CPAL

Central **P**ennsylvania **A**lliance **L**aboratory

Technical Bulletin

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HIV/HCV NAT Testing For Screening Blood Donations

Background

On June 1, 2004, CPAL will start NAT (nucleic acid-based test) testing of HIV-1 and HCV RNA in human plasma from donations of whole blood and blood components for transfusion. NAT testing can detect viremic units donated by carriers who do not seroconvert or who lack antibodies to serological markers normally detected by immunological assays. NAT testing will reduce the residual transmission risk by detecting HIV-1 RNA and HCV RNA in donations made during the seroconversion window period.

Method validation and verification:

CPAL has implemented the Roche COBAS AmpliScreen HIV-1 Test v1.5 and Roche COBAS AmpliScreen HCV Test v2.0 for screening HIV-1 and HCV in blood donations. CPAL has successfully completed Roche's proficiency panel validation for standard pools and short-run samples. The method was further validated by testing 96 blinded plasma samples from one of the Blood Centers. All of the results of the 96 samples for both HIV-1 and HCV obtained at CPAL agreed with those obtained by another NAT testing method.

The tests will be performed in a mini-pool format along with automated PCR amplification and detection. Initially, a primary pool of 24 samples will be generated and tested. Then, positive pool(s) will be resolved in 4 secondary pools of six. If a secondary pool turns out positive, all six samples of the pool will be tested individually.

Specimen collection and handling:

Collect 7 mL of blood in an EDTA tube for NAT testing. Other anticoagulants such as CPD, CPDA-1, CP2D, ACD-A and 4% Sodium Citrate are also acceptable. Blood collected in EDTA may be stored at 2-30°C for up to 72 hours from time of draw, followed by an additional two days at 2-8°C. For storage longer than five days, remove the plasma from the red blood cells. Following removal, plasma may be stored at 2-8°C for an additional seven days. Alternatively, plasma may be stored at ≤-18°C for up to one month.

In order to minimize the turn around time, we may need to pool similar specimens. Therefore, we are suggesting the following color codes for labeling different specimens:

Yellow dot for platelet pheresis donors

Red dot for autologous donors that need transferred to another institution.

Blue dot for first time donors

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For question about this, and other, information, call Central Pennsylvania Laboratory at 1-888-480-1422

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