SIEMENS Healthineers

Syva®

EMIT® II Plus Cannabinoid 100/ Semi-Quantitative Cannabinoid

Application Sheet

Shading indicates technical content that differs from the previous version.

Emit® II Plus Cannabinoid 100/ Semi-Quantitative Cannabinoid 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	115 mL Kit	1000 mL Kit
Emit® II Plus Cannabinoid Assay	9N039UL	9N029UL	9N129UL
Emit® II Plus Cannabinoid Assay		OSR9N229	

Calibrator/Control	Catalog Number
Emit® Calibrator/Control Level 0	9A509UL
Emit® Calibrator/Control Level 2	9A549UL
Emit® Calibrator/Control Level 3	9A569UL
Emit® Calibrator/Control Level 4	9A589UL
Emit® 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 Emit® Calibrator/Control Level 4. 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).

Instrument Settings

See page 2.

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Qualitative

Instrument Settings

General Screen

Reagent ID: 531

General | LIH | ISE | Range

Test Name	User Defined	◀	▶			Type	Urine	Operation	Yes
Sample	Volume	3.0	uL	Dilution	0	uL	Pre-Dilution Rate	1	
Reagents	R1 Volume	150	uL	Dilution	0	uL	Min OD		Max OD
	R2 Volume	64	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	15		Last	17		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

† – Correlation Factor B: For Results Option 1 enter 0; for Option 2 enter 0; for Option 3 enter -100

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							

	L	H		
Panic Value			Unit	Decimal Places 0

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

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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

General | ISE

Test Name: User Defined ◀ ▶ Type: Urine

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

	Cal No	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1	User Def	User Def	100	-9999	9999
Point 2					
Point 3					
Point 4					
Point 5					
Point 6					
Point 7					

1-Point Cal Point: ☐ With CONC-0 Slope Check: None Advanced Calibration: User Def

MB Type Factor: Calibration Stability Period: User Defined

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Semi-Quantitative

Calibration

Prepare a calibration curve by running the Calibrator/ Controls in the order listed in Table 1. Recalibrate as indicated by control results. Run a reagent blank (blue rack) daily to ensure consistent day to day control results.

Table 1

Assay	Level 2 ng/mL	Level 3 ng/mL	Level 4 ng/mL	Level 5 ng/mL
Cannabinoid	20	50	100	200

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	3.0	uL	Dilution	0	uL	Pre-Dilution Rate	1	
Reagents	R1 Volume	150	uL	Dilution	0	uL	Min OD		Max OD
	R2 Volume	64	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	15		Last	17		L	28	H 200
Measuring Point 2	First			Last			Correlation Factor		
Linearity			%				A	1	B 0
No-Lag-Time							Onboard Stability Period	User Defined	

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Range Screen

General | LIH | ISE | **Range**

Test Name: User Defined ◀ ▶ Type: Urine

Value Flag: Value Level L: -9999 Level H: 100

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							

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

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	20	-2.000	2.500
Point 2	User Def	User Def	50	-2.000	2.500
Point 3	User Def	User Def	100	-2.000	2.500
Point 4	User Def	User Def	200	-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

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Performance

Method Comparison

Clinical urine specimens were tested using the Emit® II Plus Cannabinoid assay on the AU400 analyzer and using the corresponding Emit® II Plus assay on the SYVA®-30R analyzer. Specimens positive by either method contained 11-nor-Δ9-THC-9-COOH. The results from the AU400 are listed below along with the percent agreement with the SYVA®-30R.

		SYVA®-30R	
		Positive	Negative
AU400	Negative	0	51
	Positive	46	3
		Agreement = 97%	

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.

Qualitative (mA/min)

	Repeatability			Within-Lab		
	Cutoff Cal.	Control 75%	Control 125%	Cutoff Cal.	Control 75%	Control 125%
Mean	396	366	430	396	366	430
SD	3.6	3.3	3.8	9.4	10.7	8.5
CV%	0.92	0.91	0.89	2.4	2.9	2.0

Semi-Quantitative (ng/mL)

	Repeatability			Within-Lab		
	Cutoff Cal.	Control 75%	Control 125%	Cutoff Cal.	Control 75%	Control 125%
Mean	95	72	138	95	72	138
SD	3.5	2.6	5.7	7.4	7.6	10.7
CV%	3.7	3.6	4.1	7.8	10.6	7.8

Analytical Recovery

Negative human urine specimens were spiked with concentrations of 11-nor-Δ9-THC-9-COOH.

Qualitative analyses 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.

Semi-Quantitative

Concentration (ng/mL)	Mean (ng/mL)
40	38
50	49
75	76
125	163
150	184
180	196
205	201

Analytical Sensitivity

The sensitivity level of the Emit® II Plus Semi-Quantitative Cannabinoid 100 Assay on the AU400 is 28 ng/mL 11-nor-Δ9-THC-9-COOH. This level represents the lowest concentration of 11-nor-Δ9-THC-9-COOH that can be distinguished from zero ng/mL with a confidence level of 95%.

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

Specificity Exception

Compounds listed in the following table produce a positive result at the 50 ng/mL cutoff at the concentration listed

Compound	Concentration (ng/mL)
11-Hydroxy-Δ^8-THC	233

NOTE: Performance on the AU480®, AU5800® and AU400® series analyzers has been shown to be equivalent.

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Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
	Manufacturer	5.1.1[a]		Authorized representative in the European Community	5.1.2[a]
	Use-by date	5.1.4[a]		Authorized representative in Switzerland	Proprietary
	Catalog number	5.1.6[a]		Batch code	5.1.5[a]
	Consult Instructions for Use	5.4.3[a]		Contains sufficient for <n> tests	5.5.5[a]
	Internet URL address to access the electronic instructions for use	Proprietary		Version of Instructions for Use	Proprietary
	*In vitro* diagnostic medical device	5.5.1[a]		Revision	Proprietary
	Prescription device (US only)	FDA[c]		Unique Device Identifier	5.7.10[b]
	CE Marking with Notified Body	EU IVDR[d]		CE Marking	EU IVDR[d]
	Temperature limit	5.3.7[a]		Keep away from sunlight	5.3.2[a]
	Upper limit of temperature	5.3.6[a]		Lower limit of temperature	5.3.5[a]
	Do not re-use	5.4.2[a]		Do not freeze	Proprietary

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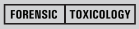
Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
	Recycle	1135[e]		This way up	0623[e]
	Biological risks	5.4.1[a]		Caution	5.4.4[a]
	Common Units	Proprietary		International System of Units	Proprietary
	Document face up[f]	1952[e]	YYYY-MM-DD	Date format (year-month-day)	N/A
	Non-sterile	Proprietary	YYYY-MM	Date format (year-month)	N/A
	Reconstitution volume	Proprietary		Contents	Proprietary
	For forensic/toxicology use only	Proprietary		Level	Proprietary
	Dropper	Proprietary		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.

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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.

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