CHOLINESTERASE

(Kinetic Method)

Intended Use

Cholinesterase assay kit is intended used for the In-vitro quantitative determination of Cholinesterase in human serum sample.

Clinical Significance

Cholinesterase Measurements are used as a test of liver function, as an indicator of organophosphate insecticide poisoning, and as a means to investigate atypical, weakly active variants of the enzyme. A decreased level of enzyme activity is an indication of any of the above condition. The test is also used to identify patients with low enzyme activity who may enter a period of prolonged apnea following the administration of succinylcholine, a drug used as a muscle relaxant in surgery.

Principle

Butyrylthiocholine is hydrolyzed to cholinesterase to produce thiocoline in the presence of potassium hexacyanoferrate (III),the absorbance decrease is proportional to the cholinesterase activity of the sample.

Reagent provided

1. Reagent R1
2. Reagent R2

Working Reagent Preparation

Prepare working reagent by mixing **Reagent R_1** and **Reagent R_2** in the ratio 5:1 as per the number of tests required.

Reagent storage and stability

The reagent kit should be stored at 2-8°C and is stable till the expiry date indicated on the label.

Specimen collection and preservation

Blood should be collected in a clean dry container. Although serum is preferred, plasma with heparin or EDTA can be used. The assay should be carried out as far as possible on the same day. Serum and plasma samples are stable for 1 week at 4°C and 1 month at -10°C. The samples should be brought to room temperature prior to use. Avoid use of haemolysed and grossly contaminated samples.

Assay guidelines for Analyzers

Reaction type	Kinetic
Reaction Slope	Decreasing
Wavelength	405 nm
Flow cell Temperature	37°C
Zero setting with	Distilled water
Delay time	60 seconds
Interval time	30 Seconds
No. of Readings	3
Sample volume	50 µl (0.05 ml)
Reagent 1 volume	1000 µl (1 ml)
Reagent 2 volume	200 µl (0.200 ml)
Factor	28000
Lower limit	4850 IU/L
Higher limit	12000 IU/L
Linearity	25000 IU/L

Assay guidelines for Manual Procedure

Prewarm the required amount of working reagent at 37°C before use. Perform the assay as given below:

Reagents	Test
Working Reagent	1200 µl (1.2ml)
Sample	50 µl (0.5 ml)

1. Mix thoroughly and transfer the assay mixture immediately to the thermo stated cuvette and start the stop watch simultaneously.
2. Record the first reading at 60th second and subsequently 3 more readings with 30 seconds interval at 405 nm.

Calculation

Serum Cholinesterase (IU/L) = (Δ OD / Min) x 28000 (Factor)

Normal Range

4850 to 12000 IU/L

Note: Expected range varies from population to population and each laboratory should establish its own normal range.

Limitations

A Sample with a Cholinesterase (15000 IU/L) Cholinesterase level exceeding(15000 IU/L)The linearity limit should be diluted Sample Multiply result with dilution factor.

Quality Control

To ensure adequate quality control, it is recommended that each batch should include a normal and an abnormal commercial reference control serum. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, and cleanliness of glassware and accuracy of pipetting.

References

1. Knedel B. .Boettger R., Klin Wschr.(1967),45,325.
2. Arbeitsgruppe enzyme der Deutschon Gesellschaft fur Klinische ,Chemie (1989) Mitt Dtsch Ges Klin Cheni PS20PS,123-124

Symbols

IVD In Vitro Diagnostics. | Caution. | Keep away from sun light. | Date of Manufacture.

LOT Batch No. | Read Instructions. | Fragile. | Product Expiry Date.

CONT Content. | Storage Temperature. | Keep Dry. | Manufactured By.

REF Catalogue No.

KEE DIAGNOSTICS PVT LTD

CIN: U24231DL2004PTC128343 .
A subsidiary of KEE PHARMA LTD
A-8 . 3RD FLOOR. NARAINA INDUSTRIAL AREA, PHASE 2.
NEW DELHI-110028.
W. www.keediagnostics.com.
E. info@keediagnostics.com, T. 011 43136000.

ISO 9001: 2015 & ISO 13485: 2016 Certified Company