



SPECIAL PROGRAMME ON AIDS STATEMENT¹
PRESENT STATUS AND FUTURE DEVELOPMENTS IN
LABORATORY TESTING FOR HIV



1. Introduction

The following types of tests are available or under development:

- measurement of antibodies against viral antigens;
- measurement of neutralizing antibodies;
- detection of viral antigens;
- detection of viral RNA or cDNA;
- virus isolation and characterization of virus isolates from various geographical regions.

2. Measurement of antibodies against viral antigens (anti-HIV)

Determination of anti-HIV should consist of a primary screening test to be followed by confirmation with a second supplemental assay based on a different test principle. Current antigen-antibody binding assays have a high degree of specificity and sensitivity. Second generation tests using recombinant antigens, or future use of synthetic peptides, promise to improve sensitivity and particularly specificity. Generally, these test systems measure antibodies of the IgG class, but test systems measuring specific IgA- and IgM-antibodies are needed also and should be developed further.

Although more specific ELISA or other antigen-binding assays may in future make supplemental (confirmatory) tests unnecessary, reactivities indicating presence of anti-HIV obtained with any of the currently available screening tests should be confirmed by another test method. Western-blots (immuno-blots) are the most widely used and reliable tests, but radioimmunoprecipitation (RIPA) or immunofluorescence may be used. The latter should, however, only be used by laboratories with extensive experience with this test system.

Test systems should be developed which detect antibodies to HIV-1 and HIV-2 either together in one test or individually. The antigenic specificities of HIV isolates from different parts of the world should be continuously characterized to assure that the diagnostic method covers the antigens of the viruses prevalent in a given region. Simplified, less expensive tests should be developed further. These test systems should have at least the same sensitivity as currently used test systems, but a slight decrease in specificity might be acceptable.

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3. Measurement of Neutralizing Antibodies

Neutralization tests are used for research purposes and for evaluation of antibody responses following vaccination. The biological relevance of the antibodies measured by the various test systems needs further study, and all test systems must be standardized so that results obtained in different laboratories can be compared.

4. Detection of Viral Antigens

The tests available today need further clinical and technical evaluation. They are not recommended for routine diagnosis or screening of blood donors. Increase of HIV p24 antigen in serum has been associated with progression of disease but this does not occur in all cases. Decrease of HIV p24 in serum has been taken as an indication of a decrease of HIV replication and is used for evaluation of the effectiveness of antiviral therapy. These preliminary observations require additional studies. Absence of detectable antigen does not guarantee lack of infectiousness of a given serum, semen, body fluid or organ.

5. Detection of Viral RNA or cDNA

Methods for detection of viral RNA or cDNA in routine diagnostic laboratories are under development and may offer the most sensitive test systems for direct demonstration of HIV in fluids or tissues.

6. Virus Isolation and Characterization of Virus Isolates from Various Geographical Regions

Techniques are still cumbersome and time-consuming but have been considerably improved, so that an almost 100 per cent isolation rate can be achieved if multiple blood samples are examined. An optimized standard protocol should be worked out and made available to laboratories using this technique for basic or clinical studies. Virus isolates should be characterized to monitor the emergence of variant or new antigenic types.

7. Standardization and Reference Reagents

All of the above-mentioned test systems need further standardization. International antibody units should be established and appropriate reference reagents (both antigens and antibodies) should be prepared. The WHO Collaborating Centres on AIDS should play an active role in the preparation and evaluation of these reference reagents and WHO standards should eventually be established. WHO should also establish a repository of HIV-1 and HIV-2 as well as HIV isolates. In addition, it would be desirable to prepare a list of available clones of human and simian retroviruses.

8. HTLV-I and HTLV-II

The prevalence of HTLV-I and HTLV-II in various population groups should be monitored, but there seems to be no current need for general screening of blood or organ donors for HTLV-I and HTLV-II.

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