SPECTRUM

The Creative Approach to Bioscience

CHOLINESTERASE DGKC

REF: 418 001 80 Test

R1 Sodium pyrophosphate (2 x 20 ml)
R2 Potassium ferricianyde (1 x 8 ml)

REF: 418 002 160 Test

R1 Sodium pyrophosphate (4 x 20 ml)
R2 Potassium ferricianyde (1 x 16 ml)

SYMBOLS IN PRODUCT LABELLING

EC REP Authorised Representative	Use by/Expiration Date
IVD For in-vitro diagnostic use	CAUTION. Consult instructions for use
LOT Batch Code/Lot number	
REF Catalogue Number	Manufactured by
Consult instructions for use	(Xi) - Irritant
Temperature Limitation	

Intended Use

Spectrum Diagnostics Cholinesterase reagent is intended for the quantitative in vitro determination of cholinesterase in biological fluids.

Background

Two related enzymes have the ability to hydrolyze acetylcholine. One is acetylcholinesterase, which is called true cholinesterase, or choline esterase I. True cholinesterase is found in erythrocytes, in the lungs and spleen, in nerve endings, and in the gray matter of the brain. It is responsible for the prompt hydrolysis of acetylcholine released at the nerve endings to mediate transmission of the neural impulse across the synapse. The degradation of acetylcholine is necessary for the depolarization of the nerve so that it can be repolarized in the next conduction event. The other cholinesterase is acylcholine acylhydrolase; it is usually called pseudocholinesterase, benzoyl cholinesterase, or choline esterase II. Although it is found in the liver, pancreas, heart, white matter of the brain, and serum, its biological role is unknown, but the assay of such a serum enzyme is clinically useful.

Method

Kinetic method.

Assay Principle

This reagent is formulated according to DGKC recommendations. Cholinesterase (pseudocholinesterase EC 3.1.1.8) catalyzes the hydrolysis of butyrylthiocholine, forming butyrate and thiocholine, which reduces the ferricyanide ions to ferrocianyde.The decrease in absorbance is followed at 405 nm and it is proportional to cholinesterase activity in examined sample.

Reagents

Reagent 1 (R1) pH.7.6

Sodium pyrophosphate 75 mM

Reagent 2 (R2)

Potassium ferricyanide 2 mM
Butyrylthiocoline 15 mM

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of water. In case of severe injuries; seek medical advice immediately.

Reagent Preparation, Storage and Stability

Serum as starter procedure:

Add 4 ml of reagent R2 to a vial of reagent R1.

Stability of working reagent:

15 days at 2-8°C, away from light sources.

Reagent as starter procedure:

Reagents are supplied ready to use.

Stability: up to expiration date on labels at 2-8°C; Stability since first opening of vials: preferably within 60 days at 2-8°C.

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Specimen Collection and Preservation

Serum, plasma (EDTA, heparin only). Avoid hemolysis. ChE is stable in sample for at least 14 days whether the sample is stored at room temperature or under refrigeration.

Procedure

Wavelength	405 nm
Optical path	1 cm
Temperature	37 °C
Sensitivity	432.3 U/L
Linearity	25000 U/L

Procedure 1(Sample as starter)

Pipette in a test tube:

Working Reagent 600 µl

Incubate at 37 °C for 5 minutes

Specimen 10 µl

Mix, read initial absorbance after 90 seconds. and start timer simultaneously. Read again after 30, 60 and 90 seconds. Determine the mean absorbance change per minute (ΔA/min).

Procedure 2(Reagent as starter)

Pipette in a test tube:

Reagent 1 500 µl
Specimen 10 µl

Incubate at 37°C for 5 minutes

Reagent 2 100 µl

Mix, read initial absorbance after 90 seconds. and start timer simultaneously. Read again after 30, 60 and 90 seconds. Determine the mean absorbance change per minute (ΔA/min).

Calculation

U/l = ΔA /min x 65800

Quality Control

Normal & abnormal commercial control serum of known concentrations should be analyzed with each run.

Performance Characteristics

Precision

Within run (Repeatability)

	Level 1	Level 2
n	10	10
Mean (U/L)	5972.9	5743.8
SD	122.8	57.5
CV%	2.06	1.0

Run to run (Reproducibility)

	Level 1	Level 2
n	10	10
Mean (U/L)	5808.5	5753.5
SD	113.4	99.6
CV%	1.95	1.73

ORDERING INFORMATION	
CATALOG NO.	QUANTITY
418 001 418 002	80 test 160 test

Methods Comparison

A comparison between Spectrum Diagnostics cholinesterase and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.996 was obtained.

Sensitivity

When run as recommended, the sensitivity of this assay is 430 U/l.

Linearity

The reaction is linear up to cholinesterase concentration of 25000 U/l. Specimens showing higher concentration should be diluted 1+1 with physiological saline and repeat the assay (result×2).

Interfering substances

No significance interferance was observed by the presence of:

Haemoglobin < 500 mg/dl
Bilirubin < 40 mg/dl
Lipids < 800 mg/dl

Expected Values

Total cholinesterase

Men 5600 - 11200 U/l
Women 4200 - 10800 U/l

Dibucaine number:

Normal homozygotes: > 75%
Hetero zygotes: 35 - 75 %
Atypical homozygotes: < 35 %

Each laboratory should establish appropriate reference intervals related to its population.

Waste Disposal

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.
P501: Dispose of contents according to national/interna-tional regulations.

References

1.Eur.J.Clin.Chem.Clin.Biochem. Vol. 30, 1992, 162-170
Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).

Egyptian Company for Biotechnology (S.A.E)
Obour city industrial area. block 20008 piece 19 A. Cairo. Egypt.
Tel: +202 4665 1848 - Fax: +202 4665 1847
www.spectrum-diagnostics.com
E-mail:info@spectrum-diagnostics.com

EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany

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