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

Technical Bulletin
No. 73

May 19, 2009

cobas® TaqScreen MPX Test (Blood Donor Testing)

Contact:
Dr. Jeffrey Wisotzkey, 717-851-1422
Technical Director

J. Matthew Groeller, MPA(HCM), MT(ASCP), 717-851-4516
Operations Manager, Infectious Disease Testing

Sue E Flowers, MT(ASCP), 717-851-4517
QA Coordinator

Effective Date:
May 11, 2009

Specimen:
EDTA Plasma

Mnemonics:
DON ACH, DON AIH, DON HBV and DON MPX

Summary:
On May 11, 2009 CPAL converted to the Roche Molecular Systems, Inc. *cobas®* *TaqScreen MPX Test*. This assay is a multiplex PCR/Taqman assay that replaces the HIV and HCV Nucleic Acid Amplification (NAT) blood donor screening tests. The MPX assay is a qualitative in vitro test for the direct detection of Human Immunodeficiency Virus Type 1 (HIV-1) Group M RNA, HIV-1 Group O RNA, Human Immunodeficiency Virus Type 2 (HIV-2) RNA, Hepatitis C Virus (HCV) RNA and Hepatitis B Virus (HBV) DNA in human plasma. This test is intended for use to screen donor samples for HIV-1 Group M RNA, HCV RNA, & HBV DNA in plasma specimens from individual human donors, including donors of whole blood and blood components.

This test detects HIV-1 Group O RNA in specimens that are positive for anti-HIV-1 Group O antibodies and HIV-2 RNA in specimens that are positive for anti-HIV-2 antibodies. However, detection of HIV-1 Group O RNA or HIV-2 RNA in specimens negative for anti-HIV-1 Group O antibodies or anti-HIV-2 antibodies, respectively, has not been demonstrated.

Testing is completed in pools of six donors. Positive pools are subjected to resolution testing to identify individual units that require subsequent testing.

Results are reported as follows: If the MPX test is negative, the DON ACH, DON AIH and DON HBV will be resulted as negative. If the MPX test is positive or unresolved, DON MPX will be added and resulted as positive or unresolved. The sample will be sent for viral resolution testing and DON ACH, DON AIH and DON HBV will remain pending until resolution testing is completed. These three tests will then be resulted with a footnote stating the name of the reference testing laboratory.

Notes:

1. Due to the nature of this testing, including the fact that resolution testing does not include testing for HIV-1 group O or HIV-2, there is a possibility that all three resolution results will remain negative once the viral resolution testing is completed.

2. Detection of the HIV-1 Group M and O RNA, HIV-2 RNA, HCV RNA, & HBV DNA is dependent on the number of virus particles present in the specimen and may be affected by specimen collection methods, patient factors, and/or stage of infection and pool size.

3. Though rare, mutations within the highly conserved regions of a viral genome covered by the cobas TaqScreen MPX Test primers and/or probe may result in failure to detect a virus.

4. These studies were conducted in a population where HIV-1 Group O and HIV-2 yield cases would not be expected to be detected. The ability of the cobas TaqScreen MPX test to detect window period cases for HIV-1 Group O and HIV-2 has not been evaluated.

5. This test is not intended for use as an aid in diagnosis of infection with HIV, HCV, or HBV.