BIOLABO
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HbA1c Control Set

Packed erythrocytes for quality control of quantitative determination of HbA1c in human blood by Turbidimetric Immunoassay or by Enzymatic Method

REF 22013	**R1** 1 x 0,5 mL	**R2** 1 x 0,5 mL

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CE

IN VITRO DIAGNOSTIC

PRINCIPLE AND INTENTED USE

Accuracy control during the determination of glycated haemoglobin (HbA1c) in human blood by turbidimetry, nephelometry or enzymatic method.
BIOLABO HbA1c Controls are suitable for manual procedure or automated instruments.

REAGENTS

R1	**HbA1c Normal Level**	
R2	**HbA1c Elevated Level**	human origin

Packed human erythrocytes lyophilized and stabilized
The concentration of this controls are batch-specific (see § **ASSIGNED VALUES**).

SAFETY CAUTIONS (1) (2)

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

- Material Safety Data Sheet is available upon request.
- Use adequate protections (overall, gloves, glasses).
- Each donor unit used to manufacture this product was tested and found non-reactive for HbsAg, antibody to Hepatitis C and antibody to HIV-1/HIV-2.
- However, no test method can offer complete assurance that infectious agents are absent. All specimens or reagents from biological origin should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions.
- In case of contact with skin and eyes, the directive of the responsible health authorities should be followed.

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 used REF 22010 ou REF 22011 HbA1c Turbidimetric Immunoassay
Controls have to be handled as patient blood.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Demineralised water.
2. BIOLABO Reagents and Standard Set (§ Procedure)

INTERFERENCES

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

STABILITY AND STORAGE

When stored at 2 - 8° C in well caped original vial, away from light, controls are stable:

- Unopened: until expiry date stated on the label.
- Once reconstituted:
  - ❖ 30 days at 2-8°C, if not frozen.
  - ❖ 3 months at -20°C (use quickly after thaw, do not freeze again)

Don't use reconstituted control after expiry date stated on the label.

QUALITY CONTROL

It is recommended to:
✓Participate to external quality control program.
✓Control as indicated in technical sheet of the reagent.
✓Validate target values and ranges when using other reagents that BIOLABO reagents.

PROCEDURE

These Controls may be used with:
REF 22012 HbA1c Standard Set
REF 22010 ou REF 22011 HbA1c Turbidimetric Immunoassay

ASSIGNED VALUES AND CONFIDENCE RANGE (3)(4)(5)(6)

Make sure that the batch number stated on the label of the vial corresponds to the batch number indicated below.

	Normal Level LOT xxxxxx	Elevated Level LOT xxxxx
HbA1c NGSP (%) with REF 22010/22011 Turbidimetric Immunoassay		

Values of Controls were obtained using BIOLABO Reagents and Calibrators traceable to IFCC Reference Measurement Procedure.
It is recommended that each laboratory validate each new batch-specific value before use. For an optimal use, laboratories must check the consistency of their own targets and ranges. These target values have to be periodically retested.
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, 3th Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p.790-796*
(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 | sufficient for | → dilute with | H2O Demineralised water | Biological hazard