

HbA1c CALIBRATOR



REF 1578-1058

Packaging: 1 x 8 mL + 5 x 2 mL

INTENDED USE

Material for the preparation of reference curves for the quantitative determination of HbA1c using Medicon reagent with Diatron Pictus® P700 and P500 analyzers. For in vitro diagnostic use only by trained laboratory professionals.

COMPOSITION

Calibrator Level 1

Sodium hydroxide 0.4%; pH 13
Surfactant; 2.5% Triton X-100
Chlorohemin

Calibrator Levels 2 to 6

Bovine Serum Albumin
Buffer; pH 3.0
Hapten

⚠ WARNINGS – PRECAUTIONS

- Exercise the normal precautions required for handling all laboratory reagents.
- Material for in vitro use only
- Dispose of all waste material in accordance with local guidelines.
- Safety data sheet available for professional user on request.
- 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

Material is ready for use. Gently invert each vial several times prior to each use to ensure a homogeneous mixture. Avoid foaming. Replace cap immediately after use and store at 2-8°C.

Unsuitable storage, handling, or errors during the analytical procedure may give erroneous results.

For calibration of the Total Hemoglobin reagent use Calibrator 1 only.

For calibration of the HbA1c reagent use Calibrators 1 to 6.

⚠ STORAGE - STABILITY

The materials are stable, unopened, up to the stated expiry date when stored at 2-8°C.

Once open, the materials are stable up to the stated expiry date, provided they are free from contamination, tightly capped immediately after each use and stored at 2-8°C.

⚠ DETERIORATION

The material should not be used:

- After prolonged exposure to direct sunlight or high temperature
- After the expiry date
- When microbial growth is evident

PROCEDURE

Refer to relevant product instructions for use. Make sure the LOT on the vial is the same as on the value sheet accompanying the material.

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