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Post-market assessment of two rapid diagnostic test kits used in the diagnosis of HIV in the Wa Municipality, Ghana, 2018

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Statement of the problem: HIV testing algorithms based on rapid diagnostic tests (RDTs) are widely used in HIV testing and counseling (HTC) programmes in areas with limited laboratory infrastructure. In the Upper West region of Ghana, First Response HIV-1-2 and OraQuick HIV-1-2 are the commonly used RDT kits. An initial survey at Wa regional hospital indicates that there is no special storage procedure for the two RDT kits being used. The survey also revealed that there have been instances of false positives recorded with OraQuick test kits. This study

was therefore conducted to assess the sensitivity and the specificity of two RDT kits used in the diagnosis of HIV in the Wa municipality.

Method: A facility based cross-sectional study was conducted at the Wa Regional Hospital, Ghana. A questionnaire was used to collect demographic information of the subjects. Each subject was tested with First Response and OraQuick test kits using a parallel algorithm. The venous blood was collected into SST tubes for ELISA at the National Public Health Reference Laboratory. Data was cleaned using Microsoft Excel and exported to Stata. Descriptive analyses were done, the sensitivities and specificities and predictive values of the test kits determined.

Findings: First Response produced a sensitivity of 88% and OraQuick 98%. The specificity of First Response was

92% and OraQuick was 94%. First Response had a PPV of 91% and OraQuick had PPV of 95%. First Response had NPV of 89% and OraQuick NPV of 98%. There was a 'patient' misdiagnosed of HIV (false positive) and on ART.

Conclusion: The test kits performed below the WHO recommendations. The general performance of OraQuick was, however, better than First Response. The National AIDS Control Programme and the Food and Drugs Authority should reassess the test kits and conduct further studies to ascertain factors affecting the sensitivity and specificity of the kits.

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