FDA clears Lumipulse G CA19-9-N assay

Feb. 21, 2020—Fujirebio Diagnostics received FDA clearance of its Lumipulse G1200 CA19-9-N chemiluminescent enzyme immunoassay for use on the Lumipulse G1200 system. The assay provides the quantitative measurement of CA 19-9 in human serum or plasma and is for use as an aid in the management of patients diagnosed with cancer of the exocrine pancreas.

The assay uses a single cartridge reagent system, has a measuring range up to 80,000 U/mL, and offers a coefficient of variation of ≤5.7 percent.