

NRL Approach to Validation of Assay Modifications

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Use of the test kits for viral screening of samples collected from blood and tissue donors is subject to various regulations. These include the Therapeutic Goods Act, which requires registration of test kits for HIV and HCV on the Australian Register of Therapeutic Goods (ARTG) and the Australian code of Good Manufacturing Practice – Human Blood and Tissues. The regulations require that the test kits are used exactly as the manufacturer intended; otherwise changes must be validated by the user.

The Roche Cobas AmpliScreen HIV-1 and HCV Tests are registered on the ARTG for screening samples collected from living and deceased blood or tissue donors for the presence of HIV-1 and / or HCV nucleic acid. The test kit manufacturer is specific about the types of sample that are validated for use, their collection and storage conditions. Practically, many donor samples that require screening do not comply with the specifications set out by the manufacturer.

The National Serology Reference Laboratory, Australia (NRL) conducts Roche Ampliscreen testing on behalf of several tissue banks in Australia. The samples tested do not always comply with the requirements of the test kit manufacturer's instructions. The NRL has developed protocols that are designed to validate the testing of samples that have been collected or stored differently from manufacturer's specifications. These protocols are currently under review by the TGA.