Hipro Biotechnology Co.,Ltd

EN
ENGLISH

25-OH-VD

25-hydroxy-Vitamin D Test Kit
(Immune Fluorescence Detection Method)

Instructions for Use

Version: A/6

REF HP-25-OH-VD-25

Manufacturer

Shijiazhuang Hipro Biotechnology Co., Ltd.
No. 3 Building, Block C, Fangyi Science Park, No. 365 Huai'an East Road, Hi-tech Zone, Shijiazhuang, 050000 Hebei P.R. China
After sale service: 400-0191-606
www.hipro.us

EC REP Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Tel: +31644168999

Product Name

General Name：25-hydroxy-Vitamin D Test Kit（Immune Fluorescence Detection Method）

Specification

Package Specification
25 Tests/ Kit.

Intended Use

This product is used to determine the content of 25-hydroxy-Vitamin D (25-OH-VD) in human serum, it is mainly used for the auxiliary diagnosis of vitamin D deficiency related diseases.

Test Principle

The 25-hydroxy-Vitamin D in the sample and the monoclonal antibody in reagent 1 become to immune complexes. The antigenic determinant-DNA coupling template in Reagent 2 binds to the remaining monoclonal antibodies, and the unbound antigenic determinant-DNA coupling template and dNTPs are used to synthesize double-stranded DNA products under the action of polymerase. This product binds to fluorescent dyes and will produce fluorescence which is proportional to the intensity of fluorescence and samples of 25-OH-VD levels. Using specific protein analyzer to measure the intensity of fluorescence, the concentration of 25-OH-VD is determined by comparing the fluorescence intensity of samples to the standard concentration.

Component

The 25-OH-VD test kit consists of two reagents R1 and R2, as shown on Figure 1.

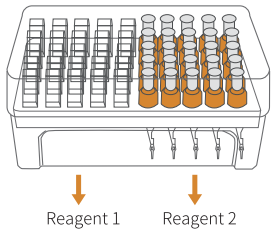


Figure 1

Name	Content	Quantity
Reagent 1 (R1)	Anti 25-hydroxy-Vitamin D antibody	>60mg/L
	Deoxyribonucleic acid (DNA) polymerase	>10U
	Triphosphate deoxyribonucleic acid (dNTP)	10mM
	DNA dye	Appropriate
Reagent 2 (R2)	Tris buffer	1mol/L
	Monoclonal antibody specific binding to determinant-DNA coupling template	>60mg/L
IC card (optional)	/	1

Do not mix different batches of reagents.

Storage&stability

Store the test kit at 2°C-8°C until the expiration date indicated on the label. The test kit is stable for one year when unopened.

Use up the test kit within one month after opening the package.

Do not freeze the test kit.

Do not mix different lots of the test kit.

Special Instrument Requirements

HP-083/4-I POCT Immunoassay System,
HP-083/4-II POCT Immunoassay System,
HP-AFS/1 Automatic Immunoassay System,
HP-AFS/3 Automatic Immunoassay System.

Specimen type

Serum, avoid hemolysis. Fasting blood collection and separation of serum as soon as possible. The sample store at 2-8°C for 3 days, -20°C for 1 month. Avoid repeated freezing. Before test, ensure fully mixed.

Procedures

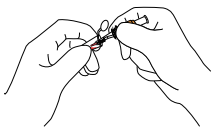
HP-083/4-I&HP-083/4-II POCT Immunoassay System

Note:

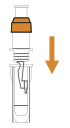
- Please read user manual of HP-083/4-I and HP-083/4-II before use.
- The analyzer will finish self check after start-up.
- Insert the IC card of 25-OH-VD test kit to let analyzer read the parameter.
- The analyzer calibration can be done with app. It is recommended that analyzer calibration should be done for each new lot of test kit.

Step 1 Sample Preparation

1a Allow the test kit back to room temperature for 30 minutes before use.



1b Use the R2 with quantitative capillary to collect sample.

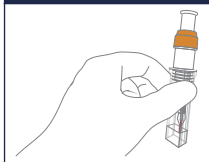


1c Insert the R2 into R1.

Note:

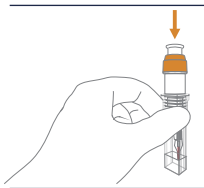
- The parameter is built in the IC card.
- Please insert the corresponding IC card into analyzer to let the analyzer read the parameter before each assay test.
- The capillary of the R2 should be fully filled.

Step 2 Testing



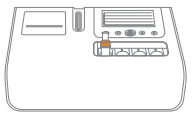
2a Hold the narrow side of R1 and shake from left to right for 12 times to let the sample completely mix with R1.

Note: Do not hold the wide sides of R1.



2b Press the piston on R2.

2c Hold the narrow sides of R1 and shake for 3-5 seconds to let R1 and R2 mix well.



2d Insert the R1 into test channel of HP-083/4-II and the analyzer will finish the test and print out results automatically.

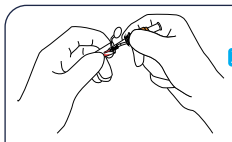
HP-AFS/1&HP-AFS/3 Automatic Immunoassay System

Note:

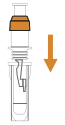
- Please read user manual of HP-AFS/1 and HP-AFS/3 before use.
- The analyzer will finish the self check after start-up.
- It is recommend to do analyzer calibration monthly and for each new lot of test kit.

Step 1 Sample Preparation

3a Allow the test kit back to room temperature for 30 minutes before use.



3b Use the R2 with quantitative capillary to collect sample.

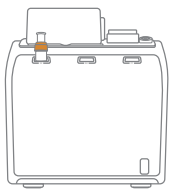


3c Insert the R2 into R1.

Note:

- Please update the standard curve with the barcode on the R1 cuvette if a new lot test kit is to be used.
- The capillary of the R2 should be fully filled.

Step 2 Testing



4a Insert the R1 into test channel of analyzer.

4b The analyzer will mix the sample from R2 capillary with R1 automatically.

4c The analyzer will mix the R2 and R1 automatically.

4d The analyzer will test and print the results automatically.

Calibration

The calibration values for the different lots of the kits are stored on the calibration IC card or the two-dimensional code on the cuvette. Before test the new lot of kits, read the calibration card parameters first. Or the instrument automatically scan the two-dimensional code on the cup to obtain the corresponding calibration curve during testing.

Quality control

3- level calibration system guarantee the results' reliability for each lot of test kits, including the instrument calibration, remote reagent calibration and the third party calibration.

The third party calibration applicable for:

1. The daily indoor quality control test.
2. New lots of reagent.
3. New operator training.
4. The results can not match the clinical symptoms.
5. The first use of the reagent.

If still can not be calibrated, contact the manufacture for further technical support.

Reference Value

30 ～ 100ng/mL recommended that each laboratory establish its own reference range.

Interpretation

The test results＜30ng/mL indicate local vitamin D deficiency; The test results>100ng/mL indicate that there may be vitamin D poisoning.

The result only for clinical reference, comprehensive consideration should be combined with the clinical management of patients with symptoms / signs, medical history, other laboratory tests and treatment response.

All laboratory tests depend on random errors. If the test results are in doubt, or if they do not match the clinical symptoms, re-test the sample or confirm the results with other methods.

Limitations

Hemoglobin>5g/L, triglyceride>5mmol/L, bilirubin>300μmol/L will affect the test result.

Performance Characteristics

1. Linearity range: 5ng/mL ～ 130ng/mL.
2. Detection limit: ⩽3.0ng/mL.

   The limit of detection means the lowest detectable analyte level that can distinguish the concentration. Calculate based on the minimum standard above the two standard deviation of the data (Blank table, 1+2SD, within-run precision, n=20).

3. Precision

   Test the control material by 25-hydroxy-Vitamin D Test Kit 2 times per day for 20 days (n=80) according to EP5-A2 of CLSI.

The data as below:

a.

HP-083/4-II POCT Immunoassay System					
Sample	Mean ng/mL	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	12.85	0.82	4.2	0.75	6.8
Control 2	48.63	1.98	5.6	2.24	4.5
Control 3	121.35	5.24	4.8	4.85	7.3

b.

HP-AFS/3 Automatic Immunoassay System					
Sample	Mean ng/mL	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	13.03	0.72	5.6	0.78	6.0
Control 2	47.56	2.14	4.5	2.37	5.0
Control 3	124.13	5.15	4.1	5.25	4.2

c.

HP-AFS/1 Automatic Immunoassay System					
Sample	Mean ng/mL	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	13.28	0.78	6.2	0.72	7.2
Control 2	48.06	2.32	4.8	2.23	6.3
Control 3	123.45	5.64	4.6	5.45	4.8

4.Methodology comparison

Compared to 25-OH-VD LIA(x) by test the same serum sample, the relative data as below:

HP-AFS/3 Automatic Immunoassay System				
Site No.	Sample Type	No.of Assays	Regression Line	Coefficient correlation
1	Serum	50	Y= 0.97X+0.78	0.96

The concentration of sample is about 5ng/mL ～ 130ng/mL.

Precautions

⚠ Attention:

Only for in vitro diagnostic.

Only for professional use.

All samples and reactive wastes are treated as sources of infection.

Do not use the kits beyond shelf life.

Do not mix different batches of reagents.

⚠ Warning:

To avoid error, do not forced to take out the cuvette from the device. Follow the device operation manual strictly, If the problem cannot be solved, contact the manufacturer for further technical support.

SYMBOLS USED ON LABELS

Symbol	Usage	Symbol	Usage
	Use-By date		Do not freeze
LOT	Batch code		Biological risks
	Manufacturer		Do Not Reuse
2°C 8°C	Temperature Limit		
Σ	Contains sufficient for <n> tests		
	Do not use if package is damaged		
	Consult Instructions for use		
	Keep Away from Sunlight		
IVD	In Vitro Diagnostic Medical device		
EC REP	Authorized Representative in the European Community		

References

1.Ren J, Sun B, Miao P, et al. Correlation between serum vitamin D level and severity of community acquired pneumonia in young children [J]. Zhongguo Dang Dai Er Ke Za Zhi, 2013,15(7): 519-521.

2.Kang Chunhua, Ye Yihua, Xie Zhichao. Vitamin D is used to treat children with community-acquired pneumonia [J]. Hainan Medical, 2013, 24(2): 194-196.

Approval Date&Revision Date

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Revision Date: May 6,2016
Revision Date: May 1, 2017
Revision Date: Jan 1, 2021
Revision Date: Apr 1, 2021
Revision Date: Jan 1, 2023
Revision Date: Dec 22,2023

CE IVD

尺寸：24*25cm展开尺寸，横向三折页再垂直方向两次对折