U.S. Food and Drug Administration

FDA News

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FDA Approves First Nucleic Acid Test to Screen for Additional Types of HIV in Donated Blood and Tissue

The U.S. Food and Drug Administration today approved the cobas TaqScreen MPX Test, the first nucleic acid test that screens for the presence of two divergent types of HIV in donated blood plasma and tissue.

"With the MPX test, blood donor testing laboratories will be able to use nucleic acid technology to screen for additional HIV strains, further assuring that donated blood and tissue are free from infection and providing better protection for patients," said Jesse L. Goodman, M.D., M.P.H., director of the FDA's Center for Biologics Evaluation and Research.

Nucleic acid is the common name for the large chemical compounds that make up the genetic material in living cells. The new FDA-approved test detects nucleic acid from HIV-2 and from HIV-1 Group O. HIV-2 infections and HIV-1 Group O infections are predominantly found on the African continent. Some cases of infection with these two types of viruses have also been detected in the United States.

In addition to HIV-2 and HIV-1 Group O, the MPX test simultaneously detects nucleic acid from the most common form of HIV, HIV-1 Group M, as well as the Hepatitis C Virus and the Hepatitis B Virus.

The MPX test is designed for use with plasma specimens from human donors of whole blood and blood components, but not for testing donated source plasma. Donated source plasma is considered plasma intended for further manufacturing.

The test is also intended for screening tissue specimens obtained while the donor's heart is still beating; it is not intended for use on specimens from donors whose heart no longer functions.

The cobas TaqScreen MPX Test runs on the fully-automated cobas s 201 System. It is manufactured by Roche Molecular Systems Inc., Pleasanton, Calif.

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