New Rapid Test for Acute HIV Is Now Available

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A new rapid test that can detect both HIV-1 and HIV-2 antibodies as well as a key antigen that indicates a recent infection with HIV-1 is now available for use in health care settings. The U.S. Food and Drug Administration approved the test, called the Alere Determine HIV-1/2 Ag/Ab Combo assay, in August. After taking blood from a finger prick, the test produces results in 20 minutes and has an accuracy exceeding 99 percent.

“We’re excited to announce the availability of the only fourth generation rapid test that can identify HIV infections in individuals earlier than ever before at the point of care by detecting the free HIV-1 p24 antigen,” Joe Medeiros, an Alere spokesperson, said in a release. “The availability of the Alere Determine Combo test will contribute measurably to public health by helping HIV-positive individuals to become aware of their HIV status earlier, thereby potentially reducing HIV transmission. Earlier diagnosis can also allow effective treatment to be started without delay.”

The test is now available to all health care facilities and labs that have a license to conduct tests of “moderate complexity” through the U.S. Centers for Medicare and Medicaid Services’ Clinical Laboratory Improvement Amendments program. Pending the results of ongoing ease of use, safety and accuracy studies of the test, Alere intends to submit an application by the year’s end to the FDA for a CLIA waiver so that the test can be used more widely in both doctor’s offices and other outreach settings.

To read a release on the new test, click here.

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http://beta.docker.poz.com/article/Alere-available-24693-6720