TOPKAL U

TopKal U

Anvisa 80115310088

ORDER INFORMATION

Cat. No.	Kit size
6050006KC	2x3mL
6050012KC	4x3mL
6050018KC	6x3mL

INTENDED USE

Multi-calibrator for use in tests for quantitative *in vitro* determination of various analytes on photometric systems

SUMMARY

TopKal U is a lyophilized calibrator based on human blood material (serum) and contains chemical additives and biological material of specified origin.

ORIGIN OF BIOLOGICAL ADDITIVES

Analyte	Origin
Acid phosphatase total	Human prostate/potato
Albumin	Bovine plasma
Aldolase	Rabbit muscle
Alkaline phosphatase	Placenta (human, recombinant)
Alanine-Aminotransferase (ALAT)	Porcine (heart)
α-Amylase	Porcine (pancreas)
Pancreatic amylase	Porcine (pancreas)
Aspartate aminotransferase (AST)	Human, recombinant
Cholesterol	Bovine plasma
Cholinesterase	Human serum
Creatine kinase (CK)	Rabbit muscle
γ- Glutamyl-transferase (GGT)	Human, recombinant
Glutamate dehydrogenase (GLDH)	Bacterium, recombinant
Lactate dehydrogenase (LDH)	Porcine (heart)
Lipase	Pancreas (human recombinant)
Triglycerides	Chicken egg yolk

The concentration of the biological material does not exceed the maximum, lot specific target value concentration of the analyte.

STORAGE AND STABILITY

Unopened vials of TopKal U should be stored at a temperature of 2 to 8 °C and are stable until the expiration date. Once reconstituted, TopKal U calibrator can be used within the period reported in the table below if stored tightly closed at the indicated temperature and bacterial contamination is avoided.

Stability of the components after reconstitution:

	- 20 °C *	4 °C	25 °C
Bilirubin (kept in the dark)	14 days	8 hours	3 hours
Other analytes	30 days	2 days	8 hours

*Only freeze once!

The criteria established for stability is within a variation of ± 5% of the initial value.

WARNINGS AND PRECAUTIONS

1. Each individual blood donation used for production of TruCal U was found to be non-reactive when tested with FDA-approved methods or CE-accepted 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 TopKal U calibrator with the same precautions used for patient specimens.
2. TopKal U contains biological material of specified origin. The calibrators 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 sealed under vacuum; therefore the vial should be opened very carefully to avoid loss of dried material. For reconstitution add exactly 3 mL of distilled water. Close the vial carefully and allow the calibrator to stand for 30 minutes swirling occasionally. Avoid foaming! Do not shake!
Defrost reconstituted and frozen aliquots of TopKal U must be protected from light and kept at room temperature (18 – 25°C). To homogenize after complete defrosting, slightly swivel aliquots and immediately afterwards use them for calibration, store in the same way as the freshly reconstituted tube.

PROCEDURE

Please refer to the reagent package inserts 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.

CALIBRATOR VALUES

The concentrations of the calibrator analytes are lot-specific and given in the value sheet of the corresponding lot. The values were determined using the method and using the reagents specified by the given catalogue number. Determinations were performed under standardized protocols using Kovalent reagents and TopKal U master calibrator or reference materials. The value sheet contains information on traceability.

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

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

LITERATURE

1. Dati F. Reference materials and guidelines for standardization of methods in laboratory medicine. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 1404-26.
2. Moss DW, Henderson AR. Enzymes . In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia: W.B Saunders Company; 1994. p. 735-896.
3. Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington 1993 (HHS Publication 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.
Rua Cristóvão Sardinha, 110 – Jd. Bom Retiro
São Gonçalo – RJ – CEP 24722-414 – Brasil
www.kovalent.com.br
CNPJ: 04.842.199/0001-56

Kit sizes variations on demand:

Anvisa No.	Kit size
80115310088	1 x 3 mL

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

Expiration date and Lot no.: See label