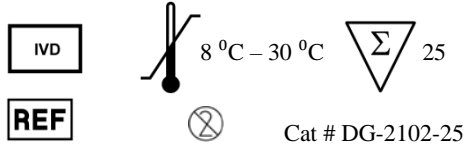




Rapid one step Semi Quantitative Detection of 25-OH Vitamin D
in human blood

Package Insert - Instructions for Use



INTENDED USE

Test4DTM is a rapid chromatographic immunoassay for the semi quantitative detection of Vitamin D levels in human blood/serum. This assay provides only a preliminary screening 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.

PRINCIPLE

Test4DTM is based on the principle of a competitive enzyme immunoassay. The assay is based on the competition for 25-OH Vitamin D present in blood/serum sample and Vitamin D present on the test line for fixed number of antibody-gold conjugate. Depending upon the concentration of Vitamin D in blood/serum, 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.

MATERIALS PROVIDED

Each package contains:
25 Test4D individually packed test devices in foil pouches.
1 Buffer Vial containing Chase Buffer (5.5 mL) with stabilizers and thimerosal.
1 Package Insert.

MATERIALS REQUIRED BUT NOT PROVIDED

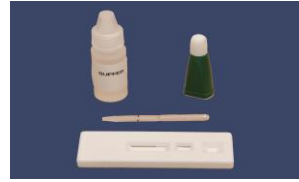
Timer or clock
Micro-pipette
Plastic tube to mix blood/serum sample.

SPECIMEN PREPARATION

Mix the blood/serum sample thoroughly by gently inverting the tube. Use 10 µl of fresh blood sample or 5ul of serum sample (Repeated freeze thaw of serum sample is not recommended. Bring frozen serum sample to room temperature before use.)
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).



Using a micropipette, add one drop or 10 µl of whole blood or 5ul of serum sample directly into the rectangular specimen well (A) of the cassette.



2. Add 3 full drops of Chase Buffer into the square buffer well (B) of the cassette (Do not move the cassette after addition of buffer).



3. Let cassette sit for 10 minutes and read your results immediately. Results may deteriorate after the 10 minute mark.



INTERPRETATION OF RESULTS

Match the color of the test line with the chart provided.

VISUAL INTERPRETATION OF RESULTS



Invalid: If control line fails to appear.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. The test is designed for use with human blood/serum only.
3. Reagents and device must be at room temperature (8 °C – 30 °C).
4. Do not use if test device packaging is open or damaged.
5. Do not use the product beyond expiration date.
6. Handle all specimens as potentially infectious. Proper handling and disposal methods should be used according to good laboratory practices.
7. Read test results at 10 minutes as required. Results may deteriorate and may not be consistent after 10 minutes.
8. In order to avoid variable results mix the blood sample thoroughly.
9. A serum sample subjected to repeated freeze thaw cycle may give variable results.

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.

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.

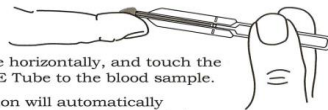
Air vent regulates volume



Fill line indicates total sample collected

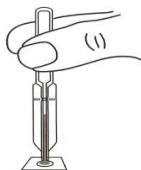
CAUTION!

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.

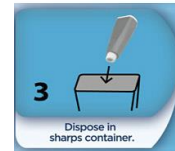


Step 2: To expel the sample, align the tip of the tube with the sample target and squeeze the bulb.

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.

08/17/10 REV 1

INSTRUCTIONS TO USE LANCET



Alternatively other types of lancets and pipettes can be used to harvest and apply the probe for the required volume.

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