callegari

EN • TOTAL CHOLESTEROL

***In vitro* diagnostic medical device – CE mark - In compliance with EC Directive 98/79**

Cod. AD19104P CLINI CHOL 40 TEST: n.1 box containing CLINI CHOL cuvettes 40 TEST (cod. AD15104P) + n.1 vial of CHOL Enzyme 40 TEST (cod. AD20100P).
Cod. AD15104P CLINI CHOL cuvette 40 TEST: n.4 foil pouches containing 10 cuvettes each; n.1 ORANGE capped vial containing 10µl capillaries; package insert. Enzymes are provided separately.

Intended Use

Reagent pack for the quantitative determination of the Total Cholesterol (CHOL) on whole blood, with Clini5 instruments series. Clini5 instruments series is an in vitro diagnostic system intended for health care professionals.

Reagent Composition

Cuvette - Buffer reagent	**Enzyme**
100mM Phosphate buffer	6,6 mM 4-AP
26 mM PhOH	>0.11 KU/L CHE
Non-ionic surfactant	>0.12 KU/L CHO
Stabilizers	>10 KU/L POD

Reagent Preparation and Storage

All reagents are ready to use.
The buffer reagents are stable if stored at room temperature (15-30°C/59-86°F) and kept in the closed aluminium foil pouch up to the date marked on the packaging. Enzymes stored at 2-8°C/35.6-46.4°F may be used until the expiry date found on the pack.

Performance Characteristics

Linearity

50-400 mg/dl (1.30-10.36 mmol/l).
When the reading obtained is outside the linearity range, <X or >Y is displayed, (X marks the lower end and Y the upper end).

Repeatability

The analytical repeatability as within-run precision was established by assaying whole blood samples and it is expressed as a percentage of the Coefficient of Variability (% CV).

Level	N° test (n)	Mean mg/dl (mmol/l)	Std Dev	CV %
High	20	230 (5.96)	2.927 (0.076)	1.27 (1.27)
Normal	20	144 (3.74)	4.523 (0.117)	3.13 (3.13)

Precision

The between series analytical precision was established by assaying blood samples and it is expressed as percent of the Coefficient of Variability (% CV).

Level	N° test (n)	Mean mg/dl (mmol/l)	Std Dev	CV %
High	20	215 (5.58)	4.172 (0.110)	1.94 (1.96)
Normal	20	160 (4.14)	6.251 (0.162)	3.91 (3.91)

Method comparison (accuracy)

A comparison study using venous blood specimens analyzed by the Clini5 method and a certified laboratory method gave the following results:

Sample number (n)	142
Measurement range	102-308 mg/dl
Passing-Bablok regression	y=0.9588x+8.7680
Correlation coefficient	0.954
Mean bias % (95% CI)	+0.02 (-0.96 a +1.00)