VITAMIN D SYSTEM PACK

(Latex Turbidimetric Method)

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200 ,
Beaconic chem 200, Beaconic B200, Beaconic analyzer 120,
Bonavera chem 100(Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack size
BA274	Vitamin D System Pack (Latex Turbidimetric Method)	1x20+1x5 ML

Intended Use

In vitro test for the quantitative determination of 25-OH VD concentration in serum or plasma.

Clinical Significance

Vitamin D is one of the essential nutrients for human body, which is of great significance to human health. In recent years, it has been found that vitamin D not only has the traditional bone effect of regulating calcium and phosphorus metabolism, but also is closely related to the occurrence of autoimmune diseases, infectious diseases, cardiovascular diseases, and plays an important non bone effect. Therefore, real-time detection of vitamin D content in the body is particularly important for the prevention of diseases and the diagnosis and treatment of diseases. 25-hydroxy vitamin D is usually used as the best index to balance the nutritional status of vitamin D. Adequate intake of vitamin D to maintain 25-OH VD at an appropriate level can not only enhance bone strength and prevent rickets, but also have more far-reaching research value in the prevention of cardiovascular diseases. When the concentration of 25-OH VD is too high, it may lead to poisoning.

Principle

The 25-hydroxy vitamin D in the sample is combined with the latex particles coated with anti 25-hydroxy vitamin D antibody in the reagent to form an insoluble immune complex. The turbidity of the reaction solution increases in direct proportion to the concentration of 25-hydroxy vitamin D in the sample, and the absorbance also increases.
Compared with the standard absorbance, the concentration of 25-hydroxy vitamin D in the sample can be calculated.

Reagent Composition

Reagent 1: Vitamin D Reagent 1
Reagent 2: Vitamin D Reagent 2
Reagent 3: Vitamin D Calibrator (5 levels Calibrator)

Reagent Prepration

Reagent are liqiud,ready to use.

Stability and Storage

1. The reagents are stable for under closed conditions at +2-+8℃ and are forbidden from freezing.
2. Store 2-8 ℃ after opening lid, stable for 30 days.
3. Calibrators and quality controls are stored at +2-+8 ℃ until the end of the expiration date, After re dissolution, it can be stored in a closed manner at + 2 ℃ ~ +8 ℃ for 7 days.

Sample Requirements

1. The samples are fasting serum and plasma (EDTA, heparin, anticoagulation).The samples should be transported and to red under low temperature conditions. After the samples are collected, they need to be refrigerated and centrifuged quickly. The samples can be stored for 48 hours at+ 2-+8 ℃. Serum needs to be refrigerated if the test is delayed.

Calibration

Multipoint calibration correction is adopted. It is recommended to use the company's supporting calibrators. Recalibration shall be carried out when the reagent batch number is changed, the quality control drifts, the instrument is maintained and important parts are replaced.

Quality control

Before testing the samples every day, quality control must be carried out to ensure the stability of the test system. It is recommended to use the company's supporting quality control products. If you use products from other manufacturers, please verify by yourself. The determination results of quality control materials shall be within the allowable range. If the result deviates from the range, please follow the following steps to find the cause:

1) Check whether the parameter setting and light source are correct.
2) Check whether the cuvette and sampling probe are clean.
3) Check whether the water is polluted and the result is incorrect.
4) Check the reaction temperature.
5) Check the validity of the kit

Outcome calculations

ΔA = [ΔA sample]- [ΔA blank]

Reference Intervals

Each laboratory should establish its own reference intervals based upon its patient population. The reference intervals measured at + 37 °C listed below were taken from literature.

Serum / Plasma:	30-100 ng/mL ;
Lack	＜ 10 ng/mL;
Insufficient	10-29 ng/mL;
Adequate	30-100 ng/mL;
Potential toxicity	＞ 100 ng/mL .

Interpretation of test results

The cuvette, light source, sample needle, hemolyzed sample, and sample placement time may affect the measurement result. When the test results are inconsistent with the clinic, a confirmation test should be performed and combined with the patient's medical history, symptoms and other results.

Limitations of the test method

Bilirubin ≤ 20mg / dl, Hemoglobin ≤ 5g / L, Triglyceride ≤ 1000mg / dl, Ascorbic acid ≤ 20mg / dl, RF ≤ 100IU/ml have no effect on the test results.

Performance Data

1. Reagent blank absorbance:

when tested with purified water as sample, the absorbance of the reagent blank is ≤ 2.0 (wavelength700 nm, optical diameter 1.0 cm).

2. Analysis sensitivity:

When measuring samples containing 10ng/mL of 25-OH- VD, Change in absorbance of 1 ng/mL 25-OH-VD(Δ A) ≥ 0.001.

3. Linear range:

3.1 When sample concentration at [4, 150] ng/mL, the linear correlation coefficient between theoretical and measured concentrations, R ≥ 0.990.

3.2 Sample concentrations at [4, 10]ng/mL, requiring that the absolute deviation should not exceed 1ng/mL; Concentrations of samples at (10, 150]ng/mL, the relative deviation was required to be no more than ± 10%.

4. Precision:

Within-run : CV≤7% Between-run: CV≤10%

5. Accuracy:

Test 25-hydroxy vitamin D quality control serum, repeat the test for 3 times, and the relative deviation of the test results shall not exceed ± 15%.

Warnings and Precautions

1. For in vitro diagnostic use.
2. Take the necessary precautions for the use of laboratory reagents.
3. Preservative contained. Do not swallow. Avoid contact with skin and mucous membranes.
4. Disposal of all waste material should be in accordance with local guidelines.

Reagents with different batch numbers cannot be mixed. Please calibrate again when changing reagent batch numbers!

Warning And Precautions

MSDS will be provided on request.

Waste Management

Please refer to local legal requirements.

Parameter For B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem200 , Beaconic chem 200,Beaconic B200,Beaconic analyzer 120,Bonavera chem 100 (Fully Auto Biochemistry Analyzer)

Test Name	VITAMIN D
Full Name	VITAMIN D
PRI Wave	700
Sec Wave	None
Assay/point	1 Point End
Start	-
End	34
Decimal	2
Unit	ng/ml
Linearity Range Low	4
Linearity Range High	150
Sample Volume	3 µL
Reagent 1 (R1) Volume	160
Reagent 1 (R2) Volume	40
Substrate Depleted/Abs.limit	-
Linearity	150 ng/ml
Out Of Linearity Range	-
Calibration Type	Spline
Points	5
Blank Type	Reagent
Concentration Blank	-
Concentration STD	Refer vial label

Note
The program is made as per the in house testing, it can be modified as per requirements.
Clinical diagnosis should not be made on findings of a single test results, but both clinical and laboratory data.

SYMBOLS USED ON LABELS

REF Catalogue Number

Manufacturer

See Instruction for Use

LOT Lot Number

CONT Content

Storage Temperature

Expiry Date

IVD In Vitro Diagnostics