

## S33-4 **Viral safety of biologicals: Evaluation of HCV NAT assay and development of concentration method of HCV for sensitive detection by NAT**

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The most important issue for the safety of biological products and blood products derived from human sources is how to prevent transmission of infectious agents. The hepatitis C virus (HCV) is a major public health problem due to its high prevalence. HCV is mainly transmitted by exposure to blood and highly infectious during the early/window period with extremely low viral loads. Therefore, it is important to develop more sensitive detection method for HCV. In the case of blood products, both serological test and nucleic acid amplification test (NAT) are required to prevent infection of HCV. Since the HCV NAT is highly sensitive, establishment of new standard is required to evaluate NAT. Establishment of the standard for HCV RNA and HCV panel for evaluation of HCV NAT assay will be presented in this symposium. On the other hand, we have developed a novel viral concentration method using polyethyleneimine (PEI)-conjugated magnetic beads (PEI beads). PEI beads concentration method is useful for sensitive detection of HCV by NAT, and applicable to a wide range of viruses including HCV. Studies using the standard for HCV RNA, HCV genotype panel and seroconversion panel suggested that virus concentration method using PEI beads is useful for HCV screening of blood samples. We will report the concentration and sensitive detection method of HCV from the perspective of the viral safety of biologicals.