# Cholinesterase FS*

## Order Information

| Cat. No. | Kit size | | |
|---|---|---|---|
| 1 1401 99 10 021 | R1 5 x 20 mL | + | R2 1 x 25 mL |
| 1 1401 99 10 930 | R1 4 x 20 mL | + | R2 2 x 10 mL |

Kits for use in conjunction with DiaSys CE applications.

## Intended Use

Diagnostic reagent for quantitative in vitro determination of cholinesterase (CHE) activity in human serum or heparin plasma on automated photometric systems.

## Summary

Cholinesterases (CHE) are a group of enzymes that hydrolyze acetylcholine into choline and acetic acid. They are divided into acetylcholinesterase (ACHE) and butyrylcholinesterase (BCHE) [1]. Decreased CHE activity is relevant in preoperative diagnostics, as individuals with low CHE activities are more sensitive to muscle relaxants, leading to e.g. breath insufficiency [1]. Furthermore, decreased values can indicate liver diseases [1,2], or poisoning with insecticides. Other reasons for decreased values are due to drugs and rarely hereditary. The most common reason for elevated CHE values is diabetes mellitus, followed by cardiovascular diseases [2]. However, due to lack of specificity CHE is used as an additional parameter, combined with alanine aminotransferase (ALAT) and gamma-glutamyltransferase (GGT) [2].

## Method

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

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.

$$\text{Butyrylthiocholine} + H_2O \xrightarrow{\text{Cholinesterase}} \text{Thiocholine} + \text{Butyrate}$$

$$2\ \text{Thiocholine} + 2\ [Fe(CN)_6]^{3-} + H_2O \longrightarrow \text{Choline} + 2\ [Fe(CN)_6]^{4-} + H_2O$$

One unit of cholinesterase is the amount of enzyme that will convert 1.0 µmol of butyrylthiocholine in presence of $H_2O$ to thiocholine and butyrate per minute at the enzyme specific conditions.

## 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 and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 15 months until expiry date.

## Warnings and Precautions

1. Components contained in Cholinesterase FS are classified according to EC regulation 1272/2008 (CLP) as follows:

⚠ Reagent 1: Danger. Contains Tetrasodium pyrophosphate-10-hydrate. H318 Causes serious eye damage. P280 Wear protective gloves/protective clothing/eye protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a POISON CENTER/doctor.

2. In very rare cases, samples of patients with gammopathy might give falsified results [3].
3. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
4. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
5. Please refer to the safety data sheets (SDS) 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.
6. For professional use only.

## Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

## Reagent Preparation

The reagents are ready to use.

## Materials Required

General laboratory equipment

## Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [4]:

| | | |
|---|---|---|
| 7 days | at | 15 – 25°C |
| 7 days | at | 2 – 8°C |
| 1 year | at | -20°C |

Only freeze once. Discard contaminated specimens.

## Assay Procedure

**Basic settings for BioMajesty® JCA-BM6010/C**

| | |
|---|---|
| **Wavelength** | 410 nm |
| **Temperature** | 37°C |
| **Measurement** | Kinetic |
| **Sample/Calibrator** | 1.5 µL |
| **Reagent 1** | 80 µL |
| **Reagent 2** | 20 µL |
| **Addition reagent** | Cycle 19 (286 s) |
| **Absorbance** | Cycle 27/40 (394 s/573 s) |
| **Calibration** | Linear |

## Calculation

**With Calibrator**

$$\text{CHE [U/L]} = \frac{\Delta A/\text{min. Sample}}{\Delta A/\text{min. Cal.}} \times \text{Conc. Cal. [U/L]}$$

**Conversion Factor**

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

## Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the molar extinction coefficient. Use DiaSys TruLab N and P for internal quality control. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

| | Cat. No. | Kit size |
|---|---|---|
| TruCal U | 5 9100 99 10 063 | 20 x 3 mL |
| | 5 9100 99 10 064 | 6 x 3 mL |
| TruLab N | 5 9000 99 10 062 | 20 x 5 mL |
| | 5 9000 99 10 061 | 6 x 5 mL |
| TruLab P | 5 9050 99 10 062 | 20 x 5 mL |
| | 5 9050 99 10 061 | 6 x 5 mL |

## Performance Characteristics

**Data evaluated on BioMajesty® JCA-BM6010/C**

| |
|---|
| Measuring range up to 19 kU/L, linearity is given within ± 5%. When values exceed this range, samples should be diluted 1 + 5 with NaCl solution (9 g/L) and the result multiplied by 6. |

| | |
|---|---|
| Limit of detection** | 0.04 kU/L |

| Interference by | Interferences ≤ 10% up to | Analyte concentration [kU/L] |
|---|---|---|
| **Ascorbic acid** | 30 mg/dL | 6.39 |
| **Bilirubin** (conjugated) | 54 mg/dL | 6.34 |
| **Bilirubin** (unconjugated) | 42 mg/dL | 6.34 |
| **Hemoglobin** | 500 mg/dL | 6.33 |
| **Lipemia** (triglycerides) | 1000 mg/dL | 6.34 |

For further information on interfering substances, refer to the literature [5].

| **Precision** | | | |
|---|---|---|---|
| **Repeatability (n=20)** | **Sample 1** | **Sample 2** | **Sample 3** |
| Mean [kU/L] | 4.34 | 5.75 | 6.90 |
| CV [%] | 1.13 | 1.08 | 0.972 |
| **Between day (n=20)** | **Sample 1** | **Sample 2** | **Sample 3** |
| Mean [kU/L] | 4.22 | 4.88 | 6.91 |
| CV [%] | 0.887 | 1.46 | 1.69 |

| **Method comparison (n=100)** | |
|---|---|
| Test x | Competitor Cholinesterase (BioMajesty® JCA-BM6010/C) |
| Test y | DiaSys Cholinesterase FS (BioMajesty® JCA-BM6010/C) |
| Slope | 1.00 |
| Intercept | -0.240 kU/L |
| Coefficient of correlation | 0.999 |

** lowest measurable activity which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

## Reference Range [2]

| | kU/L | µkat/L |
|---|---|---|
| **Women** | 3.93 – 10.8 | 65 – 180 |
| **Men** | 4.62 – 11.5 | 77 – 192 |

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

## Literature


1. Pohanka, M. (2011). CHOLINESTERASES, A TARGET OF PHARMACOLOGY AND TOXICOLOGY. Biomedical papers, 155(3), 219-223
2. Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2023 [cited 2024 Jan 03]. Available from: https://www.clinical-laboratory-diagnostics.com/
3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
4. Guder WG, da Fonseca-Wollheim F, Heil W, Schmitt Y, Töpfer G, Wisser H, Zawta B. Quality of Diagnostic Samples. 3rd edition; 2010. p. 38-9.
5. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products [Internet]. AACC Press and John Wiley and Sons, Inc; 2020 [cited 2024 March]. Available from: https://clinfx.wiley.com/ aaccweb/aacc/


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