callegari

EN • **URIC ACID**

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

Cod. AD19007P CLINI URIC 10 TEST: n.1 box containing CLINI URIC cuvette 10 TEST (cod. AD15107P) + n.1 vial of URIC Enzyme 10 TEST (cod. AD20110P).
Cod. AD15107P CLINI URIC cuvette 10 TEST: n.1 foil pouch containing 10 cuvettes; n.1 sachet containing 50µl disposable micropipette; package insert. Enzymes are provided separately.

Intended Use
Reagent pack for the quantitative determination of the Uric Acid (URIC) 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	**Enzyme**
50mM Phosphate-borate buffer	2 mM 4-AP
1mM PhOH	>500 U/L POD
Non-ionic surfactant	>250 U/L Uricase
Stabilizers	

Reagent Preparation and Storage
All reagents are ready to use. The buffer 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. Enzymes stored at 2-8°C/35.6-46.4°F may be used until the expiry date found on the pack.

Performance Characteristics
Linearity
2.5-19.5 mg/dl (0.15-1.17 mmol/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).

Test (n)	Mean mg/dl (mmol/l)	Std Dev	% CV
20	5.5 (0.33)	0.199 (0.012)	3.58 (3.58)

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 mg/dl (mmol/l)	Std Dev	% CV
20	5.4 (0.32)	0.1482 (0.009)	2.75 (2.75)

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)	68
Measurement range	2.6-7.8 mg/dl
Passing-Bablok regression	y=1.0000x-0.1000
Correlation coefficient	0.957
Mean bias % (95% CI)	-0.43 (-2.10 a +1.25)