

**Emit® 2000 N-Acetylprocainamide Assay**

September 2011 4N052.3D.C

See shaded sections:
Updated information from September 2010 version.

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The assay.

coenzyme functions only with the bacterial measured spectrophotometrically. Endogenous serum G6PDH does not interfere because the sample can be measured in terms of enzyme activity. Active enzyme converts oxidized the sample can be measured in terms of enzyme activity. Active enzyme converts oxidized

Enzyme activity decreases upon binding to the antibody, so the drug concentration in

assay is based on competition between drug in the sample and drug labeled with the

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4 REAGENTS

Reagents contain the following substances:

Mouse monoclonal antibodies reactive to N-acetylprocainamide (3.3 µg/mL), glucose-6-phosphate (22 mM), nicotinamide adenine dinucleotide (18 mM), N-acetylprocainamide labeled with glucose-6-phosphate dehydrogenase (0.22 U/mL), Tris buffer, preservatives, and stabilizers.

Precautions

- For in vitro diagnostic use.
- Contains nonsterile mouse monoclonal antibodies.
- Do not use the kit after the expiration date.
- Turbidiy yellow reagents may indicate contamination or degradation and must be discarded.

Safety data sheets (MSDS/SDS) available on www.siemens.com/diagnostics

Preparation of Reagents

The Emit® 2000 N-Acetylprocainamide Assay reagents are provided ready to use; no preparation is necessary.

Storage of Assay Components

- Improper storage of reagents can affect assay performance.
- When not in use, store reagents upright at 2–8°C and with screw caps tightly closed.
- Unopened reagents are stable until the expiration date printed on the label if stored upright at 2–8°C.
- Do not freeze reagents or expose them to temperatures above 32°C.

5 SPECIMEN COLLECTION AND PREPARATION

- Each assay requires serum or plasma. Whole blood cannot be used. The anticoagulants heparin, citrate, oxalate, and EDTA have been tested and may be used with this assay. Some sample dilution may occur when samples are collected in tubes containing citrate anticoagulant. The amount of dilution and the possible need to correct for it should be considered when interpreting assay results for these samples.
- Sample volume is instrument-dependent. Refer to the appropriate Application Sheet for specific volumes.
- Store the serum or plasma refrigerated at 2–8°C. For transporting, maintain the sample temperature at 2–8°C. Samples can be stored refrigerated at 2–8°C for up to 7 days or stored frozen (-20°C) for up to 1 month.
- Pharmacokinetic factors influence the correct time of sample collection after the last drug dose. These factors include dosage form, mode of administration, concomitant drug therapy, and biological variations affecting drug disposition.1,2
- Measure the steady-state serum concentration representing the trough level just before the next scheduled dose.
- Human serum or plasma samples should be handled and disposed of as if they were potentially infectious.

6 PROCEDURE

Materials Provided

Emit® 2000 N-Acetylprocainamide Assay

Reagent 1

Reagent 2

Materials Required But Not Provided

Emit® 2000 N-Acetylprocainamide Calibrators

Multi-level commercial controls

Calibration

Recalibrate whenever a new lot of reagents is used or as indicated by control results (see Quality Control, below). If a new set of reagents with the same lot number is used, validate the system by assaying controls.

Quality Control

- Validate the calibration by assaying multi-level (eg, low, medium, and high) controls in every run. Commercial controls are available for this purpose. Ensure that control results fall within acceptable limits as defined by your own laboratory. Once the calibration is validated, run samples.
- Follow government regulations or accreditation requirements for quality control frequency. At least once each day of use, analyze two levels of a Quality Control (QC) material with known N-Acetylprocainamide concentrations. Follow your laboratory internal QC procedures if the results obtained are outside acceptable limits.
- Refer to the instrument User’s Guide for appropriate instrument checks and maintenance instructions.
Diluting High Concentration Samples
To estimate N-acetylprocainamide concentrations above the assay range, patient samples containing more than 16 µg/mL (58 µmol/L) N-acetylprocainamide may be diluted with one or two parts distilled or deionized water or Emit® 2000 N-Acetylprocainamide Calibrator 0. After diluting the sample, repeat the entire assay sequence and multiply the results by the dilution factor. Some analyzers dilute and retest high concentration samples automatically. See the analyzer User’s Guide or appropriate Application Sheet for instructions.

Evaluation and Interpretation of Results
• This assay uses Math Model No. 1.
• Results are automatically calculated; no additional manipulation of data is required.
• The factors that can influence the relationship between N-acetylprocainamide serum or plasma concentrations and clinical response include renal and circulatory function, rate of acetylation, the severity and type of cardiac arrhythmia, general state of health, and use of other drugs.
• The concentration of N-acetylprocainamide in serum or plasma depends on the time of the last drug dose, mode of administration; concomitant drug therapy; sample condition; time of sample collection; and individual variations in absorption, biotransformation, distribution, and excretion. These parameters must be considered when interpreting results.1,2
• Results of this test should always be interpreted in conjunction with the patient’s medical history, clinical presentation and other findings.

7 LIMITATIONS OF THE PROCEDURE
This assay has no specific limitations.

8 EXPECTED VALUES
The Emit® 2000 N-Acetylprocainamide Assay accurately quantitates N-acetylprocainamide concentrations in human serum or plasma containing 1.0–16 µg/mL (3.5–58 µmol/L) N-acetylprocainamide. Since N-acetylprocainamide is a metabolite of procainamide, no therapeutic range has been established exclusively for it. However, most patients achieve a satisfactory therapeutic response when the sum of procainamide and N-acetylprocainamide concentrations in serum is 10–30 µg/mL.1,2

Note: To convert from µg/mL to pmol/L (N-acetylprocainamide), multiply by 3.81.

Because of patient-to-patient differences in metabolic activity, renal function, and type and severity of cardiac arrhythmia, some patients may require serum levels outside this range. Therefore, the expected range is provided only as a guide, and individual patient results should be interpreted in light of other clinical signs and symptoms (see Section 6, Procedure, Evaluation and Interpretation of Results).

9 SPECIFIC PERFORMANCE CHARACTERISTICS
The information presented in this section is based on Emit® 2000 N-Acetylprocainamide Assay studies performed on the AU4000®/AU6000® Clinical Chemistry System. Refer to the Application Sheet for other AU Clinical Chemistry Systems and for additional information. Results may vary due to analyzer-to-analyzer differences. The following performance characteristics represent total system performance and should not be interpreted to pertain only to reagents.

Endogenous Substances
No clinically significant interference has been found in samples to which 800 mg/dL hemoglobin, 1000 mg/dL triglycerides, or 30 mg/dL bilirubin were added to simulate hemolytic, lipemic, or icteric samples.

Precision
Within-run precision was determined by assaying 20 replicates of each level of a tri-level control. Table 1 summarizes the data.

<table>
<thead>
<tr>
<th>Level</th>
<th>Mean (µg/mL)</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2.37</td>
<td>2.8</td>
</tr>
<tr>
<td>2</td>
<td>5.65</td>
<td>1.9</td>
</tr>
<tr>
<td>3</td>
<td>10.60</td>
<td>2.7</td>
</tr>
</tbody>
</table>

Table 1 — Within-Run Precision

Total precision was calculated according to NCLLS guideline EPS-T2 using data collected from controls run in duplicate twice daily over twenty (20) days. Table 2 summarizes the data.

<table>
<thead>
<tr>
<th>Level</th>
<th>Mean (µg/mL)</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2.12</td>
<td>4.3</td>
</tr>
<tr>
<td>2</td>
<td>5.13</td>
<td>4.2</td>
</tr>
<tr>
<td>3</td>
<td>9.85</td>
<td>4.5</td>
</tr>
</tbody>
</table>

Table 2 — Total Precision

Comparative Analysis
In this study, patient samples were analyzed on the Roche Diagnostics (RD)/Hitachi 704 analyzer and on the AU600 Clinical Chemistry System. Table 3 summarizes the results.

Table 3 — Comparative Analysis Results

<table>
<thead>
<tr>
<th>Compound</th>
<th>Concentration Tested (µg/mL)</th>
<th>Mean RD/Hitachi 704</th>
<th>Intercept</th>
<th>Slope</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>100</td>
<td>5.79</td>
<td>0.06</td>
<td>0.91</td>
</tr>
<tr>
<td>Diphenhydramine</td>
<td>100</td>
<td>5.34</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disopyramide</td>
<td>100</td>
<td>5.79</td>
<td>0.06</td>
<td>0.91</td>
</tr>
<tr>
<td>Erythromycin</td>
<td>100</td>
<td>5.34</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Furosemide</td>
<td>100</td>
<td>5.79</td>
<td>0.06</td>
<td>0.91</td>
</tr>
<tr>
<td>Digoxin</td>
<td>0.1</td>
<td>5.34</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Erythromycin</td>
<td>100</td>
<td>5.79</td>
<td>0.06</td>
<td>0.91</td>
</tr>
<tr>
<td>Furosemide</td>
<td>100</td>
<td>5.34</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glycinexylidide (GX)</td>
<td>100</td>
<td>5.79</td>
<td>0.06</td>
<td>0.91</td>
</tr>
<tr>
<td>Hydrochlorothiazide</td>
<td>100</td>
<td>5.34</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lisinopril</td>
<td>100</td>
<td>5.79</td>
<td>0.06</td>
<td>0.91</td>
</tr>
<tr>
<td>Midazolam</td>
<td>100</td>
<td>5.34</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Naproxen</td>
<td>100</td>
<td>5.79</td>
<td>0.06</td>
<td>0.91</td>
</tr>
<tr>
<td>Omeprazole</td>
<td>100</td>
<td>5.34</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Propafenone</td>
<td>100</td>
<td>5.79</td>
<td>0.06</td>
<td>0.91</td>
</tr>
<tr>
<td>Procainamide</td>
<td>100</td>
<td>5.34</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quinidine</td>
<td>100</td>
<td>5.79</td>
<td>0.06</td>
<td>0.91</td>
</tr>
<tr>
<td>Tocainide</td>
<td>100</td>
<td>5.34</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monoethylglycinexylidide (MEGX)</td>
<td>100</td>
<td>5.79</td>
<td>0.06</td>
<td>0.91</td>
</tr>
</tbody>
</table>

Table 4 — Compounds that Do Not Interfere

Sensitivity
The sensitivity level of the Emit® 2000 N-Acetylprocainamide Assay is 0.25 µg/mL. This level represents the lowest measurable concentration of N-acetylprocainamide that can be distinguished from 0 µg/mL with a confidence level of 95%.

Calibration Stability
Studies have shown calibration stability of more than two weeks. When proper reagent handling, instrument maintenance, and operating procedures are followed, the calibration should remain stable for at least two weeks.

10 REFERENCES
For technical assistance:
Beckman Coulter customers contact their technical assistance center.
1-800-223-0130

Siemens Healthcare Diagnostics customers contact their technical assistance center.
1-800-227-8994 in the USA
1-800-264-0083 in Canada

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