CHOLINESTERASE DGKC FL

CH F096 CH	4 x 24 ml
CH F245 CH	12 x 24 ml

INTENDED USE

Reagent for quantitative in vitro determination of cholinesterase in biological fluids.

SUMMARY OF TEST

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 to 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.

PRINCIPLE OF THE METHOD

This reagent is formulated according to DGKC reccomendations. 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.

KIT COMPONENTS

For in vitro diagnostic use only.
The components of the kit are stable until expiration date on the label.
Keep away from direct light sources.

CHE R1 **F096: 4 x 20 ml (liquid) blue cap**
F245: 12 x 20 ml (liquid) blue cap

CHE R2 **F096: 1 x 16 ml (liquid) red cap**
F245: 3 x 16 ml (liquid) red cap

Composition in the test: sodium pyrophosphate 75 mM, pH 7.60, potassium ferricianyde 2 mM, butyrylthiocolyne 15 mM, stabilizers.

Store all components at 2-8°C.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

REAGENT PREPARATION

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:
use separate reagents 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.

PRECAUTIONS

CHE R1: Danger. Causes serious eye damage (H318). Wear protective gloves. Eye protection (P280). IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305+P351+P338). Immediately call a doctor (P310).

CHE R2: It is not classified as hazardous.

SPECIMEN

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

TEST PROCEDURE (sample as starter)

Wavelenght:	405 nm
Ligthpath:	1 cm
Temperature:	37°C

dispense in cuvette working reagent:	1200 µl
preincubate at 37°C for 5 minutes.	
add sample:	20 µl

Mix, execute a first reading of absorbance after 90 seconds, incubating at 37°C. Perform other 3 readings at 30 seconds intervals. Calculate the ΔA/min.

TEST PROCEDURE (reagent as starter)

Wavelenght:	405 nm
Ligthpath:	1 cm
Temperature:	37°C

dispense in cuvette reagent R1:	1 ml
add sample:	20 µl
incubate at 37°C for 5 minutes.	
dispense in cuvette reagent R2:	200 µl

Mix, execute a first reading of absorbance after 90 seconds, incubating at 37°C. Perform other 3 readings at 30 seconds intervals. Calculate the ΔA/min.

RESULTS CALCULATION

Perform calculation in units per litre, multiplying the ΔA/min by the factor as it is indicated.

Calculation in U/l: ΔA/min x 65800

Calculation in µkat/l: U/l x 0.0167 = µkat/l

EXPECTED VALUES

Total SChE:
Men: 5600 - 11200 U/l
Women: 4200 - 10800 U/l

Dibucaine number:
Normal homozygotes: > 75%
Heterozygotes: 35 - 75%
Atypical homozygotes: < 35%

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

QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:
QUANTINORM CHEMA
with normal or close to normal control values
QUANTIPATH CHEMA
with pathological control values.
If required, a multiparametric, human based calibrator is available:
AUTOCAL H

Please contact Customer Care for further information.

TEST PERFORMANCE

Linearity
the method is linear up to 25000 U/l.
If a ΔA/min of 0.30 is exceeded, it is suggested to dilute sample 1+9 with saline solution and to repeat the test, multiplying the result by 10.

Sensitivity/limit of detection (LOD)
the limit of detection is 432.3 U/l.

Interferences
no interference was observed by the presence of:

hemoglobin	≤ 500 mg/dl
bilirubin	≤ 40 mg/dl
lipids	≤ 800 mg/dl

Precision

intra-assay (n=10)	mean (U/l)	SD (U/l)	CV%
sample 1	5972.9	122.8	2.1
sample 2	5743.8	57.5	1.0

inter-assay (n=20)	mean (U/l)	SD (U/l)	CV%
sample 1	5808.4	113.4	2.0
sample 2	5753.5	99.6	1.7

Methods comparison
a comparison between Chema Cholinesterase FL and a commercially available product gave the following results:

SChE Chema = x
SChE competitor = y
n = 107

y = 0.985x + 51.7 U/l r^2=0.996

WASTE DISPOSAL

This product is made to be used in professional laboratories.
P501: Dispose of contents according to national/international regulations.

REFERENCES

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

MANUFACTURER

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SYMBOLS

IVD	*in vitro* diagnostic medical device
LOT	batch code
REF	catalogue number
	temperature limit
	use by date
	caution
	consult instructions for use

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