callegari

EN • CLINI FORT

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

Cod. AD19109P CLINI FORT 10 TEST: n.1 foil pouch containing 10 R1 cuvettes; n. foil pouch containing 10 R2 tubes; n.1 BLACK capped vial containing 20µl capillaries; package insert.

Intended Use

Reagent pack for the quantitative determination of the Oxidative Status (FORT) on whole blood, with Clini5 instruments series. For assessment of the oxido-reductive index (REDOX INDEX), when tested in combination with the FORD test (Cod. AD19136P and/or AD19139P). Clini5 instruments series is an in vitro diagnostic system intended for health care professionals.

Reagent composition

Cuvette – R1 reagent	**Tubes – R2 reagent**
Chromogen	pH 5.0 buffer
	Stabilizer

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. Pay attention to the info found on the labels and close the aluminium pack carefully, after use.

Performance Characteristics

Linearity

150-650 unit FORT 1.14-4.94 mmol/l H_2O_2 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 (FORT units)	Std Dev	%CV
20	298	12.326	4.13

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 (FORT units)	Std Dev	CV%
20	293	11.130	3.79

Method comparison (accuracy)

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

Sample number (n)	92
Measurement range	175-626 FORT units
Passing-Bablok regression	y=1.0165x-3.7851
Correlation coefficient	0.987
Mean bias % (95% CI)	+0.48 (-0.23 a +1.19)