FDA OKs Hydrashift 2/4 daratumumab, 4/18

April 2018—Sebia 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 human monoclonal antibody that binds to CD38. It 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.

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

***Sebia**, +33 1 69 89 80 80*