FDA clears Lumipulse G whole PTH Assay

Oct. 31, 2019—Fujirebio Diagnostics received FDA clearance for its Lumipulse G whole PTH Assay for testing on the Lumipulse G1200 immunoassay platform.

The measurement of whole parathyroid hormone (wPTH or PTH [1-84]) using the Lumipulse G whole PTH assay can be used in the differential diagnosis of hypercalcemia and hypocalcemia resulting from calcium metabolism disorders. The fully automated assay has a reaction time of 30 minutes and uses a single test cartridge. It has demonstrated excellent precision, with a coefficient of variation of ≤4.0 percent, the company reports.