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CE Mark Approval for Beckman Coulter's Vitamin D Total Assay

It was announced that Beckman Coulter has received the CE Mark approval for Access 25 (OH) Vitamin D Total assay for use on the Access 2 and UniCel DxI series of immunoassay system, an important addition to the company's bone metabolism assay menu.

Arnd Kaldowski, President of Beckman Coulter Diagnostics, is confident that the European CE Mark approval will allow the company to offer laboratories the assurance required to accurately diagnose and manage diseases related to Vitamin D deficiency. He goes on to say that the new assay enhances current vitamin D assays and that as one of the first assays standardized to the NIST-Ghent ID-LC-MS/MS reference method, the Access 25 (OH) Vitamin D Total assay affords improved diagnostic confidence. Furthermore, as a result of new creative packaging, the assay also offers increased stability and user-friendliness.

Providing enhanced performance, the new assay measures total total 25 (OH) vitamin D with equimolar measurement of 25 (OH) vitamin D2 and 25 (OH) vitamin D3, hence delivering accurate clinical assessment of vitamin D status.

Its innovative opaque reagent packaging is designed to prevent light-induced reagent degradation, and as a consequence the product's outstanding stability and reproducibility is combined with enhanced storage convenience.

Additional benefits to Laboratories include the convenient assessment of suspected deficient and elevated patient populations through a broad dynamic range, as well as the speed and flexibility many instrumentation options supplied by Beckman Coulter.

Source: Beckman Coulter

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