FDA clears Sebia Hydrashift 2/4 daratumumab assay

Feb. 26, 2018—Sebia announced it has received FDA 510(k) clearance for its Hydrashift 2/4 daratumumab assay, intended to be used with Hydragel IF, for the qualitative detection of monoclonal proteins in human serum by immunofixation electrophoresis. This in vitro diagnostic reagent mitigates the daratumumab-mediated interference seen in immunofixation results for patients with multiple myeloma treated with Darzalex (daratumumab), a fully human monoclonal antibody that binds to CD38.

The assay was developed in collaboration with Janssen Biotech to provide the clinical community with tools to monitor patients with multiple myeloma in line with the International Myeloma Working Group's recommendations.

"Sebia is excited to have developed such a novel and innovative IVD assay," Jean-Marc Chermette, CEO of Sebia, said in a statement. "Immunofixation is one of the tests referenced in the IMWG guidelines to assess complete response in a patient with multiple myeloma. This development confirms the company's commitment and strategic objective to remain the market leader in providing the most advanced diagnostic tools supporting multiple myeloma disease management."

The Hydrashift 2/4 daratumumab assay is performed on the Sebia Hydrasys 2 agarose gel platform.

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