Vitamin D Rapid Test Cassette (Whole Blood)

Package Insert

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

INTERPRETATION OF RESULTS

1. 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 using a 2:1 cut-off concentration of 30 ng/mL. This assay provides a preliminary diagnostic test result and can be used to screening for Vitamin D deficiency.

2. 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 mainly 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 medical terms, 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 health problem which may cause erroneous results.

3. Virtually each 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 more severe than previously thought. Vitamin D deficiency has been linked to various serious diseases: Osteoporosis, Osteomalacia, Multiple Sclerosis, Cardiovascular Diseases, Pregnancy Complications, Diabetes, Depression, Stroke, 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.

PRINCIPLE

The Vitamin D Test is an immunobase assay 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 antibodies 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 (C) no matter whether sufficient specimen has been added and membrane wicking has occurred.

SPECIMEN COLLECTION AND PREPARATION

1. Place the cassette on a clean and level surface.
2. Remove the test cassette from the sealed pouch and use it as soon as possible.
3. Specimen should be collected by fingerstick method using a clean and dry lancet.
4. Rinse the lancet with alcohol and then use it to draw blood into a capillary dropper.
5. Gently rub the hand from wrist to palm to remove oil and dirt from the skin.
6. Allow the blood to clot for 10 minutes.

STORAGE AND STABILITY

1. Store test cassette at room temperature or refrigerated (2-8°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 ready to use.
2. DO NOT FREEZE and DO NOT REFRIGERATE beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

1. The Vitamin D Rapid Test Cassette can be performed using whole blood (from fingerstick).
2. Use a Fingerstick Whole Blood Specimen.
3. Wash the patient's hand with soap and warm water or with an alcohol swab. Allow to dry.
4. Massage the hand without touching the puncture site by rubbing down the hand towards the finger tip of the middle or ring finger.
5. Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
6. Gently rub the hand from wrist to palm to form a rounded drop of blood over the puncture site.
7. Add the Fingerstick Whole Blood specimen to the test by using a capillary dropper.
8. Touch the end of the capillary dropper to the blood, do not squeeze the bulb of the dropper. Let the dropper drop the blood through the capillarity to the line indicated on the dropper. Avoid air bubbles.
9. Squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.
10. Testing should be performed immediately after the fingerstick Whole Blood have been collected.

MATERIALS

- Test Cassette
- Capillary Dropper
- Buffer
- Color Card
- Packaged Insert
- Lances
- Capillary Droppers
- Test Material required but not provided
- Timer

DIRECTIONS FOR USE

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.
3. Start the timer. Fill capillary tube and transfer approximately 20μL of fingerstick whole blood to the specimen area of test cassette, then add 2 drops of buffer and start the timer. See instruction below.
4. Read the result at 10 minutes by comparing the T line intensity with Color card provided with the kit. If the test remains negative, 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 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 test specimen may cause erroneous results.
3. The Cut-off for the test is 30 ng/mL with a deviation range of ±4 ng/mL. In all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. Only frozen specimens are tested if questionable results are obtained.

EXPECTED RESULTS

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

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

<table>
<thead>
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<th>Method</th>
<th>Predicate Device (Vitamin D Rapid Test)</th>
<th>Total Result</th>
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<tbody>
<tr>
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<td>Results</td>
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<td>Accuracy</td>
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Sensitivity and Cross-Reactivity

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

BIBLIOGRAPHY


Index of Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
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<tbody>
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