diatron

CHOLINESTERASE

For use on Diatron Pictus® series analyzers
Method: GSCC
Product code: 1419-0262, 1419-0260
Package: 6 x 30 ml (R1) + 6 x 6 ml (R2), 6 x 6 ml (R1) + 6 x 1.2 ml (R2)
Store at: 2°– 8°C
For *in vitro* use only

INTENDED USE
Ready to use reagents for the quantitative determination of cholinesterase in human serum or plasma specifically for use with Diatron Pictus® series analyzers. For in vitro diagnostic use only.

CLINICAL SIGNIFICANCE
Decreased levels of cholinesterase are observed in cases of organophosphate insecticide poisoning, acute or chronic hepatitis, cirrhosis, hepatic metastasis, hepatic congestion of heart failure, myocardial infarction, muscular dystrophy, pulmonary embolism.
In cholinesterase deficiency patients show increased sensitivity to certain muscle relaxant drugs used during general anesthesia, called choline esters (succinylcholine, mivacurium etc), often employed for brief surgical procedures or in emergencies when a breathing tube must be inserted quickly. Normally, these drugs are catabolized by the body within a few minutes, however, patients with cholinesterase deficiency may not be able to move or breathe on their own for a few hours after the drugs are administered and must be mechanically supported until the drugs are cleared from the body.
Patients with cholinesterase deficiency may also have increased sensitivity to certain other drugs, including the local anesthetic procaine, and to specific agricultural pesticides.

METHOD PRINCIPLE
The GSCC method is applied. The kinetic determination of cholinesterase according to the GSCC recommendations is based on the following reactions:

$$\text{Butyrylthiocholine} + H_2O \xrightarrow{\text{Cholinesterase}} \text{Butiric acid} + \text{Thiocholine}$$

$$2\ \text{Thiocholine} + 2OH^- + 2[Fe(CN)_6]^{3-} \longrightarrow \text{Dithiobis(choline)} + H_2O + 2[Fe(CN)_6]^{4-}$$

The rate of absorbance reduction at 405/490 nm is proportional to cholinesterase activity in the sample.

METHOD LIMITATIONS
Refer to the book "Effects of Preanalytical Variables on Clinical Laboratory Tests" for possible interference of other pharmaceutical agents in this particular test. Interference of other agents is described in the "Clinical Guide to Laboratory Tests".
The reagent is designed especially for use with the Diatron Pictus® series of chemistry analyzers. For chemistry protocols and further information please contact the customer support unit at Diatron.

REAGENT COMPOSITION
Reagent 1:
Phosphate buffer (pH 7.7): 92 mM
$K_4[Fe(CN)_6]$: 2 mM
Non reactive ingredients, preservative
Reagent 2:
S-Butyrylthiocholine iodide: 92 mM
Non reactive ingredients, preservative

WARNINGS - PRECAUTIONS
- This reagent is designed for in vitro diagnostic use. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory techniques. Avoid inhalation and contact with eyes and skin.
- Samples should be considered as potentially infectious. Handle with special caution.
- Avoid swallowing and contact of the reagent with skin and mucous membranes.
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON HELLAS (manufacturer) upon request.

REAGENT PREPARATION
The reagents R1 and R2 are ready to use when placed in the corresponding places on the analyzer. The vials bear barcodes for automatic recognition by Pictus® series analyzers.

REAGENT DETERIORATION
The reagents should not be used:
- When they do not exhibit the specified linearity or control values lie outside the acceptable range after recalibration.
- When they appear turbid or decolorized.
- After prolonged exposure to sunlight or high temperature.

SHELF LIFE
Unopened, the reagents are stable at 2 – 8°C up to the expiry date stated on the label. Once opened, they remain stable for 28 days when stored in the cooled reagent tray of the Pictus® series analyzers.

SAMPLE
Non hemolyzed serum or plasma with heparine or EDTA. Moderate hemolysis does not affect the results provided the red cell residues have been removed with centrifugation. The cholinesterase activity in serum is stable for 6 hours at room temperature, 1 week at 4°C and 6 months at –70°C.

CALIBRATION
Calibration is not required. The Pictus® analyzer program will calculate the activity of cholinesterase using the calibration factor programmed in the "Methods" chapter for this test. The analyzer will automatically perform a reagent blank every 14 days. Calibration factor verification should be repeated after major maintenance is performed on the analyzer, after a critical part is replaced, or when a significant shift in control values occurs.

QUALITY CONTROL
Diatron provides Clinical Chemistry Control Level 1 & 2 (1578-0901-12 & 1578-0902-12 respectively) for serum quality control.
Control recovery should lie within the acceptable range. Results outside the acceptable range even after recalibration could be due to reagent deterioration, unsuitable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

MATERIALS REQUIRED BUT NOT SUPPLIED WITH THE KIT
- Quality control materials
- Diatron Pictus® P400/P700/P500
- Common laboratory equipment

REFERENCE INTERVALS
Serum: Women: 3.93 – 10.80 kU/L
Men: 4.62 – 11.50 kU/L
Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practices.

SPECIFIC PERFORMANCE CHARACTERISTICS
The following values are representative of the reagent performance on Diatron Pictus® series analyzers. The reagent performance has been evaluated on other types of analyzers, covering all requirements of the 98/79 IVD Directive. A list of analyzers with the corresponding performance characteristics is available in the special leaflet accompanying the insert. The results taken in your laboratory may differ from these values.

	Pictus® P400	Pictus® P700/P500
Linearity	up to 13 kU/L	up to 14 kU/L
Lowest detection limit	0.31 kU/L	0.23 kU/L

The lowest detection limit (LDL) is defined as the lowest concentration of analyte that is distinguishable from zero. A sample free of analyte is assayed 20 times within the assay and the LDL is calculated as the absolute mean plus three standard deviations.
Precision: Precision is estimated on two concentration levels of analyte according to CLSI protocol EP-5T (20 consecutive days, 2 runs per day, 2 repeats per run).

Pictus® P400			Pictus® P700/P500		
Level (kU/L)	Within Run CV%	Total CV%	Level (kU/L)	Within Run CV%	Total CV%
3.74	2.20	2.63	2.37	2.75	3.14
6.10	1.78	2.47	6.49	2.34	2.68

Interferences: Criterion: recovery within ±20% from target value

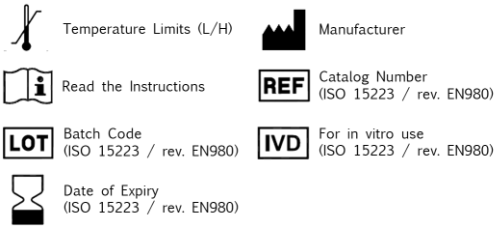
	Pictus® P400	Pictus® P700/P500
Lipemia	Insignificant up to 1000 mg/dL Intralipid®	Insignificant up to 1000 mg/dL Intralipid®
Hemoglobin	Insignificant up to 500 mg/dL	Insignificant up to 500 mg/dL
Non conj. Bilirubin	Insignificant up to 20 mg/dL	Insignificant up to 20 mg/dL
Conj. Bilirubin	Insignificant up to 20 mg/dL	Insignificant up to 20 mg/dL
Ascorbate	Insignificant up to 3 mg/dL	Insignificant up to 3 mg/dL

Correlation: A comparison was performed between this reagent on a Pictus® series analyzer, and a BECKMAN COULTER AU-series system. The results were as follows:

Pictus® P400
Y = 1.000X – 0.197 R=0.9868 N=60 Sample range =3.2 – 11.1 kU/L
Pictus® P700/P500
Y = 1.013X + 0.033 R=0.9957 N=40 Sample range = 2.4 – 12.3 kU/L

BIBLIOGRAPHY

1. Tietz, NW, ed. Clinical Guide to Laboratory Tests. 3rd. ed. Philadelphia: W.B. Saunders Company Ltd., 1995.
2. Burtis, CA and Ashwood, ER, ed. Tietz Textbook of Clinical Chemistry. 2nd. ed. Philadelphia: W.B. Saunders Company Ltd., 1994.
3. Jacobs, DJ, Demott, WR, Grady, HJ, Horvat, RJ, Huestis, DW and Kasten, BL, JR, eds. Laboratory Test Handbook. 4th. ed. Ohio, Hudson: Lexi-Comp Inc., 1996.
4. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd. ed. Washington, DC: The American Association for Clinical Chemistry Press, 1997.

SYMBOLS ON THE LABEL


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