FDA clearance for vitamin D assay, 2/15

Beckman Coulter Diagnostics has received FDA 510(k) clearance for the Access 25(OH) Vitamin D Total assay. The assay is available for use on the company's Access 2 and UniCel DxI series of immunoassay systems and provides excellent stability and convenient storage through packaging designed to prevent light-induced reagent degradation.

"The new assay delivers increased accuracy in patient results through traceability to the gold standard 25(OH) vitamin D reference measurement procedure from Ghent University and equimolar detection of 25(OH) vitamin D2 and 25(OH) vitamin D3," Beckman Coulter Diagnostics president Arnd Kaldowski said in a statement.

***Beckman Coulter Diagnostics**, 714-993-5321*