WHITE PAPER

SD BIOLINE HIV/SYPHILIS DUO

Performance characteristics and cost benefit of the SD BIOLINE HIV/ Syphilis Duo in Clinics in Zimbabwe

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INTRODUCTION

Clinics are having to provide a number of rapid tests because of the increased need at a point-of care. One such test that can simultaneously detect both HIV and syphilis using a single specimen and a single cartridge is the SD BIOLINE HIV/Syphilis Duo rapid test kit. Mother-to-child transmission of syphilis and HIV can result in severe adverse pregnancy outcomes and serious illness in infants, including miscarriage, stillbirth, preterm delivery, congenital syphilis, and pediatric HIV infection, hence the need to assess the performance characteristics of this kit (1,2).

OBJECTIVES

- To determine the laboratory-based performance of dual HIV/ syphilis rapid diagnostic test (ROT) compared to reference assays.
- To assess the operational characteristics of rapid test, including the technical complexity and inter-reader variability.
- To analyze the cost benefit of the use of a single combined HIV and syphilis test kit compared to using separate HIV and syphilis test kits.

METHODS

Specimens were collected from 321 mothers attending 3 clinics in Harare where the rapid test was carried out by the nurses at sites. Specimens were then tested in the laboratory using EIA assays with the gold standards for HIV being Anilabs (Labsystems Diagnostics Only, Finland), Vironostika HIV ag/ab (Biomerieux, France) confirming with HIV Blot 2.2 westernblot kit (MP Diagnostics, Singapore). The reference tests for syphilis were the RPR kit (Lab 21 Health Care Ltd, UK) TPHA kit (AMS, UK). For the other 5 clinics that were far from the testing lab, in the Northern part of the country inter-reader variability of the SD colour scale was assessed for positive tests from 241 pregnant mothers by 2 nurses reading results independently of each other. The cost benefit of using this single test as compared to using 2 separate tests was also assessed.

RESULTS

For HIV the sensitivity and specificity were 100% (37/37 and 284/284) respectively. For syphilis the sensitivity and specificity were also 100% (4/4 and 290/290) respectively. Concerning the inter-reader variability assessment, 63(26%) were HIV positive and 30(12.4%) were syphilis positive . According to the SD BIOLINE grading scale there was no reader variability as no results among all readers overlapped to the next category of the 3 grades. The cost of using the SD duo ($1.50/test) compared to the cost of 2 separate kits (HIV $1.00, syphilis $0.75) was cheaper by 14%. Distribution and storage costs were also reduced by half.

CONCLUSION

Simultaneous testing of two diseases using a single cartridge is cost effective in resource constraint environments as results are also comparable to laboratory results.

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