Cholinesterase FS*

Order Information

Cat. No.	Kit size
1 1401 99 10 962	Σ 1890 (R1: 6 x 315, R2: 6 x 315)

Intended Use

Diagnostic reagent for quantitative in vitro determination of cholinesterase (CHE) in serum or plasma on BioMajesty®-JCA BM6010/C.

Summary

Cholinesterases (CHE) are a group of enzymes preferably splitting choline and thiocholine esters. The denomination 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. [1]

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.

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

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

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

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 them from light.

Warnings and Precautions

1. ⚠ 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 or doctor/physician.
2. In very rare cases, samples of patients with gammopathy might give falsified results [2].
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

Refer to local legal requirements.

Reagent Preparation

The reagent is ready to use. The bottles are placed directly into the reagent rotor.

Materials Required

General laboratory equipment

Specimen

Serum or heparin plasma

Stability [1,3]:

1 week	at	15 – 25°C
2 week	at	2 – 8°C
6 months	at	–20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. TruCal U calibrator values have been made traceable to the molar extinction coefficient. Use DiaSys TruLab N and P for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 83 063	20 x 3 mL
	5 9100 99 83 064	6 x 3 mL
TruLab N	5 9000 99 83 062	20 x 5 mL
	5 9000 99 83 061	6 x 5 mL
TruLab P	5 9050 99 83 062	20 x 5 mL
	5 9050 99 83 061	6 x 5 mL

Performance Characteristics

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range up to 19 kU/L. In case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	0.04 kU/L
Onboard stability	5 weeks
Calibration stability	5 weeks

Interfering substance	**Interferences ≤ 10% up to**
Ascorbic acid	30 mg/dL
Bilirubin (conjugated)	54 mg/dL
Bilirubin (unconjugated)	42 mg/dL
Hemoglobin	500 mg/dL
Lipemia (triglycerides)	1000 mg/dL
For further information on interfering substances refer to Young DS. [4]	

Precision			
Within run (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
Test y	DiaSys Cholinesterase FS
Slope	1.000
Intercept	–0.240 kU/L
Coefficient of correlation	0.9996

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

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

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Reference Range

As follows [3]:

Women	3.93 – 10.8 kU/L	65.5 – 180 µkat/L
Men	4.62 – 11.5 kU/L	77.0 – 192 µkat/L

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

Literature

1. Hallbach J, Klinische Chemie für den Einstieg. 1st ed Stuttgart: Thieme;2001. p. 143-4.
2. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
3. Recommendations of the German Society for Clinical Chemistry. Standardization of methods for the estimation of enzyme activities in biological fluids: Standard method for the determination of Cholinesterase activity. J Clin Chem Clin Biochem 1992;30:163-70.
4. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.

IVD CE

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* Fluid Stable

BioMajesty

Cholinesterase FS

Chemistry code 10 140

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.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1,5
Sample vol (U)	1,5
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	CHE
Digits	1
M-wave L.	410
S-wave.L	****
Analy.mthd.	RRA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	1,5	1,5
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	21
M-DET.P.m	27
M-DET.P.n	40
S-DET.P.p	0
S-DET.P.r	0
Check D.P.I.	21
Limit value	0.003
Variance	10
Reac.type	Dec

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	0.7

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999