Vitamin D Rapid Test Kit

Instructions For Use

PRODUCT NAME

FRENOVO Vitamin D Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

FRENOVO Vitamin D Rapid Test 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 AND PRINCIPLES OF THE PROCEDURE

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. 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. 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. 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.

The Vitamin D Rapid Test Kit is an immunoassay based on the principle of double antibody sandwich. The membrane is pre-coated with 25 (OH) D antibodies on the test line region of the strip. During testing, the specimen reacts with 25 (OH) D antibody conjugated to colored particles and precoated on the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If no test line appears, it indicates that the 25 (OH) D level in the specimen is below 10ng/ml. If only the test line 2 (T2) appears, it indicates that the 25 (OH) D level in the specimen is between 10-30ng/ml. If all the test lines (T1, T2) appear, it indicates that the 25 (OH) D level is above 30ng/ml. 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.

MATERIALS PROVIDED

Each kit contains:

1. test cassettes: 20 pieces test cassettes individually pouched.
2. Sample collection tubes: 20 pieces tubes and 200ul collection solution in each tube.
3. Droppers: 20 pieces droppers of 20 ul.
4. Package insert: 1 piece attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Specimen collection containers
- Disposable gloves and/or protective clothing
- Micro-pipette

WARNINGS

1. Read the package insert completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. The kits for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. FRENOVO Vitamin D Rapid Test Kit is for professional use only.
2. The package insert instructions must be followed to ensure optimum test performance.
3. The kit is intended for in vitro diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.

Safety Precautions

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear protective clothing such as lab coat, safety glasses and disposable gloves when handling specimens and assay reagents.
3. Wash hands thoroughly after use.
4. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Bio safety Precautions

Appropriate bio safety practices should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

1. Do not smoke,eat,drink,apply cosmetics or handle contact lenses in areas in which specimens are handled.
2. Dispose of all specimens, used devices and tubes as though they are capable of transmitting infection. The preferred methods of disposal are by autoclave at 121°C for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach.
3. When disposing of solution, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
5. Use a separate dropper and device for each specimen tested.

Handling Precautions

1. Do not use if the kit safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix wash buffer solution/test cassettes from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. The result should be read immediately after the end of the 10 minutes incubation time following the addition of specimen and wash buffer solution. Do not read results beyond 15 minutes.

STORAGE INSTRUCTIONS

1. The kit should be stored between 2-30°C and the shelf life is 24 months.
2. The kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the wash buffer solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
4. Do not freeze the kit.

SAMPLE COLLECTION AND PREPARATION

1. Applicable samples：Whole Blood (from fingerstick).
2. 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.

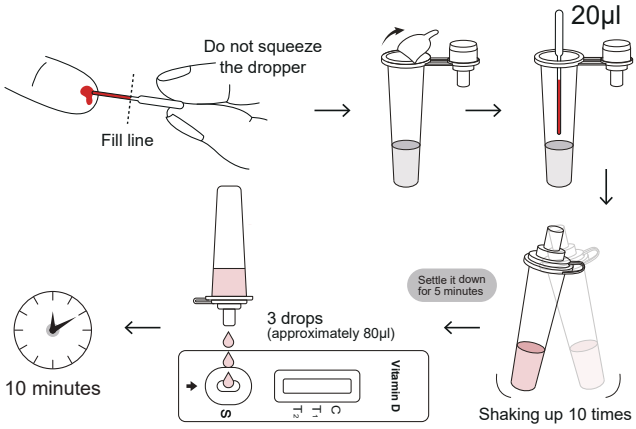
QUALITY CONTROL

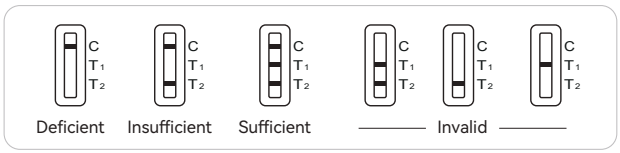
An internal procedural control is included in the test. a colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

TEST PROCEDURE

Allow the test cassette, specimen, buffer solution to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed pouch and use it within one hour. Place the test cassette on a clean and level surface.
2. Place the extraction tube on the work station and tear the aluminum film.
3. To use a Capillary droppers: Fill the capillary tube and transfer approximately 20uL of fingerstick whole blood specimen into the extraction tube and mix sample by Shaking up 10 times. Then settle it down for 5 minutes.
4. Dispense 3 drops(approximately 80μl) of mixed sample buffer to sample well of the test cassette.
5. Wait for the colored line(s)to appear. The test result should be read at 10 minutes. Do not interpret the result after 15 minutes.





INTERPRETATION OF RESULTS

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: Only one distinct colored line appears in the control region (C) .it indicates that the 25 (OH) D level in the specimen is below 10ng/ml

Insufficient: Two colored lines appear. One is in the control region (C) and another should be in the test region (T2). it indicates that the 25 (OH) D level in the specimen is between 10-30ng/ml.

Sufficient: Three colored lines appear, one is in the control region (C) ,one should be in the test region (T1) and another should be in the test region (T2). it indicates that the 25 (OH) D level is above 30ng/ml.

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.

LIMITATIONS

1. The Vitamin D Rapid Test Kit 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. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. Other clinically available tests are required if questionable results are obtained.

PERFORMANCE CHARACTERISTICS

Accuracy

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

Method		Predicate Device (Vitamin D Rapid Test)			
FRENOVO Vitamin D Rapid Test Kit	Results	Deficient	Insufficient	Sufficient	Total Results
	Deficient	6	5	0	11
	Insufficient	0	66	2	68
	Sufficient	0	0	25	25
Total Results		6	71	27	104
Accuracy		>99.9%	93.0%	92.6%	93.8%

Intra-Assay

Within-run precision has been determined by using 3 replicates of three specimens: 10ng/mL, 30ng/mL and 100ng/mL specimens. The specimens were correctly

Inter-Assay

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

Sensitivity and Cross-Reactivity

The Vitamin D Rapid Test Kit 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.

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use, Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
2°C 30°C	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
	Biological risks	CE	CE mark

Hangzhou Frenovo Biotech Co., Ltd.
Address:Room 401,Building 26, Room 401&301,Building 27,No.488-1,Donghu North Road, Donghu Street,LinPing District,Hangzhou City,Zhejiang Province.China.
Tel: +86-571-89170657
Email: business@frenovo.com

EC REP
CMC Medical Devices & Drugs S.L
Address: C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Email: info@cmcmedicaldevices.com

INSTRUCTION APPROVAL AND REVISION DATE

Revision Date: 2023.01.23
Approval Date: 2023.01.23
Date of Issue: 2023.01.23