SIEMENS Healthineers

Syva®

EMIT® II Plus Ethyl Alcohol Assay

Application Sheet

Shading indicates technical content that differs from the previous version.

Emit® II Plus Ethyl Alcohol 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 Ethyl Alcohol Assay	9K039UL	9K309UL	9K409UL
Emit® II Plus Ethyl Alcohol Assay	OSR9K229		

Emit® Ethyl Alcohol Calibrators	Catalog Number
Negative	9K029UL
100 mg/dL	9K059UL

Emit® Ethyl Alcohol Controls	Catalog Number
Low	9K049UL
High	9K079UL

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.

Instrument

Calibration

Calibrate by running the negative and 100 mg/dL calibrators whenever a new lot of reagents is used or as indicated by control results.

Instrument Settings

See page 2.

Results

Results are reported in mg/dL or g/L.

NOTE: To convert mg/dL to g/L ethyl alcohol, multiply by 0.01.

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EMIT® II Plus Ethyl Alcohol Assay

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Instrument

Instrument Settings

General Screen

Reagent ID: 524

General | LIH | ISE | Range

Test Name	User Defined	◀	▶			Type	Urine	Operation: Yes
Sample	Volume	4.0	uL	Dilution	0	uL	Pre-Dilution Rate	1
Reagents	R1 Volume	210	uL	Dilution	0	uL	Min OD	Max OD
	R2 Volume	90	uL	Dilution	0	uL	L -2.0000	H 2.5000
							Reagent OD Limit	
Wavelength	Pri	340		Sec	410		First L -2.0000	First H 2.5000
Method		FIXED					Last L -2.0000	Last H 2.5000
Reaction Slope		+					Dynamic Range	
Measuring Point 1	First	12		Last	16		L User Defined	H User Defined
Measuring Point 2	First			Last			Correlation Factor	
Linearity			%				A 1.0000	B 0.0000
No-Lag-Time							Onboard Stability Period	User Defined

Range Screen

General | LIH | ISE | **Range**

Test Name: User Defined ◀ ▶ Type: Urine

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

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 1

* mg/dL or g/L

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Calibration Specific Screen

General | ISE

Test Name: User Defined ◀ ▶ Type: Urine

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

	Cal No	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1	User Def	User Def	0.0	-2.0000	2.5000
Point 2	User Def	User Def	*	-2.0000	2.5000
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 Calibration Stability Period User Defined

* 100.0 for mg/dL or 1.0 for g/L

Performance

Method Comparison

Clinical urine and serum specimens were tested using the Emit® II Plus Ethyl Alcohol Assay on the AU600® analyzer and on the SYVA®-30R analyzer.

Ethyl Alcohol Urine

Slope	0.97
Intercept	2.9
Correlation Coefficient	1.00
Number of Samples	50

Ethyl Alcohol Serum

Slope	1.05
Intercept	-9.6
Correlation Coefficient	0.993
Number of Samples	50

Precision

Within run precision was calculated according to NCCLS Guideline EP5-A by running 2 replicates of the 100 mg/dL calibrator with positive and negative controls twice a day for 20 days (N=80). Total precision was also calculated from these data.

Ethyl Alcohol

	Within Run Precision			Total Precision		
	100 mg/dL	40 mg/dL	300 mg/dL	100 mg/dL	40 mg/dL	300 mg/dL
Mean	100	40	300	100	40	296
SD	0.9	0.5	2.5	2.4	1.7	5.6
CV%	0.8	1.1	0.8	2.4	4.1	1.9

Analytical Recovery

Negative human urine and serum were spiked with ethyl alcohol at concentrations throughout the assay range. Recovery results on the AU600 are listed below.

Ethyl Alcohol: Urine

Concentration (mg/dL)	Mean (mg/dL)
25	26.7
80	82.4
200	208
400	370

Ethyl Alcohol: Serum

Concentration (mg/dL)	Mean (mg/dL)
25	27.5
80	80.1
200	190
400	375

Analytical Sensitivity

The sensitivity level of the Emit® II Plus Ethyl Alcohol Assay on the AU600 is <10 mg/dL ethyl alcohol. This level represents the lowest concentration of ethyl alcohol that can be distinguished from zero mg/dL 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.

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.

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