SIEMENS Healthineers

Syva®

EMIT® II Plus Amphetamines Application Sheet

Shading indicates technical content that differs from the previous version.

Emit® II Plus Amphetamines Application Sheet

For the VIVA®, Viva-Jr®, Viva-E® and V-Twin® Analyzers

Refer to the appropriate instructions for use for information regarding these reagents. Also refer to the instrument manual for further 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 Healthcare Diagnostics 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		
	28mL	115mL	1000mL
Emit® II Plus Amphetamines assay	9C039UL	9C309UL	9C329UL

Emit® Calibrator/Control	Catalog Number
Calibrator/Control Level 0	9A509UL
Calibrator/Control Level 1	9A529UL
Calibrator/Control Level 2	9A549UL
Calibrator/Control Level 3	9A569UL
Calibrator/Control Level 5	9A609UL

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 Calibrator/Controls appropriate for the desired cutoff listed in Table 1.

Table 1

Assay	Level 1 (ng/mL)	Level 2 (ng/mL)	Level 3 (ng/mL)
Amphetamines	300	500	1000

Instrument Settings

See pages 2 and 4.

Results

Results are reported in ΔAbs/min.

Semi-Quantitative

Calibration

Prepare a calibration curve by running the Calibrator/Controls listed below. Recalibrate as indicated by control results.

Table 2

Assay	Level 0	Level 1	Level 2	Level 3	Level 5
Amphetamines 300	0	300	500	1000	NA
Amphetamines 500/1000	NA	300	500	1000	2000

Instrument Settings

See pages 3 and 5.

Results

Results are reported as ng/mL.

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Qualitative

Instrument Settings for the VIVA® Analyzer

TEST PARAMETERS:	
NAME	†
ABBR. NAME	††
MODE	Kinetic
WAVELENGTH	340 nm
UNITS	Abs or none
DECIMALS	3
CALIBRATOR NAME	§
REPEAT	2
NUMBER	1
CONCENTRATION	0.000
INTERVAL	0
CUT-OFF	Yes, Increase
FLAG	Yes
PROZONE CHECK	No
CONTROL 1	Control A or User Defined
CONTROL 2	Control B or User Defined
CONTROL	Control C or User Defined
***** DUAL MODE *****	
SAMPLE BLANK	No
R1 BOTTLE	28 mL
NORMAL VOLUME	200 µL
RERUN VOLUME	200 µL
SAMPLE	
NORMAL VOLUME	** µL
RERUN VOLUME	** µL
R2 BOTTLE	3 mL
NORMAL VOLUME	0.0 µL
RERUN VOLUME	0.0 µL
R3 BOTTLE	14 mL
NORMAL VOLUME	75 µL
RERUN VOLUME	75 µL
PREDILUTION	No
SLOPE BLANK	No
DELAY, MIN. TIME	77,132 sec
LINEARITY LIMIT	10.0%
LOW ABSORBANCE	-0.100 Abs
HIGH ABSORBANCE	3.000 Abs
R. ABS. L. LIMIT	-0.100 Abs
R. ABS. H. LIMIT	3.000 Abs
SUBSTR. DEPLETION	0.000 Abs
REAGENT BLANK	No
CAL. LOW LIMIT	0.000
CAL. HIGH LIMIT	0.000
CUT OFF VALUE	‡ dAbs/min
CUT OFF DEV	+/- 0.000 dAbs/min

***** MONO MODE *****

NOTE: Do not enter in values under mono mode as assay on this protocol is a dual mode assay.

† Amphet300 for the 300 ng/mL cutoff, Amphet500 for the 500 cutoff, Amphet1K for the 1000 ng/mL cutoff.

†† +AM3 for the 300 ng/mL cutoff, +AM5 for the 500 ng/mL cutoff, +AM1 for the 1000 ng/mL cutoff.

§ Enter EII Plus L1 for +AM3 , EII Plus L2 for +AM5, and EII Plus L3 for +AM1.

** Enter 8 µL for 300 ng/mL and 3 µL for 500 or 1000 ng/mL cutoff.

‡ Analyzer updates after each calibration.

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Semi-Quantitative

Instrument Settings for the VIVA® Analyzer

TEST PARAMETERS:	
NAME	†
ABBR. NAME	††
MODE	Kinetic
WAVELENGTH	340 nm
UNITS	ng/mL
DECIMALS	0
LOW CONC.	‡‡
HIGH CONC.	* ng/mL
CALIBRATOR NAME	§
REPEAT	2
NUMBER	4
INTERVAL	0 days
CUT-OFF	No
MAX. INACCURACY	5 %
PROZONE CHECK	No
REF RANGES ARE NOT APPLICABLE	
CONTROL 1	Control A or User Defined
CONTROL 2	Control B or User Defined
CONTROL 3	Control C or User Defined
CORRELAT. FACTOR	1.000
CORRELAT. OFFSET	0.000 ng/mL
*** **DUAL MODE** ***	
SAMPLE BLANK	No
R1 BOTTLE	28 mL
NORMAL VOLUME	200 µL
RERUN VOLUME	200 µL
SAMPLE	
NORMAL VOLUME	‡ µL
RERUN VOLUME	‡ µL
R2 BOTTLE	3 mL
NORMAL VOLUME	0.0 µL
RERUN VOLUME	0.0 µL
R3 BOTTLE	14 mL
NORMAL VOLUME	75 µL
RERUN VOLUME	75 µL
PREDILUTION	No
SLOPE BLANK	No
DELAY, MIN. TIME	77,132 sec
LINEARITY LIMIT	10.0%
LOW ABSORBANCE	-0.100 Abs
HIGH ABSORBANCE	3.000 Abs
R. ABS. L. LIMIT	-0.100 Abs
R. ABS. H. LIMIT	3.000 Abs
SUBSTR. DEPLETION	0.000 Abs
REAGENT BLANK	No

CALIBRATOR SETTINGS

Conc. ng/mL	Value dAbs/min	Low lim. dAbs/min	High lim. dAbs/min
**	§§	0.000	0.000
**	§§	0.000	0.000
**	§§	0.000	0.000
**	§§	0.000	0.000

† qAmphet300 for the 300 ng/mL cutoff, qAmphet500 for the 500 cutoff, qAmphet1K for the 1000 ng/mL cutoff.

†† qAM3 for the 300 ng/mL cutoff, qA5K for the 500 ng/mL or 1000 ng/mL cutoff.

‡‡ Enter 100 for the 300 ng/mL cutoff and 325 for the 500 or 1000 ng/mL cutoff.

* Enter the highest calibrator from Table 2 for the desired cutoff.

§ Enter EI Plus 0123 for the 300 ng/mL cutoff and EII Plus 1235 for the 500 or 1000 ng/mL cutoff.

‡ Enter 8 µL for 300 ng/mL and 3 µL for 500 or 1000 ng/mL cutoff.

** Enter the calibrator values from Table 2.

§§ Analyzer updates after each calibration.

Qualitative

Instrument Settings for the Viva-Jr®, Viva-E® and V-Twin® Analyzers

TEST PARAMETERS:

NAME	†
ABBR. NAME	††
MODE	Kinetic
WAVELENGTH	340 nm
UNITS	Abs
DECIMALS	3
CALIBRATOR NAME	DAT CAL
REPEAT	2
NUMBER	1
INTERVAL	0 days
CUT-OFF	Yes, Increase
FLAG	Yes
PREDILUTION	No
PROZONE CHECK	No
CONTROL 1	Level 0 or User Defined
CONTROL 2	Level 5 or User Defined
CONTROL 3	NA or User Defined
REAGENT ROTOR TYPE	EMIT
*** **DUAL MODE** ***	
SAMPLE BLANK	No
R1 BOTTLE	28 mL
NORMAL VOLUME	200 µL
RERUN VOLUME	200 µL
SAMPLE	
NORMAL VOLUME	§ µL
RERUN VOLUME	§ µL
PREDILUTION	No
R2 BOTTLE	3 mL
NORMAL VOLUME	0.0 µL
RERUN VOLUME	0.0 µL
R3 BOTTLE	14 mL
NORMAL VOLUME	75 µL
RERUN VOLUME	75 µL
SLOPE BLANK	No
DELAY, MIN. TIME	77,132 sec
LINEARITY LIMIT	10.0%
LOW ABSORBANCE	-0.100 Abs
HIGH ABSORBANCE	3.000 Abs
R. ABS. L. LIMIT	-0.100 Abs
R. ABS. H. LIMIT	3.000 Abs
SUBSTR. DEPLETION	0.000 Abs
REAGENT BLANK	No

CALIBRATOR SETTINGS

Pre-dilution	Conc. Abs	Value dAbs/min	Low lim. dAbs/min	High lim. dAbs/min	Dup-Diff dAbs/min
No	0.00	*	000	0.000	0.0150

CUT OFF VALUE	†† s/min
CUT OFF DEV	+/- 0.000 dAbs/min

† +Amphet300 for the 300 ng/mL cutoff, +Amphet500 for the 500 cutoff, +Amphet1000 for the 1000 ng/mL cutoff.

†† +AM3 for the 300 ng/mL cutoff, +AM5 for the 500 ng/mL cutoff, +AM1 for the 1000 ng/mL cutoff.

§ Enter 8 µL for 300 ng/mL and 3 µL for 500 or 1000 ng/mL cutoff.

* Analyzer updates after each calibration.

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Semi-Quantitative

Instrument Settings for the Viva-Jr®, Viva-E® and V-Twin® Analyzers

TEST PARAMETERS:	
NAME	†
ABBR. NAME	††
MODE	Kinetic
WAVELENGTH	340 nm
UNITS	ng/mL
DECIMALS	0
LOW CONC.	§
HIGH CONC.	* ng/mL
CALIBRATOR NAME	DAT Cal
REPEAT	2
NUMBER	4
INTERVAL	0 days
CUT-OFF	No
MAX. INACCURACY	5.0000 %
AUTO PREDIL.	No
PROZONE CHECK	No
REF RANGES ARE NOT APPLICABLE	
CONTROL 1	User Defined
CONTROL 2	User Defined
CONTROL 3	User Defined
CORRELAT. FACTOR	1.000
CORRELAT. OFFSET	0.000 ng/mL
REAGENT ROTOR TYPE	EMIT
*** **DUAL MODE** ***	
SAMPLE BLANK	No
R1 BOTTLE	28 mL
NORMAL VOLUME	200 µL
RERUN VOLUME	200 µL
SAMPLE	
NORMAL VOLUME	‡ µL
RERUN VOLUME	‡ µL
PREDILUTION	No
R2 BOTTLE	3 mL
NORMAL VOLUME	0.0 µL
RERUN VOLUME	0.0 µL
R3 BOTTLE	14 mL
NORMAL VOLUME	75.0 µL
RERUN VOLUME	75.0 µL
SLOPE BLANK	No
DELAY, MIN. TIME	77,132 sec
LINEARITY LIMIT	10.0%
LOW ABSORBANCE	-0.100 Abs
HIGH ABSORBANCE	3.000 Abs
R. ABS. L. LIMIT	-0.100 Abs
R. ABS. H. LIMIT	3.000 Abs
SUBSTR. DEPLETION	0.000 Abs
REAGENT BLANK	No

CALIBRATOR SETTINGS

Pre-dilution	Conc. ng/mL	Value dAbs/min	Low lim. dAbs/min	High lim. dAbs/min	Dup-Diff dAbs/min
No	**	§§	0.000	0.000	0.0150
No	**	§§	0.000	0.000	0.0150
No	**	§§	0.000	0.000	0.0150
No	**	§§	0.000	0.000	0.0150

CURVE FIT MODEL — Modified Cubic Spline

† qAmphet300 for the 300 ng/mL cutoff, qAmphet500 for the 500 cutoff, qAmphet 1000 for the 1000 ng/mL cutoff.

†† qAM3 for the 300 ng/mL cutoff, qAM5 for the 500 ng/mL, qA1K for the 1000 ng/mL cutoff.

§ Enter 100 for the 300 ng/mL cutoff and 325 for the 500 ng/mL or 1000 ng/mL cutoff.

* Enter the highest calibrator from Table 2 for the desired cutoff.

‡ Enter 8 µL for 300 ng/mL and 3 µL for 500 or 1000 ng/mL cutoff.

** Enter the calibrator values from Table 2.

§§ Analyzer updates after each calibration.

Performance

Method Comparison

Clinical urine specimens were tested using Emit® II Plus Amphetamines assay on the VIVA®/V-Twin® analyzer and on the SYVA®-30R analyzer. The discrepant sample observed at the 300 cutoff contained 363 ng/mL of amphetamines by GC/MS analysis. Discrepant samples observed at the 500 cutoff contained amphetamines ranging from 495 ng/mL to 561 ng/mL of by GC/MS analysis. Discrepant samples observed at the 1000 cutoff contained amphetamines ranging from 1088 ng/mL to 1930 ng/mL by GC/MS analysis. The results from the VIVA®/V-Twin® are listed below with the percent agreement with the SYVA®-30R.

Assay	Positive	Negative	% Agreement
Amphetamines 300	71	57	99
Amphetamines 500	41	85	98
Amphetamines 1000	55	106	95

Precision

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

Amphetamines (300 ng/mL cutoff)

	Within Run Precision			Total Precision		
	Cutoff Cal.	Control 75%	Control 125%	Cutoff Cal.	Control 75%	Control 125%
Mean	368	352	417	368	352	417
SD	1.0	1.0	1.0	2.0	2.0	2.0
CV%	0.3	0.4	0.2	0.5	0.6	0.4

Amphetamines (500 ng/mL cutoff)

	Within Run Precision			Total Precision		
	Cutoff Cal.	Control 75%	Control 125%	Cutoff Cal.	Control 75%	Control 125%
Mean	330	309	361	330	309	361
SD	2.1	1.5	2.9	3.3	2.0	3.8
CV%	0.6	0.5	0.8	1.0	0.7	1.1

Amphetamines (1000 ng/mL cutoff)

	Within Run Precision			Total Precision		
	Cutoff Cal.	Control 75%	Control 125%	Cutoff Cal.	Control 75%	Control 125%
Mean	427	390	451	427	390	451
SD	1.9	2.3	2.5	3.5	3.5	3.1
CV%	0.5	0.6	0.6	0.8	0.9	0.7

Analytical Recovery

Negative human urine specimens were spiked with concentrations of d-methamphetamine.

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.

Amphetamines 300 ng/mL cutoff

Concentration (ng/mL)	Mean (ng/mL)
200	143
350	339
600	621
750	750

Amphetamines 500/1000 ng/mL cutoff

Concentration (ng/mL)	Mean (ng/mL)
350	320
750	722
900	834
1300	1227

Analytical Sensitivity

The analytical sensitivity for the amphetamines assay is 20 ng/mL d-methamphetamine at the 300 ng/mL cutoff. The analytical sensitivity for the amphetamines assay is 325 ng/mL d-methamphetamine at the 500/1000 ng/mL cutoff. These levels represent the lowest concentration of d-methamphetamine that can be distinguished from zero ng/mL with a confidence level of 95%.

Note: Performance on the VIVA®, Viva-Jr®, Viva-E® and V-Twin® 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

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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, call
Siemens Healthcare Diagnostics:
1-800-227-8994 in the USA
1-800-264-0083 in Canada

In other countries, please contact your local representative.

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.

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