CE IVD DIALAB

Liquid Reagents – ready to use

CHOLINESTERASE

Opt. DGKC
2 Reagents

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

REF Cont.

D07730	**5 x 50 ml**	4 x 50 ml	Reagent 1
		1 x 50 ml	Reagent 2

Additionally offered:

D98485	5 x 3 ml	Calibrator	Diacal Auto
D98481	12 x 5 ml	Control normal	Diacon N
D98482	12 x 5 ml	Control abnormal	Diacon P

TEST PARAMETERS

Method:	Colorimetric, Kinetic, Decreasing Reaction
	Opt. DGKC
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

REAGENT COMPOSITION

COMPONENTS	FINAL CONCENTRATION
Reagent 1:	
Pyrophosphate pH 7.6	75 mmol/L
Hexacyanoferrate(III)	2 mmol/L
Reagent 2:	
Butyrylthiocholine	15 mmol/L

REAGENT PREPARATION

The reagents are ready to use.

REAGENT STABILITY AND STORAGE

Conditions: protect from light
close immediately after use
do not freeze the reagents

Stability: at 2 – 8°C up to the exp. date

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.

INTERFERING SUBSTANCES

no interference up to:

ascorbic acid	30 mg/dl
bilirubin	45 mg/dl
hemoglobin	1000 mg/dl
triglycerides	1400 mg/dl

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Substrate Start:

Pipette into test tubes	Blank	Sample
Reagent 1	1000 µl	1000 µl
Distilled water	20 µl	-
Sample	-	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

UNIT CONVERSION

U/L x 0,01667 = µkatal/L

REFERENCE RANGE * (U/L)

	37 °C
Females	3930 - 10800
Males	4620 - 11500

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

TEST PRINCIPLE

Cholinesterase (CHE) catalyses the hydrolysis of butyrylthiocholine, forming butyrate 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.

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

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

PERFORMANCE CHARACTERISTICS

LINEARITY

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.

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 between Dialab Cholinesterase (y) and a commercially available test (x) using 106 samples gave following results:
y = 1.013 x - 56 U/L; r= 0.992.

QUALITY CONTROL

All control sera with Cholinesterase values determined by this method can be used.
We recommend:

REF Cont.

D98481	12 x 5 ml	**DIACON N**	Assayed Control Serum Normal
D98482	12 x 5 ml	**DIACON P**	Assayed Control Serum Abnormal

CALIBRATION

The use of a Cholinesterase Calibrator is optional.
We recommend:

REF Cont.

D98485	5 x 3 ml	**DIACAL AUTO**	Assayed Multi Calibration Serum

AUTOMATION

Special adaptations for automatic analyzers can be made on request.

WARNINGS AND PRECAUTIONS

Take the necessary precautions for the use of laboratory reagents.

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. p65-71.
3. Hallbach J, Klinische Chemie für den Einstieg. 1st ed Stuttgart: Thieme; 2001. p. 143-4

2°C 8°C IVD

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