Rapid HIV tests:
Guidelines for use in HIV testing and counselling services in resource-constrained settings

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Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>ANC</td>
<td>Antenatal clinic</td>
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<tr>
<td>ARV</td>
<td>Antiretroviral</td>
</tr>
<tr>
<td>EIA</td>
<td>Enzyme Immunoassay</td>
</tr>
<tr>
<td>ELISA</td>
<td>Enzyme-linked immunosorbant assay</td>
</tr>
<tr>
<td>EQA</td>
<td>External Quality Assessment</td>
</tr>
<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
</tr>
<tr>
<td>AIDS</td>
<td>Acquired Immunodeficiency Syndrome</td>
</tr>
<tr>
<td>MCH</td>
<td>Maternal and child health</td>
</tr>
<tr>
<td>MTCT</td>
<td>Mother-to-Child transmission</td>
</tr>
<tr>
<td>NGO</td>
<td>Non-governmental organization</td>
</tr>
<tr>
<td>PLHA</td>
<td>Person living with HIV/AIDS</td>
</tr>
<tr>
<td>STI</td>
<td>Sexually transmitted infection</td>
</tr>
<tr>
<td>IDU</td>
<td>Injecting drug use(r)</td>
</tr>
</tbody>
</table>

Acknowledgements

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HIV testing and counselling is now recognized as a priority in national HIV programmes because it forms the gateway to HIV/AIDS prevention, care, treatment, and support interventions. To ensure access to HIV testing for large populations and to facilitate access to ARV treatment in the context of the WHO “3 by 5” initiative, radical scaling up of HIV testing and counselling services is urgently required. The use of rapid\(^1\) HIV tests will facilitate this in many settings, particularly in services where those most likely to benefit from knowledge of their HIV status can be reached, e.g., for diagnosis and treatment of tuberculosis, sexually transmitted infections, services providing and linked to prevention of mother-to-child transmission, and in general medical settings.

The introduction of rapid tests for HIV testing and counselling has many practical advantages, including enabling larger numbers of people to benefit from knowing their HIV status, greater test result uptake by those being tested, speed in obtaining test results, and less reliance on laboratory services for obtaining test results.

This document reviews characteristics of rapid HIV tests that make them suitable for HIV testing and counselling services and discusses practical considerations for their use. Counselling issues, advantages of, and cautions with using rapid tests are considered. Testing algorithms for the use of rapid tests and current WHO recommendations are presented. Although rapid HIV tests have been developed that use saliva and urine, this document will concentrate on rapid tests that use whole blood, serum or plasma.

Although these guidelines are aimed at testing and counselling services in resource-constrained settings, rapid tests are also recognized as an important component of efforts to increase the number of people who know their HIV status in resource-rich countries.\(^1\)

The document is aimed at policy-makers, managers of HIV testing and counselling services, and planners of HIV prevention, treatment, and care programs. It may also be useful for clinicians, laboratory staff, and HIV counsellors.

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\(^1\) The term rapid test will be used throughout this document. It is synonymous with the term simple/rapid test that has been used in previous documents (excluding those simple tests taking longer than 30 minutes to perform).
1. Introduction

1.1 Evolution of approaches to HIV testing and counselling
HIV testing and counselling have been recognised as necessarily linked since the first HIV ELISA tests were made available for identification of HIV infection in the mid-1980s. Pre and post test counselling were seen as crucial for the testing process because of the seriousness of the news of HIV infection for those receiving a positive result. Additionally, the process of pre-test counselling was designed to ensure that those tested were sufficiently informed about the testing process and potential consequences: counselling enabled informed consent and ensuring that people were not tested in a coercive manner. Those found to have HIV needed post-test counselling support to manage disclosure and coping with living with HIV, including information on future prevention of infection to partners and family, and decision-making about pregnancy.

In this context, protocols for pre-test counselling for those considering testing, and for those found negative and positive (post-test counselling) were developed, and these form the basis of pre-test counselling and education, and post-test counselling, provided today (see Appendix 1).

With the need to ensure informed consent for all those being tested, WHO recommends that all clients be provided with sufficient information to enable them to decide whether they want to undertake the test or not (see Appendix 1). This may be done with the provision of pre-test education in an individual or group setting, or, where possible, in individual pre-test counselling, and through a variety of printed information (posters or leaflets). WHO also recommends that ALL people be informed of their test result and those found HIV positive receive post-test counselling and referral for on-going support. Those found negative should be counselled on how to remain so. Results should be given to individuals or couples only – not in group settings.
Guiding principles of expanded HIV testing and counselling

WHO recommends that the following guiding principles be observed in the provision of all HIV testing and counselling services:

a. Testing and Counselling must now be scaled up
   Offering HIV testing and counselling should become standard practice wherever they are likely to enhance the health and well-being of the individual. The objective is to enable the greatest possible number of people to benefit from the ever-improving treatment, care and prevention options and realise their right to the highest attainable standard of health care.

b. HIV testing should be voluntary
   Mandatory HIV testing is neither effective for public health purposes nor ethical, because it denies individuals choice and violates principles such as the right to health, including the right to privacy and the ethical duties to obtain informed consent and maintain confidentiality.

   Although the process of obtaining informed consent will vary according to different settings, all those offered the test should receive sufficient information and should be helped to an adequate understanding of the testing process and possible consequences of being tested. The three crucial elements in obtaining truly informed consent in HIV testing are:
   - Providing pre-test information on the purpose of testing, and on the treatment and support available once the result is known
   - Ensuring understanding
   - Respecting the individual’s right to decide if they want to be tested or not.

   Only when these elements are in place will individuals be able to make a fully informed decision on whether or not to be tested in light of their own circumstances and values. Once this is assured, the actual process of obtaining informed consent can be adapted to suit the different settings under which expanded HIV testing and counselling services will be implemented.

c. Post-test support and services are crucial
   The result of HIV testing should always be offered to the person being tested. It is the person’s decision to share this result with others. Along with the result, appropriate post-test information, counselling or referral should be offered according to the result. People who receive positive test results should receive counselling and referral to care, support and treatment.

d. Confidentiality must be protected
   All medical records, whether or not they involve HIV-related information, should be managed in accordance with appropriate standards of confidentiality. Only health-care professionals with a direct role in the management of patients or clients should have access to such records or the information they contain, and only on a “need to know” basis.

   In rare circumstances, confidentiality may be breached where there is a clear indication that a third party may be harmed by the actions of the patient. Steps that apply to such a process include:
   - The HIV positive person (source client) has been thoroughly counselled as to the need for partner notification/counselling.
   - The counselling has failed to achieve the appropriate behavioural changes, including the practice of safer sex.
   - The source client has refused to notify, or consent to the counselling, of his/her partner(s).
   - A real risk of HIV transmission to the identifiable partner(s) exists.
   - The source client is given reasonable advance notice of the intention to counsel by the health worker.
   - The identity of the source client is concealed from the partner(s) if this is possible in practice.

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Follow-up is provided to ensure support to those involved as necessary and to prevent violence, family disruption, etc.
1.2 Evolution of tests for HIV
There has been a fast evolution in HIV diagnostic technology since the first HIV antibody tests became commercially available in 1985. Currently a wide range of different HIV antibody tests is available. These include enzyme linked immunosorbant assays (ELISA) and rapid HIV tests, general and operational characteristics of which are shown in Table 1.

Until the development of rapid tests (1990), the diagnosis of HIV infection was made by detecting antibodies against HIV using ELISA. The original ELISA tests used viral lysate and positive specimens were usually confirmed using Western Blot technology, which is technically difficult, time consuming, and expensive. Second and third generation ELISA tests were then developed based on recombinant proteins and synthetic peptides, which increased sensitivity and specificity and considerably shortened the interval between the time of infection and the ability to detect of HIV antibodies (window period). This window period is now even further reduced by the combined antigen-antibody (fourth generation) ELISA tests.

There are, however, essential requirements to ensure that ELISA tests can be carried out in a reliable manner. Laboratory equipment and disposables (pipette tips) have to be available for ELISA tests to be performed, a constant supply of electricity and clean water is necessary, and equipment that needs to be regularly maintained. The validity of ELISA test results depends on skilled technicians who are able to operate the equipment and who can prepare the necessary reagents and pipette accurately. ELISA testing requires stable incubation steps and reagents require refrigeration at 2-8°C.

Advances in technology have led to the development of a wide variety of rapid HIV tests including agglutination assays, dipstick assays, flow-through membrane assays, and lateral flow membrane assays. Many of these tests are presented as a strip or cartridge that incorporates the reagents and do not require additional equipment. They are suitable for performing single tests. They are also easy to use and can be carried out by any health care worker who has received appropriate training. Most rapid HIV test kits may be stored at 'room temperature' (up to +20-30°C). Furthermore, the diagnostic performance of high quality rapid tests is comparable that of traditional ELISAs. WHO has developed testing algorithms showing that using sequential combinations of 2 or 3 antibody tests (ELISAs and/or rapid tests) can be used reliably to confirm HIV test results.
Table 1: General and operational characteristics of ELISAs and rapid tests

<table>
<thead>
<tr>
<th></th>
<th>ELISAs</th>
<th>Rapid tests</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Detection</strong></td>
<td>HIV antibodies in plasma/serum</td>
<td>Several can detect HIV antibodies in whole blood (finger prick samples) as well as serum/plasma</td>
</tr>
<tr>
<td><strong>Accuracy</strong></td>
<td>Depending on the test</td>
<td>Similar diagnostic performance of ELISA and rapid tests</td>
</tr>
<tr>
<td><strong>Laboratory equipment</strong></td>
<td>Micropipette, washer, incubator, spectrophotometer</td>
<td>None to minimal (micropipette)</td>
</tr>
<tr>
<td><strong>Laboratory personnel</strong></td>
<td>Skilled laboratory technician</td>
<td>Can be performed by any health care worker who has been adequately trained, including counsellors.</td>
</tr>
<tr>
<td><strong>Ease of performance</strong></td>
<td>Level 4</td>
<td>Level 1-3 depending on test type</td>
</tr>
<tr>
<td><strong>Time to perform</strong></td>
<td>&gt; 2 hours</td>
<td>Most 10-30 minutes</td>
</tr>
<tr>
<td><strong>Shelf life</strong></td>
<td>usually 12 months</td>
<td>usually 12 months</td>
</tr>
<tr>
<td><strong>Storage conditions</strong></td>
<td>2-8°C</td>
<td>Some 2-8°C; most 2-30°C</td>
</tr>
<tr>
<td><strong>Cost per test</strong></td>
<td>US$ 0.40 – 1.20</td>
<td>US$ 0.47 – 2.0</td>
</tr>
<tr>
<td><strong>Volume of tests</strong></td>
<td>Most suitable for medium-large volume testing &gt;40-90 samples/testing tray</td>
<td>Most kits suitable for small and large volume testing 1-100 samples per day</td>
</tr>
</tbody>
</table>

*Level 1 – little or no laboratory experience required  
Level 2 – reagent preparation required, procedure has multiple steps  
Level 3 – specific skills such as making dilution series or interpretation of agglutination patterns required  
Level 4 – trained laboratory technician and complex laboratory equipment required

**Cost per test, based on WHO bulk purchase price 2004 excluding freight and other charges

1.3 HIV testing and counselling as an entry point for prevention, care, treatment and support

The linkages between the testing and counselling service and the health care facility are extremely important for further prevention and care of people living with HIV/AIDS and their families. In addition, testing and counselling services associated with prevention of mother-to-child transmission (MTCT) interventions are being promoted and expanded, particularly in high-prevalence countries. Because many women present for antenatal care late in their pregnancy, same-day testing can be of great advantage. Women who attend after 36 weeks of pregnancy can gain access to interventions such as short course ARV regimens. Single-dose nevirapine (maternal and infant) can be given if a positive result is obtained from testing conducted around the time of labour. Confirmatory testing should be done after delivery. If a rapid test is done shortly after delivery ARV prophylaxis can be given to the infant. Rapid testing in antenatal care settings has been acceptable for both clients/patients and health care providers and has greatly increased the numbers of pregnant women who learn their test results.

Rapid tests also play a critical role in the management of occupational and non-occupational exposures to HIV.
In the context of the strategy to put three million people on anti-retroviral treatments by the end of 2005 (the “3 by 5” initiative), WHO recommends that the offer of HIV testing and counselling should become commonplace in those settings where those most likely to benefit from knowledge of their HIV status can be reached, such as services for tuberculosis, sexually transmitted infections, injecting drug use and acute medical care as well as antenatal care services. At the same time, people who want to learn their HIV status should have better access to voluntary counselling and testing in a variety of venues. In a context of community mobilisation around the importance of learning one’s HIV status, HIV testing and counselling should be offered whenever a patient shows signs or symptoms of HIV infection or AIDS. It should also be offered whenever this will aid their clinical diagnosis and management. In these circumstances, the offer of testing and counselling should be considered the standard of care.
2. Advantages of using rapid tests

2.1 Feasibility of using rapid tests
In countries with limited laboratory infrastructure the use of HIV rapid testing algorithms has been more feasible and as effective as ELISA/Western blot algorithms \(^9,^{10,11,12}\).

General information related to HIV testing and operational characteristics of different types of rapid tests can be consulted and/or obtained from site: http://www.who.int/EHT/Main_areas_of_work/DIL/Test_Kit_Evaluations/HIV.htm

Box 1 contains a summary of the characteristics of rapid HIV tests recommended for use in HIV testing and counselling programmes. These characteristics are explained further below.

Box 1. Summary of characteristics of rapid HIV tests for testing and counselling programmes

- **Accuracy**
  - High sensitivity >99%
  - High specificity >99%
  - High reproducibility* >98%

- **Specimen Type**
  - Preferably for use on whole blood (finger prick samples) - for ease of collection and to avoid the need for centrifugation

- **Little laboratory equipment required**

- **No constant electricity or water supply required**

- **Easy to perform**
  - Little technical training required
  - Few steps

- **Easy to interpret**
  - Visual interpretation of results, usually without equipment
  - Stable end reading point

- **Rapid** <30 minutes

- **Storage temperature**
  - Storage at room temperature for several weeks (provided there are no significant temperature fluctuations)

- **Shelf-life** 12 months or longer

- **Number tests performed**
  - Suitable for individual and small volume testing e.g. 1-40 samples per day

- **Minimal waste and waste disposal**

- **Low cost** mostly <1.0 US$ for the initial screening.

*Reproducibility, expressed as a percentage, is calculated by dividing the number of concordant results by the total number of samples retested.

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2.2 Rapid tests enable decentralisation of HIV testing and counselling
A key advantage of using WHO pre-qualified rapid tests is that the reliance on laboratory services for obtaining test results is dramatically reduced (provided minimum standards for ensuring quality of test procedures and record-keeping are adhered to). This is of major importance, as it allows HIV testing and counselling to be decentralised to the level of community services away from major urban centres. Rapid tests are especially suited for use in rural settings. Available data shows that decentralised services have high acceptance from clients, and the speed of obtaining test results has resulted in much higher uptake of test results.
2.3 Acceptability of HIV testing and counselling

2.3.1 Client acceptance and increased client return rate to collect test results
In developed countries, a large proportion of people who are tested for HIV in clinical settings or in voluntary counselling and testing sites do not return for their test result\textsuperscript{13,14,15,16}. This wastes both financial and human resources and means that some people who test positive do not benefit from treatment, care and prevention options.

Many testing and counselling sites have reported an increased demand after rapid testing was introduced, suggesting that many people prefer services where they can receive their test result without delay\textsuperscript{17}. This is consistent with several studies that found that the majority of people tested preferred to receive their results on the same day\textsuperscript{8}. In several studies from HIV testing and counselling sites in resource-constrained settings, the proportion of patients who received post-test counselling increased significantly after the introduction of rapid testing. In a trial in Kenya where women were randomly assigned to receive either rapid or ELISA testing, rapid testing significantly increased the proportion of women receiving test results (OR 1.3, 95% CI 1.2-1.4)\textsuperscript{18}.

2.3.2 Counsellor acceptance
In some areas, counsellors initially worried about the accuracy of rapid testing and the possibility that same day testing would be more stressful for them. Counsellors often have to prepare themselves emotionally before informing a client about positive test results. Several reports\textsuperscript{4,8} and case studies\textsuperscript{19} have indicated that rapid tests improve the acceptability of HIV testing to both providers and clients.

2.4 Short time to obtain test result
Most rapid tests will provide test results within 10-30 minutes. Same-day testing is convenient for people attending HIV testing and counselling sites because it cuts down on travelling time and expenses.

2.5 Reduced cost
The cost of both ELISA tests and rapid tests has decreased substantially over time. In the WHO bulk procurement scheme, prices range between US$0.40-US$2.00 per test. In general, rapid tests are slightly more expensive than ELISA tests, but do not require the initial investment in equipment and ongoing operational expenses. Because ELISA tests are configured for multiple tests, unless all ELISA reagent wells are used (40-90), the reagent cost per test result is in practice considerably higher with ELISA than with rapid tests.

A greater proportion of clients receive their test results with rapid test algorithms leading to less wastage of test kits and increased efficiency. When compared to other testing strategies, testing algorithms based on rapid tests have a lower cost per patient who receives results\textsuperscript{20}. Client’s transportation costs and travel time are decreased, as rapid tests provide same-day results, and costs to the health service are decreased as less return visits to the clinic are required.
2.6 Ease of performance and ease of interpretation of test result
Non-laboratory health care workers can perform most of the rapid tests after basic training (see Section 4.5). This training should include how to correctly identify the client, how to perform and interpret the test within the specified reading time, assuring the quality of results, record keeping, maintaining client confidentiality, and biosafety aspects including safe waste disposal.

2.7 Minimal facilities for storage and shelf life
Most rapid tests require no laboratory equipment and can be performed in settings with limited facilities. Many rapid tests do not require refrigeration and these will be more suitable for remote and rural areas and other sites without a constant electricity supply. However, temperatures should not go below 2°C nor above 20-30°C depending on the test kit used. Extreme low and high temperatures affect the quality and shelf life of diagnostic tests, and it is advisable to monitor the temperature fluctuations in the storage room. In practice, a refrigerator or an air-conditioned room may be required in tropical climates. Central storage facilities should include adequate cold storage space for all rapid tests kept in stock. As results are read visually there should be sufficient light to allow for correct interpretation.

Stock management procedures should ensure that remote areas and sites performing a smaller number of tests receive regular supplies with appropriate kit size and a longer shelf life if required.

2.8 Flexibility in numbers of tests performed
Several rapid test kits allow the testing of single specimens whereas the design of ELISA tests makes them most suitable for batch testing, i.e., at least 40-90 specimens per run. Depending on the set up ELISA tests may be suitable for settings in which a large number of tests are performed, but in many testing and counselling sites the ability to perform single tests or small numbers of tests is a key advantage.

2.9 Reduction in occupational exposure risk
As most occupational exposure occurs during venepuncture, the risk of occupational exposure risk is substantially reduced when finger prick blood collection is used.
3. Testing strategies for testing and counselling services

3.1 Calculating the accuracy of HIV tests used in HIV testing and counselling

An essential requirement of all testing in HIV testing and counselling services is the reliability of the test result given to the individual. The rapid tests that can be obtained through the WHO bulk procurement scheme have been evaluated by WHO and have met preset criteria. The levels of sensitivity and specificity of these rapid tests are greater than or equal to 99% and 99% respectively (see Box 2). It should be remembered that no test is 100% sensitive and 100% specific. Many studies have shown that the sensitivity and specificity of rapid tests are similar to those of the standard ELISA tests. This finding has been confirmed in many different countries.

Box 2: Calculating the accuracy of HIV tests

<table>
<thead>
<tr>
<th>Test result</th>
<th>Actual HIV status</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HIV infected</td>
<td>HIV uninfected</td>
</tr>
<tr>
<td>Positive</td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>A+B</td>
<td>Total</td>
</tr>
<tr>
<td>Negative</td>
<td>C</td>
<td>D</td>
</tr>
<tr>
<td>Total</td>
<td>A+C</td>
<td>B+D</td>
</tr>
</tbody>
</table>

* A= people with HIV who test positive (true positive)
* B= people without HIV who test positive (false positive)
* C= people with HIV who test negative (false negative)
* D= people without HIV who test negative (true negative)

A+C = all people who truly are infected with HIV
B+D = all people who truly are not infected with HIV

- **Sensitivity**
  Probability of a positive test in people infected with HIV, expressed as a percentage
  \[ \frac{A}{A+C} \]

- **Specificity**
  Probability of a negative test in people uninfected, expressed as a percentage
  \[ \frac{D}{B+D} \]

- **Positive predictive value**
  Probability the person is HIV-infected when the test is positive, expressed as a percentage
  \[ \frac{A}{A+B} \]

- **Negative predictive value**
  Probability the person is uninfected when the test is negative, expressed as a percentage
  \[ \frac{D}{C+D} \]

The accuracy of the test can be described in terms of the degree to which people with and without HIV infection are correctly categorised. The **sensitivity** of a test is the capacity of a test to correctly identify those individuals that are not infected with HIV, thus a very sensitive test will have few false negatives. The **specificity** of a test is the capacity of a test to correctly identify those individuals that are infected with HIV, thus a very specific test will have few false positives.

Alternatively, the accuracy of the test can be expressed as the extent to which being categorised as positive predicts the presence HIV-infection (**positive predictive value**). Similarly, the **negative predictive value** of a test is the proportion of people with a negative test result who are uninfected. The predictive values are the factors that apply most directly to the decision to use or not use a given test or testing algorithm.
The determinants of predictive values are the specificity and sensitivity of the test, and the prevalence of HIV in the population being tested. Even with a very accurate test (high sensitivity and high specificity), in settings with a low HIV prevalence (e.g. <1%) the positive predictive value of a test may not be sufficiently reliable (see Table 2). In general, the higher the prevalence of HIV infection in the population, the greater the probability that a person testing positive is truly infected. With increasing HIV prevalence, the proportion of false-positives goes down. Conversely, the probability that a person with a negative test result is uninfected goes down as the HIV prevalence increases. It is necessary to conduct a second or supplemental test if the first test is reactive as this markedly increases the positive predictive value (see Table 2). In settings with a low-level HIV epidemic4, tests with a sensitivity or specificity greater than 99% should be used in order to achieve satisfactory positive predictive values.

Table 2: Positive and Negative predictive values* at various HIV prevalence

<table>
<thead>
<tr>
<th>HIV prevalence</th>
<th>0.1%</th>
<th>1%</th>
<th>5%</th>
<th>10%</th>
<th>30%</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPV with one</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>non-reactive</td>
<td>100.0%</td>
<td>100.0%</td>
<td>99.9%</td>
<td>99.9%</td>
<td>99.6%</td>
</tr>
<tr>
<td>test</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PPV with one</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>reactive test</td>
<td>9.0%</td>
<td>50%</td>
<td>83.9%</td>
<td>91.7%</td>
<td>98.5%</td>
</tr>
<tr>
<td>PPV with two</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>reactive tests</td>
<td>90.8%</td>
<td>99.0%</td>
<td>99.8%</td>
<td>99.9%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

*A sensitivity of 99% and specificity of 99% have been used in these calculations, Predictive values have been rounded to one decimal place
NPV-negative predictive value, PPV positive predictive value

3.2 Selection of test kits and testing algorithms

Some rapid tests may not have adequate sensitivity or specificity profiles and should not be used. WHO provides reports on evaluations21 of performance and major operational characteristics of commercially available rapid tests. This information can be used to select suitable candidates for the national algorithms. These evaluations may be found at the following website:
http://www.who.int/EHT/Main_areas_of_work/DIL/Test_Kit_Evaluations/HIV.htm

The selection of the rapid HIV tests and test algorithm to be used in testing and counselling services is a responsibility of the national government – usually the Ministry of Health and the National AIDS Control Program. This responsibility should not be delegated (either overtly or by neglect) to commercial enterprises, donor agencies, or external aid programmes. The decision on which tests to use should be made following country-level technical assessments and the evaluation of other relevant factors, such as cost, current and continued availability, shelf-life, and storage requirements. Preferably these assessments and follow up support to the testing and counselling services should be the responsibility of the national HIV reference laboratory and referral laboratories.

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4 Low-level epidemic: The epidemic state in which HIV has never spread to significant levels in any subpopulation, although HIV infection may have existed for many years. (HIV prevalence has not consistently exceeded 5% in any defined subpopulation.)
Prior to selecting rapid test kits many countries evaluate tests using local specimens to confirm sensitivity and specificity in their particular setting. Guidelines for evaluating rapid HIV tests may be found in the document, “Guidelines for Appropriate Evaluations of HIV Testing Technologies in Africa” published jointly by the WHO Regional Office for Africa, the U.S. Centers for Disease Control and Prevention, and the Association of Public Health Laboratories. This document provides practical guidance for developing country-specific protocols for conducting evaluations of HIV rapid tests. Detailed descriptions of issues to consider when planning an evaluation, quality assurance, evaluation materials, phases of the evaluation, and laboratory safety guidance are also given in the above mentioned Guidelines.

Many new rapid tests are being developed and promoted by their manufacturers, while some older tests are no longer available. It is important that the rapid tests and testing algorithms chosen for use in HIV testing and counselling have been thoroughly evaluated on samples from the particular geographic region where they are to be used.

The reliability of the result given to the individual depends on the accuracy of the individual test and the testing algorithm, as well as the overall performance of the testing and counselling service. The performance of the testing and counselling service in terms of overall quality of the test procedures and test results is influenced by:

- The quality of the kit and batch (lot number) provided by the manufacturer
- Transport and storage conditions of the kits
- Correct collection and quality of the specimens
- Skill of the staff performing the testing
- Presence of a quality assurance system (including standard operating procedures for the complete process) wherever the testing is conducted, whether it be at a rural testing and counselling service or a national reference laboratory in the capital city.
- On-going training and follow up of testing problems encountered
- The prevalence of HIV in the population tested (the proportion of those in the population with HIV infection).

Choosing the most appropriate screening tests and the combination of tests for confirmation is essential to ensure an accurate diagnosis of HIV. The algorithm in Flow Chart 1 is adapted from previously published WHO algorithms for HIV diagnosis, but takes into account the increased specificity of current rapid tests, resulting in a higher positive predictive value. Tests can be used in sequence or in parallel (see flow chart 2).
Flow Chart 1: Algorithm for the use of HIV Rapid Tests in Testing and Counselling Services (see notes below)

**NOTES:**
* In the context of labour in a MTCT-prevention setting, it is advised to give a single dose of nevirapine on the basis of a single positive rapid test. This should then be confirmed after delivery. In late pregnancy in MTCT-prevention settings, it may exceptionally be considered to use a third rapid test as a tie-breaker after inconclusive results where the need to start short-course ARV prophylaxis must be decided without delay.

When choosing the second test, it is important to select one that uses different antigens and/or a different platform and that demonstrates appropriate levels of specificity and sensitivity.

If a first positive (reactive) and a second negative (non-reactive) test result occurs in more than 5% of cases, the testing process should be reviewed.

Counselling content in the case of negative and positive test results is suggested in Appendix 1.

Where a result is inconclusive, this should be reported to the person being tested. Post-test counselling should focus on the possibility of the test being performed during the “window period”, i.e., when antibodies have not yet formed after actual exposure to HIV. All those with inconclusive results should be encouraged to avoid the possibility of future risk behaviour and be offered re-testing at the same facility in 6 weeks time to allow for the window period to have passed. Community-based or health centre-based support should also be offered during the waiting period. If the same results are obtained at re-testing after 6 weeks, the person (or a suitable specimen) should be sent to a referral laboratory for further HIV testing.
4. Practical considerations when using rapid tests

4.1 Choice of specimens to be used in testing

4.1.1 Whole blood finger prick specimens
Rapid test kits that use whole blood from finger prick samples may be preferred, as finger prick samples are easy to perform, require minimal equipment and can be carried out by the appropriately trained counsellor. Used lancets must NOT be reused but be disposed of in an appropriate sharps container and the puncture site covered. Depending on the algorithm being used, an additional finger prick may need to be performed in the case of a positive result.

4.1.2 Serum specimens
In contrast to whole blood finger prick specimens, the use of serum specimens requires that venous blood be drawn using syringes and collection tubes (e.g. vacutainers), and requires serum to be separated from blood. This requires much more time, staff with a higher level of training, and collecting venous blood samples is costly. However, there is a wider range of rapid tests that can be used with serum specimens and only one sample needs to be collected.

4.2 Parallel testing versus Serial testing (see Flow Chart 2)
Parallel testing involves testing all blood samples with two HIV tests simultaneously (‘in parallel’) and the results given as shown in the flow chart. With ‘serial testing’ an initial blood sample is taken and tested. If the result is negative the result is given. If the result is positive the blood sample is tested using a second, different HIV test. If a finger prick sample has been used a further finger prick sample might be taken for the second HIV test. In most settings, WHO recommends serial testing because it is more economic, that is, a second test is required only when the initial sample test is positive. The decision on which option to take in defined settings - serial or parallel testing - needs to be taken after a thorough analysis of scientific evidence, logistics, test performance and costing/affordability of the alternative algorithms.

4.3 Safety Precautions
Each laboratory or testing site must follow universal (standard) precautions measures designed to ensure the safety of health care staff and to prevent transmission of human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C (HCV) and other blood-borne pathogens. Under universal precautions, blood and certain body fluids of ALL patients should be considered as potentially infectious for HIV, HBV and other blood-borne pathogens. Guidelines for good laboratory practice have been developed that, if followed, will ensure safety and keep accidents to a minimum. Staff should be trained in how to deal with accidents (e.g., spills) and provided with written copies of safety precautions. For further details see the Laboratory Biosafety Manual, second edition, World Health Organization, Geneva, 1993 (ISBN 92 4 154450 3) and the Communicable Diseases Surveillance and Response section of the WHO website, http://www.who.int/emc, where information on laboratory biosafety and transport of infectious substances may be found. Box 3 (below) specifies standard testing area safety rules.
4.4 Who can perform rapid tests?
After appropriate training and with supervision, health care workers with little or no previous laboratory experience can perform most rapid tests. The use of non-laboratory staff will facilitate access to testing and counselling in small communities and rural sites where professional laboratory personnel are often not available. If non-laboratory personnel are to perform rapid tests, initial training, ongoing supervision, and periodic assessment of proficiency should be provided to ensure that the quality of testing is maintained. In some countries there are legal restrictions that must be considered regarding the qualifications of people who perform blood tests. Persons without such qualifications should work under the authority of people who have the required qualifications.
Box 3. Testing Area Safety Rules

Important rules, not necessarily in order of importance, should be adhered to when working in a laboratory or performing laboratory tests at another location:

1. Pipetting by mouth should be prohibited.
2. Eating, drinking, smoking, storing food and applying cosmetics must not be permitted in the testing work areas.
3. Labels must not be licked; materials must not be placed in the mouth.
4. The testing site should be kept neat, clean, and free of materials that are not pertinent to the work.
5. Work surfaces must be decontaminated after any spill of potentially dangerous material and at the end of the working day.
6. Needles should not be recapped. Sharps such as needles and lancets should not be reused but disposed of in a special waste container.
7. Before taking a finger prick the finger should be decontaminated and the wound afterwards covered with a plaster.
8. Members of the staff must wash their hands after handling infectious materials, and before they leave the laboratory or testing area.
9. Potentially contaminated and ordinary office waste must be kept in separate and clearly labelled waste containers.
10. All potentially contaminated materials and specimens must be decontaminated before disposal or cleaning for reuse.
11. Only persons who have been advised of the potential hazards should be allowed to enter testing working areas. Doors should be kept closed when testing is in progress; children should be excluded from testing areas.
12. Gloves appropriate for the work must be worn for all procedures that may involve accidental direct contact with blood and infectious materials. After use, gloves should be removed and destroyed with other laboratory wastes before disposal. Hands must then be washed. Do not wash or disinfect surgical or examination gloves for reuse.
13. All spills, accidents and overt or potential exposures to infectious materials must be reported immediately to the supervisor. A written record of such accidents and incidents should be maintained.
14. The supervisor should ensure that training in testing area safety is provided. A safety manual or operations manual should be adopted that identifies known and potential hazards and that specifies practices and procedures to minimize or eliminate such hazards.

4.5 Core training for people administering HIV rapid testing

Training curricula on core competencies for administering rapid tests and managing data associated with testing and counselling are being developed by WHO and key partners. However, such training is presently being provided in some settings (such as the CDC-Kenya) and the curricula they use comprise the following core topics as a 3-day module included within 3 weeks of training in testing and in counselling:

- The virology and immunology of HIV/AIDS, and the principles of test kit operation
- Standard operating procedures (SOP’s) for sample collection, packaging and transportation in relation to rapid testing and quality control/assurance
- Biosafety in testing and counselling settings
• Principles of HIV testing with particular reference to rapid HIV testing, criteria for test kit selection, testing principles and procedures, interpreting test results, and problem-solving
• Principles and concepts of quality control and quality assurance, particularly in testing and counselling settings
• Practical sessions on sample collection, HIV testing and bio-safety.
• Managing data entry and management in testing and counselling services, particularly to avoid transcription errors and to maintain confidentiality.

All topics are covered in language appropriate to the audience with appropriate examples given throughout. Trainers have practical experience of all types of testing and appropriate data management.

4.6 Detection of the difference between HIV-1 and HIV-2
In some parts of West Africa a significant proportion of HIV infection is due to HIV-2. While most rapid tests detect both HIV-1 and HIV-2, most do not differentiate between them. Although this is not an immediate concern for testing and counselling services, it may be an important consideration for ARV treatment programs in regions where HIV-2 is endemic. In these ARV treatment settings, differentiation between HIV-1 and HIV-2 may be appropriate before starting therapy. Differentiation between HIV-1 and HIV-2 infections should be carried out at referral laboratories.

4.7 The role of national reference and referral laboratories for confirmation and quality assurance

4.7.1 The role of national reference laboratories
Technical assessments and evaluation of test kits should be the responsibility of the national HIV reference laboratory(ies). The development and review of test algorithms should be undertaken by the National Reference Laboratory(ies). A successful QA program may be supported from the National Reference Laboratory(ies) or a similar institution with professionally trained laboratory staff. Requirements should be rigorously complied with to ensure the accuracy and reliability of the results given. In addition, the national reference laboratories should co-ordinate the training of personal and quality assurance procedures of testing and counselling services.

4.7.2 The role of referral laboratories
A crucial advantage of rapid tests is that they enable HIV testing to be done at a decentralised level and dependence on referral laboratories is effectively minimized (provided minimum standards for ensuring quality of test procedures and record-keeping are adhered to).

Written polices and standard operating procedures for each key activity within the entire testing process (i.e. from a client entering the testing and counselling centre to issuing of the result) will assist in identifying problems and areas needing improvement.

Where testing produces discordant results, i.e., the first test is positive (reactive) and the second is negative (non-reactive), the person should be informed that the result is unclear and counselling should be provided on the possibility of the window period and the need to avoid activities that may transmit HIV infection to others until the infection status is clarified. If the same discordant result is found when re-testing is done after six weeks, samples should be sent to the referral laboratory. In this way, referral laboratory back-up is a necessary pre-requisite for all testing and counselling facilities. When
necessary, referral laboratories can also assist with more sophisticated testing, such as differentiation between HIV-1 and HIV-2 or early detection in infants born to HIV positive mothers.

Referral laboratories should also support the training of staff in testing and counselling services, and assist with quality assurance procedures.
5. Quality assurance (QA)

Quality assurance is defined as the set of planned and systematic activities to provide adequate confidence that requirements for quality will be met.

It is critical that each facility performing HIV testing establishes and implements a QA programme to monitor and evaluate all functions and services throughout the total testing process i.e. from the client entering the service, through the counselling and testing steps, through the provision of the test result, and possible referral.

5.1 Quality control (QC)
Quality control refers to those measures that must be included to verify that the test is working, and that must be taken to monitor the validity of the technical aspects of the test procedure, e.g. were all reagents at room temperature before starting the test procedure; was the control line of the test clearly visible. Quality control includes the testing of samples with known results to verify that the testing procedure and materials are working properly. When quality control specimens that are analysed daily produce acceptable results, and all other conditions related to the test kit performance have been met, then test results on the samples from clients may be accepted as valid.

5.2 External Quality Assessment (EQA)

Every testing facility must be able to demonstrate and document its competence in performing all HIV tests. External Quality Assessment (EQA) is part and parcel of an testing QA program. The focus of EQA is on the identification of laboratories or testing sites that perform below standard so that additional training and/or other measures can be instituted to improve performance. There are three complementary ways in which the quality of testing services can be assessed by an external authority:

a. On-site Audit
Having on-site audit is necessary to review that all SOPs are adhered to, including quality control, record keeping, and observation of staff performance. Additionally, on-site audit is an opportunity to directly administer a proficiency test to each individual performing testing. A program of on-site auditing should include a standard checklist of testing service indicators. Auditors, inspectors and supervisors should be trained to perform consistent reviews of testing sites. Standard checklists and evaluation methods allow for the collection and comparison of consistent information from multiple sites.

b. Proficiency Testing (PT) or external quality assessment schemes (EQAS)
Proficiency testing or EQAS involves the distribution of small panels of well characterised test samples (6-10 specimens) by the EQAS organiser (e.g., the National Reference Laboratory or another organiser) to all testing sites. The limitations of PT/EQAS are that they are spot checks in time – they represent the upper performance level, they usually involve a small number of samples, and there are a limited number of assessments per year. Often, the test results may not represent the routine test performance.

c. Blinded Rechecking
Retesting a selected sample of specimens in a reference laboratory may also be an option to assess the quality of testing. This can be accomplished by forwarding all positive and 5-10% of negative specimens for re-testing when a serum or plasma specimen is available.
Alternatively, dried blood spots (DBS) can be used for blinded rechecking in situations where it is impractical to refer specimens for additional testing (e.g. whole blood finger prick tests). The dried blood spots are collected at the time of patient testing on filter paper and transported to a reference laboratory. The use of this method requires a reference laboratory that has demonstrated proficiency with eluting the specimens and performing standard EIA methods. Additional concerns include the logistics and methods of collecting dried blood spots in the testing protocol. Although a sample of specimens re-tested by dried blood spots may be desirable, this may be difficult to implement in the flow of testing and counseling of patients. Additionally, testing a percentage of specimens, such as 10% may be problematic. Countries may consider random sampling of dried blood spots, e.g., bimonthly, or at a given time or day. Further development of dried blood spots protocols is necessary to assist with the expansion of rapid testing for testing and counselling services, especially at remote sites.
6. Additional considerations when using rapid tests

6.1 Decision time or "thinking" time
Before rapid tests were widely available people attending voluntary counselling and testing sites would have pre-test counselling before a venous blood sample would be taken for HIV testing. There would then follow a period of 3 days to 2 weeks before returning to receive the result of their HIV test and post-test counselling. It was argued that this waiting time affords an opportunity to reflect on issues raised in pre-test counselling and to involve partners or family members in decision-making. However, for the majority of people this waiting time turns out to be a worrying period and they prefer to receive the test result the same day.

The compression of pre-test and post-test counselling sessions into a single time period with the absence of a 3-day to 2-week waiting period led to concerns that the HIV counselling associated with rapid testing may not be as effective in promoting HIV risk reduction as a counselling and testing process spread over several days. There is little information comparing the effectiveness of same day testing and counselling in outcome versus a testing and counselling process spread over a longer time.

Particular care should be taken for people who are attending services for other reasons and not primarily for HIV testing and counselling, e.g., antenatal clinic attendees, tuberculosis and general hospital service attendees, and injecting drug users attending drug dependence treatment programs. They may not have fully grasped the possible consequences of testing. When rapid tests are used in testing and counselling sites, counsellors should ensure that clients understand the implications of HIV testing and have adequate support available should they receive a positive test or inconclusive result (see "Guiding Principles", section 1.1). If a client is reluctant or uncertain about HIV testing, testing can be deferred and a further pre-test counselling session arranged.

6.2 HIV testing performed in sites not previously providing testing and counselling
Sites using ELISA tests require affiliation with a qualified laboratory that adheres to strict procedures to guarantee confidentiality and ensure the quality of testing and test procedures. With the development of rapid testing, community-based organizations such as home-based care programmes can set up testing and counselling services and integrate testing and counselling into the range of services that they routinely offer their clients. This possibility offers the advantages of increasing access to testing and counselling and providing services for people who may not have contact with routine health services or who are reluctant to attend health services.

On the other hand, unless testing and counselling in these settings is supervised closely and subject to ongoing monitoring and evaluation, it might be carried out by people without adequate training or experience. Referral procedures and access to ongoing counselling and support services must be ensured. Finally, training for all staff involved in provision of site-based testing and counselling must include principles of ethical testing and counselling, including ensuring confidentiality and appropriate information management of test-related information (see "Guiding Principles", section 1.1). Monitoring the quality of counselling and the availability of referral services for complex cases should also be ensured1.
6.3 Testing without consent
The ease of performing rapid testing could result in people being tested without adequate counselling and informed consent, and could result in discrimination, violence and other unacceptable consequences. For example, rapid testing could make it easier to test prisoners, people in custody awaiting trial and pre-operative patients. Policies to avoid inappropriate use of HIV tests need to be stated and enforced.

Section 1.1 (“Guiding Principles”) specifies the minimum ethical conditions under which HIV testing should be performed, and steps to be considered in the rare instances when confidentiality of HIV status may be breached.

6.4 Health provider testing
In testing and counselling services where rapid tests are used, counsellors or other health workers might be tempted to test themselves. This possibility should be anticipated and discussed with counsellors and other staff. Arrangements should be made to ensure that staff have appropriate access to testing and counselling for themselves and their family members (NOT self-testing), at a separate centre if necessary to ensure confidentiality. Facilities for support and treatment services for HIV positive health workers should be considered.
**APPENDIX I.**
**PROTOCOL FOR TESTING AND COUNSELLING CONTENT AND MANAGEMENT**

<table>
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<tr>
<th>ACTION</th>
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| **Group pre-test education**  | - HIV and AIDS overview  
                              - HIV transmission, sources, prevention  
                              - STIs and HIV  
                              - MTCT and its prevention  
                              - HIV-testing processes  
                              - Benefits and risks of HIV testing  
                              - Confidentiality  
                              - Implications of both positive and negative test results  
                              - Identification of supportive HIV services  
                              - Family planning  
                              - Individual counselling and risk assessment  
                              - Testing and counselling for couples |
| Basic information can be provided in group sessions by a healthcare educator who has only limited training in HIV counselling. Healthcare workers and counsellors should work together to identify clients who need one-on-one counselling and referral. It is important that each client is treated as an individual with unique concerns. |
| Key considerations when providing information to groups include the following:  
  - Adapting the scope and depth of information to the group’s knowledge  
  - Reinforcing behaviour change efforts, including community education on safe sex practices  
  - Using teaching modalities, such as videos or role plays, to reinforce key concepts  
  - Having sufficient knowledge and skills to comfortably answer questions  
  - Recognizing the need for individual counselling and referral |

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<tr>
<th><strong>Individual pre-test counseling</strong></th>
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<tr>
<td>In some cases, counsellors might need to initiate one-on-one interventions to clarify information provided in group sessions. Counsellors should assess, case by case, whether referral to skilled counselling services is necessary.</td>
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<tr>
<td>Each person should receive all the information s/he needs to make an informed decision about whether to be tested for HIV. Sometimes the decision-making process takes time and requires several visits before the client fully understands the implications—positive and negative—of knowing their HIV status.</td>
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<td>In some cultures, decision-making is conducted by consensus or by the client’s relatives in a large extended family. In such cases, health workers should make an effort to welcome family decision-makers into the care setting and provide the same information and pretest counselling that</td>
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<td>would be given to the person individually. When a second person (partner, parent) is involved in decision-making, adequate information should be provided in accordance with informed-consent requirements.</td>
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<td><strong>Obtaining informed consent</strong></td>
<td>• Ensure sufficient time to think through the issues</td>
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<td>• Check understanding and correct any misconceptions</td>
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<td>- Specifically ask the client if they agree to be tested or wish to “opt-out”</td>
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<tr>
<td><strong>Administering the test</strong></td>
<td>• Use algorithm for rapid test administration and confirmation (Flow Chart 1)</td>
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<tr>
<td><strong>Giving POSITIVE results</strong></td>
<td>• Establish client readiness to receive the result.</td>
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<tr>
<td><strong>NOTE:</strong> A person whose HIV test is confirmed positive is infected with HIV. Counselling people who test positive for HIV is a difficult task. Most providers find it difficult to inform their clients of positive HIV test results. Client reactions can range from acceptance and resignation to shock and disbelief. The provider must remain nonjudgmental, supportive, and emotionally stable throughout the counselling process. Referral for additional support often is necessary. Providers should expect that most people will not hear much of what the counsellor says after delivering the results. Education and information will need to be provided during several session over the weeks ahead. Because the client might receive care from other healthcare workers over time, it is important to document all TC education and post-test counselling services.</td>
<td>• Give the result simply and clearly, and give her/him time to consider the result.</td>
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<td>• Use open-ended questions to determine their understanding of the result.</td>
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<td>• Review facts covered in pretest sessions.</td>
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<td>• Acknowledge the difficulty of receiving the diagnosis and support their feelings.</td>
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<td>• Discuss benefits of knowing one’s serostatus.</td>
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<td>• Determine how s/he will get through the next few hours or days.</td>
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<td>• Check to see who might be available to offer immediate support.</td>
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<td>• Discuss possible disclosure of the result and when it may happen and with whom – suggest telling only closest contacts (spouse, significant other) in the short term</td>
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<td>• Discuss any immediate concerns, including personal safety.</td>
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<td>• Arrange a specific date and time for follow-up visits with the same counsellor or worker if possible.</td>
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<td>• Provide the client with a telephone number and contact person's name, if possible.</td>
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<td></td>
<td>• Provide an emergency telephone number and contact person's name, if possible.</td>
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<tr>
<td><strong>Giving NEGATIVE results</strong></td>
<td>• Establish client readiness to receive the result.</td>
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<tr>
<td><strong>NOTE:</strong> A negative result still requires an emphasis to be made on future risk reduction and avoidance, particularly PMTCT. There may therefore be a need for the counsellor to follow-up with the person who was tested, or to suggest referral to appropriate other services (e.g., TB, STI), to reinforce and</td>
<td>• Give result simply and clearly</td>
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<td>• Explain the meaning of the result and the “window period.”</td>
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<td>• Provide information on prevention of HIV infection.</td>
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<td>• Describe the risk of MTCT if she becomes</td>
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<tr>
<td>support risk reduction behaviours and messages.</td>
<td>infected during pregnancy or while breastfeeding.</td>
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<td>• Educate partner and encourage partner testing.</td>
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<td>• Provide linkage to future counselling, if needed.</td>
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<td></td>
<td>• Discuss possible disclosure and when it may happen, identify who needs to know and how to tell them</td>
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<td>• Refer to companion services if appropriate (e.g., TB, STI, ANC)</td>
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**Giving INCONCLUSIVE results**

The most important factor in evaluating inconclusive results is risk assessment - people with low or no risk history are rarely infected with HIV. However, all those with inconclusive results are likely to require some support while waiting to be re-tested.

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<td></td>
<td>• Explain the possibility of testing having happened during the “window” period, or in late-stage HIV-infection</td>
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<td>• Avoid possibility of future risk behaviour</td>
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<td>• Offer re-testing at the same facility in 6 weeks</td>
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<td></td>
<td>• Refer for community- or health centre-based support during waiting period</td>
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**Assessing and managing adverse events**

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<td></td>
<td>• Use post-test result-giving and counselling session to assess for immediate concerns including possible suicide, depression, anger, violence, and management of partner/family consequences</td>
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<td></td>
<td>• Identify trusted supports in family and social environment</td>
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<td>• Explain concern about possible adverse events and that further support is needed and will be sought with permission</td>
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**Referral for follow-up**

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<td>• ALL people found positive require medical referral</td>
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<td>• All people found positive require psychosocial referral, e.g., from NGO and community-based support organisations</td>
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<td>• Post-test follow-up counselling should be organised on site or as appropriate</td>
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<td>• Where specific adverse events arise with giving the result, make referrals to appropriate colleagues/services</td>
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<td></td>
<td>• HIV negative people may require referral for screening and treatment (e.g., STI, TB)</td>
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APPENDIX 2. Post-Test Counselling Checklist, Negative Result

- Counselling is a relationship. Connect with the client, answer questions, and make sure the client understands the information you are providing.
- Make sure you have the test results.
- Greet the client. Establish rapport.
- Ask whether the client has any questions that have come up since being tested. Answer questions and let the client know counselling will continue to be available to help with important decisions.
- Recap the pretest counselling session. Let the client know you are doing this to make sure he or she remembers important information.
- Ask the following questions:
  - Do you remember the differences between HIV and AIDS?
  - How is the knowledge of your status going to help you?
  - How can you protect yourself further from infection?
  - Who else will be affected by this result?
- Give the client time. Ask the client, “Are you ready to receive your HIV test result?”
- State in a neutral tone: “Your test result is negative.”
- Pause and wait for the client to respond before continuing. Give the client time to express any emotions.
- If the client would like to see the results, provide them.
- Check the client's understanding of the meaning of the results.
- Discuss and support the client's feelings and emotions.
- If there was a recent risk exposure, discuss the need to retest.
- Discuss ways to remain negative and assist the client in exploring future risk reduction so that his or her status remains negative, in view of the high risk associated with new infections.
- Discuss disclosure support (subsequent counselling sessions).
- Discuss risk reduction strategies with the client:
  - Good clinic attendance
  - Good nutrition status
  - Avoidance of alcohol
  - Use of condoms
  - Limiting the number of sexual partners
- Talk with the client again about partner testing.
- Inform the client that counselling is available for couples.
- Discuss disclosure.
- Discuss support issues and subsequent counselling sessions.
- Ask whether the client has questions or concerns. Give the client contact information for the clinic should any new concerns arise.
- Remind pregnant mothers and families that counselling will be available throughout the pregnancy to help them plan for the future and to obtain needed services.
APPENDIX 3 Post-Test Counselling Checklist, Positive Results

- Counselling is a relationship. Connect with the client, answer questions, and make sure the client understands the information you are providing.

- Make sure you have the test results.
- Greet the client. Establish rapport.
- Ask whether the client has any questions that have come up since being tested. Answer questions and let client know counselling will continue to be available to help with important decisions.
- Recap the pretest information provision of counselling session. Let the client know you are doing this to make sure he or she can recall the information.
- Ask the following questions:
  - Do you remember the differences between HIV and AIDS?
  - How is the knowledge of your status going to help you?
  - How can you protect yourself from further infection?
  - Who else will be affected by this result?
- Give the client time. Ask the client, “Are you ready to receive your HIV test result?”
- State in a neutral tone: “Your test result is positive.”
- Pause and wait for the client to respond before continuing. Give the client time to express any emotions.
- If the client would like to see the results, provide them.
- Check the client's understanding of the meaning of the result.
- Normalize the client's feelings and emotions.
- Discuss disclosure and support issues and subsequent counselling sessions.
- Where appropriate, revisit PMTCT issues such as:
  - Antiretroviral prophylaxis
  - Condom use
  - Infant feeding
  - Childbirth plans
  - Adequate nutrition
- Prompt medical attention, prophylaxis, and treatment of opportunistic infections
- Ways to stay healthy
- Stress management and support systems
- Reducing the risk of infecting others and screening and treatment for sexually transmitted infections
- Identify sources of hope for the client, such as family, friends, community-based services, spiritual supports, and treatment options. Make referrals when appropriate.
- Ask whether the client has questions or concerns. Give the client contact information for the clinic should concerns arise.
- Remind mothers and families that counselling will be available throughout the pregnancy to help them plan for the future and obtain needed services.
- If the client already has children, discuss and plan for testing of children.
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