TOPKON 25-OH VITAMINA D AUTO

TopKon 25-OH Vitamin D Auto

Anvisa 80115310260

ORDER INFORMATION

Cat. No.	Kit size
4280002KC	2 x 1mL

INTENDED USE

TopKon 25-OH Vitamina D Auto control set is intended for use in the quality control of the Kovalent 25-OH Vitamina D AUTO kit.
For in vitro diagnostic use only

SUMMARY [1,2]

The Kovalent TopKon 25-OH Vitamina D Auto is a set of two control levels. These two levels are to be used for the quality control of the Kovalent 25-OH Vitamina D AUTO kit, which is a direct latex-particle-enhanced assay for the quantification of vitamin D in human serum and plasma.

REAGENTS

- **Reactive Components:**
  Human serum and additives
- **Non-reactive components**
  Sodium azide (NaN_3) <0.1%

The TopKon 25-OH Vitamina D Auto is a two-level set that is supplied in liquid form (2 x 1 mL). The CONTROL set is manufactured from human serum. The assigned values for these controls are lot specific and are expressed in ng/mL.

CONTROL VALUES

The values assigned to the controls are provided in the value table that comes with the kit.
Changes in the values of some analytes defined in those controls may occur due to the restandardization of reference material.
Each laboratory should establish corrective measures to be taken if values fall outside the range.

STORAGE AND STABILITY

The controls unopened are stable until the expiration date, if stored at a temperature of 2 to 8 °C, protected from light and contamination is avoided. Do not freeze the controls!
Store the control tightly capped when not in use.

WARNINGS AND PRECAUTIONS

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Take normal precautions for handling all laboratory reagents. Each serum donor unit used in the preparation of this Control Set was tested by FDA-approved methods and was negative for Human Immunodeficiency Virus Antibody (HIV I/II Ab), Hepatitis B Surface Antigen (HBsAg), and Hepatitis C Virus Antibody (HCV). As no method can offer complete assurance as to the absence of infectious agents, this material and all patient specimens must be handled as if they could transmit infectious diseases and disposed of accordingly.
3. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
4. For professional use only!

CONTROL PREPARATION

The TopKon 25-OH Vitamina D is ready to use and supplied in liquid form. Mix carefully before each use.

LIMITATIONS

As with any latex-particle-enhanced assay, 25-OH Vitamina D AUTO Assay runs should be followed with appropriate wash steps. Please consult instrument manuals for further information.

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.

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

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

Expiration date and Lot no.: See label