The reagent for mitigating **DARZALEX®** (daratumumab) interference on Sebia IF gels Shift daratumumab interference on IF gels "

What is



DARZALEX® is a human monoclonal antibody that has been shown to provide superior clinical benefit

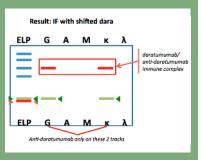
- As monotherapy in heavily pre-treated patients
- When combined with standard of care regimens for the treatment of multiple myeloma in patients with the earlier disease (.e.g, >1 prior line of therapy).

It is well known that the newer treatments for MM that use humanized monoclonal antibodies (mAbs) can interfere with the patient's native antibodies in immunofixation tests. IF is one of the tests referenced in the IMWG guidelines to establish the diagnosis of complete response in a patient with MM.



HYDRASHIFT 2/4 daratumumab

HYDRASHIFT 2/4 daratumumab is a Sebia proprietary reagent to be used in conjunction with HYDRAGEL IF on the HYDRASYS 2 platforms. This reagent allows to distinguish daratumumab interference from endogenous M protein.



MAIN BENEFITS

- · CE Mark, IVD reagent
- Direct technique, no reagent pre-treatment, no preanalytical step
- Compatible with HYDRAGEL 2IF and 4IF
- Easy-to-use and easy to implement
- Unchanged IF procedure



References

- PN 4639 HYDRASHIFT 2/4 daratumumab (20 tests)
- PN 1251 HYDRASHIFT 2/4 ACCESSORIES
- PN 4765 daratumumab control

Instrument

- HYDRASYS 2
- HYDRASYS 2 SCAN

Publications & Posters

Overcoming the interference of daratumumab with immunofixation (IFE) using an industrydevelopped DIRA test: HYDRASHIFT 2/4 daratumumab. Irimia et al., Poster 2036 at ASH 2016.

- 1. Treatment of multiple myeloma with monoclonal antibodies and the dilemma of false positive M-spikes in peripheral blood - Kazunori Murata et al.- Clinical Biochemistry 2016.
- 2. Criteria for diagnosis, staging, risk stratification and response assessment of multiple myeloma RA Kyle and SV Rajkumar - Leukemia (2009) 23, 3 - 9.
- 3. Monitoring multiple myeloma patients treated with daratumumab: teasing out monoclonal antibody interference -Christopher Mc Cudden et al. - Clin. Chem. Lab. Med. 2016; aop.

