CLIA waiver studies for HIV 1/2 assay, 7/13:106

Chembio Diagnostics has commenced CLIA waiver studies for its DPP HIV 1/2 assay. In December 2012, Chembio received FDA approval for its DPP HIV 1/2 assay, which detects antibodies to HIV 1/2 in oral fluid, fingerstick whole blood, venous whole blood, serum, or plasma samples.

The CLIA waiver studies are required by the FDA to establish the quality standards for laboratory testing, which ensures the accuracy, reliability, and timeliness of patient test results regardless of where the tests are performed.

Chembio's multi-site CLIA clinical study will test oral fluid, fingerstick blood, and venous whole blood samples prospectively collected from about 1,000 subjects who are HIV positive and of unknown HIV status. It is expected that the study will be complete within three to four months. Upon completion of the required enrollment of subjects, Chembio will submit the conclusions from the study as a CLIA waiver application to the FDA.

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