

HbA1c CALIBRATOR



REF 1578-1053

Packaging: 2 x 0.5 mL + 2 x 0.5 mL

INTENDED USE

Calibration material for the preparation of reference curves for the quantitative determination of Hemoglobin A1c assays with Medicon reagents. For in vitro diagnostic use only by trained laboratory professionals.

COMPOSITION

Hemoglobin A1c Calibrators (lyophilized) contain hemoglobin and glycosylated hemoglobin from human whole blood.

Prior to lyophilization, the calibrator matrix is an MES-buffered solution and contains ofloxacin as a preservative.



WARNINGS – PRECAUTIONS

- Material for in vitro use only. Handle according to good laboratory techniques. Avoid inhalation and contact with eyes, skin and mucous membranes.
- Every donor used for the preparation of the material was tested and found negative for HbsAg, anti-HCV and anti-HIV 1 and 2. As there is no known test method that can offer complete assurance that products derived from human blood will not transmit infectious agents this product should be handled as a potentially infectious material.
- Different lot numbers of this material should not be interchanged, as the values assigned to the materials vary from lot to lot.
- Never refill empty or half-empty vials; this will cause fast deterioration of freshly added calibration material to the old one.
- Dispose all waste according to national laws.
- SDS is available by MEDICON.
- Any serious incident that may occur in relation to this device must be reported by the user to the manufacturer and the competent authority of the country in which the user and/or the patient is established.



PREPARATION

The lyophilized calibrators should be reconstituted as follows:

1. Add 0.5 mL of purified or deionized water.
2. Close bottle and allow the contents of the bottle to sit at room temperature for at least 10 minutes.
3. Mix thoroughly by low speed vortexing or by gently inverting 10 times before use. Avoid the formation of foam

NOTE: After reconstitution, the calibrators do not require pretreatment.

ASSAY PROCEDURE

Calibrator values are printed in the Value Sheet and are specific for each lot. Please program them in the analyzer menu before first use of each lot of calibration material. Please use instructions in the analyzer operation manual and contact your supplier for assistance. The analyzer will automatically convert calibrator readings to calibration curves.



SHELF LIFE

Unopened, lyophilized Hemoglobin A1c and are stable until the expiration date when stored at 2 – 8°C.



STORAGE - STABILITY

Store reconstituted calibrators at 2 – 8°C and use within 10 days. Do not freeze.



DETERIORATION

The material should not be used in case of:

- Visible signs of leakage
- Extreme turbidity
- In case of microbial growth

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

HbA1c reagent
Purified or deionized water
Automated biochemical analyzer
Common laboratory equipment.



WASTE DISPOSAL

Dispose of contents/container in accordance with licensed collector's sorting instructions.

ASSIGNED VALUES – Lot specific

Please refer to the value sheet for the specific lot available at <https://medicondoc.com>.

SYMBOLS



Manufacturer



In vitro diagnostic medical device



Temperature Limit



Catalogue Number



Caution