Cholinesterase – Page 1

* fluid stable

Cholinesterase FS*
Diagnostic reagent for quantitative in vitro determination of cholinesterase (ChE) in serum or plasma on photometric systems

**Order information**

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Kit size</th>
<th>R1</th>
<th>R2</th>
<th>R1</th>
<th>R2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 1401 99 10 021</td>
<td>5 x 20 mL</td>
<td>1 x 25 mL</td>
<td>1 1401 99 10 030</td>
<td>4 x 20 mL</td>
<td>2 x 10 mL</td>
</tr>
</tbody>
</table>

**Summary [3]**

Cholinesterases (ChE) are a group of enzymes preferably splitting choline and thiocholine esters. The names Serum Cholinesterase and Pseudocholinesterase are also commonly used. The ChE measured in serum and plasma is synthesized in the liver and is determined in diagnosis of liver diseases, nephrotic syndrome and intestinal diseases with loss of protein (exudative enteropathy). Strongly decreased values can indicate intoxication by pesticides. Measurement of ChE is also a part of pre-operative diagnostics as ChE is needed for the inactivation of muscle relaxants often used in surgeries.

**Method**

Kinetic photometric test, optimized method according to the recommendation of the German Society of Clinical Chemistry (DGKC)

**Principle**

Cholinesterase hydrolyses butyrylthiocholine under release of butyric acid and thiocholine. Thiocholine reduces yellow potassium hexacyanoferrate (III) to colorless potassium hexacyanoferrate (II). The decrease of absorbance is measured at 405 nm.

\[
\text{Butyrylthiocholine} + \text{H}_2\text{O} \xrightarrow{\text{Cholinesterase}} \text{Thiocholine} + \text{Butyrate}
\]

2 Thiocholine + 2[Fe(CN)_6]^{3-} + H_2O → Choline + 2[Fe(CN)_6]^{4-} + H_2O

**Reagents**

**Components and Concentrations**

<table>
<thead>
<tr>
<th>R1:</th>
<th>Pyrophosphate pH 7.6</th>
<th>95 mmol/L</th>
<th>Potassium hexacyanoferrate(III)</th>
<th>2.5 mmol/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>R2:</td>
<td>Butyrylthiocholine</td>
<td>75 mmol/L</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Storage Instructions and Reagent Stability**

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided. Do not freeze the reagents and protect from light!

**Warnings and Precautions**

2. In very rare cases, samples of patients with gammopathy might give falsified results [5].
3. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient’s medical history, clinical examinations and other findings.
4. For professional use only!

**Waste Management**

Please refer to local legal requirements.

**Reagent Preparation**

The reagents are ready to use.

**Materials required but not provided**

NaCl solution 9 g/L
General laboratory equipment

**Specimen**

Serum, heparin and EDTA plasma

Stability [1,3]:
- 2 weeks at 2 – 8°C
- 1 week at 15 – 25°C
- 6 months at –20°C

Discard contaminated specimens! Freeze only once!

**Assay Procedure**

**Application sheets for automated systems are available on request.**

- Wavelength: 405 nm
- Optical path: 1 cm
- Temperature: 37°C
- Measurement: Against reagent blank

<table>
<thead>
<tr>
<th>Reagent blank</th>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 µL</td>
<td>sample</td>
</tr>
</tbody>
</table>

**Calculation**

**With factor**

\[ \Delta \text{A/min} \times 68500 = \text{ChE activity [U/L]} \]

**With calibrator**

\[ \text{ChE [U/L]} = \frac{\Delta \text{A/ min Sample}}{\text{Conc. Calibrator [U/L]}} \]

**Conversion factor**

Cholinesterase [kU/L] × 16.67 = Cholinesterase [µkat/L]

**Calibrators and Controls**

For the calibration of automated photometric systems, DiaSys TruCal U calibrator is recommended. This method is traceable to the molar extinction coefficient. DiaSys TruLab N and P controls should be assayed for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

**Performance Characteristics**

**Measuring Range**

The test has been developed to determine ChE activities up to 20000 U/L.

If such value is exceeded, the sample should be diluted 1+5 with NaCl solution (9 g/L) and results multiplied by 6.
Specificity/Interferences
No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 45 mg/dL, hemoglobin up to 1000 mg/dL and lipemia up to 1400 mg/dL triglycerides. For further information on interfering substances refer to Young DS [4].

Sensitivity/Limit of Detection
The lower limit of detection is 50 U/L.

Precision

<table>
<thead>
<tr>
<th>Intra-assay</th>
<th>Mean [U/L]</th>
<th>SD [U/L]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>4188</td>
<td>39.8</td>
<td>0.95</td>
</tr>
<tr>
<td>Sample 2</td>
<td>5518</td>
<td>27.4</td>
<td>0.50</td>
</tr>
<tr>
<td>Sample 3</td>
<td>8808</td>
<td>44.3</td>
<td>0.50</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Inter-assay</th>
<th>Mean [U/L]</th>
<th>SD [U/L]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>4082</td>
<td>49.4</td>
<td>1.21</td>
</tr>
<tr>
<td>Sample 2</td>
<td>5474</td>
<td>82.1</td>
<td>1.50</td>
</tr>
<tr>
<td>Sample 3</td>
<td>8821</td>
<td>216</td>
<td>2.45</td>
</tr>
</tbody>
</table>

Method comparison
A comparison of DiaSys Cholinesterase FS (y) with the method according to [1] (x) using 106 samples gave following results:
\[ y = 0.948 \times + 89 \ U/L; \ r = 0.994 \]

A comparison with a commercially available test (x) using 106 samples gave following results:
\[ y = 1.013 \times - 56 \ U/L; \ r = 0.992 \]

Reference Range [1]

<table>
<thead>
<tr>
<th></th>
<th>[U/L]</th>
<th>[µkat/L]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women</td>
<td>3.93 – 10.8</td>
<td>65.5 – 180</td>
</tr>
<tr>
<td>Men</td>
<td>4.62 – 11.5</td>
<td>77.0 – 192</td>
</tr>
</tbody>
</table>

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature


Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9  65558 Holzheim  Germany