Vitamin D Rapid Test Kit (Serum/Plasma/Whole blood)

For Professional / Self and In-vitro Diagnostic use only

INTENDED USE:
The Vitamin D Rapid Test Kit is an immunochromatographic assay designed for the rapid detection of Vitamin D in human serum, plasma or whole blood samples.

ORDER INFORMATION

REF	Cont.
PVTD 01	01 Test
PVTD 05	05 Tests
PVTD 10	10 Tests
PVTD 25	25 Tests
PVTD 50	50 Tests

CLINICAL SIGNIFICANCE:
Vitamin D is a group of fat-soluble secosteroids responsible for increasing intestinal absorption of calcium, magnesium, and phosphate, and for many other biological effects. Vitamin D is obtained from sun exposure, foods, and supplements. Vitamin D promotes calcium absorption in the gut and maintains adequate serum calcium and phosphate concentrations to enable normal bone mineralization and to prevent hypocalcemic tetany, rickets in children and osteomalacia in adults etc. Blood concentration of 25(OH)D is currently the main indicator of vitamin D status. It reflects vitamin D produced endogenously and has a fairly long circulating half-life of 15 days.

PRINCIPLE:
This test kit utilizes a sandwich principle and colloidal gold immunochromatographic analysis to semi-quantitatively detect the concentration of 25-hydroxy vitamin D (25-OH-VD) that measures vitamin D levels in human serum, plasma, and whole blood samples. During the test, if the sample being tested contains the Vitamin D antigen, the colloidal gold-labeled Anti- antibody reacts with the Vitamin D antigen in the sample, forming a reaction complex. The complex moves forward along the nitrocellulose membrane, it is captured by the Vitamin D antibody pre-coated in the test zone (T), ultimately forming a visible purple- red reaction line in the T zone. Different concentration samples will produce differently colored purple-red reaction lines in the T zone. Whether the sample being tested contains Vitamin D type or not, the quality control zone (C) will also react with the sample as it moves, forming a purple-red reaction line.
By comparing the results with a color chart, the concentration range of Vitamin D in the sample can be determined, enabling semi-quantitative analysis.

COMPONENTS:

1. Individually foiled Test device with desiccant
2. Sample collection dropper (10 µl)
3. Sample dispenser dropper (20 µl)
4. Instruction for use
5. Color Chart
6. Lancet
7. Alcohol Swab
8. Prefill Assay Buffer

STORAGE AND STABILITY:

1. The kit can be stored at room temperature or refrigerated (2- 30°C). The test device must remain in the sealed aluminum pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test device/strip, if the pouch is damaged or seal is broken.

PRECAUTIONS

1. Wear protective gloves while handling specimens wash thoroughly afterwards.
2. The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch before test.
3. Do not mix reagents from different lot.
4. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
5. Follow the testing procedure exactly as mention in the insert.

LIMITATIONS:

1. The Vitamin D Rapid Test Kit is for in vitro diagnostic use only. Results should be interpreted in conjunction with other clinical and laboratory findings.
2. The test may provide false-positive or false-negative results. Confirmatory testing should be conducted if necessary.
3. Interference from substances such as rheumatoid factor, heterophilic antibodies, or lipemic or hemolyzed specimens may affect the test performance.
4. This test is optimized for human serum or plasma samples. Other sample types or interference may affect the results.

SPECIMEN COLLECTION AND PREPARATION:

1. Collect a fresh serum or plasma or whole blood sample using standard laboratory procedures.
2. Remove any particulate matter or precipitate by centrifugation before testing if required.
3. Avoid hemolysis, as it may interfere with the test results.
4. **Serum (S):** Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
5. **Plasma (P):** Collect the whole blood into a collection tube (containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.
6. **Whole Blood (WB):** Use Blood samples collected by venipuncture into a collection tube containing EDTA, citrate or heparin. Alternately, collect the whole blood by lancing devices. WB can be delivered by pipette or sample dropper directly to the test card

TEST PROCEDURE:

1. Bring the test device, sample buffer, and specimens to room temperature (15-30°C) before use.
2. Open the pouch and place the test device on a clean and flat surface.

For Serum or Plasma specimen:

Hold the dropper vertically and **transfer 10 µL of Serum/plasma** to the Prefill assay buffer tube (contain **approximately 200 µL** buffer), then Close the cap of Prefill assay buffer tube and mix the sample mixture thoroughly by shaking it about 10 times. See illustration below.

For Venipuncture Whole Blood specimen:

Hold the dropper vertically and **transfer 1 drop (about 10 µL) of Venipuncture Whole Blood** to the Prefill assay buffer tube (contain **approximately 200 µL** buffer), then Close the cap of Prefill assay buffer tube and mix the sample mixture thoroughly by shaking it about 10 times. See illustration below.

For Fingerstick Whole Blood specimen:

Hold the dropper vertically and **transfer 1 drop (about 10 µL) of Fingerstick Whole Blood** to the Prefill assay buffer tube (contain **approximately 200 µL** buffer), then Close the cap of Prefill assay buffer tube and mix the sample mixture thoroughly by shaking it about 10 times. See illustration below.

3. Draw **2 drops (about 40 µL) sample mixture** by the sample dispenser dropper provided in to the kit and load it into the sample well (S) of the Test Cassette.
4. Wait for the colored line(s) to appear. **Read results at 15 minutes** by comparing the T line intensity with provided color card. Do not interpret the result after 20 minutes.
   Note: It is suggested not to use the buffer, beyond 6 months after opening the vial.

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Interpretation of Results- Please Refer Color Chart Provided in the Kit.

Vitamin D Level	Reference Range (ng/mL)
Deficient	0-20
Insufficient	20-30
Sufficient	30-100
Toxicity	Above 100

Deficient:
Strong line appears at the Control region (C) and very faint line appears at Test Line.
This indicates that the sample is below 20 ng/mL and hence indicating that the sample is deficient in Vitamin D.

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 lighter than the 30 ng/mL line depicted on the color chart provided above and darker than 20 ng/mL line depicted on color chart provided above. This indicates that the sample is insufficient.

Sufficient:
Two colored lines appear. One is in the control region (C) and another should be in the test region (T). The line intensity in region (T) is darker than the 30 ng/mL line depicted on the color chart and equal to or lighter than 100 ng/mL line depicted on color chart.
Note: Always compare the T line intensity with "Vitamin D Color chart" and interpret results accordingly.

INVALID:
Control line fails to appear.

Quality Control

Internal procedural controls are included in the test individually. A colored line appearing in control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

BIBLIOGRAPHY

1. Institute of Medicine (US) Committee to Review Dietary Reference Intakes for Vitamin D and Calcium; Ross AC, Taylor CL, Yaktine AL, et al., editors. Dietary Reference Intakes for Calcium and Vitamin D.
2. Washington ('DC): National Academies Press (US); 2011. 3, Overview of Vitamin D. Available from: https://www.ncbi.nlm.nih.gov/books/NBK56061/
3. Wacker M, Holick MF. Sunlight and Vitamin D: A global perspective for health. Dermatoendocrinol. 2013 Jan 1;5(1):51-108. doi: 10.4161/derm.24494. PMID: 24494042; PMCID: PMC3897598.
4. Sahay M, Sahay R. Rickets-vitamin D deficiency and dependency. Indian J Endocrinol Metab. 2012 Mar;16(2):164-76. doi: 10.4103/2230-8210.93732. PMID: 22470851; PMCID: PMC3313732.
5. Holick MF. Vitamin D status: measurement, interpretation, and clinical application. Ann Epidemiol. 2009 Feb;19(2):73-8. doi: 10.1016/j.annepidem.2007.12.001. Epub 2008 Mar 10. PMID: 18329892; PMCID: PMC2665033.
6. Matsui, M.S. Vitamin D Update. Curr Derm Rep 9, 323–330 (2020). https://doi.org/10.1007/s13671-020-00315-0

GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight



India office
BIOBOON BIOTECH INDIA LLP
207. Regent Square
2nd floor, Above D'mart shopping mall
Adajan
Surat-395009
Email : info@bioboonbiotech.com

USA Address:-BIOBOON BIOTECH
LLC 1526 West 3rd Street, Plainfield,
NJ, 07063 USA
Email : mahipal@bioboonbiotech.com