Vitamin D Rapid Test Cassette (Fingerstick Whole Blood)

Package Insert
For Self-testing

REF OVD-402H	English

A rapid test for the semi-quantitative detection of 25-hydroxyvitamin D in human fingerstick Whole Blood. For self-testing in vitro diagnostic use.

【INTENDED USE】

The Vitamin D Rapid Test Cassette is a rapid chromatographic immunoassay for the semi-quantitative detection of 25-hydroxyvitamin D (25 (OH) D) in human fingerstick Whole blood. This assay provides a preliminary diagnostic test result and can be used to screening for Vitamin D deficiency.

【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]

【PRINCIPLE】

The Vitamin D Rapid Test Cassette is an immunoassay based on the principle of competitive binding. During testing, the mixture migrates upward on the membrane chromatographically by capillary action. The membrane is pre-coated with 25 (OH) D antigens on the test line region of the strip. During testing, 25 (OH) D present in the specimen will compete with 25 (OH) D on the test line for limited amount of anti-25 OH Vitamin D antibodies in the conjugate. The higher concentration of 25 (OH) D in the specimen, the lighter would be the T line. The result will be read according to the Color card provided with the kit.
To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

【PRECAUTIONS】

Please read all the information in this package insert before performing the test.

- For self-testing *in vitro* diagnostic use only.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Store in a dry place at 2-30 °C (36-86 °F), avoiding areas of excess moisture. If the foil packaging is damaged or has been opened, please do not use.
- This test kit is intended to be used as a preliminary test only and repeatedly abnormal results should be discussed with doctor or medical professional.
- Follow the indicated time strictly.
- Use the test only once. Do not dismantle and touch the test window of the test cassette.
- The kit must not be frozen or used after the expiration date printed on the package.
- Keep out of the reach of children.
- The used test should be discarded according to local regulations.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use after the expiration date.

【MATERIALS】

Materials Provided

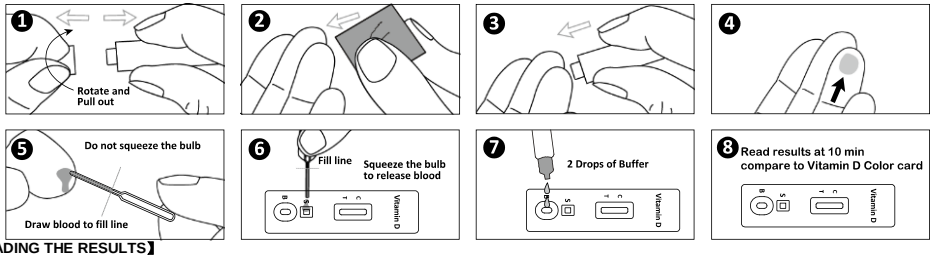
1. Test Cassette 2. Buffer 3. Lancet 4. Alcohol Pad 5. Capillary Dropper 6. Package Insert 7. Color Card

Materials Required But Not Provided

1.Timer

【PROCEDURE】

1. Wash your hands with soap and rinse with clear warm water.
2. Bring the pouch to room temperature before opening it. Open the pouch, remove the test cassette and place it on a clean and level surface. Run the test within one hour and best results will be obtained if the test is performed immediately after opening the foil pouch.
   Remove the dropper, buffer vial, lancet and Alcohol pad, place them close to the test cassette.
3. Carefully pull off and dispose the released cap of the lancet.
4. Use the provided Alcohol pad to clean the fingertip of the middle or ring finger as the puncture site. Allow to air dry.
5. Press the lancet, on the side from where the cap was extracted; the tip retracts automatically and safely after use. Massage the hand without touching the puncture site by massaging the hand towards the fingertip of the middle or ring finger to be punctured.
6. Keeping the hand down massage the end that was pricked to obtain a blood drop.
7. Without squeezing the capillary dropper bulb, put it in contact with the blood. **The blood migrates into the capillary dropper through the capillarity to the line indicated on the capillary dropper.**
   You may massage again your finger to obtain more blood if the blood does not reach the indicated line. Avoid of air bubbles.
8. **Release the blood collected into the Specimen well (S)** of the cassette, by squeezing the dropper bulb.
9. Wait for the blood to be totally dispensed in the well. Unscrew the cap of the buffer bottle and add **2 drops of buffer into the Buffer well (B)** of the cassette and start a timer.
10. Wait for the colored line(s) to appear. **Read results at 10 minutes.** Compare the T line intensity with "Vitamin D Color card" provided with the kit to get the Vitamin D level in your blood. Do not interpret the result after 20 minutes.



【READING THE RESULTS】

(Please refer to the illustration and compare the T line intensity with "Vitamin D Color card" provided with the kit.)
Note: Do not mix use Vitamin D color card from different batches.

25-OH Vitamin D Level	Reference Range (ng/mL)	Reference Range (nmol/L)	Refer to the "Vitamin D Color card" to read the results
Deficient	0-10	0-25	**Two colored lines appear.** One is in the control region (C) and another should be in the test region (T). The intensity of line in the test region (T) is **equal to Deficient line (0-10 ng/mL)** on the color card, it indicates Vitamin D level is deficient.
Insufficient	10-30	25-75	**Two colored lines appear.** One is in the control region (C) and another should be in the test region (T). The intensity of line in the test region (T) is **equal to Insufficient line (10-30 ng/mL)** on the color card, it indicates Vitamin D level is insufficient.

Sufficient	30-100	75-250	**Two colored lines appear.** One line should be always in the control region (C) and faint colored line appears in the test region (T). The intensity of line in the test region (T) is **equal to Sufficient line (30-100 ng/mL)** on the color card, it indicates Vitamin D level is sufficient.

Excess 	**One colored line appears in the control line region (C). No colored line appears in the test line region (T).** It indicates Vitamin D level maybe excess, it is recommended to consult a physician.
Invalid 	**Control line fails to appear.** Incorrect procedural techniques are the most likely reasons for control line 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.

【CONTROL PROCEDURE】

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

【LIMITATIONS】

1. The Vitamin D Rapid Test Cassette provides only a semi-quantitative analytical result. A secondary analytical method must be used to obtain a confirmed result.
2. It is possible that technical or procedural errors, as well as other interfering substances in the whole blood specimen may cause erroneous results.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. Other clinically available tests are required if questionable results are obtained.

【PERFORMANCE CHARACTERISTICS】

Accuracy

A clinical evaluation was conducted comparing the results obtained using the Vitamin D Rapid Test to predicate Device (Vitamin D Rapid Test). The in-house clinical trial included 90 whole blood specimens. The results demonstrated with an overall accuracy of 94.4%.

Method		**Predicate Device (Vitamin D Rapid Test)**			**Total Results**
	Results	Deficient	Insufficient	Sufficient	
Vitamin D Rapid Test Cassette	Deficient	4	3	0	7
	Insufficient	0	53	2	55
	Sufficient	0	0	28	28
Total Results		4	56	30	90
Accuracy		>99.9%	94.6%	93.3%	94.4%

【EXTRA INFORMATION】

1. How does the Vitamin D test work?

In medicine, a 25-hydroxy Vitamin D is the main storage form of vitamin D in the body. Therefore, the overall status of vitamin D can be determined by detecting the content of 25-hydroxy Vitamin D. 25-hydroxy Vitamin D level less than 30 ng/mL in case of a positive result, indicates Vitamin D **Deficiency** or **Insufficiency.** Vitamin D supplements can be recommended in these cases.

2. When should the test be used?

The clinical application of 25-hydroxy Vitamin D is mainly for diagnosis, treatment and monitoring of rickets (children), osteomalacia, postmenopausal osteoporosis and renal osteopathy. Vitamin D deficiency is also associated with many other diseases, including cancer, cardiovascular disease, autoimmune diseases, diabetes and depression. Monitor your vitamin D levels to determine whether to take vitamin D supplements. The Vitamin D Rapid Test can be used any time of the day.

3. Can the result be incorrect?

The results are accurate as far as the instructions are carefully respected. Nevertheless, the result can be incorrect if the Vitamin D Rapid Test cassette gets wet before test performing or if the quantity of blood dispensed in the sample well is not sufficient, or if the number of buffer drops are less than 2 or more than 3. The capillary dropper provided in the box allows making sure the collected blood volume is correct. Besides, due to immunological principles involved, there exist the chances of false results in rare cases. A consultation with the doctor is always recommended for such tests based on immunological principles.

4. How to interpret the test if the color and the intensity of the lines are different?

Please refer to the illustration and compare the T line intensity with "Vitamin D Color card" provided with the kit.

5. If I read the result after 20 minutes, will the result be reliable?

No. The result should be read at **10 minutes** after adding the buffer. The result is unreliable after 20 minutes.

6. What do I have to do if the result is deficient or insufficient?

If the result is deficient or insufficient, it means that the Vitamin D level in blood is less than 30 ng/mL and that you should consult a physician to show the test result. The physician will decide whether additional analysis should be performed.

7. What do I have to do if the result is sufficient?

If the result is sufficient, it means that the Vitamin D level is higher than or equal to 30 ng/mL and is within the normal range. A case of Vitamin D toxicity (hypercalcemia), though rare, but cannot be excluded based on such test results. However, if the symptoms persist, it is recommended to consult a physician.

【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.

Index of Symbols

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized representative in EU
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30 °C	LOT	Lot number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		Caution

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

Lancet:

CE 0123

Alcohol Pad:

EC REP
MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany

Promisemed Hangzhou Meditech CO., LTD.
No. 1388 Cangxing Street, Cangqian Community,
Yuhang District, Hangzhou City, 311121 Zhejiang,
China
CE 0197

or

Ningbo Medsun Medical Co.,Ltd.
No. 298 Huangjipu Road, Jiangbei, 315031
Ningbo, People's Republic of China
CE 0123

or

Shandong Lianfa Medical Plastic Products Co., Ltd.
No.1 Shuangshan Sanjian Road, 250200,
Zhangqiu City, Jinan, Shandong,
PEOPLE'S REPUBLIC OF CHINA
CE 0197

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