CHOLINESTERASE (2-8°C)

(DGKC – Butyrylthiocholine)

CATALOGUE NUMBER	KIT SIZE (ML)
MPRCHE1	1x25ml / 1x5ml

Intended Use:
For *In Vitro* diagnostic use by trained laboratory personnel only.
This reagent is intended for the quantitative determination of Cholinesterase in human serum or plasma.

Clinical Significance:
Serum Cholinesterase is found in the liver, pancreas, heart, serum and in the white matter of the brain. This serum enzyme should not be confused with acetylcholinesterase from erythrocytes which is also known as cholinesterase I. The biological function of cholinesterase is not known. Clinically it serves as an inhibitor of possible insecticide poisoning and is measured as an index of liver function. Pre-operative screening of cholinesterase is used to detect patients with atypical forms of enzyme and hence avoid prolonged apnea caused by slow elimination of muscle relaxants.
Reduced cholinesterase levels are found in the serum of individuals poisoned with organophosphorus compounds and with hepatitis, cirrhosis, myocardial infarction, acute infections and atypical phenotypes of the enzyme. This assay is based on the DGKC method.

Test Principle:
The activity of cholinesterase is determined according to the following reaction:
Butyrylthiocholin + H2O —CHE→ Thiocholin + Butyrate
Thiocholine + Hexacyanoferrate III (yellow) → Hexacyanoferrate II) Clear

Reagent Composition

REAGENT	COMPONENT	CONCENTRATION
Reagent 1	Pyrophosphate Buffer	pH 7.5, 75 mmol/l
	Potassium Hexacyanoferrate (III)	2.0 mmol/l
Reagent 2	s-Butyrylthiocholine iodide	15 mmol/l

Reagent Preparation and Stability:
R1 Buffer: Liquid ready to use.
R2 Substrate: Liquid ready to use.
R1 and R2 are stable until the expiry date stated when stored unopened at 2 - 8°C. Protect the reagents from Light.
When used as a Working Reagent by mixing R1 and R2 in the ratio 5+1, the Working Reagent is stable for 24 hours at 20 - 25°C and 5 days at 2 - 8°C.

Sample Collection, Preparation and Stability:
Collect serum and Heparin or EDTA plasma by separation from red blood cells after standard venepuncture technique. Do not use fluoride as a plasma anticoagulant.
Cholinesterase is stable in samples for 2 days at 20 - 25°C, 7 days at 4-8°C and up to 4 weeks at -20°C.
Centrifuge samples containing precipitate before performing the assay.

Assay Procedure: Substrate Start

WAVELENGTH	405nm (400 – 420nm)
TEMPERATURE	37°C
CUVETTE	1cm Path Length
BLANK	Against air

	Sample
Buffer / R1	1000 µl
Sample	20 µl
Mix and incubate for 5 minutes and then add	
Substrate R2	200 µl
Read initial absorbance after 90 seconds and start stopwatch at the same time. Repeat reading after exactly 30,60,90 seconds	

Calculation:
Cholinesterase Activity: (U/l) = ΔA/min x 65800

Performance Characteristics:

Measuring range:
35-25000 U/l or 0.58 – 414 uKat/l
Substrate start:
If the decrease of absorbance within one minute is higher than 0.380 at 405nm or 25 KU, dilute the sample 1:5 with saline solution and repeat test. Multiply result by 5.

Analytical Sensitivity: (Lower detection limit):
35 U/l.
The lowest detection limit represents the lowest measurable cholinesterase activity that can be distinguished from zero.

Intra-Assay Precision:

Sample	Mean (U/l)	SD (U/l)	CV %
Pool 1	4252	26.7	0.63
Pool 2	5890	41.3	0.70
Pool 3	6810	33.4	0.49

Inter-Assay Precision:

Sample	Mean (U/l)	SD (U/l)	CV %
Pool 1	4246	163	3.85
Pool 2	4848	212	4.38
Pool 3	4591	193	4.20

Method Comparison:
A comparison of the AMS Cholinesterase (y) with a commercial assay (x) gave the following result:
Y= 0.763 x +0.352; r= 0.996

Interferences:
Criterion: Recovery within +/- 10% of initial value.
Icterus: No significant interference up to an index of I 45 (approx. 45 mg/dl of Bilirubin)
Haemolysis: No significant interference up to an index H of 1000 (approx. Hb concentration of 1000 mg/dl)
Lipaemia: No significant interference up to an index L of 750 (approx. Triglycerides concentration of 1500 mg/dl). There is poor correlation between turbidity and triglyceride concentration.

Reference Range:

37°C Children, men and women over 40 years	5100 – 11700 U/l
37°C Women 16 – 39 years	4000 – 12600 U/l

Each laboratory should establish its own mean reference range according to the population. For diagnostic purposes the cholinesterase values should be always assessed in conjunction with the patient's medical history.

Application for Automated systems:
For Applications on automated systems – contact technical department.

Quality Control and Calibration Material:
It is recommended that a laboratory uses reference control sera to verify the reagent performance. Results obtained should fall within the specified ranges. If results fall outside these ranges actions should be taken in line with the laboratory's internal quality procedures.
AMS recommend the following calibrator and controls
Calibration Serum: **QCCCAL1 / QCCCAL2**
Human Assayed Control Normal: **QCCHAN1 / QCCHAN2 / QCCHAN3**
Human Assayed Control Elevated: **QCCHAE1 / QCCHAE2 / QCCHAE3**

References:

1. Glick M. R. Ryder K W, Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation. ClinChem 1986; 32:470-474
2. Bablok W. et al. A General Regression Procedure ofr Method Transformation. Clin Chem Clin Biochem 1988
3. Tietz N.W., ed, Clinical Guide to Laboratory tests, 2nd ed., Philadelphia: W.B.Saunders, 1990: 126 – 127.
4. Guder W.G.Narayanan S, Wisser H, Zawta B. list of analytes preanlytical variables. Brochure in: Samples from the patient to the laboratory. Damstadt: GIT Verlag. 1996.

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Keep away from sunlight

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