

Using Conventional HIV tests for HIV Diagnosis on Oral Fluid Specimens.

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ABSTRACT

There is a need for more tests using non-invasive specimen collection. This will be helpful to broaden the reach of testing programs and to perform large scale epidemiological studies.

In this study three different ELISA assays (Vironostika HIV Ag/Ab, Enzygnost Anti-HIV 1/2 Plus and Genscreen HIV 1/2 v2) were optimized for the detection of HIV antibodies in oral fluid specimens collected with the OraCol device. 302 paired oral fluid and blood specimens from HIV positive and HIV negative individuals were collected. ELISAs were adapted for oral fluid testing and compared with a gold standard testing algorithm. A testing algorithm for screening and surveillance purpose was elaborated.

Oral fluid is a non-invasive specimen that can be a useful for outreach HIV testing and anonymous sentinel surveillance in community settings.



BACKGROUND

Many people have never been tested and are therefore unaware of their HIV status.

Oral fluid samples are an ideal non-invasive specimen to broaden the reach of testing programs and to perform large scale epidemiological studies especially when conducted in a non clinical environment and when vulnerable people are involved.

OBJECTIVES AND METHODS

Firstly we optimized three HIV screening tests (ELISAs). Secondly we assessed the stability of the specimen and thirdly we elaborated a testing algorithm for use in epidemiological studies and for diagnosis.

Three oral fluid swabs were taken from 302 HIV positive and HIV negative individuals. The specimens were kept for three different time points (day 0-1, day 3-5 and day 7) at ambient temperature before processing the specimens and were kept at -20°C until testing.

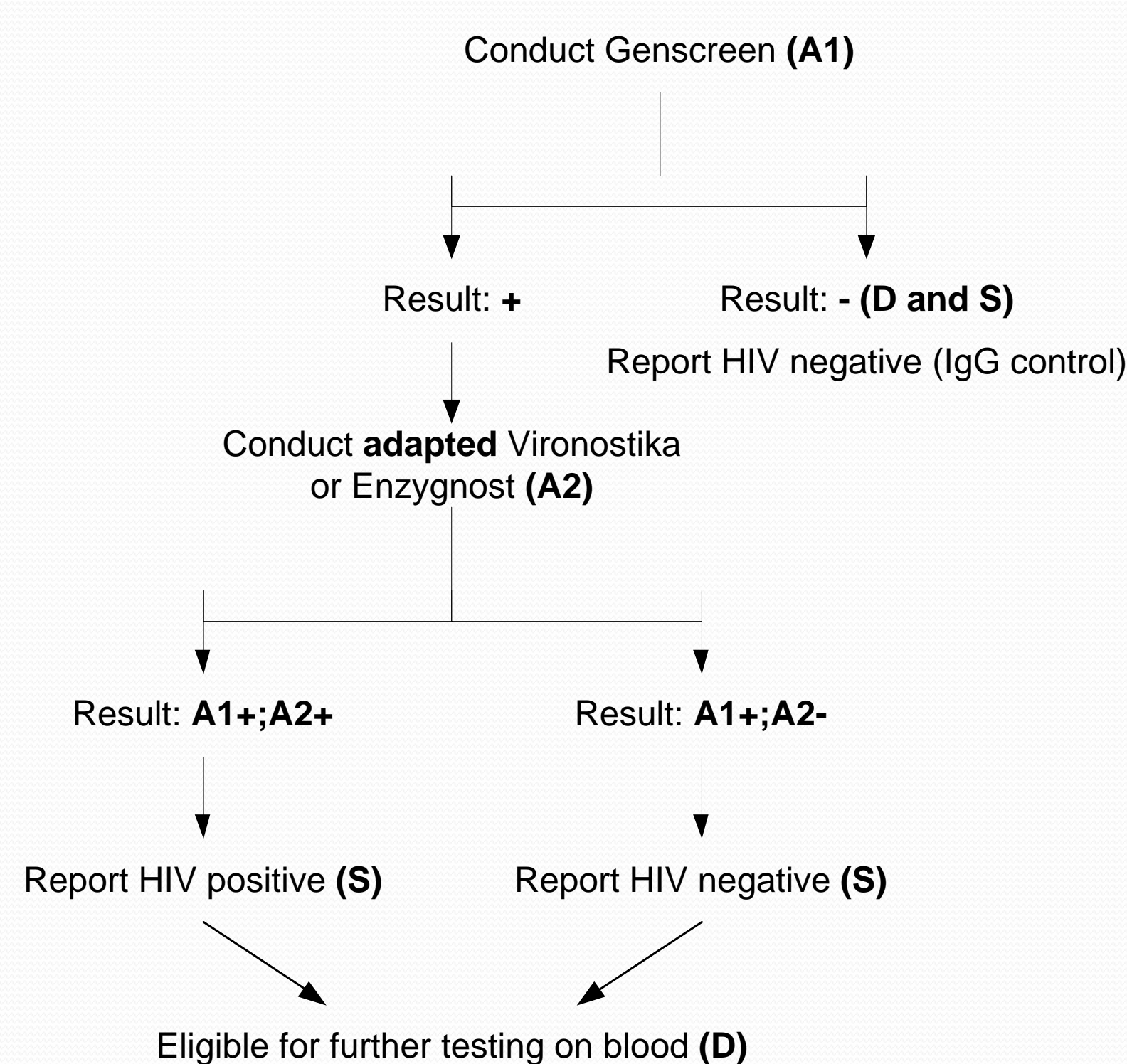
Optimization of the protocol was done by doubling the sample volume for Vironostika and Enzygnost and kept the same for Genscreen. The optimal formula to calculate the cut-off for each of the tests were assessed. Sensitivities and specificities were calculated by comparing the oral fluid tests with the gold standard testing on a paired blood sample. Testing algorithms were elaborated with a lowest misclassification rate for surveillance studies (**S**) and with a highest sensitivity for diagnosis (**D**).

RESULTS

Day 7 data on oral fluid specimen:

	Sensitivity % (95% CI)	Specificity % (95% CI)
Vironostika	97.8 (92.3 - 99.4)	100 (98.2 - 100)
Enzygnost	97.8 (92.3 - 99.4)	99.5 (97.3 - 99.9)
Genscreen	100 (95.9 - 100)	97.6 (94.5 - 99.0)

Proposed HIV Testing Algorithm using Oral Fluid Specimen:



S: Surveillance

D: Diagnosis



CONCLUSIONS

The present study has demonstrated that different ELISAs can be used with oral fluid after adaptation of the sample input and calculation of the formula for cut-off. Therefore the oral fluid collection becomes a more useful tool for outreach HIV testing and anonymous sentinel surveillance in community settings.

A serial algorithm with two tests should be used in order to obtain correct prevalence data in epidemiological studies and only one test (Genscreen) can be used to screen individuals for further testing on blood.