Instructions for Use
For *in vitro* diagnostic use

TOPKON HbA1c NÍVEL 1

TopKon HbA1c Level 1

Anvisa 80115310151

ORDER INFORMATION

Cat. No.	Kit size
6100001KC	4 x 0.25 mL

INTENDED USE

Assayed quality control material for monitoring assay performance of quantitative *in vitro* determination of hemoglobin A1c (HbA1c) on photometric systems.

SUMMARY

Topkon HbA1c is a liquid control based on human blood material (erythrocytes). The HbA1c concentration in TopKon HbA1c Nível 1 is normal.

STORAGE

The control Topkon HbA1c Nível 1 both unopened and opened must be stored at 2 – 8°C, protected from light and heat.

STABILITY

Opened or unopened bottles are stable until the end of the month from the expiry date indicated on the label, if contamination and evaporation are avoided after having opened the bottles.
Proper storage and handling of this product must be observed.

WARNINGS AND PRECAUTIONS

1. Each individual blood donation used for production of Topkon HbA1c was found to be non-reactive when tested with approved methods for HBsAg, anti-HIV 1+2 and anti-HCV. As there is no possibility to exclude definitely that products derived from human blood transmit infectious agents, it is recommended to handle the control with the same precautions used for patient specimens.
2. Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.
3. For professional use only!

PREPARATION

Topkon HbA1c liquid controls are ready to use. Controls must be treated the same way as patient samples.
Please refer to the package insert of the reagent.

WASTE MANAGEMENT

Follow the requirements of the current guidelines about technical regulation for the management of healthcare service waste, as well as other equivalent biosafety practices.

WARRANTY

These instructions for use should be read carefully before using the product and the information contained therein should be strictly adhered to. The reliability of the test results cannot be guaranteed if the instructions are not followed.

TARGET VALUES

The analyte concentration value of this control is specific and valid for the corresponding lot and is indicated in the table of values of each lot involved. The control values were traced by the reference method approved by the IFCC standardization. Values according to the DCCT/NGSP standardization in % and according to the IFCC standardization [1-4].

*Each laboratory must establish corrective actions in the event of deviations in the recovery of control.

**Changes in the analyte values defined in this control may occur due to restandardization of the reference material.

LITERATURE

1. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes in the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med.1993;329:977-86.
2. Little RR, Rohlfing CL, Wiedmeyer HM, Myers GL et al. The National Glycohemoglobin Standardization Program: A Five-Years Progress Report. Clin Chem 2001;47:1985-92.
3. Jeppsson JO, Kobold U, Barr J, Finke A et al. Approved IFCC reference method for the measurement of HbA1c in human blood. Clin Chem Lab Med 2002;40:78-89.
4. Hoelzel W, Weykamp C et al. IFCC Reference System for Measurement of Hemoglobin A1c in Human Blood and the National Standardization Schemes in the United States, Japan, and Sweden: A Method-Comparison Study. Clin Chem 2004; 50:1:166-74.
5. Röhle G, Siekmann L. Quality assurance of quantitative determination. In: Thomas L, editor. Clinical laboratory diagnostics. 1º ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 1393-1401.
6. Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington 1993 (HHS Publicação No. [CDC] 93-8395)

CONSUMER INFORMATION

Symbols used:

	Manufacturer
	Temperature limit
	In vitro diagnostic device
	Caution
	Operating instructions
	Recycling material
	Do not discard directly into the environment
	Batch code
	Date of manufacture
	Use by date
	Biological hazards
	Highly toxic
	Corrosive
	Harmful

Manufacturer:

Kovalent do Brasil Ltda.
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São Gonçalo – RJ – CEP 24722-414 - Brasil
www.kovalent.com.br
CNPJ: 04.842.199/0001-56

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Expiration date and Lot no.: See label