

Hydrashift

SHIFT
daratumumab
interference on
HYDRAGEL IF

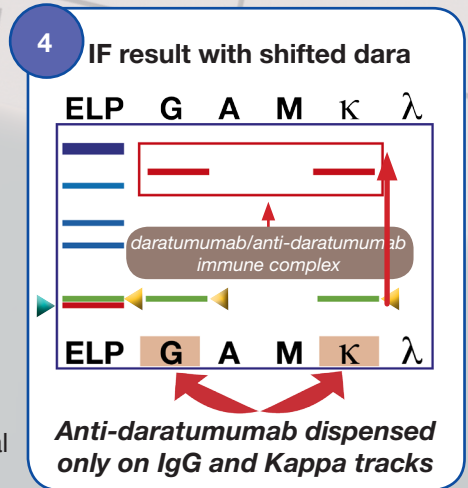
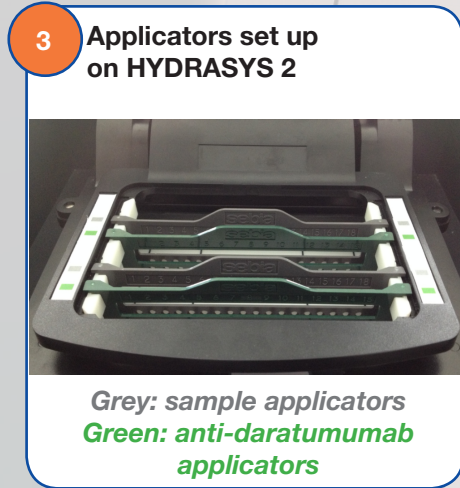
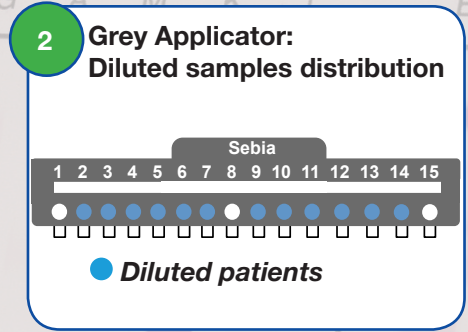
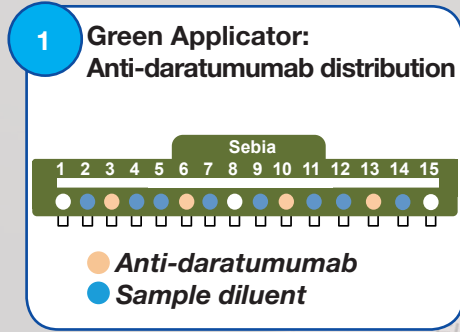
SHIFTING daratumumab INTERFERENCE on HYDRAGEL IF

Unique "SHIFT" technology

- HYDRASHIFT is a proprietary analytical shifting process developed by Sebia to be used in conjunction with HYDRAGEL IF assay on the HYDRASYS 2 platform.
- This procedure is simple and compatible with the HYDRAGEL 2 and 4 IF with both standard and dynamic masks.

Main benefits

- IVD reagent, CE mark*
- No IF procedure changes
- Easy to implement
 - No sample pre-treatment
 - Same migration program
 - Same staining program
- Flexible design**
- Same T.A.T



* For other regulatory approvals, contact your Sebia representative

** Possible to run patients with and without daratumumab treatment on the same gel

▶ daratumumab
▶ Patient's monoclonal component

HYDRASHIFT AT A GLANCE



HYDRAGEL IF KITS	PRODUCT NUMBER
HYDRAGEL 2 or 4 IF Acid violet - Dynamic mask	4302 or 4304
Antisera and Fixative for immunofixation IF - Dynamic mask	4315
OR	
HYDRAGEL 2 or 4 IF Acid violet - Standard mask	4802 or 4804
Antisera and Fixative immunofixation IF - Standard mask	4815

Instrument

- HYDRASYS 2
- HYDRASYS 2 SCAN
- HYDRASYS 2 FOCUSING
- HYDRASYS 2 SCAN FOCUSING

References

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

Publications & Posters

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

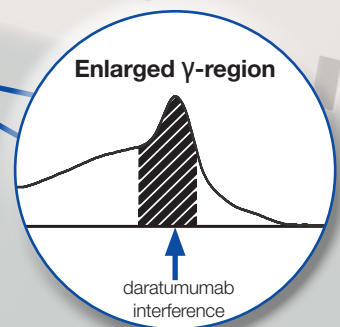
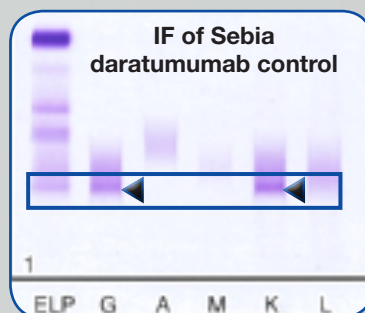
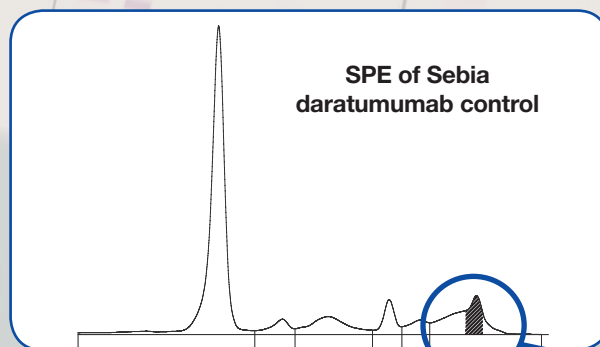
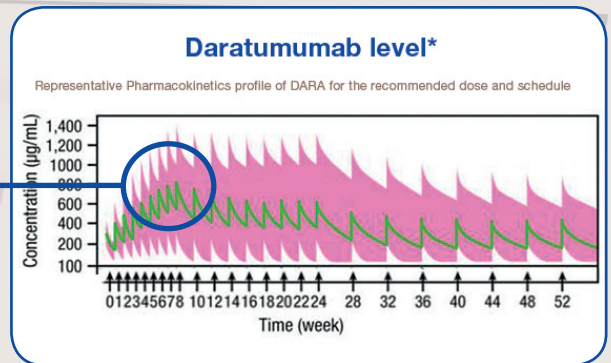
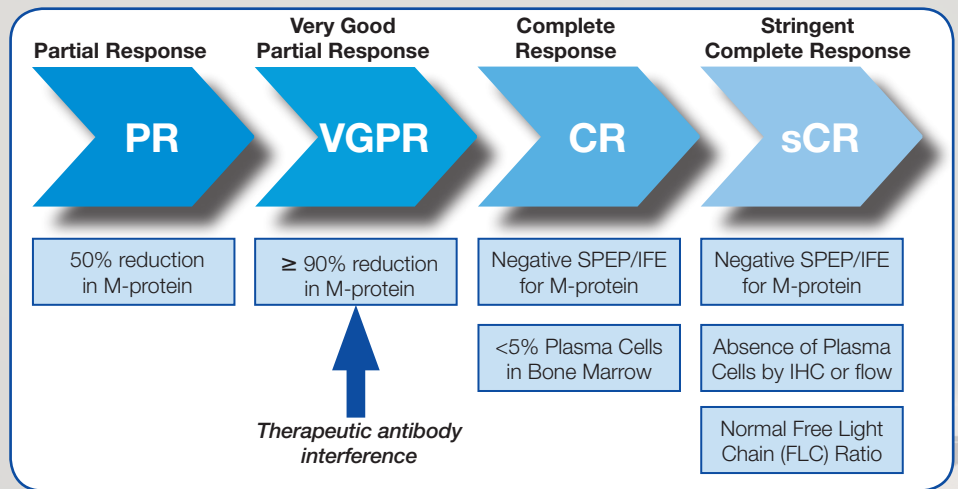
HYDRASHIFT 2/4 daratumumab

• What is DARZALEX®?

DARZALEX® (daratumumab) is a human monoclonal antibody targeting CD38 that has been shown to provide superior clinical benefit as monotherapy in heavily pre-treated multiple myeloma patients and when combined with standard of care regimens for the treatment of Multiple Myeloma (MM) patients with the earlier disease (e.g., >1 prior line of therapy).

It is well known that the newer treatments for MM using humanized monoclonal antibodies (mAbs) can interfere with the patient's native antibodies in immunofixation (IF) tests.

IF is one of the tests referenced in the IMWG guidelines to assess response to treatment in a patient with MM.



- Sources:
- 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
 - Criteria for diagnosis, staging, risk stratification and response assessment of multiple myeloma, Kyle and Rajkumar, Leukemia 2009
 - Monitoring multiple myeloma patients treated with daratumumab: teasing out monoclonal antibody interference, Christopher Mc Cudden et al., Clin. Chem. Lab. Med. 2016

* Clinical Implications of Complex Pharmacokinetics for Daratumumab Dose Regimen in Patients With Relapsed/Refractory Multiple Myeloma- Xu et al. - Clinical Pharmacology & Therapeutics 2017.

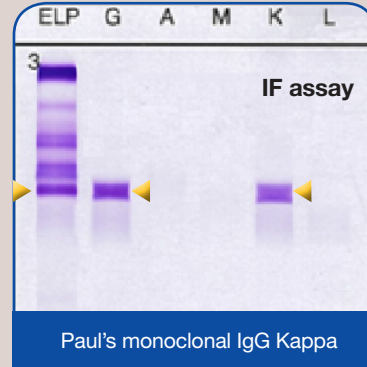
CLINICAL CASE #1

• Paul K.



- **Date of Birth**
September 2nd, 1955
- **Pathology**
Multiple Myeloma
- **Serum Peak**
IgG Kappa (K)
- **Urine Peak**
Free Light Chain Kappa

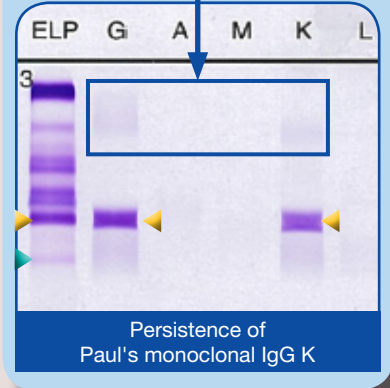
Screening



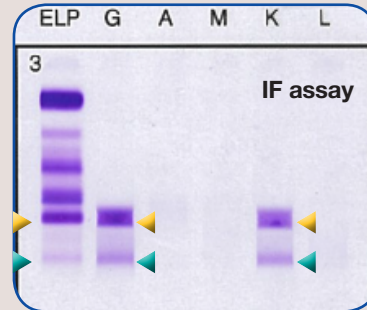
daratumumab therapy (16mg/kg)

IF with HYDRASHIFT 2/4 daratumumab

daratumumab/anti-daratumumab immune complex



Follow-up 1

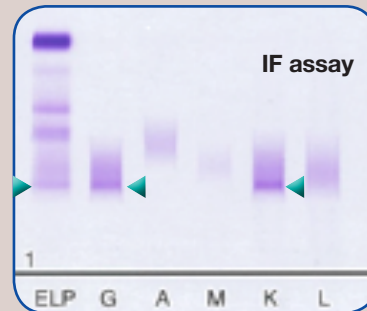


C2D1

daratumumab/anti-daratumumab immune complex



Follow-up 2



C4D1

CxDx : Cycle x Day x

Persistence on IF of initial monoclonal component

Absence on IF of initial monoclonal component

daratumumab

Patient's monoclonal component

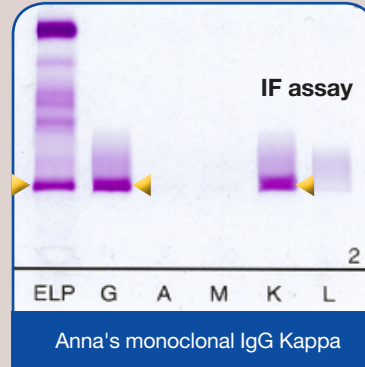
CLINICAL CASE #2

• Anna B.



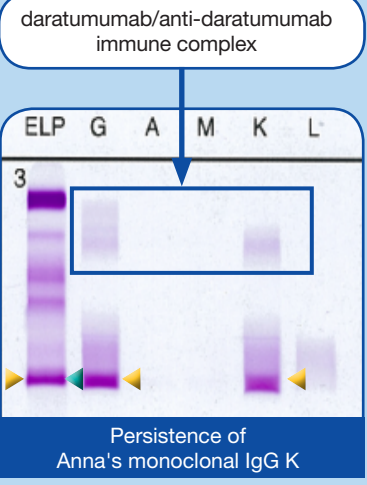
- **Date of Birth**
December 23rd, 1948
- **Pathology**
Multiple Myeloma
- **Serum Peak**
IgG Kappa (K)
- **Urine Peak**
Free Light Chain Kappa

Screening

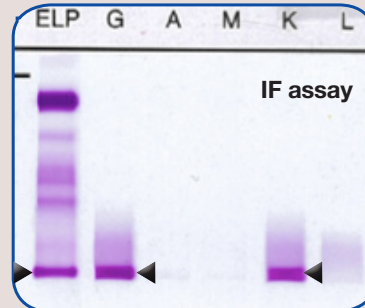


daratumumab therapy (16mg/kg)

IF with HYDRASHIFT 2/4 daratumumab



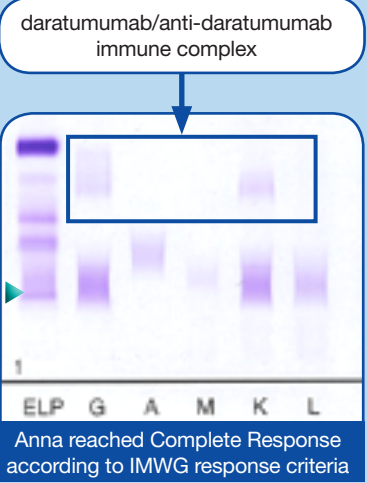
Follow-up 1



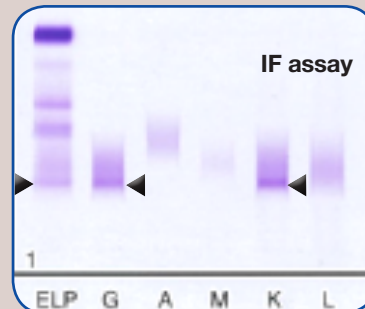
C3D1



! **Co-migration with daratumumab**
Impossible to differentiate Anna's monoclonal IgG K from daratumumab interference



Follow-up 2



C5D1



CxDx : Cycle x Day x

Persistence on IF of initial monoclonal component

Absence on IF of initial monoclonal component

daratumumab

Patient's monoclonal component

Unknown origin of the band (daratumumab and/or residual patient's monoclonal component)

CLINICAL CASE #3

• Julia M.



- **Date of Birth**
September 5th, 1942
- **Pathology**
Multiple Myeloma
- **Serum Peak**
IgG Kappa (K)
- **Urine Peak**
Free Light Chain Kappa

CxDx : Cycle x Day x

Persistence on IF of initial monoclonal component

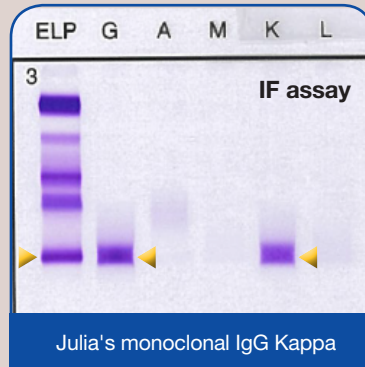
Absence on IF of initial monoclonal component

daratumumab

Patient's monoclonal component

Unknown origin of the band (daratumumab and/or residual patient's monoclonal component)

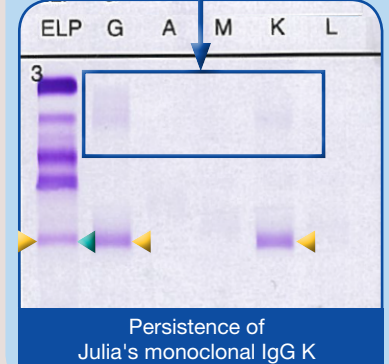
Screening



daratumumab therapy (16mg/kg)

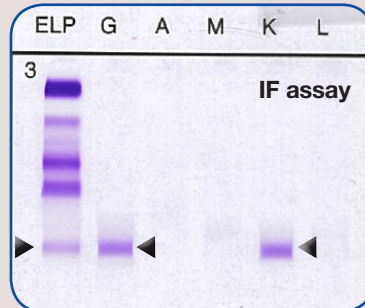
IF with HYDRASHIFT 2/4 daratumumab

daratumumab/anti-daratumumab immune complex



Follow-up 1

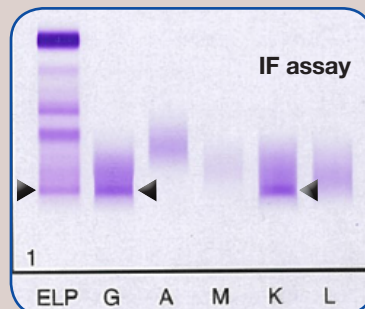
C2D1



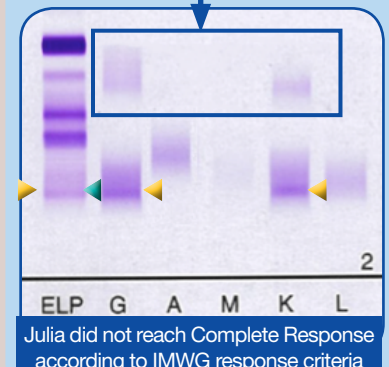
Co-migration with daratumumab:
Impossible to differentiate Julia's monoclonal IgG K from daratumumab interference

Follow-up 2

C5D1



daratumumab/anti-daratumumab immune complex



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