

WHO RECOMMENDATIONS TO ASSURE HIV TESTING QUALITY

JULY 2015



New *Consolidated guidelines on HIV testing services* from WHO recommend standardized HIV testing strategies to correctly diagnose HIV infection.

Getting the right results

An HIV test result can have life-altering and lifelong consequences. Correct test results are crucial. However, misdiagnosis of HIV status is too common – as high as 10% in one study that retested people initially diagnosed HIV-positive. To assure test results are accurate and prevent misdiagnosis, it is critical that national programmes follow validated testing algorithms and WHO-recommended testing strategies.

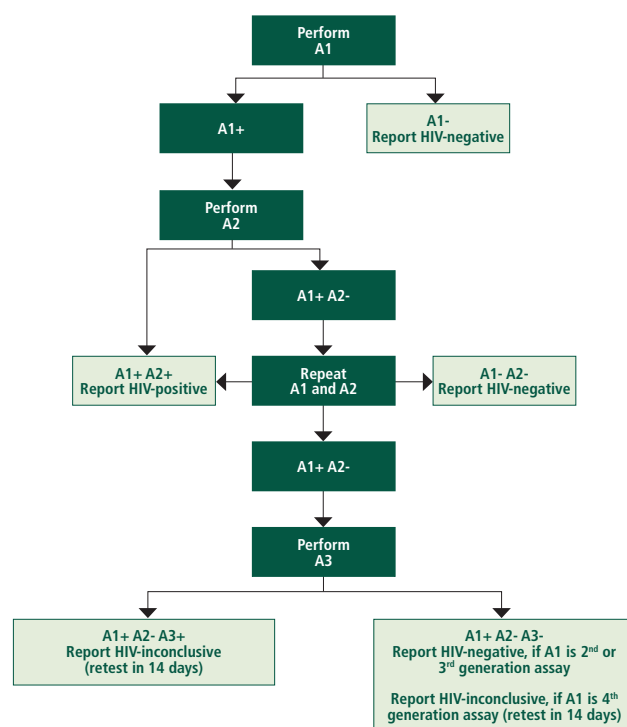
Testing strategies and algorithms

WHO's standardized **testing strategies** (Figs. 1 and 2) are simple and low-cost, and they maximize the accuracy of HIV diagnosis. These testing strategies differ for populations with high or low HIV prevalence.* In both instances, however, **a series of three different assays – rapid diagnostic tests (RDTs), enzyme immunoassays (EIAs) or other supplemental assays – may be needed** to establish an HIV diagnosis.

When serological assays with sensitivity of at least 99% and specificity of at least 98% are used in these testing strategies, the results are highly accurate and reliable.

An HIV testing algorithm describes the specific brands of assays used in a given HIV testing strategy. A correctly chosen combination of RDTs and/or EIAs used in a validated national testing algorithm, can provide results as reliable or more reliable than the results of conventional EIA/Western blot combinations, and at much lower cost. Moreover, with a testing algorithm using RDTs, a person can receive their status on the same day as HIV testing.

Fig. 1. Testing strategy for HIV diagnosis in high prevalence settings



Testing algorithms should be validated to ensure that cross-reactivity between the HIV assays is minimal. Cross-reactivity can lead to a false HIV-positive diagnosis. The assay selected to be used first (first-line, or A1 in Figs. 1 and 2) should have the highest sensitivity, the second-line assay (A2) and the third-line assay (A3) should have the highest specificity.

A **testing strategy** describes a generic sequence of testing, with the intent to provide a diagnosis, according to the presumed HIV prevalence in the population being tested for HIV.

In contrast, an HIV **testing algorithm** describes the specific brands of assays used in a given HIV testing strategy.



* For HIV testing high prevalence is defined as $\geq 5\%$ and low prevalence is defined as $< 5\%$ prevalence in the population being tested.

When to retest?

HIV testing results are highly reliable when performed according to the WHO guidelines. Nonetheless, WHO recommends retesting to assure accurate diagnosis in three instances:

1. retesting people who test HIV-negative but are at on-going risk for HIV infection (for example, key populations);
2. retesting people with an HIV inconclusive status after 14 days; and
3. retesting to verify an HIV-positive diagnosis before enrolling in care and/or starting antiretroviral therapy (ART).

Retesting people who are already on ART is not recommended. Most people who test HIV-negative do not need to retest to rule out being in the window period. Some clients will have discrepant test results and therefore would be assigned an HIV-inconclusive status. These people should be retested after 14 days.

WHO also recommends periodic retesting for individuals using ART for prevention, such as individuals using pre-exposure prophylaxis and post-exposure prophylaxis.

Fig. 3. The 12 components of a quality management system

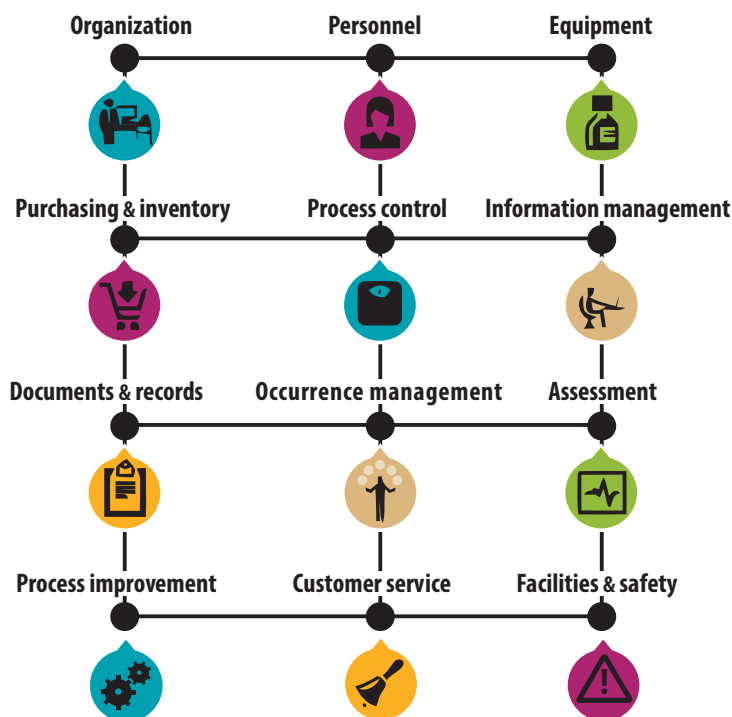
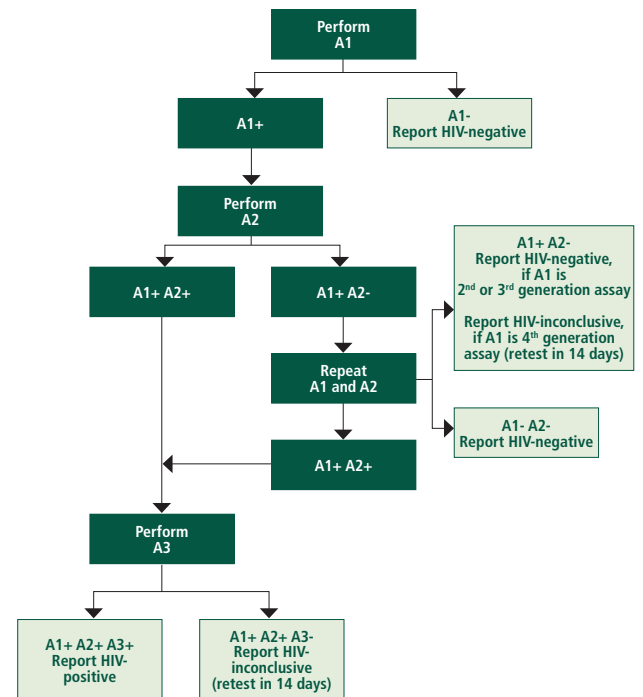


Fig. 2. Testing strategy for HIV diagnosis in low prevalence settings



Quality assurance?

Errors and possible misdiagnosis can come from a variety or a combination of factors related to the assays, the operator or the facility. Misdiagnosis can occur in any setting and regardless of whether laboratory technicians, health workers or trained lay providers conduct the testing. Thus, all HIV testing programmes need a functioning quality management system (Fig. 3). Such systems reduce the risk of errors and help to identify and correct mistakes.

For the full guidelines see <http://www.who.int/hiv/topics/vct/en/>

For more information, contact:

World Health Organization
Department of HIV/AIDS
20, avenue Appia
1211 Geneva 27
Switzerland

E-mail: hiv-aids@who.int
www.who.int/hiv
© World Health Organization 2015



POLICY BRIEF

WHO RECOMMENDATIONS TO
ASSURE HIV TESTING QUALITY