Sebia gets FDA clearance for free light chain assays

March 4, 2024—Sebia announced it has received FDA 510(k) clearance for its free light chain kappa and lambda assays, intended to aid in diagnosing and monitoring patients who have multiple myeloma or immunoglobulin light chain amyloidosis. The assays quantify kappa or lambda free light chains in human serum using an enzyme linked immunosorbent assay procedure.

“As a global leader for multiple myeloma testing, Sebia expands its offer in the U.S. with this new solution, easily adaptable to automated immunoassay instruments for a high-throughput processing. The ELISA format overcomes main challenges in analytical performance often seen in alternative testing methods,” Arnaud Collin, Sebia VP of global regulatory affairs and quality, said in a press statement.

The kits are for in vitro diagnostic use only.