

Vitamin B12 FIA Rapid Test Device (Serum/Plasma)

Catalogue Number: FI2-B12-001

A rapid test for detecting Vitamin B12 in serum or plasma with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

For professional in vitro diagnostic use only.

INTENDED USE

The Biopanda Vitamin B12 FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative determination of Vitamin B12 in serum or plasma.

BACKGROUND

Vitamin B12 (B12), a member of the corrin family, is a cofactor for the conversion of methylmalonyl Coenzyme-A (CoA) to succinyl CoA. In addition, B12 is a cofactor in the synthesis of methionine from homocysteine, is implicated in the formation of myelin, and, along with folate, is required for DNA synthesis.^{1,2}

Causes of vitamin B12 deficiency can be divided into three classes: nutritional deficiency, malabsorption syndromes, and other gastrointestinal causes. B12 deficiency can cause megaloblastic anaemia (MA), nerve damage and degeneration of the spinal cord. Lack of B12, even mild deficiencies, damages the myelin sheath that surrounds and protects nerves, which may lead to peripheral neuropathy. The nerve damage caused by a lack of B12 may become permanently debilitating, if the underlying condition is not treated. People with intrinsic factor defects who do not get treatment eventually develop a MA called pernicious anaemia (PA).²⁻⁴

Disorders associated with elevated serum B12 levels include renal failure, liver disease, and myeloproliferative diseases.⁵⁻⁶

TEST PRINCIPLE

The Vitamin B12 FIA Rapid Test Device is a quantitative membrane-based fluorescence immunoassay for the detection of Vitamin B12 in human serum or plasma specimen. During testing, the sample moves through the strip from the sample pad to the absorbent pad. Vitamin B12 in the sample will compete with the VB12-BSA antigen coated on the membrane. The less Vitamin B12 in the sample, the more fluorescent microspheres conjugated with VB12 antibodies can be captured by the VB12-BSA antigen coated on the membrane (Test line). The concentration of Vitamin B12 in the sample is inversely related to the intensity of the fluorescent signal captured on the T line. According to the fluorescence intensity of the test and the standard curve, the concentration of Vitamin B12 in the sample can be calculated by the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000). Test results will be displayed on the analyzer screen after testing.

REAGENTS

The test contains VB12-BSA coated on a cellulose nitrate membrane and VB12 antibody conjugated to fluorescence particles.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package.
3. Do not use the test if the foil pouch is damaged.
4. Do not reuse tests.
5. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
6. Do not eat, drink or smoke in the same area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and safety glasses when specimens are assayed.
7. Do not interchange or mix reagents from different lots.
8. Extremes in humidity and temperatures can adversely affect results.
9. Used testing materials should be discarded in accordance with local regulations.
10. Read the entire procedure carefully prior to any testing.
11. The Biopanda Vitamin B12 FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) by healthcare professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30°C until the expiry date printed on the foil pouch.
2. The test device must remain in the sealed foil pouch until use.
3. Do not freeze the test kit.
4. Care should be taken to protect the kit contents from contamination. Do not use components if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers, or reagents can lead to false results.

KIT CONTENTS

- 25 x Foil pouches containing Vitamin B12 rapid test device and Reagent 3
- 25 x Empty microtubes
- 1 x Reagent 1
- 1 x Reagent 2
- 1 x ID card (Vitamin B12)
- 1 x Workstation containing heating pad
- 1 x Package insert

EQUIPMENT REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- USB port
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

SPECIMEN COLLECTION AND PREPARATION

1. Collect the specimen according to standard procedures.
2. Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed specimens can be used.
3. Do not leave specimens at room temperature (15-30°C) for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days; for long term storage, keep below -20°C.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeat freeze-thaw cycles.
5. EDTA K2, Heparin sodium, Sodium citrate, and Oxalate potassium can be used as the anticoagulant for collecting the specimen. A clean tube without anticoagulants can be used to collect serum specimens.
6. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device User Manual for the complete instructions on operating the device. The test should be conducted at room temperature. Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.

Note: There are two test modes for the Biopanda Fluorescence Immunoassay Device: *Standard Test* mode and *Quick Test* mode.

Standard Test mode is a 'set and forget' method where the test will automatically be read after 10 minutes.

Quick Test mode provides an instant result but the user must monitor the 10 minute test time themselves. It is suitable when running multiple tests simultaneously.

Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for further details.

Allow the test cassette, specimen, reagent bottles, and/or controls to reach room temperature prior to testing.

1. Turn on the Analyzer and insert the ID card into the analyzer 'Code' port and wait for the 'ID card imported successfully' pop-up. Fill in the necessary details in the 'Test Info' section.
2. Connect the USB cable of the heating pad located inside the workstation to an external USB port. The pad will heat up automatically. **Allow the heating pad to preheat for 10 minutes before initiating testing.**
3. Pipette **40 µL of Reagent 1** into an empty microtube, then pipette **40 µL of serum/plasma into the same microtube**. Mix thoroughly using the pipette.
4. Place the microtube in the workstation containing the heating pad and **allow the mixture to react for 10 minutes**.
5. After 10 minutes, **pipette 160 µL of Reagent 2 into the microtube mixture**. Mix thoroughly using the pipette.
6. Remove the test device and Reagent 3 microtube from the sealed foil

pouch. Place the test device on a clean and level surface.

7. **Pipette 160 µL of the new mixture** into the **Reagent 3 microtube** to **dissolve the lyophilized powder**. Mix thoroughly using the pipette.
8. Place the Reagent 3 microtube in the workstation containing the heating pad and **allow this final mixture to react for 3 minutes**.
9. After 3 minutes, **pipette 80 µL of the Reagent 3 microtube mixture** into the sample well (S) of the test device.
10. Insert the test device into the analyzer test device slot. Then according to user requirements, select either 'Standard test' or 'Quick test' mode.
11. **Test results should be interpreted at 10 minutes** using the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

Caution: Mix the solutions thoroughly at each step. Inadequate mixing may result in erroneous results.

Caution: When heating the solutions, ensure that the bottom of the microtube is in close contact with the heating pad.

INTERPRETATION OF RESULTS

The test results are calculated by the Biopanda Fluorescence Immunoassay Device and displayed on the analyzer screen after testing is complete. For additional information, please refer to the user manual.

The concentrations of Vitamin B12 in the specimen are calculated by the analyzer and reported in pg/mL. For additional information, please refer to the user manual.

EXPECTED RESULTS

Reference range: 197-771 pg/mL or 145-569 pmol/L

Each laboratory should determine the applicability of the reference range through experiments and establish its own reference value range if necessary to ensure that it can correctly reflect the situation of a particular population.

QUALITY CONTROL

Each Biopanda Vitamin B12 FIA Rapid Test Device contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by the Biopanda Fluorescence Immunoassay Device.

An invalid result from the internal control causes an error message to pop-up on the Biopanda Fluorescence Immunoassay Device, indicating that the test should be repeated. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for an invalid result. Review the procedure and repeat using a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

PERFORMANCE CHARACTERISTICS

1. **Accuracy**
The deviation is ≤15%
2. **Analytical sensitivity**
The Vitamin B12 FIA Rapid Test Device can detect levels of Vitamin B12 as low as 50 pg/mL in serum or plasma specimens.
3. **Detection Range**
The detection range is 50-2000 pg/mL or 36.9-1476 pmol/L.
4. **Precision**
 - Intra-Assay**
Within-run precision has been determined by using 10 replicates of 2 different concentrations of Vitamin B12 control. C.V. is ≤ 15%.
 - Inter-Assay**
Between-run precision has been determined by using 10 replicates for each of three lots using 2 different concentrations of Vitamin B12 control. C.V. is ≤15%.
5. **Interfering Substances**
The following compounds have been tested using the Vitamin B12 FIA Rapid Test Device and no interference was observed.

| | | | |
|--------------------|-----------|----------------|---------|
| Triglyceride: | 100mg/dL | Ascorbic Acid: | 20mg/dL |
| Haemoglobin: | 1000mg/dL | Bilirubin: | 60mg/dL |
| Total cholesterol: | 15mmol/L | | |
6. **Method comparison**
The product was evaluated with 115 clinical samples in comparison with a commercially available CLIA test kit. The correlation coefficient (r) is 0.9672.

LIMITATIONS OF THE TEST

1. The DIRECTIONS FOR USE and the INTERPRETATION OF RESULTS must be followed closely when testing for the presence of Vitamin B12 in the serum/plasma specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
2. The Vitamin B12 FIA Rapid Test Device is for *in vitro* diagnostic use only. This test should be used for quantitative detection of Vitamin B12 in serum or plasma specimens.
3. Other factors that can interfere with the test and lead to erroneous results include technical/procedural errors, degradation of test components and the presence of interfering substances in the test samples.
4. As with all diagnostic tests, a confirmed diagnosis should only be made once all clinical and laboratory findings have been evaluated.

REFERENCES

1. Lee, D. S., & Griffiths, B. W. (1985). *Human serum vitamin B12 assay methods—a review*. *Clinical Biochemistry*, 18(5), 261-266.
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3. Carethers, M. (1988). *Diagnosing vitamin B12 deficiency, a common geriatric disorder*. *Geriatrics*, 43(3), 89-94.
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5. Dahele, A., & Ghosh, S. (2001). *Vitamin B12 deficiency in untreated celiac disease*. *The American journal of gastroenterology*, 96(3), 745-750.
6. Pratt, J. J., & Woldring, M. G. (1982). [27] *Radioassay of vitamin B12 and other corrinoids*. *Methods in enzymology*, 84, 369-406.

INDEX OF SYMBOLS

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|--|------------------------------------|--|-----------------|--|------------------------------|
| | Manufacturer | | Tests per kit | | Do not reuse test |
| | In vitro diagnostic medical device | | Expiration date | | Catalogue number |
| | Storage temperature | | Lot Number | | Consult instructions for use |
| | Do not use if package is damaged | | | | |

Thank you for purchasing Biopanda's Vitamin B12 FIA Rapid Test Device kit. Please read this manual carefully before operating to ensure proper use.



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