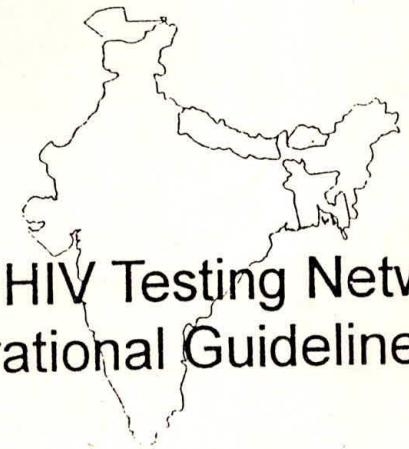
National AIDS Control Programme



National HIV Testing Network : Operational Guidelines

National AIDS Control Organization

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CONTENTS

CHAPTER 1

Review of the Existing HIV Testing Programme

The pandemic spread of HIV and its threat for the developing countries became evident by 1985. The commercial kits for testing of HIV by this time became available. During the same year, Indian Council of Medical Research (ICMR) started search for HIV infection in the country as a research issue and hence the testing facility for HIV became available at two centres (Pune and Vellore). With the evidence of infection found by 1986, the surveillance was initiated in other geographic zones. Numerous HIV testing centres were setup in the country which simultaneously acted for the surveillance, transfusion safety, identification of HIV positive individual and research. At present there are 62 surveillance centres, 150 zonal blood testing centres, and nine referral centres in the country. In the course of time it was realized that various objectives of HIV testing cannot be combined and different testing procedures and test strategies should be applied for each one of them. Unlinked anonymous HIV surveillance was implemented by the end of 80s and the advantages could be understood. The ineffectiveness of the indiscriminate screening and testing of individuals in changing high risk behaviour was also appreciated. In 1992, the National AIDS Control Organization (NACO) took over the task of HIV testing from ICMR and effort for streamlining started. The need for switching the surveillance activity from the surveillance centres to specially identified sentinel sites was realized. On the issue of blood transfusion safety the necessity for introduction of simple and rapid tests was considered. It was also decided to extend the HIV testing facilities for blood transfusion safety to every district of the country. The Government of India has spent nearly 2/3rd of its budget of National AIDS Control Programme between 1987 and 1992 for testing facilities for HIV and blood banking. During the current five Year-Plan, 30% of the budget allotted for AIDS Control will be spent on blood safety programme.

Since 1993 HIV-1 and HIV-2 mixed kits, which have been evaluated by WHO and have the desired sensitivity and specificity, have been used for all testing objectives except some research areas.

1.1 Present HIV Testing Infrastructure

Surveillance centres

By December 1993, surveillance centres were functioning in 30 of the 32 states and union territories, except union territories (UT) of Daman & Diu and Dadra and Nagar Haveli. These

two territories were covered by the neighbouring states. The surveillance centres equipped with ELISA testing equipment were primarily involved in surveillance and diagnosis of cases of AIDS.

Zonal Blood Testing Centres

In order to prevent transmission of HIV infection through blood, ICMR initially started screening of blood donors in some institutions. In December, 1989 Director General of Health Services (DGHS) in collaboration with ICMR and State Governments, drew up an action plan to start zonalised blood testing in a phased manner. In the first phase 29 zonal blood testing centres (ZBTC) started working in 4 metropolitan cities of Bombay, Madras, Delhi and Calcutta. In addition, all the surveillance centres were also carrying out HIV testing for blood donors and were also identified as ZBTC. As on December, 1992 there were 128 ZBTCs in addition to 62 surveillance centres, some of them also functioning as ZBTC in different cities.

As per decision of the Technical Advisory Committee taken in 1993, the screening of blood for blood safety purposes was delinked from the surveillance activities. Thus, 150 ZBTC in different States/UTs were identified and started functioning.

HIV Screening for Blood Transfusion at the District Level

Once the need for screening all blood units for transfusion was accepted it was decided in 1993 to extend the facilities for HIV testing to all blood transfusion centres. All the district hospitals where blood transfusion is carried out have been provided with rapid HIV test kits.

Regional Reference Centres

While the surveillance centres primarily carried out ELISA testing for initial screening, nine regional reference centres were provided, in a phased manner, the facilities for doing Western Blot (WB) test. All ELISA positive samples (excluding those detected during screening for blood safety) were sent to these reference centres for validation of ELISA results. Surveillance centres were attached to one of the Reference Centres.

Quality Control Laboratory

The National AIDS Control Organization (NACO) has delegated the coordination of the quality assurance and quality control programme to the All India Institute of Medical Sciences, New Delhi since December, 1993. During 1994 all the Regional HIV reference centres participated in the quality assessment programme started by the All India Institute of Medical Sciences.

To conclude, the HIV testing could not be efficiently managed by the present set up of coordination. The situation was further worsened by the dramatic expansion of the HIV testing facilities to almost all the district headquarters, some taluka hospitals and a number of urban hospitals.

CHAPTER 2

Current National HIV Testing Policy and Srategies

2.1 National Policy on HIV Testing

The following note covers some of the pertinent issues which are incorporated in the National HIV Testing Policy document.

a) Any testing procedure undertaken in the country must be in accordance with and a part of comprehensive control programme on HIV infection.
b) The choice of testing procedure, interpretation of testing results and pre-requisites of the testing depend on the purpose or objective of HIV testing which can be any one of the following.

   (i) To identify an individual with HIV infection under following circumstances:
   – for the diagnosis of clinically suspected cases of AIDS;
   – voluntary testing is sought by an individual for health reasons and
   – non-health purposes.
   (ii) To monitor the trend of HIV infection in a population or a sub-group for guidance of intervention programme (HIV surveillance).
   (iii) To test blood for transfusion safety or prospective donor of semen, tissue or organs for ensuring safety of the recipients (transplantation safety).
   (iv) Research on HIV infection/AIDS.
   (v) Mandatory

c) Testing procedure must be supported by social support and means and skills for intervention, even if the testing is refused or otherwise not done.
d) Any kind of mandatory testing, without explicit consent of the person when it tends to identify an individual (unless otherwise required by the court), should be discouraged. This includes testing of international travellers, refugees, women in the reproductive age group, hospital inpatients or those seeking admission, injecting drug users, sex workers, prison inmates, sports-men, pre- or in- service employment, screening for insurance purposes, or any other populations.
e) Transfusion safety should be ensured in every corner of the country under any circumstances.
f) A single ELISA/Rapid/Simple (ERS) test for both HIV-1 and 2 is recommended for

transfusion safety. Normally, the donor of any infected blood unit need not be traced back and no consent is needed for testing the blood unit for HIV. Should a donor ask for his HIV test result or for reasons as to why his blood has been rejected, the blood bank personnel should be adequately trained to properly interpret a single ERS positive test result and refer the donor to a centre for voluntary HIV testing.

g) The establishment of voluntary testing centres with the facilities for supplemental testing will be encouraged. At these centres, the persons may be offered voluntary confidential testing along with counselling facilities. The centre should offer services to all referral patients from the different health care settings.

h) The testing protocol using either three ERS tests, based on different antigen or principle, or one ERS test plus WB is considered scientific for identifying an infected individual. In view of the comparative cost of the second option which may impede the extending of case identification facilities to the peripheral level, the three ERS tests strategy is recommended for identification of a case.

i) Surveillance is to be designed by the State Epidemiologist/State AIDS Programme Officer and is to be carried out by the staff of the selected sites (health institutions). This will be done by an unlinked anonymous approach using 2 ELISA/Rapid/Simple tests for both HIV-1 and 2. The approach of sentinel surveillance needs to be expanded in preference to the present randomized approach of surveillance. The latter will be phased out.

j) The samples will be tested in any HIV testing facility suitably situated and easily approachable by the staff of the surveillance site.

k) Testing procedures for research are to be designed according to the specific research objectives and could be decided by the researchers. However, all the studies undertaken must follow the highest international standards for the scientific protocol which primarily involves in full, explicit consent of the patient and pre-decided mutually agreed terms for any eventuality of the patient due to research activities.
There is need for legal and ethical clearance and special diagnostic criteria for the patients undergoing any vaccine trial or introduction of any HIV antigenic component in the body.

l) A re-structuring of the existing HIV testing network will be necessary to carry out objective-wise testing. While transfusion safety must be ensured by any laboratory that carries out HIV testing, the identification of HIV-infected individual must be done at a limited number of institutions (voluntary testing centres, AIDS case referral hospitals, research institutions having well-trained staff).

m) Internal and external quality control programme must be rigorously implemented on a regular basis which would compel any laboratory in the country involved in the HIV testing to participate in the quality assessment programme. A centralized agency will publish a directory of all testing laboratories in the country according to the objectives of testing, type and number of kits used and a summary result of the quality assessment programme.

2.2 *WHO Recommendations for the Selection and the Use of HIV Antibody Tests*

Several different types of laboratory tests for detecting HIV antibody in human serum exist today. The selection of the most appropiate test or combination of tests for use (i.e. the testing strategy) depends on three criteria:

(1) the objective of the test;
(2) the sensitivity and specificity of the test(s) being used;
(3) the prevalence of HIV infection in the population being tested.

Objectives of HIV Antibody Testing

There are four main objectives for which HIV antibody testing is performed:

(1) Transfusion/donation safety: Unlinked and anonymous screening of blood and blood products and of serum from donors of tissues, organs, sperm or ova.
(2) Sero-surveillance: Unlinked and anonymous testing of sera for the purpose of monitoring the prevalence of and trends in HIV infection overtime in a given population.
(3) Diagnosis of HIV infection: Voluntary testing of serum from asymptomatic persons or from persons with clinical signs and symptoms suggestive of HIV infection or AIDS.
(4) Research: Voluntary testing of serum from subjects of epidemiological, clinical, virological or other HIV-related studies.

Sensitivity and Specificity of Antibody Tests

Sensitivity and specificity are two major factors that determine the accuracy and reliability of a test in distinguishing a HIV infected person from an uninfected person. A test with a high sensitivity will have very few false-negative results. Therefore, only tests of the highest possible sensitivity should be used when there is a need to minimize the rate of false-negative results (e.g. in transfusion/ donation safety). A test with a high specificity will have very few false-positive results. Therefore, it should be used when there is a need to minimize the rate of false-positive results (e.g. in sero-surveillance and in diagnosis of HIV infection in an individual).

Prevalence of HIV Infection

The probability that a test will accurately determine the true infection status of a person being tested varies with the prevalence of HIV infection in the population from which the person comes. It is expressed as predictive value.

In general, higher the prevalence of HIV infection in a population, the greater is the probability that a person testing positive is truly infected (i.e. the greater the positive predictive value, PPV). Thus, with increasing prevalence, the proportion of serum samples testing false-positive decreases. Conversely, the likelihood that a person showing negative test results is truly uninfected (i.e., the negative predictive value, NPV) decreases as prevalence increases. Therefore, as prevalence increase, so does the proportion of samples testing false-negative.

Strategies for HIV Antibody Testing

The PPV of a test is very low when a population with low HIV prevalence is tested, even if the specificity of the test is very high. For this reason a supplemental test is necessary to enhance the PPV of HIV testing. All samples found reactive by the first test are retested by a second test based on a different principle and/or a different antigen preparation (see Strategy II below). However, in some situations a third test may be considered necessary (see Strategy III).

At present, the most common strategy for HIV antibody testing uses a highly sensitive enzyme-linked immunosorbent assay (ELISA) followed by the WB assay. ERS test usually costs only Rs. 25–56 (US$ 0.75–1.75) per test. The cost is further reduced when these tests are bulk-purchased by the WHO (Table 2.1). The WB, however, may cost up to Rs. 600–1280 (US$ 19–40) per test and still produces indeterminate results of uncertain diagnostic significance. Studies have shown that combinations of ERS tests may provide results as reliable as and in some instances even more reliable than the ELISA/WB combination at a much lower cost. WHO, therefore, recommends testing strategies for HIV antibody detection which use ERS tests in place of ELISA/WB.

Table 2.1. Specifications of HIV test kits bulk-purchased by WHO

Test Type	HIV Specificity	Price (US$)	Number of Manufacturers
Rapid/Simple	HIV-1	0.65	1
Rapid/Simple	HIV-1+2	2.00–2.30	2
ELISA	HIV-1+2	0.70	3
Western Blot	HIV-1	12.40	2
	HIV-2	13.80	2

*See page 65 for details

Recommendations

WHO recommends three testing strategies to maximize accuracy while minimizing cost. The choice of the most appropriate strategy will depend on the objective of the testing and the prevalence of HIV in the population, as shown in Table 2.2.

Table 2.2. WHO recommendations for HIV testing strategies according to the objectives and prevalence of infection in the population

Objective of testing	Prevalence of infection	Testing strategy*
Transfusion/donation safety	All prevalences	I
Serosurveillance	> 10%	I
	</= 10%	II
Clinical signs/symptoms of HIV infection/AIDS	All prevalences	II
Diagnosis	> 10%	II
Asymptomatic	< 10%	III

* see text for details.

Strategy I

The serum is tested with one ERS test. If it is reactive it is considered HIV antibody positive. The non-reactive serum is considered HIV antibody negative.

Strategy II

The serum is first tested with one ERS test. If it is found reactive, it is retested with a second ERS based on a different antigen preparation and/or different test principle (e.g. indirect versus competitive). If it is found reactive on second test also it is considered HIV antibody positive. Serum that is non-reactive on the first test is considered HIV antibody negative. Any serum that is reactive on the first test but non-reactive on the second test is also considered antibody negative.

Strategy III

As in strategy II, the serum is first tested with one ERS assay, and any reactive sample is retested using a different assay. Strategy III, however, requires a third test if serum is found reactive on the second assay. The third test in this strategy should be based on a different antigen preparation and/or different test principles. A serum reactive on all the three tests is

considered HIV antibody positive. A serum that is non-reactive on the first test is considered HIV antibody negative as is serum that is reactive in the first test but non-reactive in second. Serum that is reactive in the first and second tests but non-reactive in the third test is considered equivocal (see "equivocal (borderline) tests results" below for further analysis).

In the selection of HIV antibody tests for use in strategies I, II and III, the first test should have the highest sensitivity, whereas the second and third tests should have higher specificities than the first.

When diagnosis is the objective, an additional blood sample should be obtained and tested from the person diagnosed as seropositive for the first time on the basis of one sample. This will help to eliminate any possible laboratory or clerical error which may result in wrong labelling/mixing of the samples.

For all the three strategies, it is most important that quality assurance procedures be stringently complied with so as to maximize the accuracy and reliability of the laboratory results. Procedures for detecting both laboratory and clerical errors must be included in all protocols. For example, procedures that guarantee the correct identification of HIV reactive units of donated blood are essential for the maintenance of a safe blood supply.

Any positive test result obtained with testing strategy-I must not be used for purposes of diagnosis of HIV infection in an individual. If a blood or tissue donor is to be notified of test results, the testing strategies for diagnosis must be used (Table 2). Guidelines for counselling persons regarding HIV testing, infection and disease are available from WHO.

Users should note that differentiation between HIV-1 and HIV-2 infections cannot always be achieved with the currently available antibody tests, even when the two types of WB (HIV-1 and HIV-2) are used. WHO is currently undertaking studies aimed at the development and evaluation of testing strategies for differentiation using ERS assays.

Equivocal (Borderline) Test Results

If the test results in strategy-III are equivocal, the serum should be retested. On retesting, if the results are again equivocal, testing with WB may be considered, especially for persons from low-prevalence populations ($\leq$ 1%). A second blood sample should be obtained after a minimum of two weeks following the first sample and both samples should be retested using the appropriate strategy. If the second serum sample also produces an equivocal results, the person is considered to be HIV antibody negative.

Equivocal results obtained during sero-surveillance studies must be discarded, as must units found reactive.

HIV Antibody Tests Selected for Bulk Purchase

WHO has recently started to bulk-purchase HIV tests in order to provide member countries with tests giving the most accurate results at the lowest possible cost.

Table 1 summarizes the specifications and cost of rapid/simple HIV tests, ELISA and WB assays selected by WHO for bulk purchase and available to countries through WHO during 1992. Guidelines on selecting tests for use with the strategies outlined in Table 2 are available from the Diagnostics Unit, Office of Research, Global Programme on AIDS.

Tests other than those bulk-purchases by WHO are also suitable for use with the testing strategies shown in Table 2. Information concerning their selecting is available upon request.

2.3 National HIV Testing Strategies

On September 10, 1993 the National AIDS Control Programme Technical Advisory Committee recommended implementation of the HIV testing strategy by the National AIDS Control Programme. This strategy underlines the following:

i) For transfusion purposes, only one highly sensitive, reliable, economically feasible and technically easy ERS test for both HIV-1 and HIV-2 antibodies should be carried out by the Zonal Blood Testing Centres/Blood Banks and if the results indicate that antibodies are present, the blood should be discarded and no further test needs to be done on this blood sample.

ii) For anonymous unlinked surveillance purposes, HIV-1 and HIV-2 combination kits conforming to the one used for the blood safety purposes, will be used by the surveillance centres. For the purpose of surveillance, all sera are first tested with one ERS test. Any serum found reactive on the first assay is retested with a second ERS assay based on a different antigen preparation or principle. If it is found reactive by the second assay also, it is considered antibody positive. Any serum which is reactive on the first test but non-reactive on the second test is considered antibody negative.

iii) HIV testing for diagnostic purposes will depend on the clinical status of the patient. For asymptomatic persons, all samples are first tested with one ERS test. Any reactive sample is tested further with a second ERS test based on a different antigen preparation or principle. Samples found reactive by the second test are then subjected to a third ERS test based on different antigen prparation or principle. The serum reactive on all three tests is considered HIV antibody positive. Serum that is non-reactive on the first test is considered HIV antibody negative. Serum that is reactive in the first test but non-reactive in the second test is also considered negative. The serum that is reactive in the first and second tests and non-reactive in third test is considered to be equivocal/borderline positive. These sera will be tested by the western blot assay. All patients with clinical

signs and symptoms of HIV infection/AIDS as per WHO case definition are to be tested by the same strategy which has been adopted for surveillance purposes as above i.e. two ERS tests based on different antigens or based on different principle.

iv) For research purposes, the serum samples for HIV antibody will be confirmed by WB test and facility can be provided at some of the identified research institutions only.

Note:

i) For transfusion purposes, the ERS test selected should be of a very high sensitivity and a good specificity to ensure almost negligible false negative reports and considerably reduced number of wasted blood units respectively.

ii) For anonymous surveillance purposes, the first ERS selected should be of a very high sensitivity and a good sepcificity and a second ERS should be of a very high specificity and a good sensitivity. This will ensure almost negligible false negative reports and very few false positive reports.

iii) For diagnostic purposes, the first ERS should be of a very high sensitivity and a good specificity, the second ERS should be of a very high specificity and a good sensitivity, and the third ERS should be of a good sensitivity and specificity to ensure negligible false negative as well as false positive reports.

CHAPTER 3

Structure of the Decentralized HIV Testing Network

According to the national legislation, the states and union territories are responsible for the matters related to the health. States are also implementing the National AIDS Control Programme though it is sponsored by the Central Government. In line with this policy, according to the proposed decentralisation of the HIV testing network, the state health administration would assume all responsibilities related to the planning and monitoring the state HIV testing network. NACO, the representative of the Central Government, will support the states financially and technically. It will also help the state governments in the procurement and supply of HIV test kits and related equipments. The states will periodically report to NACO on these developments.

It is proposed to create a network of different types of HIV testing laboratories and to establish quality assurance programme of HIV tests in all states of Republic of India. In addition, it is envisaged to provide training to all categories of staff so that all laboratories perform at the same level of competence and proficiency. It is also proposed to identify laboratories for evaluation of HIV test kits to be used for National AIDS Control Programme.

3.1 Identification, Establishment and Functions of HIV Testing Facilities

The structure of the decentralized HIV testing network is shown in figure 3.1. It includes four categories of institutions:

i) HIV Screening Laboratory, level 1 and level 2
ii) HIV Testing Laboratory
iii) State HIV Reference Centre
iv) National HIV Reference Centre

The proposed activities of these laboratories and their relation to NACO and the State AIDS Programme Officer (SAPO) are shown in figure 3.1 and table 3.1.

The National HIV Reference Centre (NHRC) at the national level will be responsible to NACO and will interact with the State HIV Reference Centres (SHRC). The SHRC's will be under the operational control of SAPO and will interact with HIV testing laboratories (HTL) and HIV screening laboratories (HSL) on one hand and with NHRC on the other hand.

1. HIV Screening Laboratory (HSL)

This is a laboratory facility for the primary screening of blood samples for HIV from blood units collected for transfusion purpose. HIV screening laboratory may be based at any hospital or medical institution and has staff which may be trained to carry out HIV tests. There will be two levels of HIV screening laboratories (HSL):

a) HSL level I (HSL-I) : These laboratories will test donated blood only from their own blood bank/transfusion centres for HIV antibodies by Rapid/Simple test. They will be equivalent to the present day District Hospital Blood Bank testing centres which have an yearly load of less than 3,000 tests.
b) HSL level II (HSL-II) : These laboratories will take up the function of Zonal Blood Testing Centres (ZBTC). They will generally test donated blood unit by ELISA. In addition, they will be able to test blood units of either their own blood banks or the blood banks attached to them in case of emergency by Rapid/Simple test.

Criteria for New HSL

Need for establishing HIV testing facilities will be based on the following criteria:

HSL-I

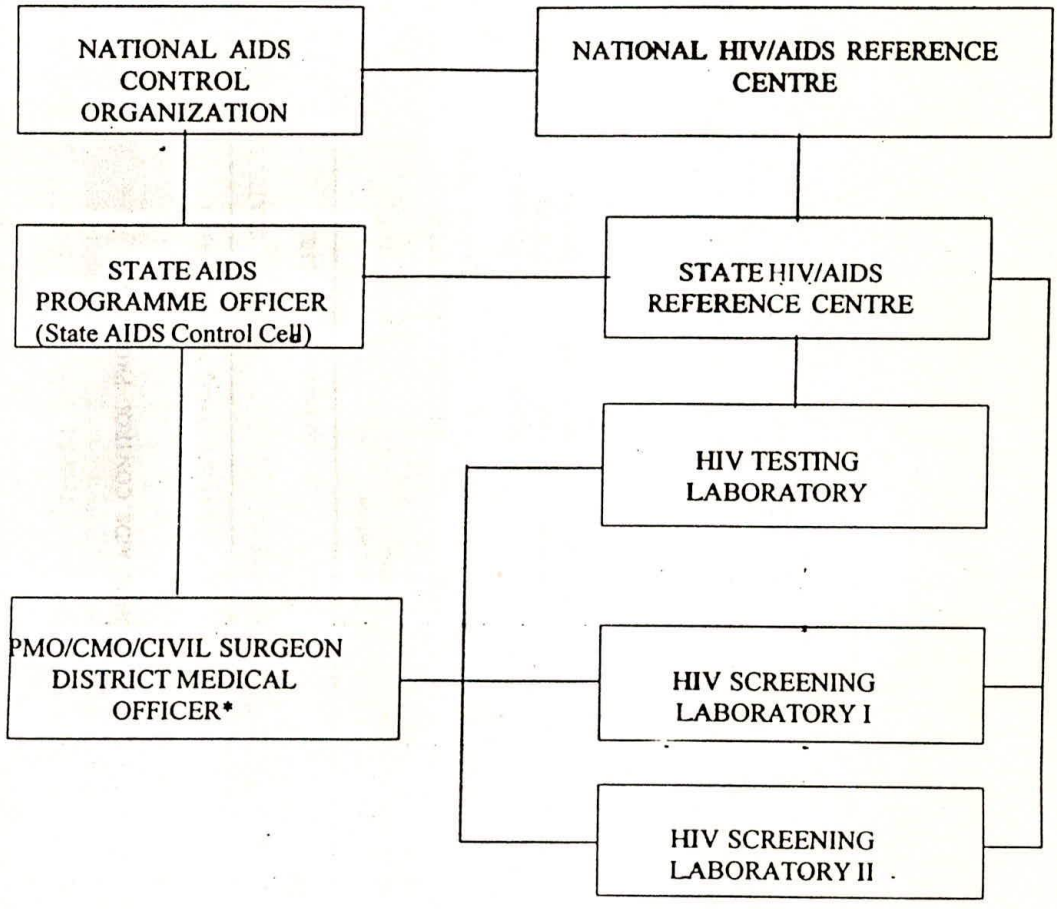
a) The institution must be interested in hosting a facility for HIV testing.
b) The medical institution to host the facility is either involved or can potentially be involved in blood transfusion and there is no HIV testing laboratory existing in its premises.
c) The yearly collection of the blood bank/transfusion centre must be 3,000 or less blood donations.
d) The institution should have a medical laboratory as well as the staff trained in HIV testing.

HSL-II

a) The institution must be interested in hosting a facility for HIV testing.
b) The medical institution to host the facility is either involved or can potentially be involved in blood transfusion and there is no HIV testing laboratory existing in its premises.
c) The yearly collection of the blood bank/transfusion centre must be more than 3,000 blood donations.
d) The institution should have a medical laboratory as well as the staff trained in HIV testing.

The State AIDS Programme Officer (SAPO) will circulate these conditions among various medical/health institutions in the state for selecting HSL I and II. The hospitals and other health institutions which meet the criteria will be offered full support in establishing HIV testing facilities.

NATIONAL AIDS CONTROL PROGRAMME



* Officer responsible for various health programmes in the district

Structure of the decentralized National HIV Testing Network

Figure 3.1

Table 3.1

NATIONAL AIDS CONTROL PROGRAMME

Summary of the activities performed by various
Institutions of the National HIV Testing Network (NHTN)

ACTIVITY	NATIONAL/REGIONAL INSTITUTIONS		STATE INSTITUTIONS			
	NACO	NHRC	SAPO	SHRC	HTL	HSL 1 & 2
itial evaluation of HIV Test ts aimed for use by NHTN	–	For the whole country	–	–	–	–
entification and assessment of tential institutions for NHTN	NHRC, SHRC (assists SAPO)	SHRC (assists SAPO)	SHRC,HTL,HSL	HTL,HSL (assists SAPO)	–	–
aining	SAPO (operational aspects)	SHRC staff (technical aspects)	SHRC staff (operational aspects)	HTL staff HSL staff (technical aspects)	HSL staff (optional)	–
pplies & Equipment) Procurement/Receipt	For NHRC and States	From NACO and self	From NACO and self for SHRC, HTL,HSL	From SAPO & self for self,HTL & HSL.	From SAPO and SHRC	From SAPO and self
) Distribution	For NHRC and States	From NACO	From NACO for SHRC, HTL and HSL	From SAPO and self for self,	From SAPO	From SAPO
Maintenance	For NHTN,	HTL, HSL Through NACO and self	For State net work	Through SAPO	Through SAPO	Through SAPO

: National HIV Reference Centre
: State HIV Reference Centre
: HIV Testing Laboratory
: HIV Screening Laboratory
: ELISA/Rapid/Simple Tests

Table 3.1 (Contd.)

ACTIVITY	NATIONAL/REGIONAL INSTITUTIONS		STATE INSTITUTIONS			
	NACO	NHRC	SAPO	SHRC	HTL	HSL 1 & 2
5. HIV test kits provision (a) Planning test kits supply	Summary of State requests	Assists NACO technically	For the State	Assist SAPO technically for the State	For itself	For itself
(b) Procurement	For NHTN	From NACO for self	From NACO for State	From SAPO for self,HSL & HTL	From SAPO or SHRC for self	From SHRC or SHRC for self
(c) Storage	-	For self	-	For self, HTL and HSL	For self.	For self
(d) Distribution/transportation of the test kits	For NHRC and SAPO/SHRC	-	From NACO for SHRC,HTL, HSL	From SAPO for HTL and HSL	From SAPO for self.	From SAPO for self
6. Screening		Single test	-	Single test	Single test	Single test
7. Testing (Complementary)		Three ERS, WB	-	Three ERS,WB	Two ERS	One ERS
8. Quality Assessment	-	Of SHRC	-	Of HTL & HSL of the state	-	-
9. Monitoring	-	Of SHRC	-	Of HTL, HSL	-	-
10. Reporting	To Central Government	To NACO	To NACO	To SAPO	To SHRC/SAPO	To SHRC/SAPO

NHRC : National HIV Reference Centre
SHRC : State HIV Reference Centre
HTL : HIV Testing Laboratory
HSL : HIV Screening Laboratory
ERS : ELISA/Rapid/Simple Tests++

Location

HSL-I : These may be located in the laboratory premises of any medical or health institution. The present day district or taluka hospital blood banks/transfusion centre will fall under this category.

HSL-II : These may be located in the laboratory premises of any medical of health institution, The present day zonal blood testing centre and surveillance centre will fall under this category.

Capacity

HSL-I : with work load of 3,000 or less tests per year will perform Rapid/Simple tests only. On the other hand, HSL-II shall be able to perform more than 3,000 single HIV antibody tests per year by ERS.

Staff

The staffing pattern of HSL-I and HSL-II will vary according to the work load. In HSL-I, with the work load less than 3,000 tests per year, the tests will be carried out by the existing staff of the institution if possible. Otherwise, one technician may be provided to carryout HIV testing. This laboratory will be under the control and supervision of blood bank officer. HSL-II may have HIV laboratory specialists and support staff. The pattern will be determined individually for each laboratory by SAPO. However, it must have at least two laboratory technicians and should be under the supervision of the blood-bank officer.

Staff Salary

The post of technicians in HSL I & II will be on a consolidated salary on contract basis as decided by NACO from time to time. The requirement of qualification and experience will be as per State Government rules. The SAPO will be the appointing authority

Functions

Both HSL I and II are responsible for the primary screening of blood samples by single HIV test. They are meant to carry out tests according to the strategy-I recommended by the Technical Advisory Committee of NACO for HIV testing.

Staff Training

HSLs will send their staff for training organized by the SAPO at the:

(i) nearest HIV Testing Laboratory, or
(ii) State HIV References Centre, or

(iii) National HIV Reference Centre, or
(iv) any other recoginized laboratory in the country.

Administrative and Technical Control

Administratively, HSLs will be under the control of the institution hosting these laboratories whereas, technically these have to comply with the National HIV Testing Policy. In addition, these must follow periodic instructions and circulars issued by the SAPO or the SHRC. The work of the HSLs will be monitored by the SAPO. They will submit report on their HIV activity to SAPO. However, SHRC will ensure quality control programme at HSLs.

Supplies and Equipment

HSLs will submit their requests for the supplies and equipments, to the SAPO/SHRC and receive supplies from the SAPO/SHRC. The HSLs will be responsible for the storage of the test kits and other reagents required by them.

Contingency

Contingency grant to each HSL will depend on the work load and will be decided by the NACO in consultation with SAPO.

2. HIV Testing Laboratory (HTL)

This is the second line of HIV testing facility which, in addition to primary screening for HIV, would have the provision for a second ERS test for surveillance and other purposes. For further validation, if necessary, they may refer the sample to SHRC. They will be equivalent to present day surveillance centres with different activities.

Location

These laboratories will be located at divisional headquarters, metropolitan cities, district headquarter and larger towns. The HTL will be located in the institutions which have reasonably advanced laboratory services in operation. They are required to have at least one trained laboratory staff members for the HIV testing.

Criteria for New HTL

Need for establishing new HTL will be based on the following criteria:

1. Inadequate existence of voluntary HIV testing centre(s) for the population in the city/town,
2. AIDS case diagnosis,
3. Serosurveillance of HIV infection/AIDS.

Functions

HTL will carry out supplementary tests by a second and a third ERS for sentinel surveillance and identification of infected individuals, respectively. In other words, it should be able to perform HIV tests according to strategies II and III for HIV testing.

Staff

Each HTL will be provided with two technicians. They will be on a consolidated salary on a contract basis as decided by NACO from time to time. The requirement of qualification and experience will be as per State Government rules. The SAPO will be the appointing authority. HTL will be under the supervision of a trained medical microbiologist/immunologist.

Staff Training

These laboratories will participate in the staff training organized by the SHRC.

Administrative and Technical Control

If located in a hospital/health institution, the HTL will be under the administrative control of that hospital/health institution. Technically it will be under the supervision of SHRC. All activities of HTL will be monitored by SHRC. It will be financially supported by SAPO and will submit report to him/her.

Supplies and Equipment

HTL will submit its requests for the supplies and equipment to the SAPO and will receive supplies from SHRC under instructions of SAPO. It will be responsible for storage of ERS kits for primary screening as well as supplementary testing for validation of the results of primary screening.

Contingency

Contingency grant to each HTL will depend on the work load and will be decided by the NACO in consultation with SAPO.

3. *State HIV Reference Centre (SHRC)*

The SHRC will be the technical headquarter for the HIV laboratory network in the State. The present day regional reference centres in different states should be recoginized as SHRC. There will be only one SHRC in a state. The SHRC will be created/identified by the NACO on the recommendation of state government.

Location

It should preferably be located in the state capital or in any city which has a better transport and communication links with other towns of the state than the capital of that state. The SHRC will be a part of a reasonably well developed medical laboratory in the city.

Staff

It should have three technicians to look after all aspects of HIV-testing. The technicians will be appointed on a consolidated salary on a contract basis as decided by NACO from time to time. The requirement for the qualifications and experience will be according to the State Government rules.

Functions

a) Perform HIV testing as outlined for strategies II and III:

   i) for serosurveillance purposes (strategy II),
   ii) for diagnosis of HIV infection/AIDS (strategy III).
   iii) for revalidation of problematic sera by WB assay.

b) Training of laboratory staff of all laboratories in the state including its own;
c) Establishing HIV testing network and conducting quality assurance programme in the state;
d) Technical supervision and monitoring the work of all HSLs and HTL in the state;
e) Reporting on all HIV testing activities excluding HIV-test reports from HSLs & HTL in the state to SAPO;
f) Participate in the National quality assessment/proficiency programme conducted by NHRC.
g) Assist SAPO to identify and establish HTLs and HSLs throughout the state.
h) Assist SAPO in implementation of requests from all state laboratories for supplies, equipment and HIV test kits.

Administration

Administratively, SHRC will be under the host institution. However, operationally it will be under the SAPO, while technically it will be coordinated by NHRC. SAPO, in consultation with the administration of the institution hosting the SHRC, should identify a professional microbiologist or immunologist as the incharge of SHRC who will also be the State Coordinator of HIV testing (SCOHT). He will be responsible for:

a) State level management of HIV testing network;
b) Assessment of the requirement and type of kits in HSLs and HTL;
c) Identifying laboratories in the state for different objective of HIV testing;
d) Quality Assurance programme in the state HIV laboratories;
e) Training of staff of all state peripheral laboratories;
f) Supervision and monitoring of the HIV testing programme in the State; and
g) Reporting on HIV testing activities excluding HIV-test reports from HSLs and HTLs to SAPO.

In addition, he will prepare a list of all laboratories in the state that can potentially participate in HIV testing and also those reporting increasing number of HIV infection/AIDS cases which may be considered for establishing HIV testing facilities.

An assessment form (page 25–26) will be circulated by him/her to review the existing operational situations and capacity of the laboratories. Willingness of the institution to participate in the State HIV testing network and communication facilities will be two important criteria for the selection.

He/She will also submit a budgetary estimate for the staff needed, their training, equipment etc. to the SAPO for funding.

Contingencies

Contingency grant to each SHRC will depend on the work load and will be decided by the NACO in consultation with SAPO.

4. State AIDS Programme Officer (SAPO)

State AIDS Programme Officer will be the incharge of AIDS Control activity in the state. He must have a basic M.B.B.S. degree with postgraduate qualification in public health/microbiology/ pathology/medicine/venereal diseases/immunohematology and blood banking recognized by the

Medical Council of India and must belong to the central or state medical/health services. He will be appointed as per state government rules.

Location

He will be located in the state capital.

Function

a) SAPO will be responsible for the HIV testing network in his state.
b) He will interact with the NACO on behalf of the State Government for implementation of HIV testing network in his state.
c) He will be responsible for the identification and assessment of potential institutions and laboratories for setting up SHRC, HTL and HSLs. He will be assisted by the SHRC for setting up HTLs and HSLs in the state.
d) He will determine the staffing pattern of HSLs, HTLs and SHRC.
e) He will be the appointing authority of the laboratory staff in the HSLs which is not located in any institution.
f) He will be responsible for the operational aspects, e.g. training of the staff of HSLs, HTLs and SHRC in his state.
g) He will monitor the work of HSLs, HTLs and SHRC.
h) He will be responsible for the procurement of HIV kits from NACO, their appropriate storage under him and further distribution to SHRC, HTLs and HSLs according to their requirement.
i) In case of purchase of HIV kit for use in his state, he will take help of NACO and NHRC.
j) He will be responsible for the timely distribution of funds to all HSLs, HTLs and SHRC in his state.
k) He will be responsible for the procurement of equipments required for HIV testing at HSLs, HTL and SHRC from NACO.
l) He will be responsible for identifying an appropriate firm for the service maintenance of all equipments required for HIV antibody testing and located in the SHRC, HTLs and HSLs.
m) He will be responsible for establishing QA/QC programme in the SHRC, HTLs and HSLs.
n) He will ensure that SHRC of his state will participate in the National HIV Quality Assessment Programme of the NHRC.

Administrative Control

Administratively SAPO will under State Government (Health Ministry/Director of State Health Services)

5. *National HIV Reference Centre (NHRC)*

National HIV Reference Centre will be the apex institution for laboratory diagnosis of HIV infection. It will provide technical support to NACO on all aspects of HIV testing, monitoring, quality assurance and training. It will be located in one of the national laboratories and will have the most advanced laboratory facilities for carrying out different immunological and virological HIV tests and studies. One of the nine regional reference centres will be recoginized as NHRC by NACO on the basis of expertise available at the centre. The regional references centres other than those recoginized as either NHRC or SHRC will be involved in the national quality assessment programme (page 47) as National Participating Centres. The budget for this purpose will be made available with the budget of NHRC.

The institution/laboratory acting as NHRC should have specially trained staff for carrying out the activities of the national reference centre. It should also have expertise for evaluation of test kits, quality assurance and quality control programmes. The NHRC should be provided with form technicians on a consolidated salary on a contract basis as per guidelines of the Indian Council of Medical Research.

Functions

a) Evaluation of HIV test kits to be used in National AIDS Control Programme;
b) Developing draft policy documents and operative guidelines for the National HIV testing network and laboratories participating in it;
c) Plan and assist SHRC for HIV testing quality assurance and quality control programme;
d) Train staff of the SHRC;
e) Provide technical support to NACO, SAPO and SHRC for the procurement of equipment and material, reagents etc;
f) Provide facilities for confirmation of laboratory findings of SHRC;
g) Monitoring the HIV testing activity in the country.
h) Report on the HIV testing activities to NACO.
i) NHRC will assist SAPOs of various states in identification and establishment of SHRC in their state.

NHRC will be under operational control of NACO whereas, administratively it will be under the hosting institute. NACO will provide necessary funds for its activity.

NATIONAL AIDS CONTROL, INDIA

ASSESSMENT REPORT

For hospital and blood bank laboratory facility

I. Identification of Institution:

1. State _____ District _____ City _____
2. Name of the hospital which plans to accommodate HIV testing facility:
   _____
3. Average number of blood transfusions inthe hospital per month _____
4. Location of laboratory:
   In hospital _____ (Name)
   In blood bank _____ (Name)
   Other _____
   (Where)
5. It if is out of hospital, distancefrom the hospital _____ Km.

II. Minimum requirements for HIV testing facility:

1. Room or space available > 8 Sq. Mtrs. Yes _____ No_____
2. Ventilation: Window One _____ Two _____ Airconditioner_____
3. Electricity available for 24 hours Yes _____ No_____
4. Sourceof electricity: Main supply ___ Generator ___ Both ___
5. Source of water supply: Municipal _____ Protected well ____
6. Sewerage system: Septic tank ____ Others _____
7. Working table (bench) with drawers Yes _____ No _____
8. Shelve medium size Yes ____ No ____

9. Chairs or stool available Yes ____ No ____

10. Separate tank with tap water Yes ____ No ____

11. Refrigerator adjustable, 2–8°C of 250+liters Yes ___ No ___

12. Incubator adjustable, medium size Yes ____ No ____

13. Electric centrifuge medium size Yes ___ No ____

14. Sterilization equipment:Autoclave _____ Hot air oven ____

15. Water distilator with capacity of one liter/hour or more Yes _____ No _____

III. Incinerator available: Yes _____ No ____

IV. Daily load of the laboratory:

1. Number of tests _____
2. Number of lab technicians _____

V. Additional remarks on the laboratory facilities:

_____
_____
_____
_____

Recommendations:

a) Type and number of HIV tests to be provided per month:
_____
_____

b) Staff training requirements:
_____
_____

c) Equipment to be supplied:
_____
_____

Assessed by_____

On_____199

_____
(Signature)

CHAPTER 4

Training Programme for the Staff of HIV Laboratories

There are two aspects of this programme in relation to the functions of the decentralised HIV testing network.

i) *Operational Aspect:* This will help the participating institution to understand the structure of the network in relation to the state and central government, administration, supplies, monitoring, reporting etc. Such guidelines will be prepared by NACO. The initial training on the operational guidelines will be conducted by NACO and SAPO for NHRC and SHRC respectively. Eventually it will be integrated into the training programme on the technical aspect.

ii) *Technical Training Aspect:* A person should be identified at the national & state level to develop and implement training programmes. This individual may be a whole time officer or a consultant on contractual basis. The NACO will identify this officer at national level & SAPO will identify at the state level in consulation with NACO.

Objectives

The objectives of this technical training will be to create capabilities for:-

a) HIV testing: performance and interpretation of ELISA/Rapid/Simple tests. Also to know the principles of other tests.
b) Quality Assurance/quality control programme and quality assessment programme or proficiency testing.
c) Evaluation of HIV test kits.

Three types of training programme will be conducted to achieve these objectives:

a) Training of Microbiologists/Immunologists and Technicians in the Evaluation of Test Kits & Quality Assurance Programme.

Three to four workshops may be planned for training of staff from SHRC (microbiologists/ immunologists and laboratory technicians). Each workshop should be of two weeks duration. The number of participants may be restricted to 10–15. Faculty for training may be drawn by and large from the expertise available in the country. Experts from other countries may be inducted if necessary. These workshops will be held at NHRC.

b) Training of Microbiologists/Immunologists for HIV testing.

Training workshops for the microbiologists/immunologists from SHRC for HIV antibody testing by ERS tests and WB assay and interpretation of the results may be planned. Each workshop will be of 5 days duration. The number of participants will be restricted to 15. The faculty will be drawn from NHRC and other centres in the country. These workshops will be held at NHRC.

c) Training of Laboratory Technicians of SHRC, HTL and HSL for HIV testing.

Training workshops for training of laboratory technicians from SHRC, HTL and HSL for HIV antibody testing by ERS tests and their interpretation may be planned. Each workshop will be of 5 days duration. The number of participants will be restricted to 20. The faculty will be drawn from the expertise available at the SHRC, NHRC and other national centres. These workshops will be held at SHRC.

HIV TESTING WORKSHOPS FOR SHRC/HTL/HSL

Daily Schedule

Day 1

0800 – 0900	Registration
0900 – 1030	Inauguration and Inaugural tea
1030 – 1130	Introduction and pre-test
1130 – 1230	Lecture # 1: HIV infection and AIDS–an overview
1230 – 1330	Lecture # 2: HIV virology and immunology
1330 – 1430	Lunch
1430 – 1530	Practical demonstration–collection, labelling, handling, transportation, initial processing and storage of specimen
1530 – 1630	Practical demonstration–methods of sterilization, disinfection and discarding and disposal

Day 2

0900 – 1000	Lecture # 3: Laboratory diagnosis of HIV infection including diagnosis in new born
1000 – 1100	Lecture # 4: ELISA, Rapid and simple tests for detection of HIV antibodies
1100 – 1130	Tea
1130 – 1300	Demonstration–ELISA, Rapid and Simple test
1300 – 1400	Lunch
1400 – 1630	Practical # 1: ELISA, Rapid and simple test

Day 3

0900 – 1000	Lecture # 5: Western Blot Assay–Theory, untility and interpretation.
1000 – 1100	Lecture # 6: Bio-safety and universal precautions
1100 – 1130	Tea
1130 – 1300	Demonstration–ELISA, Rapid and Simple tests
1400 – 1430	Practical # 2: ELISA, Rapid and Simple tests

Day 4

0900 – 1000	Lecture # 7: National policy on HIV testing; Evaluation and comparison of screening and diagnostic tests (sensitivity, specificity and predictive values)

1000 – 1100	Lecture # 8: Laboratory quality assurance, quality control and proficiency testing
1100 – 1130	Tea
1130 – 1300	Demonstration–ELISA, Rapid and Simple tests
1400 – 1630	Practical # 3: ELISA, Rapid and Simple Tests

Day 5

0900 – 1000	Lecture # 9: Counselling: skills, pre & post test counselling, role play.
1100 –1300	Practical # 4: QA/QC/Proficiency testing for ELISA, Rapid and simple tests
1400 – 1630	General questions and answers session Closing ceremony

There will be two plenary sessions of one hour duraction each day except the last (fifth) day.

- There will be 1 h 30 min demonstration on the practical exercise to be carried out by the participants each day except first and last day;
- There will be 2 h and 30 min practical exercise each day by the trainees except first and last day.

receive the requisition and compile them for the entire state in the proforma given on pages 36 and 37. The number of tests required will be calculated on the following basis:

a) For Blood Transfusion

The calculation is based on the number of blood units collected during the previous year. One test for each unit of blood collected in the last year plus 20% to meet emergency needs and wastage. (Ten percent of the total demand may be for rapid tests to meet the requirement of transfusion in emergency situations). For HSL-I total requirement should consist of Rapid/Simple tests.

b) For surveillance purposes

Two types of ERS kits should be procured. The number of tests for screening should be obtained from surveillance protocol of each sentinel site. For the second test (supplemental test), twice the number of positives expected in the population should be requested. In addition, 10% more kits will be given to meet emergency and wastage.

c) For Identification of HIV Positive Individuals

Three types of ERS should be procured. The number of first test should be equal to the total number of persons to be screened. The number of first and second supplemental tests required should be equal to twice the number of expected positives. In addition, 10% more kits will given to meet emergency and wastage

d) For AIDS Case Diagnosis

During the first year, ten tests will be allocated per each district PRAM (Physician Responsible for AIDS Management), 100 tests per each State PRAM, plus ten to fifty tests for each million of the urban population in the State depending on the number of AIDS cases reported during the previous year. The number of supplemental tests will be counted as for the identification of HIV positive individuals. Allocation for the following years will be based on the number of suspected AIDS patients submitted during the first year of operation multiplied by two.

e) For Research, Monitoring Intervention Projects, and Quality Assurance

The number of tests will be calculated according to the protocols approved by SAPO/NACO.

5.3 Procurement

The HIV kits will be procured by the NACO through the WHO. These kits are selected from the

list of the kits which have been evaluated by the WHO as well as by NHRC and are suitable for Indian conditions. These are ordered by NACO for delivery to the four Regional Store Depots at Bombay, Madras, Calcutta and Delhi. From these store depots, subject to an agreement between SHRC, SAPO and NACO, the kits will be collected by SAPO or his representative for his state and stored at SHRC. Once the kits are in the SHRC stores, distribution in the state will be the responsibility of SAPO and SHRC.

5.4 Storage

The kits must be stored at 4°C. The kits with earlier expiry dates should be quickly dispensed and used. SAPO will be provided with walk-in cooler for storage of kits.

5.5 Distribution

The distribution of the kits from SHRC depot to the peripheral laboratories should be planned jointly by the SCOHT and SAPO considering the geographic location, transport, communication network and convenience of the peripheral laboratories.

NATIONAL AIDS CONTROL PROGRAMME

Record for requisition of HIV test kits by a HIV Laboratory (NHRC SHRC, HTL, HSL)

Name of the HIV Laboratory: _____ Requisition for the year _____

Type of kits	Manufacturer or Trade mark	Received last year	Used last year	Kits in stock	Blood Transfusion*	Surveillance ***	Suspected AIDS****	Voluntary Testing	Research *****	Monitoring of Intervention projects*****	Quality Assurance *****	Total
ELISA	1.											
	2.											
RAPID	1.											
	2.											
SIMPLE	1.											
	2.											

* Based on the number of blood transfusion performed during the last year, plus 10%

** Based on the calculations made for each surveillance site, plus 10%

*** Ten tests for each district PRAM, 100 kits for each State PRAM, plus ten to fifty kits for each million of urban population in the State

**** Based ont the past and planned performance of every recognized by SAPO Voluntary Testing Centre.

***** According to the protocols.

NATIONAL AIDS CONTROL PROGRAMME

RECORD OF ANNUAL REQUIREMENT OF HIV TEST KITS BY QUARTER OF THE YEAR.

Type of kit		Quarters of the year				
		I	II	III	IV	Total per year*
ELISA	1					
	2					
RAPID	1.					
	2.					
SIMPLE	1.					
	2.					

* This figure should match the same one on the record (a).

Date of requisition _____

Officer in charge of HIV Laboratory: Name _____

Designation _____

Signature _____

NATIONAL AIDS CONTROL PROGRAMME, INDIA

State HIV test kits requirement, by activity

State _____ Year _____

Activity	No. of tests kits required						
	ELISA		RAPID		SIMPLE		Total
	1	2	1	2	1	2	
Blood Safety							
HIV Surveillance							
AIDS Case Diagnosis							
HIV Voluntary Testing							
Others:							
Total							

HIV test kits requirement, by quarter of the year

State _____ Year _____

Quarter of the year	HIVtests kits required						
	ELISA		RAPID		SIMPLE		Total
	1	2	1	2	1	2	
I							
II							
III							
IV							
Total							

Date _____ Designation _____

SAPO Name _____ Signature _____

Chief, SHRC Name _____ Signature _____

NATIONAL AIDS CONTROL PROGRAMME, INDIA

State report on annual requisition of HIV test kits

State _____ Year _____

No.	HIV Laboratory	No. of tests required						
		ELISA		RAPID		SIMPLE		Total
		1	2	1	2	1	2	
Total								

CHAPTER 6

Procurement, Distribution and Maintenance of Equipment

6.1 List of Equipments

The following equipments will be required for HIV Testing network.

(1) HIV Screening Laboratory-I (HSL-I)

Micropipettes, dilution tubes
Centrifuge machine
Domestic Refrigerator (one)
Incinerator (1/2-1 kgm capacity)

(2) HIV Screening Laboratory-II (HSL-II)

ELISA Reader with filters & washer
Micropipettes, dilution tubes
Centrifuge machine
Incubator
Domestic Refrigerator
Incinerator (1/2–1 kgm capacity)
Voltage stabilizer (5 kva) (one)

(3) HIV Testing Laboratory (HTL)

ELISA Reader with filters & washer
Micropipettes, dilution tubes
Centrifuge machine
Incubator
Air Conditioner (Hot & Cold) (one)
Domestic Refrigerator (one)
Incinerator (1/2-1 kgm capacity)
Voltage stabilizer (Two) - 5 kva - (one); 3 kva (one)

(4) **State HIV Reference Centre**

ELISA Reader with filters & washer (Two)
Micropipettes, dilution tubes
Centrifuge machine
Incubator
Air Conditioner (Hot & Cold) (one/two)
Domestic Refrigerator (two)
Incinerator (1-2 kgm capacity)
Computer PC/AT (one)

Deep Freezers of –40°C (one/two)
Generator (one)
Voltage stabilizer (Two) 10 kva each

(5) **State AIDS Programme Officer**

a) Walk in cooler (one/two)
b) Generator (one/two)
c) Polyurethane boxes with ice-packs (two per laboratory)
d) Domestic refrigerator (one)
e) Voltage stabilizer (one) 10 kva

(6) **National HIV Reference Laboratory**

ELISA Reader with filters & washer (Two)
Micropipettes, dilution tubes
Centrifuge machine
Incubator
Air conditioner (Hot & Cold) (two)
Domestic Refrigerator (two)
Incinerator (1-2 kgm capacity)

Deep Freezers of –40°C (two)
Walk-in cooler (one)
Flow Cytometer (one)
Computer PC-AT (one)
Generator (one)
Voltage stabilizer (Two) 10 kva each

6.2 Procurement and Distribution

Procurement of the equipment costing more than Rs. 100,000/- may be done at central level through DGS & D rate contract by NACO.

Equipment costing less than Rs. 1 Lakh may be procured by the State AIDS Control Cell through central/state/DGS & D rate contract.

Equipment will be installed by the suppliers who will also help in standardising the equipment.

6.3 Maintenance

A panel of minimum three firms for the maintenance of the equipments alongwith their rates and the price list of spare parts will be finalised by NACO on all India basis. SAPO will have the freedom to choose and cancel any one of them depending upon their performance. The payment of maintenance charges and the spare parts will be made by SAPO after satisfying himself with the maintenance of equipments in the state.

CHAPTER 7

Quality Assurance Programme

7.1 Necessity and Importance

The diagnostic tests to detect antibodies to HIV have sensitivity and specificity which are not absolute. In all these tests we have false negative results as well as false positive results which are inherent and cannot be avoided. The percentage of false positive results will increase as the prevalence rate of persons with HIV antibodies in a population decreases. *These two problems are compounded with the fact that during screening programmes, laboratories will rarely be able to perform to the level of accuracy that the tests are technically capable of achieving.* Thus, the validity of diagnostic test results is dependent to a very large extent on the quality of the technical conditions under which the tests are performed. Meaning thereby, consistent production of reliable results requires a stringent overall assurance programme which would control technical conditions before, during and after each assay.

The Quality Assurance Programme ensures that the final results reported by the laboratory are correct, reliable and accurate as far as possible. This programme oversees reporting results in a timely manner and to the appropriate individual. It also ensures use of the most reliable tests for the diagnosis of HIV infection. It is dependent on a good **Quality Control Programme** and its efficacy may be verified by a good **Quality Assessment Programme.**

a) *Quality Control Programme:* This programme includes measures which are introduced during each assay to verify the validity and reliability of the test. However, this does not indicate that the results generated are accurate (which,indeed,is the characteristic of the test). It also does not indicate that the results have been reported timely, properly and correctly.

b) *Quality Assessment Programme:* This is a means to determine the quality of results. It is an external evaluation of a laboratory performance by incorporating proficiency panels as the means to evaluation. **For a laboratory to be considered a respected testing facility, it must be a laboratory that can always produce accurate, reliable and reproducible results.**

7.2 Guidelines to Improve Quality of Testing

i) Condition of the Specimens

All specimens must be inspected at the time of receiving and also before testing to ensure that they are suitable. Use of lipaemic, haemolysed and contaminated sera should be avoided. If they have to be used, the reporting officer should mention on the report that the result of the test may not be valid because of the condition of the serum samples. A new specimen should be requested for repeat testing.

All specimens should be properly labelled before acceptance. The label should include following information: a) name of the patient, b) collection date, c) patient's identification number if applicable. Each specimen must be accompanied with a test request form,which should include age and sex of the patient, name of the physician requesting the investigation, risk group of the patient, reason for the investigation in addition to the information given on the label. In case of unlinked anonymous testing, only code number and collection date may be mentioned on the label as well as on the request form.

If the serum or plasma sample is frozen before testing, it is essential that after thawing at room temperature/37°C, the sample should be inspected for any clot or floating particles. The sample should be clarified before testing. The sample should be well-mixed before testing.

Presently, all the test kits distributed by the NACO, are meant for testing serum or plasma only. Therefore, these kits may not reliably detect presence of antibodies in other body fluids.

ii) Quality of kits and equipments

The test kits must be used within the expiration date stated on the kit to ensure valid results.

Every batch of the kit should be tested and certified for its efficacy (sensitivity and specificity) before distribution (see page 50 for details).

ELISA reader, washers, incubators, pipettes should be checked regularly for their optimal performance. They need to be calibrated at least annually.

iii) Controls used in the tests

Each test run requires a set of controls to validate the results. These controls must be treated in the same manner as unknown samples. They are run simultaneously and under the same conditions as the unknown samples. Upon completion of the test, the results of the controls and the samples are examined using the same criteria for interpretation. The assay is valid and the results are reliable when the controls produce acceptable results.

There are two types of controls which must be included in each run :

a) *Internal Controls:* These controls (positive and negative) are included in each HIV-test kit by the manufacturer and are to be included in each test run. These are essential for quality control measures for each run. They are intended for use with the same lot number of the kit in which they have been packed. Internal kit controls are generally adjusted by the manufacturer so that an expected range of values are obtained with each lot of kits. To avoid considerable fluctuations in the OD values due to variable coating of the antigen on the solid surface during manufacturing, the manufacturer artificially stabilizes kit controls to give the same values as the previous lot.

b) *External Controls:* These should be included with each test-run to monitor consistent performance and lot to lot variation which cannot be detected using internal controls for the reasons mentioned above. These controls are made from pooled test kit controls or made from pooled sera from HIV-positive or negative individuals in each laboratory (in-house controls). However, for monitoring the performance of other laboratories, the serum samples for external controls are drawn in sufficient quantities to last for at least 12 months.

The most important external control to include is a borderline reactor. This control would indicate any minor change specially around cut off value because such changes would effect the results of unknown samples with OD values near the cut off. It may take several months to establish ranges for external controls. Nonetheless, this type of control system can be very effective in helping to identify potential problems and inaccuracies in the laboratory setting.

c) *Standardization of the Quality of External Controls:* Reproducibility and quality of internal and external controls must be standardized by **intra-run reproducibility** and **inter-run reproducibility**. The control samples (either internal or external) are tested atleast three times on the same test-run. This will indicate intra-run reproducibility. This exercise is then carried out on test-runs on three consecutive days to determine inter-run reproducibility. By either of these methods variations should not exceed 10%. These serum samples may also be evaluated at NHRC/SHRC.

iv) Interpretation of data

The test kit inserts carry instructions to establish range of internal controls and to define the outliners. Since the external controls are included in each test run to monitor consistent performance of the test kit , it is necessary to determine the limit of acceptability statistically by calculating arithmetic mean, standard deviation and error, coefficient of variation etc. However, the values for the internal controls, external controls and the cut off can be monitored easily by quality control graphs. This is because the graphic presentation of the control values overtime will make subtle changes in controls more easily discernible.

An accurate method of graphically representing the values of control of each test run is to plot OD/Cut-off (CO) ratio on Y-axis. In this method the control values are expressed relative to the cut-off value. This is important as the OD as well as CO values will change slightly between test-runs. Therefore, the controls should be compared with the respective calculated CO value.

Two types of changes can be observed in the quality control graphs. These are.

a) *Shifts:* When control values of six consecutive test runs fall on one side of the mean, it is called shifts. This indicates a major change in the test-performance due to i) switching to a new lot of kits, ii) new reagents, iii) changes in incubation temperature, iv) changes of pipettes, v) a new technician, etc.

b) *Trends:* When control values of six consecutive test are distributed in one general direction, it is called trends. This is generally due to i) deterioration of reagents,and ii) a routinely used pipette slowly losing its calibration.

v) Calculation of gray-zone reactors

During routine testing, many samples may have slightly elevated OD values just above CO value which may suggest presence of low antibody activity. Such samples are called **gray-zone reactors** or **borderline reactors**. This reactivity may be due to a) early seroconversion; b) very low antibody reactivity present in the serum; c) false positive reactivity.

Therefore, it is very essential to repeat any HIV reactive result having OD values greater than or equal to the cut-off value. Any repeatedly positive result is then validated by a more specific supplemental test.

Sometimes, due to a technical error a serum with low antibody reactivity may give an OD value just below the cut-off value. Therefore, many laboratories advocate a repeat HIV test on all the samples which give an OD value of 10% below the cut-off. Although this is very arbitrary, this approach increases the chance of finding some early HIV seroconversion.

vi) Accuracy of Enzyme Immunoassay (EIA)

Since no assay can be 100% sensitive and 100% specific, it is likely to give false negative as well as false positive results.

Any EIA may be **false negative** under following conditions:

a) Biological Conditions

i. The test may be false negative during early stages of HIV infection. This period generally

varies from 2–24 weeks but may be as long as 42 months. The false negative rate varies from 16% to 50% during this period. (Farzadegan et al, J. Clin. Microbiol 27: 1882, 1989)

ii. In some patients there is an early production of antibodies followed by a cessation of antibody production and disappearance of antibodies from blood. This may be due to sequestration of the virus.

b) Technical Conditions

i. The test kit generally has a sensitivity ranging from 99.4% to nearly 100%. However, if performed under less optimal conditions the sensitivity may drop considerably.

The EIA may be **false positive** under following conditions:

a) Biological Conditions

i. Certain conditions increase false positivity rates of ELISA. These are chrouce alcoholism, parenteral drug abuse, haemodialysis, multiple pregnancies and multiple blood transfusions.
ii. False positivity rises if the prevalence of HIV antibodies in the population decreases.

b) Technical Conditions

i) False positive rates vary from one ELISA kit to another. Even the same type of kit may show a significant variation in specificity from batch to batch.
ii) Human error, e.g., specimen mixing may account for false positivity.
iii) Laboratories with less than optimum performance also account for higher false positivity rates.

vii) Reporting of Results

Unlike any other test report, the HIV-test reports must be handled with care. Since HIV infected individuals may face social stigma, improper reporting may sometimes lead to emotional breakdown of an individual or even suicides. Therefore, before reporting the result of HIV-antibody test it must be borne in mind that:

a) The results of any screening test (ERS) are only presumptive and should not be reported. These must be validated by a supplemental test.
b) In blood-banking only donated blood is screened by a single ERS as per recommendations of Govt. of India. Therefore, these results should not be used to identify the individuals.
c) In serosurveillance studies since the positive results of first ERS are validated by a second ERS and not by a supplemental test, these results may not be used to identify the individuals.

d) For making a diagnosis of HIV-infection, the recommendations of the Govt. of India (chapter 2, page1 1) must be followed.
e) HIV test results should be reported to the physician who has requested the test. All HIV testing, in which an individual is identified, must be preceeded and followed by pre-test and post-test counselling respectively.
f) All test results must be kept confidential and should never be discussed in public. The test results should never be communicated on telephone.

7.3 Proficiency Testing of Laboratory

Proficiency testing is synonymous with Quality Assessment. Recently, National AIDS Control Organisation has formulated a Quality Assessment Programme. Under this programme coded panels of known HIV antibody positive and negative sera are provided to the participating laboratories for HIV proficiency testing on a regular basis. These panels are processed and tested within a specified period so that results from all the participating laboratories may be analysed together. The participating laboratories are requested to handle these coded panels in exactly the same manner as the other routine samples for HIV testing in ELISA. This is because the purpose of such a programme is to identify the problems in HIV testing.

While analyzing the results and preparing a comprehensive report, care is taken not to identify any of the participating laboratory either by name or by location. These reports are then transmitted to the participating laboratories where the laboratory in-charge may assess the adequacy of quality assurance and quality control measures in his own laboratory and compare the performance of his laboratory with other laboratories. In case there is a problem he may investigate, identify and take appropriate timely action to rectify the problem.

Since every laboratory aspires to be a respected testing facility it must initiate a good and effective quality assurance/quality control (QA/QC) programme. Effectiveness of such a programme may be assessed by an external quality assessment. However, a good QA/QC programme cannot be substituted by quality assessment programme, but a good QA/QC programme may substitute for quality assessment.

Many a time false negative and false positive results may be due to technical errors especially if the tests are performed under less optimal conditions. Therefore, it is necessary to monitor the performance of the laboratory workers periodically by incorporating the samples with known results with the routine samples without the knowledge of the laboratory workers. This is done to ensure the accuracy, reliability and reproducibility of the test results reported by the laboratory.

7.4 Structure of the National HIV Quality Assessment Programme

In view of the proposed structure of the HIV antibody testing network in the country (Chapter 3, page 13), the quality assessment programme may also be structured accordingly (see Figure 7.1, page 53). The NHRC will send coded panels of known HIV antibody positive, bordline positive and negative serum samples to each SHRC on a regular basis for HIV proficiency testing by ERS and western blot assay. Each participating laboratory will be asked to process and test the panel sent to them within a specified period and submit their results to NHRC in a specified form (see page 55). The results from all the laboratories will be analyzed together.

Similarly, each SHRC will send coded panels of known HIV antibody positive, borderline positive and negative serum samples to all HTL, HSL-I and HSL-II in its respective state on a regular basis for HIV proficiency testing by ERS. Each participating laboratory will be asked to process and test the panel sent to them within a specified period and submit the results to SHRC in the specified form (see page 55). The results from all the laboratories will be analyzed together.

The regional reference centres other than those recoginized as either NHRC or SHRC, will be involved in the quality assessment programme as National Participating Centres. The details of their involvement will be determined by NACO with the help of NHRC.

All the participating laboratories may be asked to enrol in the quality assessment programme (see Laboratory Enrollment form, page 54).

7.5 Record Keeping

a) A laboratory must maintain a log book for recording of the laboratory specimens. The information contained in the log book should be kept confidential.
b) A work sheet (see page 56) containing the identification numbers of sera to be tested must be prepared each time before the test run is performed.
c) Daily records of temperature of water baths, incubators, refrigerators and freezers should be maintained.
d) Micropipettes should be calibrated atleast annually.
e) ELISA readers should be calibrated to ensure accuracy of their readings.
f) The laboratory should maintain a file where all procedures/package inserts are kept for ready reference.
g) Number of ELISA positive samples being reported by each laboratory from various risk groups: high risk group, moderate risk group and low risk group should be maintained (see pages 57 to 64).
h) Number of ELISA positive samples which have been found negative by Western blot assay should be manitained (see pages 57 to 64).

i) Number of times an ELISA positive serum sample was rerun before subjecting it to supplemental test should be maintained (see pages 57 to 64).

These data will reflect upon the technical problems any existing in a laboratory.

7.6 Laboratory Aspects

a) Specimen collection and processing

Five ml blood is collected by venipuncture using either a disposable plastic syringe or an autoclaved glass syringe. After collection of the sample the disposable syringe is properly discarded, whereas the glass syringe is kept in a beaker containing liquid bleach disinfectant for 10 to 15 min before resterilization. Since lipaemic, haemolysed and contaminated serum samples donot yield reliable results, care should be taken to collect blood fasting or after a light breakfast in a dry sterile container. Haemolysis can be avoided by a) not leaving the tourniquet on the arm for more than 1 min; b) not forcefully transferring the blood through a needle to a tube. Universal precautions including wearing gloves must be followed while drawing the blood. It is very important to prevent infection being passed from an individual to the laboratory worker and vice-versa. Labelling of the sample for proper identification of the individual is extremely important to avoid incorrect reporting of HIV status. Therefore, the tube must be labelled properly immediately upon collection of blood sample. The sample is allowed to sit at 37°C for 30 min and then at 4°C for clot retraction.

Thereafter, the sample is spun at 1500 rpm at 4°C and the serum is collected aseptically in a sterile container. No preservative is added. In case it is not tested for HIV antibodies, it may be stored at 4°C for 1–10 days or at –30°C for long term storage. Repeated freezing and thawing should be avoided.

b) Preparation of the external controls

Positive & NegativMe Controls

One unit of blood from each donor,tested negative for hepatitis B surface antigen, but tested (i) positive for HIV antibody by ELISA and Western blot, or (ii) negative for HIV antibody (out dated blood sample), or (iii) positive for HIV antibody by ELISA but negative by Western blot assay (False positive result) is collected from the blood bank. The plasma is separated, heat inactivated at 56°C for 30 min and then recalcified. It is then incubated at 37°C for clotting to occur. The clot is spun down and the serum is separated aseptically. It is filtered through a millipore filter (0.2 um or 200nm pore size) to remove any bacterial contamination. No preservative is added. It is aliquoted, labelled properly and stored at –40°C. Once thawed, the aliquot is stored at 2°C to 8°C. It is discarded after using it once.

HIV positive serum samples should not be discarded. These should be sent to SHRC/NHRC for long term storage in serum bank at -40°C.

c) Borderline or low positive control

Ten fold serial dilutions (10^{-1} to 10^{-6}) of a known positive serum are prepared in the serum from HIV negative donor which is used as a diluent in place of normal saline or buffered salt solution to keep the proteins in a natural environment. Each dilution is assayed in sextuplicates for HIV antibodies. The mean OD of each dilution and SD are calculated. A graph with OD of each 10 fold dilution is then plotted. The highest dilution of the serum giving positive result in ELISA is taken as an end point. Three dilutions, viz., end point dilution+1 SD, end point dilution and end point dilution-1 SD are tested by ELISA in sextuplicates and also by WB assay. If these dilutions give reproducible results (intra-run variability), they are tested on six consecutive days for inter-run variability.

Care must be taken not to select a sample with so low antibody titer that the OD fluctuates above and below the cut off due to normal variations. Also the sample with a very high antibody titer should not be selected. It will be of limited use for borderline monitoring.

d) Recalcification of plasma

Ideal material for quality control and quality assessment is serum. This is because plasma tends to be unstable on long storage and may clot spontaneously during transport. Since under many circumstances blood collected from a blood bank may be the only source for HIV positive and HIV negative sample, plasma must be recalcified to produce serum. However, recalcification should be done with care because excessive recalcification may affect some assays like gelatin particle agglutination adversely. Only citrated blood should be recalcified.

a) Make a **10X Recalcification solution** ($CaCl_2.6H_2O$ 55g, $MgCl_2.6H_2O$ 16g, in 100 ml distilled water; autoclave at 121°C for 20 min).
b) Add 1.5 ml of recalcification solution to 1 unit of blood or 250 ml of plasma which has been brought to room temperature.
c) Incubate at 37°C for 30-60 min (until clot formation).
d) Keep at 4°C overnight.
e) Spin at 1500 rpm for 20 min.
f) Separate the serum aseptically.
g) Label and store in small aliquots at –40°C.
h) Test small aliquot from each sample for HIV antibodies by ERS tests and Western blot assay.

e) Preservatives for serum samples

Although Seitz filters may be used to remove bacteria and fungi from the serum samples, filtration of recalcified serum is often difficult as filters tend to clog due to fibrin clots. Centrifugation would

remove clots by and large before filtration. Use of prefilters will also help in clarifying the serum samples.

Even though one may start with sterile serum sample, subsequent use and manipulation in the laboratory may easily contaminate it. Therefore, addition of Bronidox L (5-bromo-5-nitro-1,3-dioxane in propylene glycol, Henkel Chemicals) to the serum sample to a final concentration of 0.05% may help in preventing growth of contaminants. Thiomersal (mercuric chloride) is generally used in a final concentration of 0.01% but it is effective only for a few weeks. This is because it loses its activity especially when exposed to light. Sodium azide should not be used as it inactivates peroxidase conjugate.

f) Storage of serum

Serum stocks are best stored at –40°C or below in small aliquots of 5–10 ml. Repeated freezing and thawing should be avoided. Once thawed, it should be further aliquoted in smaller size and kept at 4°C until used.

g) Use of Freeze-dried Controls

Freeze drying of a serum sample is an effective method for storage of serum sample at 2–8°C for a very long time. In addition, the shipment of freeze dried sample is very simple and straight forward. However, during the process of freeze drying, antibody activity especially of the borderline samples may be lost.

h) Preparation of Proficiency Panels

A proficiency panel consisting of two strong positive, two negative and two borderline positive serum samples is prepared from the aliquots of external controls stored at -40° C and coded. If possible, representative serum samples from different areas of the country may be included in the panel.

i) Tracking the performance of the kit under field conditions:

Each laboratory performing ELISA should maintain the following information to ensure good performance of the kit.

i) OD values of internal and external positive controls of each test run
ii) OD values of internal and external negative controls of each test run
iii) OD values of external borderline positive controls of each test run
iv) Cut off value of each test run
v) Name, batch and lot number of the kit used.
vi) Expiry date of the kit used.
vii) Date of the test run.

This information will help to keep a track of the performance of the kit under the field conditions.

j) Quality control of HIV antibody test kits

i) Monitoring of different lots of HIV Kit

Sometimes a manufacturer produces a reagent-lot that passes quality control requirement in his unit but fails to perform adequately in the field. This could be due to several factors including artificial stabilization of the controls by the manufacturer, substandard storage and shipping conditions etc. Therefore, it is imperative that these lots of reagents must be identified quickly before distribution to the surveillance centres. This is done by a technique called "Parallel testing" in which performance of new lots of kit with the previous lots via a common control material (external controls and the controls from previous lots) is compared. If all controls produce expected results, the new lot has passed the parallel test and may be used for routine testing.

ii) Monitoring of different ELISA Kits

There are four main objectives of HIV-antibody screening programme, namely :

a) safe blood banking
b) sero surveillance
c) sero diagnosis
d) research

For safe blood banking, it is imperative that the ELISA or any other test kit should correctly identify all antibody positive sera. In other words the test kit should have 100% sensitivity. The sensitivity is generally expressed in terms of percentage which is a qualitative measure. A quantitative expression of sensitivity in terms of positive delta value (delta +) is better and more reliable than percentage value. This helps in selecting among ELISA kits with equal sensitivity. The higher the delta + value, the higher is the probability that this test will correctly identify antibody positive sera.

For sero-diagnosis and sero-surveillance, an ELISA kit with a high sensitivity and high specificity is needed.

A negative delta value (delta-) is quantitative expression of specificity. The greater the negative delta (delta-) value, the higher is the possibility that this assay will correctly identify the true negative sera.

iii) Calculation of Delta Values

1. To calculate the delta values, 50 confirmed positive and 50 confirmed negative sera are tested.
2. Cut off value is calculated as suggested by the manufacturer.
3. Mean OD and standard deviation of positive and negative samples is calculated.
4. Mean OD/CO ratio of positive and negative samples is calculated by the following formula

$$\text{OD/CO ratio} = \frac{\text{mean OD of the samples}}{\text{mean CO value}}$$

Delta value is calculated by the following formula :

$$\text{Delta} + = \frac{\text{Mean OD/CO ratio of positive samples (log 10)}}{\text{Standard deviation of positive samples}}$$

$$\text{Delta} - = \frac{\text{Mean OD/CO ratio of negative samples (log 10)}}{\text{Standard deviation of negative samples}}$$

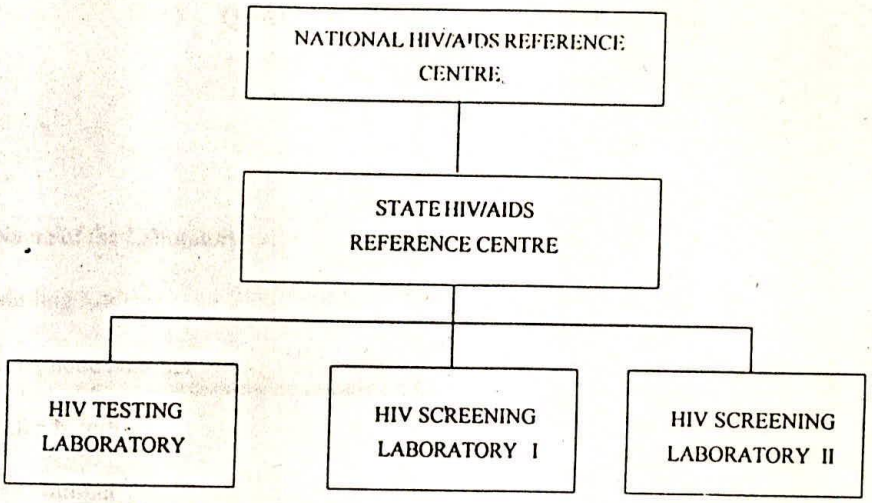
k) Evaluation of Indirect Immunofluorescence Assay (IFA) as a supplemental test

Although the Western Blot (WB) Assay has the advantage of being able to indicate actual antibodies that react with the specific HIV antigens, it is very expensive and time consuming. Sometimes the results are difficult to interpret. In addition, it is very much technique dependent.

On the other hand, the IFA offers several advantages over the WB assay. It is easy to perform , much less expensive than WB and can be completed in a short period of time. The test is easy to read but requires an expertise to do that.

Therefore, IFA may be used as a supplemental test in parallel with WB assay. IFA kits are commercially available.

NATIONAL AIDS CONTROL PROGRAMME



STRUCTURE OF THE QUALITY ASSESSMENT PROGRAMME

Figure 7.1

NATIONAL AIDS CONTROL PROGRAMME

QUALITY ASSESSMENT PROGRAMME

Laboratory Enrollment Form

1. Name of the Laboratory
2. Mailing Address
3. Telephone Number Extn.
4. Telex Number
5. Fax Number
6. Laboratory Incharge (Name)
7. Laboratory Incharge (Title)
8. I wish to enrol in the Quality assessment programme of the NHRC/SHRC.
   YES / NO

Signature of the Incharge

Please mail the completed form to NHRC/SHRC

National AIDS Control Organisation

QUALITY ASSESSMENT PROGRAMME

1. Name of the laboratory
2. Location
3. Name of the Laboratory Incharge

Results of Proficiency Panel

1. Name of the kit:
2. Lot #:
3. Date of expiry:
4. Date of test run:
5. Technician:
6. Results: Cut-off Value =

Panel Serum #	OD	Interpretation	Panel Serum #	OD	Interpretation	Controls	OD	Interpretation
1			11			Negative		
2			12			Negative		
3			13			Negative		
4			14			Positive		
5			15			Positive		
6			16			Positive		
7			17					
8			18					
9			19					
10			20					

The negative and positive controls are provided by the manufacturer with the kit. In case you are incorporating your external controls, please enter their OD values in the blank spaces above.

NATIONAL AIDS CONTROL PROGRAMME

HIV-SCREENING TEST WORKSHEET

1. Name of the kit: 2. Lot #:

3. Date of expiry:

4. Date of test run: 5. Technician:

6. Results: CUT-OFF VALUE =

INSTRUCTIONS : Fill in Sample Number and Results into Appropriate Space												
	1	2	3	4	5	6	7	8	9	10	11	12
A												
B												
C												
D												
E												
F												
G												
H												

Comments : _____

_____

_____

NATIONAL AIDS CONTROL PROGRAMME, INDIA
Monthly Laboratory Report on Serological Testing

Name of the Testing Centre/Laboratory_____

City_____ State _____

Date of report: / /199 Report for the month of /199

POPULATION/ AREA	NUMBER OF PERSONS TESTED					
	BY ONE TEST			BY SUPPLEMENTAL TESTS		
	TESTED	POSITIVE	PERCENT	TESTED	POSITIVE	PERCENT
STD CLINIC ATTENDANTS						
MALES						
FEMALES						
COMMERCIAL SEX WORKERS						
MALES						
FEMALES						
HOMOSEXUALS						
INJECTING DRUG USERS						
MALES						
FEMALES						
MOBILE MEN, SPECIFY						
ANTENATAL CLINIC ATTENDANTS						
BLOOD DONORS, ALL						
VOLUNTARY						
REPLACEMENT						
PROFESSIONAL						
SUSPECT AIDS/ARC CASES						
OTHER GROUPS, SPECIFY:						
NOT SPECIFIED						
TOTAL, DURING THIS MONTH						
TOTAL, SINCE INCEPTION 198						
TOTAL, DURING 1992						
FOR REFERENCE LAB. ONLY	X	X	X	X	X	X
NO. OF CONFIRMATORY/ SUPPLEMENTARY TESTS						
NO. OF TESTS FOR QUALITY CONTROL						

NATIONAL AIDS CONTROL PROGRAMME, INDIA
Monthly Laboratory Report on Serological Testing

Name of the Testing Centre/Laboratory _____

City _____ State _____

Date of report: / /199 Report for the month of /199

AGE/SEX DISTRIBUTION OF HIV TESTED PERSONS

AGE GROUP	TESTED BY SUPPLEMENTAL TESTS					
	MALES		FEMALES		BOTH SEXES	
	TESTED	POSITIVE	TESTED	POSITIVE	TESTED	POSITIVE
0–10						
11–20						
21–30						
31–40						
41 and above						
All ages						

TEST KITS SUPPLY

TEST KIT TYPE AND NUMBER OF TESTS PER KIT	RECEIVED THIS YEAR	USED BY REPORT DATE	IN STOCK	REPLACEMENT REQUIRED

COMMENTS, PROBLEMS _____

_____

Reporting Officer _____
(Name & Designation)

Date: _____ Signature: _____

To be sent on the first day of each month for the previous month activities, to the State AIDS Programme Officer .

NATIONAL AIDS CONTROL PROGRAMME, INDIA

Monthly State Report on HIV Serological testing

State _____ Number of Testing Centres/Laboratories_____

Date of report: / / 199 Report for the month of / 199

POPULATION/AREA	NUMBER OF PERSONS TESTED					
	BY ONE TEST			BY SUPPLEMENTAL TESTS		
STD CLINIC ATTENDANTS	TESTED	POSITIVE	PERCENT POSITIVE	TESTED	POSITIVE	PERCENT POSITIVE
MALES						
FEMALES						
COMMERCIAL SEX						
WORKERS						
MALES						
FEMALES						
HOMOSEXUALS						
INJECTING DRUG USERS						
MALES						
FEMALES						
MOBILE MEN, SPECIFY						
ANTENATAL CLINIC ATTENDANTS						
BLOOD DONORS, ALL						
VOLUNTARY						
REPLACEMENT						
PROFESSIONAL						
SUSPECT AIDS/ARC CASES						
OTHER GROUPS, SPECIFY:						
NOT SPECIFIED						
TOTAL, DURING THIS MONTH						
TOTAL, SINCE INCEPTION 198						
TOTAL, DURING 1992						
FOR REFERENCE LABS						
NO OF CONFIRMATORY/ SUPPLEMENTARY TESTS						
NO. OF TESTS FOR QUALITY CONTROL						

NATIONAL AIDS CONTROL PROGRAMME, INDIA
Monthly State Report on HIV Serological testing

State_____ Number of Testing Centres/Laboratories

Date of report : / / Report for the month of / 199

AGE/SEX DISTRIBUTION OF HIV TESTED PERSONS

AGE GROUP (years)	TESTED BY SUPPLEMENTAL TESTS					
	MALES		FEMALES		BOTH SEXES	
	TESTED	POSITIVE	TESTED	POSITIVE	TESTED	POSITIVE
0-10						
11-20						
21-30						
31-40						
41 and above						
All ages						

TEST KITS SUPPLY

TEST KIT TYPE AND NUMBER OF TESTS PER KIT	RECEIVED THIS YEAR	SENT TO LABORATORIES BY REPORT DATE	IN STOCK		REPLACEMENT REQUIRED
			IN LABS	WITH SAPO	

COMMENTS, PROBLEMS _____

_____

Reporting Officer_____
(Name & Designation)

Date : _____ Signature:_____

To be sent on the fifth day of each month for the previous month activities to the Additional Director (Tech), NACO, IRCS Building, 1 Red Cross Road, New Delhi 110 001.

NATIONAL AIDS CONTROL PROGRAMME, INDIA
Monthly Donors Screening Report of Blood Bank/Transfusion Centre

Blood bank/transfusion centre _____

City _____ State _____ Date of report / / 199 ___

Report for the month of _____ 199 ____

NAME OF THE CENTRE/ No. OF TESTS PERFORMED/ No.OF POSITIVE	No. OF SAMPLES FROM DONORS											
	Voluntary			Replacement			Professional			Total		
	M	F	T	M	F	T	M	F	T	M	F	T
ZBTC												
TESTED												
POSITIVE												
BLOOD BANKS ATTACHED TO ZBTC												
1.												
TESTED												
POSITIVE												
2.												
TESTED												
POSITIVE												
3.												
TESTED												
POSITIVE												
4.												
TESTED												
POSITIVE												
5.												
TESTED												
POSITIVE												
6.												
TESTED												
POSITIVE												
TOTAL FOR REPORTING MONTH												
TOTAL SINCE INCEPTION (198)												
TOTAL DURING 199												

NATIONAL AIDS CONTROL PROGRAMME, INDIA

Monthly Donors Screening Report of Blood Bank/Transfusion Centre

Blood bank/transfusion centre_____

City _____ State _____ Date of report / / 199 ____

Report for the month of _____ 199 _____

HIV Testing protocol: One screening test ___ two or more screening tests __ Screening and Western Blot tests _____

TESTS AND RESULTS	NUMBER OF SAMPLES FROM DONORS											
	VOLUNTARY			REPI ACEMENT			PROFESSIONAL			TOTAL		
	M	F	T	M	F	T	M	F	T	M	F	T
HBs Ag: TESTED												
POSITIVE												
VDRL: TESTED												
POSITIVE												
MALARIA: TESTED												
POSITIVE												

TESTS PERFORMED DURING THE CALENDAR YEAR

TESTS	TESTED			POSITIVE		
	M	F	T	M	F	T
HBsAg						
VDRL						
MALARIA						

HIV TEST KITS SUPPLY

TEST KIT TYPE AND NO. OF TESTS PER KIT	RECEIVED THIS YEAR	USED BY REPORT	IN STOCK	REPLACEMENT REQUIRED

PROBLEMS, COMMENTS _____

Reporting Officer_____

(Name & Designation)

Date : _____ Signature:_____

To be sent on the first day of each month for the previous month activities to the State AIDS Programme Officer.

NATIONAL AIDS CONTROL PROGRAMME, INDIA
Monthly State Donors Screening Report

State _____
Report for the month of _____ 199 ____

NAME OF THE TRANSFUSION CENTRE/# TESTS PERFORMED/ No.OF POSITIVE	No. OF SAMPLES FROM DONORS											
	Voluntary			Replacement			Professional			Total		
	M	F	T	M	F	T	M	F	T	M	F	T
1.												
TESTED												
POSITIVE												
2.												
TESTED												
POSITIVE												
3.												
TESTED												
POSITIVE												
4.												
TESTED												
POSITIVE												
5.												
TESTED												
POSITIVE												
6.												
TESTED												
POSITIVE												
TOTAL FOR REPORTING MONTH												
TOTAL SINCE INCEPTION (198)												
TOTAL DURING 199												

TOTAL DURING 199

NATIONAL AIDS CONTROL PROGRAMME, INDIA

Monthly State Donors Screening Report

State _____ Date of report / / 199 ____

Report for the month of _____ 199 _____

TESTS AND RESULTS	NUMBER OF SAMPLES FROM DONORS											
	VOLUNTARY			REPLACEMENT			PROFESSIONAL			TOTAL		
	M	F	T	M	F	T	M	F	T	M	F	T
HBs Ag: TESTED												
POSITIVE												
VDRL: TESTED												
POSITIVE												
MALARIA: TESTED												
POSITIVE												

TESTS PERFORMED DURING THE CALENDAR YEAR

TESTS	TESTED			POSITIVE		
	M	F	T	M	F	T
HBsAg						
VDRL						
MALARIA						

HIV TEST KITS SUPPLY

TEST KIT TYPE AND NO. OF TESTS PER KIT	RECEIVED THIS YEAR	SENT TO ZBTCs BY REPORT DATE	IN STOCK		REPLACEMENT REQUIRED
			AT ZBTs	AT STATE	

PROBLEMS, COMMENTS _____

Reporting Officer _____

(Name & Designation)

Date : _____ Signature: _____

To be sent on the first day of each month for the previous month activities to the State AIDS Programme Officer.

SPECIFICATIONS OF HIV TEST KITS BULK-PURCHASED BY WHO

Assay Name, (Manufacturer)	HIV Serotype	Test type, Antigen	Equipment Requirement	Cost/test (US$)*	No. of tests per kit
DETECT HIVI+II (Biochem)	HIV-1+2	ELISA (450nm) synthetic peptides	A,B,C,D,E,F	0.50	96 192
GENLAVIA MIXT (Sanofi Diagnostic Pasteur)	HIV-1+2	ELISA (492nm) recombinant	A,B,C,D,E,F	0.50	96 480 960
INNOTEST HIV-1/HIV-2 (Innogenetics)	HIV-1+2	ELISA (450nm) recombinant	A,B,C,D,E,F	0.50	96 480
UBI ELISA United Biomedical)	HIV-1+2	ELISA (492nm) viral lysate synthetic peptide	A,B,C,D,E,F	0.50	192 960
Recombigen HIV-1//2 EIA (Cambridge Biotech)	HIV-1+2	ELISA (492/603)	A,B,C,D,E,F	0.50	192
HIVSPOT (HIVCHEK) (Genelabs Diagnostics)	HIV-1+2	RAPID TEST recombinent antigen synthetic peptide	G	1.50	20 100
Immunocomb Bispot (PBS Orgenics)	HIV-1+2	RAPID TEST recombinant antigen	G	1.50	36
SERODIA-HIV (Fujirebio)	HIV-1	SIMPLE TEST viral lysate	D,F,G	0.65	100 220

A: ELISA reader, B: ELISA washer, C: Consumables, D: Pippette, E: Power supply F: For large volume testing more than 40 samples daily, G: For small volume testing 1 to 40 samples daily

*Please note that this price does not include freight and other taxes.

**The cost of Serodia HIV1+2 is expressed in Japanese Yen.