Guidelines for the Blood Transfusion Services

12.10: Mandatory testing of blood donations

http://www.transfusionguidelines.org/red-book/chapter-12-donation-testing-red-cell-immunohaematology/12-10-mandatory-testing-of-blood-donations

12.10: Mandatory testing of blood donations

Blood groups shall be determined using reagents that comply with Chapter 11 of these guidelines.

All mandatory tests must be performed using an automated test system in the first instance (see section 12.13). Any persistent failures may be resolved using manual methods (see section 12.14).

12.10.1: ABO blood grouping

- The ABO blood group must be determined on each blood donation.
- For a donor whose ABO blood group is unknown to the test centre (e.g. a first-time donor), the ABO blood group must be determined by testing the plasma/serum with group A_1 and B red cells. The red cells of the donation must be tested twice with anti-A and anti-B as a minimum. The ABO group can only be accepted if the results are in agreement.
- If the security of sampling analysis and data transfer is assured, it is sufficient to test the red cells from previously tested donors with anti-A and anti-B once. There is no requirement to test the plasma. The ABO blood group shall be accepted only if the results are in agreement with those of previous tests.
- Where an anti-A which detects A_x is deployed in the testing of all donations, anti-A,B is not required.

12.10.2: Quality control of ABO blood grouping

- Quality control procedures recommended by reagent and equipment manufacturers should be followed.
- The following minimum test monitors are required for each batch of ABO blood grouping tests:
    - anti-A, anti-B (and anti-A,B where used) must give appropriate reactions with A_1, B and O cells. A_2 and A_2B cells may also be used; however, where CE-marked reagents, validated as per guidelines in section 11.2 are used, they are not mandatory
    - reagent red cell samples must give appropriate reactions with anti-A, anti-B (and anti-A,B where used).

12.10.3: D grouping

- The D blood group must be determined on each donation of blood.
- In the testing of donors being grouped for the first time, two anti-D blood grouping reagents should be used capable of detecting between them D^{IV}, D^{V} and D^{VI} antigens. If two monoclonal anti-Ds are used, they should be from different clones.
- Donors whose blood gives an unequivocal positive reaction with both anti-D reagents should be regarded as D positive.

- Donors whose blood is unequivocally negative with both anti-D reagents should be regarded as D negative.
- If the results with the anti-D reagents are discordant or equivocal, the tests should be repeated. Where the D group is in doubt it is safer to classify such donors as D positive.
- For known (repeat) donors one anti-D reagent, or blended reagent, that detects weak D, D^{IV}, D^{V} and D^{VI} can be used.

12.10.4: Quality control of D grouping

- Quality control procedures recommended by reagent and equipment manufacturers should be followed.
- The following minimum test monitors are required for each batch of D grouping tests:
  - each series of D blood grouping tests must obtain appropriate reactions with R_1r red cells as a positive and with r'r or rr red cells as a negative
  - appropriate reactivity with red cell samples expressing weak D should also be assured as a minimum during validation as indicated in section 11.2.

12.10.5: Antibody screening

Blood and blood components with antibodies of probable clinical significance may be released, as shown in Table 12.1.

12.10.5.1: Routine antibody screen

- All donations must be tested for the presence of red cell antibodies. This is achieved by testing the donor's serum or plasma using a validated technique capable of detecting anti-D at 0.5 IU/mL or lower.
- Reagent red cells for routine antibody screening (see 11.2.3.7) may be:
  - provided from a minimum of two individual donations (not pooled); or
  - as a pool of red cells in equal proportions from no more than two donations; or
  - red cells from a single donation.
- As a minimum the following antigens should be expressed: D, C, c, E, e and K.
- Each batch of tests must include a test monitor of <=0.5 IU/mL anti-D.
- Donations found to be reactive in the routine antibody screen should be further tested by an indirect antiglobulin test to determine the fate of the products as specified in Table 12.1.

12.10.5.2: Antibody screen for blood for neonates

- Blood for neonatal use must be screened and found negative for antibodies by an indirect antiglobulin test, performed using a two-cell panel expressing the following antigens as a minimum:
  - C, c, D, E, e, K, k, Fy^a, Fy^b, Jk^a, Jk^b, S, s and M.

Table 12.1 Minimum release criteria for blood products with antibodies of probable clinical significance

Component	Antibody screen for blood for neonates	Donation plasma sample diluted 1 in 10	Donation plasma sample diluted 1 in 50
For neonatal use	Negative	n/a	n/a
Red cells in SAGM	n/a	n/a	Negative

All other components	n/a	Negative	n/a