Guidelines for the Blood Transfusion Services

9.1: General requirements

http://aws-lon-jpac.targetservers.uk/red-book/chapter-9-microbiology-tests-for-donors-and-donations-general-specifications-for-laboratory-test-procedures/9-1-general-requirements

9.1: General requirements

All screening must be performed within Blood Safety and Quality Regulations[1] (BSQR) compliant laboratories and meet any other appropriate regulatory requirements.

Secure and effective procedures must be in place to ensure that:

- all donations, any subsequent components/products and their laboratory samples are correctly identified by barcoded and eye-readable numbers
- donations can be linked to their donor
- information about previous test results which would preclude issue of a subsequent donation cannot be automatically overridden by a subsequent negative test result
- donor samples are suitably stored under appropriate conditions of temperature and time to preserve the targets for which they will be screened
- the screening assays used are properly evaluated and validated
- tests are appropriately performed and controlled, and the results properly and accurately recorded, using validated procedures
- test results and other relevant test information are retained for the appropriate period, as set out in the BSQR[1] and any other appropriate regulations
- appropriate confirmatory testing is available to investigate screen reactivity
- relevant data relating to screening and confirmatory test results are reported to a centralised surveillance system, allowing the monitoring of trends in screening test reactivity and confirmed positive results

9.1.1: Test reagents, kits and equipment

All assays used must be UKCA or CE marked and must have been assessed in respect of sensitivity and, if appropriate or necessary, specificity, and deemed suitable by the UK Blood and Tissue Establishments kit evaluation groups (NHSBT KEG or SNBTS MTEG) for the detection of the required markers in the donation types being screened. Unless specifically validated for alternative use/performance, test kits and reagents must be stored and used according to the manufacturer’s instructions.

Each new manufacturer’s lot of each assay must be assessed prior to being accepted and put into use (Lot Release Testing - LRT). Each additional delivery of an existing lot should be assessed before use (Delivery

Acceptance Testing - DAT). Each manufacturer’s batch/lot of microbiology test kits must be shown to conform with nationally established minimum criteria for specificity and sensitivity prior to being accepted for use for screening.

Additionally, all testing laboratories must ensure that the expected standard of performance of the assays used is being achieved through the use of the appropriate Quality Control (QC) samples and the statistical monitoring of assay control and QC sample results. Appropriate reactivity with manufacturers’ and QC samples must be demonstrated with every series of tests. All test procedures must be documented, and an inventory maintained of kits and reagents in stock, including supplier, batch number, expiry date, date of receipt, version number of product insert and record of pre-acceptance testing.

Procedures must ensure the traceability of the batch number and manufacturer of kits and reagents and the serial number of equipment used to test every donation.

Equipment must be validated, calibrated and maintained. Appropriate records for these activities must be made and retained as defined in extant regulations (currently 30 years).

A series/batch of tests is defined as the number of tests set up at the same time, under the same conditions and processed in a similar manner:

- Where the microplate format is used each plate constitutes a series of tests even if only a few wells are used.
- Where a closed system is used the size of a series/batch of tests must be determined by each individual Service through an appropriate risk assessment.

9.1.2: Recording and reporting of results

The laboratory final output should indicate the result of every test performed, using a system that provides positive sample identification. Each test result should be recorded by a system that does not require transcription. If manual completion of screening is performed it must be thoroughly documented and controlled and the results handled electronically following the same basic principles applied to fully automated testing.

9.1.3: Release of tested components/products

Standard procedures must ensure that no donations, or components/products prepared from them, can be released for issue until all the required laboratory tests (mandatory and additional) have been completed, documented and approved within a validated system of work. Compliance with this requirement can only be achieved by the use of a validated computerised system that requires the input of valid and acceptable test results for all the mandatory and required laboratory tests to permit the release of each individual donation.