

Manual for the Preventis *SmarTest Pro*[®] Vitamin D rapid test for the quantitative determination of 25(OH)-vitamin D in capillary blood

→REF PST80100G5
PST80100GP

Intended Use

Test system for the quantitative determination of 25(OH)-vitamin D in capillary blood for *in-vitro* diagnostic use by professional users.

Introduction

„Vitamin D“ is the term for a group of molecules that perform important functions in the body. Vitamin D is either assimilated through food, or is produced in the skin when it is exposed to the sun. In the human body, vitamin D is stored as 25(OH)-vitamin D. 25(OH)-vitamin D accounts for about 95% of the total amount of vitamin D, and is therefore determined as a marker for the supply of vitamin D. A vitamin D deficiency is associated with lower bone density, muscle disorders, cardiac and circulatory diseases, disorders of the nervous system and diabetes. A vitamin D insufficiency can facilitate the development of cancer, diabetes, hypertension, myocardial infarction and autoimmune diseases. A regular check of vitamin D levels is especially recommended in the case of risk groups such as infants, elderly people, people with darker skin colour, and people who spend very little or no time outside.

Test Principle

The **Preventis *SmarTest Pro*[®] Vitamin D** test system consists of an immunological rapid test that detects 25(OH)-vitamin D via specific antibodies, and a smartphone app that analyses the result of the rapid test quantitatively based on the colour intensity of the control and test lines. The result is displayed and stored on the smartphone.



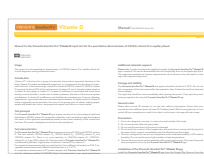
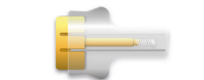


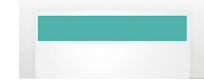

Test Characteristics

The **Preventis *SmarTest Pro*[®] Vitamin D** has a measuring range of 5-100 ng/ml 25(OH)-vitamin D. The test detects 25(OH)-vitamin D₂, 25(OH)-vitamin D₃, 1,25(OH)₂-vitamin D₂ and 1,25(OH)₂-vitamin D₃. There is no cross-reactivity to 1,24(OH)₂-vitamin D₂, 1,24(OH)₂-vitamin D₃ or 3-epi-(OH)-vitamin D₃. The test result of **Preventis *SmarTest Pro*[®] Vitamin D** is not affected by bilirubin, triglycerides, cholesterol, vitamin B12 or vitamin C. For repeated measurements with one rapid test lot, the coefficient of variation is 25.8 %, for repeated measurements with different rapid test lots, it is 3–37 %. A comparative measurement of 27 patient samples with **Preventis *SmarTest Pro*[®] Vitamin D** and the reference method LC-MS/MS (liquid chromatography mass spectrometry/ mass spectrometry) showed a very good correlation between the two methods (87.5 %).

Materials

Preventis *SmarTest Pro*[®] Vitamin D is available in two pack sizes:

- REF PST80100G5: 5 test devices, 1 camera test card, 1 manual and 5 sample collection sets (each with 1 lancet, 1 capillary tube, 1 tube with buffer 1 alcohol pad, 1 plaster), additional 1 sample collection set as reserve
- REF PST80100GP: 20 test devices, 1 camera test card, 1 manual and 20 sample collection sets (each with 1 lancet, 1 capillary tube, 1 tube with buffer, 1 alcohol pad, 1 plaster), additional 4 sample collection sets as reserve

Materials provided		Number	
		PST80100G5	PST80100GP
	Test device, individually packed TEST	5	20
	Camera test card CARD	1	1
	Manual	1	1
Sample collection set:		6	24
	Lancet LANCET Sarstedt AG & Co., Nümbrecht, Germany CE 0124		
	Capillary tube PIP		
	Tube with buffer BUF		
	Alcohol pad WIPE B. Braun Melsungen AG, Melsungen, Germany		
	Plaster PLASTER BSN medical GmbH, Hamburg, Germany CE		

Additional Materials Required

Please note: In order to analyse the rapid test results, the **Preventis *SmarTest Pro*[®] Vitamin D** app is required. This can be downloaded from the Google Play Store or the Apple App Store. The supported smartphones (system requirements) can be found here: <https://vitd.preventis.com>.

Storage and Stability

The **Preventis *SmarTest Pro*[®] Vitamin D** test system should be stored at 4-30°C. Do not use the components of the test system after the expiration date. Protect the test from heat and direct sunlight. The rapid test should be used immediately after opening the pouch. Only open the pouch when prompted to do so by the **Preventis *SmarTest Pro*[®] Vitamin D** app.

General Notes

Please allow around 20 minutes to run the test, without interruption. Ensure that your smartphone has sufficient power (at least 20 % battery level). While running the test, do not switch off your smartphone or switch it to silent, as the timer in the app will emit a beep.

Precautions

- For *in-vitro* diagnostic use only, i.e. only to be used outside of the body.
- Do not use the test after the expiry date.
- Do not use the test device if the pouch is damaged.
- Do not drink the content of the sample tube, and avoid direct contact with the liquid. In the event of skin contact, immediately wash the affected area thoroughly.
- The test is designed for use at room temperature and moderate humidity (<60% relative humidity). Do not use the test in high humidity or high temperatures.
- The test device must be used immediately after opening the pouch. Only open the pouch when prompted to do so by the **Preventis *SmarTest Pro*[®] Vitamin D** app.

Installation of the Preventis *SmarTest Pro*[®] Vitamin D app

Install the **Preventis *SmarTest Pro*[®] Vitamin D** app from the Google Play Store or from the Apple App Store. The supported smartphones (system requirements) can be found here: <https://vitd.preventis.com>.

Setting up the Preventis *SmarTest Pro*[®] Vitamin D app

- Before initial use, the Preventis SmarTest Pro[®] Vitamin D app must be set up. To do this, carry out the following:
- Start the **reventis *SmarTest Pro*[®] Vitamin D** app.
 - Read the General Terms and Conditions carefully and confirm that you agree to them by clicking „Continue“.
 - Perform the camera check using the camera test card supplied. In order to do this, follow the instructions in the app. Carry out the camera test in the same location that you will later use to analyse the rapid test, in order to include the light conditions in the test. Note: If the camera test repeatedly fails, check the camera lens for scratches or dirt, and remove them if necessary. Also check the camera card test for possible damage, and ensure that there is even lighting. If the test continues to fail, please contact your **Preventis *SmarTest Pro*[®] Vitamin D** supplier.
 - Assign a four-digit personal identification number (PIN) and confirm this by entering it again. You will need your PIN every time you start the app.
 - The **reventis *SmarTest Pro*[®] Vitamin D** app is now set up and ready to use right away.

Functionality of the Preventis *SmarTest Pro*[®] Vitamin D app

In the main menu you have the following options:

- „Prepare test“ provides information on the preparation of the test, and guides you through the sampling process, running the test, and test analysis, with short illustrated sequences.
- „Direct scan“ directly brings up the test analysis in the app (only for experienced users).
- „Results“ displays the stored results.
- The „gear symbol“ takes you to the settings. Here, amongst other things, you can change the PIN, redo the camera check and reset the app. You can also see detailed instructions here regarding the **Preventis *SmarTest Pro*[®] Vitamin D**.



Preparation

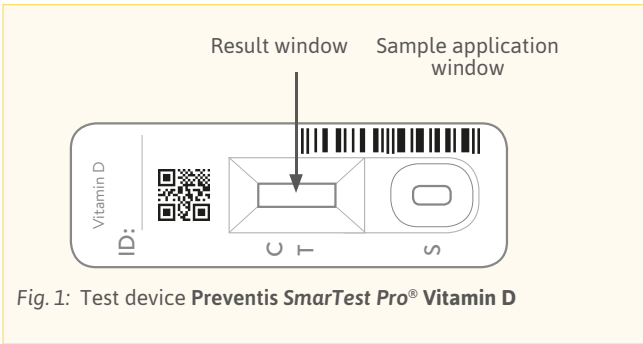
Ensure that the test equipment is at room temperature. Check the internet connection on your smartphone and turn on the sound. Have the pouch with the test device and all other test components ready. Please take care that the tip of the capillary tube doesn't touch anything. Start the **Preventis SmarTest Pro[®] Vitamin D** app on your smartphone. **Important!** Do not remove the test device from the pouch yet! Please allow approximately 20 minutes to complete the test.

Sample Collection

The sides of the finger tips of your middle or ring finger are particularly suitable for taking a capillary blood sample. Rub the selected finger until it is warm, with good blood circulation. Clean the area with the alcohol pad, then allow the cleaning solution to dry completely. Rotate the lancet securing device and remove it. Hold the lancet against the clean finger, and press the yellow button. The lancet is triggered, and punctures the finger. Rub the finger and then press it slightly in the direction of the puncture point, until a sufficiently large drop of blood has formed. Hold the capillary tube horizontally or from below against the blood drop in order to collect it. Fill the capillary tube with blood completely, without interruption. If air bubbles are visible in the capillary tube, the procedure must be repeated with a new capillary tube. Stick the filled capillary into the tube with buffer, piercing the film. Press the capillary tube and tube with buffer tightly together until the bridge of the capillary tube rests on the edge of the tube with buffer. Shake the tube with buffer with the capillary tube inside until the blood and buffer have mixed well. You can now cover the puncture point on the finger with a plaster.

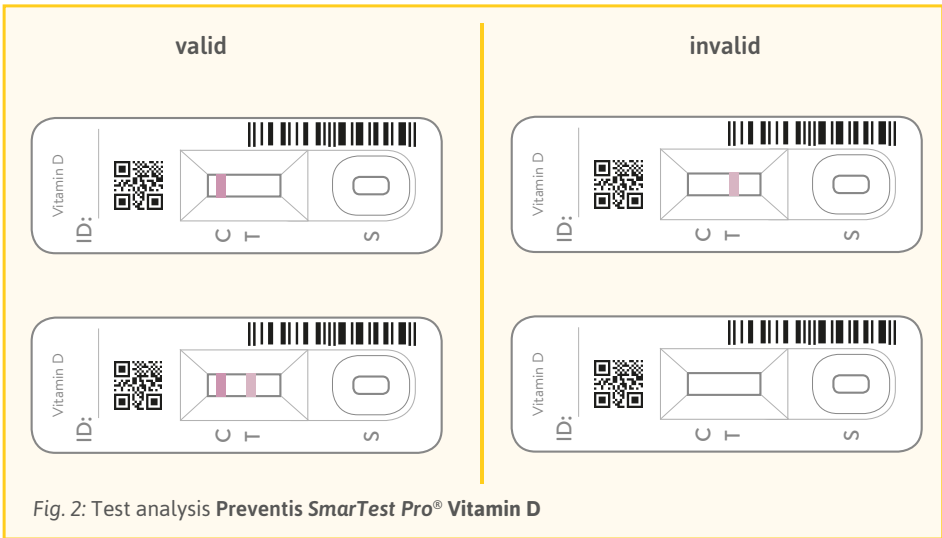
Test Procedure

Remove the test device from its pouch. Unscrew the cap from the tube with buffer/capillary tube. Applying even pressure to the tube, place **3 drops** of the liquid onto the sample application window of the test device (Fig. 1). Start the timer of the **Preventis SmarTest Pro[®] Vitamin D** app immediately, by pressing „Start test“. The incubation time of the sample is 15 minutes.



Test Analysis

A beep will be emitted following the incubation time. You now have 2 minutes to analyse the rapid test using the app. First check to see whether there is a control line in the results window of the test device. The position of the control line in the results window is indicated by a „C“ on the test device. If no control line is visible, the test is not valid and cannot be analysed! The position of the test line is indicated by a „T“ (Fig. 2).



When analysing the rapid test, place the test device on a bright, flat surface. Make sure the light conditions are similar to those in the camera test. Avoid shadows, strong light from the side and direct sunlight. Press „Scan test“ in the app. You will see a template of the test device on your screen. Align the template on your screen with the test device in front of you. While doing this, hold your smartphone horizontally, parallel to the test device and avoid tilting it. Hold it in this position briefly until the **Preventis SmarTest Pro[®] Vitamin D** app automatically triggers the camera several times, and goes to the analysis screen. After a successful calculation, the **Preventis SmarTest Pro[®] Vitamin D** app shows the reading on the screen of the smartphone. You can return to the main menu of the app by pressing „Continue“.

If you exceed the time window for the test analysis by more than 2 minutes, the rapid test can still be analysed, but the test result could be inaccurate. If you exceed the time window for the test analysis by more than 10 minutes, the rapid test can no longer be analysed. In such an event, the measurement must be repeated, with a new test.

Interpretation of the Reading^{1,2,3}

0–10 ng/mL	The result indicates a deficiency.
11–30 ng/mL	The result indicates an insufficiency.
31–100 ng/mL	The result indicates an optimal level.
>100 ng/mL	The result indicates an excessive level.

Please note: Interpretation of the reading may vary from this table, depending on individual health and physical conditions.

Disposal

After use, dispose of all components of the Preventis SmarTest Pro[®] Vitamin D test kit in the residual waste.

Test Limitations

The **Preventis SmarTest Pro[®] Vitamin D** test system detects 25(OH)-vitamin D with a high degree of reliability; however, in certain cases it may produce incorrect results. In the case of questionable results, additional clinical tests should be carried out. As with all diagnostic tests, a definitive diagnosis should not be made on the basis of a single result but only after a doctor has performed a full evaluation of your condition.

References:

- Bischoff-Ferrari HA (2014) Optimal serum 25-hydroxyvitamin D levels for multiple health outcomes. In Sunlight, Vitamin D and Skin Cancer (Advances in experimental medicine and biology), Reichrath J (ed) pp 500–25. New York: Springer-Verlag.
- Gupta AK, Jamwal V, Sakul & Malhotra P (2014) Hypervitaminosis D and systemic manifestations: A comprehensive review. J. Int. Med. Sci. Acad. 27: 236–237.
- Kimball SM, Mirhosseini N & Holick MF (2017) Evaluation of vitamin D₃ intakes up to 15,000 international units/day and serum 25-hydroxyvitamin D concentrations up to 300 nmol/L on calcium metabolism in a community setting. Dermatoendocrinol. 9: e1300213.

Short Instructions

Preventis SmarTest Pro[®] Vitamin D

- Clean the fingertip with the alcohol pad and leave to dry.
- Puncture the skin of the fingertip, using the lancet.
- Fill the capillary tube completely with blood.
- Stick the capillary tube into the tube with buffer, push them together, and shake vigorously.
- Remove the test device from its pouch.
- Unscrew the cap from the tube with buffer. Place **3 drops** of the sample solution into the oval sample application window.
- Observe the 15-minute incubation period.
- After the beep, analyse the result within 2 minutes, using the app.
- The result is displayed and stored on the smartphone.



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Temperature limitation	Manufacturer
In vitro diagnostic device	Lot number
Catalogue number	Expiry date
To be used with	Do not reuse
Read user instructions	Contains sufficient for <n> tests
Keep away from sunlight	

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