

## The history of Standardisation of Genome Amplification Techniques (SoGAT)

In 1994 the European Plasma Fractionation Association (EPFA) and NIBSC held a workshop to discuss applications of nucleic acid amplification techniques in the detection of blood borne viruses in blood donation screening. It was recognised that the future importance of PCR warranted the formation of a group dedicated to standardisation of NAT for the detection of blood borne viruses.

The first meeting of the International Working Group on the Standardisation of Genomic Amplification Techniques (SoGAT) for the virological safety testing of Plasma and Blood derived Products took place in April 1995.

The rapid development of commercial assays for NAT and the appreciation of the scope of this new technology by many diagnostic and research laboratories, led to a decision that there was a need for reference materials for blood borne viruses.

Over the last 20 years the group has played a primary role in the standardisation of blood virology; this has been achieved by facilitating the provision of working reagents and international standards for HIV-1/2 RNA, HBV DNA, HCV RNA and B19.

Using the experience and knowledge gained by the SoGAT group focusing on blood virology, a new SoGAT group was formed in 2008 to address the area of clinical virology, which remains largely unstandardised.

The areas of blood virology and clinical diagnostics historically conducted separate meetings; however the topic of standardisation has common thread which runs through both clinical diagnostics and blood virology. The meetings were merged in 2012.

Participation is encouraged from transfusion laboratories, plasma manufactures, clinical laboratories, manufacturers of diagnostic assays and quality control reagents, providers of external quality assessment schemes and regulatory and public health authorities.

