Incorporating the Siemens Healthineers Vitamin D Total Assay in Your Practice

Selecting the Siemens Healthineers Vitamin D Total assay provides assurance in your patient values:

- Accurate results through equimolar measurement of 25(OH)vitamin D_2 and 25(OH)vitamin D_3
- Traceable to the ID-LC/MS/MS Reference Method Procedure (RMP) which is traceable to the NIST SRM 2972[8,9]
- Reduced variability in results with proprietary monoclonal antibody
- Minimal (1.1%) cross-reactivity to 3-epi
- Fastest throughput and time to first result available on the Atellica® IM, ADVIA Centaur® systems, and Dimension® EXL
- All assays are currently (March, 2019) certified by the Centers for Disease Control

References:

1. Souberbielle JC, et al. Autoimmunity Review. 2010;9:709–715.
2. Freedman DM, et al. Looker AC, Chang SC, Graubard BI. J Natl Cancer Inst. 2007;99: 1594–1602.
3. Ng K, et al. J Clin Oncol. 2008;26;2984-2991.
4. Hypponen E, et al. Lancet. 2001;358:1500-3.
5. Wang TJ, et al. Circulation. 2008;117:503-511.
6. Bischoff-Ferrari HA, et al. Am J Clin Nutr 2006;84:18-28.
7. Malabanan A, et al. Redefining vitamin D insufficiency. Lancet 1998;351:805-6.
8. Sempos CT, et al. Scandinavian Journal of Clinical & Laboratory Investigation, 2012; 72(Suppl 243): 32–40
9. Thienpont L, et al. Scandinavian Journal of Clinical & Laboratory Investigation, 2012; 72(Suppl 243): 41–49

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Vitamin D

Improving Patient Management in Bone and Beyond

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Importance of Vitamin D Testing in the Clinical Setting

Vitamin D deficiency is a global issue impacting an estimated one seventh of the world's population. Vitamin D deficiency has been statistically linked to various cancers, diabetes, multiple sclerosis, cardiovascular, and autoimmune diseases.

In 2010, 25 experts from various medical disciplines published recommendations for vitamin D to answer who/when should be tested/supplemented and the requirements for a vitamin D test. The experts divided clinical conditions into two areas (Table 1): (1) Classical—level of evidence is high based on numerous randomized controlled trials (RCTs), and (2) Non-classical—level of evidence is increasing but RCTs are needed. Regardless of which group, the experts recommend vitamin D testing for patients at risk of developing or already with the disease.[1]

Table 1. Clinical Conditions for Vitamin D Testing

Classical	Non-classical
• Individuals with or at risk for osteoporosis • Elderly subjects with a recent fall • Pregnant women • Chronic kidney disease • Transplants • Conditions/treatments leading to bone loss • Obesity • Diabetics • Hospitalization • Bone/muscle pain or aches	• Cardiology – Hypertension • Autoimmunity – Autoimmune disease – At high risk for autoimmune disease – Starting or beginning corticosteroids • Oncology – Undergoing treatment*

*Emphasis on: (1) Premenopausal women with early breast cancer receiving adjuvant chemotherapy or gonadotropin-releasing hormone analogs; (2) Breast cancer patients under anti-aromatase therapy; (3) Prostate cancer patients under hormone ablative treatment.

Below are a few of the cited statistical links between vitamin D deficiency and non-bone-related disorders:

- NHANES III (16,818 participants) showed that participants with a higher vitamin D level of ≥32 ng/mL had a 72% lower risk of colorectal mortality than those with a level <20 ng/mL.[2] In a prospective study of 304 patients from the NHS and HPFS studies, Ng et al concluded that higher vitamin D plasma levels prior to a diagnosis of colorectal cancer were associated with improved overall survival.[3]
- A Finnish study (10,366 children) showed that infants who had received 2000 IU/day of vitamin D_3 their first year of life were 80% less likely to develop type 1 diabetes, while children who were deficient had an increased risk of 200%.[4]
- Wang et al measured vitamin D levels for 1739 Framingham Offspring Study participants without CVD for a mean follow-up of 5.4 years. Participants with lower levels of vitamin D were associated with a higher risk (~60–80%) of a cardiac event.[5]

Recommendations for Maintaining Optimal Vitamin D Levels

The consensus panel recommendations for the who, when, and what for vitamin D testing stated:[1]

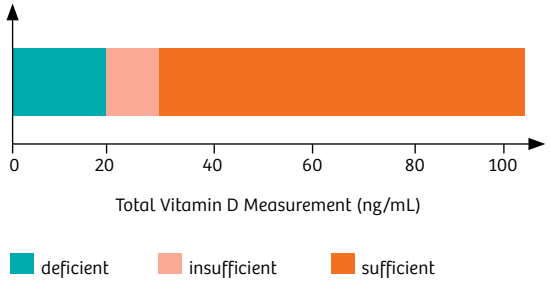
- Levels should be >30 ng/mL for patients with or at risk for musculoskeletal, cardiovascular, autoimmune diseases, and cancer
- Supplement first, then test individuals with little sun-exposure or dark skin
- Interval between starting supplementation and measuring/monitoring should be at least three months
- Upper safety limit is 100 ng/mL
- Maintenance dose is 800 IU/day

Guidelines for the Laboratory

For assay management, the consensus panel advised:[1]

- Reported patient values should be a single total 25(OH)vitamin D assay reported in ng/mL, measuring both 25(OH)vitamin D_2 and 25(OH) vitamin D_3.
- Serum is the recommended sample type.
- Reports should include recommended total 25(OH)vitamin D health-based reference values, not population-based reference ranges

Figure 1. Vitamin D Sufficiency



Although there is no consensus document on serum 25-hydroxy-vitamin D level, most experts[6,7] agree that vitamin D sufficiency is above 30 ng/mL (75 nmol/L), an insufficient level is between 20 and 30 ng/mL (50 to 75 nmol/L), and a deficient level is any value below 20 ng/mL (50 nmol/L).