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United States Patent [19]

Allen et al.

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[45] **Date of Patent: * Oct. 8, 1996**

[54] **METHOD FOR TREATMENT AND PREVENTION OF DEFICIENCIES OF VITAMINS B_{12}, FOLIC ACID, AND B_6**

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[73] Assignee: **Metabolite Laboratories**, Denver, Colo.

[*] Notice: The portion of the term of this patent subsequent to Dec. 20, 2011, has been disclaimed.

[21] Appl. No.: **999,499**

[22] Filed: **Dec. 29, 1992**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 727,628, Jul. 10, 1991, Pat. No. 5,374,560, which is a continuation-in-part of Ser. No. 333,124, Apr. 3, 1989, abandoned, and Ser. No. 345,885, May 1, 1989, abandoned, which is a continuation-in-part of Ser. No. 933,553, Nov. 20, 1986, Pat. No. 4,940,658.

[51] **Int. Cl.**[6] **A61K 31/70**; A61K 31/495; A61K 31/44

[52] **U.S. Cl.** **514/52**; 514/249; 514/345

[58] **Field of Search** 514/52, 249, 345, 514/814

[56] **References Cited**

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Primary Examiner—Raymond Henley, III

Attorney, Agent, or Firm—Davis, Graham & Stubbs, L.L.C.

[57] **ABSTRACT**

A method for orally administering vitamin preparations is described which combine vitamin B_{12} (B_{12}, cobalamin) and folic acid (folate), with and without pyridoxine (B_6), for preventing and treating elevated serum homocysteine (HC), cystathionine (CT), methylmalonic acid (MMA), or 2-methylcitric acid (2-MCA) levels. These metabolites have been shown to be indicative of B_{12} and/or folic acid deficiencies. Further, it is likely that a B_6 deficiency may be present with a B_{12} or folate deficiency. The method of the invention is also for use in lowering serum HC, CT, MMA, or 2-MCA in patients with or at risk for neuropsychiatric, vascular, renal or hematologic diseases. One embodiment of the invention is the use of a non-prescription formulation containing 2.0 mg B_{12} and 0.4 mg folic acid, with and without 25 mg B_6. Another embodiment uses a prescription strength formulation containing 2.0 mg B_{12} and 1.0 mg folic acid, with and without 25 mg B_6. The method of the present invention eliminate the costly and time consuming steps of distinguishing between vitamin deficiencies once a deficiency is found by measurement of serum metabolite levels. The present invention is of particular benefit to the populations at risk for elevated serum metabolite levels, such as the people over the age of 65, and populations that have or are at risk for neuropsychiatric, vascular, renal and hematologic diseases.

10 Claims, 11 Drawing Sheets

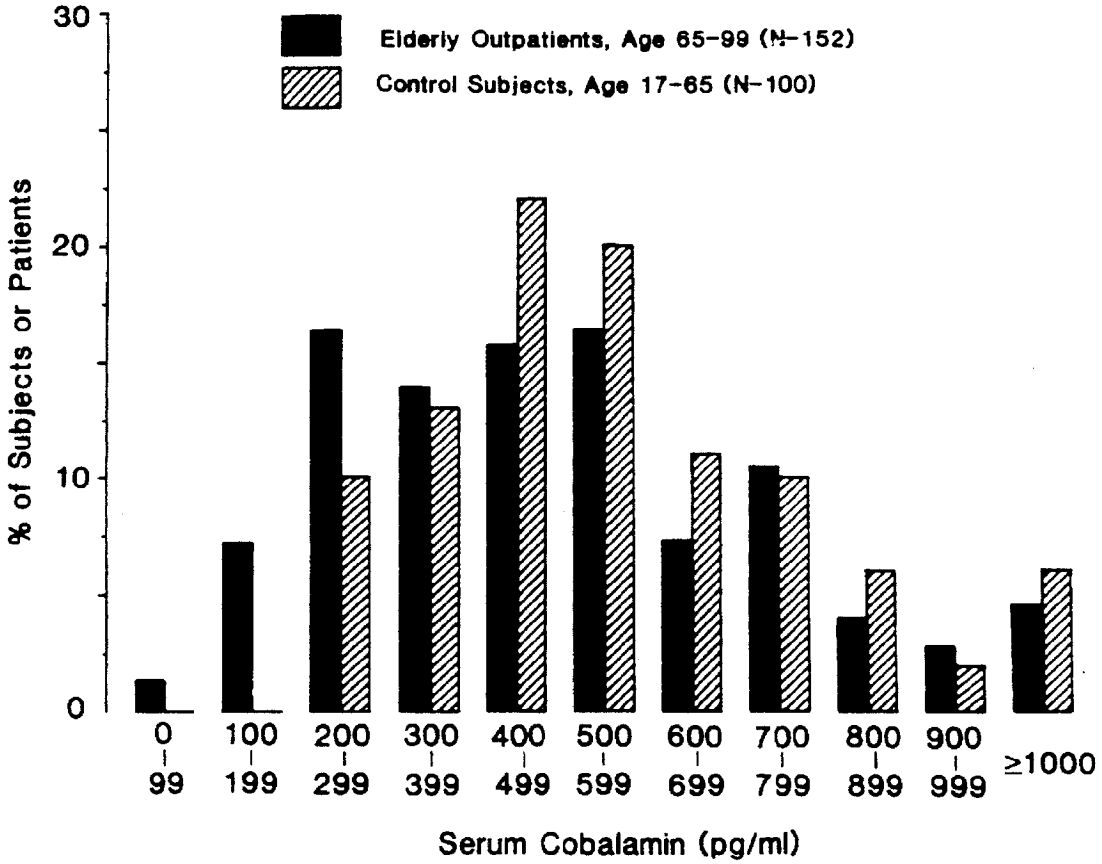

FIG. 1

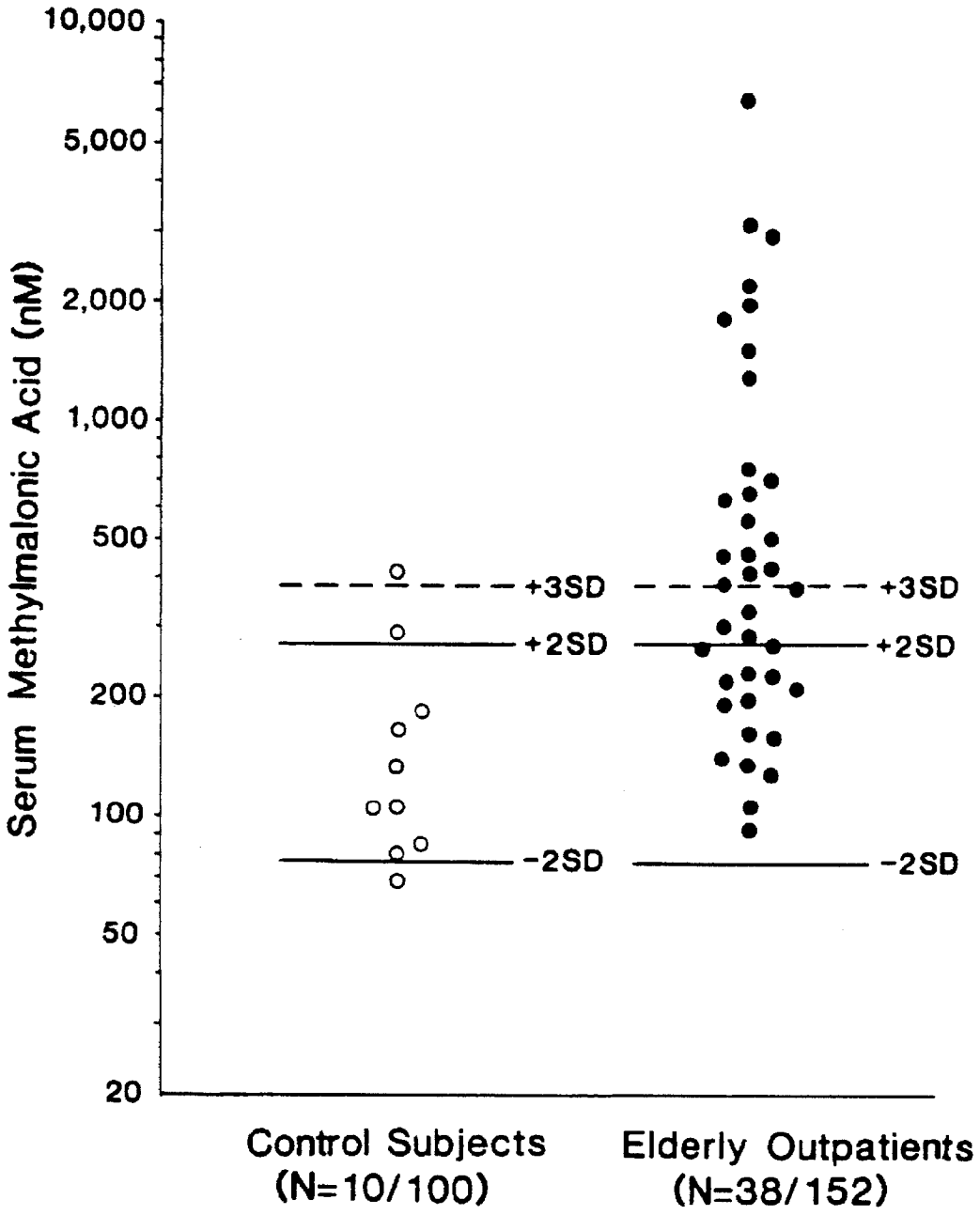

FIG. 2

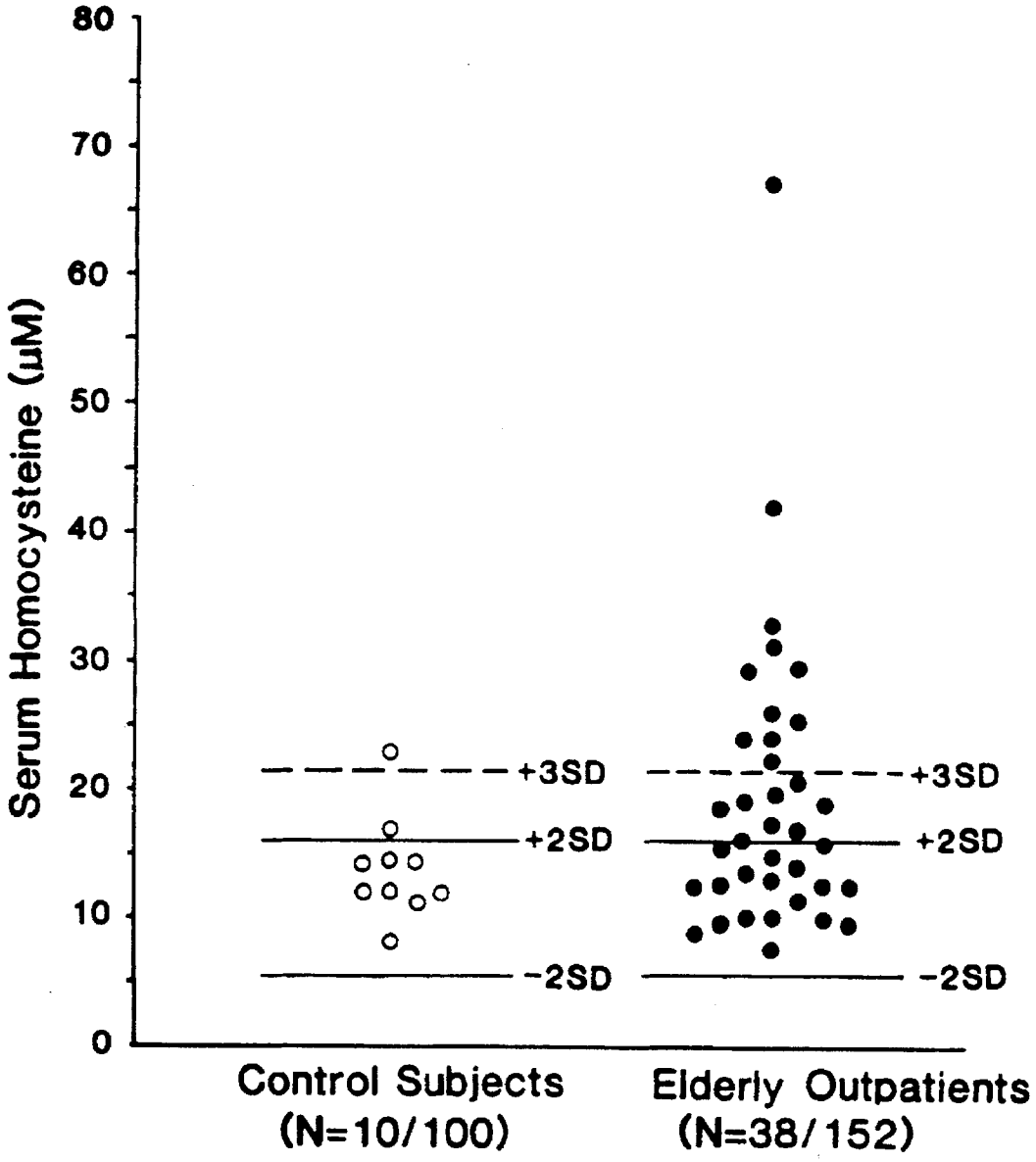

FIG. 3

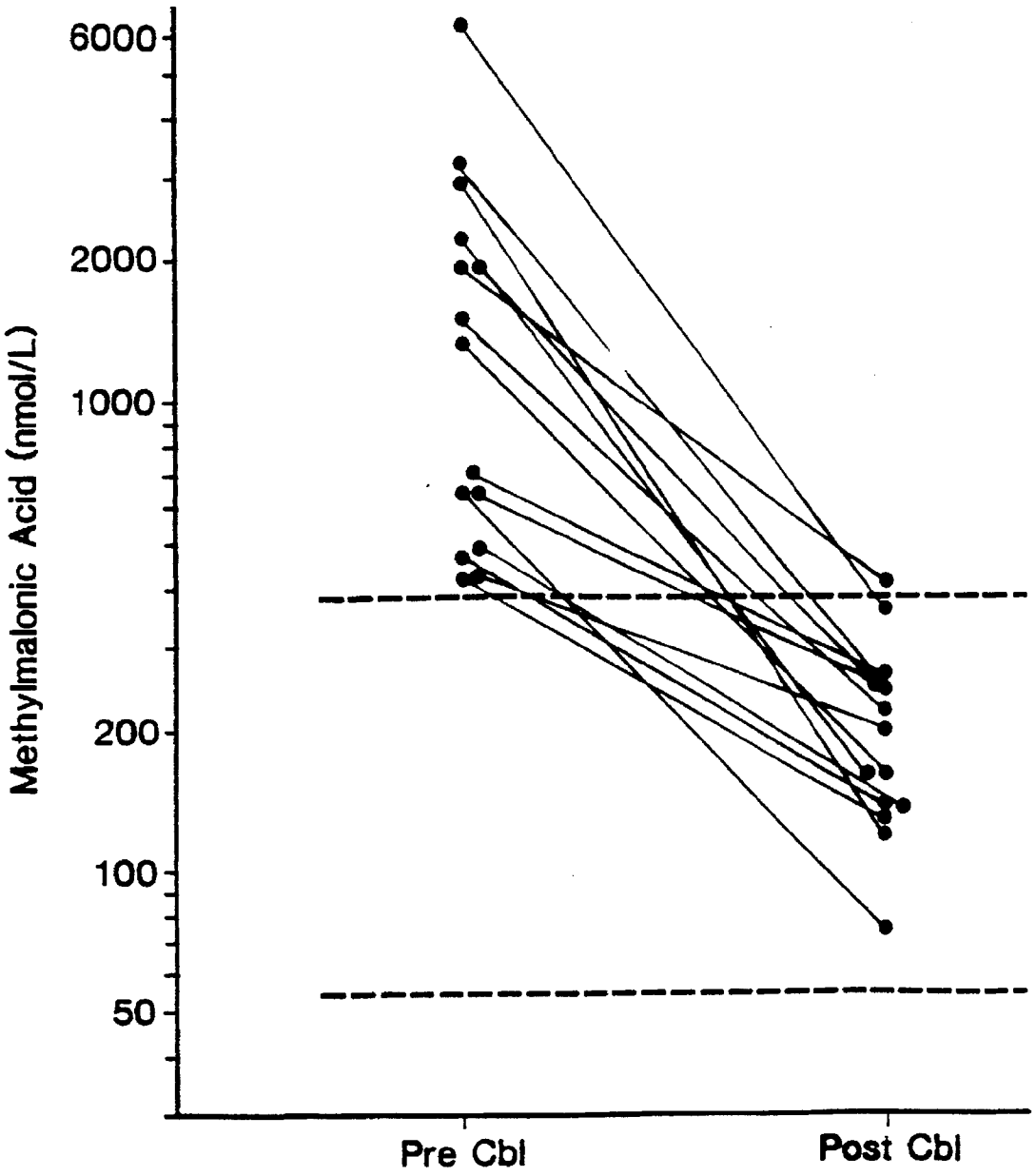

FIG. 4

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