FDA clears Lumipulse G whole PTH assay

January 2020—Fujirebio Diagnostics received FDA clearance for its Lumipulse G whole PTH assay for testing on the Lumipulse G1200 immunoassay platform. The 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.

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