BIOLABO
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CHOLINESTERASE Butyrylthiocholine

Reagent for quantitative determination of Cholinesterase activity (SChE) [EC 3.1.1.8] in human serum or plasma

REF 82526 **R1** 5 x 10 mL

TECHNICAL SUPPORT AND ORDERS
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CE

IVD IN VITRO DIAGNOSTIC USE

CLINICAL SIGNIFICANCE (1) (2)

Serum Cholinesterase (pseudocholinesterase, benzoil cholinesterase or cholinesterase II) is found in the liver, pancreas, heart, white matter of the brain and serum. SchE should not be confused with the acetylcholinesterase (true cholinesterase or cholinesterase I) which is found in erythrocytes, lungs and spleen, nerve endings and grey matter of the brain.
The serum enzyme (SChE) is the one whose assay is clinically useful, particularly in the evaluation of liver function (impaired synthesis), atypical enzymes variants, and in the detection of possible insecticide poisoning.
Identification of patients with atypical form of the enzyme is important to prevent prolonged apnea caused by administration of succinylcholine anesthesia used in surgery.
Decreased levels of serum enzyme are also found in patients with acute infections, pulmonary embolism, and muscular dystrophy, as well as after surgical procedures.

PRINCIPLE (4) (5) (6)

Cholinesterase (SChE) catalyses the hydrolysis of butyrylthiocholine to thiocholine and butyric acid. Reaction scheme is as follows:

Butyrylthiocholine + H_2O $\xrightleftharpoons{\text{SChE}}$ Thiocholine + Butyric acid

2 Thiocholine + 2 OH^- + 2 Hexacyanoferrate (III) $\longrightarrow$ Dithiobis (choline) + H_2O + 2 Hexacyanoferrate (II)

The decrease in absorbance due to the conversion of Hexacyanoferrate (III) into Hexacyanoferrate (II), and proportional to SChe activity in the specimen, is measured at 405 nm.

REAGENTS COMPOSITION

Vial R1 **WORKING REAGENT**

Phosphate buffer	75	mmol/L
Hexacyanoferrate (III)	2	mmol/L
Butyrylthiocholine	15	mmol/L
pH	7.6	

Before reconstitution:
Xi, R36/37/38: Irritating to eyes, respiratory system and skin.
S22-26: Do not breathe dust. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36/37/39: Wear suitable protective clothing, gloves and eyes/face protection.

Once reconstituted: None

REAGENTS PREPARATION

Add promptly to the contents of the vial the amount of demineralised water indicated on the label.

Mix gently and wait for complete dissolution before using reagent (approximately 2 minutes).

SAFETY CAUTIONS

BIOLABO reagents are designated for professional, in vitro diagnostic use.

- Verify the integrity of the contents before use.
- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In case of contact with skin or eyes, thoroughly wash affected areas with plenty of water and seek medical advice.
- Reagents contain sodium azide (concentration < 0.1%) which may react with copper and lead plumbing. Flush with plenty of water when disposing.
- Material Safety Data Sheet is available upon request.
- Waste disposal: Respect legislation in force in the country.

All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

STABILITY AND STORAGE

Store away from light, well cap in the original vial at 2-8°C.

- Unopened, reagent is stable until expiry date stated on the label of the kit when stored and used as described in the insert.
- Once reconstituted, working reagent is stable for 2 weeks when free from contamination.
- Discard reagent if cloudy or if absorbance at 405 nm < 1.300.
- Don't use working reagent after expiry date stated on the label of the Kit.

SPECIMEN COLLECTION AND HANDLING (2)

Unhemolized serum, heparinized or EDTA plasma.

SChE activity is stable in serum or plasma for:

- 7 days at 2-8°C.

INTERFERENCES (3)

Triglycerides:	No significant interference up to 1000 mg/dL
Bilirubin:	No significant interference up to 20 mg/dL
Hemolysis:	Positive interference due to Cholinesterase activity released by erythrocytes.

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Medical analysis laboratory equipment.
2. Normal and pathological control sera

CALIBRATION

Results will depend on the accuracy of the instrument calibration, the time counting, the respect of reagent/specimen ratio and the temperature control.

It is recommended to use the theoretical calibration factor or to use a multiparametric calibrator traceable to a reference method or material (§ **CALCULATION**).

QUALITY CONTROL

- REF 95516 HDL LDL CK-MB and lipids Control
- REF 95526 HDL LDL CK-MB and lipids Control
- External quality control program.

It is recommended to control in the following cases:

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:

1. Repeat the test with the same control.
2. If control is still out of range, prepare a fresh control serum and repeat the test.
3. If control is still out of range, verify analysis parameters: Wavelength, temperature, specimen/reagent ratio, time counting, calibration factor.
4. If control is still out of range, use a new vial of reagent and reassay
5. If control is still out of range, please contact BIOLABO technical support or your local Agent.

EXPECTED VALUES (2)

at 37°C	IU/L	µKat/L
Men	5900-12200	98-203
Women	4700-10400	78-173

Each laboratory should establish its own normal ranges for the population it serves.

PERFORMANCE CHARACTERISTICS

Within-run N = 20	*Low level*	*High level*
Mean IU/L	5416	11279
S.D. IU/L	54.2	79
C.V. %	1.0	0.7

Beetwen run N = 25	*Low level*	*High level*
Mean IU/L	5416	11279
S.D.IU/L	54.2	68
C.V. %	1.0	0.6

Detection limit: approximately 123 IU/L (2µKat/L)

Sensitivity for 1 IU/L: approximately 0.015 mAbs/min
(+/- 15 % during the lifetime of the working reagent)

Comparison studies with commercially available reagent:

y (IU/L) = 1.007 x - 56

LINEARITY

The assay is linear up to 25000 IU/L (417 µKat/L).

Above, reduce dilute specimen (1 + 1) with demineralised water and reassay taking into account the dilution factor to calculate the result. Linearity will depend on the specimen/reagent ratio.

MANUAL PROCEDURE

Let stand reagents and specimens at room temperature.

Pipette into 1 cm path length thermostated cuvette:	
Reagent	1.5 mL
Bring to 37°C, then add:	
Specimen	25 µL

Mix. Start a timer. Record initial absorbance after 90 seconds at 405 nm.
Record the absorbance again every 30 seconds during 90 seconds.

Calculate absorbance change per minute (ΔAbs/min).

Note: Specific procedures are available upon request for automated instruments. Please contact BIOLABO technical support.

CALCULATION

Calculate the result as follows:

With theoretical factor:

IU/L = (ΔAbs/min) x 65804

µKat/L = (ΔAbs/min) x 1097

With serum multicalibrator:

$$\text{SChe Activity} = \frac{(\Delta\text{Abs/min) Assay}}{(\Delta\text{Abs/min) Calibrator}} \times \text{Calibrator Activity}$$

REFERENCES

(1) *TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 708-711*

(2) *Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 250-251.*

(3) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p. 3-68 to 3-79*

(4) *DGKC. Proposal of standard methods for the determination of enzyme catalytic concentrations in serum and plasmas at 37°C. II Cholinesterase. Eur J Clin Chem Chim Biochem 1992; 30 / p.163-170.*

(5) *Pantheghini . and Bonora R. Evaluation of a new continuous colorimetric method for determination of serum pseudo-cholinesterase activity and its application to a centrifugal fast analyzer. J Clin Chem Clin Biochem 1984; 22: p.671-676.*

(6) *Whittaker M., Britten J.J., and Dawson P. J. Comparison of a commercially available system with two reference methods for the etermination of plasma cholinesterase variant. Clin Chem 1983; 29: p.1746-1751*

Manufacturer | Use by | IVD In vitro diagnostic | Temperature limitation | REF Catalogue number | See insert | LOT Batch number | Store away from light | Σ sufficient for | → dilute with