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LOOK BACK STUDIES OF ANTI-HCV NEGATIVE/ HCV RNA POSITIVE BLOOD DONORS IDENTIFIED LOW VIREMIC DONATION NOT DETECTED BY MINI-POOL NAT

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Background

HCV RNA screening in pools of 48 donations by Cobas Ampliscreen HCV was introduced in Poland in 2000, and in 2003 in some Blood Centres this system was replaced by single donation testing for HIV and HCV by CHIRON TMA HIV1/HCV. Among 3.69 million donations tested between March 2000 and December 2004, 52 were HCV RNA positive/anti-HCV negative (frequency of window period donors 1: 71 000). Forty nine donors were detected by mini-pool testing and 3 by single donation testing. Thirty seven individuals were repeat donors. Their look back samples (if available) were individually tested for HCV RNA in the Reference Lab. If the result was positive the recipients of blood components were informed and tested for viral markers. The aim of the study is to present the results of look back studies of HCV RNA mini-pool positive/anti-HCV negative blood donors. Methods: NAT screening at Regional Blood Transfusion Centers: Mini-pools prepared with Genesis Robotic Sample Processor 200 (Tecan, Switzerland) were tested for HCV RNA by Cobas Ampliscreen HCV (Roche Diag). Reference Lab: Look back samples

were tested individually by the same method, level of HCV RNA by Cobas Amplicor Monitor (Roche Diag) and HCV genotype by InnoLipa HCV (Innogenetics)

Results

Twenty four HCV RNA (+)/anti-HCV(-) repeat donors were previously tested in routine HCV RNA in mini-pools and were negative. Twenty available look back samples were individually tested for HCV RNA and in one the virus was detected. To make sure that the failure of HCV RNA detection in routine NAT was not due to the pooling procedure, the HCV RNA was tested in undiluted look back sample and dilutions of this sample by HCV negative plasma: 2/2 repeats of 48x dilution and 2/2 repeats of 24x dilution were HCV RNA negative, whereas 1/1 repeat of 8x dilution and 2/2 repeats of undiluted sample were positive. The results of Cobas Amplicor Monitor (sensitivity 600 IU/ml) were negative, which means that viremia in HCV RNA mini-pool negative donation was below 600 IU/ml. In the recipient of red blood cell concentrate from this donation hepatitis C was diagnosed. However, the possibility of pretransfusion HCV infection cannot be excluded as no HCV marker tests were performed before transfusion. The patient and the donor were infected with genotype 3a.

Conclusions

The low HCV viremia (below 600 IU/ml) in the pre-seroconversion window period was responsible for no HCV RNA detection in routine mini-pool HCV RNA testing.