# 25-OH-VD Test Kit User Manual(Dry Fluorescence Immunoassay)

**[PRODUCT NAME]**

25-OH-VD Test Kit (Dry Fluorescence Immunoassay)

**[PACKAGE SPECIFICATION]**

1 test/kit
5 tests/kit
25 tests/kit
50 tests/kit
100 tests/kit

**[INTENDED USE]**

25-OH-VD Test Kit (Dry Fluorescence Immunoassay) is intended for in-vitro quantitative measurement of 25-OH-VD (total 25 hydroxy vitamin D) in human serum, **plasma** and **whole blood**. This test is used as an aid in the assessment of vitamin D sufficiency.

**[TEST PRINCIPLE]**

25-OH-VD Test Kit (Dry Fluorescence Immunoassay) uses the principle of antigen-antibody reaction. The testing sample will migrate forward due to capillary action, then the 25-OH-VD of the sample will combine with antibody which is attached to fluorescence microspheres. This marked complex is attached to the detection area of immobilized antigen and the other fluorescence microspheres are attached to the control area. When the test strip is inserted into the analyzer, the analyzer automatically scans two ribbons and detected the fluorescence intensity of the composite emission from the testing area and the control area. The ratio of the two fluorescence values was used to calculate the content of the detected substances.

**[MAIN COMPONENTS]**

1. Test strip and special tip in sealed pouch with desiccant.....25 tests
2. Sample diluent.....25 pieces
3. QR code card for calibration.....1 piece
4. User Manual.....1 piece
5. Quantitative suction and dropping tube (Optional).

**Note: Do not mix or interchange different batches of kit.**

**[STORAGE AND VALIDITY]**

Store the test kit at 4°C-30°C, with a valid period of 18 months.
Test strip should be used within 30 minutes once the foil pouch is opened.

**[APPLICABLE DEVICES]**

1. LS-1000 Dry Fluorescence Immunoassay Analyzer
2. LS-2000 Dry Fluorescence Immunoassay Analyzer
3. LS-1100 Dry Fluorescence Immunoassay Analyzer
4. LS-2100 Dry Fluorescence Immunoassay Analyzer
5. LS-4000 Hand-Held Dry Fluorescence Immunoassay Analyzer
6. LS-7000 Dry Fluorescence Immunoassay Analyzer
7. LS-7100 Microfluidic and Dry Fluorescence Immunoassay Analyzer
8. LS-7800 Automatic Microfluidic and Dry Fluorescence Immunoassay Analyzer
9. LS-3000 Automatic Fluorescence Immunoassay Analyzer
10. LS-3100 Automatic Fluorescence Immunoassay Analyzer

**[SAMPLE REQUIREMENT]**

1. Used for human **serum, plasma and whole blood**. Other bodily fluids and samples may not get the accurate result.
2. At room temperature, the test should be performed within 4 hours after the sample collection.
3. It is suggested to use fresh sample to test. Blood sample with hyperlipidemia, jaundice, or hemolysis may not get accurate result.
4. The sample before testing should be recovered to room temperature (15°C-30°C).
5. **Sample Volume: serum/plasma 5μL, whole blood 20μL.**

**[TEST PROCEDURE]**

1. Collect samples according to user manual.
2. Before the test, the sample, test strip and sample diluent should be recovered to room temperature (15°C-30°C).

**For LS-1100:**

3. Perform QR code calibration when necessary. (Details refer to LS-1100 User Manual)
4. On the main interface of LS-1100, press “Test” icon to enter testing interface. Input patient information, sample information, doctor information when necessary. (Details refer to LS-1100 User Manual)
5. Remove test strip from sealed pouch and put it on a clean table, horizontally placed.
6. **Serum/plasma sample:**
   Use pipette to draw 5μL the sample into diluent, then blow gently and thoroughly for more then 10 times. And then blow more than 10 times with the special tip to ensure complete mixing of the material in the special tip and then standing for 10 minutes.
   **whole blood**
   Draw 20 μL whole blood sample into micro-anticoagulant tube, then centrifuge in the condition of 3000 rpm and 1min. Use pipette to draw 5μL the sample into diluent, then blow gently and thoroughly for more then 10 times. And then blow more than 10 times with the special tip to ensure complete mixing of the material in the special tip and then standing for 10 minutes.
   **Note: It is required to use the special tip which is sealed in the sealed pouch.**
7. Draw 100μL mixed fluid into the sample port in the test strip.
8. **Reaction Time: 10 minutes**
   For panel inside: Insert the test strip into the analyzer immediately after sample dispensing. Then click “Test”.
   For panel outside: After reaction time 10 minutes is elapsed, insert the test strip into the analyzer and then click “Test”.
9. The result will be shown on the screen and printed automatically.

**Notes: It is required to perform QR code calibration when starting to use one new batch of kit.**

**[EXPECTED VALUE]**

**Reference Range: >30ng/mL**

25-OH-VD concentration is determined using samples obtained from 200 apparently healthy individuals.
It is recommended that each laboratory establish its own reference range for the population it serves.

**[INTERPRETATION OF RESULT]**

1. If the test result of the sample is more than 70ng/mL, the analyzer displays ">70ng/mL", and if the result is less than 5.0ng/mL, the analyzer displays "<5.0ng/mL". Specific data can be exported through related software as needed.
2. When the sample concentration exceeds the detection limit, the maximum dilution ratio is 3 times when the sample is diluted with calf serum or negative sample.

**[LIMITATION]**

1. This kit is only for the serum and plasma test.
2. The test result of this kit are only one of the diagnostic aids for the clinicians.
3. The result of the test should be evaluated in the context of all the clinical and laboratory data available. In those instances where the laboratory results do not agree with the clinical evaluation, additional tests should be performed accordingly.

**[PRODUCT PERFORMANCE]**

1. Measuring Range: 5.0-70ng/mL.
2. Lower Detection Limit: ≤5.0ng/mL.
3. Accuracy: Verify with comparison experiments, the relative deviation ≤15%, the correlation coefficient r≥0.990.
4. Within-Run Precision: ≤15%.
5. Between-Run Precision: ≤15%.
6. Specificity: When the specificity test was performed, the results met the requirements.

**[PRECAUTIONS]**

1. Only used for in vitro diagnostics.
2. Do not use the kit beyond the expiration date.
3. After the test strip is removed from the sealed pouch, it should be tested as soon as possible to avoid excessive time in the air, resulting in dampness.
4. Do not reuse the test strip.
5. The damaged test strip or package cannot be used.
6. Do not mix the components of different kits.

**[REFERENCES]**


1. Lips P. Vitamin D physiology. Prog Biophs MolBiol, 92(2006) 4-8.
2. Holick MF, C Hen TC. Vitamin D deficiency a worldwide problem with health consequences. Am J Clin Nutr, 87(2008)1080-1086.
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5. Vitamin D and cancer: research status and prospects, vol. 25, no. 2, February 2013, life sciences.



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Production date and expiration see the label.


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| IVD | For in vitro diagnostic use only |
| REF | Catalog number |
| | Manufacturer |
| LOT | Lot number |
| EC REP | European Authorized Representative |
| | Date of Manufacture |
| | Use by date |
| | Consult instructions for use |
| 30℃ 4℃ | Store between 4-30℃ |
| Σ 25 | Contents Sufficient for < n > Tests |
| | Do not reuse |
| | Keep away from sunlight |
| | Fragile handle with care |
| | Keep dry |
| | Forbidden to inversion |