ACCUCARE®

CHOLINESTERASE

Butyrylthiocoline potassium hexacyanoferrate (III) method

Quantitative determination of Cholinesterase in serum/plasma
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Cont.
CHOLEN 25	1 x 25 ml

CLINICAL SIGNIFICANCE

There are two forms of cholinesterase; acetyl cholinesterase and cholinesterase is also commonly referred to as psuedocholinesterase. Acetylcholinesterase is found predominantly in erythrocytes. Cholinesterase is synthesised in the liver and is present in plasma and is the form of the enzyme routinely measured. Cholinesterase is most commonly measured as an indicator of exposure to anticholinesterases (organophosphates, including many insecticides), or inherited abnormal variants of the enzyme, which cause a decreased level of plasma cholinesterase.
Increased levels of activity may be present in nephrotic syndrome or in the recovery from liver damage.
Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Method

Kinetic photometric test, optimized method according to the recommendation of the German Society of Clinical Chemistry (DGKC).

PRINCIPLE

Butyrylthiocholine iodide is hydrolyzed by cholinesterase to produce thiocoline in the presence of potassium hexacyanoferrate (III), the absorbance decrease at 405nm is directly proportional to the cholinesterase activity in the sample.

REAGENT

Reagent I : Buffer Reagent
Reagent II : Butyrylthiocholine iodide Reagent

REAGENT PREPARATION

Mix 4 parts (4.0 ml) of Reagent I and 1 part (1.0 ml) of Reagent II.

REAGENT STORAGE AND STABILITY

Prior to use:
When stored between 2-8°C the reagent is stable until the expiration date stated on the bottle and kit box label.

Reconstituted Reagent:
When stored capped at 2-8°C, the reagent is stable for at least 7 days.

WARNING AND PRECAUTIONS

- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.
- Indication of reagent deterioration: Turbidity, Absorbance > 0.8 at 405nm (1cm); and/or Failure to recover control values within the assigned range.

WASTE MANAGEMENT

Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED

- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION

Serum, heparin plasma or EDTA plasma
Stability: 2 weeks at 2 – 8°C
6 months at –20°C
Discard contaminated specimens! Freeze only once!

ASSAY PROCEDURE

Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28°C, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	405 nm
Cuvette	1 cm light path
Temperature	37° C
Measurement	Against water
Sample Volume	15 µl
Reagent Volume	1000 µl
Reaction	Kinetic
Reaction Direction	Decreasing
Delay/Lag/Time	60 Secs
Interval Time	30 Secs
No. of Readings	03
Factor	73000
Blank Absorbance Limit	> 0.800
Low Normal at 37°C	4850 IU/L
High Normal at 37°C	12000 IU/L
Linearity	12000 IU/L

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

Sample	15 µl
Working Reagent	1000 µl

- Mix well and wait for 1 minute. Measure absorbance decrease after 30, 60 and 90 seconds. Determine the ΔAbs/minute.

SAMPLE DILUTIONS

- This method is linear upto a concentration of 12000 IU/L.
- Dilute samples above this concentration 1:5 with 0.9% saline
- Repeat assay. Multiply the result by 6.

CALCULATION

Results are calculated, usually automatically by the instrument, as follows:
Activity in IU/L = Δ Abs/min x 73000

CALIBRATORS AND CONTROLS

For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

This method is traceable to the molar extinction coefficient.

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

Each laboratory should establish corrective action in case of deviations in control recovery.

PERFORMANCE CHARACTERISTICS

WITHIN RUN

Sample	Mean Concentration	SD	CV %
Norm	4329	3.42	0.08%
Path	5723	4.23	0.07%

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Art No.: IFU/BC/CHOLEN
Effective Date: 20/09/2019
Revision No.: 01

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Norm	4329	3.57	0.08%
Path	5729	3.24	0.06%

LINEARITY

The method is linear upto a concentration of 12000 IU/L. Dilute samples above this concentration 1:5 with 0.9% saline solution and repeat assay. Multiply the result by 6.

Limit of detection: The limit of detection for Cholinesterase is 50 IU/L.

METHOD COMPARISON

A comparison of Accucare Cholinesterase with a commercially available assay (x) using 20 samples gave following results: $R^2 = 0.9900$

REFERENCE VALUES

Serum/Plasma 37°C	4850 –12000 IU/L

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

INTERFERENCE

- Bilirubin: No interference found upto Bilirubin 50mg/dl.
- Hemoglobin: No interference found upto 500 mg/dL.
- Lipemia: No interference found upto 800 mg/dL.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY

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

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer	IVD	For *in vitro* Diagnostic use only
	Keep away from sunlight	CONT	Content of the kit

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
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