

BEFORE PERFORMING THE TEST, PLEASE READ THESE INSTRUCTION CAREFULLY

# Vitamin D Rapid Test

Single-use home test for the semi-quantitative determination of vitamin D (25-hydroxyvitamin D - 25(OH)D) levels in a human whole blood sample taken from a fingertip.

**Medical device for self-testing.**

## INTRODUCTION

Vitamin D is a group of fat-soluble steroidal organic chemicals that has a primary role in calcium-phosphate metabolism. Vitamin D3 is naturally produced in human skin by exposure to ultraviolet light, while vitamin D2 is mainly obtained from food. Vitamin D is transported to the hepatic, where it is metabolised to 25-hydroxy vitamin D-25(OH)D. The concentration of 25-hydroxyvitamin D (including D2 and D3) in the blood is considered the best indicator of vitamin D levels. Vitamin deficiency has been linked to various serious diseases including: osteoporosis, osteomalacia, multiple sclerosis, cardiovascular disease, complications of pregnancy, diabetes, depression, stroke, autoimmune diseases, influenza, various cancers, infectious diseases, Alzheimer's disease, obesity, etc. Therefore, detecting vitamin D - 25(OH)D levels is now considered necessary. Maintaining sufficient vitamin D levels is important not only to improve bone health, but also to improve overall health and well-being.

## CONTENTS

Package contains the equipment necessary to perform one test:

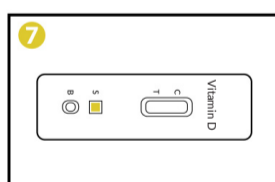
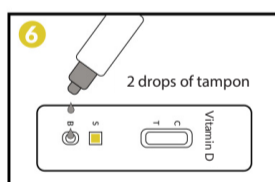
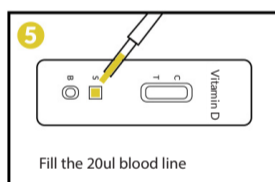
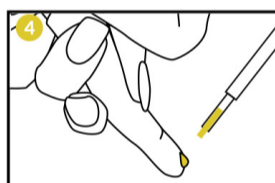
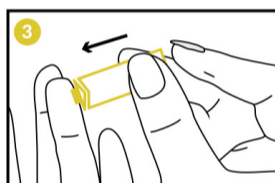
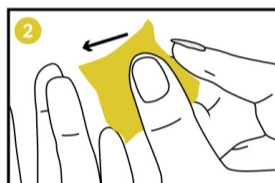
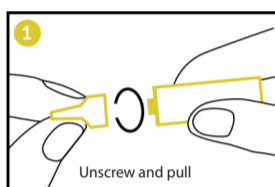
- » 1 sealed aluminum bag, containing: 1 cassette test, 1 plastic pipette and 1 desiccant
- » 1 buffer vial
- » 1 sterile lancet
- » 1 alcohol pad
- » 1 instruction for use
- » 1 card for reading the test result

The test should be removed from the plastic bag immediately prior to testing. Desiccant present in the package should be discarded in household garbage.

Before the test, prepare a means to disinfect the fingertip (e.g. cotton swab with 70% alcohol), a piece of paper towel and watch that you will need to measure the time of reading the test result.

## IMPORTANT NOTES PRIOR TO TESTING

- » Wash your hands with soap and warm water (to increase the blood supply to the finger that will be pricked) and dry them thoroughly.
- » It is not required to be fasting before the test is performed.
- » Test must be performed in strict compliance with the instructions below.



## TEST PERFORMANCE

» Remove the cassette test from the plastic bag and place it on an even clean surface. Perform the test within one hour, but best results will be obtained if the test is performed immediately after opening the package. Remove the pipette, buffer vial, sterile lancet and alcohol swab and place them close to the test plate. Carefully remove and discard the cap of the sterile lancet.

» Use the alcohol-soaked swab provided to clean the pad of the middle or ring finger as a puncture site. Allow to dry.

» Press the lancet with the side from which the cap has been removed, the tip retracts automatically and is safe after use. Massage the hand, without touching the puncture site, towards the pad of the middle or ring finger to be punctured.

» Holding the hand down, massage the finger that has been punctured to obtain a drop of blood. Without squeezing the bubble of the pipette, apply it to the formed drop of blood. **Blood enters the pipette due to capillary forces up to the line indicated on the pipette.** You can re-massage the finger for more blood if the blood does not reach the indicated fill line. Avoid the formation of air bubbles.

» Place the collected blood sample in the sample spot (S) located on the test plate by squeezing the pipette bulb.

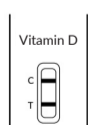
» Wait until the blood from the pipette is completely transferred to the sample spot. Unscrew the cap of the buffer vial and add 2 drops of buffer to the buffer spot (B) located on the test plate and start timing.

» Wait until the lines appear. Read the test result 10 minutes after solution adding. Compare the intensity of the T-line with the 'test reading card' provided with the kit to determine the vitamin D level in the blood. Do not take into account the result obtained after a period longer than 20 minutes.

## INTERPRETATION OF TEST RESULTS

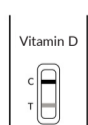
To interpret the test result, refer to the vitamin D reading 'test reading card' included in the package. Compare the intensity of the colour of the obtained T-line with the lines on the 'test reading card'. The test does not measure toxic vitamin D concentrations. A result above 100ng/ml (>250nmol/l) is considered a potentially toxic level.

Vitamin D level	Reference range (ng/ml)	Reference range (nmol/l)
Deficit	0-10	0-25
Deficiency	10-30	25-75
Normal levels	30-100	75-250



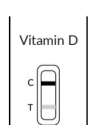
### DEFICIT

**Two clear lines appear.** One is in the control area (C) and the other should be in the test area (T). The line in the test area (T) is equal to or darker than the 10 ng/ml line shown on the reading test card provided with the kit..



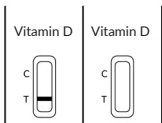
### DEFICIENCY

**Two lines appear. One is in the control area (C) and the other should be in the test area (T).** The line in the test area (T) is darker than the 30 ng/ml line on the reading test card provided with the kit and lighter than the 10 ng/ml line on the reading test card provided.



### NORMAL LEVELS

**Two lines appear, one should always be in the control area (C) and a faintly coloured line appears in the test area (T).** The line in the (T) area is darker than the 100 ng/ml line shown on the reading test card provided with the kit and lighter than the 30 ng/ml line shown on the reading test card provided with the kit.



**Invalid**  
The control line (C) does not appear. Insufficient sample volume or incorrect procedural techniques are the most likely reasons for the absence of the control line (C). Review the test procedure and repeat the test with a new kit. If the problem persists, stop using the test kit immediately and contact the manufacturer.

PRECAUTIONS

- » Test is for external use only. Do not eat, drink or smoke in the test room.
- » Test package should be stored at 2-30°C. Do not freeze.
- » Do not use the test kit after the expiry date shown on the packaging.
- » Do not use the test if the bag is damaged, because the moisture from the air can damage the test.
- » This test kit is intended for pre-testing only and repeated abnormal results should be discussed with medical personnel.
- » Strictly respect the indicated reading time.
- » Test kit for single use, do not disassemble the test and do not touch the test window on the test plate.
- » Do not use the lancet if it is incomplete or damaged.
- » Keep the test out of the reach of children.
- » The test and lancet are intended for single use only.
- » Dispose of the used test and lancet like any other household waste.
- » Do not make any medical decisions without prior consultation with medical personnel.

LIMITATIONS OF THE METHOD

1. The Vitamin D test provides only a semi-quantitative analytical result. A different 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 sample, may cause erroneous results.
3. As with all diagnostic tests, all results should be considered in association with other clinical information available to the clinician.
4. If questionable results are obtained, laboratory testing is required.

FREQUENTLY ASKED QUESTIONS (FAQ)

**What is the vitamin D test?**  
In medicine, 25-hydroxyvitamin D is the main storage form of vitamin D in the body. Therefore, the overall vitamin D level can be determined by determining the 25-hydroxyvitamin D content. With the test, a 25-hydroxyvitamin D level is tested, which, if positive, below 30 ng/ml indicates a vitamin D deficit or deficiency. In such cases, vitamin D supplementation may be recommended.

**When should the test be used?**  
The test is used to determine and monitor vitamin D levels e.g.: rickets disease (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. Vitamin D levels should be monitored to decide whether to take vitamin D supplements. The Vitamin D Rapid Test can be used at any time of day.

**Could the result be wrong?**  
The result may be invalid if the Vitamin D Rapid Test becomes wet before the test is performed, or if the amount of blood placed in the sample well is insufficient, or if the number of drops of buffer is less than 2 or more than 3. The pipette included in the package helps to ensure that the volume of blood collected is correct. It is always advisable to consult your doctor and arrange for extended diagnostics.

**How to interpret the test if the colour and intensity of the lines are different?**  
The reading of the test result depends on the intensity of the test line (T) appearing. Please refer to the ‘test reading card’ provided with the kit, with which you can interpret the test result.

**If I read the result after 20 minutes, will the result be valid?**  
No. The result should be read 10 minutes after adding the buffer to the test plate. A result read after 20 minutes is not valid.

**What should I do if the test result indicates a deficiency or deficit levels?**  
If the result indicates a deficiency or deficit, this means that the vitamin D level in the blood is below 30 ng/ml and you should consult your doctor by showing him the test result. The doctor will then decide whether additional analysis should be carried out.

**What should I do if the test result is at the correct level?**  
If the result is at a normal level, this means that the vitamin D level is greater than or equal to 30 ng/ml and is within the normal range. There is a risk, however rare, of toxic vitamin D levels. If you experience worrying symptoms of hypervitaminosis, you should consult your doctor.

**What is the accuracy of the test?**  
The clinical studies performed indicate that the results obtained with Vitamin D Rapid Test are consistent with those obtained with laboratory diagnostic methods

Date of the last revision of the instruction: 08.06.2022  
Version 5/EN

SYMBOLS

	Read the instructions carefully before performing the test		Only for in vitro diagnostics
	For single use only		Store at room temperature 2-30°C
	Lot number		Expiration date

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