LOMINA
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Lomina Vitamin D Test

Instructions for use (IFU)

[PACKAGING SPECIFICATION]

Variants	1 pc in package - box/ pouch	2 pcs in package - box	25 pcs in package - box	50 pcs in package - box
REF	La-D-Pro /1P or 1B	La-D-Pro /2B	La-D-Pro /25B	La-D-Pro /50B
IVD test strip in plastic cassette [pcs]	1	2	25	50
Sterile Lancet [pcs]	1	2	25	50
Stabilization fluid - buffer [pcs]	1	2	25	50
15 µl dropper [pcs]	1	2	25	50
Disinfecting pad [pcs]	1	2	25	50
IFU [pcs]	1	1	1	1

[INTRODUCTION]

Vitamin D is a group of fat-soluble secosteroids that increase 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 human skin by exposure to ultraviolet radiation and vitamin D2 is obtained mainly from food. Vitamin D is transported to the liver where it is metabolized to 25-hydroxy vitamin D. The concentration of 25-hydroxy vitamin D (including D2 and D3) in the blood is considered the best indicator of vitamin D status. Vitamin D deficiency is now considered a worldwide problem. Virtually every cell in our body has receptors for vitamin D, which means they all require „sufficient" levels of vitamin D to function adequately. The health risks associated with vitamin D deficiency are much more serious than previously thought. Vitamin deficiency is associated with a variety of serious diseases: osteoporosis, osteomalacia, multiple sclerosis, cardiovascular disease, pregnancy complications, diabetes, depression, stroke, autoimmune disease, influenza, various cancers, infectious diseases, Alzheimer's disease, obesity and higher mortality rates, etc.

[INTENDED USE]

The Lomina Vitamin D Test is a rapid chromatographic immunoassay for the semi-quantitative detection of 25-hydroxyvitamin D (25(OH)D) in the human body, It is designed for detection from a finger prick sample of whole blood. This test provides an indicative diagnostic result and can be used to screen for vitamin D deficiency.

[TEST PRINCIPLE]

The vitamin D test is based on the principle of competitive binding immunoassay. During testing, the compound migrates through the membrane where an immunochemical reaction occurs during capillary migration. The membrane is pre-coated with 25-OH vitamin D antigens in the control area (‚C'). The 25-OH vitamin D in the sample is competent to the 25-OH vitamin D in the test area, against a limited amount of anti-25-OH vitamin D antibodies in the conjugate. If all conjugated antibodies are saturated with 25-OH vitamin D in the sample, no coloured line is formed in the test region, indicating a concentration greater than 30 ng/ml. The presence of a visible coloured line in the test area (T) indicates the absence of 25-OH Vitamin D or its presence at a level below 30 ng/ml. The higher the concentration of 25-OH Vitamin D in the sample, the lighter the line will be in test area T. The result is read according to the line color intensity card provided in this manual. As a check on the procedure, a colored line C will always appear in the control area to indicate that the correct volume of sample has been added and that membrane activation has occurred.

[PACKAGE CONTENTS]

1. IVD test strip in plastic cassette
2. Desiccant
3. Lancet for disposable blood sample collection (HTL-Strefa S.A. CE0344; Type Actilance STERILE R nebo wellion MED TRUST CE0197; Type 23G double protection STERILE R)
4. Stabilization fluid (buffer)
5. 15 µl dropper
6. Disinfecting pad (alcohol-based disinfection)
7. Instructions for use

[NOT INCLUDED IN THE PACKAGE]

Stopwatch/clock for measuring the duration of the test.

⚠ [ATTENTION !]

- Please read all information in this manual before performing the test.
- For use by medical professional in in vitro diagnostics only.
- Do not eat, drink or smoke in the area where samples or kits are handled.
- Store in a dry place at a temperature of 2-30 °C, avoid areas with excessive humidity. If the foil packaging is damaged or has been opened, do not use it.
- This test kit is intended for preliminary testing only.
- Strictly observe the specified sample reading time.
- Use the test only once. Do not disassemble or touch the test window of the test cassette.
- The kit must not be frozen or used beyond the expiry date on the packaging.
- Keep out of the reach of children.
- Dispose of the used test in accordance with local regulations.

[STORAGE CONDITIONS]

1. The test pack shall be stored at a temperature of 2 °C to 30 °C.
2. The components of different batches shall not be mixed. Each component is stable under the specified conditions and may reach the specified shelf life of the kit.
3. The contents of the kit are stable until the expiry date marked on the packaging and the shelf life is set at 18 months (based on stability studies).
4. Prolonged exposure to heat and moisture will render the reagent unusable.
5. Do not freeze.

[SAMPLE QUALITY REQUIREMENT]

1. The sample should be treated with stabilization fluid (buffer) immediately after sample collection.
2. Reagent bottles should not be opened until the sample has been applied.
3. Long-term storage of samples is not recommended.

[TEST LIMITATIONS]

1. The Lomina Vitamin D Test 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 sample, may cause erroneous results.
3. In case of questionable results, additional clinically available tests must be performed.

[INSTRUCTIONS FOR USE]

1. Open the pouch, remove the test cassette and place it on a clean, flat surface. Test within one hour and best results are obtained if you test immediately after opening the foil pouch. Remove the dropper, reagent-buffer bottle, lancet and alcohol pad and place them near the test cassette.
2. Carefully withdraw and discard the loose lancet cap.
3. Using the alcohol pad provided, clean the tip of the patient's middle finger or ring finger as the injection site. Allow to air dry.
4. Squeeze the lancet on the side from which the cap was removed; the tip will automatically and securely retract after use. Massage the hand without touching the puncture site by massaging the hand towards the tip of the middle or ring finger to be punctured.
5. Massage the end of the patient's finger that has been punctured to obtain a drop of blood.

6. Squeeze the dropper bulb to release the collected blood into the sample well (S) of the cassette.
7. Unscrew the cap of the stabilization fluid (buffer) and add 2 drops of the stabilization fluid (buffer) on the cassette to the B - Buffer well and start the timer.
8. Wait for a coloured line (or two lines) to appear. Read the results after 10 minutes. Compare the intensity of the T line with the „Line Color Intensity Card" figure later in the instructions for use to obtain a blood vitamin D level. Do not interpret the result after 20 minutes.

- Testing should be done immediately after drawing whole blood from the finger.

[INTERPRETATION OF TEST RESULTS]

After applying the sample, start the stopwatch. After applying the sample, start the stopwatch, wait 10 minutes. Do not tamper with the plastic cartridge! After 10 minutes, read the result in the „T" section of the test card. The line may appear within a few seconds for strong concentrations, weaker concentrations will show the line a little later. The result is interpreted by the visible line in the „T" area on the body of the test cartridge (see picture below), The results of the visual inspection are as follows:

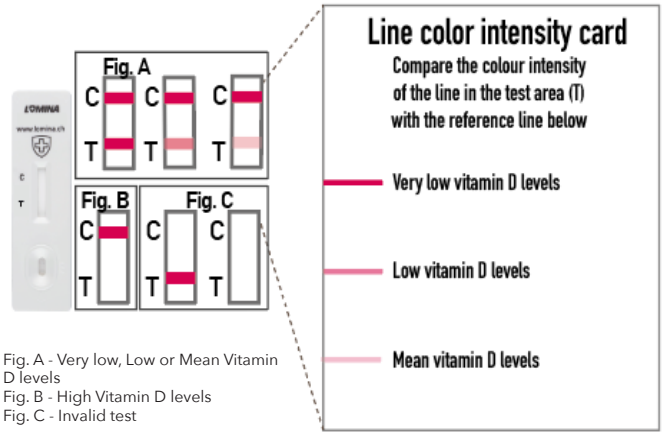

Fig. A - Very low, Low or Mean Vitamin D levels
Fig. B - High Vitamin D levels
Fig. C - Invalid test

Very low vitamin D levels:

Two distinctive coloured lines appear (Figure A). One is in the control area (C) and the other should be in the test area (T). The intensity of the line in the test area (T) is equal to or darker than the line corresponding to the low vitamin D level depicted on the „line color intensity card" provided in this manual.

Low Vitamin D levels:

Two coloured lines will appear (Figure A). One is in the control area (C) and the other should be in the test area (T). The intensity of the line in the test area (T) is darker than the line corresponding to the medium level of vitamin D on the ‚line color intensity card' provided in these instructions for use and lighter than the line corresponding to the very low level of vitamin D.

Mean Vitamin D levels:

Two colored lines will appear (Figure A), one line should always be in the control area (C) and a faint colored line will appear in the test area (T).
The intensity of the line in area (T) is equal to or lighter than the line corresponding to the mean vitamin D level shown on the „line color intensity card".

High Vitamin D levels:

A single coloured line appears in the control area (C). In the test area (T), no apparent coloured line appears (Figure B).

Invalid test:

If the line does not appear in the control area (Figure C), it is a invalid test. The most likely cause of the failure to display in the control area is insufficient sample volume or incorrect testing procedure. Check the procedure and repeat the test with a new test line. If the problem persists, stop using the test kit immediately and contact your local distributor.

[CROSS-REACTIVITY]

No cross-reactivity has been demonstrated for the following substances: Vitamin A, Vitamin B, Vitamin C, Vitamin E, Vitamin K and Vitamin M.

[INTERFERENCE FACTORS]

There was no interference with the following substances: acetoaminophen, acetylsalicylic acid, ascorbic acid, atropine, bilirubin, caffeine, gentisic acid, glucose, hemoglobin, triglycerides, albumin.

[PERFORMANCE CHARACTERISTICS]

Method		Commercially Available Vitamin D Rapid Test			Total
Lomina Vitamin D test	Results	Very low level	Low level	Mean level	
	Very low level	4	4	0	8
	Low level	0	64	2	66
	Mean level	0	0	23	23
Total		4	68	25	97
Accuracy		>99.9%	94.1%	92.0%	93.8%

The accuracy of the Lomina Vitamin D test is 93.8%.

[ATTENTION]

- Invalid negative results may occur if the sample is incorrectly collected, transported or handled - in other words, if these instructions for use are not followed.
- Do not mix different lots (LOTs) of tests and reagents!
- Read the instructions for use (IFU) carefully before testing and follow the procedures in the manual carefully.
- Insert the test sample into the test card very slowly and observe the exact amount of 2 drops of sample!
- The reaction time of the test is 10 minutes. When the reaction is complete, do not read the result later than 20 minutes. In other words, the result is invalid 20 minutes after the test solution is inserted.
- The Lomina Vitamin D test is intended for in vitro diagnostic use by healthcare professionals and should only be used for qualitative detection of the presence of Vitamin D in a sample. The intensity of the colour or the thickness of a positive strip should not be considered „quantitative or semi-quantitative".
- The test is only intended to give an indication of the level of vitamin D in the body. The patient's overall condition should always be considered.

[SYMBOL INDEX]

	Consult instructions for use		Caution		Use by date
IVD	In vitro diagnostic medical device		Do not use if package is damaged		Do not re-use/Intended for one use
	Manufacturer	LOT	Batch code	REF	Catalogue number
	Keep away from sunlight	Σ	Contains sufficient for <n> tests	2°C 30°C	Temperature limit 2-30 °C
	Keep dry				

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CE
REF La-D-PRO

IVD 2°C 30°C

Date of last revision: 2022/07/14
Version: La-D-PRO / CZ-IFU-1.0