SIEMENS Healthineers

Syva®

EMIT® *tox*™ Acetaminophen Application Sheet

Shading indicates technical content that differs from the previous version.

Emit® *tox*™ Acetaminophen 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 Calibrator(s) listed below only.

Assay	Catalog Number
Emit® *tox*™ Acetaminophen Assay	7A319UL
Emit® *tox*™ Acetaminophen Assay	OSR7A229

Calibrators	Catalog Number
Emit® *tox*™ Acetaminophen Calibrators	7A409UL

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

Prepare a calibration curve whenever a new lot of reagent is used or as indicated by control results. Calibrate by placing the appropriate calibrators in the assigned positions in the calibration rack (yellow rack). Run a reagent blank (blue rack) with each calibration curve.

Instrument Settings

See page 2.

Results

Results are reported in µg/mL [µmol/L].

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Instrument

Instrument Settings

General Screen

Reagent ID: 517

General | LIH | ISE | Range

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

Sample	Volume	3.0	uL	Dilution	0	uL	Pre-Dilution Rate	
Reagents	R1 Volume	150	uL	Dilution	0	uL	Min OD	Max OD
	R2 Volume	75	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	RATE		Last L -2.0000	Last H 2.5000
Reaction Slope	+		Dynamic Range	
Measuring Point 1	First 15	Last 23	L 0.3	H 200
Measuring Point 2	First NA	Last NA	Correlation Factor	
Linearity	100 %		A 1.000000	B 0.0
No-Lag-Time			Onboard Stability Period	User Defined

Range Screen

General | LIH | ISE | **Range**

Test Name: User Defined ◀ ▶ Type: Serum

Value Flag: Value Level L: NA Level H: NA

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	User Defined	User Defined	Unit µg/mL	Decimal Places 1

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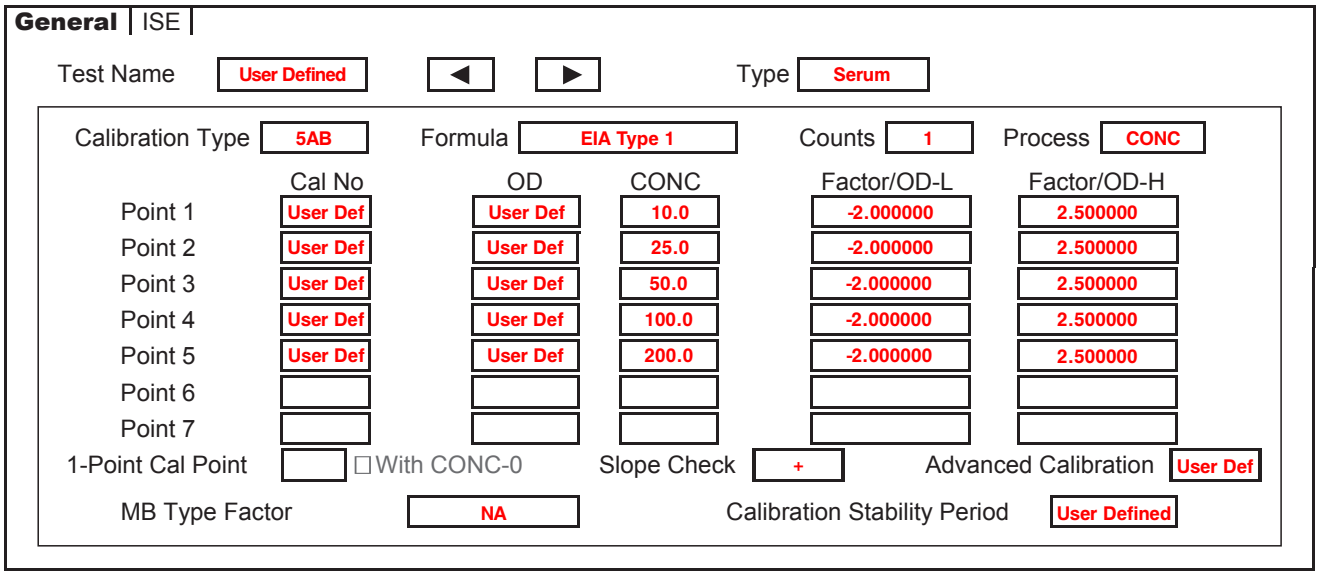
Calibration Parameters Screen



Performance

Method Comparison

Clinical specimens were tested using each Emit® *tox*™ Acetaminophen Assay on the AU600 analyzer and on the Syva®-30R analyzer. The results from the AU600 are as follows:

Slope	0.98
Intercept (µg/mL)	-1.34
Correlation Coefficient	0.992
Number of Samples	50

Precision

Within run precision was calculated according to NCCLS Guideline EP5-A by running 2 replicates of each control level twice a day for 20 days (N=80). Total precision was also calculated from these data and presented in µg/mL.

	Within Run Precision			Total Precision		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Mean	15.8	45.2	135.3	15.8	45.2	135.3
SD	0.6	1.1	5.1	0.7	1.9	6.8
% CV	3.6	2.5	3.8	4.4	4.1	5.0

Endogenous Substances

No clinically significant interference has been found in samples to which 800 mg/dL hemoglobin, 30 mg/dL bilirubin or 750 mg/dL triglycerides were added to simulate hemolytic, icteric, or lipemic samples.

Analytical Sensitivity

The sensitivity level of the Emit® *tox*™ Acetaminophen Assay on the AU600 is 0.3 µg/mL acetaminophen. This level represents the lowest concentration of acetaminophen that can be distinguished from 0 ng/mL with a confidence level of 95%.

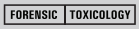
NOTE: Performance on the AU400, AU600, AU640, AU680, AU2700, and AU5400 series analyzers has been shown to be equivalent.

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]
	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.

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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