diatron

CHOLINESTERASE

2°C 8°C

Specifically for use with Diatron PICTUS® 700 and PICTUS® 500 Analyzers

REF 1419-0260 **Packaging:** 6 x 6 mL (R1) + 6 x 1.2 mL (R2)

Σ 180

INTENDED USE

Reagents for In Vitro quantitative automated determination of Cholinesterase - CHE (EC 3.1.1.7) in samples of human serum or plasma from the general patient population. Measurements of CHE are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid for diagnosis of liver and heart related disorders and, preoperatively, for identification of patients with increased sensitivity to certain anesthetic drugs.

This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers.
For in vitro diagnostic use only by trained laboratory professionals.

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". This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers. For additional information please contact customer support at Diatron or Medicon.

REAGENT COMPOSITION

Reagent 1 (R1)	Reagent 2 (R2)
Phosphate buffer (pH 7.7): 92 mM K4[Fe(CN)6]: 2 mM Non-reactive ingredients, preservative	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.
- Any serious incident that may occur in relation to this device must be reported by the user to the manufacturer and the competent authority of the country in which the user and/or the patient is established!
- 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 upon request.

⚠ **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 Diatron Pictus® P700 / P500 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 1 month when stored in the cooled reagent tray of the Diatron Pictus® P700 or P500 analyzers.

⚠ **SAMPLE** Serum, EDTA or Li-heparin plasma may be used as specimen. Use established Good Laboratory Practices for sampling, transport and separation from blood cells. Do not use hemolyzed, contaminated or turbid sample specimens. Anti-coagulants other than EDTA or Li-heparin have not been tested and should not be used. Centrifuge sample as soon as possible, and store properly if analysis cannot take place right after sample separation. Cholinesterase is stable in serum and plasma for 1 week at 2 – 8°C. Do not freeze samples, as loss of activity is observed.

CALIBRATION Diatron offers MEDICON MEDI-CAL (1578-0891) traceable to SRM 909b NIST for serum calibration. Perform a blank measurement every 2 weeks. Recalibration should be repeated after major maintenance is performed on the analyzer or after a critical part is replaced or when a significant shift in control values occurs.

QUALITY CONTROL Diatron offers MEDICON 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 PROVIDED WITH THE KIT

- Quality control materials
- Diatron Pictus® analyzer
- 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® P700 or P500 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.

Linearity up to 14 kU/L
Lowest detection limit 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® P700 and P500	
Level (kU/L)	**%CV**
2.37	1.75
6.49	1.04
Level (kU/L)	**TOTAL %CV**
2.37	2.14
6.49	1.68

INTERFERENCES - Criterion: recovery within ±10% from target value

	(Insignificant up to)
Triglycerides	3000 mg/dL
Hemoglobin	500 mg/dL
Bilirubin	20 mg/dL
Conj. Bilirubin	20 mg/dL
Ascorbate	3 mg/dL

Correlation: A comparison was performed between this reagent on a Diatron Pictus® P700 and P500 analyzer and another commercially available product. The results were as follows:
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

Manufacturer	IVD *In vitro* diagnostic medical device
Temperature Limit	REF Catalogue Number
Caution	Σ Contains sufficient for <n> tests

MEDICON HELLAS S.A. - Melitona 5-7, 153 44 Gerakas, Greece. Tel: +302106606000 - Fax: +302106612666 – www.mediconsa.com

Version 4 - Last updated 2020.06.30

CE IVD