

Intended Use

This reagent is intended for *in vitro* quantitative determination of cholinesterase in serum or plasma.

- New DGKC method
- Ready to use liquid stable reagents
- High linearity and high sensitivity

Clinical Significance

Cholinesterase also known as acetyl-cholinesterase and is found mainly in the nerve endings and the grey matter of brain. It hydrolyses acetylcholine, released at the nerve endings to mediate transmission of impulses. A similar enzyme acyl choline acylhydrolase also known as pseudocholinesterase is present in the serum, brain, heart, liver and pancreas but its biological role is unknown.

Cholinesterase levels in serum are useful as a test of liver function and as an indicator of possible insecticide poisoning. Among the organic phosphorous compounds that inhibit cholinesterase activity are mainly insecticides such as Parathion, Sarin and Tetraethylpyrophosphate. During poisoning the level of enzymes decreases as its activity is inhibited.

Principle

Cholinesterase catalyses the hydrolysis of butyrylthiocholine substrate forming butyrate and thiocholine.

$$\text{CHE}$$

$$\text{butyrylthiocholine} + \text{H}_2\text{O} \longrightarrow \text{Thiocholine} + \text{Butyrate}$$

Thiocholine reduces hexacyanoferrate(3) to hexacyanoferrate(2)

$$\text{Thiocholine} + \text{hexacyanoferrate}(3) \longrightarrow \text{Hexacyanoferrate}(2)$$

The decrease of absorbance is followed at 405 nm and is proportional to the activity of cholinesterase in the sample

Kit Components

Reagent/Component	Product code: 11419002	Description
Cholinesterase (S.L) R1	2 x 8 mL	Pyrophosphate Buffer, (pH 7.6) - 75mmol/L Hexa cynoferrate(3) 2 mmol/L
Cholinesterase (S.L) R2	2 x 2 mL	Butyrylthiocholine 15 mmol/L

Risk & Safety

Material Safety data sheets (MSDS) will be provided on request.

Reagent Preparation

Mix 4 volume of Reagent 1 (R1) with 1 volume of Reagent 2 (R2)

Working reagent is stable only for 3 hrs at 15 – 25°C.

Reagent Storage

The sealed reagents are stable up to the expiry date stated on the label, when stored at 2- 8°C and protected from light.

Open Vial Stability

Once opened, the reagent is stable up to 4 weeks at 2-8°C if contamination is avoided.

Onboard Calibration Stability

On-board Calibration stability is 7 days

Reagent Deterioration

Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Agappe control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

Precaution

To avoid contamination, use clean laboratory wares. Avoid direct exposure of working reagent to light.

Waste Management

Reagent must be disposed off in accordance with local regulation.

Sample

Use fresh serum / plasma.

Do not use sodium fluoride as an anticoagulant because it inhibits cholinesterase. Samples are stable for 15 days at 2-8°C.

Interferences

No interference for

Bilirubin up to	20 mg/dL
Hemoglobin up to	500 mg/dL
Triglycerides up to	1000 mg/dL

Materials Provided

Cholinesterase S.L Reagent R 1 & R2 .

Materials required but not provided

- Pipettes & Tips
- Test Tubes & racks
- Timer
- Incubator
- Analyzer

Test Procedure

Mode of Reaction	Kinetic
Slope of reaction	Decreasing
Wavelength	405 nm
Temperature	37°C
Factor	22653
Linearity	41400 U/L
Blank	DI Water
Delay	30 sec
No of reading	3
Interval	30 sec
Sample volume	50 µL
Reagent volume	1000 µL
Cuvette	1 cm light path

Application parameters for various instrument are available. Please contact customer support department for specific information.

Unit Conversion

Traditional Unit	SI Unit	Conversion from Traditional to SI
U/L	µ Kat/L	x 0.01667

Calibration

Agappe multicalibrator is recommended for calibration of this assay on fully auto analyzers.

Use provided factor (22653) for estimation of this assay on semi auto analyzers.

Procedure notes

Laboratory procedure for Semi Auto Analyzer	
Working reagent	1000 µL
Sample	50 µL
Mix and incubate at 37°C for 30 seconds. Measure the change in absorbance per 30 second during 90 seconds.	

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE  SEE PACKAGE INSERT FOR PROCEDURE **LOT** LOT NUMBER  MANUFACTURER'S ADDRESS  MANUFACTURING DATE  EXPIRY DATE  TEMPERATURE LIMIT

**AGAPPE DIAGNOSTICS LTD.**

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REV. NO.: ADL/IFU/CHE/LIQ/R02

CE ISO 9001 : 2015
EN ISO 13485: 2016

Calculation

Cholinesterase activity (U/L) = $(\Delta OD / 60 \text{ sec}) \times 22653$

Quality control

It is recommended to use Agappe Qualicheck Norm & Path (11601001) to verify the performance of the assay. Each laboratory has to establish its own internal quality control scheme and procedure for corrective action, if control do not recover within the acceptable range.

Reference Range

It is recommended that each laboratory has to establish its own reference values. The following value may be used as guide line.

Females : 3930 – 10800 U/L

Males : 4620 – 11500 U/L

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance**1. Linearity**

This reagent is linear upto 41400 U/L.

2. Precision

Accuracy (U/L)		
Control	Expected Value	Measured Value
Agappe Control Level 1	5850 ± 715	5850
Agappe Control Level 2	5900 ± 690	5925
Control Level 1	7587 ± 2564	7426
Control Level 2	5168 ± 2128	4979

3. Sensitivity

Lower detection Limit is -50 U/L

Bibliography

1. Eur. J. Clin. Chem; Clin. Biochem 30, 163(1992)
2. Tietz, Text book of Clinical chemistry, 2nd Edition, Brutis, Ashwood (1994)
3. Knedel, M and Bottger, R; Klin. Wschr. 1967; 45;30


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