CHOLESTEROL

INTENDED USE
Diagnostic reagent for quantitative in vitro determination of Cholesterol in human serum and plasma.

CLINICAL SIGNIFICANCE
Measurement of serum cholesterol levels can serve as an indicator of liver function, biliary function, intestinal absorption, propensity towards coronary artery disease, thyroid function and adrenal disease. Cholesterol levels are important in the diagnosis and classification of hyperlipoproteinaemias. Stress, age, gender, hormonal balance and pregnancy affect normal cholesterol levels.

PRINCIPLE
This reagent is based on the formulation of Ailain et al and the modification of Roeschau with further improvements to render the reagent stable in solution. 1. Cholesterol ester + H₂O → CHE Cholesterol + Fatty acids
2. Cholesterol + O₂ → CHO Cholest-4-en-3-one + H₂O₂
3. 2H₂O₂ + 4AAP + Phenol → POD Quinoneimine dye + 4H₂O

REAGENT COMPOSITION
R1: Good’s Buffer 50 mmol/l Phenol 5 mmol/l 4-aminoantipyrine 0.3 mmol/l Cholesterol esterase ≥ 200 U/l Cholesterol oxidase ≥ 50 U/l Peroxidase ≥ 3 KU/l
R2 standard: See bottle label

REAGENT PREPARATION
Reagent is liquid, ready to use.

STABILITY AND STORAGE
The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2–8°C.

SPECIMEN COLLECTION AND HANDLING
Use serum, plasma (heparin, EDTA). It is recommended to follow NCCLS procedures (or similar standardized conditions).

Stability
in serum / plasma: at 20–25°C 7 days
at 4–8°C 7 days
at -20°C 3 months

CALIBRATION
Calibration is with the standard included in the kit or calibrator XL MULTICAL, Cat. No. XSYS0034 is recommended.

QUALITY CONTROL
For quality control ERBA NORM, Cat. No. BLT00080 and ERBA PATH, Cat. No. BLT0081 are recommended.

EXPECTED VALUES
Adult
Desirable blood Cholesterol < 200 mg/dl
Borderline high blood Cholesterol 200 – 239 mg/dl
High blood Cholesterol > 239 mg/dl
Child
Desirable blood Cholesterol < 170 mg/dl
Borderline high blood Cholesterol 170 – 199 mg/dl
High blood Cholesterol > 199 mg/dl

It is recommended that each laboratory verify this range or derive reference interval for the population it serves.

PERFORMANCE DATA
Data contained within this section is representative of performance on ERBA XL systems. Data obtained in your laboratory may differ from these values.

Limit of quantification:
4.2 mg/dl
Linearity: 695 mg/dl
Measuring range: 4.2 – 695 mg/dl

PRECISION
Within run (n=20) Mean (mg/dl) SD (mg/dl) CV (%)
Sample 1 126.81 1.58 1.26
Sample 2 226.85 2.15 0.96

COMPARISON
A comparison between XL-Systems Cholesterol (y) and a commercially available test (x) using 40 samples gave following results:
y = 0.995x + 4.59 mg/dl
r² = 0.980

INTERFERENCES
Following substances do not interfere: haemoglobin up to 5 g/l, bilirubin up to 20 mg/dl, triglycerides up to 2000 mg/dl.

WARNING AND PRECAUTIONS
For in vitro diagnostic use. To be handled by entitled and professionally educated person.
Reagent of the kit is not classified like dangerous but contains less than 0.1% sodium azide - classified as highly toxic and dangerous for the environment.

WASTE MANAGEMENT
Please refer to local legal requirements.

ASSAY PROCEDURE

ASSAY PARAMETERS FOR PHOTOMETERS
REFERENCES

SYMBOLS USED ON LABELS
- **REF** Catalogue Number
- **LOT** Lot Number
- **CE Mark - Device comply with the Directive 98/79/EC**
- **See Instruction for Use**
- **Cont** Content
- **In Vitro Diagnostics**
- **Erba Lachema s.r.o., Karásek 1d, 621 00 Brno, CZ**
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