SIEMENS Healthineers

Syva®

EMIT® II Plus Ecstasy Assay

Application Sheet

Shading indicates technical content that differs from the previous version.

Emit® II Plus Ecstasy Assay Application Sheet

For the AU400®, AU600®, AU640®, AU680®, AU2700®, AU5400® Clinical Chemistry Systems

Refer to the appropriate Instructions for Use for information regarding these reagents. Also refer to the instrument manual for additional instructions.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

The parameters defined in this application sheet have been developed by Siemens Healthineers to optimize product performance. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results.

Reagents

These reagents are qualified for use with the Calibrators/Controls listed below only. Other material may be used however, for quality control purposes.

Assay	Catalog Number	
	28 mL Kit	1000 mL Kit
Emit® II Plus Ecstasy Assay	9X029UL	9X129UL
Emit® II Plus Ecstasy Assay	OSR9X229	

Calibrator/Control	Catalog Number
Emit® Calibrator/Control Level 0	9A509UL
Emit® II Plus 6-AM/Ecstasy Calibrator/Control Level 1	9R529UL
Emit® II Plus 6-AM/Ecstasy Calibrator/Control Level 2	9R549UL
Emit® II Plus 6-AM/Ecstasy Calibrator/Control Level 3	9R569UL
Emit® II Plus 6-AM/Ecstasy Calibrator/Control Level 4	9R589UL

Storage

Reagents which are in use may be stored on board the analyzer for up to 4 weeks or as long as the control results fall within acceptable limits.

Qualitative

Calibration

Calibrate by running the Level for the appropriate cutoff listed in Table 1. Select the appropriate Option to use based on how results should be flagged (see Results section below).

Run a reagent blank (blue rack) and place the appropriate calibrator in a white rack for Option 1 or in its assigned position in a yellow rack for Option 2 or 3. Recalibrate as indicated by control results.

Results

Results are reported based on the Option chosen.

Option

1. Results are printed as OD values. Positive samples ***are NOT*** flagged. Operator must compare the sample response to the cutoff calibrator response and determine if the sample is positive or negative.
2. The cutoff is normalized to 100. Positive samples are ≥ 100 and are flagged with a (P).
3. The cutoff is normalized to 0. Positive samples are ≥ 0 and are flagged with a (P).

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Table 1

Assay	Level 2 ng/mL	Level 3 ng/mL
Ecstasy	300	500

Instrument Settings

See page 2.

Qualitative

Instrument Settings

General Screen

Reagent ID: 525

General | LIH | ISE | Range

Test Name	User Defined	◀	▶			Type	Urine		Operation	Yes
Sample	Volume	§	uL	Dilution	0	uL	Pre-Dilution Rate	1		
Reagents	R1 Volume	130	uL	Dilution	0	uL	Min OD		Max OD	
	R2 Volume	55	uL	Dilution	0	uL	L	-2.000	H	2.500
							Reagent OD Limit			
Wavelength	Pri	340		Sec	410		First L	-2.000	First H	2.500
Method		FIXED					Last L	-2.000	Last H	2.500
Reaction Slope		+					Dynamic Range			
Measuring Point 1	First	13		Last	15		L	User Defined	H	User Defined
Measuring Point 2	First			Last			Correlation Factor			
Linearity			%				A	1	B	†
No-Lag-Time							Onboard Stability Period		User Defined	

§ – Sample Volume: Enter 7.0 uL for the 300 cutoff; 5.0 uL for the 500 cutoff
† – Correlation Factor B: For Results Option 1 enter 0; for Option 2 enter 0; for Option 3 enter -100

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Range Screen

General | LIH | ISE | **Range**

Test Name: **User Defined** ◀ ▶ Type: **Urine**

Value Flag: **Flag** Level L: **-9999** Level H: **††**

Normal Ranges

	Sex	Age L Year	Age L Month	Age H Year	Age H Month	L	H
☐ 1							
☐ 2							
☐ 3							
☐ 4							
☐ 5							
☐ 6							
7 None Selected							
8 Out of Range							

Panic Value: L ____ H ____ Unit ____ Decimal Places: **0**

†† – Level High: For Results Option 1 enter 9999; for Option 2 enter 100; for Option 3 enter 0

Calibration Specific Screen — Results Option 1

General | ISE

Test Name: **User Defined** ◀ ▶ Type: **Urine**

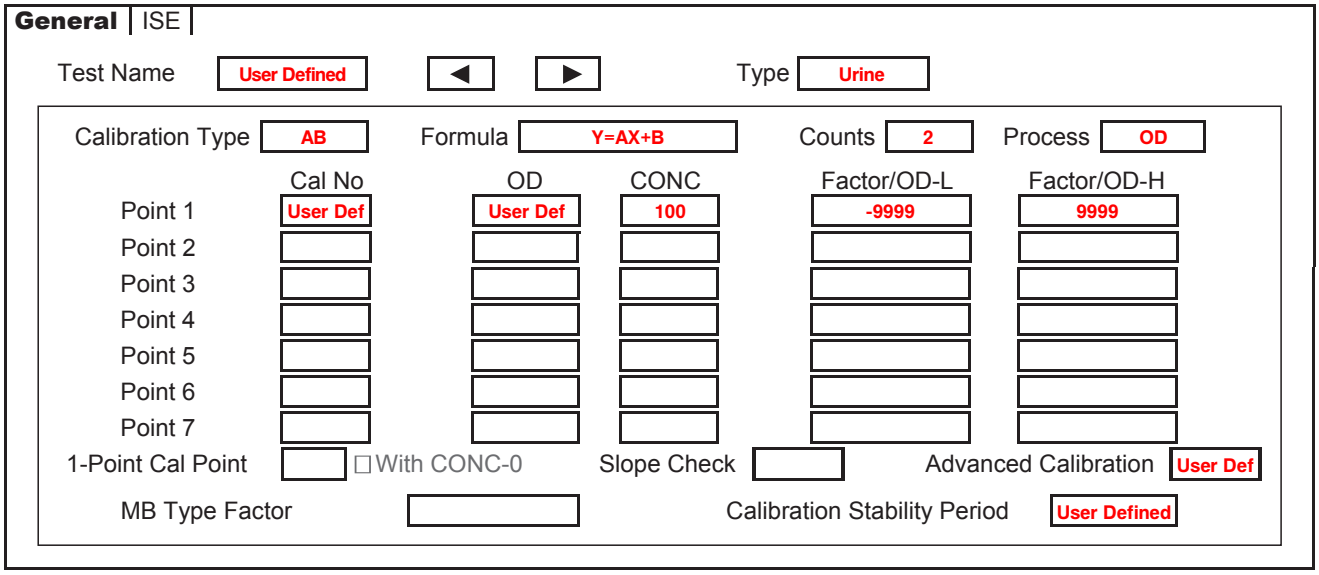
Calibration Type: **MB** Formula: **Y=AX+B** Counts: **2** Process: **OD**

	Cal No	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1					
Point 2					
Point 3					
Point 4					
Point 5					
Point 6					
Point 7					

1-Point Cal Point: ____ ☐ With CONC-0 Slope Check: ____ Advanced Calibration: **User Def**

MB Type Factor: **1000.000** Calibration Stability Period: **User Defined**

Calibration Specific Screen — Results Option 2 or 3



EMIT® II Plus Ecstasy Assay

Application Sheet

Semi-Quantitative

Calibration

Prepare a calibration curve by running the Calibrator/ Controls in the order listed in Table 2. Recalibrate as indicated by control results. Run a reagent blank (blue rack) daily to ensure consistent day to day control results.

Table 2

Assay	Level 0	Level 1 ng/mL	Level 2 ng/mL	Level 3 ng/mL	Level 4 ng/mL
Ecstasy 300	0	150	300	500	NA
Ecstasy 500	NA	150	300	500	1000

Results

Results are reported as ng/mL.

Instrument Settings

General Screen

General | LIH | ISE | Range

Test Name: User Defined ◀ ▶ Type: Urine Operation: Yes

Sample	Volume	§	uL	Dilution	0	uL	Pre-Dilution Rate	1
Reagents	R1 Volume	130	uL	Dilution	0	uL	Min OD / Max OD	
	R2 Volume	55	uL	Dilution	10	uL	L -2.000 / H 2.500	
Wavelength	Pri	340		Sec	410		Reagent OD Limit	
Method		FIXED					First L -2.000 / First H 2.500	
Reaction Slope		+					Last L -2.000 / Last H 2.500	
Measuring Point 1	First	13		Last	15		Dynamic Range	
Measuring Point 2	First			Last			L 75 / H †	
Linearity			%				Correlation Factor	
No-Lag-Time							A 1 / B 0	
							Onboard Stability Period: User Defined	

§ – Sample Volume: Enter 7.0 uL for the 300 cutoff; 5.0 uL for the 500 cutoff
† – Dynamic Range High: Enter 500 for the 300 cutoff; 1000 for the 500 cutoff

Range Screen

General | LIH | ISE | **Range**

Test Name: User Defined ◀ ▶ Type: Urine

Value Flag: Value Level L: User Defined Level H: †

Normal Ranges

	Sex	Age L Year	Age L Month	Age H Year	Age H Month	L	H
☐ 1							
☐ 2							
☐ 3							
☐ 4							
☐ 5							
☐ 6							
7 None Selected							
8 Out of Range							

Panic Value: L ____ H ____ Unit: ng/mL Decimal Places: 0

† – **Level High:** Enter the concentration of the cutoff calibrator from Table 1

Calibration Specific Screen

General | ISE

Test Name: User Defined ◀ ▶ Type: Urine

Calibration Type: 4AB Formula: Polygonal Counts: 2 Process: CONC

	Cal No	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1	User Def	User Def	‡	-2.000	2.500
Point 2	User Def	User Def	‡	-2.000	2.500
Point 3	User Def	User Def	‡	-2.000	2.500
Point 4	User Def	User Def	‡	-2.000	2.500
Point 5					
Point 6					
Point 7					

1-Point Cal Point: ____ ☐ With CONC-0 Slope Check: + Advanced Calibration: User Def

MB Type Factor: ____ Calibration Stability Period: User Defined

‡ – **Conc:** Enter the Calibrator/Control concentration from Table 2 for the desired cutoff

Performance

Method Comparison

Clinical urine specimens were tested using the Emit® II Plus Ecstasy Assay on the AU600 analyzer and on the SYVA®-30R analyzer. Discordant samples were not observed at the 500 ng/mL cutoff. The discordant specimen at the 300 ng/mL cutoff contained 265 ng/mL methylenedioxymethamphetamine (MDMA) by GC/MS analysis. The results from the AU600 are listed below along with the percent agreement with the SYVA®-30R analyzer.

Assay	Positive	Negative	% Agreement
Ecstasy 300	56	52	98
Ecstasy 500	51	48	100

Precision

Within run precision was calculated according to NCCLS Guideline EP5-A by running 2 replicates of the cutoff Calibrator/Control and positive and negative controls twice a day for 20 days (N=80). Total precision was also calculated from these data. The following data are presented in mAU/min.

Ecstasy (300 ng/mL cutoff)

	Within Run Precision			Total Precision		
	Cutoff Cal.	Control 75%	Control 125%	Cutoff Cal.	Control 75%	Control 125%
Mean	465	435	500	465	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

Ecstasy (500 ng/mL cutoff)

	Within Run Precision			Total Precision		
	Cutoff Cal.	Control 75%	Control 125%	Cutoff Cal.	Control 75%	Control 125%
Mean	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	0.8	1.0	0.8

Analytical Recovery

Negative human urine specimens were spiked with concentrations of MDMA.

Qualitative analysis of the specimens spiked with drug concentrations lower than the cutoff concentration 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.

Results from semi-quantitative analysis of the specimens are listed below.

Ecstasy (300 ng/mL cutoff)

Concentration (ng/mL)	EIA Type 1 Mean (ng/mL)	Polygonal Mean (ng/mL)
100	107	78
250	257	260
375	393	402
450	448	455

Ecstasy (500 ng/mL cutoff)

Concentration (ng/mL)	EIA Type 1 Mean (ng/mL)	Polygonal Mean (ng/mL)
250	259	267
375	404	413
450	485	468
550	613	644
750	791	871

NOTE: Performance on the AU400®, AU600®, AU640®, AU680®, AU2700®, and AU5400® series analyzers has been shown to be equivalent.

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title	Source
	Manufacturer	5.1.1[a]
	Use-by date	5.1.4[a]
	Catalog number	5.1.6[a]
	Consult Instructions for Use	5.4.3[a]
	Internet URL address to access the electronic instructions for use	Proprietary
	*In vitro* diagnostic medical device	5.5.1[a]
	Prescription device (US only)	FDA[c]
	CE Marking with Notified Body	EU IVDR[d]
	Temperature limit	5.3.7[a]
	Upper limit of temperature	5.3.6[a]
	Do not re-use	5.4.2[a]

Symbol	Symbol Title	Source
	Authorized representative in the European Community	5.1.2[a]
	Authorized representative in Switzerland	Proprietary
	Batch code	5.1.5[a]
	Contains sufficient for <n> tests	5.5.5[a]
	Version of Instructions for Use	Proprietary
	Revision	Proprietary
	Unique Device Identifier	5.7.10[b]
	CE Marking	EU IVDR[d]
	Keep away from sunlight	5.3.2[a]
	Lower limit of temperature	5.3.5[a]
	Do not freeze	Proprietary

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
	Recycle	1135[e]		This way up	0623[e]
	Biological risks	5.4.1[a]		Caution	5.4.4[a]
UNITS C	Common Units	Proprietary	UNITS SI	International System of Units	Proprietary
	Document face up[f]	1952[e]	YYYY-MM-DD	Date format (year-month-day)	N/A
	Non-sterile	Proprietary	YYYY-MM	Date format (year-month)	N/A
	Reconstitution volume	Proprietary	CONTENTS	Contents	Proprietary
FORENSIC TOXICOLOGY	For forensic/toxicology use only	Proprietary	LEVEL	Level	Proprietary
DROPPER	Dropper	Proprietary	CASSETTE	Cassette	Proprietary
	Not for self-testing	EU IVDR[d]		Not for near-patient testing	EU IVDR[d]

[a] International Standard Organization (ISO). ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied.

[b] ISO 15223-1:2020-04.

[c] Federal Register. Vol. 81, No 115. Wednesday, June 15, 2016. Rules and Regulations: 38911.

[d] IVDR REGULATION (EU) 2017/746

[e] International Standard Organization (ISO). ISO 7000 Graphical symbols for use on equipment.

[f] Indicates Assay-*e*Note.

For technical assistance:

Beckman Coulter customers, contact the Customer Technical Support Center at 1-800-854-3633 (USA & Canada)

In other countries, please contact your local Beckman Coulter representative.

Siemens Healthineers customers, contact the Technical Solutions Center at 1-800-227-8994 In the USA.

Technical Assistance

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.
siemens-healthineers.com

Siemens Healthcare Diagnostics Inc.
500 GBC Drive
Newark, DE 19714 USA

CE 0197

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