GLYCATED HEMOGLOBIN CONTROL N

Lyo Control from Human Blood with Glycated Hemoglobin values within a pathological range

1 x 0,5 ml REF 3660

INTENDED USE

Kit for *in vitro* control of Glycated Hemoglobin with values in a pathological range, from human blood.

PRINCIPLE

Glycated hemoglobin A_{1c} control N consists in a lyo hemolysate obtained from human blood, in which glycated hemoglobin A_{1c} concentration is within a pathological range. It is used for quality control for glycated hemoglobin A_{1c} chromatographic determination.

Follow the determination procedure described in the GLYCATED HEMOGLOBINE A1c kit leaflet using hemoglobin control P instead of the sample hemolysate.

The average value and time intervals were defined by several tests by FAR and by some reference independent laboratories. The obtained values consider variations on equipment, reagents, techniques and methodologies. The assigned time intervals are only indicative: each laboratory should define its own reference values. STABILITY: sealed and stored at 2-8°C, the product is stable up to the expiration date on the label.

NOTE: only blood coming from apparently healthy donors was used to prepare the product. Donors were negative to anti-HIV/HTLV III and HBsAG antibody tests.

Since it is impossible to totally exclude the HIV/HTLV III and HBsAG infection dangers, it is advisable to handle the product with all the precautions required for human blood and its derivatives. Refer to MSDS.

RECONSTITUTION OF CONTROL P

Reconstitute the contents of a vial of **glycated hemoglobin control** ${\bf P}$ with 0.5 ml of distilled water. Close the vial and let stand at room temperature for 5-10 minutes. Shake gently until complete dissolution.

Reconstituted control P is a hemolyzed, to be diluted before use the same way used for blood samples, following the related procedure.

STABILITY: 7 days at 2-8°C or 3 months at -20°C, if de-frozen only once.

CONCENTRATION OF GLYCATED HEMOGLOBIN

Method: FAR ion exchange chromatography

VALUE	10.3 %
INTERVAL	8.7 – 11.8%
LOT no.	018AC



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