

Finecare™ Vitamin D Rapid Quantitative Test

Catalog No. W241P0008, W241P0009

INTENDED USE

The Finecare™ Vitamin D Rapid Quantitative Test along with Finecare™ FIA Meters (Model No.: FS-113, FS-114 or FS-205) is a fluorescence immunoassay for quantitative determination of total 25(OH) D2/D3 level in human serum, plasma, whole blood specimen. The test is used as an aid in the diagnosis of vitamin D deficiency.

For *in vitro* diagnostic use only. For professional use only.

SUMMARY

Vitamin D (VD) is a fat-soluble vitamin that is a cyclopentanoid, a group of vitamins that are structurally related to sterols and functionally protect against rickets.

Vitamin D deficiency is common and results in important consequences. The effects on bone (osteoporosis and osteomalacia) are mediated through the influence of vitamin D on calcium, phosphate and parathyroid hormone (PTH) homeostasis. The main effects of vitamin D deficiency on muscular function are negative effects on muscle strength mobility and falls risk. Identifying vitamin D deficiency in order to target supplementation to high risk subpopulations is important to optimise bone and muscle function. Furthermore, it is important to define optimal sufficiency of vitamin D in order to accurately define an appropriate target of therapy.

Serum concentration of 25 hydroxyvitamin D (25OHD) is the best clinical indicator of vitamin D metabolism. Since 25-hydroxylation is substrate but not product dependent, 25OHD and not 1,25OHD is associated with fracture risk. Hence 25OHD reflects total body reserves of vitamin D.

PRINCIPLE

The Finecare™ Vitamin D Rapid Quantitative Test is based on fluorescence immunoassay technology. The Finecare™ Vitamin D Rapid Quantitative Test uses a sandwich immunodetection method. Add the specimen to detection buffer and mix well. When the sample mixture is added into the sample well of the Test Cartridge, the fluorescence-labeled detector antibody on the conjugate pad will bind to antigen in specimen and form immune complexes. As the sample mixture migrates on the nitrocellulose membrane of test strip by capillary action, the complexes of detector antibody and antigen are captured to the other antibody that has been immobilized on membrane. Thus the more antigen in specimen, the more complexes are accumulated on membrane.

Signal intensity of fluorescence of detector antibody reflects amount of 25(OH)D captured and Finecare™ FIA Meters shows 25(OH)D concentrations in blood specimen. The signal is proportional to the 25(OH)D concentration. The default result unit of this test is displayed as XX.XX ng/mL from Finecare™ FIA Meters.

PRECAUTIONS

1. This kit is for *in vitro* diagnostic use only. Do not swallow.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date printed on the package.
4. Do not use Test Cartridge if its Lot No. does not match with Lot No. of ID Chip

that is inserted to the Finecare™ FIA Meters.

5. The desiccant is for storage purpose only, is not used in the test procedures.
6. The Finecare™ Vitamin D Rapid Quantitative Test is only operational in the Finecare™ FIA Meters. The tests should be applied by well-trained healthcare professionals, and conducted in central laboratories, GP offices, clinics, pharmacy etc.
7. The Test Cartridge should remain in its original sealed pouch until ready to use. Do not use the Test Cartridge if the pouch is punctured or not well sealed. Discard after single use.
8. There is a blue line on the test membrane, it will disappear after sample adding. This indicates that Test Cartridge has been used. Do not reuse the Test Cartridge.
9. Do not use damaged or stained materials provided in the test kit.
10. The test kit and instrument should be used away from vibration and magnetic field. During normal usage, the instrument may introduce minute vibration, which should be regarded normal.
11. The Test Cartridge, Pipette Tip, Sample Collector and Detection Buffer Tube, Sterile Lancet, Alcohol Pad and Band-Aid should be used for one specimen only. Discard after single use.
12. Do not use whole blood specimen when hemolysis or blood clot appears.
13. Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
14. The blood specimens and used materials, such as Test Cartridges, Detection Buffer Tubes, Sample Collectors and Pipette Tips, Sterile Lancet, Alcohol Pad and Band-Aid are potentially infectious. Proper safety techniques, handing and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by biological hazard materials.
15. The Finecare™ Vitamin D Rapid Quantitative Test should not be used as absolute evidence for vitamin D deficiency.
16. The results should be interpreted by the physician along with clinical findings and other laboratory test results.
17. If you have any questions or need help, please contact the local distributor to solve problems timely.
18. Notice to the users: Any serious incident that has occurred in relation to the Finecare™ Vitamin D Rapid Quantitative Test shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

MATERIAL

Material Provided

For Catalog No. W241P0008:

1. 25 individual Sealed Pouches, each containing:
 - 1 Test Cartridge
 - 1 Desiccant Pouch
2. 1 ID Chip
3. 1 Leaflet with Instructions for Use
4. 1 Leaflet with Quick Manual
5. 25 Pipette Tips
6. 25 Detection Buffer Tubes
7. 25 Sample Collectors

For Catalog No. W241P0009:

1. 25 individual Sealed Pouches, each containing:
 - 1 Test Cartridge
 - 1 Desiccant Pouch

2. 1 ID Chip
3. 1 Leaflet with Instructions for Use
4. 1 Leaflet with Quick Manual
5. 25 Detection Buffer Tubes
6. 25 Sample Collectors

Material Required But Not Provided

Function	Material Name	Note
Test instrument	Finecare™ FIA Meter Plus	Model No.: FS-113
	Finecare™ FIA Meter II Plus SE	Model No.: FS-114
	Finecare™ FIA Meter III Plus	Model No.: FS-205
Quality control	Finecare™ Vitamin D Control	Catalog No. W867-Z0P1-AG
Separate the serum/plasma	Centrifuge	For serum or plasma specimen only
Blood sampling	Vacuum blood collection tube	For venous whole blood, serum or plasma specimen
	Transfer pipette sets	100 µL specification
	Sterile lancets	Single-use, for fingerstick whole blood only
	Alcohol pads	Clean the finger or wipe away the blood
	Medical gloves	Well-fitting
Timekeeping for specific test step	Timer	/
Disposal	Biohazard container	Puncture proof is needed

STORAGE AND STABILITY

1. Store test kit for 24 months at 4 ~ 30°C.
2. Do not remove the Test Cartridge from the pouch until ready to use. The Test Cartridge should be used within 1 hour once opened.

SPECIMEN COLLECTION AND PREPARATION

For whole blood collected by fingerstick:

Puncture the finger with sterile lancet and proceed with blood collection by placing a Sample Collector on the finger. It is recommended that the specimen should be tested immediately.

For Venous Whole Blood:

Collect blood with a suitable vacuum blood collection tube (containing EDTA or Heparin). It is recommended that specimens should be tested immediately. If the specimen is not tested within 4 hours after collecting, it can be stored at 2 ~ 8 °C for 2 days.

For Serum or Plasma:

Separate the serum or plasma from blood as soon as possible to avoid hemolysis. It is recommended that specimens should be tested immediately. If the specimen is not

7tested within 8 hours after collecting, it can be stored at 2 ~ 8 °C for up to 3 days. For long-term storage, it can be kept below -20°C up to 3 months.

Note: Bring specimens to room temperature before testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. Only clear, non-hemolyzed specimens can be used.

TEST PROCEDURE

For complete information and operating procedures, please refer to Finecare™ FIA Meters Operation Manual. Bring all materials to room temperature before use. Tests should be performed at room temperature.

For Catalog No. W241P0008:

Step 1: Preparation

Ensure that the lot number of Test Cartridge matches the lot number of ID Chip as well as the Detection Buffer. Insert ID Chip into Finecare™ FIA Meters. Be aware not to touch the insertion tip of the ID chip.

Step 2: Sampling

For fingerstick whole blood, Quick Manual provided:

Puncture the patient's finger with a sterile lancet. Wipe away the first drop of blood. Draw 15 µL fingerstick whole blood specimen horizontally by using the Sample Collector. Put the Sample Collector into the Detection Buffer Tube.

For venous whole blood or Serum or Plasma:

Draw 15 µL whole blood, serum or plasma with a transfer pipette and add it to the Detection Buffer Tube, or draw 15 µL whole blood, serum or plasma with the Sample Collector and put the Sample Collector into the Detection Buffer Tube.

NOTE: The specimen may be inadequate if the Sample Collector is not placed horizontally.

Step 3: Mixing

Close the lid of Detection Buffer tube and mix the sample mixture thoroughly by shaking it about 10 times.

Step 4: Loading

Draw 75 µL sample mixture with a transfer pipette and load it into the sample well of Test Cartridge.

Step5: Testing

There are two test modes for Finecare™ FIA Meters, Standard Test mode and Quick Test mode. Please refer to the Operation Manual of Finecare™ FIA Meters for details.

a) For Standard Test Mode: For FS-113, FS-114, insert the Test Cartridge onto the Test Cartridge holder of Finecare™ FIA Meters right after adding sample mixture to the sample well. Press “Start Test” to start test (Apply to FS-113, FS-114). For FS-205, press “Test” then input the specimen types, press “Start” then insert the Test Cartridge into the Test Cartridge holder of Finecare™ FIA Meters right after adding sample mixture to the sample well to start test. The test result will be displayed on the screen after 10 minutes.

b) For Quick Test Mode: Set the timer and count down right after adding sample mixture into the sample well and leave the Test Cartridge at room temperature for 10 minutes. Then immediately insert the Test Cartridge into the holder of Finecare™ FIA Meters. Press “Start Test” to start test (Apply to FS-113, FS-114). The instrument will

automatically start to scan the Test Cartridge immediately. Read the results on the display screen of Finecare™ FIA Meters.

Step 6: Printing

If needed, test result can be printed by clicking “Print”.

For Catalog No. W241P0009:

Step 1: Preparation

Ensure that the lot number of Test Cartridge matches the lot number of ID Chip as well as the Detection Buffer. Insert ID Chip into Finecare™ FIA Meters. Be aware not to touch the insertion tip of the ID chip.

Step 2: Sampling

For fingerstick whole blood, Quick Manual provided:

Pre-pierce the sealing film of the Detection Buffer Tube using the Sample Collector lancet tip for later use. Puncture the patient's finger with a sterile lancet. Wipe away the first drop of blood. Draw 15 µL fingerstick whole blood specimen horizontally by using the Sample Collector.

For venous whole blood or Serum or Plasma:

Pre-pierce the sealing film of the Detection Buffer Tube using the Sample Collector lancet tip for later use. Draw 15 µL whole blood, serum or plasma with the Sample Collector.

NOTE: The specimen may be inadequate if the Sample Collector is not placed horizontally.

Step 3: Mixing

Insert the Sample Collector into the buffer tube and gently rotate the Sample Collector until the buffer tube is completely closed and then mix the sample mixture thoroughly by shaking it about 10 times.

Step 4: Loading

Gently remove the lid from the Detection Buffer Tube and squeeze the first 2 drops into the lid, then drop 4 drops of the sample mixture into the sample well of the Test Cartridge.

NOTE: All movement should be lightly, including piercing, inserting and rotating. Be careful not to overflow the buffer.

Step5: Testing

There are two test modes for Finecare™ FIA Meters, Standard Test mode and Quick Test mode. Please refer to the Operation Manual of Finecare™ FIA Meters for details.

a) For Standard Test Mode: For FS-113, FS-114, insert the Test Cartridge onto the Test Cartridge holder of Finecare™ FIA Meters right after adding sample mixture to the sample well. Press “Start Test” to start test (Apply to FS-113, FS-114). For FS-205, press “Test” then input the specimen types, press “Start” then insert the Test Cartridge into the Test Cartridge holder of Finecare™ FIA Meters right after adding sample mixture to the sample well to start test. The test result will be displayed on the screen after 10 minutes.

b) For Quick Test Mode: Set the timer and count down right after adding sample mixture into the sample well and leave the Test Cartridge at room temperature for 10 minutes. Then immediately insert the Test Cartridge into the holder of Finecare™ FIA Meters. Press “Start Test” to start test (Apply to FS-113, FS-114). The instrument will automatically start to scan the Test Cartridge immediately. Read the results on the

display screen of Finecare™ FIA Meters.

Step 6: Printing

If needed, test result can be printed by clicking “Print”.

INTERPRETATION OF RESULTS

The Finecare™ FIA Meters calculates 25(OH)D test results automatically and displays the exact concentrations of 25(OH)D on the screen as form of XX.XX ng/mL.

Reference Interval

1. A reference range study was conducted with samples from apparently healthy population from the China. There were approximately equal numbers of males and females. The age range was 5 to 85 years.

Sample	N	2.5 th percentile (ng/mL)	Median (ng/mL)	97.5 th percentile (ng/mL)
China apparently healthy population	400	11.99	25.00	39.13

2. Most experts agree that the vitamin D status as shown in the table below ⁶:

Concentration	Vitamin D Status
Total 25(OH) D2/D3 ≤ 20 ng/mL	Deficient
20 ng/mL < Total 25(OH) D2/D3 < 30 ng/mL	Insufficient
Total 25(OH) D2/D3 ≥ 30 ng/mL	Sufficient

Note: Each laboratory should establish a reference interval that is representative of the population to be evaluated. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.

Invalid: When the Finecare™ FIA Meters flag that no sample or sample volume is insufficient, it indicates an invalid test (the signal on the scan strip is below the preset minimum signal). Please retest.

QUALITY CONTROL

Each Finecare™ Vitamin D Rapid Quantitative Test contains internal control that satisfies routing quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test cartridge was inserted and read properly by Finecare™ FIA Meters. An invalid result from the internal control causes an error message on Finecare™ FIA Meters indicating that the test should be repeated.

Finecare™ Vitamin D Control (Catalog No. W867-Z0P1-AG) is recommended for Finecare™ Vitamin D Rapid Quantitative Test and can be used in the following cases:

- When a box of a new lot is opened;
- In case the Finecare™ FIA Meters or Finecare™ Vitamin D Rapid Quantitative Test are not working properly;
- In case the result and the symptoms are not consistent or if there are doubts about their accuracy.

Note: Please refer to the Instructions for Use of the Finecare™ Vitamin D Control for detailed operation.

TRACEABILITY

The Finecare™ Vitamin D Rapid Quantitative Test has been standardized against the certified reference material SRM 2972a.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human whole blood, serum and plasma specimen only.
2. This test has been verified for healthcare professionals use. Refer to point 6 of the PRECAUTIONS in this instruction for requirements of training and qualifications required by the users. Note that this test is not used for self-testing.
3. The results of Finecare™ Vitamin D Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If the test results of total 25(OH) D2/D3 do not agree with the clinical evaluation, additional tests should be performed.
4. The false negative results include non-specific adhesion of some components in specimen that have similar epitopes to bind captured and detector antibodies.
5. In the case of false positive results, the most common factors are: non-responsiveness of antigen to the antibodies by that certain unknown components are masking its epitope, such that antigen cannot be seen by the antibodies; instability of 25(OH)D, resulting in degradation with time, or temperature, such that they become no longer recognizable by antibodies; and degraded other test components.
6. Whole blood using anticoagulants other than EDTA or Heparin has not been evaluated in Finecare™ Vitamin D Rapid Quantitative Test and thus should not be used.
7. Other factors may interfere with Finecare™ Vitamin D Rapid Quantitative Test and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

PERFORMANCE CHARACTERISTICS

Measuring Range and Detection Capability

- **Measuring Range:** 5 ~ 100 ng/mL
- **Limit of Detection (LoD):** 5 ng/mL

Precision

Intra-Lot Precision:

Intra-Lot precision has been determined by using Vitamin D precision controls with one lot of test, the CV was ≤10%.

Inter-Lot Precision:

Inter-Lot precision has been determined by using Vitamin D precision controls with three lots of tests, the CV was ≤15%.

Linearity

Within the range of 5 ng/mL ~ 100 ng/mL, the linear correlation coefficient (r) is ≥

0.9900.

BIBLIOGRAPHY OF SUGGESTED READING

1. Bischoff-Ferrari, H. A., Giovannucci, E., Willett, W. C., Dietrich, T., & Dawson-Hughes, B. Estimation of optimal serum concentrations of 25-hydroxyvitamin D for multiple health outcomes. The American journal of clinical nutrition, 2006, 84(1), 18–28.
2. Malabanan, A., Veronikis, I. E., & Holick, M. F. Redefining vitamin D insufficiency. Lancet (London, England), 1998, 351(9105), 805–806.
3. Autier, P., Boniol, M., Pizot, C., & Mullie, P. Vitamin D status and ill health: a systematic review. The lancet. Diabetes & endocrinology, 2014, 2(1), 76–89.
4. Glendenning, P., & Prince, R. L. What is the therapeutic target level of 25-hydroxyvitamin D in osteoporosis and how accurately can we measure it?. Internal medicine journal, 2012, 42(10), 1069–1072.
5. Glendenning, P., & Inderjeeth, C. A. Vitamin D: methods of 25 hydroxyvitamin D analysis, targeting at risk populations and selecting thresholds of treatment. Clinical biochemistry, 2012, 45(12), 901–906.
6. Chinese Society of Osteoporosis And Bone Mineral Research. Consensus on the clinical applications of Vitamin D and its analogues. Chinese Journal of Osteoporosis and Bone Mineral Research, 2018, 11(1):1-19.

INDEX OF SYMBOLS

	Consult instructions for use		Contains sufficient for <n> tests		Date of manufacture
	In vitro diagnostic medical device		Use-by date		Do not re-use
	Temperature limit		Batch code		Catalogue number
	Keep away from sunlight		Keep dry		Manufacturer
	CE marking		Authorized representative in the European Community/European Union		



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