FDA OKs First Rapid Test for Acute HIV

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The U.S. Food and Drug Administration (FDA) has announced its approval of the first rapid HIV test that can, with a finger prick, detect both HIV-1 and HIV-2 antibodies as well as a key antigen that indicates a recent infection with HIV-1. Results take just 20 minutes and have an accuracy of greater than 99 percent.

“It’s going to be a game changer for prevention,” says Cynthia Tucker, director of prevention and community partnerships at AIDS Foundation of Chicago (AFC), “because it will allow us to tell individuals at an earlier time that they’re HIV positive.” She says AFC is eager to adopt the test when it becomes available.

Because the HIV-1 p24 antigen appears 12 to 26 days after infection, which on average is five to seven days earlier than HIV antibodies, the Alere Determine HIV-1/2 Ag/Ab Combo assay can accurately diagnose certain early cases of HIV that would otherwise produce a false negative result with a standard antibody test. Thus, testing with Alere will narrow the notorious “window period,” which calls into question a test’s accuracy when someone has had recent potential exposures to HIV. The antigen test can also detect an acute, or very recent, infection.

With minimal training, outreach workers can use the easily portable test among populations who might not have access to testing in a traditional health care environment.