


G6PDH-RED CELL LYSING REAGENT (only for automation)

For *in Vitro* Diagnostic use only

LIQUID REAGENT for PREPARATION of HOMOGENEOUS HEMOLYSATES for QUANTITATIVE UV DETERMINATION of GLUCOSE 6 PHOSPHATE DEHYDROGENASE (G6PDH) and COLORIMETRIC of TOTAL HEMOGLOBIN on ERYTHROCYTES with Automatic Analyzer

 (4 x 25 mL)

REF NAGB1129

I. INTENDED USE

G6PDH-RED CELL LYSING REAGENT (only for automation) is necessary to prepare the homogeneous hemolysates to run ONLY on Automatic Analyzers the kit for the quantitative determination UV method of GLUCOSE 6 PHOSPHATE DEHYDROGENASE (G6PDH) and colorimetric method of TOTAL HEMOGLOBIN (Hb) in erythrocytes with the reagents:
- G6PDH – GLUCOSE 6 PHOSPHATE DEHYDRIGENASE **REF** **NAGP68905**

II. PRINCIPLE

To use it follow the procedures shown on the Information for Use of the kits for the determination of each single analyte.

III. PRECAUTION FOR USE

1. This product has been formulated for *in vitro* diagnostic use.
2. A proportional variation of the reaction volumes does not change the result.
3. DO NOT mix Reagents from different Production lots.
4. It is recommended to handle the reagents carefully, avoiding ingestion and contact with eyes, mucous membranes and skin; to use reagents according to good laboratory practice. On the material safety data sheet are detailed the operating procedures for the manipulation of this product. Material safety data sheet should be supplied on request.

ATTENTION!

A) Applications on routine analyzers may be totally different from what developed as manual determination; in addition the procedures are specific for each analyzer.

B) The reagent must be used ONLY for the intended destinations, by expert and trained people and in according to good laboratory practice.

C) The clinical diagnosis cannot be done correctly using the result of only one test, but have to be done integrating critically the results of different laboratory tests and clinical data.

D) A lot of factors, as ambient temperature, the working reagent temperature, wash accuracy and the type of spectrophotometer, may affect the tests performances.

E) **G6PDH is very unstable in hemolysates. 20/30 minutes after dilution (see SAMPLE PRETREATMENT **REF** NAGB1129) a precipitate may appear, probably due to the biological variability of the patient's sample.**

F) The calibration curve has to be always repeated at each change of the lot of the Reagent and/or calibrator.

G) All the precautions normally used in the laboratory must be respected for reagents handling.

All the calibrators and controls must be considered as human sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.

IV. REAGENTS AND MATERIALS PROVIDED

Kit composition:

REF NAGB1129

R1 - Lysing

4 x 25 mL

Buffer mod.

Stabilizers

NaN₃

MATERIAL REQUIRED BUT NOT PROVIDED

Normal laboratory equipment.

Micropipettes to deliver from 3 to 1000 µL.

Disposable micropipettes tips.

Transparent glass tubes for sample dilution.

Distilled water, Calibrators, Controls and Reagents.

Spectrophotometer or automatic analyser for Clinical Chemistry.

V. AUXILIARY REAGENTS FOR QUALITY CONTROL

To grant the right performances use following kits (see the relative information for use (IFU)):

- G6PDH-GLUCOSE 6 PHOSPHATE DEHYDROGENASE **REF** **NAGB1129**

- G6PDH CONTROLS SET

REF **NAG6CON**

- G6PDH CALIBRATORS

REF **NAG6CAL3**

The calibration curve has to be always repeated at each change of the lot of the Reagent and/or calibrator.

VI. STORAGE AND STABILITY

The Reagents are stable up to the expiry date mentioned on the labels, if closed and stored at 2-8°C in their intact primary container; if not exposed to heat sources and/or pressure variations. In case of damaging of the primary



container organize the waste disposal.

VII. PREPARATION OF THE WORKING REAGENT

Ready-to-use. Mix kindly before use and let the reagent reach the room temperature before use. Close immediately after handling. The Reagents have to be used correctly, to avoid contamination. An incompetent handling relieves us from any responsibility.

VIII. STABILITY AFTER THE FIRST OPEN

The product is stable up to the expiry date mentioned on the labels after the first open if stored at 2-8°C.

IX. SAMPLES

- Whole blood collected with EDTA, heparin or ACD (Acid-Citrate-Dextrose). Samples collection in compliance with CLSI (NCCLS) (see References 3). The sample can be stored at 2-8°C, up to 6 days. (see References 1).

X. WASTE DISPOSAL

Observe all federal, state and local environmental regulations for waste disposal.

XI. PRETREATMENT OF SAMPLES, CALIBRATORS and CONTROLS

For the quantitative determination of G6PDH and Total Hemoglobin is necessary to prepare the hemolysate solution mixing 1 part of whole blood and 9 part of **R1 – Lysing**; mix gently and assay immediately. G6PDH activity is unstable in hemolysate.













XII. ANALYTICAL PROCEDURE

Let reagents reach the working temperature before use. Dispense the required volume of lysate in a test tube then perform analytical procedures as indicated for the specific analyte kits. The ranges of calibration and control shall conform to the characteristics of the equipment supplied in your laboratory.

XIII. ANALYTICAL PERFORMANCES (Validate on MINDRAY BS300)

The analytical performances of GLUCOSE 6 PHOSPHATE DEHYDROGENASE (G6PDH) and TOTAL HEMOGLOBIN are detailed on the relative Information for Use

XIV. REFERENCES (see Italian version)

 IVD	In Vitro Diagnostic Medical Device	 Temperature limitation	 LOT	Batch code (XXX)	 Manufacturer	 Keep dry	 Non-sterile	Non-sterile
 Consult Instructions for use	Consult Instructions for use	 Use by (year/month)	 REF	Catalogue number	 Do not reuse	 Fragile, handle with care	 Keep away from heat	Keep away from heat

CONTENT

R1 - Lysing
Instruction for use

 **NAGB1129**

4 x 25 mL
1 item

EDMA (EDMS) CODE 13019001

