New protocol for HIV screening for life assurance

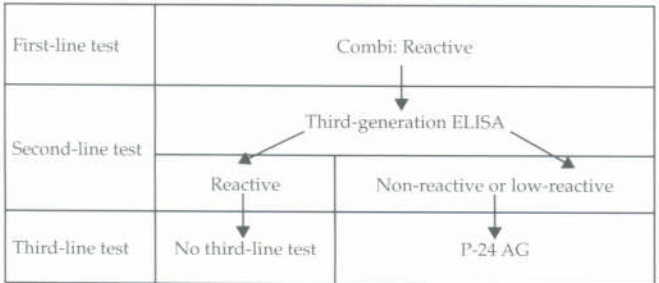
To the Editor: The insurance industry has used the third-generation ELISA protocol as a screening test for human immunodeficiency virus (HIV) infection over the last number of years. In order to utilise new technology and keep up with developments in the clinical field, the fourth-generation Combi protocol has been developed in consultation with experts and discussion with the National Pathology Group. The third-generation protocol will be used concurrently with the fourth-generation protocol for the next 2 years.

This protocol uses one of the LOASPA approved fourth-generation combination HIV tests (Combi test). The Combi tests for both the HIV antibodies and the virus itself (P24, antigen component), shortening the window period from an average of 16 days to an average of 7 days.

The Medical and Underwriting Standing Committee (MUSC) of the Life Offices' Association of South Africa (LOA) has extensively investigated the results of the new test on local blood samples for the last 18 months. The aim was to ensure that there is not an increase in the false-positive test ratio, as this has serious implications. Two major studies have been done by Ampath and the University of Pretoria to compare the existing ELISA tests to the combination tests. The latter study is ongoing.

As with all underwriting tests, as well as the previous protocol, these tests must be regarded as screening tests and further testing is recommended in the event of a reactive test. Any further tests will be for the client's own cost.

A non-reactive Combi test result is reported as such and no follow-up test is done. A new category of 'low-reactive' results has been defined. Any low-reactive or reactive result will be retested with a third-generation ELISA immuno-assay to retest the antibody component. If this does not confirm the result of the first test, it will be followed with a P24 antigen test to retest the antigen component. Any low-reactive third-generation test will also be followed with a P-2 antigen test. All second and third line follow-up tests will be from a different manufacturer than that of the Combi test (Fig. 1).



Cut-off values for 'reactive' as well as 'low reactive' results for all approved third-generation ELISAs, as well as fourth-generation Combi tests, will be defined from time to time by mutual agreement between the National Pathology Group and the Medical and Underwriting Standing Committee of the LOA.

The LOA is confident that the use of 'low-reactive' values with sequential follow-up tests of both the antigen and antibody components will reduce the possible number of false-reactive results to a minimum.

Further information is available on http://www.loa.co.za Chapter 6 HIV Testing Protocol.

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