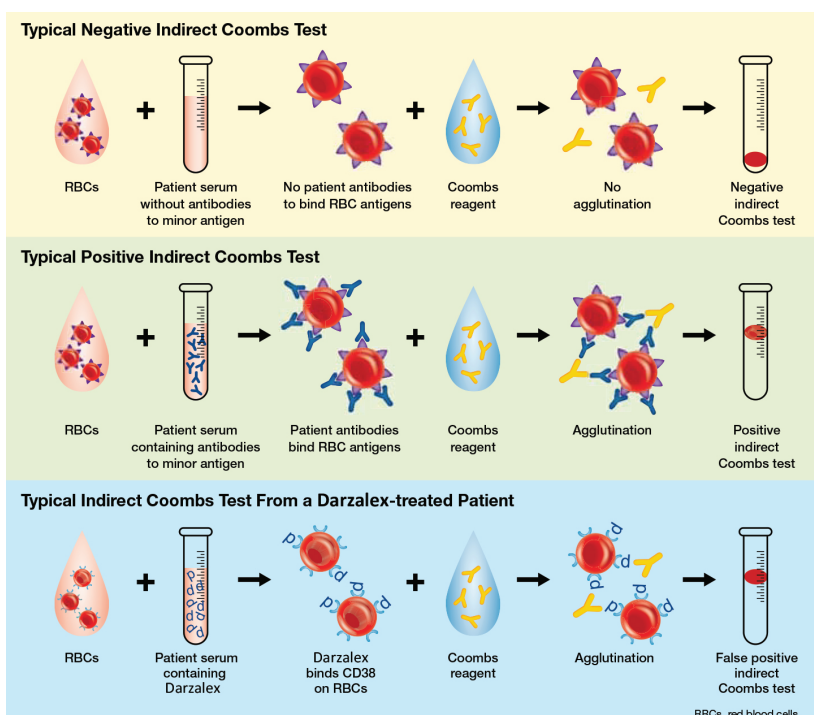
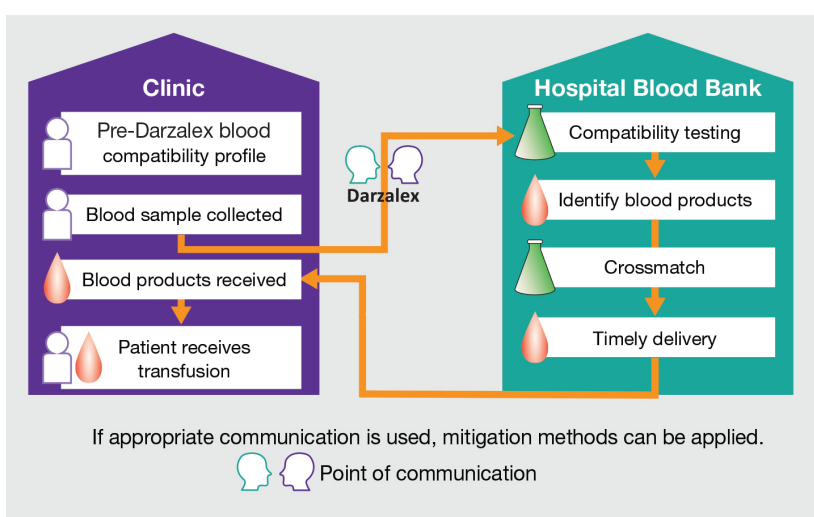


daratumumab Results in a False Positive Indirect Coombs Test



- ▶ daratumumab is a human monoclonal antibody for the treatment of multiple myeloma¹
- ▶ daratumumab binds to CD38, 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 in the patient's serum. This interferes with blood bank compatibility tests, including the antibody screening and crossmatching² (both indirect Coombs tests) that are part of a routine pretransfusion work up

Help Prevent Blood Transfusion Delays



- ▶ Blood compatibility testing can still be performed on daratumumab-treated patients
- ▶ Blood products for transfusion can be identified for daratumumab-treated patients using protocols available in the literature^{2,6}, or locally validated methods. Genotyping may also be considered
- ▶ To ensure that your patient receives a timely transfusion, type and screen patients prior to starting daratumumab and inform the blood bank that they will receive a sample from a daratumumab-treated patient. Phenotyping may be considered prior to starting daratumumab treatment as per local practice.

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 RBC and whole blood transfusions (data on file)
- ▶ daratumumab does not interfere with identification of ABO/RhD antigens²
- ▶ If an emergency transfusion is required, non-crossmatched, ABO/RhD-compatible RBCs can be given, per local blood bank practices⁶
- ▶ Once treatment with daratumumab is discontinued, pan-agglutination may persist; the duration of this effect varies from patient to patient, but may persist for up to 6 months after the last daratumumab infusion⁶. Therefore, patients should carry their Patient ID Card for 6 months after the treatment has ended
- ▶ Patients should be advised to consult the Patient Information Leaflet (PIL) for further information

HCPs are asked to report any suspected adverse reactions via the national reporting system at the following:
To the Ministry of Health according to the National Regulation by using an online form <https://sideeffects.health.gov.il/> or to be reported to Janssen on telephone 09-9591111

Detailed information on this medicinal product is available in the DARZALEX Summary of Product Characteristics.
For any further information on the use of DARZALEX, please contact Janssen Medical Information Services on telephone 09-9591111
The format and the content of this HCP Brochure was checked and approved by the Ministry of Health in July 2021.

DARATUMUMAB ▼

Darzalex 20mg/ml IV
Darzalex 120mg/ml SC, 1800mg

Understanding daratumumab Interference with Blood Compatibility Testing



References

1. de Weers M, Tai YT, van der Veer MS, et al. Daratumumab, a novel therapeutic human CD38 monoclonal antibody, induces killing of multiple myeloma and other hematological tumors. *J Immunol.* 2011;186(3):1840-1848.
2. Chapuy CI, Nicholson RT, Aguad MD, et al. Resolving the daratumumab interference with blood compatibility testing. *Transfusion.* 2015;55(6Pt 2):1545-1554.
3. Albeniz I, Demir O, Türker-Sener L, Yalcintepe L, Nurten R, Bermek E. Erythrocyte CD38 as a prognostic marker in cancer. *Hematology.* 2007;12(5):409-414.
4. Mehta K, Shahid U, Malavasi F. Human CD38, a cell-surface protein with multiple functions. *FASEB J.* 1996;10(12):1408-1417.
5. Zocchi E, Franco L, Guida L, et al. A single protein immunologically identified as CD38 displays NAD⁺ glycohydrolase, ADP-ribosyl cyclase and cyclic 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 antibody therapy. *Transfusion.* 2015;55(6 Pt 2):1555-1562.
7. Hannon JL, Clarke G. Transfusion management of patients receiving daratumumab therapy for advanced plasma cell myeloma. *Transfusion.* 2015;55(11):2770.

EM-000000

To Ensure Timely Transfusions

REMEMBER

If a patient who received daratumumab requires a transfusion:



Type and screen patients prior to starting daratumumab. Inform the blood bank that your patient has been treated with daratumumab which interferes with indirect antiglobulin tests



Ensure that your patient's blood sample is identified as containing daratumumab



Double-check standing orders for transfusions to determine if your patient received daratumumab within the last year
Ensure patients are given a Patient ID Card for daratumumab and provide your patient's pre-daratumumab compatibility profile, if available, to the blood bank



Ask your patient to tell their other HCPs that they have received daratumumab, particularly before a transfusion