GENETRACK Diagnostics

Vitamin B12

WHAT IS VITAMIN B12?
Vitamin B12 is a water-soluble vitamin that is naturally present in some foods. It is required for red blood cell formation, neurological function, and DNA synthesis (1). Vitamin B12 is bound to protein in food and must be released from the protein by hydrochloric acid and gastric protease in the stomach. Synthetic vitamin B12 in fortified foods and supplements is already in a free form. Free vitamin B12 combines with intrinsic factor before it is absorbed (2).

SOURCES OF VITAMIN B12
Many animal products contain vitamin B12, including fish, meat, poultry, eggs, milk, and milk products, but it is generally not present in plant foods. Fortified food products include breakfast cereals and nutritional yeast. Dietary supplements containing vitamin B12 are also available, usually containing the cyanocobalamin form of vitamin B12, with some supplements also containing other forms of vitamin B12 (3).

VITAMIN B12 REQUIREMENTS
Vitamin B12 requirements vary depending on age and pregnancy/breastfeeding status. Infants require 0.4 mcg/day (0-6 months) and 0.5 mcg/day (7-12 months). The recommended dietary allowance for children is 0.9 mcg/day (1-3 years), 1.2 mcg/day (4-8 years), and 1.8 mcg/day (9-13 years). Adults require 2.4 mcg/day, except for 2.6 mcg/day during pregnancy and 2.8 mcg/day while breastfeeding (4).

VITAMIN B12 DEFICIENCY
Serum vitamin B12 levels below approximately 170-250 pg/mL indicate deficiency in adults. However, serum levels might not be an accurate reflection of intracellular concentrations, and additional analyses may be required, such as measurement of methylmalonic acid levels, which are dependent on vitamin B12 activity (4).

Vitamin B12 deficiency is most often caused by malabsorption from food, pernicious anemia (an autoimmune disease that affects gastric mucosa), postsurgical malabsorption, and dietary deficiency (5). However, for many deficient individuals the cause is unknown.

Deficiency is characterized by megaloblastic anemia, which causes weakness, fatigue, difficulty concentrating, irritability, headaches, heart palpitations, and shortness of breath. Other symptoms can include neurological changes (e.g. numbness and tingling in the extremities), balance difficulties, depression, confusion, poor memory, dementia, and mouth sores. Early diagnosis and intervention is important to avoid irreversible damage associated with neurological symptoms of vitamin B12 deficiency (4).

POPULATIONS AT RISK OF DEFICIENCY
Older adults have an increased risk of vitamin B12 deficiency often due to atrophic gastritis (affects 10-30% of older adults), or pernicious anemia (affects 1-2% of older adults) (4). Atrophic gastritis decreases hydrochloric acid secretion in the stomach, inhibiting the release of vitamin B12 bound to protein in food sources (6), and potentially increasing the levels of bacteria that utilize vitamin B12 (7). Synthetic vitamin B12 (in fortified foods and supplements) is in the free form so is still well absorbed by affected individuals. Pernicious anemia is an autoimmune disorder characterized by a lack of intrinsic factor, which usually binds to free vitamin B12 before it is absorbed in the small intestine. It is usually treated by intramuscular vitamin B12 (3).

Individuals who suffer from gastrointestinal disorders (e.g. celiac disease and Crohn's disease) or have had gastrointestinal surgeries (e.g. weight loss surgery) may have reduced vitamin B12 absorption (5, 8). Vegetarians and vegans are also at increased risk of deficiency as natural food sources of vitamin B12 are restricted to animal sources (3). There is a heightened risk for pregnant and lactating vegetarians and their infants, as vitamin B12 crosses the placenta during pregnancy and is present in breast milk.

SPECIAL INSTRUCTIONS
Avoid high doses of biotin consumption (e.g. vitamin B7 or B8, vitamin H, or coenzyme R) for at least 72 hours prior to specimen collection.

TEST PROCEDURE
Correct specimen collection and handling is required for optimal assay performance.

This test requires a blood sample from a finger prick. All supplies for sample collection are provided in this kit. First wash and dry hands. Warm hands aid in blood collection. Clean the finger prick site with the alcohol swab and allow to air dry. Use the provided lancet to puncture the skin in one quick, continuous and deliberate stroke. Wipe away the first drop of blood (as it may be contaminated with tissue fluid or skin debris). Massage finger to increase blood flow at the puncture site and hold in a position that gravity facilitates the collection of blood on the fingertip. Transfer the blood to the blood collection card or blood collection tube (microtainer).

Avoid squeezing or 'milking' the finger excessively. If blood flow stops, perform a second skin puncture on another finger if more blood is required.

Dispose of all sharps safely and return sample to the laboratory in the provided prepaid return shipping envelope.

Upon receipt at the laboratory, the blood sample is analyzed by the fully automated Alinity i B12 chemiluminescent microparticle Intrinsic Factor assay on the Alinity ci series analyzer. This assay measures vitamin B12 levels by binding to intrinsic factor coated microparticles. The amount of vitamin B12 in the blood sample is measured in relative light units by a chemiluminescent reaction.

TEST INTERPRETATION
This assay will provide an accurate vitamin B12 level for the tested blood specimen. Healthy serum levels are typically above 170 pg/mL .

DISCLAIMERS/LIMITATIONS
Certain medications (e.g., neomycin and phenytoin), large doses of vitamin C, excess alcohol consumption, and a recent CT scan that used dyes can affect vitamin B12 results.

These results should be interpreted in conjunction with other laboratory and clinical information. Further testing in addition to this assay is required to diagnose vitamin B12 deficiency.

Additional testing is recommended if vitamin B12 levels are inconsistent with clinical evidence.

Hemolyzed specimens should not be analyzed, as hemolysis exhibits negative interference in this assay.

Assay interference may occur in specimens from individuals routinely exposed to animals or to animal serum products. Additional clinical or diagnostic information may be required for these specimens.

Correct specimen collection and handling is required for optimal assay performance.

A B12 level in the low normal range does not ensure that B12 levels are healthy and symptomatic patients should be further evaluated with tests for holotranscobalamin, homocysteine and methylmalonic acid (10).

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