Emit® 2000 Phenobarbital Assay
Application Sheet

For the
VITROS® 5,1 FS Chemistry System
VITROS® 4600 Chemistry System
VITROS® 5600 Integrated System
VITROS® XT7600 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.

<table>
<thead>
<tr>
<th>Emit® 2000 Phenobarbital Assay</th>
<th>Catalog Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>4D019UL</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Emit® 2000 Phenobarbital Calibrators</th>
<th>Catalog Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>4D109UL</td>
<td></td>
</tr>
</tbody>
</table>

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.

Calibration stability can be as long as 42 days for a single reagent lot.

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.
Syva®
Emit® 2000 Phenobarbital Assay

Instrument Settings

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:

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

EDIT CALIBRATION PARAMETERS:

<table>
<thead>
<tr>
<th>BOTTLE NUMBER</th>
<th>DILUTION FACTOR</th>
<th>CALIBRATOR REPLICATE RESPONSE RANGE</th>
<th>CALIBRATOR VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.0</td>
<td>0.20</td>
<td>0.0</td>
</tr>
<tr>
<td>2</td>
<td>1.0</td>
<td>0.20</td>
<td>5.0</td>
</tr>
<tr>
<td>3</td>
<td>1.0</td>
<td>0.20</td>
<td>10.0</td>
</tr>
<tr>
<td>4</td>
<td>1.0</td>
<td>0.20</td>
<td>20.0</td>
</tr>
<tr>
<td>5</td>
<td>1.0</td>
<td>0.20</td>
<td>40.0</td>
</tr>
<tr>
<td>6</td>
<td>1.0</td>
<td>0.20</td>
<td>80.0</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th></th>
<th>REPORTABLE CONCENTRATION</th>
<th>TRIPLE READ LIMIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>REPORTABLE MIN</td>
<td>5.0</td>
<td>5.0</td>
</tr>
<tr>
<td>CRITICAL CONCENTRATION</td>
<td>20.0</td>
<td>8.0</td>
</tr>
<tr>
<td>REPORTABLE MAX</td>
<td>80.0</td>
<td>8.0</td>
</tr>
</tbody>
</table>

**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.
Syva®

Emit® 2000 Phenobarbital Assay

Application Sheet

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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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