Change Notification UK National Blood Services No. 01 - 2017

Chapter 11 – Section 11.2.3.2


Please replace Section 11.2.3.2 “General guidelines for reagent red cell manufacture” with the following:

11.2.3.2: General guidelines for reagent red cell manufacture

- When testing reagent red cells, in order to confirm the presence or absence of antigens listed in the antigen profile, a sample from each individual should have the phenotype confirmed either by duplicate testing on this sample or by confirming a historical type by single testing on the current sample.

- Reagent red cells should be shown not to produce unwanted positive reactions by the methods recommended for use by the manufacturer.

- Except for IgG-sensitised and C3-sensitised red cells, reagent red cells should be negative in the direct anti-human globulin technique with anti-IgG, anti-complement and polyspecific anti-human globulin reagents.

- With the exception of umbilical cord blood, red cells used to test a patient’s samples for irregular antibodies should not be pooled.

- Reagent red cells should be processed by a method and suspended in a medium that consistently ensures stability of the antigens specified in the antigen profile included within the package insert.

- All red cell reagents should be free of ABH-specific blood group substances and blood group antibodies, including anti-A and anti-B, demonstrable by the manufacturer’s recommended methods of use.
• The method of manufacture should ensure that white cells are removed from donations of red cells before the white cells lyse and release enzymes, which may adversely affect the properties of the red cells.

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