


## Vitamin D Calibrator

<b>LOT</b>	Expiry date 
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### Intended Use

The Vitamin D calibrator set is intended for use in the calibration of the Vitamin D assay. **For in vitro diagnostic use only.**

### Summary

The Vitamin D calibrator set is a set of five calibrator levels. These five levels are to be used for the five-point calibration of the Vitamin D assay, which is a direct particle-enhanced assay for the quantification of vitamin D in human serum and plasma.

### Reagents – Working solutions

#### Reactive components

- Human serum and additives

#### Non -reactive components

- Sodium azide (NaN<sub>3</sub>) < 0.1 %

The Vitamin D Control set is supplied in liquid form (5x1 ml). The calibrator set is manufactured from human serum. The assigned values for these calibrators are not specific and are expressed in ng/mL.

### Calibrator values

The assigned calibrator values are provided on the Certificate of Analysis.

### Precautions

- For *in vitro* diagnostic use only. Rx Only.
- Exercise the normal precautions for handling all laboratory reagents. Each donor unit of serum in the preparation of these materials were tested by approved methods and found negative Hepatitis B surface antigen (HBsAg), and Hepatitis C Virus antibody (HCV). Because no method can offer complete assurance as to the absence of infectious agents, this material and all samples should be handled as though capable of transmitting.
- Additional safety information concerning storage and handling of this product is provided within the MSDS for this product.
- Avoid contact with skin and eyes.
- Contains sodium azide, which may react with lead or copper plumbing to form explosive compounds. Flush drains with copious amounts of water when disposing of this reagent.

### Handling, Storage and Stability

The Vitamin D calibrator set is supplied in liquid form. Mix carefully before each use.

Store at 2 to 8 °C. **DO NOT FREEZE.**

Note: Store calibrator tightly capped when not in use.

#### Stability

Unopened vial: stability is up to the expiration date on label when stored at 2 to 8 °C.

### Materials provided

The Vitamin D control set consists of 5 vials.

### Materials required but not provided

- Vitamin D assay reagents cod. R000000005
- General laboratory equipment

### Limitations

As any particle – enhanced assay, Vitamin D Assay runs should be followed with appropriate wash steps. Please consult instrument manuals for further information.

Vitamin D reagent, calibrator and control should be stored at 2-8 °C. **DON NOT FREEZE**

### Disposal of reagent








Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

**The product is in conformity with D.L: 8 September 2000, no. 332 "Actuation of the directive 98/79/EC regarding in vitro medical diagnostic devices".**

### Assigned Values

Calib. Level	Value
1	
2	
3	
4	
5	

### Symbols on labels and packaging

	In vitro diagnostic medical device
	Catalog Number
	Lot number
	Manufacturer
	Expiry date
	Temperature limitation
	Consult Instructions for use

### History Revision

08/2018	First Emission
10/2023	General reorganisation

