Direct Healthcare Professional Communication

June 2023

Darzalex (Daratumumab): "Interaction with Blood Compatibility Testing- Information for Blood Transfusion Management Departments (Blood Banks)"

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

Summary:

- Darzalex (Daratumumab) is a human monoclonal antibody for the treatment of multiplemyeloma1.
- Darzalex (Daratumumab) binds to CD38,2 a protein that is expressed at low levels on red blood cells(RBCs)3-5.
- Darzalex (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.
- 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.

Further Information ;

- 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.
- In case of urgent need for transfusion, non-cross matched ABO/RhD compatible RBC units can be administered as per local bank practices;
- Daratumumab-mediated positive indirect Coombs test (interfering with cross-matching of blood) may persist for up to 6 months after the last product's infusion,
- Therefore, the HCP should advise the patient to carry the Patient Alert Card until 6 months after the treatment has ended.

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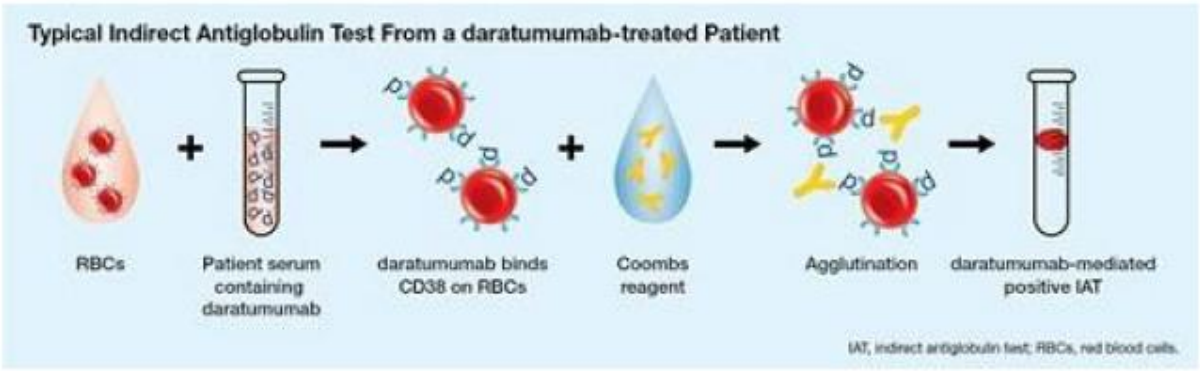
Figure 1. DARA Results in a Positive Indirect Antiglobulin test which may persist for up to 6 months after the last product's infusion.



References

1- de Weers M, Tai YT, van der Veer MS, et al. Daratumumab, a novel therapeutic human CD38 mono clonal anti:body,induces killing of multiple myeloma and other hematologicail tumors. *J fmmunol.*. 2011;186(3):1840-1848.
2- Chapuy Cl, Nicholson RT, Aguad MD, et al.. Reso lving the daratumumab interferencewith blood compatibili ty testing.*Transfusion.* 2015;55(6Pt 2):1545-15

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://primaryreporting.who-umc.org/EG
QR Code:

Hotline: 15301

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