ISE S.r.l.

CUSTOMISED SOLUTIONS
FOR YOUR LABORATORY

Cholinesterase – Instructions for use

CE IVD

R1: 2x 18 mL R2: 2x4,5 mL **R3330000015** REF

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

TEST PARAMETERS

Method:	Colorimetric, kinetic, decreasing reaction, opt. DGK
Wavelength:	405 nm
Temperature:	37°C
Sample:	Serum, heparin or EDTA Plasma
Linearity:	up to 20000 U/L (manual test procedure)
Sensitivity:	The lower detection limit is 50 U/L

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.

REAGENT COMPOSITION

COMPONENTS		FINAL CONCENTRATION	
Reagent 1:			
Pyrophosphate	pH 7.6	95	mmol/L
Potassium Hexacyanoferrate(III)		2.5	mmol/L
Reagent 2:			
Butyrylthiocholine		75	mmol/L

REAGENT PREPARATION

The reagents are ready to use.

REAGENT STABILITY AND STORAGE

Conditions:	protect from light Avoid contamination. close immediately after use do not freeze the reagents	
Stability:	at 2 – 8°C	up to the exp. Date indicated on the label

MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution (9 g/L)
General laboratory equipment

SAMPLE STABILITY AND STORAGE

Use fresh serum, plasma, not haemolized (Heparin, EDTA) and promptly separated from red blood cells.
Do not use sodium fluoride as an anticoagulant, because it inhibits cholinesterase.

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

Discard contaminated specimens. Freeze only once!

SPECIFICITY / INTERFERENCES

No interference up to:

Ascorbic acid	30 mg/dl
Bilirubin	45 mg/dl
Hemoglobin	1000 mg/dl
Triglycerides	1400 mg/dl

For further information on interfering substances refer to Young DS (4).

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Substrate Start:

Pipette into test tubes	Blank	Sample/Calibrator
Reagent 1	1000 µl	1000 µl
Distilled water	20 µl	-
Sample/Calibrator	-	20 µl
Mix, incubate for about 3 minutes at 37°C, than add.:		
Reagent 2	250 µl	250 µl
Mix and read the absorbance of the Reagent Blank and the Sample after 2 minutes. Start a stop watch and read absorbance again after 1, 2 and 3 minutes. Calculate: ΔA/min = [ΔA/min Sample] – [ΔA/min Blank]		

CALCULATION (light path 1 cm)

Cholinesterase (U/L) = ΔA/min x Factor
Factor: 68500

With calibrator:

$$\text{CHE [U/L]} = \frac{\Delta A/\text{min Sample}}{\Delta A/\text{min Calibrator}} \times \text{activity calibrator [U/L]}$$

UNIT CONVERSION

U/L x 0,01667 = µkatal/L

REFERENCE RANGE [1] * (U/L)

	37 °C	µkat/L
Females	3930 - 10800	65.5-180
Males	4620 - 11500	77.0-192

* It is recommended that each laboratory establishes its own normal range.

TEST PRINCIPLE

Cholinesterase hydrolyses butyrylthiocholine, under release of butyric acid and thiocholine.
Thiocholine reduces yellow potassium hexacyanoferrate(III) to colourless potassium hexacyanoferrate(II).
The decrease of absorbance at 405 nm is proportional to the activity of CHE in the sample.

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

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

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PERFORMANCE CHARACTERISTICS

LINEARITY, MEASURING RANGE

The test has been developed to determine cholinesterase activities 20000.
If this value is exceeded the sample should be diluted 1+5 with NaCl solution (9 g/L sodium chloride in dist. water) and results multiplied by 6.

SENSITIVITY / LIMIT OF DETECTION

The lower limit of detection is 50 U/L.

PRECISION (at 37 °C)

Intra-assay n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	4188	39.8	0.95
Sample 2	5518	27.4	0.50
Sample 3	8808	44.3	0.50

Inter-assay n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	4082	49.4	1.21
Sample 2	5474	82.1	1.50
Sample 3	8821	216	2.45

METHOD COMPARISON

A comparison of Dialab Cholinesterase (y) with the method according to [1] using 106 samples gave following results:
Y = 0.948 x + 89 U/L; r = 0.994
A comparison of Dialab Cholinesterase (y) with a commercially available test (x) using 106 samples gave following results:
y = 1.013 x - 56 U/L; r= 0.992

CALIBRATION

The use of a Cholinesterase Calibrator is optional.
We recommend the our multi calibration serum. This method is traceable to the molar extinction coefficient.

QUALITY CONTROL

All control sera with Cholinesterase values determined by this method can be used.
We recommend the our serum controls (control serum with values in the normal and abnormal range).
Each laboratory should establish corrective action in case of deviations in control recovery.

AUTOMATION

Special applications for automatic analysers can be made on request.

WARNINGS AND PRECAUTIONS

1. In very rare cases, samples of patients with gammopathy might give falsified results [8].
2. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
3. 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.

REFERENCES

1. 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
2. Thomas L, Clinical Laboratory Diagnostics. 1st ed Frankfurt: TH-Books Verlagsgesellschaft; 1998. p.65-71.
3. Hallbach J, Klinische Chemie für den Einstieg. 1st ed Stuttgart: Thieme; 2001. p. 143-4
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.
5. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007; 45(9): 1240-1243.

Symbols on labels and packaging

IVD = In vitro diagnostic medical device

REF = Catalog Number

LOT = Lot Number

= Manufacturer

= Expiration date

= Temperature limitation

= Instruction for use

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