AMPATH LAB UPDATE

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(endorsed by the Ampath Infectious Diseases Peer Group)

Adult HIV diagnosis

The standard approach to the laboratory diagnosis of HIV infection in children older than 18 months and adults is to test for HIV infection by serological means, whereby the presence of HIV-specific antibodies in a patient's blood specimen is determined by a screening enzyme-linked immunosorbent assay (ELISA). Screening HIV ELISA tests are designed to be extremely sensitive tests so that the negative predictive value of the test is almost 100% (excluding those with window period infections). 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 HIV ELISA tests need to be confirmed by a second confirmatory test.

Ampath Laboratories HIV testing algorithm

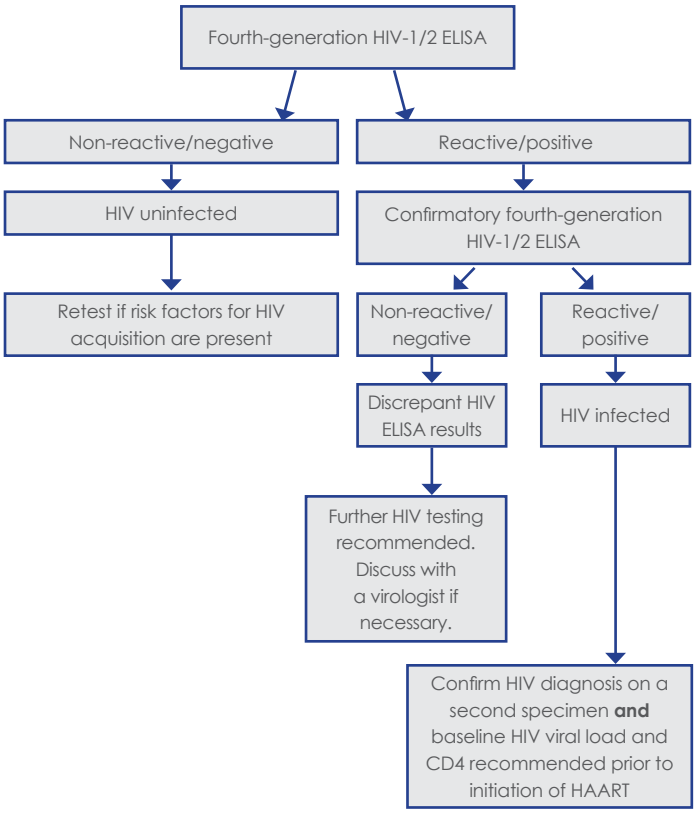
Since March 2013, Ampath Laboratories have been using an HIV testing algorithm that starts with a screening fourth-generation ELISA assay, followed by an HIV-1 viral load assay to confirm reactive screening ELISA results. For instances where the confirmatory HIV viral load was below 5 000 copies/mL, further serological testing in the form of a Western blot was used to confirm seroreactivity.

In our experience, a large percentage of patients who have undetectable or low confirmatory HIV-1 viral loads are patients who were previously diagnosed with HIV infection and are on antiretroviral therapy, which suppresses the HIV-1 viral load. In view of the ever-increasing proportion of HIV-infected patients who are initiated on antiretroviral therapy, Ampath has decided to implement a new cost-saving HIV ELISA testing algorithm, which eliminates the need for HIV-1 Western blot testing in the majority of patients. In essence, screening will still be performed on a fourth-generation HIV ELISA, but a second confirmatory HIV ELISA will replace the confirmatory HIV viral load when the screening HIV ELISA is positive (reactive). A positive HIV result on a single blood specimen should still be confirmed by means of an ELISA on a follow-up specimen to guard against the unlikely risk of false positive results due to mislabelled specimens or laboratory error.

Dedicated specimen tubes for HIV testing

Ampath has 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 in an attempt 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 where HIV serology is performed on analysers that also run other tests such as 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: Flow diagram of Ampath's new HIV testing algorithm



References provided on request.

AMPATH LABORATORIES

Please contact your local Ampath pathologist for more information.