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Sebia’s Hydrashift 2/4 daratumumab assay got FDA acceptance

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Hydrashift 2/4 daratumumab Immunofixation assay is the result of collaboration between Sebia and JanssenBiotech to provide better tools to monitor patients with multiple myeloma

Sebia, a world leader in multiple myeloma diagnostics testing and monitoring, announces that it has received 510(k) clearance from the United States Food and Drug Administration (FDA) for its Hydrashift 2/4 daratumumab assay.

It is to be used with Hydragel IF, for the qualitative detection of monoclonal proteins in human serum by immunofixation electrophoresis.

This in vitro diagnostic (IVD) 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 Hydrashift 2/4 daratumumab Immunofixation assay is the result of collaboration between Sebia and Janssen Biotech to provide the clinical community with better tools to monitor patients with multiple myeloma in line with the International Myeloma Working Group’s (IMWG) latest recommendations.

Sebia received development rights from Janssen and is the worldwide supplier of this assay.