NIST Develops Serum-Based Standard Reference Materials to Assess Nutritional Status

NIST is working with the National Institutes of Health Office of Dietary Supplements (NIH/ODS) and the Centers for Disease Control and Prevention (CDC) to develop a series of serum-based Standard Reference Materials. The goal of these Standard Reference Materials is to reduce the interlaboratory variability of clinical vitamin measurements and to enhance the accuracy of nutritional status data in the National Health and Nutrition Examination Survey (NHANES).

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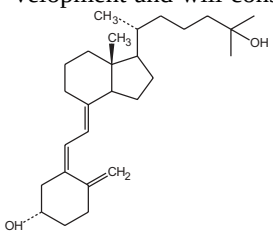
A variety of nutrients are essential for normal functioning of the human body, and deficiencies can lead to serious illnesses. In addition, a number of studies have suggested that certain nutrients may provide some benefit in reducing the risk of cancer and other diseases. Accurate measurement of vitamin levels is therefore essential for identifying individuals affected by nutritional deficiencies and for evaluating the potential health benefits associated with dietary supplementation.

Previous interlaboratory comparisons have indicated that discrepancies can exist between different assays used to assess nutritional status and that there is a significant need for reference materials to reduce this variability. NIST is developing a series of serum-based Standard Reference Materials (SRMs) that can be used as control materials by laboratories measuring vitamins (e.g., folate, D, B_6, B_{12}) in human serum. NIST is also developing higher-order analytical methods (e.g., isotope dilution liquid chromatography with mass spectrometric detection (ID LC/MS)) for use in characterizing these SRMs. Values in these serum-matrix materials will be assigned using a combination of NIST data, including data from higher-order methods, and data provided by collaborating laboratories.

> NHANES surveys are designed to assess the health and nutritional status of Americans and have been conducted since 1971. Interviews, physical examinations, diagnostic procedures, and lab tests are conducted on approximately 5000 people each year to provide information on diseases, conditions, health indicators, and risk factors.

SRM 1955 Homocysteine and Folate in Human Serum is currently available and consists of three sera with different analyte concentrations. Homocysteine is a risk factor for heart disease, and folate counteracts effects of homocysteine. Folic acid has also been shown to reduce the risk of neural tube defects in fetuses. Both NIST and CDC provided certification measurements for this SRM, which was issued in 2005.

SRM 972 Vitamin D in Human Serum is currently in development and will consist of four different sera. Vitamin



D deficiency is associated with muscle weakness and osteoporosis that can contribute to an increased risk of falls and fractures. Vitamin D status is generally monitored by measuring levels of 25-hydroxyvitamin D (25-OH-D). Because vitamin D has two forms, D_2 and D_3, accurate assessment of vitamin D status should include measurement of both hydroxylated forms (25-OH-D_2 and 25-OH-D_3 [shown]). The levels of both analytes, as well as that of a related compound 3-epi-25-OH-D, will be characterized in the SRM.

SRM 3950 Vitamin B_6 in Human Serum is another vitamin-related SRM that is currently in development and will consist of two sera with different analyte concentrations. Vitamin B_6 is converted to pyridoxal 5′-phosphate (PLP), the analyte of clinical interest when assessing vitamin B_6 dietary status. Although PLP deficiency is believed to be rare, tests for PLP deficiency are not widely performed because of a lack of accepted analytical methodology and because quality control materials are not readily available. In addition, questions remain about the level of PLP that should be anticipated in healthy individuals. There is some evidence that low levels of PLP may be associated with an increased risk for cardiovascular and other diseases.

SRM 3951 Vitamin B_{12} in Human Serum is the final serum-based SRM currently being developed and will consist of three sera with different analyte concentrations. Vitamin B_{12} (cobalamin compounds) is necessary for the formation of healthy red blood cells and in maintenance of the central nervous system. It has been estimated that 10% to 15% of adults over the age of sixty are affected by vitamin B_{12} deficiency, but most of these individuals lack any overt symptoms of deficiency. Previous comparisons of vitamin B_{12} diagnostic kits have shown that different assay techniques often do not provide comparable results.

The serum-based SRMs with values assigned for vitamins are necessary to ensure that vitamin measurements are reliable and that patients are provided with appropriate treatments when necessary.