SBM
Smith BioMed

Vitamin D *Deficiency Test*

Detects Deficiency Quickly & Easily

A rapid test for detecting Vitamin D deficiency.

INTENDED USE

The Vitamin D Rapid Test Cassette is a rapid test for the semi-quantitative detection of 25-hydroxy vitamin D (25 (OH) D) in human fingerstick whole blood. It can be used to screen for Vitamin D deficiency.

SUMMARY

Vitamin D deficiency is now recognized as a global epidemic. Virtually every cell in our body has receptors for Vitamin D, requiring sufficient levels for adequate functioning. The health risks associated with vitamin D deficiencies are far more significant than previously thought. Vitamin D deficiency has been linked to various serious diseases.

Those at risk of having low levels of vitamin D include:

• people who don't get much exposure to the sun

• older adults

• people with obesity

• babies who are breastfed only (formula is usually fortified with vitamin D)

• people who have had gastric bypass surgery

• people who have a disease that affects the intestines and makes it difficult for the body to absorb nutrients, such as Crohn's disease.

Maintaining sufficient levels of vitamin D is not just important to improve bone health, but your overall health and well-being.

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. 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 the vitamin D (including D2 and D3) concentration in the body which is considered the best indicator of vitamin D status.

PRECAUTIONS

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.

Do not make any important medical decisions after taking the test without first referring to your doctor.

• Read the Instructions carefully before performing the test.

• For external use only.

• For self-test in vitro diagnostic use only.

• Keep out of the reach of children.

• Do not drink any part of the test kit components

• After the test is completed ensure all components of the test kit are disposed of safely

• Do not use after the expiry date or if the pouch is damaged.

• Follow the indicated time strictly.

• Use the test only once.

STORAGE AND STABILITY

Store as packaged at room temperature (2-30 degrees) in a cool dark place protected from light

DO NOT FREEZE.

Do not use beyond the expiration date. The test is stable through to the expiration date printed on the sealed pouch.

All components of the test must remain in their sealed pouches until use.

MATERIALS PROVIDED

• Test Cassette
• Capillary Dropper
• Buffer
• Alcohol pad
• Lancet
• Instruction Leaflet
• Colour Card

PROCEDURE - HOW TO DO THE TEST

1. Wash your hands with soap and rinse with clear warm water.

2. Open the foil pouch and get out the Cassette-place on a flat surface.

3.Use the provided alcohol pad to clean the fingertip of the middle or ring finger as the puncture site.

4.Carefully twist and pull off and dispose the round cap of the lancet.

5. Press the lancet, against your fingertip on the side from where the cap was extracted. This will allow the lancet to pierce the skin. The tip of the lancet retracts automatically and safely after use.

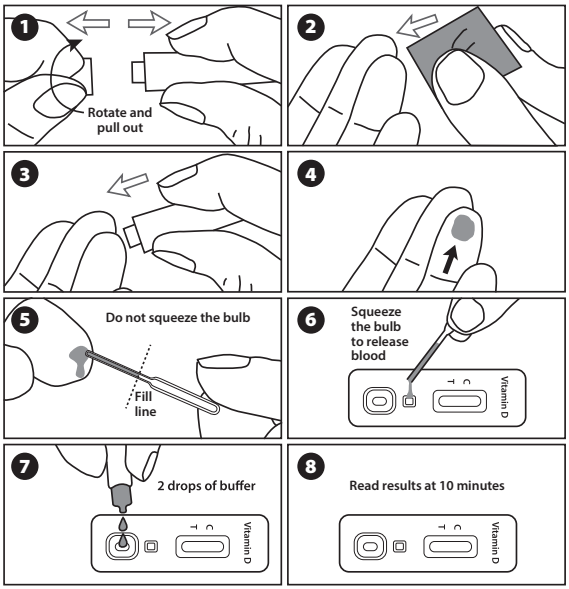
6. Keeping your hand down massage the end of the finger to obtain a blood drop.

7. Without squeezing the capillary dropper bulb, put it in contact with the blood. The blood will migrate into the capillary dropper through the capillarity to the line indicated on the capillary dropper. You may massage your finger to obtain more blood if the line is not reached.

8. Put the blood collected into the square well, marked 'S', of the cassette, by squeezing the dropper bulb.

9. Wait for all the blood to be in the well then unscrew the cap of the buffer bottle and add 2 drops of buffer into the round sample well, marked 'B', of the cassette.

10. Wait for the coloured line(s) to appear. Read results at 10 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

Please refer to the illustrations below and compare the T line intensity with the 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: 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 equal to or darker than 10 ng/mL line depicted on the colour card provided with the kit.

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 and lighter than 10 ng/mL line depicted on the colour card provided with the kit.

Sufficient: Two colored lines appear. One is in the control region (C) and faint coloured line appears in the test region (T). The line intensity in region (T) is equal to or lighter than the 30 ng/mL line depicted on the colour card.

Excess: One colored line appears in the control line region (C). No coloured line appears in the test line region (T). If the result is excess, it is recommended to consult a physician.

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.

QUALITY CONTROL

A coloured line appearing in the control line region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

EXTRA INFORMATION

1. Can the result be incorrect? The results are accurate as long as the instructions are carefully followed.

2. What is the line that appears under the C (control) line? When this line appears, it only means that the test is performing well.

3. 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 not reliable after 20 minutes.

4. What do I have to do if the result is abnormal? If the result is abnormal showing a deficient or insufficient result, it means that the Vitamin D level is lower than the normal range. If the result is abnormal showing an excess result, it means that the Vitamin D level is higher than the normal range. In both cases you should consult your doctor and show the test result to him/ her. Your doctor will then decide whether additional analysis should be performed.

5. What do I have to do if the result is normal? If the result is normal, it means that the Vitamin D level is higher than 30 ng/mL and is within the normal range. However, if the symptoms persist, it is recommended to consult your doctor.

Who can I contact if I have more questions?

For further information or advice on using the **Professional Vitamin D Deficiency Test**, either contact the pharmacy you purchased the tests from ***OR*** contact **Smith Biomed (NZ) Ltd** by email to info@smithbiomed.com.

Index of Symbols

Consult instructions for use	Tests per kit	EC REP	Authorized Representative
IVD For in vitro diagnostic use only	Use by		Do not reuse
Store between 2-30°C	LOT Lot Number	REF	Catalog #
Do not use if package is damaged	Manufacturer		

Manufactured by:
Hangzhou Alltest Biotech Co., Lt
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