Understanding daratumumab Interference with Blood Compatibility Testing

DARATUMUMAB

References

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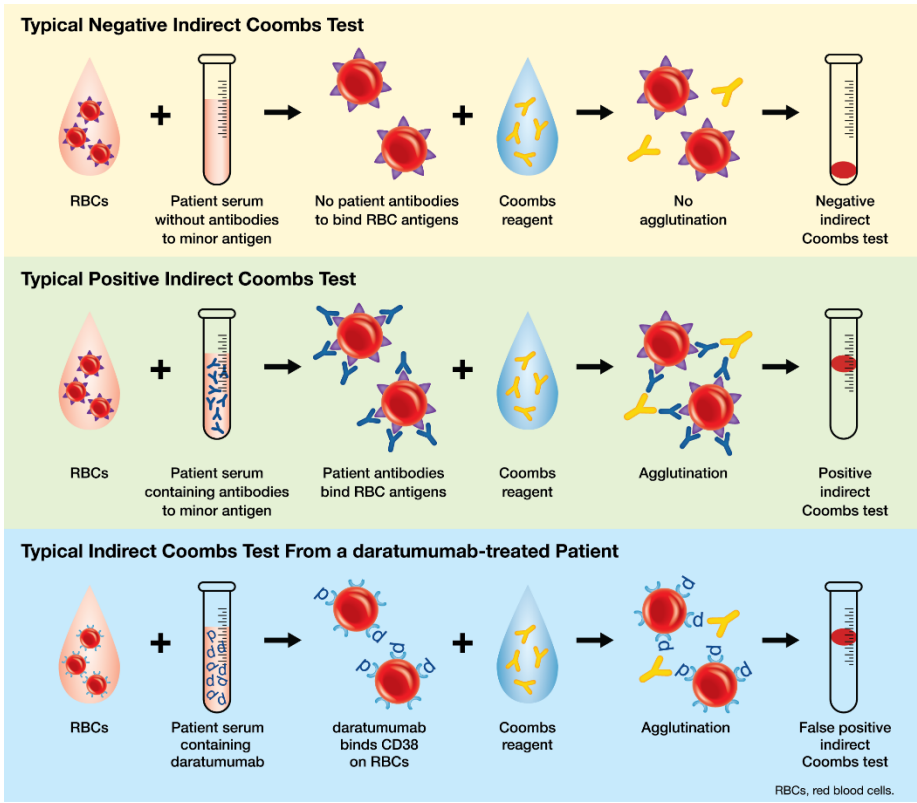
To Ensure Timely Transfusions

REMEMBER

If a patient who received daratumumab requires a transfusion:

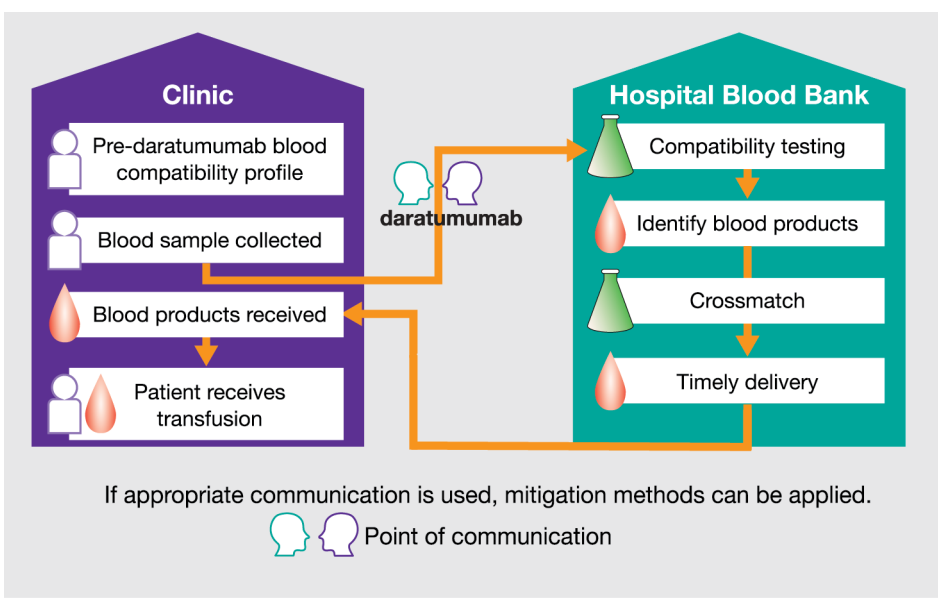
- Type and screen patients prior to starting daratumumab. Inform the blood bank that your patient has been treated with daratumumab which interferes with indirect antiglobulin tests
- Ensure that your patient's blood sample is identified as containing daratumumab
- Double-check standing orders for transfusions 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

daratumumab Results in a False Positive Indirect Coombs Test



- daratumumab is a human monoclonal antibody for the treatment of multiple myeloma or AL Amyloidosis[1]
- daratumumab binds to CD38,[2] 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 crossmatching[2] (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 antigens[2]
- If an emergency transfusion is required, non-crossmatched, ABO/RhD-compatible RBCs can be given, per local blood bank practices[6]
- 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 infusion[6]. 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

Additional Resources

For full prescribing information, please refer to the data sheet or contact Johnson & Johnson Middle East FZ LLC, Mohamed Bin Rashid Academic Medical Centre – Building 14, Level 4, P.O. Box 505080, United Arab Emirates, Tel: +97144297200, Fax: +97144297150

Adverse events reporting guidance:

Ministry of Health

Pharmaceutical and Herbal Medicine, Registration and Control Administration, Ministry of Health, Sulaibkhat - Jamal Abdel Nasser Street, PO Box 5 Zip Code 13001, Kuwait,

Tel: +96524815382, https://eservices.moh.gov.kw/HSDrugComplaints.aspx.

Or to Janssen:

Email :GCC-PV2@its.jnj.com, Hotline: +971559816775

In order to improve the traceability of Darzalex, the tradename and the batch number of the administered product should be clearly recorded in the patient file and when reporting an Adverse Event.