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LOT RELEASE OF MICROBIOLOGY BLOOD SCREENING KITS AND HCV NAT IN THE ENGLISH NATIONAL BLOOD SERVICE

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**Introduction:** As a requirement of the English NBS quality system, all manufacturer's lots of blood screening microbiology serology kits are formally assessed for their suitability for use prior to delivery to the testing sites. A similar system has recently been developed for the HCV NAT.

**Objective:** The NTMRL was tasked with developing a national lot release testing (LRT) system to replace the long-standing statistical batch pre-acceptance testing system for the microbiology serology kits. Subsequently an initial system has been developed and is being trailed to monitor the HCV NAT. Purpose built panels or individual samples are utilised to enable objective assessment of individual assay performance. The sensitivity of each panel/sample is set at that deemed acceptable when each assay was first evaluated for use for blood screening within the NBS.

**Materials and Methods:** LRT panels were built from selected, characterised samples that give known and consistent results. Panel members were prepared, aliquoted in 'single use' volumes and stored at -850C. For the serology kits one kit from each manufacturer's kit lot to be supplied to the NBS is sent to NTMRL for testing prior to delivery to any testing sites. The results are compared to those expected. NTMRL authorise the release of lots and, the kits are then delivered as required to the testing sites. Limited delivery acceptance testing (DAT) is still performed at each site. Any problems are referred to NTMRL for investigation and authorisation after comparison with the original LRT data. For the HCV NAT system the LRT samples are transported to the testing sites, the testing performed at the site and the results finally reviewed and authorised by NTMRL.

**Results:** LRT of serological microbiology blood screening kits started on 01/10/02, and HCV NAT on 01/03/06. As of the 17/02/06 438 manufacturer's kit lots of serological kits have been tested with one identified problem.

**Conclusion:** The LRT system provides an objective and scientifically valid approach to the assessment and monitoring of the performance of new lots of test kits.