

EMIT® 2000 Phenytoin

Application Sheet

Shading indicates technical content that differs from the previous version.

Emit® 2000 Phenytoin Application Sheet

For the AU480® and AU5800® 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.

<u>Assay</u>	<u>Catalog Number</u>
Emit® 2000 Phenytoin Assay	4A019UL
Emit® 2000 Phenytoin Assay	OSR4A229

<u>Calibrators</u>	<u>Catalog Number</u>
Emit® 2000 Phenytoin Calibrators	4A109UL

Storage

Reagents which are in use may be stored on board the analyzer for up to 9 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 Settings

General Screen

Reagent ID: 506

General		LIH		ISE		HbA1c		Calculated Tests		Range	
Test Name	User Defined		<	>	Type	Serum		Operation		Yes	
Sample Volume	1.6 uL		Dilution		0 uL		OD Limit				
Pre-Dilution Rate			Min OD		-2.0000		Max OD		2.5000		
Reagent Volume	R1(R1-1) 72 uL		Dilution		0 uL		Reagent OD limit				
			First Low		-2.0000		High		2.5000		
			Last Low		-2.0000		High		2.5000		
	R2(R2-2) 52 uL		Dilution		* uL		Dynamic Range				
			Low		0.5		High		40.0		
Common Reagent	Type			Name			Correlation Factor				
Wave Length	Pri.	340 nm		Sec.	410 nm		Factor for Maker				
Method	RATE						A		1.000000		
Reaction Slope	+						B		0.000000		
Measuring Point-1	First	19		Last	27		Onboard Stability Period		User Defined		
Measuring Point-2	First			Last			Day		User Defined		
Linearity Limit	100 %						Hour				
Lag Time Check	No										

* First enter 0. If problems are encountered with poor precision, enter 10. If problems persist, contact technical assistance.

Range Screen

General		LIH		ISE		HbA1c		Calculated Tests		Range	
Test Name	User Defined		<	>	Type	Serum					
Value/Flag Level	Value										
			Low		High		Panic Value				
			-999999		999999.9		Low		High		
			User Defined		User Defined						
Specific Ranges											
	Sex	From Year	Month	To Year	Month	Low	High				
☐ 1											
☐ 2											
☐ 3											
☐ 4											
☐ 5											
☐ 6											
7 No Demographics											
8 Not within expected values											
Unit	µg/mL		Decimal Places		1						

Calibration Specific Screen

Calibrators		Calibration Specific		STAT Table Calibration																																																																					
General		ISE																																																																							
Test Name		User Defined		Type Serum																																																																					
Calibration Type		5AB		Formula EIA Type 1																																																																					
<Calibration Parameters>		Counts 1		Slope Check +																																																																					
<table border="1"> <thead> <tr> <th rowspan="2"></th> <th rowspan="2">Calibrator</th> <th rowspan="2">OD</th> <th rowspan="2">Conc</th> <th colspan="2">OD Range</th> </tr> <tr> <th>Low</th> <th>High</th> </tr> </thead> <tbody> <tr> <td>Point-1</td> <td>User Defined</td> <td></td> <td>2.5</td> <td>-2.000000</td> <td>2.500000</td> </tr> <tr> <td>Point-2</td> <td>User Defined</td> <td></td> <td>5.0</td> <td>-2.000000</td> <td>2.500000</td> </tr> <tr> <td>Point-3</td> <td>User Defined</td> <td></td> <td>10.0</td> <td>-2.000000</td> <td>2.500000</td> </tr> <tr> <td>Point-4</td> <td>User Defined</td> <td></td> <td>20.0</td> <td>-2.000000</td> <td>2.500000</td> </tr> <tr> <td>Point-5</td> <td>User Defined</td> <td></td> <td>40.0</td> <td>-2.000000</td> <td>2.500000</td> </tr> <tr> <td>Point-6</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Point-7</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Point-8</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Point-9</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Point-10</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>							Calibrator	OD	Conc	OD Range		Low	High	Point-1	User Defined		2.5	-2.000000	2.500000	Point-2	User Defined		5.0	-2.000000	2.500000	Point-3	User Defined		10.0	-2.000000	2.500000	Point-4	User Defined		20.0	-2.000000	2.500000	Point-5	User Defined		40.0	-2.000000	2.500000	Point-6						Point-7						Point-8						Point-9						Point-10					
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Point-2																																																																									
Stability Reagent Blank Calibration																																																																									
MB Type Factor 1-Point Calibration Point None with Conc-0																																																																									

Performance

Method Comparison

Clinical specimens were tested using the Emit® 2000 Phenytoin Assay on the AU600® analyzer and on the Roche/Hitachi 704 analyzer. The results from the AU600® are as follows:

Slope	1.06
Intercept (µg/mL)	-0.52
Correlation Coefficient	0.973
Number of Samples	55

Total precision was calculated according to NCCLS guideline EP5-T2 using data collected from controls run in duplicate twice daily over twenty days for 80 replicates. Precision observed during the testing is outlined below.

	Within Run Precision			Total Precision		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Mean (µg/mL)	4.2	12.9	22.5	4.0	11.7	23.1
% CV	3.8	3.1	3.3	6.0	5.9	8.2

NOTE: Performance on the AU480®, AU5800® and AU600® series analyzers has been shown to be equivalent.

Precision

Within run precision was determined by assaying 20 replicates of each level of a tri-level control. Precision observed during the testing is outlined below.

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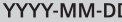
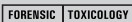
Definition of Symbols

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
	<i>In vitro</i> 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 ^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 ^f	1952 ^a		Date format (year-month-day)	N/A
	Non-sterile	Proprietary		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-eNote.

Syva®

EMIT® 2000 Phenytoin

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Emit® and Syva® are trademarks of Siemens Healthineers.

AU®, AU480®, AU600®, and AU5800® 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.

[siemens-healthineers.com](https://www.siemens-healthineers.com)

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