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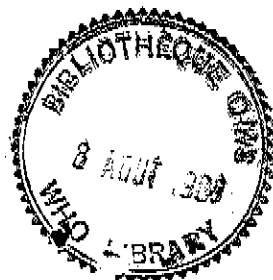
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GLOBAL  
PROGRAMME  
ON  
**AIDS**

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REPORT OF THE MEETING ON  
STRATEGIES FOR THE EVALUATION AND  
IMPLEMENTATION OF LABORATORY  
DIAGNOSIS OF HIV INFECTION

GENEVA  
31 AUGUST – 2 SEPTEMBER 1988



WORLD  
HEALTH  
ORGANIZATION



*Aids-areas*

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Contents

	<u>Page</u>
1. INTRODUCTION .....	1
2. RECOMMENDATIONS .....	1
2.1 Choice of test .....	1
2.2 Training.....	2
2.3 Quality control procedures .....	2
2.4 Research .....	3
Annex 1. List of participants .....	5

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## 1. INTRODUCTION

1.1 A World Health Organization (WHO) meeting on strategies for the evaluation and implementation of laboratory diagnosis of HIV infection was convened in Geneva from 31 August - 2 September 1988. Dr I. Gust (Australia) chaired the meeting and Dr B. Galvao Castro (Brazil) acted as Vice Chairman and Dr M. O'Shaughnessy (Canada) as Rapporteur. A list of participants is given in Annex 1.

1.2 The objectives of the meeting were to review strategies for WHO activities in the area of laboratory diagnosis of HIV infection, and to propose practical ways to further implement the recommendations of the WHO meeting on "Criteria for evaluation and standardization of diagnostic tests for detection of HIV antibody" which was held in Stockholm from 7-8 December 1987<sup>1</sup>.

1.3 The meeting commended the WHO Global Programme on AIDS (GPA) on the progress which had been made in the past eight months in evaluating new test systems, training laboratory workers, and monitoring test performance. The group was encouraged by evidence that a number of informal links had been established between GPA, WHO Collaborating Centres on AIDS, and laboratories in developing countries.

## 2. RECOMMENDATIONS

### 2.1 Choice of Test

The ability of a laboratory to generate accurate results is a function of the tests being used, the competence and training of the staff performing the tests, and implementation of quality control procedures. To assist this process a number of specific recommendations were made, as follows:

(a) WHO should support evaluation of selected commercially available antibody assays for HIV-1 and HIV-2 infection. These studies should be undertaken in WHO Collaborating Centres and in national reference laboratories in developing countries. In selecting assays for study the following criteria should be taken into account:

- a high level of sensitivity and specificity;
- long shelf life at ambient temperature;
- reasonable costs (generally not exceeding the test cost of the readily available enzyme immunoassays);
- ease of performance (requiring no special equipment and locally prepared reagents);
- rapidity of performance; and
- appropriateness for use in small blood collection centres and hospitals.

(b) Data from these evaluations should be presented to GPA in a standard format so that the results can be compared and summarized. The purpose of these evaluations is to provide objective data of use to Member States. WHO should not act as a de facto regulatory authority and should not undertake activities which are more properly the responsibility of the manufacturers.

(c) GPA should recruit a consultant to review the literature and data generated by WHO Collaborating Centres on the performance of tests for HIV antibodies. The review should include criteria which should be used for selection of assays. This report should be updated as required.

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<sup>1</sup>Unpublished WHO document WHO/GPA/BMR/88.1. Available from Global Programme on AIDS, World Health Organization, 1211 Geneva 27, Switzerland

(d) Due to the high cost of existing confirmatory tests, the complexity of their performance and interpretation, there is a need to look for alternative strategies for confirming results. GPA should request selected WHO Collaborating Centres to evaluate alternative strategies.

## 2.2 Training

(a) WHO should continue to assist Member States in training relevant laboratory staff. Wherever possible this training should be directed at individuals who will be capable of teaching additional staff in their countries or region so that responsibility for these activities is rapidly transferred to Member States. All training programmes should contain information on safe procedures for collection, transport and handling of samples, and disposal of waste as well as information on preferred methods of recording of data.

(b) General principles: Participants in training programmes should be carefully selected to ensure that they (and their country or region) will benefit from their attendance. Training courses should be conducted under conditions which are similar to those in which the tests will be performed. WHO should ensure that staff engaged to conduct the training programmes are adequately briefed. This would be facilitated by development of WHO training manuals or adapting programmes which have been produced by other organizations.

(c) Consideration should be given to establishing small groups in selected WHO Collaborating Centres on AIDS which would be responsible for conducting training programmes in their regions. These groups should be responsible for follow-up of trainees, assistance with technical or logistic problems and would provide a link between national authorities and the WHO Collaborating Centres.

(d) WHO should consider providing fellowships to enable selected scientists from national reference laboratories to spend several weeks or months overseas developing relevant skills.

## 2.3 Quality control procedures

(a) GPA should continue to assist Member States to establish accurate testing procedures by encouraging links between WHO Collaborating Centres on AIDS, national or regional reference centres, and peripheral laboratories.

(b) The WHO Collaborating Centres should develop panels of sera which can be used for validation of test procedures and proficiency testing. GPA should arrange for the storage and distribution of these panels.

(c) Validation panels: Before inclusion in the panel, serum (or plasma) samples should be tested in at least two different WHO Collaborating Centres, both of which agree upon the result. Because of the differing patterns of infection with HIV-1, HIV-2, and other retroviruses, and differing prevalence of endemic diseases which may affect the test result, the group recommended that separate validation panels be established for Africa, the Americas and South-East Asia and the Western Pacific. Additional panels will also be needed to validate tests for HIV-2.

(d) Proficiency testing: GPA should encourage WHO Collaborating Centres on AIDS and national reference laboratories to distribute small coded panels of sera to each testing centre on a regular basis. These panels, which should contain strong positive, weak positive and negative samples, should be distributed at least twice a year. The data from these studies should be analyzed by the WHO Collaborating Centres or national reference laboratories and assistance offered to any centre whose performance needs to be improved.

#### 2.4 Research

Due to the high cost of Western blot and radioimmunoprecipitation (RIPA) and the complexity of their performance and interpretation, there is a need to look at alternative strategies for confirming results. GPA should enlist the support of the WHO Collaborating Centres to evaluate a range of alternative strategies.

WHO should also encourage studies on:

- the standardization of Western blot procedures;
- the use of filter paper discs for serological surveys and proficiency test programmes; and
- whether serum samples can be pooled and tested for anti-HIV without loss of sensitivity and specificity.

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