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

QBL/PVTD/RPT_065

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.
Only for *In vitro Diagnostics* use

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. Prefilled Assay buffer vials
3. Human sample collection dropper (20 µl sampling device)
4. Sample dropper (25 µl dropper)
5. Instruction for use

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.

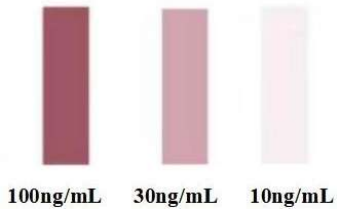
SPECIMEN COLLECTION AND PREPARATION:

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.
3. Dispense 1 drop of specimen using the dropper provided, into the pre filled buffer tube with assay buffer, mix well.
4. Dispense 3 drops (75 µL) mixture into the sample well of the device using the dropper provided, start the timer.
5. Read the results at 15 minutes, do not read results after 20 minutes.

Color Chart:



Interpretation of Results

Vitamin D Level	Reference Range (ng/mL)
Deficient	0-10
Insufficient	10-30
Sufficient	30-100

Deficient:
Only one line appears at the Control region (C).
This indicates that the sample is below 10 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 10 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

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GLOSSARY OF SYMBOL

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

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