Vitamin D Magic...

There is large concerns about the increase in Vitamin D deficiency around the world. This deficiency can be blamed on several factors, for example a reduction of sun (UV) exposure which prevents Vitamin D synthesis in the skin, the application of sunscreen which blocks UV light. Whatever the reasons, it's very serious...



It's not easy to know what our vitamin D levels are. It has only just come to light that not everyone gets the same benefit from the same vitamin D dosage. The only way to tell whether

you're getting enough vitamin D is by measuring it. You have to measure what's in the blood, because the response to a given dose varies over six-fold range. Different people have different capacities of producing the enzyme 25-hydroxylase in their livers. This enzyme converts vitamin D into the form that we measure in the blood stream, that is 25-HO-D. Some people are what is called very slow hydroxylaters, and others are very fast hydroxylaters, which means they have a lot of the enzyme necessary to do it, and in the other case means they don't have much of the enzyme, so they don't get as much for their vitamin D dose as somebody else does, and that means they need twice as much, or three times as much, or maybe even six times as much as another person.

Test4D3 is a true self test using a proprietary point-of-care -test (POCT) platforms that will allow the user (patient or your Doctor) to have quick and accurate access to crucial personal health information such as: Vitamin D level. The POCT for Vitamin D level in blood has amazing implications in delivering this crucial personal health information that everyone can simply be informed of their personal blood serum so as to implement Vitamin D supplementation as necessary.

Vitamin D Deficiency Linked to Many Diseases

As consumers we can make it our choice to keep ourselves healthy and promote our personal health by eating the right food, exercising regularly, and testing our blood. Test4D3 is bringing this opportunity to the consumer, to make sure that we are in fact getting the right amount of Vitamin D in our system to keep ourselves healthy.

Vitamin D deficiency has been linked to:

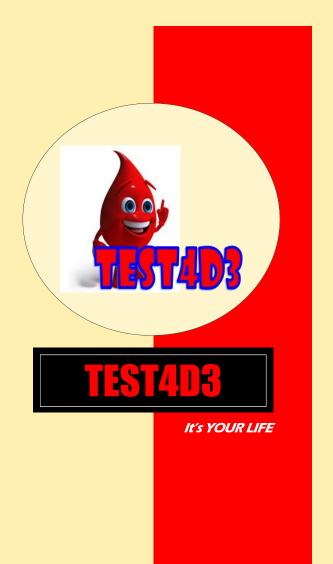
- 17 types of cancer
- Osteoporosis & Ricketts
- Heart disease & blood pressure
- Depression
- Multiple Sclerosis
- Dementia & Alzheimer's
- A Weak immune system, colds and flu prevention
- Depression
- Crucial for pregnant women and development of newborns
- Fatigue, sluggishness

You can now take action and be in control of your own health by testing at home (or at your Doctor's if you visit frequent) by testing your Vitamin D levels to be certain you are not deficient.

Test4D3™ is the only true **rapid** test available. It is **easy to use**, so everyone can know for certain what their Vitamin D levels are. No need to go to a lab to have your blood drawn and potentially wait weeks only to find out what you could have found out with Test4D™ in 10 minutes. With an accuracy of 99% and its simplicity to use, there is no test like it.



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Whose a slow hydroxylater then? Finding out could mean good or poor health.

Test Principle

Rapid three step assay for vitamin D3 levels:

TEST4D3 is based on the principle of a competitive enzyme immunoassay. The assay system utilizes a monoclonal antibody specific for vitamin D. The assay relies on the competition for binding antibody between vitamin D present in blood sample and vitamin D present on the test strip. The vitamin D present in the blood competes with the vitamin D on the test strip for limited number of antibody - gold conjugate. When the amount of vitamin D is 32ng/mL (80nmol/L) or more, it will prevent the binding of vitamin D present on the test strip to antibody-gold conjugate. Therefore a vitamin D sufficient sample will not show the coloured line in the test line zone. When amount of vitamin D is less than 32ng/mL (80nmole/L), there will be free antibody-gold conjugate molecule that will bind to vitamin D on the test strip and will show a coloured line in test line zone.

Materials Provided

- 1. TEST4D3 test device
- 2. Microtainer® Contact-Activated Lancet
- 3. Disposable transfer pipette
- 4. Buffer solution

Directions for Use

1. Remove the cassette from sealed pouch & place it on a hard flat surface with the view window facing up (use the cassette as soon as possible).



2. Using the dropper (*refer specimen collection), add one drop of blood/serum from the dropper directly into the square specimen well (A) of the cassette



3. Add 7 full drops of buffer into the circular buffer well(B) of the cassette (Do not move the cassette after addition of buffer)



4. Let cassette sit for 10 minutes and read your results immediately. Results may deteriorate after the 10 minute mark



Storage and Stability

The test device should be stored at 22±2 \(\text{C}\) C and will be stable until the expiration date stated on the package. The product is humidity sensitive and should be used immediately after being open.

Precautions

- 1. For In Vitro blood test use only.
- 2. Do not use product beyond expiration date.
- 3. Handle all blood specimens as potentially infectious.

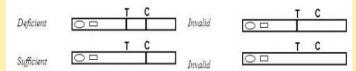
Limitation of the Assay

This assay is designed for use with blood/serum and provides the information about deficient or sufficient vitamin D levels in blood.

It does not provide a quantitative estimation of vitamin D levels, only 25(OH)D levels.

Sensitivity:

The sensitivity level of TEST4D is $32 \text{ng/mL} \pm 6 \text{ ng/mL}$ Results:



Results interpretation

Invalid: If control line fails to appear.

Review "Directions for use" and repeat the test with a new cassette Sufficient levels >32ng/ml OR >80nmol/L of 25(OH) D Deficient levels <32ng/ml OR <80nmol/L of 25(OH) D



Blood Specimen Collection.

State of the art, safe, fast & almost painless.

The **Contact-Activated Lancet h**as FDA Certifications of Compliance & Sterility (COS, CofS).

Easy to use – Twist off the protective tab and place on contact point.

BD Microtainer® Contact-Activated Lancet

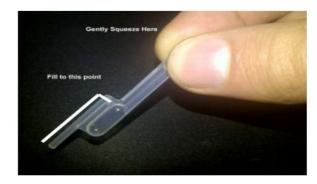
The BD Microtainer® Contact-Activated Lancet has been designed with a positive patient experience in mind. The contact activation method facilitates a consistent puncture depth and minimizes the likelihood of having to repeat the



puncture. It covers only a small area at the contact point, resulting in improved visibility of the puncture site for the clinician and greater accuracy of lancet positioning when performing the puncture. Its innovative, ergonomic design allows for a more comfortable grip. The lancet automatically retracts into the device, which prevents the lancet from being reused.

Puncture Procedure: Clean skin contact area with alcohol swap. Press safety lancet firmly against the puncture site. Do not remove the device from the site until an audible click is heard. Blood drop is sucked into vial.

Remove required amount of blood into Heparin/EDTA coated vial



 Hold and touch the end of the dropper to the drop of blood and let the blood fill to the complete length of the dropper (up to reservoir bulb), equivalent to 20μL