ImmunoScience INDIA

ImmunoQuick

Vit- D

Rapid Vitamin D Detection Test – Device

A rapid competitive assay for determination of Vitamin D Deficiency.

For Self - Testing & In-Vitro Diagnostic Use Only **Store at 4°C to 30°C**

OVERVIEW

Vitamin D is a fat-soluble vitamin that are needed for normal cell function, growth, and development. It promotes calcium absorption in the gut and maintains adequate serum calcium and phosphate concentrations to enable normal bone mineralization and to prevent hypo calcemic tetany (involuntary contraction of muscles, leading to cramps and spasms).

INTENDED USE

It is a rapid chromatographic immunoassay for the semi-quantitative detection of vitamin D from human serum/plasma/whole blood.

This test is for healthcare professional use as well as for home use.

PRINCIPLE

The Vitamin D test is an immunoassay based on the principle of competitive binding. During testing, the mixture migrates upward on the membrane chromatographically by capillary action. The membrane is pre-coated with antigens on the test line region of the strip. During testing, 25 (OH) D present in the specimen will compete with 25 (OH) D on the test line for limited amount of anti-25 OH Vitamin D antibodies in the conjugate. The higher concentration of 25 (OH) D in the specimen, the lighter would be the T line. The result will be read according to Color card provided with the kit. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

CONTENTS OF KIT

1. Test Device with desiccant
2. Dropper.
3. Assay Buffer.
4. Package Insert.

OPTIONAL MATERIAL REQUIRED

1. Stopwatch

PRECAUTIONS/KIT STORAGE AND STABILITY

1. Please read all the information in this package insert before performing the test. Pay particular attention to the position of the Control and Test lines.
2. Do not use after the expiration date printed on the foil pouch.
3. Store in the sealed pouch in a dry place in between temperature 4°C to 30°C.Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of the reach of children.

WARNINGS

1. Do not reuse the test.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose hygienically in domestic waste.
5. Do not touch the membrane.
6. Treat the samples and used test as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the specimen sample or interchange the different specimen.
10. The manufacturer and distributor of this product shall not be liable for any loses, liability, claims, costs or damages whether director cons sequential rising out for related to an incorrect diagnosis.

SPECIMEN COLLECTION

Fresh anti coagulated whole blood should be used as a test sample. EDTA or Heparin or Oxalate can be used as suitable anticoagulants. Fresh serum or plasma can also be used as a test sample. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then store the specimen at 2°C to 8°C for up to three days before testing. Clotted, contaminated or hemolyzed blood samples should not be used for performing the test.

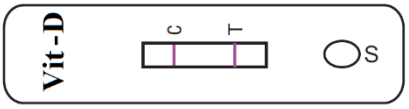
Fresh finger pricked blood samples can also be used as a sample for testing

TEST PROCEDURE

1. Bring the kit components to room temperature before testing.
2. Open the pouch and retrieve the test and desiccant pouch. Check the color of the desiccant. It should be blue, if it has turned colorless or pink, discard the test and use another test. Once opened, the test must be used immediately.
3. Label the test with patient's identity. Tighten the vial cap of the assay buffer provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.
4. Keep the device on plain surface & add one drop (Approx.10 µl) serum/plasma or two drops (Approx.20 µl) whole blood sample in sample 'S' well by using dropper.
5. Add 2 drops of assay buffer in sample well "S".
6. Start the timer.
7. Read the result at 15 minutes. Do not read the result after 20 minutes.

INTERPRETATION OF RESULTS

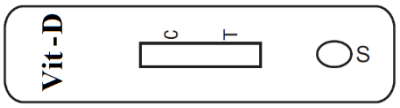
Negative (Normal Vitamin D): If colored line appears at control region 'C' as well as at test region T, then sample contains normal levels of Vitamin D.



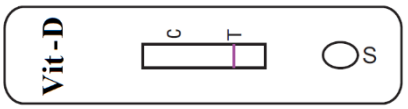
Positive (Vitamin D deficient): If a distinct clearly visible colored line appears at control region 'C' only with Absence or presence of very faint colored line at test region 'T', then specimen have Vitamin D deficiency.

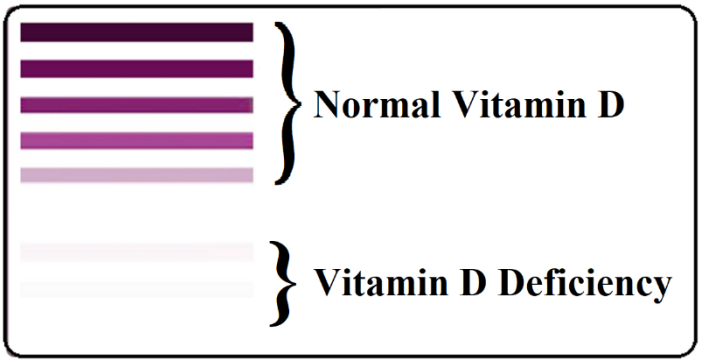
Invalid: Test should be considered invalid and repeat the test using fresh test if

a. No line appears at control side 'C' and line appears only at test side 'T'.



b. No line appears at control side 'C' and test side 'T'.





LIMITATIONS

1. As with all diagnostic tests, the test result must always be correlated with clinical findings.
2. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context. When it seems indicated, reference correlation should be considered.
3. Any modification to the above procedure and / or uses of other reagents will invalidate the test procedure.
4. The test is limited to the determination of Vitamin D, Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

DISCLAIMER

The all precautions shall be taken to ensure the diagnostic ability and accuracy of this product.Thisproduct is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results.

	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
	Lot Number
	Store at 4°C to 30°C
	Single Use
	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
	Read package insert before use

MANUFACTURED BY

ImmunoScience India Private Limited
Gat No. 41, Kusgaon, Shivapur-Velhe Road,
Tal- Bhor, Pune, Maharashtra (India) -412205.