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Implementation: To be determined by each Service

Change Notification UK National Blood Services No. 23 - 2009

Colour Coding of Reagents

Applies to the Guidelines for the Blood Transfusion Services in the United Kingdom – 7th Edition 2005

Existing guidelines (colour coding of reagents) prohibit the use of tinted antisera except for anti-A, anti-B and AHG. Bespoke antisera for use on Olympus (automated blood grouping) platforms exist and antisera other than anti-A and anti-B are coloured by the manufacturer (Diagast Laboratories, France). Adhering to the existing guidelines may result in Olympus users not being able to utilise bespoke antisera. These reagent bottles have the specificity and product and Lot specific details contained within a barcode so the operator (Olympus machine) is recording details from the label prior to each run.

CE Marking legislation and Food and Drug Administration regulations do not exclude the use of coloured antisera except if the colour affects the ability of the antiserum to react with the target antigen (implied generally in the *In Vitro Diagnostic Medical Device* Directive for CE marking of reagents and specifically in FDA requirements). There are no specific comments relating to coloured antisera in ISBT or WHO publications.

12.1.4 General manufacturing considerations

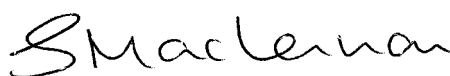
f) *Colour coding of reagents (page 151)*

No colouring agent should be added to reagents for blood group serology except that:


- Polyspecific anti-human globulin reagents may be coloured green, anti-A may be coloured blue, anti-B may be coloured yellow.
- The colourant should not interfere with the observation of the test result.
- ‘Bespoke’ antisera for use on automation may be coloured providing the information contained in the barcode on each bottle contains sufficient identifiers (specificity and lot number) to provide assurance that the intended test has been performed. The colours used for other specificities should not be coloured blue or yellow to avoid confusion with those for anti-A and anti-B reagents


Please add 3rd bullet:

Further information: The supporting paper, JPAC 09-43, Proposal to amend section 12.1.4 (f) colour coding of reagents in the Red Book, leading to this Change Notification can be found in the Document Library/Supporting Papers of the JPAC website:
<http://www.transfusionguidelines.org.uk/Index.aspx?Publication=DL&Section=12&pageid=7528>.



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