callegari

EN • CLINI FORD

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

Cod. AD-19136P CLINI FORD 30 TEST: n.3 foil pouches containing 10 C1 cuvettes each; n.1 foil pouch containing 30 S1 tubes; n.1 foil pouch containing 30 S2 tubes; n.1 GREEN capped vial containing 50µl capillaries; n.1 sachet containing disposable pipette tips; package insert.

Intended Use

Reagent pack for the quantitative determination of the total Antioxidant Status (FORD) on whole blood, with Clini5 instruments series. For assessment of the oxido-reductive index (REDOX INDEX), when tested in combination with the FORT test (Cod. AD19107P and/or AD19109P). Clini5 instruments series is an in vitro diagnostic system intended for health care professionals.

Reagent composition

WHITE tube - S1 Reagent	*BLUE tube – S2 Reagent*
Hyperosmolar buffer	pH 5.2 acetate buffer
Vial - S3 Reagent	*Cuvette - C1 Reagent*
Iron solution	Chromogen

Reagent Preparation and Storage

Reagents are ready to use. 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.

Performance Characteristics

Linearity

0.80-5.00 mmol/l trolox eq.

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).

Test (n)	Mean (mmol/l trolox eq)	Std Dev	%CV
20	1.22	0.048	3.89

Precision

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

Test (n)	Mean (mmol/l trolox eq)	Std Dev	%CV
20	0.92	0.039	4.24

Method comparison (accuracy)

A comparison study with capillary blood as specimen type measured using the Clini5 instrument instrument gave the following results:

Sample number (n)	106
Measurement range	0.72-2.22 mmol/l trolox eq
Passing-Bablok regression	y=1.0000x-0.0050
Correlation coefficient	0.934
Mean bias % (95% CI)	-0.72 (-1.52 a +0.08)