Instruction for use

ABO-trol® forte plus

FOR IN-VITRO-DIAGNOSTIC USE ONLY

30 bedside-test cards ready for use for verification of ABO-compatibility prior to blood transfusion. Pre-dropped fluid antisera with 70 µl of each monoclonal anti-A (mouse), anti-B (mouse) and anti-D (human) sufficient for one determination. The test cards are intended be used by qualified and technical personnel only.

Clone designation	**anti-A:**	**celline BIRMA-1**
	anti-B:	**celline LB-2**
	anti-D:	**celline RUM-1**

Manufacturer:
ANTITOXIN GmbH
Industriestrasse 88,
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ImuMed ANTITOXIN GmbH

CE 0483

Testsera anti-A and anti-B used for ABO-trol® forte plus are produced from monoclonal antibodies (mouse) that are distinguished by quick and strong reactions also with A-subgroups and immature A and B antigens. Used anti-D test serum is also a monoclonal antibody (human), but strong D-antigens only are detected within 1 minute in this technique.

Introduction

„Right before a transfusion the transfusing physician himself or under his direct supervision the ABO-identity test (bedside-test) has to be done with the recipient (e.g. with test card). The test serves to confirm the results for ABO-blood grouping antigens of the recipient obtained from previous tests. The ABO-identity test additionally can be carried out with the erythrocyte concentrate that should be transfused". (Literature: „Richtlinien zur Gewinnung und zur Anwendung von Blutprodukten (Hämotherapie)").

Product

ABO-trol® forte plus consists of a plastic card with 6 trough-shaped cavities acting as reaction chambers. Each of these chambers is filled with 70 µl of antiserum, blue coloured anti-A on the left, yellow coloured anti-B in the middle and uncoloured anti-D on the right. The reaction chambers filled with antisera are sealed with a transparent film. The chambers are intended for confirmation testing of patient erythrocytes and donor erythrocytes relating to ABO compatibility and D-antigen.

Performance of testing

For identity testing erythrocyte concentrate, native blood and blood with anticoaggulatives can be used.

1. **Collect blood from the patient**
2. **Penetrate the transparent film of chambers „anti-A" and add 1 single small drop of patient erythrocytes or donor erythrocytes free falling into these chambers.**
3. **As described under point 2 add 1 single small drop of patient erythrocytes or donor erythrocytes free falling into chambers "anti-B" and "anti-D".**
4. **Mix erythrocytes and antisera by gentle striking.**
5. **Check for agglutination (= positive reaction) after 1 minute. (Reactions with anti-A and anti-B are visible within 10 seconds).**

Interpretation

ABO compatibility is ascertained when blood group of determined patient erythrocytes is identical with blood group on label of the bag for transfusion.
The following schedule shows compatibility of ABO-different erythrocytes with poor plasma.

Anti-A	Anti-B	Compatible donor erythrocytes
pos.	neg.	A or O
neg.	pos.	B or O
pos.	pos.	AB, A, B or O
neg.	neg.	O

A different determination of blood group of patient erythrocytes by this agglutination method compared to the signalised blood group on the label of the bag for transfusion means that the blood group of the bag has no identity with the blood group of recipient.

For results of anti-D this is restricted valid only. A different picture of agglutination therefore special attention has to be taken to previous laboratory results.

Limitations of the procedure

False positive reactions may occur by:
Bacterial contamination of serum and/or of erythrocytes, Wharton'sche Sulze, antibodies diverted against colour ingredients or preservatives, medicinal therapy or pathological discrepancies, dextranes or other plasma expanders.
False negative results may occur by:
Drying up of test serum in reaction chambers or false concentration of erythrocytes.
Weaker D-antigens and D-categories, especially category D^{VI} are not detected.

Storage and stability

ABO-trol® forte plus is to be stored at + 2 to 8 °C. Under adequate storage the antisera keep their reactivity up to shelf life printed on the label.

Remarks

As preservative the testsera in ABO-trol® forte plus contain sodium azide (<1 g/l). Harmful if swallowed, avoid contact with skin and mucous membranes

Warning:

These reagents were not tested for murine viruses. Do not pipette with mouth.