

Emit® 2000 Phenobarbital Application Sheet

For the VITROS® 5,1 FS and the VITROS® 4600 Chemistry Systems and the VITROS® 5600 Integrated System

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 Healthcare Diagnostics 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 listed below only.

<u>Assay</u>	<u>Catalog Number</u>
Emit® 2000 Phenobarbital	4D019UL

<u>Calibrators</u>	<u>Catalog Number</u>
Emit® 2000 Phenobarbital	4D109UL

Storage

Reagents which are in use may be stored on-board the analyzer for up to 28 days or as long as acceptable quality control results are obtained.

Instrument

Calibration

Prepare a calibration curve whenever a new lot of reagents is used or as indicated by control results.

Instrument Settings

See page 2.

Results

Results are reported in µg/mL [µmol/L]. If µmol/L units are needed, set unit choice in Result Parameter: Units to µmol/L. Then enter calibrator values for µmol/L as shown in the Calibrator IFU

Instrument Settings

VITROS® 5,1 FS and VITROS® 4600 Chemistry Systems and VITROS® 5600 Integrated System

CONFIGURE ASSAY:

FULL ASSAY NAME EMIT 2000 Phenobarb Assay
 SHORT ASSAY NAME PHENO
 FLUID TYPE SERUM
 ASSAY MODEL TYPE 2 POINT RATE
 TEMPLATE *2Pt R1-S-R2
 CAL MODEL TYPE LOG4
 CALIBRATOR BOTTLES 6
 REAGENT REPS PER CAL 2

REAGENT LOT INFORMATION:

ON BOARD STABILITY 28 DAYS
 REAGENT LOT NUMBER KIT LOT
 SHELF EXPIRATION DATE KIT EXP DATE

EDIT DILUTION PARAMETERS:

DILUENT NONE
 STANDARD DILUTION FACTOR 1.0
 REFLEX DILUTION OFF
 DILUTION FACTOR 1.0
 REDUCTION FACTOR 1.0

EDIT RESULT PARAMETERS:

RESULT PARAMETERS
 REPORTING TYPE QUANTITATIVE
 UNITS µg/mL
 SIGNIFICANT DIGITS 3
 PRECISION DIGITS 2
 USER ADJUSTED PARAMETERS
 SLOPE 1.0
 INTERCEPT 0.0
 CUVETIP EXPIRATION TIME 35
 TEMPERATURE SENSITIVE NO
 RANGES
 REFERENCE INTERVAL 0.0 to 9000000000
 SUPPLEMENTARY 0.0 to 90000000
 REPORTABLE RANGE 5.0 to 80.0

EDIT 2 POINT RATE ADDITIONAL PARAMETERS:

INITIAL ABSORBANCE LIMITS -0.20 to 2.70
 SECOND ABSORBANCE LIMITS -0.20 to 2.70
 ANTIGEN EXCESS FACTOR 9.0

EDIT PROTOCOL PARAMETERS:

STEP	VOLUME	PACK ID	SECONDS	WAVELENGTH
1. REAGENT	150 µL	UDxx /A		
2. INCUBATION			0.0	
3. SAMPLE	3.0 µL			
4. INCUBATION			304.0	
5. REAGENT	75 µL	UDxx /B		
6. INCUBATION			114	
7. READ				340 nm
8. INCUBATION			114	
9. READ				340 nm

EDIT CALIBRATION PARAMETERS:

CALIBRATOR LOT CAL KIT LOT
 CALIBRATOR EXPIRATION DATE CAL KIT LOT

BOTTLE NUMBER	DILUTION FACTOR	CALIBRATOR REPLICATE RESPONSE RANGE	CALIBRATOR VALUE
1	1.0	0.20	0.0
2	1.0	0.20	5.0
3	1.0	0.20	10.0
4	1.0	0.20	20.0
5	1.0	0.20	40.0
6	1.0	0.20	80.0

EDIT LINEAR OR LOGIT/LOG ADDITIONAL PARAMETERS:

MONOTONICITY INCREASE
 MAX RESPONSE HIGH 3.00
 MAX RESPONSE LOW -3.00
 CAL FIT GOODNESS LIMIT 0.990
 MIN RESPONSE HIGH 3.0
 MIN RESPONSE LOW -3.0
 CALIBRATION INTERVAL 999

EDIT TRIPLE READ PARAMETERS:

	REPORTABLE CONCENTRATION	TRIPLE READ LIMIT
REPORTABLE MIN	5.0	5.0
CRITICAL CONCENTRATION	20.0	8.0
REPORTABLE MAX	80.0	8.0

Reagent Packs: Reagents are liquid ready-to-use and must be split into at least 2 UDA packs. For splitting into 2 packs, add 14 mL of Reagent 1 (28 mL bottle) into chamber 1 (flat bottom bottle) and 7 mL of Reagent 2 (14 mL bottle) into chamber 2 (v-bottom bottle). This should provide roughly 65 tests per pack (~130 per kit). Splitting into more packs will produce fewer tests per pack.

Note: Once the individual UDxx pack number is selected for use during the protocol programming, that is the only UDxx pack number to use for this protocol.

Performance

Method Comparison

Clinical specimens were tested using the Emit® 2000 Phenobarbital assay on the AU640® and the VITROS® Chemistry Systems. The results for the VITROS® Chemistry Systems are shown below.

	VITROS® 5,1 FS	VITROS® 4600	VITROS® 5600
Slope	0.97	1.00	0.99
Intercept	1.45	1.22	0.83
Correlation Coefficient	0.99	0.99	0.99
Number	68	68	68

Precision

Within run precision was calculated according to CLSI Guideline EP5-T2 by running 2 replicates of each control level twice a day for 20 days (N=80). Total precision was also calculated from these data. The following data are presented in µg/mL:

VITROS® 5,1 FS

	Within-Run			Total Precision		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Mean	14.4	26.6	52.9	14.4	26.6	52.9
SD	0.3	0.5	1.1	0.4	0.8	1.8
CV%	1.9	1.8	2.0	3.1	3.2	3.3

VITROS® 4600

	Within-Run			Total Precision		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Mean	14.7	27.3	54.8	14.7	27.3	54.8
SD	0.3	0.5	1.5	0.6	1.1	2.8
CV%	1.9	1.8	2.7	4.0	3.9	5.1

VITROS® 5600

	Within-Run			Total Precision		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Mean	14.2	26.2	53.2	14.2	26.2	53.2
SD	0.2	0.4	1.8	0.3	0.7	1.5
CV%	1.3	1.7	2.0	2.5	2.7	2.8

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AU640® is a registered trademark of Beckman Coulter, Inc.

VITROS®, VITROS® 5,1 FS, VITROS® 4600, and VITROS® 5600 are trademarks of Ortho Clinical Diagnostics.

For technical assistance, call Siemens Healthcare Diagnostics:

1-800-227-8994 in the USA

1-800-264-0083 in Canada

In other countries, please contact your local representative.

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Symbols Key Symbolschlüssel Explication des Symboles Interpretazione simboli Clave de los Símbolos	
	Do not reuse / Nicht zur Wiederverwendung / Ne pas réutiliser / Non riutilizzare / No reutilizar
EXP CCYY-MM-DD	Use By / Verwendbar bis / Utiliser jusque / Utilizzare entro / Fecha de caducidad
LOT	Batch Code / Chargenbezeichnung / Code du lot / Codice del lotto / Código de lote
REF	Catalogue Number / Bestellnummer / Référence du catalogue / Numero di catalogo / Número de catálogo
	Caution, consult accompanying documents / Achtung, Begleitdokumente beachten / Attention voir notice d'instructions / Attenzione, vedere le istruzioni per l'uso / Atención, ver instrucciones de uso
	Manufacturer / Hersteller / Fabricant / Fabricante
EC REP	Authorized Representative in the European Community / Bevollmächtigter in der Europäischen Gemeinschaft / Mandataire dans la Communauté européenne / Mandatario nella Comunità Europea / Representante autorizado en la Comunidad Europea
	Contains sufficient for <n> tests / Inhalt ausreichend für <n> Tests / Contenu suffisant pour "n" tests / Contenuto sufficiente per "n" saggi / Contenido suficiente para <n> ensayos
IVD	In Vitro Diagnostic Medical Device / In-Vitro-Diagnostikum / Dispositif médical de diagnostic in vitro / Dispositivo medico-diagnostico in vitro / Producto sanitario para diagnóstico in vitro
	Temperature Limitation / Temperaturbegrenzung / Limites de température / Limiti di temperatura / Limite de temperatura
	Consult Instructions for Use / Gebrauchsanweisung beachten / Consulter les instructions d'utilisation / Consultare le istruzioni per l'uso / Consulte las instrucciones de uso
	Non-sterile / Nicht steril / Non stérile / Non sterile / No estéril
CE	CE Mark / CE Zeichen / Marquage CE / Marchio CE / Marca CE
CONTENTS	Contents / Inhalt / Contenu / Contenido / Contenido
	Reconstitution Volume / Rekonstitutionsvolumen / Volume de reconstitution / Volume di ricostituzione / Volumen de reconstitución
LEVEL	Level / Konzentration / Niveau / Livello / Nivel

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