callegari

EN • **HEMATOCRIT**

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

Cod. AD12102P EMAT (10 TEST): n.1 foil pouches containing 10 cuvettes; n.1 ORANGE capped vial containing 10µl capillaries; package insert.

Intended Use

Reagent pack for the quantitative determination of Hematocrit (HCT) 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
2,5 mM Acetic acid
250 mM Sodium sulphate
Stabilizers

Reagent Preparation and Storage

The buffer reagent is ready to use. The buffer reagent is 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

20.0-60.0 %.

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 %	Std Dev	%CV
Low	20	35.2	0.659	1.87
Normal	20	44.3	0.485	1.10

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 %	Std Dev	%CV
High	20	57.2	1.105	1.93
Normale	20	42.3	0.580	1.37

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)	95
Measurement range	29.2-51.1 %
Passing-Bablok regression	y=1.0121x-0.4398
Correlation coefficient	0.940
Mean bias % (95% CI)	+0.58 (-0.16 a +1.31)