

HbA1c CONTROL



REF 1578-1057 **Packaging:** 2 x 2 x 0.5 mL

INTENDED USE

Material for internal quality control of HbA1c assays using Medicon reagent with Diatron Pictus® P700 and P500 analyzers. For in vitro diagnostic use only by trained laboratory professionals.

COMPOSITION

Lyophilized whole blood of human origin	HbA1c Level 1	lyophilized powder
	HbA1c Level 2	lyophilized powder

⚠ WARNINGS – PRECAUTIONS

- Exercise the normal precautions required for handling all laboratory reagents.
- Dispose of all waste material in accordance with local guidelines.
- To avoid the possible build-up of azide compounds, flush waste-pipes with water after the disposal of undiluted reagent.
- Biological materials of human origin contained in this product have been tested and shown to be free from hepatitis B surface antigen (HbsAg), antibodies to hepatitis C (HCV), and antibodies to Human Immunodeficiency Virus (HIV-1 and HIV-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.
- 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

1. Remove the rubber stopper very carefully. As the material is packed under vacuum, sudden air influx may force material out of the vial.
2. Reconstitute the contents of the vial with exactly 0.5 mL of deionized or distilled water.
3. Carefully replace the cap, mix contents by inversion 2-3 times and leave to stand at room temperature for 10 min.
4. After 10 minutes, coat all surfaces of the control bottle by rotating and inverting the bottle.
5. Continue mixing until the solution is homogenous and all lyophilized material is reconstituted. Ideally place in hematology sample-tube mixer for 20min. Avoid foaming.

Note: Before use, pre-treat reconstituted controls by adding 25 µL of control to 1000 µL of Hemoglobin Denaturant (Cat No. 1518-1059) [1:41 dilution]. Mix thoroughly, avoid foaming, and incubate for 5 minutes at room temperature before use.

Whole Blood Application: Reconstituted materials should be placed on board the analyzer without pre-treatment

Replace cap immediately after use and store at 2-8°C. Unsuitable storage, handling, or errors during the analytical procedure may give erroneous results.

⚠ STORAGE - STABILITY

The materials are stable, unopened, up to the stated expiry date when stored at 2-8°C. Appearance of moisture in the bottle prior to reconstitution is an indication of deterioration of the material and renders the material unsatisfactory for use. The reconstituted materials are stable at 15-25°C for 30 minutes and for 1 month when stored at 2-8°C, provided they are free from contamination, tightly capped immediately after each use.

TEST PROCEDURE

Refer to relevant product instructions for use.

Each laboratory should establish its own control frequency however good laboratory practice suggests that controls be tested each day patient samples are tested and each time calibration is performed.

The results obtained by any individual laboratory may vary from the given mean value. It is therefore recommended that each laboratory generates analyte-specific control target values and intervals based on multiple runs according to their requirements. These target values should fall within the corresponding acceptable ranges given in the enclosed table.

If any trends or sudden shifts in values are detected, review all operating parameters.

Each laboratory should establish guidelines for corrective action to be taken if controls do not recover within the specified limits.

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



Biological Risks