FDA clearance for Access Total βhCG (5th IS) assay, 3/14

March 2014—Beckman Coulter Diagnostics received FDA 510(k) clearance for its Access Total βhCG (5th IS) assay, the first βhCG assay standardized to the highly purified World Health Organization 5th International Standard (IS) for chorionic gonadotropin.

The assay features a broad dynamic range with automatic onboard dilution capability, reducing the need for manual sample dilutions. As a part of the standardization, reference ranges have been updated to include women over the age of 40 and postmenopausal women. Beckman Coulter has improved the Total βhCG (5th IS) to make it more resilient to preanalytical factors.

***Beckman Coulter Diagnostics**, 714-961-3909*