Evaluation of a commercial enzyme immunoassay for HIV (1&2) screening in urine at the University of Port Harcourt Teaching Hospital

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Abstract

Objectives: *This study was undertaken to validate human immunodeficiency virus(HIV) 1&2 testing in urine samples as a screening process.*

Method and Materials: *160 samples of urine were collected from people living with HIV who attended the adult antiretroviral clinic and 38 urine samples of pregnant women attending the antenatal clinic of the university of Port Harcourt Teaching Hospital who had tested negative previously and two others who came for routine test in the laboratory were screened for HIV using a urine kit.*

Results: *One hundred and sixty (160) of these samples from the adult clinic which were known to be positive previously from serum tests still were positive giving a sensitivity of 100% while the rest 40 which were negative with serum, one was found to be positive and another discrepant result making the specificity to be in the range of 95-97.5%*

Conclusions: *The sensitivity and specificity of the urine test kit is adequate for screening purposes but all positive samples must be confirmed with an alternative test or Western blot.*

Keywords: Evaluation, HIV(1&2), Screening, Urine kit

Introduction

The gold standard for detecting HIV antibodies in serum has been the conventional immunoassay(EIA) which has both sensitivity and specificity above 99%,[1] but over the past decades ,new advances have been made for the rapid testing of serum and other alternative specimens such as saliva and urine for HIV(1&2) antibodies.[1] and these alternative specimens have been proven useful for screening and surveillance.[2]

Saliva has been investigated extensively with good laboratory results,[3,4,5] and has been used for routine surveillance purposes in sentinel populations.[6] Urine has been found to be more convenient and safer alternative to blood in terms of collection, processing, equipment ,specialized personnel and disposal.[7]

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There have been variations in results of urine testing ,some encouraging while others are not in terms of sensitivity and specificity, therefore there is a need for each setting and population to evaluate urine based tests that will be used in such places.

The advanced Quality Rapid Anti-HIV(1&2) Test (Urine) kit is available here and there is the need to evaluate it in this setting, the University of Port Harcourt Teaching Hospital(UPTH) being a screening centre before advocating for its use in screening.

Methods and Materials

This study was undertaken within a time frame of two weeks involving clinic days only. A total of 200 samples of urine were collected from consenting adults aged 21-55 years for the study.

One hundred and sixty (160) of the urine samples were from known people living with HIV and who have been on antiretroviral therapy from 4 months-4 years as at the time of the study and were attending the adult antiretroviral therapy (ART) clinic of UPTH.

40 other urine samples were taken from 38 HIV negative pregnant women who had been screened previously 5-6 months before the study as part of the prevention of mother to child transmission(PMTCT) programme; and one male and female who came for routine serum HIV screening in the haematology laboratory.

The urine samples which were collected with clean plain bottles were tested within one hour of collection with the Advanced Quality Rapid Anti-HIV(1&2) test which is a simple visual qualitative test that detects antibodies in human urine, based on immuno- chromatography and gives results within 15 minutes. It comes as a test card for each urine sample to be tested. One drop of urine is dispensed to a well of the test card and another 2 drops of diluent to another well and then allowed to react, after which the result is read and interpreted within 15 minutes based on the principle of antigen conjugate in the test strip forming a complex with HIV antibody in the urine sample.

Results

The urine test samples were all positive for the 160 previously positive with serum tests and who were on antiretroviral therapy. Anti-HIV antibodies were detected in all the urine samples of the positive patients, and therefore the diagnostic sensitivity was 100%.

In the other 40 urine samples ,the male and female who came for routine screening were found to be negative for both the serum as well as the urine screening test, while in the other 38 samples of the pregnant negative mothers,36 were still negative ,while 1 was positive and 1 was indeterminate, the specificity ,therefore, was in the range of 95-97.5%. The positive test of the antenatal patient could not be confirmed as the client was not readily available to get a blood specimen within the period of study.

Conclusion

The Advanced Quality Rapid Anti HIV(1&2) Test for urine can be used for screening purposes but all positive tests must be confirmed using an alternative test or Western blot on same specimen.

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