RAPID VITAMIN D TEST

Rapid one step Qualitative Detection of 25-OH Vitamin D in human blood

Package Insert - Instructions for Use

INTENDED USE

Test4D™ is a rapid chromatographic immunoassay for the detection of Vitamin D levels in human blood at a cut-off concentration of 32 ± 6 ng/mL (80 ± 15 nmol/L). This assay is designed for qualitative determination of Vitamin D and may be used at the point of care setting.

This product is meant for Professional Use Only. This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. The performance characteristics of this assay have not been established in a pediatric population. The device contains other ingredients which might influence the measurement.

SUMMARY AND EXPLANATION

The testing of Vitamin D in serum is an important tool for physicians and individuals to determine whether or not one is deficient in the vitamin. Vitamin D deficiency has been linked to:

- Osteoporosis, Osteomalacia (other bone related diseases)
- Weak immune system (colds and flu)
- Heart disease, blood pressure
- 17 types of cancers
- Alzheimer’s and Depression

PRINCIPLE

Test4D™ is based on the principle of a competitive enzyme immunoassay. The assay system utilizes a monoclonal antibody specific for 25-OH Vitamin D. The assay is based on the competition for 25-OH Vitamin D present in blood sample and Vitamin D present on the test line for fixed number of antibody-gold conjugate. When the amount of 25-OH Vitamin D in blood is 32 ng/mL or more, it will completely bind to antibody-gold conjugate, and prevent the binding of active 25-OH Vitamin D present on the test line to active ingredient antibody-gold conjugate representing 32 ng. Therefore a sufficient sample will not show the colored line in the test line zone. When amount of Vitamin D is less than 32 ng/mL, there will be free antibody-gold conjugate molecule that will bind to Vitamin D on the test strip and will show a colored line in test line zone. A control line is present in the test window to work as procedural control. This colored band should always appear on the control line zone if the test device is stored in good condition and the test is performed appropriately.

MATERIALS PROVIDED

Each package contains:
1. 25 Test4D individually packed test devices in foil pouches.
2. 25 Disposable transfer pipettes - dropper.
3. 25 Lancets.
4. 1 Buffer Vial (5 mL) containing buffered solution with stabilizers and thimerosal.
5. 1 Package Insert.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or clock

SPECIMEN COLLECTION

1. Clean and rub the chosen finger towards the tip.
2. Twist off the protective tab and place on contact point.
3. Press safety lancet firmly against the puncture site. Do not remove the device from the site until an audible click is heard.
4. Hold and touch the end of the dropper to the drop of blood and let the blood fill to the complete length of the dropper.

Assay must be performed immediately

PROCEDURE

1. Remove the cassette from sealed pouch and place it on a hard flat surface with the view window facing up (use the cassette as soon as possible).

2. Using the lancet and dropper, add one drop of blood from the dropper directly into the square specimen well (A) of the cassette

3. Add 4 full drops of buffer into the circular buffer well (B) of the cassette (Do not move the cassette after addition of buffer)

4. Let cassette sit for 10 minutes and read your results immediately. Results may deteriorate after the 10 minute mark.
INTERPRETATION OF RESULTS

Deficient: Two red color lines appear.
One is at the control region (C) and another should be in the test region (T).

Note: The shade of the red color line at the test region may vary, but is considered deficient whenever there is a faint or intense red color line.

Sufficient: One red color line appears.
One red color line appears at the control region (C) and no line appears at the test region (T).

Invalid: If control line fails to appear.
Review “Procedure for use” and repeat the test with a new cassette.

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PRECAUTIONS

1. For in vitro diagnostic use only.
2. This kit is for professional use only.
3. The test is designed for use with human whole blood only.
4. Reagents and device must be at room temperature (8 °C – 30 °C).
5. Do not use if test device packaging is open or damaged.
6. Do not use the product beyond expiration date.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be used according to good laboratory practices.
8. Never re-use a lancet.
9. Read test results at 10 minutes as required. Results may deteriorate and may not be consistent after 10 minutes.

STORAGE AND STABILITY
The test device should be stored at 8 °C – 30 °C and will be stable until the expiration date stated on the package. The product is humidity sensitive and should be used immediately after being open.

PERFORMANCE CHARACTERISTICS

- **Specificity**
  This value is found to be 95.6% (95% C.I.: 84.8%; 99.3%), which indicates that Test4D will correctly identify a sufficient Vitamin D level only about 96% of the time.

- **Sensitivity**
  The sensitivity of Test4D at 32 ± 6 ng/mL is found to be 98.8% (95% C.I.: 95.7%; 99.8%), which indicates that Test4D will correctly identify a deficient Vitamin D level about 99% of the time.

- **Accuracy**
  The accuracy of the “Test4D” test was evaluated in comparison to approved device. Human blood samples were tested and results from “Test4D” were found to be in agreement with the approved device.

INSTRUCTIONS TO USE BLOOD TRANSFER PIPETTE

MICROSAFE Tube
An air vent is strategically positioned on the sidewall of the tube to provide automatic air venting and sample volume control. Air vent regulates volume.

Fill line indicates total sample collected

CAUTION!
Filling is automatic. Never squeeze the tube while sampling.

Step 1: Hold the tube horizontally, and touch the tip of the MICROSAFE Tube to the blood sample. Capillary action will automatically draw the sample to the fill line and stop.

Step 2: To expel the sample, align the tip of the tube with the sample target and squeeze the bulb.
If a sample won’t expel, you probably didn’t allow the tube to fill all the way. Touch the tip to the blood sample again and allow it to fill completely. Then align the tip with the sample target and squeeze the bulb.

INSTRUCTIONS TO USE LANCET

1. Twist and remove cap.
2. Push gently against test site.
3. Dispose in sharp container.

DR DNA DIAGNOSTICS SDN BHD
No. 207A Jalan Shahbandar
83000 Batu Pahat
Johor
Te: 0127455093