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EN • **TRIGLYCERIDES**

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

Cod. AD19143P CLINI TRIG 10 TEST: n.1 box containing CLINI TRIG cuvette 10 TEST (AD15115P) + n.1 box of CLINI TRIG Enzyme 10 TEST (cod. AD20104P).
Cod. AD15115P CLINI TRIG cuvette 10 TEST: n.1 foil pouch containing 10 cuvettes each; n.1 ORANGE capped vial containing 10µl capillaries; a package insert.
Cod. AD20104P CLINI TRIG Enzyme 10 TEST: n.10 foil pouches containing 1 singledose enzyme each.

Intended Use

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

Composition

Cuvette – Buffer reagent	**Enzyme**
44mM PIPES buffer	9 mM 4-AP
0.5mM PhOH	>0.5 KU/L Lipase
Non-ionic surfactant	>15 KU/L GPO
Stabilizers	>0.5 KU/L GK
	>0.5 KU/L POD
	>0.5mM ATP
	15g/L Bovine albumin V

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

90-600 mg/dl (1.02-6.78 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	Test (n)	Mean mg/dl (mmol/l)	Std Dev	% CV
High	20	418 (4.72)	10.849 (0.123)	2.60 (2.60)
Normal	20	129 (1.46)	4.065 (0.046)	3.15 (3.15)

Precision

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

Level	Test (n)	Mean mg/dl (mmol/l)	Std Dev	% CV
High	20	414 (4.68)	11.913 (0.135)	2.88 (2.88)
Normal	20	128 (1.44)	4.378 (0.049)	3.43 (3.43)

Method comparison (accuracy)

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

Sample number (n)	88
Measurement range	88-391 mg/dl
Passing-Bablok regression	y=1.0571x-12.0429
Correlation coefficient	0.991
Mean bias % (95% CI)	-0.73 (-3.85 a +2.39)