

# VITAMIN D SYSTEM PACK

(Latex Turbidimetry Method)

B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic chem 400 (Fully Auto Biochemistry Analyzer)



Code	Product Name	Pack Size
UNI74	Vitamin D System Pack	1x20 + 1x5 ml

## INTENDED USE

Vitamin D is one of the essential nutrients for the human body and has significant implications for human health.

Vitamin D Diagnostic Reagent Kit is used for quantitative in vitro determination of Vitamin D in human serum.

## CLINICAL SIGNIFICANCE

Vitamin D is an indispensable trace element in the human body. A large number of studies have shown that with age, the blood pressure increase of people who are deficient in vitamin D is 20% higher than that of people with sufficient Vitamin D; people with low Vitamin D levels has much higher risk to develop their first cardiovascular accidents within 5 years and their cardiovascular disease mortality is double that of people with sufficient Vitamin D.

Adequate Vitamin D levels can effectively reduce the risk of colon tumors, breast tumors, and ovarian tumors. At the same time, studies have confirmed that Vitamin D levels are positively correlated with insulin sensitivity, and the incidence of type 2 diabetes is negatively correlated with Vitamin D levels. It can be seen that ensuring adequate Vitamin D levels can reduce the risk of type 2 diabetes. In addition, Vitamin D can also regulate gene expression and further regulate immune cells. Vitamin D receptor (VDR) polymorphisms and serum Vitamin D status are both closely associated with the risk of autoimmune diseases such as multiple sclerosis (MS), type 1 diabetes, systemic lupus erythematosus (SLE), and rheumatoid arthritis (RA).

## PRINCIPLE

When the vitamin D in the sample binds to the latex-coated anti-vitamin D antibody in the reagent, an antigen-antibody complex forms, producing a certain turbidity. The level of turbidity is proportional to the amount of antigen in the presence of a certain amount of antibody. The quantitative determination of vitamin D can be performed by measuring turbidity at a wavelength of 700 nm and using a multi-point calibration curve.

## REAGENT COMPOSITION

### Reagent 1: Vitamin D Reagent 1

Phosphate buffer	<100 mmol/L
Sodium chloride	131 mmol/L
Perfluorohexanoic acid	< 1%
Methanol	< 10%

### Reagent 2: Vitamin D Reagent 2

Bovine serum albumin	0.1g/L
Phosphate buffer	<100 mmol/L

Reagents are liquid, ready to used

## Reagent 3: Vitamin D Calibrator (6 levels Calibrator)

Calibrator are liquid, ready to used

## STORAGE AND STABILITY

This kit stays stable during its shelf life when stored in a dark condition at +2-+8°C (do not freeze). After being opened for the first time, the kit

can be stored at +2-+8°C in an anti-pollution environment and stays stable for 30 days.

On board stability: Min 20 days if refrigerated (+8-+14°C) and not contaminated.

## SPECIMEN PREPARATION

Fresh serum.

+2-+8°C, stable for 3 days.

## REFERENCE INTERVAL

30-100 ng/mL

It is recommended that each laboratory should establish its own reference interval.

## QUALITY CONTROL

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits

## PERFORMANCE CHARACTERISTICS

### 1.Measuring range: 8 - 150ng/mL

Samples above this concentration should be diluted 1+1 with 0.9% NaCl solution and the result multiplied by 2.

### 2.Sensitivity: 8 ng/mL

### 3.Precision

Intra-assay precision Within run (n=20)	Mean (ng/mL)	SD (ng/mL)	CV (%)
Sample 1	20.227	0.38	1.90
Sample 2	41.787	0.88	2.12

  

Inter-assay precision Run to run (n=20)	Mean (ng/mL)	SD (ng/mL)	CV (%)
Sample 1	31.54	0.46	1.45

## COMPARISON

A comparison between Beacon vitamin D (y) and a commercially available test (x) using 20 samples gave following results:  $y = 0.9673x - 0.9903$  ng/mL  $r = 0.9848$

## INTERFERENCE

Bilirubin  $\leq 40$ mg/dL, hemoglobin  $\leq 500$ mg/dL, intralipid  $\leq 3\%$  do not affect the test results. In order not to affect the test results, please pay special attention by the operation.

### GENERAL PRECAUTIONS

For in vitro diagnostic use only.

Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration. Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines.

### PRECAUTIONS FOR MEASUREMENT

Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.

Reagents with different lot numbers should not be interchanged or mixed.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Material safety data sheet available for professional user on request.

Parameter For B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic chem 400 (Fully Auto Biochemistry Analyzer)

Test Name	VITAMIN D
Full Name	VITAMIN D
Pri Wave	700 nm
Sec Wave	-
Assay/point	2 Point end
Start	10
End	30
Decimal	2
Unit	ng/mL
Linearity Range Low	8 ng/mL
Linearity Range High	150 ng/mL
Sample Volume	3.0 µl
Reagent 1 (R1) Volume	160 µl
Reagent 2 (R2) Volume	40 µl
Substrate Depleted	-
Linearity	150 ng/mL
Out Of Linearity Range	-
Calibration Type	Spline
Points	6
Blank Type	Reagent
Concentration Blank	0.00
Concentration Std	Refer calibrator vial label

### Symbols Used On Labels



Catalogue Number



Manufacturer



See Instruction for Use



Lot Number



Content



Storage Temperature



Expiry Date



In Vitro Diagnostics

BEA/24/VID/UN/IFU Ver-01  
07/12/2025

