

## 4. TESTING FOR HIV INFECTION

### 4.1 Introduction

HIV infection is usually diagnosed by testing for antibodies against HIV. Screening tests for HIV antibody include the enzyme-linked immunosorbent assay (ELISA) test or the simple/rapid tests. Samples of sera that are found to be positive by screening tests are then tested for confirmation of the presence of HIV antibodies using a supplementary test. A supplementary test may be another ELISA test or another simple/rapid test based on a different antigen preparation or a different test principle. The objectives of HIV testing include:

- Screening of donated blood for transfusion
- Surveillance of HIV prevalence or trends over time in a given population
- Diagnosis of infection in individuals

### 4.2 Laboratory tests

Persons who become infected with HIV produce HIV antibodies over the next 3 to 12 weeks. Numerous different tests are available for the detection of HIV antibody.

#### 4.2.1 ELISA tests

The most commonly used type of test for screening is the ELISA. ELISA tests are most efficient for testing large numbers of samples per day. They are used widely in large blood banks and in surveillance studies. ELISA tests are usually performed on serum or plasma and hence a specimen of venous or capillary blood is needed.

#### 4.2.2 Simple/rapid tests

These tests are easy to perform. They do not require highly trained staff and require simple equipment. They can easily be performed in a VCT centre and results are obtained within the hour. They are suitable for use in small laboratories and for emergency testing.

### 4.2.3 Diagnosis of HIV infection

For diagnosis of HIV infection, all samples that test positive on screening should be subjected to a second test. This can be another ELISA or a simple/rapid test based on a different antigen preparation and a different test principle.

### 4.2.4 Tests to detect the virus itself

New technologies based on the amplification of viral nucleic acids, such as polymerase chain reaction (PCR) and nucleic acid sequence based assay (NASBA), have made it possible to detect minute amounts of viral material. These sensitive procedures are well suited to early diagnosis of mother-to-child transmission and to monitoring the viral load of patients who are taking antiretroviral therapy. However, the tests are very expensive, need complex equipment, rigorous laboratory conditions and highly trained staff.

## 4.3 Measuring immunosuppression

Among the white blood cells, lymphocytes are responsible for cellular immunity. There are two main types of lymphocytes in circulation: the B lymphocytes, which produce natural antibodies, and the T lymphocytes which are responsible for cell-mediated immunity.

T lymphocytes bearing the CD4 molecule play a crucial role in the immune response and are the target cells for HIV. With the destruction of the CD4+ lymphocytes by the virus, their levels in the peripheral blood drop leading to immune deficiency. The severity of HIV infection is related to the level of CD4+ lymphocytes concentrations in the peripheral blood.

The normal range of CD4+ lymphocytes in the peripheral blood varies tremendously, ranging between 500 and 1500/mm<sup>3</sup>. When the peripheral blood CD4+ lymphocyte count falls below 200/mm<sup>3</sup>, the incidence of opportunistic infections increases. It has also been shown that the peripheral blood total lymphocyte count of less than 1200/mm<sup>3</sup> is an approximate indication of peripheral blood CD4+ lymphocyte level of less than 200/mm<sup>3</sup> in symptomatic patients. Methods for measuring CD4+ lymphocytes counts require sophisticated equipment, costly reagents and need well-trained laboratory personnel.

#### 4.4 Interpreting results of HIV antibody tests

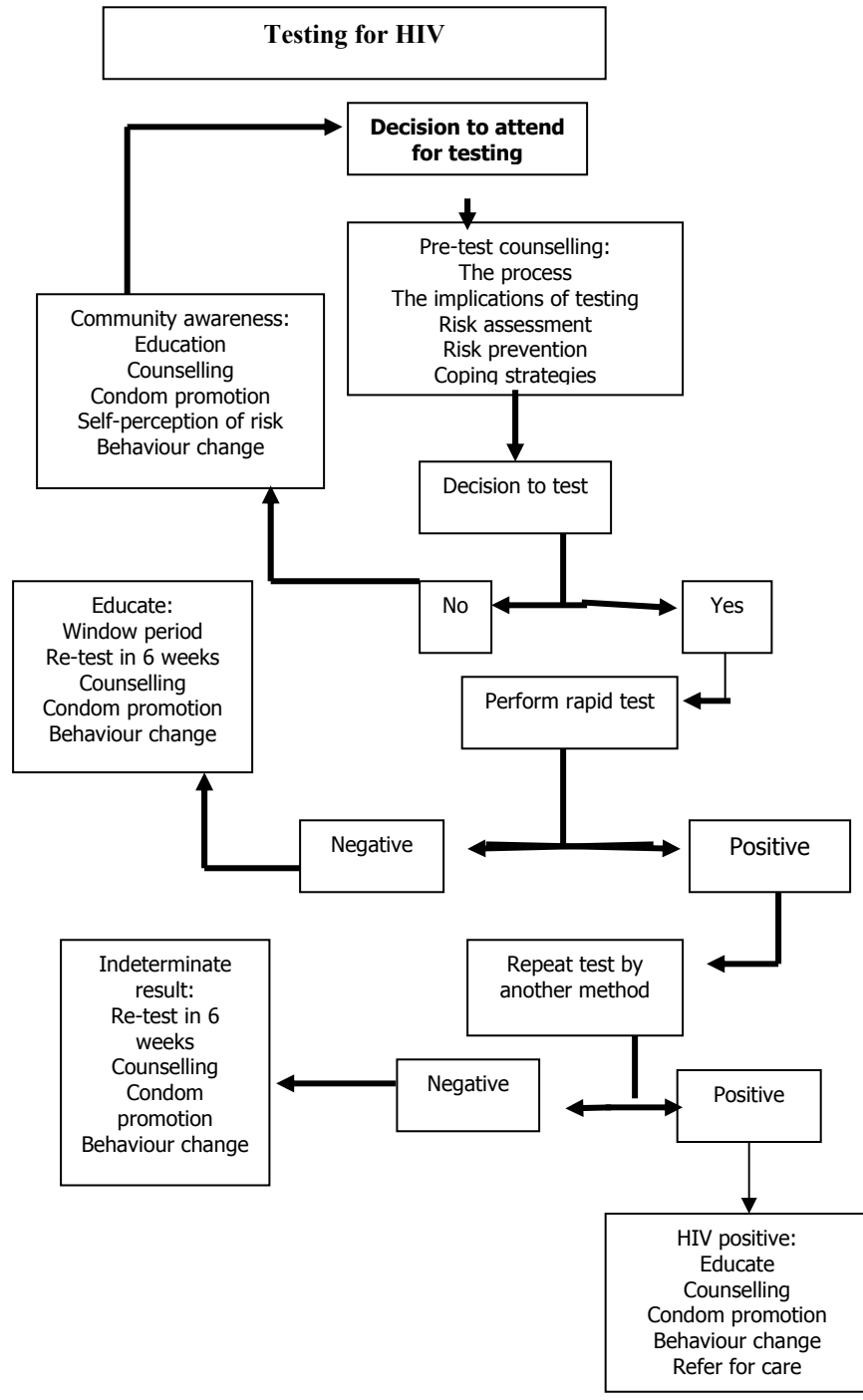
The serologic diagnosis of HIV infection can be made by examining the test results and considering the clinical findings in the patient. Table 4.1 summarises the interpretation of results of HIV antibody tests.

**Table 4.1: Interpreting results of HIV tests**

Interpretation of results of HIV ELISA and rapid tests				
Result of Test	HIV-related symptoms/signs present	Client at risk for HIV infection	Interpretation of result	Action to be taken
First ELISA or rapid test negative	No	No	Negative	Nil
	No	Yes	Negative (possible window period)	Repeat test in 6 to 12 weeks
	Yes	Yes or No	Negative (possible false negative result)	Repeat test
First ELISA or rapid test positive and second test negative	Yes or No	Yes or No	Indeterminate	Repeat tests. If positive, patient is positive
First ELISA or rapid test positive and second test positive	Yes or No	Yes or No	Positive	Patient is positive and should be counselled

#### 4.5 HIV testing algorithm

The following algorithm summarises the approach to HIV testing in adults and children over the age of 18 months.



#### **4.6 Laboratory diagnosis of HIV infection in children using antibody tests**

The vast majority of children with HIV acquire the infection through mother-to-child transmission. Without any prevention interventions such as ART in pregnancy, caesarean section and replacement feeding, about thirty per cent of infants born to mothers with HIV infection become infected. However all children born to women with HIV infection will have antibody transferred from their infected mothers. Therefore tests that detect antibodies, such as, the ELISA and the rapid tests, cannot tell whether the child is infected or not until the age of 18 months when the child loses maternal antibodies. In a child who has stopped breastfeeding, maternal HIV antibodies may still be present and antibody tests will pick these. If however a child has stopped breastfeeding for at least 3 months and his/her HIV antibody tests are negative on two occasions 1 month apart then it may be concluded that the child is HIV negative as he/she has lost the maternal antibodies and has no antibodies of his/her own.

#### **4.7 Laboratory diagnosis of HIV infection in children using virologic tests**

HIV PCR tests are the preferred virologic method for diagnosing HIV infection during infancy. If the child is not breastfeeding, HIV infection can be excluded with two or more negative tests performed at the age of 3 months and at the age of 6 months. HIV infection in non-breastfed infants can be diagnosed by age three to six months using viral diagnostic assays. A positive virologic test (i.e., detection of HIV by culture or DNA or RNA polymerase chain reaction [PCR]) indicates possible HIV infection and should be confirmed by a repeat virologic test on a second specimen as soon as possible after the results of the first test become available.

If the child is being breastfed a negative virologic test at 3 to 6 months does not exclude infection because the risk of HIV transmission continues throughout the duration of breastfeeding. In such an infant, once breastfeeding has ceased for at least 3 months and if the child is over 18 months of age an HIV antibody test can be used to make a diagnosis of infection. HIV culture can also be used for diagnosing HIV infection during infancy. However, HIV culture is more complex and expensive to perform than PCR, and definitive results may not be available for two to four weeks.