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CE IVD

25-OH-VD
Fast Test Kit
(Immunofluorescence Assay)

IF1031 for Getein1100
IF5031 for Getein1160
IF3031 for Getein1180
REF IF2031 for Getein1600
IF4031 for Getein1200

User Manual

INTENDED USE

25-OH-VD Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of 25-OH-VD in human serum and plasma samples. This test may help understand the metabolic changes of bone.

SUMMARY

Vitamin D3 is a fat-soluble precursor for steroid-like hormone. It is transformed into the biologically active molecule 1,25 dihydroxy vitamin D. After being synthesized in the skin or absorbed (in chylomicrons) from the gastrointestinal (GI) tract, most vitamin D is bound to specific carrier proteins in the blood (vitamin D–binding protein [DBP] and albumin) and transported to the liver. In the liver, vitamin D is hydroxylated by the enzyme 25-hydroxylase (CYP2R1) to become 25(OH)D. 25(OH)D is the major circulating form of vitamin D, testing of 25(OH)D help assessing the total-body vitamin D status.
Vitamin D is a major contributor for maintaining bone health, and vitamin D deficiency is also related with immunomodulation, diabetes, kinds of cancer, cardiovascular disease, autoimmune disease, congenital immune disease.

PRINCIPLE

The test is based on the principle of competitive immunoassay, it uses a high sensitive anti-human 25-OH-VD monoclonal antibody and 25-OH-VD antigen, the antibody is conjugated with fluorescence latex and coated on the junction of NC membrane and sample pad, the 25-OH-VD antigen is coated on the test line. The sample applied to the test strip moves by the suction of absorbent paper, the fluorescence latex-labelled anti-human 25-OH-VD monoclonal antibody binds with the 25-OH-VD in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone. Then marked antigen-antibody complex is captured on the test line by the anti-human 25-OH-VD antigen. Meanwhile, 25-OH-VD antigen would compete with the 25-OH-VD in the sample for fluorescence latex-labelled anti-human 25-OH-VD monoclonal antibody.
Then insert test card into Getein1100/Getein1160/Getein1180 Immunofluorescence Quantitative Analyzer / automatically inserted by Getein1200/Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1160, Getein1180, Getein1200 and Getein1600), the concentration of 25-OH-VD in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

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1. A kit for Getein1100/Getein1160/Getein1180 contains:
Package specifications: 25 tests/box, 10 tests/box
1) Getein 25-OH-VD test card in a sealed pouch with desiccant
2) Disposable pipet
3) Sample diluent 1
4) User manual: 1 piece/box
5) SD card: 1 piece/box

2. A kit for Getein1200/Getein1600 contains:
Package specifications: 2×24 tests/box, 2×48 tests/box
1) Sealed cartridge with 24/48 Getein 25-OH-VD test cards
2) User manual: 1 piece/box
Materials required for Getein1200/Getein1600:
1) Sample diluent 1: 1 bottle/box
2) Box with pipette tips: 96 tips/box
3) Mixing plate: 1 piece/box

3. Sample diluent 1 composition:
Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

4. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labeled anti-human 25-OH-VD monoclonal antibody, the test line is coated with 25-OH-VD antigen, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.
Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICES

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months.
Use the test card for Getein1100/Getein1160/Getein1180 within 1 hour once the foil pouch is opened.
For test card of Getein1200/Getein1600: If the cartridge is opened, it could be used up within 7 days once exposure to air. Please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch or the cartridge is damaged.
4. Do not open pouches or the cartridge until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
8. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum and plasma. Heparin, sodium citrate and EDTA*** can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
2. If testing is delayed, serum and plasma samples may be stored up to 7 days at 2~8℃ or stored at -20℃ for 6 months before testing.
3. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
4. Do not use heat-inactivated or hemolysis samples.
6. SAMPLE VOLUME ***(for Getein1100/Getein1160/Getein1180): 40 μL***.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should reach to room temperature before test.

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
4. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
5. Put the test card on a clean table, horizontally placed.
6. Using sample transfer pipette, deliver ***40 μL*** of sample into one tube of sample diluent 1, mix gently and thoroughly for 2 mins. Then drop ***100 μL*** of the sample mixture into the sample port on the test card.
7. ***Reaction time: 15 minutes***. Insert the test card into Getein1100 and click on “Start” icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:

8. Confirm SD card lot No. in accordance with test kit lot No..Perform “SD card” calibration when necessary.
9. Enter testing interface of Getein1160/Getein1180.
10. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
11. Put the test card on a clean table,horizontally placed.
12. Using sample transfer pipette, deliver ***40 μL*** of sample into one tube of sample diluent 1, mix gently and thoroughly for 2 mins. Then drop ***100 μL*** of the sample mixture into the sample port on the test card.
13. ***Reaction time: 15 minutes***. Insert the test card into Getein1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time

and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1200/Getein1600:

14. Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
15. Place the sample diluent 1 at the correct position in Getein1200/Getein1600.
16. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1200/Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform “SD card ” calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits for Getein1100/Getein1160/Getein1180.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1160/Getein1180/Getein1200/Getein1600.

EXPECTED VALUE

The expected normal value for 25-OH-VD was determined by testing samples from 453 apparently healthy individuals. The reference range of 25-OH-VD is 30.00 ng/mL~50.00 ng/mL calculated by using normal distribution methods giving a level of confidence of approximately 95%. The concentration of 25-OH-VD varies with gender, age, season, geographical latitude and race.

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	8.00~70.00 ng/mL
Lower Detection Limit	≤8.00 ng/mL
Within-Run Precision	≤10%
Between-Run Precision	≤15%

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Samples containing interferent may influence the results. The table below listed the maximum allowance of these potential interferent.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	2 g/L	4 g/L	0.6 g/L

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1. Houghton LA, Vieth R. The case against ergocalciferol (vitamin D2) as a vitamin supplement. Am J Clin Nutr 2006; 84: 694-697.
2. Armas LAG, Hollis BW. Heaney RP. Vitamin D2 is much less effective than Vitamin D3 in humans. J Clin Endocrinol Metab 2004; 89 (11): 5387-5391
3. Souberbielle JC, Body JJ, Lappe JM, et al. Vitamin D and musculoskeletal health, cardiocascular disease, autoimmunity and cancer. Recommendations for clinical practice. Autoimmun Rev 2010; 9: 709-715.
4. Lip P. Vitamin D deficiency and secondary hyperparathyroidism in the elderly: consequences for bone loss and fractures and therapeutic implications. Endocr Rev 2001 Aug; 88 (8): 3501-3504.
5. Willet AM. Vitamin D status and its relationship with parathyroid hormone and bone mineral status in older adolescents. Proceeding of the Nutrition Society 2005; 64: 193-203.
6. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
7. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO18113-2:2011).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on 25-OH-VD Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult *instructions for use* or consult electronic *instructions for use*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
Σ	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community/ European Union
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		

Thank you for purchasing 25-OH-VD Fast Test Kit (Immunofluorescence Assay).

Please read this user manual carefully before operating to ensure proper use.

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