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INITIAL RESULTS FROM HIV-1 AND HCV NAT SCREENING OF BLOOD DONORS WITH THE CHIRON PROCLEIX® ASSAY AT THE KOREAN RED CROSS

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Background

The Korean Red Cross (KRC) collects ~ 2.1 million units of blood annually, 80% of which comes from repeat volunteer donors. The HCV and HIV seroprevalence in our donors is 0.08% and 0.21, respectively. To increase blood safety, the KRC implemented nucleic acid testing (NAT) for HCV and HIV-1 on February 1, 2005. The Jungbu Blood Test Laboratory (JBL) screens ~ 700,000 donations annually, or 30% of all donations, using the Chiron Procleix® Assay (Chiron Corp. Emeryville CA US). Two other institutes test the remaining 70% by the Roche AmpliScreen Assay (Roche Molecular Systems, Brandenburg NJ US).

Methods

Between February 1 and June 30, 2005, JBL screened 286,060 donor samples using the Procleix Assay. Initially reactive samples were tested in the HIV-1 and HCV discriminatory assays to identify the reactive viral nucleic acid. All samples were previously screened by enzyme immunoassay at 3 regional centers, using Genedia HIV Ag- Ab (Green Cross,

Yong-in, Korea) for anti-HIV and Abbott Murex 4.0 (Abbott, Kyalami, South Africa) (2 centers) and LG HCD 3.0 TMB (LG, Ik-san, Korea) (1 center) for anti-HCV.

Results

Of the 286,060 samples screened, 163(0.06%) and 858(0.3%) were serologically reactive for HIV and HCV, respectively. All samples that were reactive by the Procleix Assay were also reactive by the Discriminatory assay. Of the 286,060, 31 (0.01%) were confirmed NAT reactive (25 for HCV and 6 for HIV). Three of these 31 were seronegative/ NAT only positive (NAT yield), 2 for HCV and 1 for HIV-1. The distribution of serology-reactive and confirmed NAT reactive samples is shown in the following table:

% of 286,060 (n/286,060 x100)	HIV-1	HCV	Combined Total %
% total seroreactive	0.06 (n=163)	0.30 (n=858)	0.36 (n=1021)
% total seroreactive/ NAT non-reactive	0.05 (n=157)	0.29 (n=833)	0.35 (n=990)
% total NAT reactive	0.002 (n=6)	0.009 (n=25)	0.011 (n=31)
% total NAT reactive/sero-nonreactive	0.0003 (n=1)	0.0007 (n=2)	0.001 (n=3)

Of the 31 NAT reactive donations, 18 were from first time donors, but all NAT yield cases were from repeat donors. Follow-up samples from the 2 HCV NAT yield donors obtained 22 and 31 days, respectively after the index donation showed HCV antibody seroconversion. All HCV reactive donations were confirmed with an alternative NAT. Follow-up of HIV reactive donors is conducted by the government.

Conclusions

Our combined NAT yield of 0.001% for HIV-1 and HCV is much higher than that observed in the U.S.(0.0005%), but lower than that recently reported in India (0.01%). NAT screening should help increase the safety of our blood supply.

