Instructions for Use
For *in vitro* diagnostic use

TOPKON N

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Anvisa 80115310226

ORDER INFORMATION

Cat. No.	Kit size
6020010KC	2x5mL
6020020KC	4x5mL
6020030KC	6x5mL

INTENDED USE

Assayed quality control material for monitoring accuracy and precision of quantitative *in vitro* determination of various analytes in photometric systems.

SUMMARY

TopKon N is a lyophilized control based on human serum and contains drugs, organic and non-organic chemicals and biological material of specified origin. The concentrations are either at normal or at borderline pathological levels.

STORAGE

The unopened bottles of TopKon N must be stored at 2 - 8 °C.

STABILITY

Unopened until the end of the indicated month of expiry. Once reconstituted, TopKon N can be used within the period reported in the table below if stored tightly closed at the indicated temperature.

	4 °C
Bilirubin (in the dark), ALAT (TGO), ASAT (TGP)	2 days
Other analytes	7 days
	25 °C
ALAT (TGP)	2 hours
CK-NAC, CK-MB	4 hours
Other analytes	8 hours
	-20 °C *
Bilirubin	14 days
Other analytes	30 days

*Only freeze once!

WARNINGS AND PRECAUTIONS

1. Each individual blood donation used for production of TopKon N 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. Topkon N contains biological material of specified origin. The controls should be handled as potentially infectious and with the same precautions used for patient specimens.
3. Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.
4. For professional use only!

PREPARATION

The lyophilizate is vacuum sealed; therefore, the vial should be opened very carefully to avoid loss of dried material. For reconstitution add exactly 5 mL of distilled water. Close the vial carefully and allow the control to stand for 30 minutes swirling occasionally. Avoid foaming! Do not shake!

PROCEDURE

Please refer to the reagent package insert for instructions for use.

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.

ASSAY VALUES AND RANGES

The analyte concentrations contained in TOPKON N are specific and only valid for the corresponding lot and thus stated in the value sheet of the lot involved. All assay values have been established within standardized conditions with the method stated in the value sheet by using the reagents specified via the product code.

Ranges of acceptance were calculated as assigned value ± the maximum tolerable deviation of a single value according to the Guidelines of the German Federal Medical Council (Rilibaek) from 2003 [3]. For analytes not listed in the Guidelines of the German Federal Medical Council (Rilibaek) ranges are indicated with a deviation of ± 20% from the given mean value.

*Each laboratory should establish corrective action in case of deviations in control recovery.

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

LITERATURE

1. Röhle G, Siekmann L. Quality assurance of quantitative determination. En: Thomas L, editor. Clinical laboratory diagnostics. 1ª ed., Francfort: TH-Books Verlagsgesellschaft; 1998. pp. 1393-1401.
2. Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington 1993 (HHS Publication No. [CDC] 93-8395).
3. Richtlinie der Bundesärztekammer zur Qualitätssicherung quantitativer laboratoriumsmedizinischer Untersuchungen. Deutsches Ärzteblatt 2003;100:A 3335-38.

CONSUMER INFORMATION

Symbols

	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.
Rua Cristóvão Sardinha, 110 – Jd. Bom Retiro
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