

## HCV-RNA SCREENING IN SWISS BLOOD DONORS IS REDUNDANT TO ESTABLISHED SURROGATE MARKER TESTING

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**Introduction:** In 1992, antibody testing (ELISA) for Hepatitis C (HCV) of blood donors (BD) was introduced. However, even applying 3<sup>rd</sup>/4<sup>th</sup> generation of ELISA tests, the ELISA neg. period following infection (window period, WP) remained 60 – 80 days. Additionally, based on nucleic acid testing (NAT) of German plasma donors, the incidence of potentially infectious individuals in WP was estimated to 1: 50'000 - 1: 120'000 (PEI, 25.2.98). Therefore, the Swiss Red Cross (SRK) introduced routine NAT testing for HCV of all Swiss BDs by 1.5.99. Here, we present the complete data set of NAT testing of donations taken by the Zürcher Blutspendedienst SRK (ZHBSD) between 1.5.99 and 28.2.02. **Material and Methods:** NAT testing was performed by HCV-RT-PCR (Cobas Amplicor v2.0, Roche) applying minipool technique and donor stratification (group A: first time donor, group B: repeat time donor, group C: platelet apheresis donor). Ref: B.M. Frey et al, 68.Jahresv. SGH/SGIM, Zürich, 2000. Standard surrogate marker testing SSMT (anti-HCV-ELISA, ALAT, RIBA, Western Blot (WB)) was performed using commercially available kits and according to the manufacturer's recommendations. **Results:** 188'994 donations (A: 12.2%, B: 78.1%, C: 9.7%) were tested for HCV in parallel by NAT and SSMT. 27/161 (16.8%) of ELISA pos. donations were found pos. by HCV-PCR. 134/161 (83.2%) of donations were found pos. by ELISA only. There was no NAT-only pos. donation (WP donation). The prevalence of NAT pos. minipools of the donor groups A,B and C were 1.25%, 0.50% and 0.08%, resp. Of 37 WB pos. donations, only 27 (73%) were pos. in NAT testing. The HCV specific antibody signals of WB (anti-c22, anti-c33, anti-c100, anti-NS5) showed similar probability (62% - 73%) to yield a pos. HCV-PCR reaction in the same serum sample. In PCR pos. donations, the signal strength of all anti-HCV specific bands of WB was chiefly 4+, while in PCR neg. donations the signal strength of HCV specific bands spread evenly between 1+ to 4+. Similarly, 50% of WB and PCR pos. donations showed simultaneously elevated ALAT, while WB pos. donations with neg. PCR revealed elevated ALAT in only 12% of cases. **Conclusions:** 1.HCV-NAT testing of Swiss BDs is redundant to established HCV-SSMT. 2.The incidence of HCV window donations by Swiss BDs is lower than initially expected. 3.Despite HCV-NAT testing, HCV screening by SSMT is indispensable. 4.Blunted surrogate marker activity in PCR negative individuals may indicate HCV virus elimination