TOPKON L

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Anvisa 80115310105

ORDER INFORMATION

Cat. No.	Kit size
6010003KC	1 x 3 mL

FINALITY

Assayed quality control material for monitoring analytical assay performance of quantitative *in vitro* determination of lipids and apolipoproteins in photometric systems.

SUMMARY

TopKon L is a lyophilized control based on human blood material (serum) with additives of purified material of human origin

STORAGE

The unopened vials of TopKon L must be stored at 2 – 8°C. Avoid contamination and protect from light.

STABILITY

The unopened vials of TopKon L are stable until the end of the indicated month of expiry. After reconstitution, Topkon L can be used within the period reported in the table below if stored tightly closed at the indicated temperature:

	- 20 °C *	2 to 8 °C	15 to 25 °C
NEFA	Do not store	7 days	8 hours
Other analytes	30 days	7 days	8 hours

*Freeze only once!

Proper storage and handling of this product must be observed. Avoid contamination!

WARNINGS AND PRECAUTIONS

1. Each individual blood donation used for production of Topkon L 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

The lyophilizate is vacuum sealed; therefore, the vial should be opened very carefully to avoid loss of dried material. For reconstitution add exactly 3.0 mL of distilled water. Close the vial carefully and allow the control to stand for 30 minutes swirling occasionally. Avoid foaming! Do not shake!

Leave frozen aliquots of the reconstituted Topkon L in the dark at room temperature (18 – 25°C) until they are completely unfrozen. To homogenize after complete defrosting, slightly swivel aliquots and immediately afterwards use them for determination accordingly to the freshly reconstituted Topkon L.

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 L 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.
Due to the use of different reagents and methods, slight variations in the test values may occur. The test values indicated apply only to the batch numbers indicated.

*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 quantitative determination. In: Thomas Clinical laboratory diagnostics. 1 st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 1401.
2. U.S. Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories. Washington, DC:US; 2009 Dec. HHS Publication No.: [CDC] 21–1112.
3. Richtlinie der Bundesärztekammer zur Qualitätssicherung quantitativer laboratoriumsmedizinischer Untersuchungen. Deutsches Ärzteblatt Jg. 100, Heft 50 ; 12. Dezember 2003.

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.
Rua Cristóvão Sardinha, 110 – Jd. Bom Retiro
São Gonçalo – RJ – CEP 24722-414 – Brasil
www.kovalent.com.br
CNPJ: 04.842.199/0001-56

Kits sizes commercialized on demand:

Anvisa no.	Kit size
80115310105	2x3mL

Customer Service: sac@kovalent.com.br - (21) 3907-2534 / 0800 015 1414

Expiration date and Lot no.: See label