LANCET LABORATORIES
Tanzania

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HIV DIAGNOSIS

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HIV-1/2 is diagnosed either by detecting HIV- specific antibodies or the virus itself. In individuals >18 months old the detection of HIV-specific antibodies remains the recommended method for routine diagnosis.

ANTIBODY DETECTION

- 4th generation HIV-1/2 ELISA Detects HIV-specific antibodies and p24 antigen (a component of the virus) simultaneously. Window period: ± 18 days.
- Rapid HIV-1/2 Detects HIV-specific antibodies. (There are many different rapid tests available. Only those with high sensitivity and specificity, and FDA/CE marking should be used.) Window period: ± 24-28 days.
- According to WHO guidelines, all positive HIV results should be confirmed with: A second test on the same specimen.
- Repeat testing on a second specimen. (Although the ELISA has a sensitivity of close to 100% and specificity of ± 99.6%, the serious nature of HIV warrants confirmatory testing.)

P24 ANTIGEN DETECTION

The p24 antigen is detectable from approximately 2 weeks after infection. During the seroconversion phase it is detected in the majority of patients. However, when high levels of HIV-specific antibodies develop, the p24 antigen usually becomes undetectable.

A negative p24 result does not exclude HIV infection. Specific p24 antigen testing may be used to detect an acute infection, but should not be used for routine diagnosis.

HIV-1 DNA PCR

The HIV-1 DNA PCR detects the HIV genome that has integrated into theCD4+ cells. It provides a qualitative result. (positive/negative.) The HIV-1 DNA is detectable from approximately 2 weeks after infection. It is more expensive than the HIV-1/2 ELISA and only detects HIV-1, but it can be used to detect acute infection or to resolve discrepant ELISA results.

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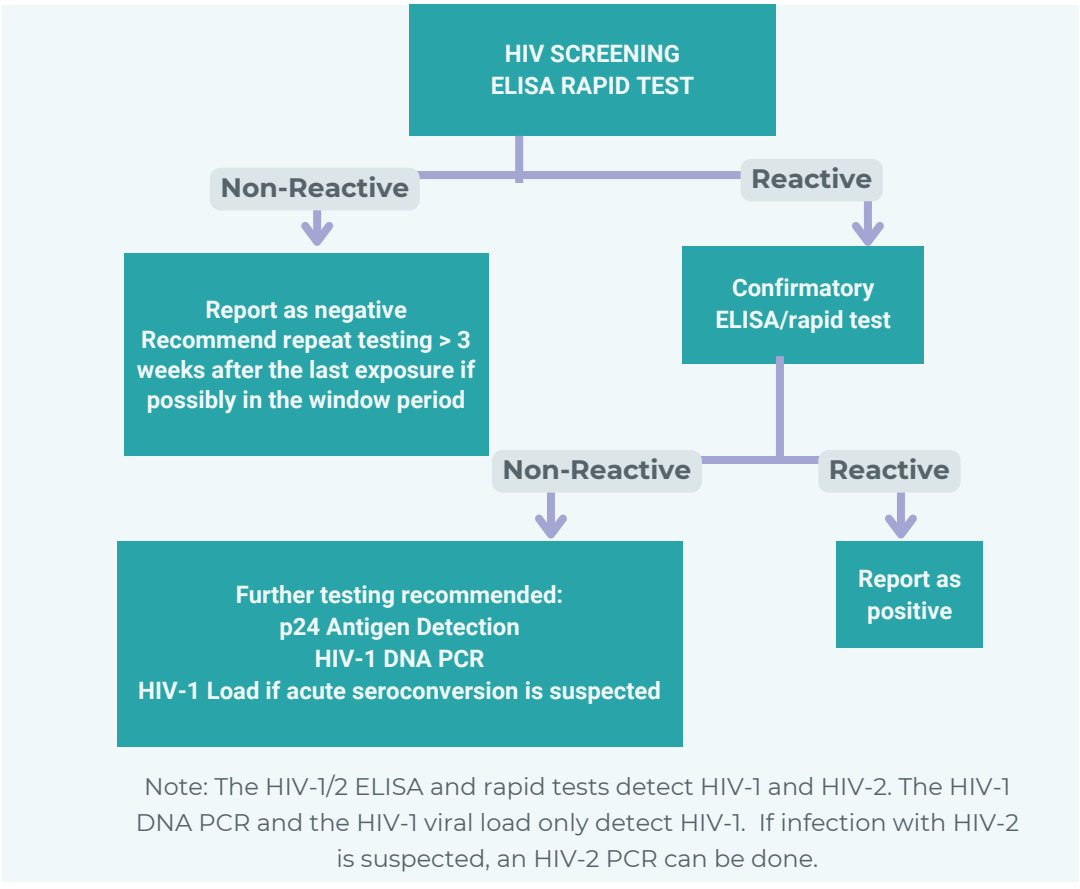
D) HIV-1 VIRAL LOAD

The HIV-1 viral load quantifies the amount of viral RNA in plasma. It should not be used routinely for diagnosis of HIV infection for the following reasons:

- The HIV-1 viral load only detects HIV-1.
- An undetectable HIV-1 viral load does not mean that the patient is HIV negative.
- Due to the nature of the test, a low-level viral load is not considered to be diagnostic of HIV infection.
- Viral RNA can be detected in the plasma as early as11 days after infection. In cases where acute seroconversion is suspected, an HIV-1 viral load of >10 000 copies/ml is considered diagnostic of HIV infection.

Recommended testing algorithm:



Note: The HIV-1/2 ELISA and rapid tests detect HIV-1 and HIV-2. The HIV-1 DNA PCR and the HIV-1 viral load only detect HIV-1. If infection with HIV-2 is suspected, an HIV-2 PCR can be done.

1. The HIV-1 viral load only detects HIV-1
2. An undetectable HIV-1 viral load does not mean that the patient is HIV negative
3. Due to the nature of the test, a low level viral load is not considered to be diagnostic of HIV infection

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