SCREEN®

Vitamin D Rapid Test Cassette
（Whole Blood）
Package Insert

REF OVD-402	English

A rapid test for the semi-quantitative detection of 25-hydroxyvitamin D in human fingerstick Whole Blood.
For professional in vitro diagnostic use only.

【INTENDED USE】

The Vitamin D Rapid Test Cassette is a rapid chromatographic immunoassay for the semi-quantitative detection of 25-hydroxyvitamin D (25 (OH) D) in human *fingerstick* Whole blood at a cut-off concentration of 30 ± 4ng/mL. This assay provides a preliminary diagnostic test result and can be used to screening for Vitamin D deficiency.

【SUMMARY】

Vitamin D refers to a group of fat-soluble secosteroids responsible for increasing intestinal absorption of calcium, iron, magnesium, phosphate and zinc. In humans, the most important compounds in this group are vitamin D3 and vitamin D2.[1] Vitamin D3 is naturally produced in the human skin through the exposure to ultraviolet light and Vitamin D2 is mainly obtained from foods. Vitamin D is transported to the liver where it is metabolized to 25-hydroxy Vitamin D. In medicine, a 25-hydroxy Vitamin D blood test is used to determine Vitamin D concentration in the body. The blood concentration of 25-hydroxy Vitamin D (including D2 and D3) is considered the best indicator of Vitamin D status. Vitamin D deficiency is now recognized as a global epidemic.[2] Virtually every cell in our body has Receptors for Vitamin D, meaning that they all require “Sufficient” Level of Vitamin D for adequate functioning. The health risks associated with Vitamin D deficiency are far more severe than previously thought. Vitamin deficiency has been linked to various serious diseases: Osteoporosis, Osteomalacia, Multiple Sclerosis, Cardiovascular Diseases, Pregnancy Complications, Diabetes, Depression, Strokes, Autoimmune Diseases, Flu, Different Cancers, Infectious Diseases, Alzheimer, Obesity and Higher Mortality etc.[3] Therefore, now detecting (25-OH) Vitamin D level is considered as “Medically Necessary Screening Test”, and maintaining sufficient levels not just to improve bone health, but to improve overall health and well-being.[4]

【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 25 (OH) D 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.

【REAGENTS】

The test contains anti-25 OH Vitamin D antibody coated particles and 25-OH Vitamin D antigen coated on the membrane.

【PRECAUTIONS】

Please read all the information in this package insert before performing the test.

1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. The test should remain in the sealed pouch until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. The used test should be discarded according to local regulations.

【STORAGE AND STABILITY】

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch or label of box. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The Vitamin D Rapid Test Cassette can be performed using whole blood (from fingerstick).
- To collect **Fingerstick Whole Blood specimens**:
  - Wash the patient’s hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using **a capillary dropper**:
    - Touch the end of the capillary dropper to the blood, do not squeeze the bulb of the dropper, the blood migrates into the dropper through the capillarity to the line indicated on the dropper. Avoid air bubbles.
    - Squeeze the bulb to dispense the whole blood to the specimen area of the test Cassette.
- Testing should be performed immediately after the fingerstick Whole Blood have been collected.

【MATERIALS】

Materials provided

- Test Cassettes
- Color Card
- Capillary Droppers
- Package Insert
- Buffer

Materials required but not provided

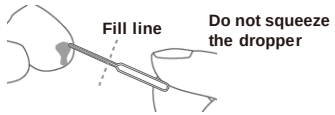
- Lancets
- Timer

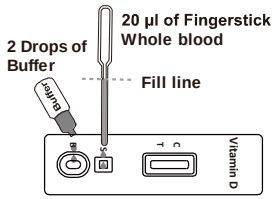
【DIRECTIONS FOR USE】

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing

1. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface.
- To use a Capillary droppers: Fill the capillary tube and **transfer approximately 20µL of fingerstick whole blood specimen** to the specimen area of test cassette, then add **2 drops of buffer** and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read results at 10 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.





10 min

Compare the T line with Color card provided with the kit

【INTERPRETATION OF RESULTS】

(Please refer to the illustration and compare the T line intensity with “Vitamin D Color card” provided with the kit.)

25-OH Vitamin D Level	Reference Range (ng/mL)	Reference Range (nmol/L)
Deficient	0-10	0-25
Insufficient	10-30	25-75
Sufficient	30-100	75-250

Deficient: Two distinct 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 equal to or darker than 10 ng/mL line depicted on color card provided with the kit.

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 darker than the 30 ng/mL line depicted on the color card provided with the kit and lighter than 10 ng/mL line depicted on Color card provided with the kit.

Sufficient: Two colored lines appear, one line should be always in the control region (C) and faint colored line appears in the test region (T). The line intensity in region (T) is darker than the 100 ng/mL line depicted on the Color card and lighter than 30 ng/mL line depicted on color card.

Note: Always compare the T line intensity with **“Vitamin D Color card”** and interpret results accordingly.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that standard controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The Vitamin D Rapid Test Cassette 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 specimen may cause erroneous results.
3. The Cut-off for the test is 30 ng/mL with a deviation range of ± 4 ng/mL.
4. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
5. Other clinically available tests are required if questionable results are obtained.

【EXPECTED VALUES】

The Vitamin D Rapid Test Cassette (Whole Blood) has been compared with predicate Device (Vitamin D Rapid Test), demonstrating an overall accuracy of 93.8%.

【PERFORMANCE CHARACTERISTICS】

Accuracy

The Vitamin D Rapid Test Cassette has been compared with predicate Device (Vitamin D Rapid Test).The following results was tabulated:

Precision

Method		Predicate Device (Vitamin D Rapid Test)			Total Results
	Results	Deficient	Insufficient	Sufficient	
Vitamin D Rapid Test Cassette	Deficient	4	4	0	8
	Insufficient	0	64	2	66
	Sufficient	0	0	23	23
Total Results		4	68	25	97
Accuracy		>99.9%	94.1%	92.0%	93.8%

Intra-Assay

Within-run precision has been determined by using 3 replicates of four specimens: 10ng/mL, 30ng/mL, 45ng/mL and 100ng/mL specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 3 independent assays on the same 4 specimens: 10ng/mL vitamin D, 30ng/mL vitamin D, 45ng/mL vitamin D, 100ng/mL vitamin D standard samples. Three different lots of the Vitamin D Rapid Test Cassette have been tested using these specimens. The specimens were correctly identified >99% of the time.

Sensitivity and Cross-Reactivity

The Vitamin D Rapid Test Cassette can detect levels of Vitamin D in human fingerstick whole blood as low as 30ng/mL. The addition of Vitamin A, B, C, E, K and M showed no cross-reactivity.

【BIBLIOGRAPHY】

1. Holick MF (March 2006). High prevalence of vitamin D inadequacy and implications for health.Mayo Clinic Proceedings. 81 (3): 353–73.
2. Eriksen EF, Glerup H (2002). Vitamin D deficiency and aging: implications for general health and osteoporosis. Biogerontology. 3 (1-2): 73–7.
3. Grant WB, Holick MF (June 2005). Benefits and requirements of vitamin D for optimal health: a review. Alternative Medicine Review.10 (2): 94–111.

Index of Symbols

	Consult Instructions For Use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by	2	Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number		Catalog #
	Do not use if package is damaged		Manufacturer		

SCREEN ITALIA S.r.l.
Via dell’Artigianato, 16
06089 - Torgiano - Perugia - Italia
www.screenitalia.it info@screenitalia.it

CE

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