BIOLABO
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MANUFACTURER:
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G6-PDH Deficient control (Lyophilised human hemolysed blood)

For quality control of G6-PDH activity in red blood cells

REF 95289 **R1** 6 x 0.5 mL **R2** 1 x 5 mL

TECHNICAL SUPPORT AND ORDERS
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CE

IVD **IN VITRO DIAGNOSTIC USE**

INTENTED USE (1) (2) (3)

This Control is intended to monitor the reproducibility and accuracy of methods and analysis performed with BIOLABO kits for the following analysis: G6-PDH (Kinetic method)
REF 97089**,** REF 97099
In case of use with another G6-PDH reagent, refer to corresponding instructions (see § TARGET VALUES AND RANGES).

REAGENTS COMPOSITION

Vial R1 **G6-PDH DEFICIENT CONTROL**

Lyophilised red cells hemolysate (Human Source material)
Stabiliser

Vial R2 **DILUENT**

G6-PDH activity (batch specific value) is indicated in the label of the vial.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.

PREPARATION (4) (5)

- Open the vial carefully, avoiding any loss of lyophilised material.
- Reconstitute with exactly 0.5 mL (500 µL) of vial R2.
- Close the vial and allow standing for 15 minutes at room temperature.
- Dissolve completely the contents by swirling gently before use.
- After reconstitution, the hemolysate requires no further Digitonine pre-treatment.

Do not shake (to prevent foam formation).

STABILITY AND STORAGE

Store at 2-8°C, well recapped in the original vial and away from light.

- Unopened, Control is stable until expiry date stated on the label.
- Without contamination , stored and used as described in the insert, reconstituted Control is stable for:
  - ✓7 days at 2-8°C
  - ✓30 days at -20°C

Discard any control if cloudy or contaminated.
Don't use reconstituted Control after expiry date stated on the label.

This kit should be refrigerated during transport.

REFERENCES

(1) *TIETZ N.W. Textbook of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 1645-1650.*
(2) *Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 456-457*
(3) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p. 3-294*
(4) *BEUTLER et Al., International comittee for standardisation in Haematology: « Recommended Methods for Red Cell Enzyme Analysis » British Journal of Haematology, (1977), 35, p.331-340.*
(5) *BEUTLER E., Red cell metabolism,: A manual of biochemical methods (3rd Ed.) Orlando, Grune et Stratton (1984), p.68-70.*
(6) *SMQ BIOLABO: Document interne réf. 81 INS 01 « évaluation et titrage des sérums de contrôles et calibrateurs »*

SAFETY CAUTIONS

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

- **Caution: Human origin**. Each component of this product has been tested with FDA-approved methods and found nonreactive for the presence of HBsAg, HCV and antibodies to HIV1/2. Because no known test method can offer complete assurance that infectious agents are absent, this material should be handled as potentially infectious.
- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In case of contact with skin or eyes, thoroughly wash affected areas with plenty of water and seek medical advice.
- Reagent contains 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.

All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

TARGET VALUES AND RANGES (6)

Target values and ranges, indicated on the label of the vial, are obtained with BIOLABO erythrocyte's theoretical factor (*) by using:

- Recommended and validated statistical technics.
- Metrologically controlled instrument.

Target values are the mean of values obtained during several determinations and ranges are ±2 or 3 standard deviations.

Control value is expressed in IU/L of blood.

(*) For further information, refer to the technical data sheet of the reagent REF 97089, REF 97099 or contact BIOLABO technical support.

G6-PDH Activity at 37°C

BATCH	Target value (IU/L of blood)	Confidence Range
With Reagent REF 97089, REF 97099		
With RANDOX* Reagent (same method with different preparation of the hemolysate and different reagent/specimen ratios).		

It is recommended that each laboratory validate each new batch-specific value before use. For an optimal use, laboratories should establish their own targets and ranges. These target values have to be periodically retested.

*RANDOX does not belong to BIOLABO

Made 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