

Chembio files for CLIA waiver, 2/14

written by CAP TODAY
February 18, 2014

February 2014—Chembio Diagnostics, a provider of point-of-care diagnostic tests for infectious diseases, has filed a CLIA waiver application with the FDA for its DPP HIV 1/2 Assay.

In support of the application, Chembio sponsored studies at multiple sites evaluating the accuracy and simplicity of the assay. DPP HIV 1/2 is a rapid point-of-care assay for the detection of HIV 1/2 antibodies in either oral fluid or blood samples. Approximately 1,100 individuals infected with HIV, or at risk for infection with HIV, participated in the studies, which included testing on oral fluid, fingerstick whole blood, and venous whole blood samples from each patient.

A CLIA waiver will allow Chembio to make the test available to U.S. customers in outreach clinics, community-based organizations, and physicians' offices.

[Chembio Diagnostics](#), 631-924-1135



©2026 CAP TODAY, all rights reserved.