CHOLINESTERASE
For discrete analyzers
Method: GSCC
Product Code: 1418-0260 4 x 7.5 mL (R1) + 4 x 1.5 mL (R2) 1418-0267 4 x 30 mL (R1) + 4 x 6 mL (R2)
Store at 2 – 8°C
For in vitro use

QUALITY CONTROL
MEDICON provides the following products for quality control: MEDICON Clinical Chemistry Control levels 1 and 2 (1578-0901-12, 1578-0902-12) or BECKMAN COULTER CONTROL SERUM OD0003 and OD0004 (MEDICON code: 4476-0941 and 4476-0942). Control values and limits should fall within acceptable intervals adjusted to the requirements of each laboratory. Target values for Cholinesterase should be verified with the corresponding working protocol. Results outside the specified values 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 material
Automated biochemistry analyzer
Common laboratory equipment

REFERENCE INTERVALS
Serum:
Women: 3.03 – 10.8 kU/L
Men: 4.62 – 11.5 kU/L

SPECIFIC PERFORMANCE CHARACTERISTICS
Linearity
The assay is linear within measuring range 0.13 – 15 kU/L. When values exceed this range samples should be diluted accordingly.

Sensitivity
The lowest detectable level of Cholinesterase is estimated at 0.00 kU/L.

ERROR SOURCES
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".

REAGENT COMPOSITION
Reagent 1:
Phosphatid buffer (pH 7.7): 92 mM
K[Fe(CN)6]: 2 mM
Non reactant components
Reagent 2:
S-Butyrylthiocholine iodide: 92 mM
Non reactant components and preservatives

WARNINGS – PRECAUTIONS
• The reagent is designed for in vitro diagnostic use only. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory practices and techniques. Avoid inhalation and contact with eyes and skin.
• 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".

PREPARATION
Reagents R1 and R2 are liquid and ready to use. Vials bear barcode for recognition by BECKMAN COULTER AU Analyzers.

REAGENT DETERIORATION
The reagent should not be used:
• When it does not exhibit the specified linearity or recovery of control values lies outside the acceptable range after recalibration.
• When it appears cloudy or decolorized.
• After prolonged exposure to high temperature.

SHELF LIFE
Unopened, reagents are stable up to the stated expiry date when stored at 2 – 8°C. Once opened, reagents remain stable for 1 month when stored refrigerated on the instrument.

SAMPLE
Non hemolyzed serum or plasma with heparin 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 several weeks at 20 – 25°C or at 2 – 8°C.

CALIBRATION
Determination takes place in MB Calibration Mode. The calibration factor depends on the optical path. For an optical path of 1 cm, calibration factor is 64.0 (kU/L).