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

REF RVD-402S **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 BIOZEK 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 of the adult population. This assay provides a preliminary diagnostic test result and can be used to screening for Vitamin D deficiency.

SUMMARY

Vitamin D deficiency is a global health problem caused mainly by insufficient exposure to sunlight. It is estimated that 1 billion people have vitamin D deficiency or insufficiency worldwide, particularly prevalent among elderly people. [1] 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. [2] 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. The consequences of vitamin D deficiency cannot be under estimated. There has been an association of vitamin D deficiency with a myriad of acute and chronic illnesses including preeclampsia, childhood dental caries, periodontitis, autoimmune disorders, infectious diseases, cardiovascular disease, deadly cancers, type 2 diabetes and neurological disorders. [3] 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. [4]

PRINCIPLE

The Vitamin D test 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

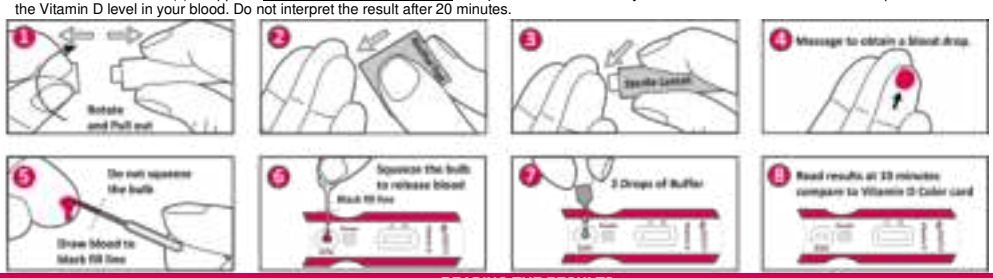
Materials Provided

Description	Quantity
• Test Cassette	1
• Buffer (For single use only)	1
• Sterile Lancet	1
• Alcohol Pad	1
• Capillary Dropper	1
• Package Insert	1
• Color Card/Instruction Guide	1

Materials Required But Not Provided
- Timer

DIRECTIONS FOR USE

1. Wash your hands with soap and rinse with clear warm water.
2. Bring the test kit 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 result will be obtained if the test is performed immediately after opening the foil pouch. Remove the capillary dropper, buffer, sterile lancet and alcohol pad, place them close to the test cassette.
3. Carefully pull off and dispose the released cap of the sterile 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 removed, 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 punctured middle or ring finger.
6. Keep the hand down to massage the finger to obtain a blood drop.
7. **Without squeezing the capillary dropper bulb**, put it in contact with the blood. Let the blood migrate into the capillary dropper through the capillarity to the black fill line indicated on the capillary dropper. You may massage again your finger to obtain more blood if the blood does not reach the indicated fill line in black. Avoid of air bubbles.
8. **Release all the collected blood into the specimen well (Sample) of the cassette.** by squeezing the dropper bulb.
9. Wait for the blood to be totally dispensed in the specimen well. Unscrew the cap of the buffer vial and **add 2 drops of buffer into the buffer well (Buffer)** 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 "BIOZEK 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 table below and compare the T line intensity with the provided "BIOZEK Vitamin D Color Card" to interpret the result.)

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 colored 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 color card provided with the kit.
 Insufficient	**Insufficient** **Two colored 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 color card provided with the kit and **lighter than 10 ng/mL line** depicted on Color card provided with the kit.
 Sufficient	**Sufficient** **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 line intensity in region (T) is **equal to or lighter than 30 ng/mL line** depicted on Color card.
 Excess	**Excess** **One colored line appears in the control line region (C).** No apparent colored 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.

LIMITATIONS

1. The BIOZEK 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.

EXTRA INFORMATIONS

1. How does the BIOZEK 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 30ng/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, 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 BIOZEK Vitamin D Rapid Test cassette gets wet before test performing or if the quantity of blood dispensed in the specimen 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 "BIOZEK 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 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, but cannot be excluded based on such test results. However, if the symptoms persist, it is recommended to consult a physician.

BIBLIOGRAPHY

1. Sahota O (2014 Sep). Understanding vitamin D deficiency. Age Ageing. 43(5):589-91.
2. Wilson LR, Tripkovic L, Hart KH, Lanham-New SA (2017 Aug). Vitamin D deficiency as a public health issue: using vitamin D2 or vitamin D3 in future fortification strategies. 76(3):392-399.
3. Holick MF (2017 Jun). The vitamin D deficiency pandemic: Approaches for diagnosis, treatment and prevention. Rev Endocr Metab Disord. 18(2):153-165.
4. Holick MF, Binkley NC, Bischoff-Ferrari HA, Gordon CM, Hanley DA, Heaney RP, Murad MH, Weaver CM (2011 Jul); Endocrine Society. Evaluation, treatment, and prevention of vitamin D deficiency: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 96(7):1911-30.

INDEX OF SYMBOLS

	Consult Instructions For Use		Contains sufficient for 1 test		Do not use if package is damaged
IVD	*in vitro* diagnostic medical device		Manufacturer		Do not re-use
	Temperature limit 2-30 C	REF	Catalogue number		

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EC REP
Lotus NL B.V.
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Alcohol Pad:

Ningbo Medsun Medical Co., Ltd.
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CE

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BIOZEK medical

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