

Vitamin D3 Rapid Tests (DTS9325)

This product is for research use only and is not intended for diagnostic use.

PRODUCT INFORMATION

Size 96T

Intended Use

Vitamin D3 Strip Test is a qualitative and rapid lateral flow assay designed to detect Vitamin D3 residues in serum. This test uses a Vitamin D3 receptor binding protein which eliminates the need for a heating block. This test is designed for point-of-care use or reference lab settings.

The unique features of the kit are:

1. Rapid strip test method – 7 minutes
2. Novel binding protein that requires no heating step
3. High sensitivity
4. High reproducibility

Principles of Testing

The assay uses a competitive colloidal gold based format. 200uL of the serum sample to be tested is added to a transparent test paper card plastic reaction well or tube, which is used to make the lyophilized reagent a uniform pink suspension at the bottom of the microwell. A brief 3 minute incubation allowed the gold particle-labeled Vitamin D3 complexing protein to bind to Vitamin D3 in

the serum. Then insert the test strip vertically into the sample hole in the direction of the arrow, so that the sample flows to the test strip. All gold-labeled particles that are not bound to vitamin D3 in the serum will bind to Vitamin D3 on the test line (T-line). A red marker line is formed at the detection line position.

Reagents And Materials Provided

1. Reaction wells 12x8 (96 total)
2. Test strips 48x2 (96 total)

Please store at RT(25°C +/- 2.5) and keep in a dry and dark place.

A 96-well plastic frame is also provided in each kit to anchor the reaction vessels in place during testing, and can be re-used

as required.

Materials Required But Not Supplied

1. Timer
2. Additional positive and negative controls
3. Polypropylene tubes
4. Distilled water
5. Scissors to cut strip caps
6. Fixed-volumer pipettor to deliver 200 μ L
7. Detekt RDS-1000 test strip reader (optional)
8. Fixed-volumer pipettor to deliver 200 μ L (optional)

Note: this product was developed using the Detekt RDS-1000 reader, and is highly recommended for optimal performance. For customers already possessing the Detekt RDS-1000 reader, or wishing to use an alternate reader, please contact Creative Diagnostics for instructions on how to program the reader for use.

Storage

The Creative Diagnostics Vitamin D3 Strip Test has the capacity for 96 or 192 determinations. The shelf life is 12 months when the kit is properly stored.

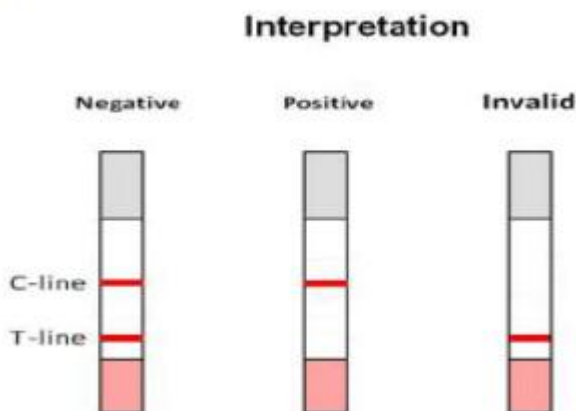
Assay Procedure

1. Using scissors, carefully cut and remove the number of wells and test strips appropriate for the number of samples that will be tested. Ensure that unused wells remain firmly capped. Promptly restore the remaining components at 4°C. To maintain assay timing do not run more than 6 tests at the same time.
2. Shake the serum vigorously, aliquot sample into a small polypropylene tube (1.5 mL– 15 mL), and allow serum sample to reach ambient temperature.
3. Attach a disposable pipet tip to the end of the pipettor.
4. Insert the pipet tip into the serum sample, depress the plunger of the pipettor to the first stop, then slowly release the plunger to aspirate 200 μ L of serum into the pipet tip.
5. Position the pipet tip (loaded with serum) over a well with lyophilized gold , and depress the plunger to completely expel the serum sample into the well. When more than one sample is being analyzed, note the order in which they are placed in the wells.
6. Using the same pipet tip, aspirate the sample up and down about 10 times to completely resuspend the lyophilized gold particles in the serum, while avoiding bubbles. The sample should turn a uniform pink color. After resuspending the particles, remove and discard the pipet tip.
7. Incubate the sample for 3 min at ambient temp (25°C +/- 5). During this time, label one or more test strips as needed for the number of samples being tested.
8. After 3 min, insert the bottom of the test strip into the well containing the serum sample (see Figure 1). The strip should be inserted such that the arrows are pointing down. Be sure the strip is oriented vertically (not leaning to the side) and is inserted all the way to the bottom of the well. Set a timer for 4 min.

9. After 6 min, remove the strip and place it on a horizontal surface with the unmarked side facing up.
10. Visually examine the intensity of the signal at the T -line and C-line.

Interpretation Of Results

Figure 1. Test Strip Orientation and Test Interpretation



Negative: Test line and the C-line both appear ,indicates the serum sample is negative.

Positive: Test line which corresponding position is no colored and the C-line appear, indicates the serum sample is positive for the corresponding drug.

Invalid results: The test is invalid if no colored line appears in the C (control) area even if a colored line appears in the T (Test line) area. Re-test serum sample if broken lines are observed. Colored lines which appear after 20 minutes are not diagnostic and should be ignored. If the sample does not flow up the dipstick, the serum sample may be clotted, invalidating the test result. To avoid serum sample clotting, always use fresh serum.

Detection Limit

The detection limit of Vitamin D3 in serum sample is 1.0 IU/mL.

Precautions

1. Do not use the kit past the expiration date.
2. Do not re-use pipette tips or polypropylene tubes.
3. Be sure unused wells remain tightly sealed with the plug caps.
4. Incubations of assay should be timed as precisely as possible.
5. Always store test strips in provided vials to maintain stability.