

Vitamin D Rapid Test Cassette (Fingerstick Whole Blood) Package Insert For Self-testing

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 at a cut-off concentration of 30 ± 4ng/mL. This assay provides a preliminary diagnostic test result and can be used in 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's, Obesity and Higher Mortality etc.^[3] Therefore, now detecting (25-OH) Vitamin D level is considered as a "Medically Necessary Screening Test", and maintaining sufficient levels not just to improve bone health, but to improve overall health and well-being.^[4]

【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 a 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

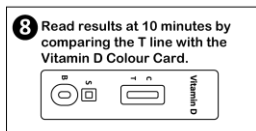
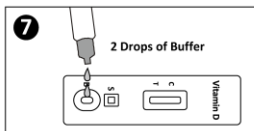
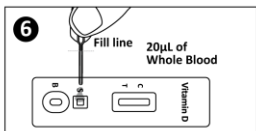
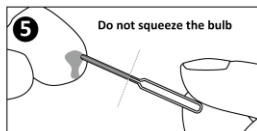
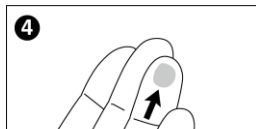
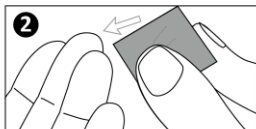
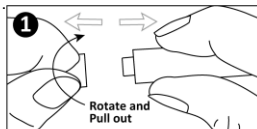
1. Test Cassette
2. Buffer
3. 2 x Lancets
4. Alcohol Pad
5. Capillary Dropper
6. Package Insert
7. Colour Card

Materials Required But Not Provided

- 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 testing 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, lancets and Alcohol pad and place them close to the test cassette.
3. Carefully pull off and dispose of the clear plastic cap of the lancet. The lancet is a single use lancet so make sure you do not fire the lancet prematurely.
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 removed) firmly against the fingertip. The tip retracts automatically and safely after use.
6. Keeping the hand down, massage the finger that was pricked to obtain a blood drop.
7. **Without squeezing the capillary dropper bulb**, gently put it in contact with the edge of the blood drop. The blood should automatically be drawn up the dropper by capillary action. You should fill the dropper up to the black line.
You may continue to massage your finger to obtain more blood if the line is not reached. As far as possible, try to avoid air bubbles.
8. Transfer the collected blood into the sample 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 coloured line(s) to appear. Read results at **10 minutes**. Compare the intensity of the Test Line (T) with the provided "Vitamin D Colour Card" to determine the Vitamin D level in your blood. Results obtained after 10 minutes may be inaccurate.



【READING THE RESULTS】

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

25-OH Vitamin D Level	Reference Range (ng/mL)	Reference Range (nmol/L)
Deficient	0-10	0-25
Insufficient	10-30	25-75
Sufficient	30-100	75-250

 Deficient	Deficient Two distinct coloured lines appear. One is in the control region (C) and another should be in the test region (T). The line intensity in the test region (T) is equal to or darker than the 10ng/mL line depicted on the colour card provided with the kit.
 Insufficient	Insufficient Two coloured lines appear. One is in the control region (C) and another faint line should be in the test region (T). The line intensity in the test region (T) is darker than the 30ng/mL line depicted on the colour card provided with the kit but lighter than the 10ng/mL line .
 Sufficient	Sufficient Two coloured lines appear. One is in the control region (C) and another faint line should be in the test region (T). The line intensity in region (T) is darker than the 100ng/mL line depicted on the Colour card but lighter than the 30ng/mL line .
 Invalid	INVALID: Control line fails to appear. Insufficient specimen volume or 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.

【LIMITATIONS】

- 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.
- It is possible that technical or procedural errors, as well as other interfering substances in the whole blood specimen may cause erroneous results.
- The Cut-off for the test is 30ng/mL with a deviation range of $\pm 4\text{ng/mL}$.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
- Other clinically available tests are required if questionable results are obtained.

【EXTRA INFORMATIONS】

1. How does the Vitamin D test work?

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 levels less than 30ng/mL, 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 performing the test, 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 enables you to ensure the collected blood volume is correct. Due to immunological principles involved, there is also the possibility of false results in rare cases. A consultation with a doctor is always recommended for such tests based on immunological principles.

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

Please refer to the illustration and compare the T line intensity with the "Vitamin D Colour 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 **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 30ng/mL and that you should consult a physician. The physician will then 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 30ng/mL and is within the normal range.





8. Can my Vitamin D levels be too high?





A case of Vitamin D toxicity (hypercalcemia) is rare, but cannot be excluded based on the test results. If symptoms persist, it is recommended to consult a physician.





【BIBLIOGRAPHY】

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

Index of Symbols

	Attention, see instructions for use
	For in vitro diagnostic use only
	Store between 2-30°C
	Do not use if package is damaged

	Tests per kit
	Use by
	Lot Number
	Manufacturer

	Authorized Representative
	Do not reuse
	Catalog #
	Consult Instructions for Use

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




MedNet GmbH
Borkstrasse 10
48163 Muenster Germany

Lancet:
Suzhou Zhenwu Medical Co., Ltd.
No.248, Chijianwan Road
Beishu Town, Fenuh Development Area, Wujiang District, Suzhou City
215214 Jiangsu, China




TÜV Rheinland LGA Products GmbH
Tillystraße 2 - 90431 Nürnberg

Alcohol Pad:
Jiangsu Sunclen Medical Co., Ltd
No.11 Fenghuang South Road,
Hutang Town, Wujin District
213162 Changzhou City,
Jiangsu Province, P.R.China


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