BIOLABO
www.biolabo.fr
MANUFACTURER :
BIOLABO SAS,
Les Hautes Rives
02160, Maizy, France

HbA1c ENZYM Standard Set

For calibration of quantitative determination of the HbA1c in the human blood by Enzymatic Method

REF 22052 **R1** 1 x 0.5 mL **R2** 1 x 0.5 mL

CE

IVD **IN VITRO DIAGNOSTIC**

TECHNICAL SUPPORT AND ORDERS
Tel : (33) 03 23 25 15 50
Fax : (33) 03 23 256 256

PRINCIPLE AND INTENTED USE

Standard Set for the preparation of reference curve for quantitative immunochemical determination of the HbA1c in the human blood, only with reagents REF 22050 HbA1c ENZYM.
Suitable for manual procedure or automated instruments.

REAGENTS

Vial R1	**HbA1c ENZYM Cal1**
Vial R2	**HbA1c ENZYM Cal2**

2 vials of HbA1c Standards (2 different levels) lyophilized and stabilized, prepared from human blood,
The concentration of each standard is batch-specific
(see § **ASSIGNED VALUES**).

SAFETY CAUTIONS (1) (2)

BIOLABO reagents are designated for professional, in vitro diagnostic use.

- Each individual donation intended for use in manufacture of calibrator was tested negative for hepatitis B surface antigen (HBsAg), anti-hepatitis C (anti-HCV) and anti-HIV 1 and HIV 2 by FDA approved test.
- However absence of infectious agents can never be proven, these vials and all specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.
- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In the event of exposure the directive of the responsible health authorities should be followed.
- Reagents contain sodium azide (concentration < 0.1%) which may react with copper and lead plumbing. Flush with plenty of water when disposing.
- Material Safety Data Sheet is available upon request.

Waste disposal: Respect legislation in force in the country.

REAGENTS PREPARATION

Reconstitute with exactly 0.5 mL of demineralised water.
Let stand at room temperature for 30 min before use to ensure complete dissolution.
Lyse as described in § "Specimen Collection and Handling" of the reagent HbA1c ENZYM REF 22050.
This calibrator has to be handled as patient blood

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Reagents and controls.

INTERFERENCES

Factors which may influence results are bacterial contamination, respect of automated instrument procedure, temperature control...

STABILITY AND STORAGE

Store at 2 - 8° C, in well capped original vial, away from light and heat. Do not freeze.

- Unopened, Standards are stable until expiry date stated on the label.
- Once reconstituted, Standards are stable at least for 14 days when free from contamination.

PROCEDURE

This Standard Set should be used with BIOLABO reagents REF 22050 HbA1c ENZYM in accordance with technical data sheet of the reagent/instrument in use. Standards have to be handled as patient blood.

QUALITY CONTROL

- REF 22013 Control Set (Normal Level and Elevated Level)

or other assayed control referring to the same method.
It is recommended to:
✓Participate to external quality control program.
✓Control as indicated in technical sheet of the reagent.
✓Validate Calibration values when using other reagents that BIOLABO reagents.

ASSIGNED VALUES (3)(4)(5)(6)

Assigned values are valid only for HbA1c ENZYM Method.
Make sure that the batch number stated on the label of each vial corresponds to the batch number indicated below.

	HbA1c NGSP (%)	
	3 Reagents Method	2 Reagents Method
HbA1c ENZYM Cal1 LOT XXXXXXXX	xx	xx
HbA1c ENZYM Cal2 LOT XXXXXXXX	xx	xx

Values of Standards were obtained by replicate analysis using HbA1c ENZYM Reagents, controls and a representative number of patient bloods with HbA1c known values assigned with IFCC reference measurement method legally available on the market. IFCC values (mmol/mol Hb) corresponding to NGSP values can be determined using following formula: NGSP=0.09148 x IFCC+2.152

REFERENCES

(1) *Occupational Safety and Health Standards ; Bloodborne pathogens (29CFR1910.1030) Federal Register July 1, (1998) ; 6, p.267-280*
(2) *Directive du conseil de l'Europe (90/679/CEE) J. O. de la communauté européenne n°L374 du 31.12.1990,p.1-12*
(3) *TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p.798, 800*
(4) *Hoelzel W et al. IFCC Reference system of measurement of Hemoglobin HbA1c in human blood and the national standardization schemes in the United States, Japan, and Sweden : a method-comparison studiy. Clin Chem (2004):50, p.166-174*
(5) *Report of the ADA/EAS/IDF Working Group of the HbA1c Assay, London, UK, January 2004. Diabetologia (2004): 47.R53-4*
(6) *ADA/EAS/IDF Working Group of the HbA1c Assay, clin Chem (2005): 51 (4): p.681-683*

Manufacturer | Use by | IVD In vitro diagnostic | Temperature limitation | REF Catalogue number | See insert | LOT Batch number | Store away from light | Σ sufficient for | → dilute with