Vitamin D Test

Vitamin D Rapid Test Cassette

CE 0123 REF OVD-402H ENGLISH

A rapid test for the semi-quantitative detection of 25-hydroxy Vitamin D in human finger-prick whole blood.
For self-testing *in vitro* diagnostic use.

INTENDED USE

The Vitamin D Test (Vitamin D rapid test cassette) is a rapid chromatographic immunoassay for the semi-quantitative detection of 25-hydroxy Vitamin D (25 (OH) D) in human finger-prick whole blood. This assay provides a preliminary diagnostic test result and can be used to screen 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 metabolised 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 recognised 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 D 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]

PRINCIPLE

The Vitamin D Test (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 a 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 Vitamin D colour card provided with the kit. To serve as a procedural control, a coloured 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 the instructions for use 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 or 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 PROVIDED

- Test cassette
- Capillary dropper
- Vitamin D colour card
- Plaster
- Product summary
- x2 Lancets
- Alcohol pad
- Buffer
- Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

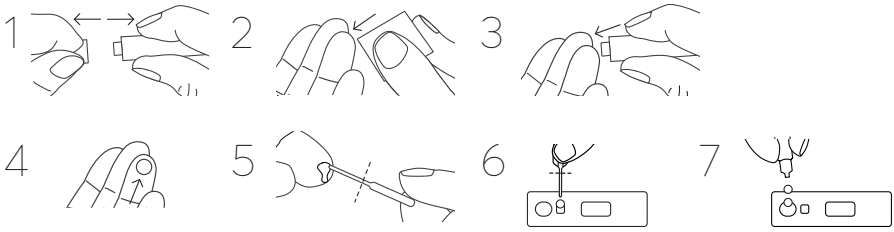
- Timer

PREPARATION

1. Wash your hands with soap and rinse with clean warm water.
2. Bring the pouch to room temperature before opening it.
3. Open the pouch, remove the dropper, buffer vial, lancet, alcohol pad and test cassette placing them on a clean, level surface.
4. Perform the test within one hour with best results obtained if the test is performed immediately after opening the foil pouch.

INSTRUCTIONS

1. Carefully pull off and dispose of the cap on the lancet.
2. Use the alcohol pad to clean the fingertip which will be pricked with the lancet. Allow to air dry.
3. Press the lancet down against the fingertip to prick the puncture site. The tip retracts automatically and safely after use.
4. Without touching the puncture site, massage the hand towards the fingertip, keeping the hand pointing downwards to obtain the sample of blood.
5. Without squeezing the capillary dropper bulb, place the end of the capillary tube in the blood until it reaches the fill line. Massage your finger again to obtain more blood if the blood does not reach the indicated line. Avoid air bubbles.
6. Transfer the collected blood into the sample well (S) of the cassette, by squeezing the dropper bulb. Apply the spot plaster to puncture site if required.
7. Unscrew the cap of the buffer vial and add 2 drops of buffer into the buffer well (B) of the cassette.
8. Start a timer and wait for the coloured line(s) to appear.
9. Read results at 10 minutes. Compare the T line colour intensity against the 'Vitamin D colour card' provided to evaluate 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 the Vitamin D colour card provided.

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
Excess	>100	>250

 Deficient	**Deficient** Two 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 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 should be in the test region (T). The line intensity in the test region (T) is darker than the 30 ng/mL line depicted on the colour card provided with the kit and lighter than 10 ng/mL line.
 Sufficient	**Sufficient** Two coloured lines appear. One is in the control region (C) and another should be in the test region (T). The line intensity in region (T) is equal to or lighter than 30 ng/mL line depicted on colour card.
 Excess	**Excess** One coloured line appears in the control line region (C). No apparent coloured line appears in the test line region (T). If the result is excess, it is recommended to consult a physician.
 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.

CONTROL PROCEDURE

A procedural control is included in the test. A coloured 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 Test (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 validate the Vitamin D Rapid Test. The in-house clinical trial included 90 whole blood specimens. The results demonstrated an overall accuracy of 94.4%.

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

FAQs

1. How does the Vitamin D rapid test work?

In medicine, 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. A 25-hydroxy Vitamin D level less than 30 ng/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 cassette can be used any time of the day.

3. Can the result be incorrect?

The results are accurate providing the instructions are carefully followed. Nevertheless, the result can be incorrect if the Vitamin D Test (Vitamin D rapid test cassette) gets wet before performing the test, if the quantity of blood dispensed in the sample well is not sufficient, or if the number of buffer drops is fewer than 2 or more than 3. The capillary dropper provided in the box ensures the correct volume of blood is collected. However, due to immunological principles involved, there is the chance of false results in rare cases. A consultation with the doctor is always recommended 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 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 to show the test result. Then, 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 30ng/mL and is within the normal range. A case of vitamin D toxicity (hypercalcemia), though rare, 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

	Manufacturer		Tests per kit	EC REP	Authorised Representative in EU
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
	Store between 2-30°C	LOT	Lot Number	REF	Catalogue #
	Do not use if package is damaged		Consult Instructions for Use		Non-recyclable
	Pap 21 recyclable material		Pap 22 recyclable material		

CE 0123 — EC REP
MedNet EC-REP GmbH, Borkstrasse 10, 48163
Muenster, Germany

CE 0197 — EC REP
MT Promedt Consulting GmbH, Altenhofstr. 80 66386
St., Ingbert, Germany

CE 0123 — EC REP
Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

CE 0123 — EC REP
Medpath GmbH, Mies-van-der-Rohe Strasse 8, 80807
Munich, Germany

CE — EC REP
Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537, Hamburg, Germany

CE 0197 — EC REP
SUNGO Europe B.V. Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands

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