GP

CE IVD

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

Instructions for use

INTENDED USE

25-OH-VD Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of 25-OH-VD in human serum, plasma, whole blood and fingertip blood samples. This test is mainly used for the auxiliary diagnosis of vitamin D deficiency related diseases. For professional and laboratory use only.

SUMMARY

Vitamin D3 is a fat-soluble precursor for steroid-like hormone, which can transform into bioactive molecule 1,25 dihydroxy vitamin D. After being synthesized in the skin or absorbed (in chylomicrons) by the gastrointestinal (GI) tract, most vitamin D is bound to specific carrier proteins in the blood (vitamin D–binding protein [DBP] and albumin) and is 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, measurement of 25(OH)D helps to assess 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, various cancers, cardiovascular disease, autoimmune disease, congenital immune disease.

PRINCIPLE

25-OH-VD Fast Test Kit (Immunofluorescence Assay) is based on the lateral flow immunoassay technology in a sandwich design. Once the sample is applied to the test strip, the fluorescence latex-labelled anti-25-OH-VD monoclonal antibody will bind with 25-OH-VD in sample and form marked antigen-antibody complexes. These complexes move to the test card detection zone by capillary action. Then marked antigen-antibody complexes will be captured on test line by another anti-25-OH-VD monoclonal antibody. Fluorescent signals intensity can be analyzed by applicable device thus the amount of 25-OH-VD in the sample can be detected quantitatively.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer

CONTENTS

Materials provided	Getein 1100/ Getein 1160/ Getein 1180		Getein 1200/Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
25-OH-VD test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Sample diluent**	10*0.2 mL/tube	25*0.2 mL/tube	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

*25-OH-VD test card
A test card consists of: Fluorescence latex-labelled 25-OH-VD monoclonal antibody, 25-OH-VD monoclonal antibody and goat anti-mouse IgG antibody.
** Sample diluent
(1)Sample diluent for Getein 1100/Getein 1160/Getein 1180 is 0.2 mL contained in each tube consists of:
-Sample diluent main contains phosphate buffer (10 mmol/L), Preservative (0.05%).
(2)Sample diluent for Getein 1200/Getein 1600 is an independent packing box consists of:
-Sample diluent main contains phosphate buffer (10 mmol/L), Preservative (0.05%) (25 mL/bottle for Getein 1200, 4 mL/bottle for Getein 1600)
-Box with pipette tips (96 tips/box),
-Mixing plate (1 piece/box).
Note:
1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
2. Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Realtime stability:
Store the kit at 4~30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.
In-use stability:
For the test card of Getein 1100/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.
For test card of Getein 1200/Getein 1600: If the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, 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 disposable pipet.
6. Handle all specimens as potentially infectious. The foil bag is nondegradable. Proper handling and disposal methods should be followed in accordance with local regulations.
7. Carefully read and follow instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. Serum, plasma, whole blood and fingertip blood can be used as samples in the assay.
2. Heparin, sodium citrate and EDTA can be used as the anticoagulant for plasma and whole blood. EDTA can be used as the anticoagulant for fingertip blood. Do not use hemolysis specimens. It is recommended to use serum or plasma for more accurate test results.
3. This assay was designed and validated for use with human blood, other specimens or body fluids may not get accurate results.
4. This assay should be performed within 4 hours after samples being collected. If testing is delayed, serum and plasma may be stored up to 7 days at 2~8°C or stored at -20°C for 6 months before testing. Whole blood and fingertip blood may be stored up to 3 days at 2~8°C.
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.

TEST PROCEDURE

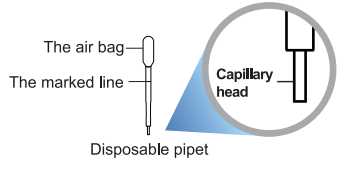
1. User must carefully read the instructions for use and operate in strict accordance with the instructions before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.

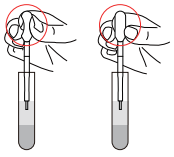
For Getein 1100:
(1) Confirm SD card lot No.in accordance with the test kit lot No., perform “SD card” calibration when necessary.
(2) Select the corresponding “Sample” on the analyzer according to the sample type (see the user manual of analyzer for details).
(3) Remove test card and disposable pipet from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
(4) Using disposable pipet or pipette, add 20 μL sample to the sample diluent, mix gently and thoroughly. Using the same disposable pipet or pipette, deliver 100 μL of the mixture into the sampling area of the test card.
(5) After reaction time (8 minutes) is elapsed, insert the test card into Getein 1100 and press "ENT" button or click on "Start" icon. The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:
(1) Confirm SD card lot No.in accordance with the test kit lot No., perform “SD card” calibration when necessary.
(2) Select the corresponding “Sample” on the analyzer according to the sample type (see the user manual of analyzer for details).
(3) Remove test card and disposable pipet from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
(4) Using disposable pipet or pipette, add 20 μL sample to the sample diluent, mix gently and thoroughly. Using the same disposable pipet or pipette, deliver 100 μL of the mixture into the sampling area of the test card.
(5) Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (8 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

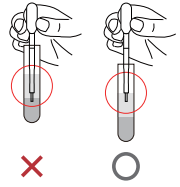
For Getein 1600/Getein 1200:
(1) Each cartridge for Getein 1600/Getein 1200 contains a specific RFID card which can calibrate automatically.
(2) Place the sample diluent at the correct position in Getein 1600/Getein 1200.
(3) Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1600/Getein 1200 will do the testing and print the result automatically.

Note:
The directions for using disposable pipet are as follow:



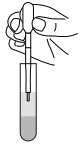


Note1: Do not depress the air bag of the disposable pipet with your finger during sampling.



Note 2: The capillary head of the disposable pipette touches the sample level gently and draws the sample automatically.

a.

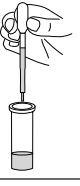


Gently hold the air bag of the disposable pipet and insert the disposable pipet into the sample collection tube. The sample will be sucked into the disposable pipette by capillary action.

b.

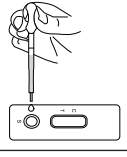
Insert the disposable pipette into the sample diluent. Squeeze the air bag 8 to 10 times to ensure the sample is fully mixed with the sample diluent.

c.



Squeeze the air bag, suck the sample mixed solution to **the marked line** on the disposable pipette.

d.



Add all the sucked sample vertically to the sampling area of test card.

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 the other test results and clinical information such as clinical signs and symptoms.
2. Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of each is as follows:

Interferent	Concentration (Max)
Triglyceride	400 mg/dL
Bilirubin	60 mg/dL
Hemoglobin	200 mg/dL

EXPECTED VALUE

The expected normal value for 25-OH-VD was determined by testing samples from 300 apparently healthy individuals. The reference range of 25-OH-VD is 10 ng/mL~50 ng/mL calculated by using normal distribution methods giving a level of confidence of approximately 95%.

At present, the consensus among most experts is that vitamin D deficiency should be defined as a 25-hydroxyvitamin D level of 20 ng/mL or less. Insufficiency of vitamin D is indicated when levels fall within the range of 21-29 ng/mL. The ideal concentration of 25-hydroxyvitamin D is considered to be 30 ng/mL or higher. The concentration of 25-OH-VD varies with gender, age, season, geographical latitude and race. It is recommended that each laboratory establishes its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	8.00~100.00 ng/mL
Limit of Detection	≤5.00 ng/mL
Within-Run Precision	≤10%
Between-Lot Precision	≤15%

REFERENCES

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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.
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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.
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9. Bailie G R , Massry S G .K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease[J].Pharmacotherapy, 2006, 25(12):1687-1707.
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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 detail 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
	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		Caution

Thank you for using 25-OH-VD Fast Test Kit (Immunofluorescence Assay). Please read this instructions for use carefully before operating to ensure proper use.

Version: WIF47-SJ-06

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Catalogue number	Applicable analyzer	Package specification
IF1031-10T	Getein 1100	10 T/kit
IF1031	Getein 1100	25 T/kit
IF5031-10T	Getein 1160	10 T/kit
IF5031	Getein 1160	25 T/kit
IF3031-10T	Getein 1180	10 T/kit
IF3031	Getein 1180	25 T/kit
IF4031	Getein 1200	2*24 T/kit
IF4031-96T	Getein 1200	2*48 T/kit
IF2031	Getein 1600	2*24 T/kit
IF2031-96T	Getein 1600	2*48 T/kit