Feasibility and Performance of SD BIOLINE Dual HIV/Syphilis Point-of-Care Test Based Screening Strategy in Ethiopia

Authors; *Yimam Getaneh*[1], TesfayeTilahun[2], Seble Girma[3], Mulu Gima[3], Yemane Abreha[3]

Correspondence; Yimam Getaneh, Ethiopian Public Health Institute, HIV and TB Research Directorate, Addis Ababa, Ethiopia, P.O.Box 1242, Email: yimamgetaneh@gmail.com

Abstract

Background: Diagnostic tests are needed for the control of sexually transmitted infections. Rapid advances in molecular biology have led to the development of sensitive and specific diagnostic tests. Immunochromatographic test for dual diagnosis of both HIV and syphilis by detecting IgG/IgM antibodies to HIV and recombinant Treponema pallidum antigens to syphilis testing has recently been developed as a novel point-of-care testing technology. New diagnostics tests must be evaluated in the situations in which they will be deployed. However, this product has yet not been evaluated in pregnant mothers in Ethiopia.

Method: A total of 1,888 characterized repository plasma samples, previously collected from pregnant mothers were used. HIV ELISA Ag-Ab test (Vironostica) as a screening and Bio-Meurex as a confirmatory were used as gold standards for evaluation of HIV, ELISA (Trepanostica-TPPA) recombinant were also used as a gold standard for syphilis testing. The samples were assayed for the presence of antibodies to HIV and *T. Pallidum* by the SD Bioline HIV/syphilis Duo. Moreover, the samples were characterized using SPINREACT RPR kit for syphilis.

Result: The sensitivity and specificity of SD Bioline HIV/syphilis Duo in HIV testing were 97.6% and 100%. The sensitivity and specificity of SD Bioline HIV/syphilis Duo in detecting syphilis were 95.2% and 97%. Moreover, the kappa value for SD Bioline HIV/syphilis Duo had 0.99 and 0.616 in HIV and syphilis testing respectively. Inter reader variability of SD Bioline HIV/syphilis Duo was greater than 3%.

Concussion: SD Bioline HIV/syphilis Duo was found to be highly specific but with limited sensitivity in detecting both HIV and syphilis. It can also be performed in clinics without laboratory training and require no equipment or refrigeration. SD Bioline HIV/syphilis Duo compared favorably with TPPA and ELISA. SD Bioline HIV/syphilis Duo can be used for simultaneous screening of HIV and syphilis at antenatal care settings in Ethiopia.

Key words: Sensitivity, Specificity, Positive Predictive Value, Negative Predictive Value