

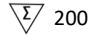
HbA1c

Specifically for use with Diatron PICTUS® 700 and PICTUS® 500 Analyzers



REF 1518-1059

Packaging: 2 x 100 mL



INTENDED USE

Accessory (Lysing) reagent for pretreatment of human whole blood samples for In Vitro quantitative automated determination of Hemoglobin A1c - HbA1c. The Medicon reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers.

For in vitro diagnostic use only by trained laboratory professionals.

COMPOSITION

- Porcine Pepsin
- Buffer pH 2.4
- Preservative

WARNINGS – PRECAUTIONS

- Exercise the normal precautions required for handling all laboratory reagents.
- Dispose of all waste material in accordance with local guidelines.
- 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 Medicon Hemoglobin Denaturant is ready for use.

STORAGE – STABILITY

Hemoglobin Denaturant is stable, unopened, up to the stated expiry date when stored at 2-8°C. Once open, Hemoglobin Denaturant is stable up to the stated expiry date, provided it is free from contamination, tightly capped immediately after each use and stored at 2-8°C.

SPECIMEN

K2-EDTA or NH4-heparinised blood.

Before use, pre-treat samples and controls manually by adding 25µL of whole blood to 1000µL of Medicon Hemoglobin Denaturant [1:41 dilution] mix thoroughly, avoid foaming, and incubate for 5 minutes at room temperature before use. Calibrators do not require pre-treatment.

TEST PROCEDURE

Refer to the table of assigned values. The range represents the maximum acceptable deviation for one measurement only.

SYMBOLS



Manufacturer



In vitro diagnostic medical device



Temperature Limit



Catalogue Number



Caution



Contains sufficient for <n> tests