INTENDED USE
MEDICON Cholinesterase is a set of reagents for the quantitative determination of Cholinesterase in human serum, with BECKMAN COULTER AU400/600/650-VD/840/2700/5400 and other discrete analyzers. For in vitro diagnostic use only.

CLINICAL SIGNIFICANCE
Decreased levels of cholinesterase are observed in cases of organophosphorus insecticide poisoning, acute or chronic hepatitis, cirrhosis, hepatic metastasis, hepatic congestion of heart failure, myocardial infarction, muscular dystrophy, pulmonary embolism. Reduced enzyme activity detected in pre-operative control may indicate difficulty in recovery from anesthesia.

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

\[
\text{Butyrylthiocholine} + H_2O \rightarrow \text{Butyric acid} + \text{Thiocholine}
\]

\[
2 \text{Thiocholine} + 20H + 2\text{Fe(CN)}_5^2- \rightarrow \text{Dithiobis(thiocholine)} + H_2O + 2\text{[Fe(CN)]}_5^2-
\]

The reduction of the absorption at 410 nm is proportional to cholinesterase concentration in the sample.

METHOD LIMITATIONS
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 or skin.

Refer to the "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:
Phosphates buffer (pH 7.7): 92 mM
K[Fe(CN)]5: 2 mM
Non reactive components
Reagent 2:
S-Butyrylthiocholine iodide: 92 mM
Non reactive 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 or skin.
- Samples should be considered as potentially infectious. Handle according to the universal precautions and good laboratory practices.
- Dispose all waste according to national laws.
- MSDS is available by MEDICON upon request.

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

REAGENT DEGRADATION
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
Analysis takes place in MB calibration mode. The calibrations factor is derived by the mean of at least 3 separate calibration series on different days, in single point calibration mode (AB). For every series of human samples, a new vial of calibrator should be used. The MEDICON MEDICAL calibrator (1578-0891) or BECKMAN COULTER SYSTEM CALIBRATOR Cat. No. 66300 (MEDICON code: 4478-0891) can be used for calibration. Calibrate the assay following preventive maintenance or replacement of a critical part of the analyzer, when using a new reagent kit or a new lot number, or when Quality Control results are out of range.

QUALITY CONTROL
MEDICON provides the following products for quality control: MEDICON Clinical Chemistry Control levels 1 and 2 (1578-0891-12, 1578-0892-12) or BECKMAN COULTER CONTROL SERUM OECD0003 and OECD004 (MEDICON code: 4479-0941 and 4479-0942). 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
Cholinesterase calibrator
Quality control material
Automated biochemistry analyzer
Common laboratory equipment

REFERENCE INTERVALS
Serum: Women: 3.93 – 10.8 kU/L
Men: 4.62 – 11.5 kU/L
Each laboratory should determine its own expected values as dictated by good laboratory practice.

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.

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

<table>
<thead>
<tr>
<th>Level</th>
<th>Within run</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>kU/L</td>
<td>%CV</td>
<td>%CV</td>
</tr>
<tr>
<td>3.8</td>
<td>0.63</td>
<td>1.62</td>
</tr>
<tr>
<td>6.3</td>
<td>0.65</td>
<td>1.48</td>
</tr>
</tbody>
</table>

Precision is estimated on two concentration levels of analyte according to NCLLS protocol EP-57 (20 consecutive days, 2 runs per day, 2 repeats per run).

Interference
Lipemic:
insignificant up to 1000 mg/dL, intralipid®
Hemoglobin:
insignificant up to 75 mg/dL
Non Chol. Bilirubin:
insignificant up to 12 mg/dL
Conj. Bilirubin:
insignificant up to 20 mg/dL
Ascorbic acid:
insignificant up to 3 mg/dL

Refer to Young® for further information on interfering substances.

Method Comparison:
A comparison was performed between this reagent and another commercially available product. The results were as follows on a BECKMAN COULTER AU series analyzer:

\[ Y = 0.9965 + 0.058 \]
\[ R = 0.9997 \]
\[ N = 100 \]
Sample range: 1.7 – 10.69 kU/L

BIBLIOGRAPHY

SYMBOLS