Instructions for Use

For *in vitro* diagnostic use

TOPKAL MULTI TURBI

TopKal Multi Turbi

Anvisa 80115310203

ORDER INFORMATION

Cat. No.	Kit size
6240001KC	1 x 1 mL

INTENDED USE

Preparation of reference curves for quantitative immunochemical determination of proteins in human serum.

COMPOSITION

Protein calibrator composed of defibrinated human plasma, liquid stabilized and filtered at 0.2 µ.
Contains sodium Azide (0.095%) as a preservative.

STORAGE AND STABILITY

The calibrator is ready to use and is stable until the expiration date indicated on the kit, if stored at 2 – 8°C and contamination is avoided.
After first opening the container, the serum can be used for 6 weeks if stored tightly closed at + 2 ° to 8 °C after use.
Do not freeze.

WARNINGS AND PRECAUTIONS

1. For *in vitro* Diagnostic use.
2. Take the necessary precautions when handling laboratory reagents.
3. Each individual donation intended for use in manufacture of the calibrators and controls was tested for hepatitis B surface antigen (HBsAg), anti-hepatitis C virus (anti-HCV) and anti-HIV1 and HIV 2 by FDA required test. Only donations with negative findings were used for its manufacture. Nevertheless, every product obtained from human body fluids should be handled with appropriate care in accordance with recommended procedures for biohazardous materials since absence of infectious agents can never be proven.
4. Reagents containing sodium azide must be handled with due caution: Do not ingest or allow to contact skin or mucous membranes! Sodium azide can form explosive azides when contacting heavy metals such as copper or lead.

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.

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.

MATERIALS REQUIRED, BUT NOT PROVIDED

1. Reagent for the measurement of the marked analyte.
2. General laboratory equipment.

ASSAY PROCEDURE

Applications for automatic systems are available upon request or on our website: www.kovalent.com.br

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

ASSIGNED VALUES

The analyte concentration values of this calibrator are specific and valid only for the corresponding batch and are indicated in the table of values of each batch involved. The values were based on the reference preparation (ERM-DA470k/IFCC) of the International Federation of Clinical Chemistry (IFCC) and the Siemens reference material.

*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.

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
www.kovalent.com.br
CNPJ: 04.842.199/0001-56

Kit sizes variations on demand:

Anvisa No.	Kit size
80115310203	2 x 1 mL
80115310203	4 x 1 mL

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

Expiration date and Lot no.: See label