

CHOLINESTERASE

Colorimetric Kinetic method

R1: 2 x 50 ml + R2: 2 x 10 ml

CL25-120

INTENDED USE

Kit for quantitative determination of Cholinesterase (EC 3.1.1.8) in serum and plasma.

CLINICAL MEANING

Cholinesterase is a hepatic enzyme which hydrolyses acetylcholine and other esters of choline. Its concentration in serum increases in acute and chronic liver diseases. The quantity of this enzyme is used to analyze the functionality of the liver.

PRINCIPLE

The cholinesterase present in serum catalyzes hydrolysis of the butyrylthiocholine substrate and forms butyrate and thiocholine. The liberated thiocholine reduces esaferricyanide (III) to esaferricyanide (II). The absorbance decrease at 405 nm is proportional to the cholinesterase activity in the sample.

SAMPLE

Serum, heparinized or EDTA plasma. Do not use hemolyzed samples. Do not use sodium fluoride as anticoagulant: it inhibits cholinesterase. The cholinesterase in the sample is stable 15 days at 2-8°C.

REAGENTS

Only for in Vitro diagnostics. Liquid reagents ready to use.

Package contents	CL25-120
REAGENT 1 Pyrophosphate buffer (pH 7,6) 92 mmol/L, esaferricyanide (III) 2,5 mmol/L	2 x 50 ml
REAGENT 2 Butyrylthiocholine 91 mmol/L	2 x 10 ml

Stability: Store at 2-8°C and protect from light to keep the reagents stable up to the expiration date on the label. Once opened reagents are stable for 2 months at 2-8°C if contamination is avoided.

Keep bottles closed when not in use. Do not use turbid reagents.

NECESSARY ITEMS – NOT PROVIDED

Usual laboratory equipment: UV/VIS Spectrophotometer with temperature control; automatic micropipettes; Optical glass cuvettes or, alternatively, disposable ones in optical polystyrene; Saline solution.

MANUAL PROCEDURE

Analysis:	decreasing kinetic
Wavelength:	405 nm
Optical path:	1 cm
Temperature:	37°C
Reaction Time:	8 minutes
Reading:	against air or distilled water
Sample/Reagent 1/ Reagent 2:	1/50/10

Bring the reagents to the chosen temperature for the analysis.

Pipette in cuvette:

	Blank Reagent	Sample
Distilled water	20 µl	-
Sample	-	20 µl
Reagent 1	1000 µl	1000 µl

Mix and incubate at 37°C for 5 minutes. Add:

Reagent 2	200 µl	200 µl
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Stir accurately. Read the absorbance after 90 seconds and repeat readings after exactly 30, 60 and 90 seconds. Calculate the average variation of absorbance for 30 seconds ($\Delta A/30''$).

Reaction volumes can be proportionally varied without any change in calculation.

CALCULATION

Calculate the enzymatic activity in the sample using the following formula:

Cholinesterase [KU/L] = ($\Delta A/30''$ sample – $\Delta A/30''$ blank) x 131,6

REFERENCE VALUES

Male	5.1 ÷ 11.7 KU/L
Female	4.0 ÷ 12.6 KU/L

Each laboratory should define its own reference values for this method.

QUALITY CONTROL – CALIBRATION

All Clinical Chemistry laboratories should implement a quality control program. Control serums of human origin are available for this purpose on request:

PRE-NORM serums with normal values

PRE-PATH serums with pathological values

If the method requires it, a multiparameter calibrator of human origin is available.

PERFORMANCE CHARACTERISTICS

Sensitivity: the sensitivity of the method is 160 U/L.

Linearity: up to 25 KU/L (at 37°C).

For higher values, dilute the samples with saline solution and multiply the result by the dilution factor.

Precision:

Within run (n=10)	Average [U/L]	SD	CV %
Sample 1	3850	57,04	1,46
Sample 2	6735	155,22	2,30
Sample 3	13749	166,17	1,21

Between run (n=20)	Average [U/L]	SD	CV %
Sample 1	3850	46,70	1,21
Sample 2	6744	92,66	1,37
Sample 3	13758	126,87	0,92

Interferences: up to 20 mg/dl of bilirubin does not interfere.

Correlation against a reference method: the correlation of FAR method (Y) against a reference BTC method (X) gives this equation:

$$Y = 0,3194X + 527 \quad r = 0,9831$$

DISPOSAL

The product must be used for professional analysis only. The product must be disposed of according to national/international laws.

WARNINGS AND PRECAUTIONS

Contact with the skin and ingestion should be avoided. Use the normal precautions expected with correct behavior in laboratory.

REFERENCES

1. Deutsche Gesellschaft für Klinische Chemie. Proposal of Standard Methods for the determination of enzymecatalytic concentrations in serum and plasma at 37°C. II Cholinesterase (acetylcholine acylhydrolase). Eur. J.Clin.Chem; Cljn. Biochem. 30, 163 (1992).

MANUFACTURER

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KEY SYMBOLS

	In Vitro diagnostic medical device
	batch number
	catalog number
	temperature limits
	use by
	caution
	consult accompanying documents

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