Chuangxingwell

25-Hydroxyvitamin D (25-OH-VD) Rapid Test Kit instruction for Use

A Fluorescence Immunoassay test for quantitative detection of 25-Hydroxyvitamin D in human serum or plasma with the use of Immunofluorescence Analyzer.

- For *in-vitro* diagnostic use

IVD

PACKING SPECIFICATION

25 Tests/ Kit

INTENDED USE

The 25-Hydroxyvitamin D (25-OH-VD) Rapid Test Kit is intended for *in-vitro* quantitative determination of total Vitamin D in serum or plasma. Measurement of total Vitamin D (D2+D3) is used as an aid to assessment of Vitamin D levels. The test is intended for healthcare professionals use.

SUMMARY

Vitamin D refers to a group of fat-soluble secosteroids responsible for increasing intestinal absorption of calcium, iron, magnesium, phosphate, and zinc. In humans, the most important compounds in this group are vitamin D3 and vitamin D2[1]. Vitamin D3 is naturally produced in the human skin through the exposure to ultraviolet light and Vitamin D2 is mainly obtained from foods. Vitamin D is transported to the liver where it is metabolized to 25-hydroxy Vitamin D. In medicine, a 25-hydroxy Vitamin D blood test is used to determine Vitamin D concentration in the body. The blood concentration of 25-hydroxy Vitamin D (including D2 and D3) is considered the best indicator of Vitamin D status.

Vitamin D deficiency is now recognized as a global epidemic.[2] Virtually every cell in our body has Receptors for Vitamin D, meaning that they all require "Sufficient" Level of Vitamin D for adequate functioning. The health risks associated with Vitamin D deficiency are far more severe than previously thought. Vitamin deficiency has been linked to various serious diseases: Osteoporosis, Osteomalacia, Multiple Sclerosis, Cardiovascular Diseases, Pregnancy Complications, Diabetes, Depression, Strokes, Autoimmune Diseases, Flu, Different Cancers, Infectious Diseases, Alzheimer, Obesity and Higher Mortality etc.[3]

Therefore, now detecting (25-OH) Vitamin D level is considered as "Medically Necessary Screening Test", and maintaining sufficient levels not just to improve bone health, but to improve overall health and well-being.[4]

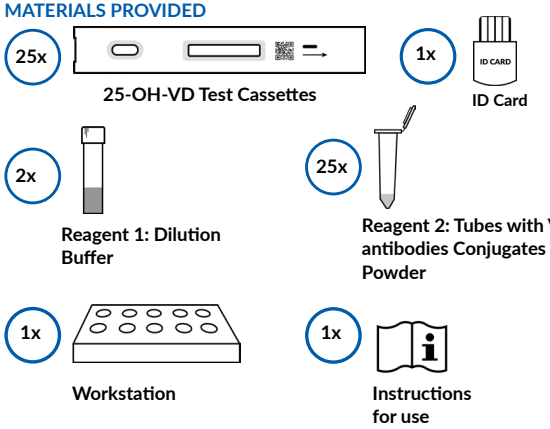
PRINCIPLE

The 25-Hydroxyvitamin D (25-OH-VD) Rapid Test Kit detects Vitamin D based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. Vitamin D in the sample will compete with the VD-BSA antigen coated on the membrane. The less Vitamin D in the sample, the more fluorescent microspheres conjugated with anti-VD antibodies can be captured by the VD-BSA antigen coated on the membrane (Test line). The concentration of Vitamin D in the sample is inversely related to the intensity of the fluorescent signal captured on the T line. According to the fluorescence intensity of the test and the standard curve, the concentration of Vitamin D in the sample can be calculated by the Immunofluorescence Analyzer to show Vitamin D concentration in the sample.

REAGENTS

The test includes VD antibody coated particles and VD-BSA antigen coated on the membrane.

MATERIALS PROVIDED



MATERIALS REQUIRED BUT NOT PROVIDED

- Immunofluorescence Analyzer
- Pipette
- Specimen Collection Containers
- Centrifuge
- Timer

PRECAUTIONS

1. For professional *in-vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The Vitamin D Test Cassette should only be used with the Immunofluorescence Analyzer by professionals

STORAGE AND STABILITY

1. The test should be stored at 4 - 30 °C until the expiry date printed on the sealed pouch. Shelf life is 24 months.
2. The test must remain in the sealed pouch until use and must be used within 1 hour if opened.
3. Do not freeze.
4. Care should be taken to protect the components of the test from contamination.
5. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SAMPLE COLLECTION AND PREPARATION

Specimen Collection

Collect the specimens according to standard procedures. EDTA K2, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the plasma specimens.

A clean tube without anticoagulants can be used to collect serum specimens.

Specimen Storage and Shipping

Serum and plasma specimens may be stored at 2 - 8 °C for up to 7 days, and -20 ℃ for long term. Frozen specimens should be thawed and mixed before testing. Speci-mens should not be frozen and thawed repeatedly.

If specimens are to be shipped, these should be packed in compliance with local regulations covering the transportation of etiological agents.

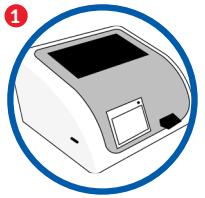
Preparation

Before performing the test, please balance the sample to room temperature (15 - 30 °C). Frozen specimens must be completely thawed and mixed well prior to testing.

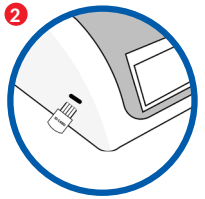
TEST PROCEDURE

Refer to Immunofluorescence Analyzer User Manual for the complete instructions for use of the Test.

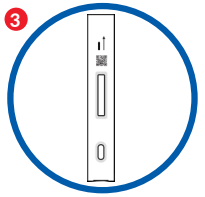
Allow the test cassette, specimen and buffer to reach room temperature (15 - 30 °C) prior to testing.



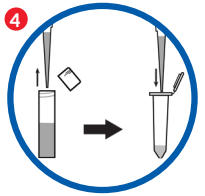
Turn on the Analyzer power.



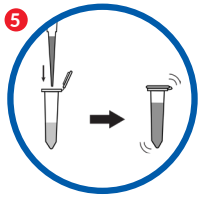
Take out the ID card and insert it into the Analyzer ID Card Slot. Choose test mode and/or sample type according to needs.



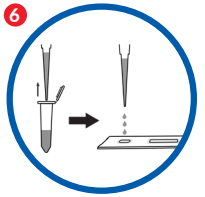
Remove the test cassette from the sealed foil pouch and use it within 1 hour. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
Place the test on a flat and clean surface.



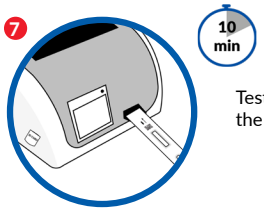
Pipette **100 µL of Reagent 1** into the Reagent 2 Tube, and dissolve the lyophilized powder thoroughly.



Pipette **40 µL of serum or plasma** into the dissolved reagent 2; mix the specimen and the buffer well. Then leave the mixture reaction for **15 minutes**.



After **15 minutes**, pipette **80 µL of diluted specimen** into the sample well of test cassette. Start the timer at the same time.



Test results should be interpreted at **10 minutes** with the use of Immunofluorescence Analyzer.

Caution: There are different test modes of the Immunofluorescence Analyzer. The difference between them is incubation of the test cassette is outside or inside the analyzer. Choose test mode accordingly and confirm sample type. Consult the user manual of the analyzer for detailed operation information. Operator must consult the Immunofluorescence Analyzer User Manual prior to use and become familiar with the processes and quality control procedures.

INTERPRETATION OF TEST RESULTS

Results read by Immunofluorescence Analyzer.

The test result of Vitamin D is calculated by Analyzer and reported as the numerical value with unit ng/mL and results with Def/Insuf/Suf (shorted from Deficient/Insufficient/Sufficient). The detection range of Vitamin D Test Kit is 5 - 100 ng/mL.

QUALITY CONTROL

Each 25-Hydroxyvitamin D (25-OH-VD) Rapid Test Kit contains internal control that satisfies routine quality control requirements. This internal control is performed each time a sample is tested. This control indicates that the test cassette was tested and read properly by Immunofluorescence Analyzer. An invalid result from the internal control causes a message on Immunofluorescence Analyzer and indicates that the test should be repeated. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The 25-Hydroxyvitamin D (25-OH-VD) Rapid Test Kit should be used only with the corresponding Immunofluorescence Analyzer.
2. The test should preferably be performed with freshly collected samples. For stored specimens, please refer to specimen storage.
3. The 25-Hydroxyvitamin D (25-OH-VD) Rapid Test Kit is for professional *in-vitro* diagnostic use, and should only be used for the quantitative detection of Vitamin D.
4. The test may yield low results due to Vitamin D epitopes being covered by some unknown components. Low results may also be obtained due to instability or degradation of Vitamin D antigen with time and temperature.
5. Other factors interfering with the test and causing erroneous results include technical/procedural errors, degradation of the test components as well as presence of interfering substances in the test samples.
6. The 25-Hydroxyvitamin D (25-OH-VD) Rapid Test Kit will only indicate the presence of Vitamin D in the specimen and should not be used as the sole criteria for diagnosis.
7. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

Concentrations	Clinical Reference
<10 ng/mL	Deficient
10 - 30 ng/mL	Insufficient
>30 ng/mL	Sufficient

Each laboratory should determine the applicability of the reference range through experiments, and establish its own reference value range if necessary to ensure that it can correctly reflect the situation of a particular population.

PERFORMANCE CHARACTERISTICS

1. Method comparison

For 98 specimens, the test results of Vitamin D Test Cassettes were consistent with a commercial CLIA test kits, and correlation coefficient (R) is 0.978.

2. Accuracy

The test deviation is ≤±15%.

3. Assay Range

Assay Range is 5 - 100 ng/mL.

4. Precision

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 different concentrations Vitamin D control, C.V. is ≤15%.

Inter-lot precision

Between-run precision has been determined by using 10 replicates for each of three lots using 2 different concentrations Vitamin D control, C.V. is ≤15%.

BIBLIOGRAPHY

1. Holick MF (March 2006). "High prevalence of vitamin D inadequacy and implications for health". Mayo Clinic Proceedings. 81 (3): 353–73.
2. Eriksen EF, Glerup H (2002). "Vitamin D deficiency and aging: implications for general health and osteoporosis". Biogerontology. 3 (1-2): 73–7.
3. Grant WB, Holick MF (June 2005). "Benefits and requirements of vitamin D for optimal health: a review". Alternative Medicine Review.10 (2): 94–111.
4. Moyad MA. Vitamin D: a rapid review. DermatolNurs. 2009, 21:25-30.

SYMBOLS

	Caution	IVD	In Vitro Diagnostic Medical Device
	Manufacturer		Date of Manufacture
CE	CE Marking		Do Not Re-use
	Keep Dry		Keep Away From Sunlight
LOT	Batch Code		Do Not Use if Package is Damaged
REF	Catalogue Number	Σ	Contains Sufficient for <n> Tests
	Use-By Date		Temperature Limit
	Consult Instructions for Use	EC REP	Authorized representative in the European Community

Manufacturer
Jinan Chuangxingwell Biotech Co., Ltd.
Add.: Building 1-2B-402, Liando U Valley, Gangyuan Sixth Road, Jinan Zhangjin Comprehensive Bonded Zone, Gaoxin District, Jinan city, Shandong Province, China
Tel: +86-0531-88894020
Email: s@1stiot.com

EC REP

Riomavix S.L.
Add.: Calle de Almansa 55, 1D, Madrid 28039 Spain
E-mail: leis@riomavix.com
Tel.: +34 658 396 230
(SRN: ES-AR-000001202)