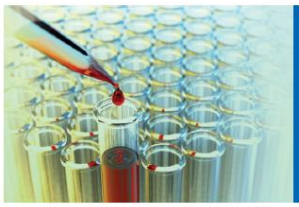

5

Microbiological Testing of Blood Donations

Chapter summary

- The mandatory infectious disease tests required for the release of blood and blood components are HBsAg, anti-HIV, anti-HCV, anti-syphilis, anti-HTLV, and NAT for HCV RNA, HIV RNA, and, for some countries, HBV DNA.
- Discretionary tests are performed for anti-CMV, anti-malaria, anti-Chagas (T. cruzi), and anti-HBc.
- All tests are performed on individual donations. In some countries testing by NAT and for anti-HTLV may be conducted on pools of 24 samples (or less) particularly where the prevalence of the viral agent is low.

- The tests are performed on automated systems using ISBT 128 barcoded samples and the results are uploaded to the host computer online to reduce transcription errors.
- Tests for syphilis are either performed on a Beckman Coulter blood testing analyser by TPHA or TPPA, or by ELISA.
- All other serological tests are performed on automated systems using ELISA or chemiluminescent methods.
- In the UK, NAT is performed on the Roche cobas s201 using a multiplex assay for HBV DNA and HCV, and HIV RNA.
- All reagents used are subjected to batch pre-acceptance testing to ensure that they meet minimum standards of quality.
- External or in-house controls should be included in each batch of tests.
- Any donation which is serologically reactive (initial reactive) is retested in duplicate on the same system and same manufacturer assay. If both duplicate tests are negative, the donation and all components can be released for transfusion. Otherwise, all components from that donation must be discarded and a sample referred to a reference centre for confirmatory testing.
- Donors who are confirmed by the reference centre as microbiology positive for any marker must be removed from the donor panel. Donors must be notified as a preventative health measure.
- The commonest microbiological risk to the blood supply is bacterial contamination. Some blood transfusion centres test platelet components for these using automated culture systems.
- Testing for West Nile virus is not a requirement for blood collected in the UK, but plasma products imported from the USA must be negative WNV NAT.
- Variant CJD is a threat to the UK blood supply and leucodepletion has been introduced as a precaution to reduce transfusion transmission. Also, donors who have two or more members in the family with familial CJD or were transfused since 1 January 1980 cannot donate. A test is not currently available and CE-marked prion reduction filters for RBCs are under evaluation.