callegari

EN • **TOTAL CHOLESTEROL • GLUCOSE**

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

Cod. AD19158P CLINI C+G 40 TEST: n.1 box containing CLINI C+G cuvette 40 TEST (cod. AD15158P) + n.1 vial of Enzyme 1 C+G 40 TEST (cod. AD20108P) + n.1 vial of Enzyme 2 C+G 40 TEST (cod. AD20109P).
Cod. AD15158P CLINI C+G 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 and Glucose (C+G) 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
100mM Phosphate buffer
26mM PhOH
Non-ionic surfactant
Stabilizers

Enzyme 1	**Enzyme 2**
6,6mM 4-AP	7 mM 4-AP
>0,11 KU/L CHE	>6 KU/L Mutarotase
>0,12 KU/L CHO	>5 KU/L GOD
>10 KU/L POD	>5 KU/L POD

Reagent Preparation and Storage

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

	mg/dl	mmol/l
Total cholesterol	50-400	1.30-10.36
Glucose	50-400	2.78-22.20

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).

	n	Mean mg/dl (mmol/l)	Std dev mg/dl (mmol/l)	%CV
CHOL	20	158 (4.09)	3.500 (0.091)	2.22
GLU		94 (5.19)	3.923 (0.218)	4.19
CHOL	20	263 (6.48)	2.434 (1.526)	0.92
GLU		200 (11.11)	2.634 (0.146)	1.32

Precision

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

	n	Mean mg/dl (mmol/l)	Dev std mg/dl (mmol/l)	CV%
CHOL	20	133 (3.46)	3.458 (0.090)	2.59
GLU		70 (3.89)	1.799 (0.100)	2.57
CHOL	20	227 (5.89)	8.103 (0.210)	3.56
GLU		222 (12.34)	10.938 (0.607)	4.92

Method comparison (accuracy)

A comparison study using venous blood specimens analyzed by the Clini5 bi-analyte C+G method and the Clini5 mono-analyte methods for Cholesterol and Glucose gave the following results:

Total cholesterol	
Sample number (n)	53
Measurement range	127-386 mg/dl
Passing-Bablok regression	y=1.0208x-5.7083
Correlation coefficient	0.983
Mean bias % (95% CI)	-1.40 (-2.28 a -0.51)

Glucose	
Sample number (n)	56
Measurement range	50-327 mg/dl
Passing-Bablok regression	y=1.0419x-3.1560
Correlation coefficient	0.989
Mean bias % (95% CI)	+1.53 (+0.22 a +2.83)