callegari

EN • ALT Alanine aminotransferase/Glutamic-pyruvic transaminase

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

Cod. AD19123P CLINI ALT 10 TEST: n.1 sachet containing 10 empty semicuvettes and 10 caps; n.1 foil pouch containing 10 R1 tubes; n.1 foil pouch containing 10 R1 tubes; n.1 R2 reagent vial; n.1 sachet containing 1 dropper; 1 GREEN capped vial containing 50µl capillaries; package insert.

Intended Use

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

Composition

WHITE conical tube R1 Reagent	Vial R2 Reagent
80mmol/l Goods buffer	≥1,18 mmol/l NADH
500.0mmol/l L-alanine	80mmol/l Goods buffer
≥1500 U/l LDH	50mmol/l α-ketoglutarate

Reagent Preparation and Storage

Reagents are ready to use. Store reagents refrigerated at +2 to +8°C/35.6-46.4°F. Reagents should be allowed to stand at room temperature (+20 to + 25°C/68-77°F) before use. It is suggested to store empty cuvettes and caps at room temperature. Reagents are stable if stored properly and kept in the CLOSED aluminium foil pouch until the expiry date stated on the labels.

Performance Characteristics

Linearity

11-400 U/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 U/l	Std Dev	%CV
1	20	34	1.223	3.57
2	20	89	2.184	2.47

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 U/l	Std Dev	%CV
1	20	33	1.073	3.25
2	20	95	4.314	4.53

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)	39
Measurement range	11-89 U/l
Passing-Bablok regression	y=1.0774x-0.7807
Correlation coefficient	0.980
Mean bias % (95% CI)	+2.71 (-0.14 a +5.57)