



Commit for Life.

**TO: Medical Director
 Blood Bank Managers
 Blood Bank Supervisors
 Laboratory Directors**

**FROM: Susan N. Rossmann, M.D., Ph.D.
 Chief Medical Officer**

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 Chief Technical Officer**

DATE: June 2, 2009

SUBJECT: Announcing Changes in Nucleic Acid Testing

Improvements in nucleic acid testing (NAT) continue to reduce the risk of the transmission of infectious diseases through blood transfusion which; in turn, provides safer blood components for patients. We are pleased to announce that we will soon be implementing an automated NAT triplex testing system which allows us to test for the detection of the Hepatitis B Virus.

Currently, we perform testing for Hepatitis B surface antigen (HBsAg) and for the antibody to Hepatitis B core antigen (HBc). Detection of actual Hepatitis B virus (HBV) by NAT is expected to reduce the rate of transmission of hepatitis B. We rarely receive reports of transfusion-transmitted Hepatitis B, but mathematical calculations show it is one of the higher infectious risks of transmission today. While we know from clinical trials that this test can effectively detect donors with HBV viremia, not all of these donors have clinical disease and we are not sure how many of these units will transmit hepatitis. FDA guidance on HBV NAT is expected to be forthcoming.

In addition to HBV, HCV and HIV-1, the implementation of the cobas® TaqScreen MPX Test will allow us to detect HIV-1 Group M RNA, HIV-1 Group O RNA and HIV-2 RNA in human plasma. The MPX test will be performed using a 6 member pool. The results of the test will be reported as a single result either positive or negative. Each member of a positive pool will be tested individually to select the positive member(s). Once this phase of resolution testing is completed, viral resolution testing (VRT) will be performed to determine the specific virus present. VRT involves testing a positive sample individually on the Cobas Ampliscreen for NAT HIV-1, HCV and HBV. The results of a VRT panel are considered confirmatory and will be formatted in a data file similar to other confirmation results. We are pleased to report that there will be no fee changes made in 2009 to offset these testing improvements.

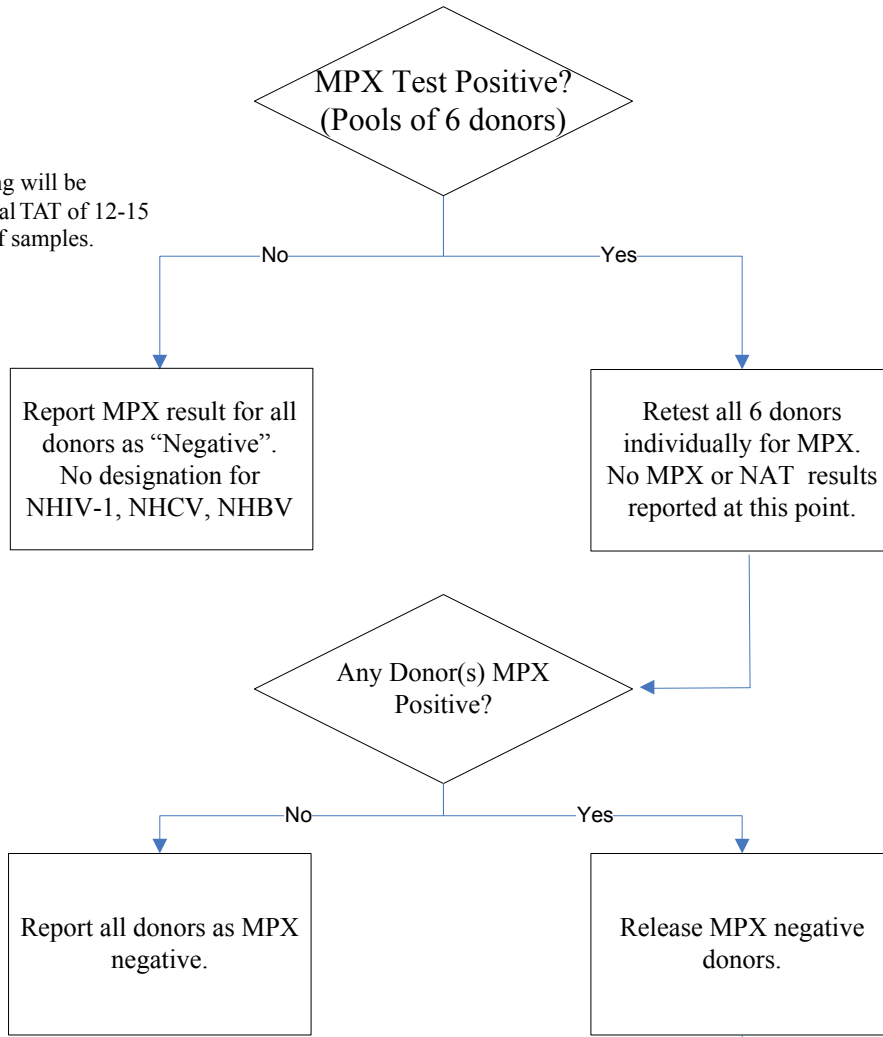
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Changes in Nucleic Acid Testing

Although, implementation of the MPX test is still several months away, we wanted to let you know our plans. We understand that you will need to work with your blood bank information systems to prepare for the changes in the reporting of NAT results for your donors. As the time approaches, we will be providing additional information on the reporting format and test designations.

A flowchart describing the testing logic is attached. As questions arise, please do not hesitate to contact Cheri Jennings, 713-791-6316, cjennings@giveblood.org.

Your Lab
 Testing Flow Chart
 cobas® TaqScreen MPX Test
 NAT HIV-1 Group M, HIV-1 Group O,
 HIV-2, HCV, HBV on the cobas s201 System.

NOTE:
 This portion of testing will be
 Completed within our normal TAT of 12-15
 hours after receipt of samples.



NOTE:
 Viral resolution testing
 will be performed
 2-3 times weekly

