

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.

Run a reagent blank (blue rack) daily to ensure consistent day to day 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.

Instrument

Instrument Settings

General Screen

Reagent ID: 524

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

Range Screen

General		LIH	ISE	Range							
Test Name	<input type="text" value="User Defined"/>			◀ ▶		Type	<input type="text" value="Ser or Urine"/>				
Value Flag	<input type="text" value="Value"/>			Level L	<input type="text" value="User Defined"/>		Level H	<input type="text" value="User Defined"/>			
Normal Ranges		Age L	Age H				L	H			
	Sex	Year	Month	Year	Month						
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<input type="checkbox"/>	6	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>			<input type="text"/>	<input type="text"/>		
7 None Selected								<input type="text"/>	<input type="text"/>		
8 Out of Range								<input type="text"/>	<input type="text"/>		
Panic Value	<input type="text"/>							Unit	<input type="text" value="*"/>	Decimal Places	<input type="text" value="1"/>

* mg/dL or g/L

Calibration Specific Screen

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* 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








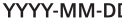




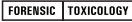





The sensitivity level of the Emit® II Plus Ethyl Alcohol Assay on the AU600 is <10 mg/dL ethyl alcohol. This level represents the lowest concentration of ethyl alcohol that can be distinguished from zero mg/dL with a confidence level of 95%.

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	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
	<i>In vitro</i> diagnostic medical device	5.5.1 ^a		Revision	Proprietary
RxOnly	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

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
	Recycle	1135 ^a		This way up	0623 ^a
	Biological risks	5.4.1 ^a		Caution	5.4.4 ^a
	Common Units	Proprietary		International System of Units	Proprietary
	Document face up [†]	1952 ^a		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
	For forensic/toxicology use only	Proprietary		LEVEL Level	Proprietary
	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.

[†] Indicates Assay-eNote.

Syva[®]

EMIT[®] II Plus Ethyl Alcohol Assay

Application Sheet

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AU[®], AU400[®], AU600[®], AU640[®], AU680[®], AU2700[®], and AU5400[®] are registered trademarks of Beckman Coulter, Inc.

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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