Daratumumab Interference Is Clinically Manageable

- To date, no clinically significant hemolysis has been observed in patients receiving daratumumab, and no transfusion reactions have occurred in patients requiring transfusions (data on file)
- daratumumab does not interfere with identification of ABO/RhD antigens¹
- If an emergency transfusion is required, non-crossmatched, ABO/RhD-compatible RBCs can be given, per local blood bank practices⁶
- A patient's compatibility profile, determined prior to their first dose of daratumumab, is recorded on the patient's ID card

Additional Resources

For full prescribing information, please refer to the Tobe completed by Middle East FZ LLC, Mohamed Bin Rashid Academic Medical Centre - Building 14, Level 4

P.O. Box 505080, United Arab Emirates, Tel: +97144297200





Hotline: +971559816775

Email: GCC-PV2@its.inj.com

Or to Janssen:

P.O. Box 1853 Dubai

Email: pv@mohap.gov.ae

Telephone 80011111

Ministry of Health and Prevention/Drug Department/Pharmacovigilance and Medical Device section

Adverse events reporting guidance:

- 8. Westhoff CM, Reid ME. Review: the Kell, Duffy, and Kidd blood group systems. Immunohematology. 2004;20(1):37-49.
 - .0172:(11)32;8102
- 7. Hannon JL, Clarke G. Transfusion management of patients receiving daratumumab therapy for advanced plasma cell myeloma. Transfusion.
 - antibody therapy. Transfusion. 2015;55(6 Pt 2):1555-1562.
- ADP-ribose hydrolase activities at the outer surface of human erythrocytes. Biochem Biophys Res Commun. 1993;196(3):1459-1465.

 6. Oostendorp M, Lammerts van Bueren JJ, Doshi P, et al. When blood transfusion medicine becomes complicated due to interference by monoclonal
- 5. Zocchi E, Franco L, Guida L, et al. A single protein immunologically identified as CD38 displays NAD+ glycohydrolase, ADP-ribosyl cyclase and cyclic
 - 4. Mehta K, Shahid U, Malavasi F. Human CD38, a cell-surface protein with multiple functions. FASEB J. 1996;10(12):1408-1417.
 - 7007,12(5):409-414
 - 3. Albeniz I, Demir O, Türker-Sener L, Yalcintepe L, Murten R, Bermek E. Erythrocyte CD38 as a prognostic marker in cancer. Hematology.
 - 2. Daratumumab Summary of Product Characteristics, Janssen-Cilag International MV, Beerse, Belgium.
 - 2015;55(6 Pt 2):1545-1554.
 - 1. Chapuy CI, Nicholson RT, Aguad MD, et al. Resolving the daratumumab interference with blood compatibility testing. Transfusion.

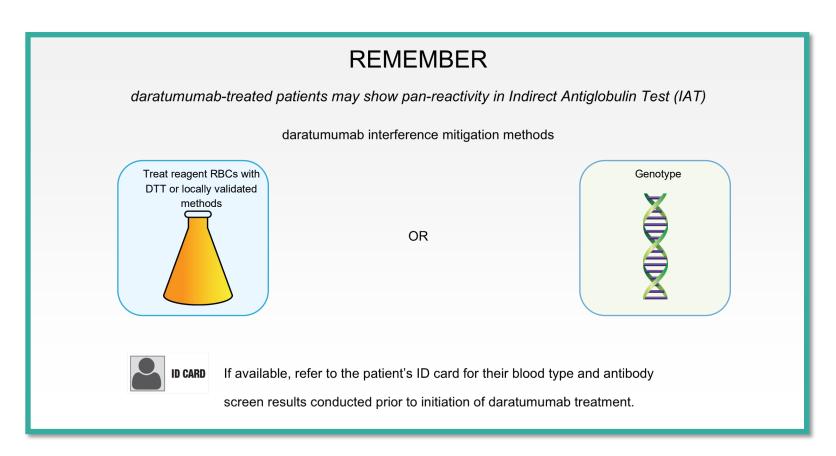
References

DARATUMUMAB

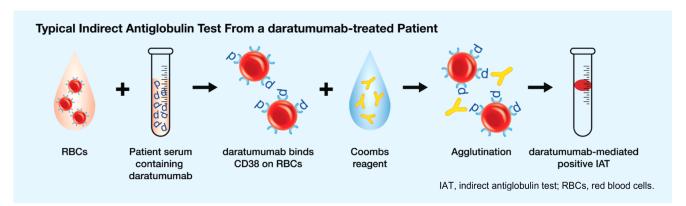
Understanding & Mitigating daratumumab Interference with Blood Compatibility Testing



daratumumab Interference Mitigation Methods

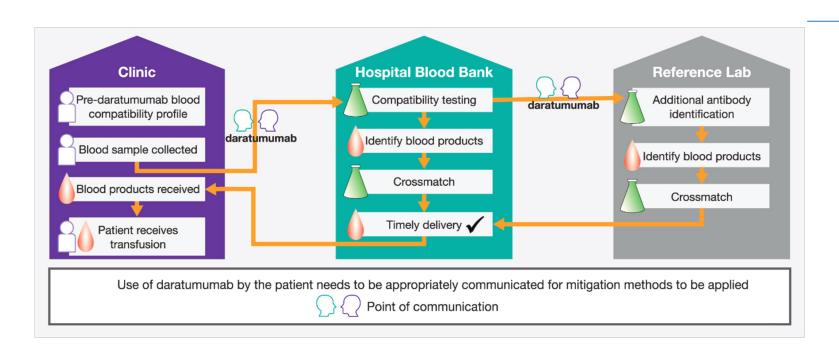


Daratumumab Results in a Positive Indirect Antiglobulin Test which may persist for up to 6 months after the last product's infusion



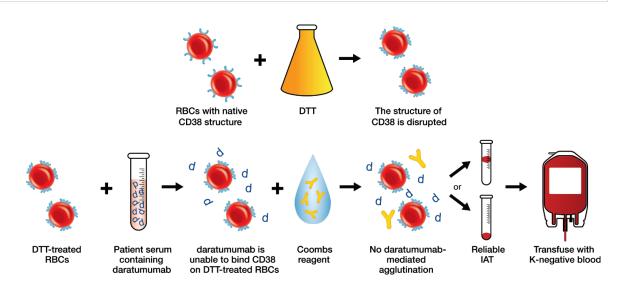
- daratumumab is a human monoclonal antibody for the treatment of multiple myeloma or AL amyloidosis²
- daratumumab binds to CD38,1 a protein that is expressed at low levels on red blood cells (RBCs)3-5
- daratumumab binding to RBCs may mask the detection of antibodies to minor antigens. This interferes with compatibility tests, including the antibody screening and crossmatching¹

Help Prevent Delays by Applying Mitigation Methods



- If steps are not taken to mitigate daratumumab interference, delays in the release of blood products for transfusion may occur
- Blood products for transfusion can be identified for daratumumab-treated patients using protocols available in the literature^{1,6}
 or by using genotyping⁷
- Mitigation methods should be used until pan-agglutination is no longer observed

Treat Reagent RBCs With DTT or Locally Validated Method



DDT, dithiothreitol; IAT, indirect antiglobulin test; RBC, red blood cells.

- Treat reagent RBCs with dithiothreitol (DTT) to disrupt daratumumab binding, thus allowing antibody screening or crossmatching to be performed; the protocol can be found in Chapuy et al¹. Alternative locally validated methods can also be used
- Blood products for transfusion were identified for daratumumab-treated patients, after using DTT-treated reagent RBCs for antibody screening¹
- Since the Kell blood group system is also sensitive to DTT treatment,⁸ K-negative units should be supplied after ruling out or identifying alloantibodies using DTT-treated RBCs