SIEMENS Healthineers

Syva®

EMIT® 2000 Phenytoin Assay Application Sheet

Shading indicates technical content that differs from the previous version.

Emit® 2000 Phenytoin Assay Application Sheet

For the DxC 700 AU® Clinical Chemistry System

Refer to the appropriate Instructions for Use for information regarding these reagents. Also refer to the Operator's Guide 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.

Emit® 2000 Phenytoin Assay	Catalog Number
Syva® Kit	4A019UL
Beckman Coulter Kit	OSR4A229

Calibrators	Catalog Number
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 quality control results are within acceptable limits.

Important Information

For performance characteristics, intended use, limitations and a detailed description how to perform the method, refer to the Emit® 2000 Phenytoin Assay Instructions for Use.

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.

Table 1

Calibrator			PHY1G-1	PHY1G-2	PHY1G-3	PHY1G-4	PHY1G-5
Phenytoin Concentration	µg/mL	0	2.5	5.0	10	20	40
	µmol/L	0	10	20	40	79	158

Results

Results are reported in µg/mL (µmol/L).

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Instrument Settings

General Screen

Reagent ID: 506

General	LIH	ISE	Calculated Test	Range

Test Name: PHY1G ▼ **Type:** Serum ▼ **Operation:** Yes ▼

Sample Volume		1.6 µL	Dilution	0 ▼ µL	OD Limit				
Pre-Dilution Rate		1 ▼				Min. OD	-2.0000	Max. OD	2.5000
Reagent Volume	R1 (R1-1)	72 µL	Dilution	0 µL	Reagent OD Limit				
	R1-2	µL	Dilution	µL	1st	Low	-2.0000	High	2.5000
	R2 (R2-1)	52 µL	Dilution	10 µL	Last	Low	-2.0000	High	2.5000
Common Reagent	Type	None	Name	None	Analytical Measuring Range	Low	0.5†	High	40.0†
Wavelength	Pri	340 ▼ nm	Sec	410 ▼ nm	Correlation Factor	A	1	B	0
Method		RATE ▼			Manufacturer Factor	A	1	B	0
Reaction Slope		+ ▼			Onboard Stability Period		63 Day	0	Hour
Measuring Point-1	1st	19	Last	27	LIH Influence Check		Yes ▼		
Measuring Point-2	1st		Last		Lipemia		+++++ ▼		
Linearity Limit		100 %			Icterus		++++ ▼		
Lag Time Check		No ▼			Hemolysis		+++++ ▼		

† Values set for working in µg/mL. To work in µmol/L, multiply by 3.96.

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Range Screen

General	LIH	ISE	Calculated Test	Range

Test Name: PHY1G ▼ **Type:** Serum ▼

Value/Flag: Value

Level — Low: -999999.9 High: 999999.9

Specific Ranges

	Sex	From Year	From Month	To Year	To Month	Other Type	Low	High
☐ 1:	# ▼	#	#	#	#	None	#	#
☐ 2:	# ▼	#	#	#	#	None	#	#
☐ 3:	# ▼	#	#	#	#	None	#	#
☐ 4:	# ▼	#	#	#	#	None	#	#
☐ 5:	# ▼	#	#	#	#	None	#	#
☐ 6:	# ▼	#	#	#	#	None	#	#
7:	Standard demographics						#	#
8:	Not within expected values						#	#

Critical Limits — Low: # High: # Unit: µg/mL Select Decimal places: 1

User Defined

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Calibration Specific Screen

Calibrators | **General** | **ISE**

Test Name: PHY1G ▼ **Type:** Serum ▼

Calibration Type 5AB ▼ Formula EIA Type 1 ▼ Counts 2

< Calibrator Parameters > ☐ Use Serum Cal.

	Calibrator	OD	Conc	Range Low	Range High
Point-1	PHY1G-1* ▼		2.5††	-2.0000	2.5000
Point-2	PHY1G-2* ▼		5.0††	-2.0000	2.5000
Point-3	PHY1G-3* ▼		10††	-2.0000	2.5000
Point-4	PHY1G-4* ▼		20††	-2.0000	2.5000
Point-5	PHY1G-5* ▼		40††	-2.0000	2.5000
Point-6	▼				
Point-7	▼				

MB Type Factor ____ 1-Point Calibration Point None ▼ ☐ with Conc-0

Slope Check + ▼

Allowable Range Check
☐ Reagent Blank ____
☐ Calibration ____

Advanced Calibration
Operation Yes ▼
Interval (RB) Lot ▼
Interval (ACAL) Lot ▼

Stability
Reagent Blank # Day ____ Hour
Calibration # Day ____ Hour

* Syva® Calibrator
†† Calibrator concentrations in µg/mL. Refer to Table 1 for µmol/L.
\# User Defined

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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