LiquiMAX CHOLINESTERASE

Butyrylthio Choline Method

ORDERING INFORMATION

Ref. No.	Pack Size	Presentation
AVCHE - 12	12 ml	Two Liquid Reagents
AVCHE - 24	24 ml	

INTENDED USE:

LiquiMAX CHOLINESTERASE is an in-vitro diagnostic kit for the quantitative determination of cholinesterase in human serum.

PRODUCT FEATURES :

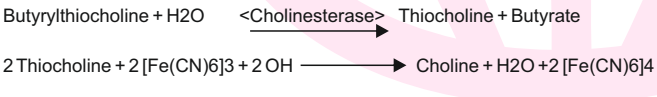
1. Liquid Stable, Ready to use Two Reagents (R1, R2)
2. 100 Seconds decreasing kinetic reaction (10 Sec Delay+ 90 Sec Measuring)
3. Measuring Wavelength 405 nm
4. Result by kinetic factor 14920
5. Linearity : 17000 U/L
6. Serum and Heparin Plasma are the specimens
7. Available as multipurpose reagents and dedicated system Packs

CLINICAL SIGNIFICANCE:

Serum cholinesterase (pseudocholinesterase, cholinesterase II or PCHE) is found in the liver, pancreas, heart, serum and in the white matter of the brain. This serum enzyme should not be confused with cetylcholinesterase from erythrocytes (EC 3.1.1.7), which is also referred to as cholinesterase I. The biological function of cholinesterase is unknown. Clinically, it serves as an indicator 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. Depressed cholinesterase levels are found in cases of intoxication with organophosphorus compounds and in hepatitis, cirrhosis, myocardial infarction, acute infections and atypical phenotypes of the enzyme.

PRINCIPLE:

Cholinesterase (CHE) catalyses the hydrolysis of butyrylthiocholine, forming butyrate and thiocholine. Thiocholine reduces yellow potassium hexacyanoferrate(III) to colourless potassium hexacyanoferrate(II). The decrease of absorbance at 405 nm is proportional to the activity of CHE in the sample.



STORAGE AND STABILITY:

All the reagents are ready to use. They are stable till the expiry date indicated on the reagent labels. Working reagent stability is not suggested. Working reagent needs to be made fresh and used immediately

KIT COMPONENTS

1. Reagent R1
2. Reagent R2

COMPOSITION

R1:

Pyrophosphate buffer (pH 7.6) 75 mMol/l
Potassium Cyanoferrate III 0.2 mMol/L

R2:

S- Butyrylthiocholine iodide 15 mmol/l

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard any turbid reagent or blank reagent absorbance less than 0.7 at 405 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN COLLECTION AND STORAGE

Serum is the only preferred specimen. Heparin Plasma can also be used. Never use Sodium Flouride Plasma as it inhibits CHE Activity

Collect serum using standard sampling tubes. Stability of the specimen is
7 days at + 4°C to + 8°C
4 weeks at -20°C.

Centrifuge samples containing precipitate before performing the assay.

SYSTEM PARAMETERS:

Reaction Type (Mode) : Kinetic
Reaction Direction : Decreasing
Wave Length : 405nm
Flow Cell Temp. : 37°C
Zero Setting with : Distilled Water
Delay time : 10 seconds OR { Delay : 10 Seconds
Measuring Time : 90 seconds Interval : 30 Seconds
Reagent Volume : 500 µl R1+100 µl R2 Number of Readings : 4 }
Sample Volume : 25 µl
Factor : 14920
Linearity : 17000
Units : U/L

TEST PROCEDURE:

Reagent	Test
R1	500 µl
Serum	25 µl
R2	100 µl

Mix well and immediately aspirate in to the Analyzer. Take the absorbance after 10 seconds incubation (Delay) and measure the change of optical density per 30 seconds during next 90 seconds (Measuring) against distilled water at 405 nm as follows.

Ao - Exactly after 10 seconds
A1, A2, A3 - Exactly after every 30 seconds for 90 seconds.

CALCULATION:

From the absorbance reading calculate ΔA/min and multiply by the corresponding factor 14920

CHE activity [U/L] = ΔA/ Min x 14920

EXPECTED VALUES:

Children : 4500 -11500 U/L
Males up to and above 40 Year : 4000-11500 U/L
Females up to and above 40 Years : 3830-10800 U/L

Each laboratory should investigate the transferability of the expected Values to its own patient population and if necessary determine its own reference range. For diagnostic purposes, the CHE results should always be assessed in conjunction with the patient's medical history, clinical examinations and other findings.

QUALITY CONTROL & CALIBRATION:

All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.

Controls should be assayed: Prior to reporting patient results. Following any maintenance procedure on the photometer used. At intervals established by the Laboratory Q.C. Programme.

PERFORMANCE CHARACTERISTICS

1. Linearity

Linearity : 17000 U/L

2. Sensitivity/ Limit of Detection (LOD)

Detection limit : 850 U/l

The lower detection limit represents the lowest measurable cholinesterase activity that can be distinguished from zero.

3. Interferences

Icterus : No significant interference up to approximate bilirubin concentration : 45 mg/dl

Hemolysis : No significant interference up to approximate hemoglobin concentration : 1000 mg/dl

Lipemia (Intralipid) : No significant interference up approximate triglycerides concentration : 1500mg/dl

4. Precision:

Reproducibility was determined using samples in an internal protocol.
The following results were obtained.

Intra-Assay

Sample	Mean (U/L)	SD (U/L)	CV%
Control serum 1	4252	4.6	0.110
Control serum 2	5890	4.5	0.076
Control serum 3	6810	4.8	0.070

Inter-Assay

Sample	Mean (U/L)	SD (U/L)	CV%
Control serum 1	4246	4.8	0.113
Control serum 2	5848	4.7	0.080
Control serum 3	6891	4.9	0.071

5. Method comparison:

A comparison of the LIquiMAX CHE (y) with a commercial obtainable assay (x) gave the following correlation (U/l) : y= 0.763 x + 0.352; r = 0.996

LIMITATIONS

LIquiMAX Cholinesterase kit is linear up to 17000 U/L. If the value exceeds 17000 U/L, the sample should be diluted 1+1 with Normal saline and the result should be multiplied by 2

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

NOTES

1) Follow strictly the addition sequence of the reagents and sample as per the procedure.
2) Do not deviate the addition sequence.
3) Never make working reagent and keep it.
4) Reagent 1 + Specimen + Reagent 2 and immediately aspirate.
5) After adding R2 immediately aspirate in to the Analyzer.

REFERENCES

1. Bablok W et al. A General Regression Procedure for Method Transformation. J Clin Chem Biochem 1988;26:783 – 790.
2. Glick M.R., Ryder K.W., Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation: Clin Cheim 1986; 32:470 - 474
3. Guder W.G., Narayanan S., Wisser H., Zawta B. List of Analytes Preanalytical Variables. Brochure in: Samples: From the Patient to the Laboratory. Darmstadt: GIT Verlag, 1996.

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		

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