

2 new vitamin D blood tests are often highly inaccurate, researchers say

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Two new blood tests for vitamin D are inaccurate in at least 40 percent of laboratory specimens analyzed, a new study finds. The results to be presented at The Endocrine Society's 94th Annual Meeting in Houston.

"Inaccurate results obtained from vitamin D blood tests could lead to misdiagnoses of patients," said Earle Holmes, PhD, professor of pathology and pharmacology at Loyola University Stritch School of Medicine in Maywood, Ill. "These inaccuracies also could confound efforts to identify the optimal levels of vitamin D for good health."

Doctors are increasingly ordering blood tests to measure vitamin D in patients, and these tests are now among the most frequently ordered medical tests, Holmes said.

The increase in orders likely stems from recent scientific reports that a growing percentage of the population has low vitamin D levels and that insufficient vitamin D may raise the risk of diabetes, heart disease and some cancers as well as osteoporosis. To meet the growing demand, some manufacturers have developed fully automated immunoassays for serum 25-hydroxyvitamin D, a precursor of vitamin D. Although it is the recommended test for evaluating vitamin D insufficiency, there is no universally accepted gold standard technique for measuring 25-hydroxyvitamin D, Holmes said.

Holmes and his research team compared results of two new 25-hydroxyvitamin D [immunoassay](#) tests in 163 randomly selected blood

samples submitted for testing to Loyola University Health System between March 2 and March 7, 2011. Of the blood samples, 123 came from women (median age, 54) and 40 were from men (median age, 59). One test used the reagent kit and the Architect lab testing platform from Abbott Laboratories, based in Abbott Park, Ill., and the other used the reagent kit and Advia Centaur platform from Siemens Healthcare Diagnostics in Tarrytown, N.Y. Holmes said the investigators performed these tests in the clinical laboratory at Loyola according to the manufacturers' instructions.

They then tested the same [blood samples](#) using a third method for measuring 25-hydroxyvitamin D, called liquid chromatography/tandem mass spectrometry. That test, which Holmes considers "more definitive," was performed by Quest Diagnostics in Wood Dale, Ill.

The researchers performed statistical analysis (linear regression and bias analysis) of the results. In 40 percent of the Architect-tested specimens and in 48 percent of the Centaur2-tested specimens, the results were at least 25 percent too high or 25 percent too low, compared with the third technique, Holmes reported. The maximum recommended allowable error for 25-hydroxyvitamin D tests is plus or minus 25 percent, and he stated that the sizes of the observed errors ranged from ± 25 to +80 percent.

With the Centaur2 test, 71 of the 163 test results indicated vitamin D deficiency, which is a level of less than 20 nanograms per milliliter. The Architect results indicated vitamin D deficiency in 45 of the samples, whereas liquid chromatography/tandem mass spectrometry results indicated Vitamin D deficiency in only 33 of the samples, the authors reported in their abstract.

"Both of the immunoassays erred on the side of overestimating [vitamin D](#) deficiency, which could lead to overtreatment," Holmes said. He reports no financial conflicts of interest.

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