LABUPDATE no. 20 (version 2)

November 2023

ADULT HIV DIAGNOSIS

The standard approach to the laboratory diagnosis of HIV infection in adults and children older than 18 months is to detect the presence of HIV-specific antibodies in a blood specimen, usually by means of an enzyme-linked immunosorbent assay (ELISA). Screening HIV ELISA tests are designed to be extremely sensitive tests so that the negative predictive value of the tests is almost 100% (excluding those with window period infections). Most commercially available HIV ELISA assays detect HIV antibodies and the p24 antigen simultaneously, thereby reducing the window period of these tests. The downside to having a sensitive screening test is that false positive results may occur in a small percentage of positive specimens, which is why international guidelines recommend that all positive screening HIV ELISA tests need to be confirmed by a second confirmatory test.

AMPATH'S HIV TESTING ALGORITHM

Ampath's current HIV testing algorithm (Figure 1) was implemented in 2020. Prior to this, Ampath performed an HIV-1 viral load assay to confirm reactive screening ELISA results. If the HIV-1 viral load was below 5 000 copies/mL, further serological testing in the form of a Western blot was used to confirm seroreactivity. The decision to implement the current algorithm was largely based on a growing percentage of undetectable HIV viral loads, most likely attributed to the retesting of HIV-infected individuals who were already virally suppressed and on antiretroviral therapy (ART). The current cost-saving HIV algorithm eliminates the need for HIV-1 Western blot testing in the majority of patients. In essence, a 4th generation HIV ELISA test is used as a screening test and, if reactive, a second confirmatory HIV ELISA is performed on a different test platform. The 4th generation HIV assay that is used for confirmatory testing can also differentiate p24 antigen and HIV antibody results, which allows for the possible identification of early HIV infection.

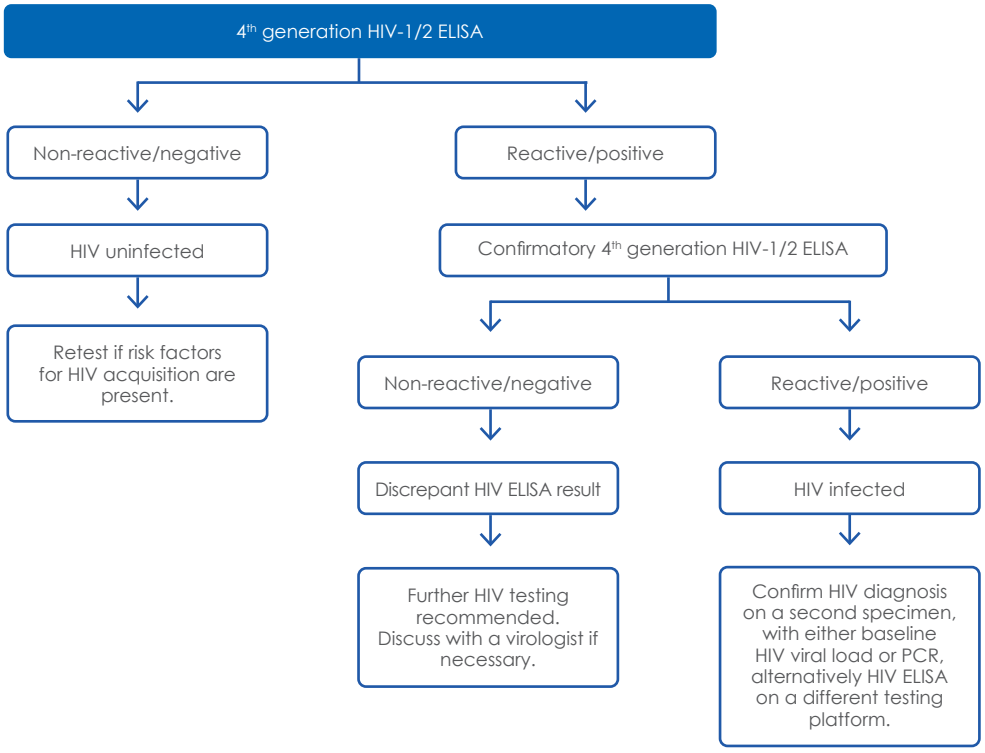
A positive HIV test result on a single blood specimen should still be confirmed on a follow-up specimen to guard against the unlikely risk of false positive results due to mislabelled specimens or laboratory error. The 2023 South African HIV Clinicians Society guidelines recommend that a baseline HIV viral load or PCR may also serve as a confirmatory HIV test in newly diagnosed patients. Alternatively, confirmation by means of an additional HIV ELISA on a different testing platform can be considered.

If a newly diagnosed (ART-naïve) patient has an undetectable HIV-1 viral load, the possibility exists that the individual may have immune control over the HIV infection (also referred to as elite controllers). Alternative explanations such as a false reactive HIV ELISA and an HIV-2 infection should also be considered. Further test options can be discussed with your local Ampath pathologist.

DEDICATED SPECIMEN TUBES FOR HIV TESTING

Ampath implemented HIV testing on a dedicated serum tube from 28 October 2017. The implication is that whenever blood is drawn from a patient, an additional clotted tube should be drawn if an HIV test is requested. This was implemented to eliminate the risk of contamination posed by opening and recapping tubes, as well as testing on other analysers prior to the HIV ELISA being performed. Recent findings published by local researchers (Hardie et al., 2017) demonstrated that false positive results can occur in high HIV prevalence areas if HIV serology is performed on analysers that also run other tests (e.g. general chemistry). In line with Ampath's dedication to quality results, the use of dedicated serum tubes will reduce the number of false positive HIV results and minimise unnecessary confirmatory testing, which will reduce cost.

FIGURE 1: AMPATH HIV TESTING ALGORITHM



REFERENCES AVAILABLE ON REQUEST