POC HIV 1/2 rapid test, 2/13:111

Chembio Diagnostics has received FDA approval to market its point-of-care Dual Path Platform (DPP) HIV 1/2 assay for the rapid detection of HIV-1/2 antibodies in oral fluid or blood samples.

DPP enables samples to bind directly with target analytes before detection reagents are introduced to visualize the test results. It detects antibodies to HIV-1/2 in oral fluid, fingerstick whole blood, venous whole blood, serum, or plasma samples and provides a simple “reactive/ nonreactive” result.

In a multisite study of about 2,800 patients across five clinical settings, including a pediatric hospital, the diagnostic sensitivity of the assay to detect HIV infection was 99.8 percent for fingerstick samples; 99.9 percent for venous whole blood, serum, and plasma samples; and 98.9 percent for oral fluid samples. The specificity of the assay was 100 percent for fingerstick specimens and 99.9 percent for oral fluid, venous whole blood, plasma, and serum samples.

The test is intended to be used in the preliminary diagnosis of patients with HIV in point-of-care settings such as public health and other clinics, hospital emergency rooms, and physician offices. DPP HIV 1/2 is approved to detect HIV in patients two years old and older. It provides visual results within 15 minutes.

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