BIOLABO
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MANUFACTURER:
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HbA1c Control Set

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

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

TECHNICAL SUPPORT AND ORDERS
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CE

IVD

Made in France

I: corresponds to significant modifications

PRINCIPLE AND INTENTED USE

I Titrated controls for the quality control of quantitative immunochemical determination of glycated haemoglobin (HbA1c) in human blood.
Suitable for manual procedure or automated instruments with BIOLABO reagents:
REF 22010, 22011, REF K1010, K2010, K4010

REAGENTS

R1	HbA1c Normal Level	
R2	HbA1c Elevated Level	human origin

Packed human erythrocytes lyophilized and stabilized

SAFETY CAUTIONS (1) (2)

BIOLABO reagents are designated for professional use in laboratory.

- Material Safety Data Sheet is available upon request.
- 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.
- Waste disposal: Respect legislation in force in the country.

Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Reconstitute with exactly 0.5 mL of demineralised water

MATERIAL REQUIRED BUT NOT PROVIDED

1. BIOLABO Reagents (§ INTENDED USE)
2. REF 22012: HbA1c Standard Set

QUALITY CONTROL

Verify the integrity of each vial and batch-specific values before use.
Run in accordance with the IFU of the reagent used.

STABILITY AND STORAGE

Stored away from light, in well capped original vial, at 2-8°C, stored and used as indicated, controls are stable:
Unopened,

- Until expiry date stated on the label.

Once opened:

- Reconstitute promptly

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.

PROCEDURE

Run in accordance with the IFU of the reagent used.

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

- Values of Controls are traceable to IFCC Reference Measurement Procedure.
- IFCC values (mmol/mol Hb) were converted to NGSP values using following formula:

NGSP=0.09148 x IFCC+2.152

- **Batch specific** values are indicated in the table below
- Make sure that the batch on the label of each vial corresponds.

	Normal Level LOT xxxxxx	Elevated Level LOT xxxxx
HbA1c NGSP (%)		

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 must be periodically retested.

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	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with