

## EN • ERYTHROCYTES

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

Cod. AD12103P ERIT (10 TEST): n.1 foil pouches containing 10 cuvettes; n.1 UNCOLOURED capped vial containing 5µl capillaries; package insert.

### Intended Use

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

### Reagent Composition

<i>Cuvette - Buffer reagent</i>
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

2.00-7.00 mil/mmc.

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).

Sample	Test (n)	Mean mil/mmc	Std Dev	%CV
1	20	4.64	0.053	1.13
2	20	5.87	0.091	1.55

#### Precision

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

Sample	Test (n)	Mean mil/mmc	Std Dev	%CV
1	20	4.73	0.152	3.21
2	20	5.93	0.119	2.01

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## 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)	81
Measurement range	3.77-5.66 mil/mmc
Passing-Bablok regression	$y=0.9211x+0.4100$
Correlation coefficient	0.908
Mean bias % (95% CI)	+0.30 (-0.61 a +1.20)