University of Colorado Hospital

UNIVERSITY OF COLORADO HEALTH

Test Update
Vitamin D, 25 Hydroxy
Standardization to International Reference

Effective November 25, 2014, the University of Colorado Hospital Clinical Laboratory is pleased to announce that our 25-hydroxy Vitamin D assay will be aligned to the Ghent isotope-dilution liquid chromatography-tandem mass spectrometry reference measurement procedure, a reference method for the Vitamin D Standardization Program (VDSP) certified by the CDC.

The NIH Office of Dietary Supplements, CDC National Center for Environmental Health, National Institute of Standards and Technology, and Ghent University established the VDSP primarily for the purpose of standardizing measurements completed in national health surveys. It is hoped that this will also improve measurements across test manufacturers and laboratories. Numerous vitamin D assays are currently available; however, the sensitivity and specificity of these tests are unknown due to the lack of studies using an internationally recognized reference standard. Variability between assay methods and between laboratories using the same methods may vary by 10% to 20%, and classification of samples as “deficient” or “nondeficient” may vary by 4% to 32% depending on which assay is used.

The ADVIA Centaur Vitamin D Total assay (our new assay) is expected to meet a performance criterion of ±5% mean bias to the CDC and Ghent University 25-hydroxy vitamin D2/D3 reference method with an overall imprecision of less than 10% in the range of 8.8 – 110 ng/mL for total 25-hydroxy vitamin D.

A side effect of this change is that a sample measured by the old assay may produce a slightly different result by the standardized assay. Average observed differences are as follows (values are in ng/mL):

Vitamin D concentration	Average change from old to new assay
<15	-1.5
15-30	+2.1
30-50	-1.2
>50	-10

In general the magnitude of these changes is about the same as one might encounter upon repeated testing of a specimen with the old assay.

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In the past we found that values for apparently healthy adults ranged from 13-68 ng/mL by the old method. Our validation of the new assay indicates that 13-62 ng/mL is a better estimate. The following interpretive comment will appear with results:

> "On 11/25/2014 this test was standardized to a reference for the CDC's VDSP. By this method, results for apparently healthy adults are expected to be 7.4-44 ng/mL. At UCH, results for such adults range from 13-62 ng/mL. Results can vary by laboratory. 20 ng/mL is a sufficient level for practically all individuals, per the IOM. For individuals at risk of deficiency, the Endocrine Society defined less than 20 ng/ml as deficient, 21–29 ng/mL insufficient, and 30-100 ng/mL sufficient."

Please call Dr. Greg Bocsi, Clinical Chemistry Medical Director at 720-848-7050 if you have any questions or visit our website at https://www.uchealth.org/professionals/Pages/Clinical-Laboratory.aspx for additional information.

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