
450	478.9	106.4
500	514.7	102.9
625	651.4	104.2
750	782.1	104.3
1000	1025.7	102.6

Non-Interfering Substances

The compounds listed in Table 13 do not yield a false response relative to the 300 ng/mL and 500 ng/mL cutoffs when any of the compounds are added to urine that contains MDMA at +/-25% concentration of the cutoff levels.

These results were obtained testing the same reagent on an analyzer with the same assay conditions.

Table 13: 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

Compound	Concentration
Oxalic Acid	0.1 g/dL
Riboflavin	7.5 mg/dL
Sodium Chloride	6.0 g/dL
Urea	6.0 g/dL

Actual results will vary depending on the study design, the levels of the potential interferences tested, and the samples used. Results obtained at individual laboratories may vary from the data provided.

Standardization

The Emit Calibrators/Controls and Emit II Plus 6-AM/Ecstasy Calibrators/Controls are referenced to gravimetrically prepared standards. These standards are qualified by GC/MS from an independent laboratory and must quantitate within ±10% of nominal.

Technical Assistance

For customer support, please contact your local technical support provider or distributor.

siemens.com/healthcare

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Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Definition	Symbol	Definition
IVD	*In vitro* diagnostic medical device	REF REF	Catalog number
	Legal manufacturer	EC REP	Authorized Representative in the European Community
CE	CE Mark	CE 0088	CE Mark with identification number of notified body
	Consult instructions for use		Biological risk
	Keep away from sunlight and heat		Temperature limitation
	Lower limit of temperature		Upper limit of temperature
	Do not freeze (> 0°C)		Up
	Use by	Σ (n)	Contains sufficient for (n) tests
	Recycle	PRINTED WITH SOY INK	Printed with soy ink
Rev.	Revision	YYYY-MM-DD	Date format (year-month-day)
LOT	Batch code	**RxOnly**	Prescription Device (US only)

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