VITAMIN D, 25-Hydroxy by HPLC-MS (82306)

**Clinical Use:** For use in establishing Vitamin D deficiency, sufficiency or intoxication. To monitor Vitamin D therapy in treated individuals. Test includes Total OH25D, OH25D2 and OH25D3.

**Clinical Background:** 25-Hydroxyvitamin D is the major circulating form of Vitamin D and the precursor of the active form (1,25-dihydroxyvitamin D). Because of its long half-life, 25OHD measurements are useful for assessing vitamin D status in patients.

Vitamin D occurs in two forms: vitamin D3 (cholecalciferol) and vitamin D2 (ergocalciferol). Vitamin D3 is obtained from foods or animal origin and from ultraviolet light-stimulated conversion of 7-dehydrocholesterol in the skin, whereas small amounts of vitamin D2 are obtained from foods or plant origin. Both forms are metabolized to their respective 25OHD forms (25OHD2 and 25OHD3). Analytical methods that can accurately measure both forms are essential for diagnosis and monitoring patients with vitamin D disorders.

Most current methods do not differentiate between the two forms; only the total 25OHD concentration is reported. The method we use has the sensitivity and specificity for both forms of vitamin D so that an accurate result of each fraction as well as total 25OHD is achieved. Our LC-MS/MS method does not have problems inherent to other methods such as antibody cross-reactivity, method to method variation, laboratory to laboratory variation and use of radioactive isotopes. In fact, our LC-MS/MS method uses traceable standards and is a methodology that is being evaluated by the CDC and NIST as an RMP (Reference Method Procedure) for vitamin D testing.

**Specimen Requirements:** 0.5mL of Serum in a plastic screw-top vial. Serum must be separated from cells or from gel tube ASAP.

**Specimen Stability:** Specimen is stable at Room Temperature for 21 days. **PROTECT SPECIMEN FROM LIGHT.**

**Specimen Rejection Criteria:** Gross hemolysis, grossly lipemic specimens, serum not separated from cells, serum not separated from gel-barrier tube, EDTA specimens, Heparin specimens.

**Shipping/Transport/Hours of Operation:** Laboratory operates from 7:30 am to 5:00pm, please deliver specimens to Sarofim Research Building, Institute for Molecular Medicine, 1825 Pressler Street, Suite 511, Houston, TX 77030. Specimens may be mailed in accordance with local, state and federal law and must comply with D.O.T. standards for transportation of biological hazards.

**Turnaround Time:** 48 hours from receipt in lab.

**Methodology:** LC-MS/MS with precipitation and internal standard.

This test was developed and its performance characteristics determined by ProteoPath Dx Laboratory. The U.S. Food and Drug Administration (FDA) has not approved or cleared this test. However, FDA approval or clearance is currently not required for clinical use of this test. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. ProteoPath Dx Laboratory is authorized under Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity testing.

**Reference Range:** Total 25-Hydroxyvitamin D is considered the best assessment of vitamin D status. The test reflects vitamin D from all sources (diet, supplements, and sun exposure). No common definition exists for adequate vitamin D status. A 2011 Endocrine Society clinical Practice Guideline suggested,

- Vitamin D deficiency <20 ng/ml
- Insufficiency 21 – 29 ng/ml
- Sufficiency 30 – 100 ng/ml