FDA approves rapid diagnostic test for HIV antigen, antibodies

9 August 2013

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(HealthDay)—The first rapid test to detect the HIV-1 antigen, as well as blood antibodies for the HIV-1 and HIV-2 strains, has been approved by the U.S. Food and Drug Administration.

The Alere Determine HIV-1/2 Ag/Ab Combo test can detect these markers for the virus in human serum, plasma, and blood specimens, the agency said in a news release.

Detection of the HIV-1 antigen may allow doctors to diagnose the viral infection earlier than detection of the antibodies alone, the FDA said.

Some 50,000 people are infected with HIV each year in the United States, the agency said, citing statistics from the U.S. Centers for Disease Control and Prevention. Of the more than one million people living with HIV in the United States, about 20 percent haven't been diagnosed, the FDA added.

The new test is produced by Orgenics Ltd., whose parent, Alere Inc., is based in Yavne, Israel.

More information: More Information