callegari

EN • **HDL CHOLESTEROL**

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

Cod. AD19118P CLINI HDL 10 TEST: n.1 foil pouch containing 10 HDL R1 cuvettes; n. foil pouch containing 10 HDL R2 tubes; n.1 RED capped vial containing 30µl capillaries; package insert.

Intended Use

Reagent pack for the quantitative determination of the HDL cholesterol on whole blood, with Clini5 instruments series. Clini5 instruments series is an in vitro diagnostic system intended for health care professionals.

Reagent composition

Cuvette – R1 reagent	**Tube – R2 reagent**
0.5 mM α-cyclodextrin	0.5g/L 4-AP
0.5g/L dextran sulfate	>0,8 KU/L PEG-CHE
2.0mM magnesium chloride	>5 KU/L PEG-CHO
0.3 g/L HSDA	>15 KU/L POD
Buffer	Surfactant
Preservative	Buffer
	Preservative

Reagent Preparation and Storage

Reagents are ready to use.

Store reagents refrigerated at +2 to +8°C/35.6-46.4°F.

Protect the reagents from direct sunlight. Reagents are stable if stored properly and kept in the CLOSED aluminium foil pouch until the expiry date stated on the labels. Alterations in the physical appearance of the reagents may be an indication of reagent instability.

Performance Characteristics

Linearity

40-90 mg/dl (1.04-2.33 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).

Sample	Test (n)	Mean mg/dl (mmol/l)	Std Dev	% CV
1	20	57 (1.47)	2.394 (0.062)	4.23 (4.23)
2	20	78 (2.03)	3.258 (0.084)	4.15 (4.15)

Precision

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

Sample	Test (n)	Mean mg/dl (mmol/l)	Std Dev	% CV
1	20	57 (1.47)	2.719 (0.070)	4.78 (4.78)
2	20	75 (1.93)	3.454 (0.087)	4.63 (4.63)

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)	93
Measurement range	37-79 mg/d
Passing-Bablok regression	y=0.9643x+2.1429
Correlation coefficient	0.747
Mean bias % (95% CI)	-0.93 (-3.86 a +1.99)