



Tanzania

LABORATORIES

**Compiled by: Dr. Allison Glass** 

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.

#### **A) 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.)

## **B) 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.

## C) 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

## 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.



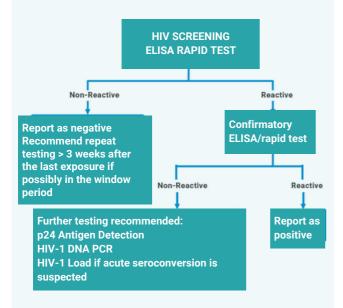
Lancet Mwanza | Olympic House Plot Number 493 | Kirumba Valley Tanzania I Tel: +255 757 815 929 I info@lancet.co.tz customerservice.tanzania@lancet.co.tz

www.cerbalancetafrica.co.tz flancetlabstanzania



#### E) HIV-1 VIRAL LOAD

#### **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.

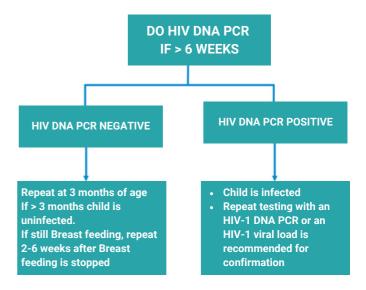
If infection with HIV-2 is suspected, an HIV-2 PCR can be done.

- 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

# HIV DIAGNOSIS IN INFANTS (<18 MONTHS OLD)

Maternal HIV-specific antibodiesmay be detectable in the infant up to the age of 18 months. For this reason, the diagnosis of HIV infection in infants depends on detection of the virus. HIV-1 DNA PCR is the test of choice.

- Testing at 6 weeks of age will detect ante- and intra-partum infection in 98% of infants.
- If the 6 week test is negative, repeat testing is recommended at 3 months.
- If the baby is breastfed and tests negative, testing should be repeated 2-6 weeks after breastfeeding is stopped.
- If the baby is exposed to antiretrovirals as part of prevention of mother-to-child transmission (PMTCT), the HIV-1 DNA PCR should be done >2 weeks after discontinuing the antiretrovirals.



Note: The HIV-1 DNA PCR only detects HIV-1. If an infection with HIV-2 is suspected, an HIV-2 PCR can be done.

#### **References:**

World Health Organisation. WHO recommendations on the diagnosisof infection in infants and children. WHO
Press 2010. ww.who.int/ entity/ hiv/ pub/ paediatric/ diagnosis/en/ index. html, Photo created by user3802032



Lancet Mwanza | Olympic House Plot Number 493 | Kirumba Valley Tanzania I Tel: +255 757 815 929 I info@lancet.co.tz customerservice.tanzania@lancet.co.tz

www.cerbalancetafrica.co.tz