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EN • **GLUCOSE**

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

Cod. AD19126P CLINI GLU 10 TEST: n.1 box containing CLINI GLU cuvette 10 TEST (cod. AD15126P) + n.1 vial of GLU Enzyme 10 TEST (cod. AD20103P).
Cod. AD15126P CLINI GLU cuvette 10 TEST: n.1 foil pouch containing 10 cuvettes; n.1 ORANGE capped vial containing 10µl capillaries; package insert. Enzymes are provided separately.

Intended Use
Reagent pack for the quantitative determination of the Glucose (GLU) 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**
100mM Phosphate buffer	7 mM 4-AP
26 mM PhOH	>6 KU/L Mutarotase
Non-ionic surfactant	>5 KU/L GOD
Stabilizers	>5 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
50-500 mg/dl (2.78-27.75 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	135 (7.47)	5.004 (0.278)	3.72 (3.72)
Normal	20	85 (4.72)	2.637 (0.146)	3.10 (3.10)

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	144 (8.01)	2.850 (0.158)	1.98 (1.98)
Normal	20	88 (4.89)	4.293 (0.238)	4.87 (4.87)

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)	102
Measurement range	68-141 mg/dl
Passing-Bablok regression	y=1.0000x+0.0000
Correlation coefficient	0.898
Mean bias % (95% CI)	-0.31 (-1.25 a +0.63)