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Implementation: To be determined by each Service

Change Notification UK National Blood Services No. 6 - 2010

Test reagents and test systems

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

Previous editions of the guidelines allowed (under controlled conditions) expired antisera to be used. The current wording could be interpreted as not allowing this and in response to specific concerns words need to be added to prevent a situation where a working example of a rare antibody cannot be used in investigations.


14.5 Test reagents and test systems

Please delete: 14.5.1 Where manufacturers define protocols for the preparation and storage of reagents and test kits these should be followed.

Replace with: 14.5.1. Where manufacturers define protocols for the preparation and storage of reagents and test kits these should be followed. In situations where the use of rare antisera is required then the use of such material post-expiry should be demonstrated as appropriate by the use of controls. Using rare antisera in this way must be approved and documented by Quality Assurance. The inability to obtain / unavailability of a replacement rare antiserum in time for the completion of the investigation must be clearly documented as part of the process.

Further information: The supporting paper, JPAC 10-17, Addition to 14.5.1 of the Red Book to allow rare antisera to be used in investigations (amended 19-03-10), leading to this Change Notification can be found in the Document Library/Supporting Papers of the JPAC website:

<http://www.transfusionsguidelines.org.uk/Index.aspx?Publication=DL&Section=12&pageid=7528>



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