

Additional Resources

For additional information, please refer to the Summary of Product Characteristics (SmPC) or contact AM Mangion Medical Information by using one of the following methods:

Phone (24/7): 00356 2397 6888

Email: medicalaffairs@ammangion.com

Reporting of side effects:

To report Suspected Adverse Reactions, contact AM Mangion on the following:

Phone (24/7): 00356 2397 6333

Email: pv@ammangion.com

Address: AM Mangion Ltd, Mangion Building, N/S Off Valletta Road, Luqa, LQA 6000, MALTA

If you get any side effects, talk to your doctor or nurse. You can also report side effects directly via ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal. By reporting side effects you can help provide more information on the safety of this medicine

▼ **This medicinal product is subject to additional monitoring and it therefore important to report any suspected adverse reactions related to this medicinal product**

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DARZALEX ▼

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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.

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1. Chapuy CI, Nicholson RT, Aguad MD, et al. Resolving the daratumumab interference with blood compatibility testing. *Transfusion*. 2015;55(6 Pt 2):1545-1554.

References

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Understanding & Mitigating daratumumab Interference with Blood Compatibility Testing

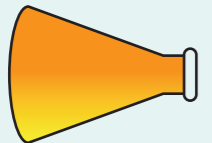
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daratumumab Interference Mitigation Methods

REMEMBER

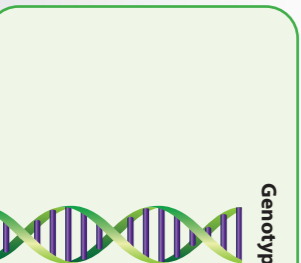
daratumumab-treated patients may show pan-reactivity in Indirect Antiglobulin Test (IAT)
daratumumab interference mitigation methods

Treat reagent RBCs with DTT
or locally validated methods



OR

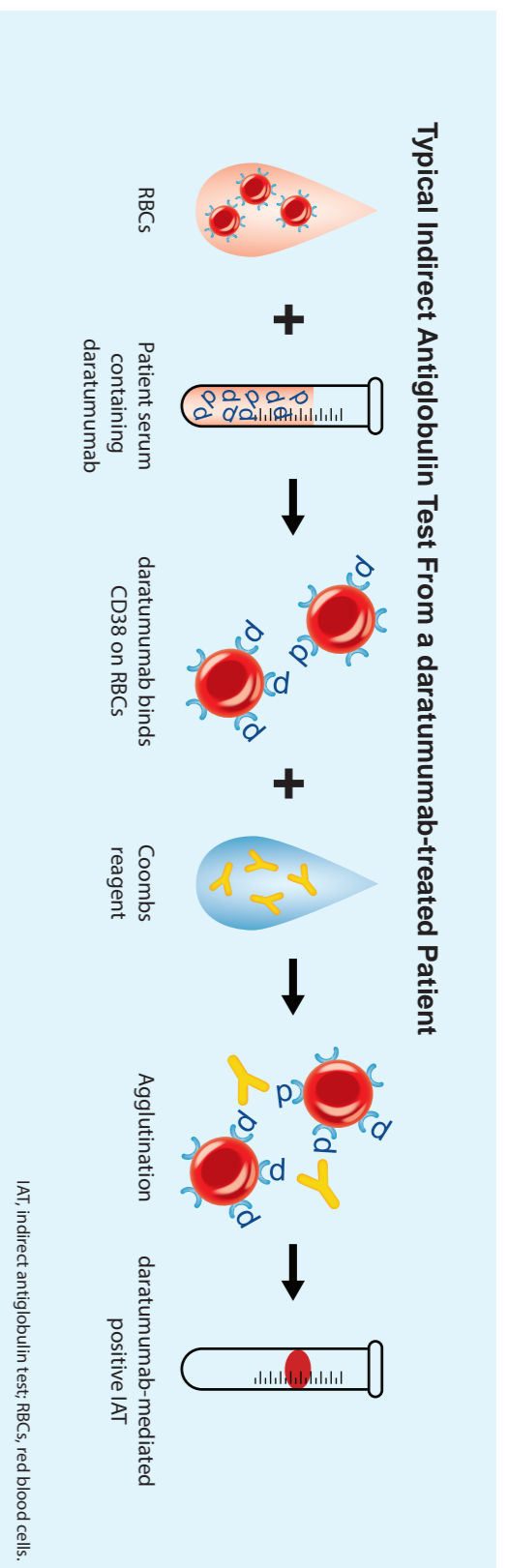
Genotype



If available, refer to the patient's ID card for their blood type and antibody screen results conducted prior to initiation of daratumumab treatment.

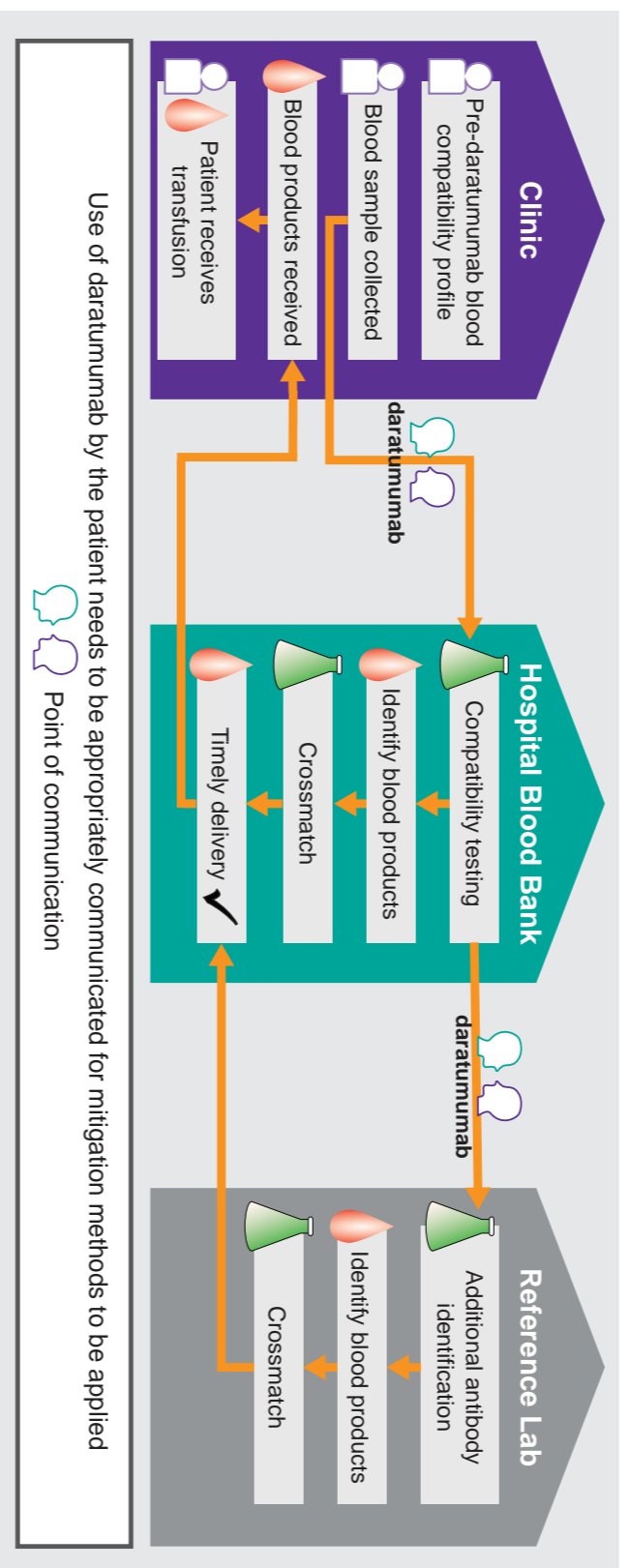
DTT, dithiothreitol; RBCs, red blood cells.

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



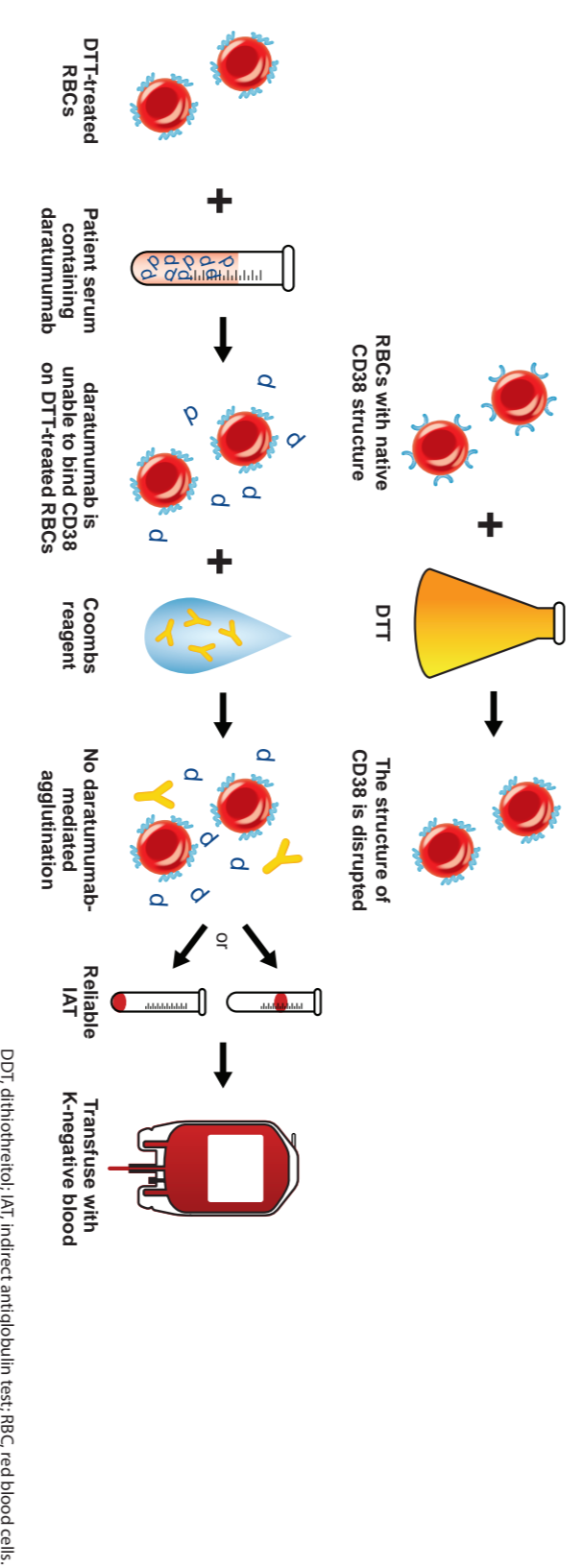
- daratumumab is a human monoclonal antibody for the treatment of multiple myeloma or AL amyloidosis²
- daratumumab binds to CD38,¹ a protein that is expressed at low levels on red blood cells (RBCs)³⁻⁵
- daratumumab binding to RBCs may mask the detection of antibodies to minor antigens. This interferes 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 literature⁶ 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



- 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,² K-negative units should be supplied after ruling out or identifying alloantibodies using DTT-treated RBCs

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, 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