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

Cod. AD19160P CLINI TRIG 20 TEST: n.1 box containing CLINI TRIG cuvette 20 TEST (cod. AD15142P) + n.1 box of CLINI TRIG Enzyme 20 TEST (cod. AD20107P).
Cod. AD15142P CLINI TRIG cuvette 20 TEST: n.2 foil pouches containing 10 cuvettes; n.1 ORANGE capped vial containing 10µl capillaries; a package insert.
Cod. AD20107P CLINI TRIG Enzyme 20 TEST: n.20 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)

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<u>Precision</u>

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)

<u>Method comparison (accuracy)</u>

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)