callegari

EN • GLYCATED HEMOGLOBIN

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

Cod. AD19164P CLINI HbA1c 10 TEST: n.1 foil pouch containing 10 R1 tubes; n.1 foil pouch containing 10 R2 cuvettes; n.1 foil pouch containing 10 HbA1c R3 tubes; 1 ORANGE capped vial containing 10µl capillaries; package insert.

Intended Use

Reagent pack for the quantitative determination of Glycated Hemoglobin (HbA1c) on whole blood, with Clini5 instruments series. An estimated average glucose level (eAG)[3] is provided by the system. Clini5 is an in vitro diagnostic system intended for health care professionals.

Composition

Blue Tube – R1 reagent	*Cuvette – R2 reagent*
Water	Latex 25 mmol/L
Stabilizer	Buffer 15 mmol/L
	Stabilizer 0.95g/L
White Tube – R3 reagent	
Anti-HbA1c monoclonal antibody 5.6 mg/dL	
Anti-IgG antibody 12 mg/dL	
Buffer 15 mmol/L	
Stabilizer 0.95g/L	

Reagent Preparation and Storage

Reagents are ready to use. Store reagents refrigerated at +2 to +8°C/35.6-46.4°F. Reagents should be allowed to stand at room temperature (+20 to + 25°C/68-77°F) before use. Reagents are stable if stored properly and kept in the CLOSED aluminium foil pouch until the expiry date stated on the labels.

Performance Characteristics

Linearity

4.5-12.0 % (26-108 mmol/mol).

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 is expressed as a percentage of the Coefficient of Variability (% CV).

Level	Test (n)	Mean % (mmol/mol)	Std Dev (mmol/mol)	%CV
1	20	5,3 (34)	0.094 (1.353)	1.78 (3.93)
2	20	6,3 (45)	0.119 (1.298)	1.89 (2.88)
3	20	8,3 (67)	0.085 (0.851)	1.03 (1.27)

Precision

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

Level	Test (n)	Mean % (mmol/mol)	Std Dev (mmol/mol)	%CV
1	20	5.3 (34)	0.107 (1.468)	2.03 (4.31)
2	20	6.3 (45)	0.122 (1.333)	1.94 (2.98)
3	20	8.1 (65)	0.179 (1.785)	2.19 (2.73)

Method comparison (accuracy)

A comparison study using venous blood specimens analyzed by the Clini5 method and a certified laboratory method delivered the following results:

Sample number (n)	62
Measurement range	4.7-10.3 %
Passing-Bablok regression	y=1.0000x+6.217249E-015
Correlation coefficient	0.959
Mean bias % (95% CI)	+0.024 (-1.14 a +1.19)