BIOLABO
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MANUFACTURER:
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HbA1c Standard Set

For calibration of quantitative determination of the HbA1c in the human blood by Turbidimetric Immunoassay

REF 22012 **R1** 1 x 0.5 mL **R2** 1 x 0.5 mL
R3 1 x 0.5 mL **R4** 1 x 0.5 mL

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CE

IVD

Made in France

I: corresponds to significant modifications

INTENTED USE

Standard Set for the preparation of reference curve for quantitative immunochemical determination of the HbA1c in the human blood.
I Suitable for manual procedure or automated instruments with BIOLABO reagents:
REF 22010, 22011, REF K1010, K2010, K4010

REAGENTS

R1	HbA1c Cal 1	Human origin
R2	HbA1c Cal 2	
R3	HbA1c Cal 3	
R4	HbA1c Cal 4	

4 vials of HbA1c Standards (4 different levels)

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.

I 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 22013: HbA1c Control Set

QUALITY CONTROL

Verify the integrity of each vials 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, standards are stable:
Unopened,

- Until expiry date stated on the label.

Once opened:

- Reconstitute promptly

Once reconstituted,

- at least for 30 days when free from contamination.

Do not freeze.

PROCEDURE

Run in accordance with the IFU of the reagent used.

CALIBRATION VALUES (3)

- NGSP values were obtained by assaying representative samples of the entire lot against materials referenced to NGSP values using BIOLABO Reagents.
- IFCC values were calculated using « Master equation »from IFCC: IFCC Value (mmol/mol Hb) = (NGSP Value - 2,15)/0,915*10
- **Batch specific** values are indicated in the table below
- Make sure that the batch on the label of each vial corresponds.

		HbA1c NGSP (%)	HbA1c IFCC (mmol/mol Hb)
cal 1	LOT xxx	xx	xx
cal 2	LOT xxx	xx	xx
cal 3	LOT xxx	xx	xx
cal 4	LOT xxx	xx	xx

LIMITATIONS

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

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. Textbook of clinical chemistry, 3th Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p.790-796

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