

Proposal to amend the content of 12.1.4 f) of the 2005 Guidelines.

This section (page 151) of the current Guidelines state that:

f) *Colour coding of reagents*

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.

These requirements are unchanged from the first edition. One of the reasons for not colour coding antisera is that operators should read the label rather than assume that a bottle of say purple coloured liquid is the required specificity. There is obviously a limit on the number of colours that could be used and apart from blue, yellow and green; no convention agreed that all manufacturers follow so an orange coloured antiserum may be anti-K or anti-Jka.

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 IVDD- *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.

There has been an increase in the use of automated blood grouping since the first Guidelines were published. Bespoke antisera for use on Olympus platforms exist and antisera other than anti-A and anti-B are coloured by the manufacturer (Diagast Laboratories, France). Each bottle has 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. It is desirable that the bespoke Olympus antisera are used on Olympus machines within the Blood Services but we would currently need a policy statement that conflicts with the Red Book to allow bespoke antisera to be used.

It is suggested that the wording is amended to include a third bullet point:

- '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.