Cholinesterase Estimation Kit

High-Q Cholinesterase
Butyrylthio Choline Method

Pariksha Biotech
A game changer in IVD

HIGH®
Command on Quality

Intended Use:

Kit for the quantitative determination of cholinesterase (CHE, EC 3.1.1.8) in human serum

Summary & 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.

Test 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.

Butyrylthiocholine+H2O<Cholinesterase>Thiocholine + Butyrate
2 Thiocholine +2 [Fe(CN)6]3 + 2 OH ---------- >Choline + H2O + 2 [Fe(CN)6]4

Reagent Compositions:

R1:

Pyrophosphate buffer (pH 7.6)	80 mMol/L
Potassium Cyanoferrate III	0.2 mMol/L

R2:

S- Butyrylthiocholine iodide	15 mmol/L

Preparation and stability:

All the reagents are ready to use. They are stable till the expiry date indicated on the reagent labels. Reagents must be used as indicated. No working reagent should be made and kept.

Specimen:

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.

Limitations - interference:

Icterus : No significant interference up to approximate bilirubin concentration : 50 mg/dl
Hemolysis : No significant interference up to approximate hemoglobin concentration : 1200 mg/dl
Lipemia (Intralipid) : No significant interference up approximate triglycerides concentration : 1600 mg/dl

Testing procedure:

Reagent Addition

R1	500 µl
Serum	50 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.

Precautions:

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.**

Calculation:

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

CHE activity [U/L] = Δ A/ Min x 14920

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**
Measuring Time	:	**90 seconds**
Reagent Volume	:	**500 µl R1+100 µl R2**
Sample Volume	:	**50 µl**
Factor	:	**14920**
Linearity	:	15000
Units	:	U/L

Reference 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**

Cholinesterase Estimation Kit

High-Q Cholinesterase
Butyrylthio Choline Method

Command on Quality

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.

Linearity :
High-Q Cholinesterase kit is linear up to 15000 U/L. If the value exceeds 15000 U/L, the sample should be diluted 1+1 with Normal saline and the result should be multiplied by 2

Analytical sensitivity (lower detection limit):
Detection limit : 850 U/l
The lower detection limit represents the lowest measurable cholinesterase activity that can be distinguished from zero.

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

Within run

Sample	Mean (U/l)	SD (U/l)	CV%
Control serum 1	4252	26.7	0.63
Control serum 2	5890	41.3	0.70
Control serum 3	6810	33.4	0.49

Between day

Sample	Mean (U/l)	SD (U/l)	CV%
Control serum 1	4246	163	3.85
Control serum 2	4848	212	4.38
Control serum 3	4591	193	4.20

Method comparison:
A comparison of the High-Q CHE (y) with a commercial obtainable assay (x) gave the following correlation (U/l) : $y = 0.763\,x + 0.352$; $r = 0.996$

Literature:

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 Chem 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.

Ordering Information:

Ref./Cat. No.	Pack Size	Presentation
P-CHE -12	12 ml	Two Liquid Reagents
P-CHE -24	24 ml	

Product Features

- **Liquid Stable, Ready to use Two Reagents (R1, R2)**
- **100 Seconds decreasing kinetic reaction (10 Sec Delay+ 90 Sec Measuring)**
- **Measuring Wavelength 405 nm**
- **Result by kinetic factor: 14920**
- **Linearity : 15000 IU/L**
- **Serum and Heparin Plasma are the specimens**
- **Available as multipurpose reagents and dedicated system Packs**

Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C 8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

eIFU Indicator

Pariksha's world inside
SCAN TO EXPLORE MORE

Manufactured in India by :
Pariksha Biotech Pvt Ltd,
Plot no.1/B-14, SVICE,
Balanagar,
Hyderabad-500037
Telangana State

+91 7075706709 info@parikshabio.com www.parikshabio.com