Features and Advantages

- Easy to implement in routine serology
- Even faster and easier procedure due to express protocol: no pre-incubation of cells required!
- Specific inhibition of anti-CD38 antibodies Daratumumab, Isatuximab, and
 Felzartamab without affecting other antigens or alloantibody reactions
- No side effects like destruction of blood group antigens or hemolysis as described for the standard DTT treatment
- No need for expensive anti-idiotypic antibodies or soluble CD38 protein for blocking anti-CD38
- Anti-CD38 antibody as positive and process control (Dara-PC) available
- Shelf life of 15 months
- Now also available as CE-IVD product DaraEx plus





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DaraEx and DaraEx plus

Anti-CD38 antibody neutralizing agents.

DaraEx and DaraEx plus

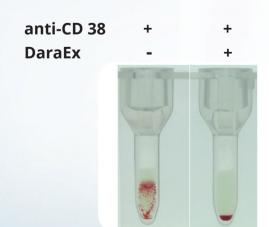
Drug induced masking of Blood Group Antigens

Antibody based drugs can disturb serological blood group testing since the relevant antigens cannot be examined due to the therapeutic antibodies. The anti-CD38 antibodies show a strong interference in the indirect antiglobulin test (IAT) where most of the reactions turn to unspecifically (false) positive. The time consuming standard technique using Dithiothreitol (DTT) counteracts the interference, but has major drawbacks like destruction of Kel antigens or hemolysis.

The imusyn DaraEx (For Research Use Only) and the CE-IVD marked DaraEx *plus* compounds inhibit the agglutination effect of anti-CD38 in IAT without side effects.

Method:

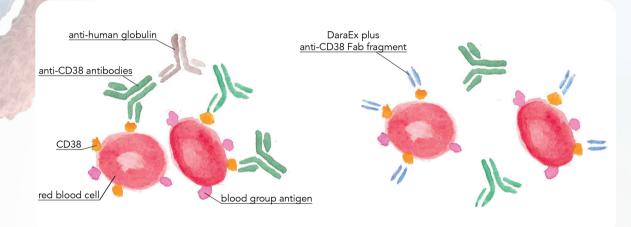
- DaraEx / DaraEx plus is a Fab-fragment of an anti-CD38 antibody.
- DaraEx / DaraEx plus masks the CD38 on the erythrocytes surface and therefore inhibits the binding of the anti-CD38 antibodies Daratumumab, Isatuximab, and Felzartamab.
- One uniform express protocol that applies for the Antibody Screening and Identification as well as for Cross-Matching.
- No preincubation of DaraEx / DaraEx plus with the test cells necessary: DaraEx / DaraEx plus is directly added to the test cells in the gel card.
 - >> to 1 volume of cells (0.8 %) 0.2 volume of DaraEx / DaraEx plus is added
 - » e.g. for 50 μL cells 10 μL DaraEx / DaraEx plus is required
- Procedure of the indirect antiglobulin test with standard gel card systems (Bio-Rad ID-System, ORTHO MTS).



Principle: Antigen masking indirect antiglobulin test (AMIAT)

Left side of the picture: When an anti-CD38 antibody (green) is present in a patient sample, it binds to the CD38 (yellow) on the surface of the red blood cells. The cells are then agglutinated by the anti-human globulin (purple) in the IAT.

Right side of the pictutre: In the Antigen Masking Indirect Antiglobulin Test (AMIAT), a specific antigen on the surface of the red blood cells is masked before anti-human globulin is added. In the case of DaraEx / DaraEx plus (blue), which is the Fab-fragment of an anti-CD38 antibody, CD38 is masked, thereby preventing anti-CD38 antibodies from binding.



Source: see Reference

Reference:

 Habicht CP, Adolph S, Schneeweiss C: Antigen Masking Indirect Antiglobulin Test: A New Reagent with Improved Protocols. DGTI 2022; e-Poster P-2-2

Ordering information

DaraEx - For Research Use Only

• Article number: 004 020 001 300 μL vial

DaraEx plus - CE-IVD

Article number: 004 020 004 300 μL vial

DaraPC: 0.5 mg/ml anti-CD38 antibody - For Research Use Only

• Article number: 004 020 005 450 μL vial