

# Vitamin B12 (VB12) Rapid Test (DTS832L)

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

## PRODUCT INFORMATION

**Size** 50T

### Intended Use

Vitamin B12 Rapid Test is a rapid, one step test for the qualitative detection of Vitamin B12 in human serum or whole blood samples.

### General Description

Vitamin B12 is a water-soluble vitamin that is necessary for DNA synthesis, the metabolism of amino acids and fatty acids<sup>1</sup> which are required for normal blood formation, cell synthesis, and neurological functions in the human body. A deficiency in vitamin B12, which can occur due to inadequate absorption or intake, can lead to neurological, psychiatric, and hematological disorders. Vitamin B12 deficiency is defined as a serum vitamin B12 level of less than 148 pmol/L. The primary dietary sources of vitamin B12 are meats, fish, shellfish, and dairy products and as such the deficiency has been reported to be the highest among populations with predominantly a vegetarian or vegan diet. In the US, the deficiency rate among vegetarians has been estimated at 60%. At present, the main technical methods used in the detection of vitamin B12 are HPLC, ELISA, etc., these require professional equipment and instruments, and should not be popularized. The immunocolloid gold chromatography technique is simple, fast, and specific, and can be used for the rapid detection of vitamin B12.

### Principles of Testing

The Vitamin B12 rapid test is based on competitive inhibition immuno-chromatographic principle. In the flow process, VB12 in the sample combined with VB12 specific colloidal gold-labeled monoclonal antibody, inhibit the combination between antibody and VB12-BSA conjugate on Test line of NC membrane, lead to the color change of Test line. When the sample has no VB12 residue or concentration lower than detection limit, T line appears; when the concentration is equal to or higher than detection limit, T line has no color. No matter whether there is VB12 residue in sample, C line will appear, it means the test is valid.

### Reagents And Materials Provided

1. VB12 Testing Device: 50 tests/kit
2. Buffer: 1 bottle
3. Sample Dropper: 50 pcs
4. User Instructions

### Materials Required But Not Supplied

1. Specimen collection container.

2. Clock or timer.
3. Centrifuge capable of 1,000 g centrifugal force (for centrifugation of whole blood specimens).

### Storage

Store at 4-30°C, DO NOT FREEZE or use beyond the expiration date. The shelf life is 12 months.

### Specimen Collection And Preparation

Collect blood aseptically by venipuncture into a clean tube without anticoagulants. Permit blood to clot for twenty to thirty minutes at room temperature. Centrifuge to obtain clear serum and transfer serum into a clean plastic or glass tube. The test may be performed using human serum or whole blood.

If specimens are not immediately tested they should be refrigerated at 2°C -8°C. For storage periods greater than three days, freezing is recommended (-20°C). If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

### Assay Procedure

NOTE: Bring an unopened foil pouch and the sample specimen to room temperature before performing the test.

1. Remove the test cassette from the sealed pouch.
2. Holding the dropper vertically, add 1 drops of serum or whole blood directly to the sample well "S" of the test device, then add 2 drops of buffer and start the time.
3. Read the result at 10-15 minutes.

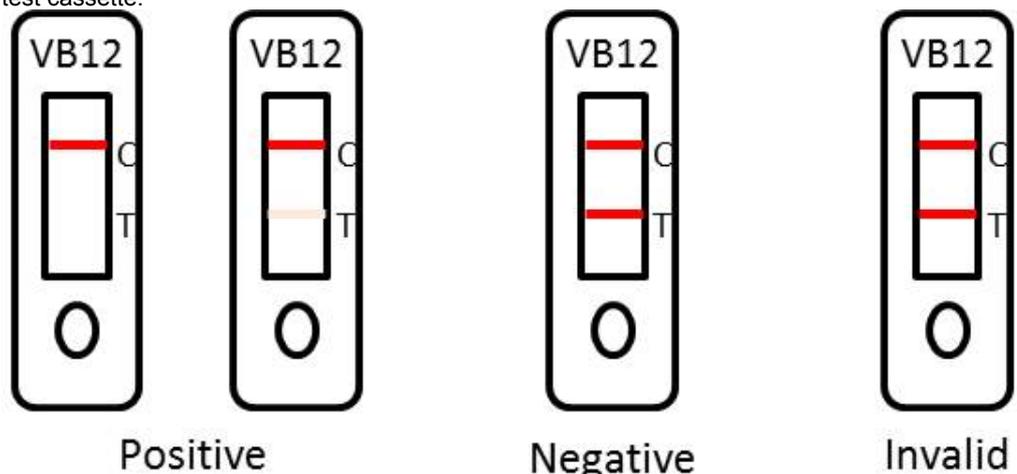
Important: Discard the test device after reading the result. Do not interpret the result after more than 15 minute.

### Interpretation Of Results

Negative (-): Color of Test Line (T line) is deeper than Control Line(C line) or the same color, indicating that the content of Vitamin B12 in sample is lower than the LOD of the kit.

Positive (+): No color shows in Test line or Color of Test Line is lighter than Control Line indicating that the Vitamin B12 in sample is higher than the LOD of the kit.

Invalid: No color shows in Control Line, indicating the operation is incorrect or the test kit is out of date. In this case, please read the instruction again carefully, and repeat the assay with a new test cassette.



### Detection Limit

The detection limit of VB12 with this test is about 0.5 ng/mL (ppb)

### Precautions

1. When handling serum, preclude any pipetting by mouth.
2. Do not allow smoking or eating where the specimens are being handled.

3. Wear disposable gloves while handling kit reagents or specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Wipe up spills thoroughly using an appropriate intermediate-to-high level disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials as if they were infectious in a biohazard container.
7. Do not use the kit or reagents after the expiration date.

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**Limitations**

1. The Vitamin B12 Rapid Test is limited to the qualitative determination of Vitamin B12 in serum, or whole blood.
  2. Although the Vitamin B12 Rapid Test is very accurate in detecting elevated Vitamin B12 levels, a low incidence of false results can occur.
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