Finecare™ Vitamin D Rapid Quantitative Test

Catalog No. W241

INTENDED USE

The Finecare™ Vitamin D Rapid Quantitative Test along with Finecare™ FIA Meter (Model No.: FS-114, FS-112, FS-113 or FS-205) is a fluorescence immunoassay quantitative determination of total 25(OH) D2/D3 level in human serum or plasma. Results are to be used in conjunction with other clinical and laboratory data to assist the clinician in the assessment of vitamin D sufficiency.

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

SUMMARY

Vitamin D from the diet or dermal synthesis from sunlight is biologically inactive and is a fat soluble steroid hormone involved in the active intestinal absorption of calcium and in the regulation of its homeostasis. In humans, the most important compounds in this group are vitamin D3(also known as cholecalciferol)and vitamin D2(ergocalciferol). In the liver, vitamin D3 is converted to calcidiol, 25-hydroxycholecalciferol(abbreviated 25(OH)D3. And vitamin D2 is converted in the liver to 25-hydroxyergocalciferol(25(OH)D2). It is widely known that circulating of total 25(OH)VD is the best indicator of vitamin D status. 25(OH)D3 is then converted in the kidneys into 1,25-(OH)2D3, a steroid hormone that is the active form of vitamin D. It can also be converted into 24-hydroxycalcidiol in the kidneys via 24-hydroxylation. Vitamin D has a significant role in calcium homeostasis and metabolism. Its discovery was due to effort to find the dietary substance lacking in rickets (the childhood form of osteomalacia).

PRINCIPLE

This assay is based on competitive fluorescent immunoassay technology. When sample is mixed with reconstituted marker, the target material in the sample binds to the fluorescent-labeled detection antibody, to form the complex as sample mixture. When the sample mixture is added into the sample well of the test device, the excessive fluorescent-labeled antibody moves forward to the test line by capillary action and combines with the 25(OH) D which is immobilized on test strip. The more target material in blood specimen, the less fluorescent-labeled antibody accumulated on the test zone. Signal intensity of fluorescence of detector antibody reflects amount of 25(OH) D captured and Finecare™ FIA Meter shows 25(OH) D concentrations in blood specimen. The signal is inversely proportional to the 25(OH) D concentration. The default results unit of this test is displayed as XXX ng/mL from Finecare™ FIA Meter.

PRECAUTIONS

1. This kit is for *in vitro* diagnostic use only. Do not swallow.
2. The desiccant is for storage purposes only, is not used in the test procedures.
3. Do not mix components from different kit lots. Please make sure that the test device, the buffer and the ID Chip are the same lot before use.
4. Do not use test kit beyond the expiration date.
5. Protective measure should be taken when sample collection, handling, storage and mixing.
6. The Finecare™ Vitamin D Rapid Quantitative Test is only operational in the Finecare™ FIA Meter. And tests should be applied by professionally trained staff working in certified laboratories and clinics at which the sample(s) is taken by qualified medical personnel.
7. The test device should remain in its original sealed pouch until ready to use. Do not use the test kit if the pouch is punctured or not well sealed. Discard after single use.
8. Disappearance of the blue line on the right of result window of the test will indicate the test device has been used.
9. The Test device and Analyzer should be used away from vibration and magnetic field. During normal usage, the Test Kit may introduce minute vibration, which should be regarded normal.
10. Do not pull out the ID Chip when test are in procedure.
11. Bring the test device to room temperature before open. Test should be performed in the required environment.
12. Do not insert the test in the analyzer when the cartridges cover is bedewed with blood or other fluid. Or else, the analyzer may be damaged.
13. The blood specimens, used Test Cartridges, Pipette Tips and Buffer vials are potentially infectious. They should be handled carefully and disposed by an appropriate method according to relevant local regulations.
14. Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
15. The Finecare™ Vitamin D Rapid Quantitative Test should not be used as absolute evidence for vitamin D status. The results should be interpreted by the physician along with clinical findings and other laboratory test results.

16. The test will be applied on a routine basis and not in emergency situations.

MATERIAL

Material Provided

Each box contains:

Test Cartridge in a sealed pouch with desiccant	25
ID Chip	1
Releasing Buffer A (contains 7.2% TCEP)	1× 2.5mL
Releasing Buffer B (contains 4% NaOH)	1× 2.5mL
Detection Buffer C	1× 3mL
Solid marker bottle	1
Centrifuge Tubes	50
Pipette Tips	25
Instructions for Use	1

Warning: TCEP and NaOH are classified as Skin Corr 1B:H314 according to CLP 1272/2008

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Danger
H314: Causes severe skin burns and eye damage
P280: Wear protective gloves/protective clothing/eye protection/face protection
P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting
P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower
P310: Immediately call a POISON CENTER/doctor
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.

Material Required But Not Provided

1. Finecare™ FIA Meter (Model No.: FS-114, FS-112, FS-113 or FS-205)
2. Transfer Pipette set
3. Specimen Collection system
4. Heating block
5. Timer

STORAGE AND STABILITY

1. Store at 4°C～30°C up to the expiration date.
2. The solid marker bottle can be stored at 2°C～8°C for 28 days after being reconstituted.
3. Do not remove the device from the pouch until ready to use. The Test Cartridges should be used within 1 hour once opened.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with serum or plasma:

1. Following standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collection plasma, use a blood collection tube containing suitable anticoagulant (Heparin，lithium heparin orsodium citrate is recommended).
2. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
3. Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged period. Specimens may be stored at 2°C～8°C for up to 4 days. For long-term storage, specimens should be kept below -20°C .

Note:

1) Frozen plasma or serum must be rapidly thawed to reach room temperature then mixed thoroughly before use.
2) No more than a single freeze/thaw cycle is recommended. Clotted or severely hemolytic specimens are not suitable for testing and shall be rejected. Another specimen should be obtained and tested.

TEST PROCEDURE

Refer to operation manuals of Finecare™ FIA Meter for complete instructions of the test device. Bring all materials to room temperature before use.

Step 1: Preparation

Ensure that the lot number of Test Cartridges matches ID Chip as well as the Buffers. Insert ID Chip into Finecare™ Meter. Be aware not to touch the insertion tip of the ID chip.

Step 2: Sampling

Draw 75 µL specimen, 75 µL Releasing Buffer A and 75 µL Releasing Buffer B into a blank centrifuge tube.

Step 3: Mixing

Close the lid of centrifuge tube and mix the sample mixture well then insert it into the heating block at 37°C for 10 minutes.

Step 4: Reconstituting

Draw 2.5 mL detection buffer C into the solid marker bottle and shake it thoroughly.

Step 5: Reacting
Draw 75 µL reconstituted marker, 75 µL releasing sample mixture into a blank centrifuge tube, mix it well then insert it into the heating block at 37°C for 5 minutes.
Step 6: Loading
Draw 75 µL sample mixture and load it into the sample well of Test Cartridge.
Step 7: Testing
There are two test modes for Finecare™ FIA Meter, Standard Test mode and Quick Test mode. Please refer to the Operation Manual of Finecare™ FIA Meter for details.

a) For Standard Test mode: Insert the Test Cartridge onto the Test Cartridge holder of Finecare™ FIA Meter right after adding sample mixture to the sample well. Press "Test" to start testing. (Apply to FS-114, FS-112, FS-113 and FS-205)
b) For Quick Test mode: Set the timer and count down right after adding sample mixture into the sample well and leave it at room temperature for 15 minutes. Then insert the Test Cartridge onto the Test Cartridge holder of Finecare™ FIA Meter. Press "Test" to start testing. Finecare™ FIA Meter will start scanning the sample-loaded Test Cartridge immediately. (Apply to FS-114, FS-112 and FS-113)

Results are displayed on main screen or be printed by press "Print".
Discard the used Test Cartridge according to local regulations and procedures after released from Finecare™ FIA Meter.

INTERPRETATION OF RESULTS

The Finecare™ FIA Meter calculates 25(OH) D2/D3 test results automatically and displays the exact concentrations of 25(OH) D2/D3 on the screen as XX ng/mL.

The assay range is 5~100 ng/mL. The test result will be shown as ＜5 ng/mL if the 25(OH) D2/D3 concentration is below 5 ng/mL and the test result will be shown as ＞100 ng/mL if the 25(OH) D2/D3 concentration is more than 100 ng/mL.
For further information, refer to the Operation Manual for the Finecare™ FIA Meter The 25(OH) D2/D3 concentration values can be used in conjunction with other clinical and laboratory data to assist the clinician in the assessment of vitamin D sufficiency.

QUALITY CONTROL

Each Test device 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 device was inserted and read properly by Finecare™ FIA Meter. An invalid result from the internal control causes an error message on Finecare™ FIA Meter indicating that the test should be repeated.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human serum and plasma specimen only.
2. 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.
3. The false high results include cross-reactions with some components of human blood from individual to antibodies; and non-specific adhesion of some components in human whole blood that have similar epitopes to capture and detector antibodies.
4. In the case of false low 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)/D3 antigen, resulting in degradation with time and, or temperature, such that they become no longer recognizable by antibodies; and degraded other test components. The effectiveness of the test is highly dependent on storage of kits and sample specimens at optimal conditions.
5. 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.

EXPECTED RESULTS

Reference range:

Total 25 OH Vitamin D（ng/mL）	Vitamin D Status
Total 25 OH VD ≤ 20	Deficient
20＜Total 25 OH VD＜30	Insufficient
30 ≤ Total 25 OH VD ≤ 100	Sufficient
Total 25 OH VD >100	Toxic

Note: Recommend that each laboratory formulates its own Reference Range according to geographical, ethnic, gender and age differences,

TRACEBILITY

The metrological traceability of values assigned to calibrators can be traced to:

International standard reference material	SRM972a (NIST standard)

PERFORMANCE CHARACTERISTICS

Accuracy

A comparison study is tested for 150 clinical samples in using Finecare™ Vitamin D Rapid Quantitative Test and Roche Cobas reagent kit. The Correlation Coefficient (R) is 0.95.

Assay Range and Detection Limit

- **Assay Range:** 5~100 ng/mL
- **Detection Limit (Analytical Sensitivity):** 5 ng/mL

Linearity

A serial concentration of Vitamin D controls from 5~100 ng/mL were each tested for three times, the Correlation Coefficient (R) is ≥0.9900.

Precision

Intra-Lot Precision:
Within-run precision has been determined by using two concentration of Vitamin D controls with one batch of test, C.V. is ≤10%.

Inter-Lot Precision:
Between-run precision has been determined by using two concentration of Vitamin D controls with three batches of tests. C.V. is ≤15%.

BIBLIOGRAPHY OF SUGGESTED READING

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8. Glendenning P, Prince RL. What is the therapeutic target level of 25-hydroxyvitamin D in osteoporosis and how accurately can we measure it? Intern Med J 2012,42:1069-72.
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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	Authorized representative in the European Community
Manufacturer	First Part of Kit	Second Part of Kit
Caution		

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Any complaints, questions, problems, suggestions or comments, please contact us by phone, e-mail or in writing.

EC REP
Qarad b.v.b.a.
Cipalstraat 3
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Rev. A2 Rel.: 2020/04/01

Wondfo 万孚

物料编码及项目名称：13008464 VD免疫荧光试剂CE说明书(340x125mm)英文V02

尺寸规格：340*125mm	颜色：K100 K60 K20	设计师：杨晓洁
材质：80克铜版纸+左右对折	申请人：廖翠玲	设计时间： 2020.04.01