SIEMENS Healthineers

Syva®

EMIT® 2000 Carbamazepine, Gentamicin Plus, N-Acetylprocainamide, Procainamide, Quinidine

Application Sheet

Shading indicates technical content that differs from the previous version.

Emit® 2000 Carbamazepine, Gentamicin Plus, *N*-Acetylprocainamide, Procainamide, Quinidine 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	Storage (weeks)
Emit® 2000 Carbamazepine Assay	4F019UL	7
Emit® 2000 Gentamicin Plus Assay	4T039UL	7
Emit® 2000 *N*-Acetylprocainamide Assay	4N019UL	4
Emit® 2000 Procainamide Assay	4K019UL	4
Emit® 2000 Quinidine Assay	4Q019UL	4
Emit® 2000 Carbamazepine Assay	OSR4F229	7
Emit® 2000 Gentamicin Plus Assay	OSR4T229	7
Emit® 2000 *N*-Acetylprocainamide Assay	OSR4N229	4
Emit® 2000 Procainamide Assay	OSR4K229	4
Emit® 2000 Quinidine Assay	OSR4Q229	4

Calibrators	Catalog Number
Emit® 2000 Carbamazepine Calibrators	4F109UL
Emit® 2000 Gentamicin Plus Calibrators	4T209UL
Emit® 2000 *N*-Acetylprocainamide Calibrators	4N109UL
Emit® 2000 Procainamide Calibrators	4K109UL
Emit® 2000 Quinidine Calibrators	4Q109UL

Storage

Reagents which are in use may be stored on board the analyzer as listed in *Reagents* 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: Carbamazepine: 501, Gentamicin Plus: 503, N-Acetylprocainamide: 504, Procainamide: 507, Quinidine: 508

General | LIH | ISE | Range

Test Name	User Defined	◀	▶			Type	Serum		Operation	Yes
Sample	Volume	2	uL	Dilution	0	uL	Pre-Dilution Rate			
Reagents	R1 Volume	100	uL	Dilution	0	uL	Min OD		Max OD	
	R2 Volume	50	uL	Dilution	*	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	19 †		Last	27 ‡		L	**	H	***
Measuring Point 2	First	NA		Last	NA		Correlation Factor			
Linearity		100	%				A	1.000000	B	0.000000
No-Lag-Time		NO					Onboard Stability Period	User Defined		

* – For assays other than Gentamicin Plus, first enter 0. If problems are encountered with poor precision, enter 10. If problems persist, contact technical assistance. Enter 20 for Gentamicin Plus.
† – Enter 11 for Quinidine
‡ – Enter 15 for Quinidine
** – Enter assay sensitivity listed in the package insert.
*** – Enter the concentration of the highest calibrator. Enter 12.0 for Procainamide.

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Range Screen

General | LIH | ISE | **Range**

Test Name: User Defined ◀ ▶ Type: Serum

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	Unit	Decimal Places
Panic Value	User Defined	User Defined	µg/mL	1

Calibration Parameters Screen

General | ISE

Test Name: User Defined ◀ ▶ Type: Serum

Calibration Type: 5AB Formula: EIA Type 1 Counts: 1 Process: CONC

	Cal No	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1	User Def	User Def	‡‡	-2.000000	2.500000
Point 2	User Def	User Def	§§	-2.000000	2.500000
Point 3	User Def	User Def	§§	-2.000000	2.500000
Point 4	User Def	User Def	§§	-2.000000	2.500000
Point 5	User Def	User Def	§§	-2.000000	2.500000
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

‡‡ – Enter the concentration of the first non-zero assay specific calibrator.
§§ – Enter the remaining assay specific calibrator concentrations.

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Performance

Method Comparison

Clinical specimens were tested using each Emit® 2000 Assay on the AU600 analyzer and on the reference analyzer indicated. The results from the AU600 are as follows:

Carbamazepine

Slope	1.03
Intercept (µg/mL)	0.35
Correlation Coefficient	0.99
Number of Samples	57
Reference analyzer was the Abbott TDx®	

Gentamicin Plus

Slope	0.94
Intercept (µg/mL)	0.38
Correlation Coefficient	0.987
Number of Samples	60
Reference analyzer was the Syva®-30R	

N-Acetylprocainamide

Slope	0.91
Intercept (µg/mL)	0.06
Correlation Coefficient	0.994
Number of Samples	56
Reference analyzer was the Roche/Hitachi 704®	

Procainamide

Slope	1.00
Intercept (µg/mL)	0.02
Correlation Coefficient	0.995
Number of Samples	54
Reference analyzer was the Abbott TDx	

Quinidine

Slope	1.02
Intercept (µg/mL)	-0.05
Correlation Coefficient	0.978
Number of Samples	53
Reference analyzer was the Abbott TDx	

Precision

Within run precision was determined by assaying 20 replicates of each level of a tri-level control.

Total precision was calculated according to NCCLS guideline EP5-A using data collected from controls run in duplicate twice daily over twenty days. Precision observed during our testing is outlined below.

Carbamazepine

	Within Run Precision			Total Precision		
	Level 1	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
Mean (µg/mL)	4.7	10.5	15.3	4.4	10.2	15.0
% CV	2.9	2.2	2.2	6.3	4.8	6.5

Gentamicin Plus

	Within Run Precision			Total Precision		
	Level 1	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
Mean (µg/mL)	1.3	3.7	6.6	1.4	3.9	7.1
% CV	3.6	2.0	1.7	6.3	5.0	6.3

N-Acetylprocainamide

	Within Run Precision			Total Precision		
	Level 1	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
Mean (µg/mL)	2.4	5.6	10.6	2.1	5.1	9.8
% CV	2.8	1.9	2.7	4.3	4.2	4.5

Procainamide

	Within Run Precision			Total Precision		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Mean (µg/mL)	2.5	6.9	12.3	2.4	6.7	11.1
% CV	1.3	1.7	4.8	3.7	3.6	7.9

Quinidine

	Within Run Precision			Total Precision		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Mean (µg/mL)	1.5	3.3	4.7	1.4	3.3	4.7
% CV	2.9	3.4	3.0	8.5	6.7	9.3

NOTE: Performance on the AU400, AU600, AU640, AU680, AU2700, and AU5400 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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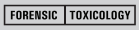
Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
	Recycle	1135[e]		This way up	0623[e]
	Biological risks	5.4.1[a]		Caution	5.4.4[a]
	Common Units	Proprietary		International System of Units	Proprietary
	Document face up[f]	1952[e]	YYYY-MM-DD	Date format (year-month-day)	N/A
	Non-sterile	Proprietary	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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