

## Instructions for Use

For *in vitro* diagnostic use

## CONTROLE MULTIPARAMÉTRICO DE PROTEÍNAS

### Multiparametric Proteins Control

Anvisa 80115310078

#### ORDER INFORMATION

Cat. No.	Kit size
4140002KC	2 x 1 mL

#### INTENDED USE

Accuracy control for the determination of proteins in serum by turbidimetry and nephelometry.

#### COMPOSITION

A dilution of human plasma with phosphate buffered saline.

Stabilizer: Sodium azide 0.095 g %

Ready for use.

#### STORAGE AND STABILITY

Liquid control, ready to use.

The expiration date of the product stored between +2°C and +8°C is indicated on the label.

Once the bottles have been opened, they can be used for 6 weeks if well closed and stored between +2°C and + 8°C.

Do not freeze.

#### WARNINGS AND PRECAUTIONS

1. Take the necessary precautions when handling laboratory reagents.
2. Each individual donation intended for use in manufacture of the controls and standards was tested negative 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.
3. 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 parameter
2. Micropipettes and tips

#### ASSAY PROCEDURE

Applications for automatic systems are available upon request or on our website: [www.kovalent.com.br](http://www.kovalent.com.br)

Use the control as if it were a sample, following the procedure described in the instruction for use of the Kit.

Please refer to the marked Protein Instructions for Use.

#### ASSIGNED VALUES















The values of the analyte concentrations of this control are specific and valid only for the corresponding lot and are indicated in the table of values of each lot involved. The values were based on the ERM-DA470k standardization of the International Federation of Clinical Chemistry (IFCC), the World Health Organization (WHO) and Siemens.

\*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.

#### 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.grupokovalent.com.br](http://www.grupokovalent.com.br)

CNPJ: 04.842.199/0001-56

#### Kit sizes variations on demand:

Anvisa No.	Kit size
80115310078	1 x 1 mL
80115310078	1 x 2 mL
80115310078	1 x 5 mL

Customer service: [sac@kovalent.com.br](mailto:sac@kovalent.com.br) - (21) 3907-2534 / 0800 015 1414

Expiration date and Lot no.: See label