CHOLINESTERASE

Diagnostic reagent for quantitative in vitro determination of cholinesterase (pseudocholinesterase) in serum or plasma on photometric systems.

Liquid. Dual Reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack
AB2130	5 x 50 mL
AB2131	5 x 25 mL

INTENDED USE

The test is applied for the quantitative determination of cholinesterase in serum or plasma.

Cholinesterases are a group of enzymes preferably splitting choline and thiocholine esters.The names Serum Cholinesterase and Pseudocholinesterase are also commonly used.The ChE measured in serum and plasma is synthesized in the liver and is determined in diagnosis of liver diseases,nephritic syndrome and intestinal diseases with loss of protein (exudative enteropathy).Strongly decreased values can indicate intoxication by pesticides. Measurement of ChE is also a part of pre-operative diagnostics as ChE is needed for the inactivation of muscle relaxants often used in surgeries.

TEST PRINCIPLE

ChE hydrolyses butyrylthiocholine under release of butyric acid and thiocholine. Thiocholine reduces yellow potassium hexacyanoferrate (III) to colorless potassium hexacyanoferrate(II). The decrease of absorbance is measured at 405 nm.

$$\text{Butyrylthiocholine} + H_2O \xrightarrow{\text{Cholinesterase}} \text{Thiocholine} + \text{Butyrate}$$

$$2\ \text{Thiocholine} + 2\ [Fe(CN)6]^{3+} + H_2O \longrightarrow \text{Choline} + 2[Fe(CN)_6]^{4} + H_2O$$

TEST PARAMETERS

Method	: Kinetic
Wavelength	: 405 nm
Temperature	: 37°C
Sample	: Serum or Heparin plasma
Linearity	: 50 U/L - 25000 U/L

REAGENT COMPOSITION

Reagent 1:

Pyrophosphate	pH 7.6 ≤ 77 mmol/L
Potassium hexacyanoferrate(III)	≤ 2.4 mmol/L

Reagent 2:

Butyrylthiocholine	≤ 18 mmol/L

REAGENT PREPARATION

Working reagents are stable at 2-8ºC in case of closed vials and avoiding contamination after preparation.

For manual working procedures; if working reagent will be used; shake the Reagent 2 vial gently before pouring its contents into the Reagent 1 bottle. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

REAGENT STABILITY AND STORAGE

Once opened vials are stable minimum 30 days at 2-8°C at optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

SAMPLE

Serum and heparin plasma are collected by standard procedures.

Specimens should be protected from direct exposure to light.
Samples are stable for 15 days at 2-8ºC.

TEST PROCEDURE

Sample Start

There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.
There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

Substrate Start
There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

ΔA/Min x 68500 = Che Activity in U/L

REFERENCE INTERVAL (NORMAL VALUES)*

Women	3930 U/L	10800 U/L
Men	4620 U/L	1150 U/L

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

Commercially available control material with established values determined by this method may be used.
We recommend:

"ARCON N", Assayed Control Serum Normal
Cat.No. A3910

"ARCON P", Assayed Control Serum Abnormal
Cat.No. A3920

The assay requires the use of a Cholinesterase Standard or Cholinesterase Calibrator. We recommend: ARCHEM Standard

ARCAL Calibrator ("Arcal Auto")
Cat. No. A39050

Any commercially available Standard or Calibrator suitable for this method may be used.

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 7 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

The test has been developed to determine CHE activities.

Low linearity: 50 U/L

High Linearity: The method is linear up to up to 25000 U/L.

If these values are exceeded the sample should be diluted 1+5 with NaCl solution (9 g/L) and results multiplied by 6.

Linearity may considerably vary depending on the instrument used.

Precision Studies:

Repeatibility (within run) (Intra-assay)

Mean conc.	SD (U/L)	CV	n
4188 U/L	39.8	0.95%	20
5518 U/L	27.4	0.50%	20
8805 U/L	44.3	0.50%	20

Reproducibility (run to run) (Inter-assay)

Mean conc.	SD (U/L)	CV	n
4082 U/L	49.4	1.21%	20
5474 U/L	82.1	1.50%	20
8821 U/L	216	2.45%	20

Sensitivity (LOD): The lower limit of detection is 40 U/L.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Interferences: No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 45 mg/dL, hemoglobin up to 1000 mg/dL and lipemia up to 1400 mg/dL triglycerides.

Method Comparison: A comparison between Archem ChE (y) and the method according to(1) (x) using 106 samples gave following results:

y = 0,948 x + 89 U/L;
r = 0.994

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1&R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

ChE : Cholinesterase
CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

REFERENCES

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SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
R2	Reagent 2
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

CE

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