Cholinesterase FS

Diagnostic reagent for quantitative in vitro determination of cholinesterase (CHE) in serum or plasma on DiaSys respons® 910

Order Information
Cat. No. 1 1401 99 10 921
4 twin containers for 120 tests each

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 thiocholine and butyrate. Thiocholine reduces yellow potassium hexacyanoferrate (III) to colorless potassium hexacyanoferrate (II). The decrease of absorbance is measured at 405 nm.

Butyrylthiocholine + H₂O ⇄ Cholinesterase ⇄ Thiocolline + Butyrate
2 Thiocolline + 2[Fe(CN)₆]³⁻ + H₂O
Dithiobis(choline) + 2[Fe(CN)₆]²⁻ + H₂O

Reagents
Components and Concentrations
R1: Pyrophosphate pH 7.6 95 mmol/L
Potassium hexacyanoferrate(III) 2.5 mmol/L
R2: Butyrylthiocholine 75 mmol/L

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, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagents!

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. The bottles are placed directly into the reagent rotor.

Specimen
Serum, heparin or EDTA plasma

Stability [1,2]:
1 week at 15 – 25°C
2 weeks at 2 – 8°C
6 months at –20°C
Discard contaminated specimens. Freeze only once.

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

Precision
Within run (n=20)
Sample 1
Mean [kU/L] 2.86
Coefficient of variation [%] 1.95
Sample 2
Mean [kU/L] 4.74
Coefficient of variation [%] 1.62
Sample 3
Mean [kU/L] 4.23
Coefficient of variation [%] 2.41

Between run (n=20)
Sample 1
Mean [kU/L] 3.06
Coefficient of variation [%] 1.42
Sample 2
Mean [kU/L] 4.67
Coefficient of variation [%] 1.28
Sample 3
Mean [kU/L] 9.08
Coefficient of variation [%] 1.24

Method comparison (n=134)
Test x DiaSys Cholinesterase FS (Hitachi 917)
Test y DiaSys Cholinesterase FS (respons® 910)
Slope 1.032
Intercept 0.038 kU/L
Coefficient of correlation 0.998

Conversion Factor
Cholinesterase [kU/L] x 16.67 = Cholinesterase [µkat/L]

Reference Range [1]
Women 3.93 – 10.8 kU/L
Men 4.62 – 11.5 kU/L

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

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Literature

Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany
Cholinesterase FS

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

**Identification**
- This method is usable for analysis: Yes
- Twin reaction: No
- Name: CHE
- Reagent barcode reference: 028
- Host reference:

**Technic**
- Type: Linear kinetic
- First reagent [µL]: 160
- Blank reagent: Yes
- Sensitive to light
- Second reagent [µL]: 40
- Blank reagent: Yes
- Sensitive to light
- Main wavelength [nm]: 405
- Secondary wavelength [nm]:
- Polychromatic factor:
- 1st reading time [min:sec]: 06:48
- Last reading time [min:sec]: 10:00
- Reaction way: Decreasing
- Linear Kinetics
- Substrate depletion: Absorbance limit
- Linearity: Maximum deviation [%]: 100
- Fixed Time Kinetics
- Substrate depletion: Absorbance limit

**Reagents**
- Decimals
- Units

**Sample**
- Diluent: DIL A (NaCl)
- Hemolysis: 0 (no hemolysis)
- Cleaner
- Sample [µL]: 0
- Technical limits
- Concentration technical limits-Lower: 0.1
- Concentration technical limits-Upper: 20
- SERUM
- Normal volume [µL]: 3
- Normal dilution (factor): 1
- Below normal volume [µL]: 5
- Below normal dilution (factor): 1
- Above normal volume [µL]: 3
- Above normal dilution (factor): 6
- URINE
- Normal volume [µL]: 3
- Normal dilution (factor): 1
- Below normal volume [µL]: 5
- Below normal dilution (factor): 1
- Above normal volume [µL]: 3
- Above normal dilution (factor): 6
- PLASMA
- Normal volume [µL]: 3
- Normal dilution (factor): 1
- Below normal volume [µL]: 5
- Below normal dilution (factor): 1
- Above normal volume [µL]: 3
- Above normal dilution (factor): 6
- CSF
- Normal volume [µL]: 3
- Normal dilution (factor): 1
- Below normal volume [µL]: 5
- Below normal dilution (factor): 1
- Above normal volume [µL]: 3
- Above normal dilution (factor): 6
- Whole blood
- Normal volume [µL]: 3
- Normal dilution (factor): 1
- Below normal volume [µL]: 5
- Below normal dilution (factor): 1
- Above normal volume [µL]: 3
- Above normal dilution (factor): 6

**Range**
- Gender: Male
- Age: 20-50
- SERUM: >=4.62<=11.5
- PLASMA: >=4.62<=11.5
- CSF: >=3.93<=10.8
- URINE: >=3.93<=10.8
- Whole blood

**Contaminants**
- Please refer to r910 Carryover Pair Table

**Calibrators details**
- Calibrator list
- Concentration
- Cat. 1/Blank: 0
- Cat. 2: 1
- Cat. 3: 4
- Cat. 4: 6
- Cat. 5: 8
- Cat. 6: 10
- Max delta abs.
- Cat. 1: 0.003
- Cat. 2: 0.010
- Cat. 3: 0.011
- Cat. 4: 0.008
- Cat. 5: 0.010
- Cat. 6: 0.100
- Drift limit [%]: 0.8

**Calculations**
- Model: X
- Degree: 1

* Enter calibrator value